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Original Paper

# Development of a Connected Sensor System in Colorectal Surgery: User-Centered Design Case Study

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## Abstract

**Background:** A successful innovative medical device is not only technically challenging to develop but must also be readily usable to be integrated into health care professionals' daily practice. Through a user-centered design (UCD) approach, usability can be improved. However, this type of approach is not widely implemented from the early stages of medical device development.

**Objective:** The case study presented here shows how UCD may be applied at the very early stage of the design of a disruptive medical device used in a complex hospital environment, while no functional device is available yet. The device under study is a connected sensor system to detect colorectal anastomotic leakage, the most detrimental complication following colorectal surgery, which has a high medical cost. We also aimed to provide usability guidelines for the initial design of other innovative medical devices.

**Methods:** UCD was implemented by actively involving health care professionals and all the industrial partners of the project. The methodology was conducted in 2 European hospitals: Grenoble-Alpes University Hospital (France) and Erasmus Medical Center Rotterdam (the Netherlands). A total of 6 elective colorectal procedures and 5 ward shifts were observed. In total, 4 workshops were conducted with project partners and clinicians. A formative evaluation was performed based on 5 usability tests using nonfunctional prototype systems. The case study was completed within 12 months.

**Results:** Functional specifications were defined for the various components of the medical device: device weight, size, design, device attachment, and display module. These specifications consider the future integration of the medical device into current clinical practice (for use in an operating room and patient follow-up inside the hospital) and interactions between surgeons, nurses, nurse assistants, and patients. By avoiding irrelevant technical development, this approach helps to promote cost-effective design.

**Conclusions:** This paper presents the successful deployment over 12 months of a UCD methodology for the design of an innovative medical device during its early development phase. To help in reusing this methodology to design other innovative medical devices, we suggested best practices based on this case.

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**KEYWORDS**

user-centered design; usability; formative evaluation; medical device; innovation; Internet of Things; IoT; colorectal surgery; colorectal anastomotic leakage; mobile phone

## Introduction

### Background

Developing a successful innovative medical device is a real challenge. In all, 3 dimensions must be considered: technical aspects, regulatory framework, and usability of the device. To be adopted, the medical device must be usable, useful, satisfying, and safe for future users. Furthermore, medical devices should not only address unmet clinical needs but also provide demonstrable benefits for patients. The industrial development must also be cost-effective, to avoid jeopardizing the commercial launch and economic viability of the device.

The technical dimension of development is essential to obtain a functional device. The initial stages naturally often focus on and devote efforts to these aspects.

The regulatory dimension is complex owing to the multiple specificities of each project. Full compliance with the European

**Textbox 1.** Benefits of a user-centered design approach.

- Adoption—when all potential users are involved from the early design phases, clinical adoption of the device is generally much high [2].
- Better adaptation of the device to future users' needs [3-5].
- Better engagement between users, designers, and other stakeholders [6].
- Better communication regarding design [6].
- Heightened dynamics—“The iterative nature of user-centered design means that assumptions are continually challenged and revised throughout the development process. This means the perspectives of team members evolved throughout the project as more information was uncovered and incorporated” [7].
- Economic gain—lack of use analysis is a cause of budget underestimation for information technology and health projects [8,9]. “An investment in usability testing can benefit manufacturers in myriad ways, including optimising development schedules, increasing sales, simplifying training and product support, and reducing legal exposure” [10].

This paper presents a case study illustrating the integration of the usability dimension from the early design phase in the development of an innovative medical device, with the aim of reducing costs and avoiding slowing down of the development phase between concept and proof of concept.

### Study Context

This case study is related to the design of a device to monitor postsurgical complications following colorectal surgery.

Abdominal surgery is continuously improving owing to the development of new surgical procedures, particularly, minimally invasive techniques such as laparoscopy and robot-assisted surgery. In addition, patient care has evolved with fast-track management [11,12]. Despite these significant advances, complications continue to occur. The most detrimental postsurgical complication following colorectal surgery is colorectal anastomotic leakage (CAL). CAL occurs frequently and can be serious, with incidence varying between 3% and 19% [13-17] and mortality rates between 2% and 18% [14,16,18,19]. Moreover, CAL remains challenging to detect at an early stage. On average, CAL is detected 7 to 9 days after surgery [20,21], when the patient may be recovering at home. A total of 18% of cases of CAL are diagnosed after the patient has been discharged from the hospital [22]. This situation can be problematic, as delay of 2.5 days in diagnosis has been linked

regulations relating to medical devices (European Union Medical Device Regulation 2017/745) is required for the device to enter the market. In the early phases of development, ergonomic features are often understudied. These features are essential to ensure the safety of the medical device for all users. Compliance with the European regulations is presumed when the standard *Application of usability engineering to medical devices* (International Electrotechnical Commission [IEC] 62366-1:2015) is followed.

A user-centered design (UCD) approach aims to place future users at the center of the design process. Benefits of this approach are described in [Textbox 1](#). Co-design is managed by combining technical and user expertise, including cycles with a requirement analysis phase; a design, test, and realization phase; and an implementation and monitoring phase [1]. The entire cycle or specific phases can be repeated until the objectives are achieved to the satisfaction of all the stakeholders.

to increase in mortality from 24% to 39% [23]. Consequently, early detection of CAL is key to improving postoperative outcome for patients.

One of the main challenges is to identify biomarkers that predict CAL. An innovative strategy involves detecting biomarkers in wound exudates collected from an intra-abdominal drain. The identification of the most relevant, indirect, and predictive markers of infection has been previously studied by the present authors and collaborators [24,25]. These studies involved 540 patients who were treated for colorectal resection and underwent colorectal surgery between 2007 and 2018. On the basis of the good specificity and selectivity of the combination of pH and lactate, both biomarkers have been selected as the most promising candidates [26,27] because changes in the levels of these biomarkers in real time could help to correctly monitor the onset of CAL and modify therapeutic strategies. To meet the challenge of monitoring these biomarkers, a breakthrough innovation was considered: a smart sensor system connected to the drain, deployed and activated at the end of the surgery. This system would provide early alerts to adapt patient care immediately upon the detection of biomarkers of concern.

### Presentation of the Connected Sensor System

The Exucheck project was designed to develop a system that will provide early alerts for postoperative infections, for

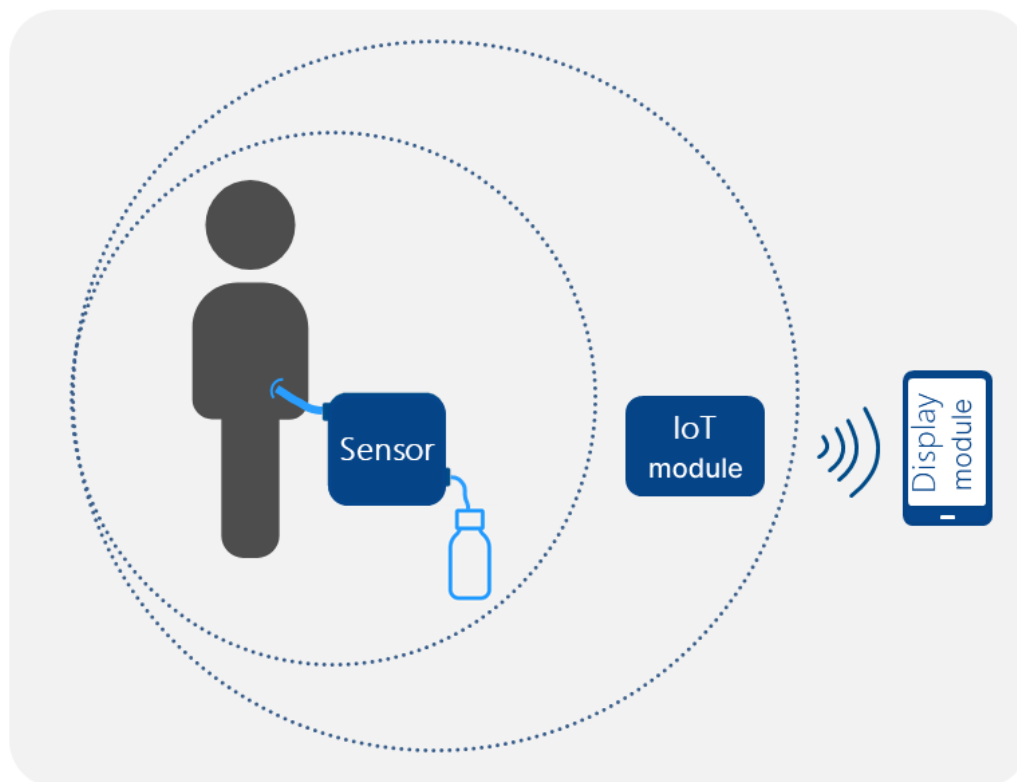
example, anastomotic leakage following colorectal surgery or infected hematomas. The system is based on a sensor device that analyzes wound exudate following abdominal surgery. Exudate or peritoneal fluid is routinely collected using a drain placed during surgery for rectal cancer. The obtained exudate

can be analyzed by the sensor system in real time. The additional data generated can alert nurses and physicians to infection, even before clinical signs become observable. The medical device is composed of 3 components (Textbox 2; Figure 1).

**Textbox 2.** Components of the medical device.

- A sensor module is connected to the patient's drain. The exudate passes through the measuring chamber in the sensor module. It is set up by health care professionals.
- A reusable Internet of Things module or communication board is clipped to the sensor module, converting it into a wireless communicative medical device. It is set up by health care professionals.
- A display module shows all the information transmitted and computed from the data generated by the sensor and Internet of Things modules. It is used by health care professionals.

**Figure 1.** Overview of the Exucheck solution system. IoT: Internet of Things.



Once the sensor and Internet of Things (IoT) module is connected to the patient's drain by the health care professionals in the operating room (OR), this unit remains attached to the patient during their hospital stay (approximately 3-5 days until discharge).

In the OR, after surgery, the surgeon will connect the sensor module to the drain. Then, the IoT module is connected to the sensor module. The setup is done using the display module. Regularly (configurable timing), the IoT module retrieves the information of pH and lactate values measured by the sensor

module. The staff uses a dedicated smartphone app to assess the sensor values on the display module. One display module can follow several patients and can be shared among health care professionals. The patient is not expected to interact with either the device or the display module.

### Project Partners

All the partners were involved in the device design (Table 1); they incorporated their own requirements (electronic, electrochemical, and industrialization) and the clinical and patient needs into the design process.

**Table 1.** Project partners and their roles.

Partner	Type	Role and expertise
Medtronic	Industrial	Project leader and MedTech expertise (industrialization process and business)
Maatel	Industrial	Electronic and IoT <sup>a</sup> expertise and design and develop the IoT module
CEA <sup>b</sup>	Academic	Electrochemical sensor expertise and design and develop the lactate sensor
Grenoble-Alpes University Hospital	Academic	Clinician expertise and formative evaluation
Erasmus Medical Center	Academic	Clinician expertise and formative evaluation
Grenoble-Alpes University	Academic	UCD <sup>c</sup> expertise

<sup>a</sup>IoT: Internet of Things.

<sup>b</sup>CEA: Commissariat à l'énergie atomique et aux énergies alternatives.

<sup>c</sup>UCD: user-centered design.

## Methods

### Ethics Approval

All participants in Rotterdam provided oral consent and participated voluntarily without a dependency situation. Ethical approval was not sought in the Netherlands for this study, as it is not subject to the Medical Research Involving Human Subjects Act (Wet Medisch-Wetenschappelijk Onderzoek met Mensen [28]), according to the guidelines of the Erasmus Medical Center's ethical committee (Medisch Ethische Toetsings Commissie [29]) and the Netherlands' national legislation [30].

All participants in Grenoble provided oral consent. Ethical approval was not sought in France. As a noninterventional human factors study, which posed minimal risk to the participants, this study was deemed to fall outside the scope of the Jardé Law [31].

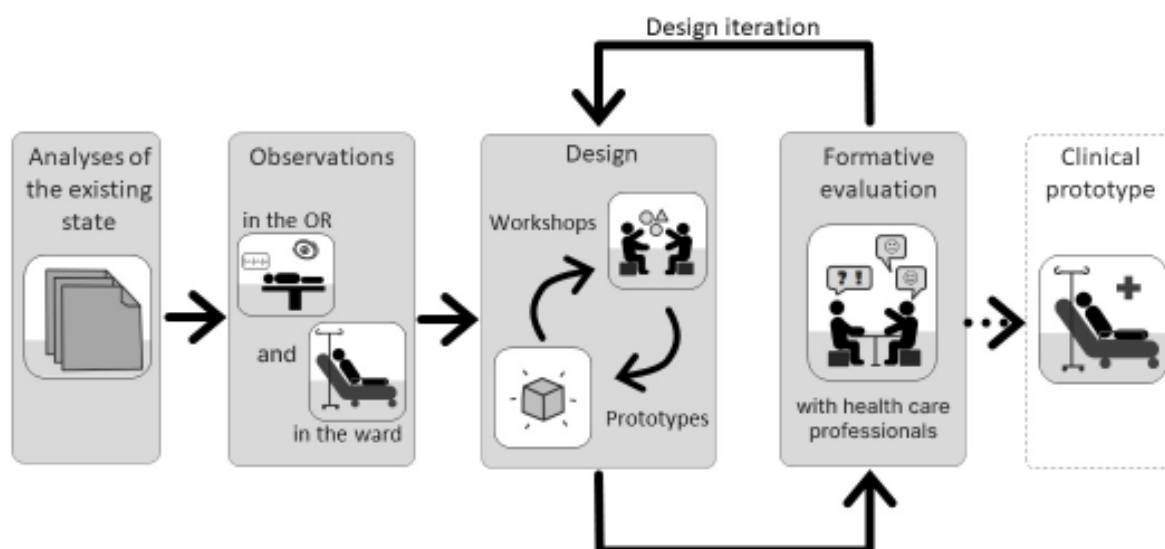
### A Cooperative Design Methodology

To develop this system, a UCD approach was implemented as described in standard International Standards Organization 9241-210 and standard IEC 62366-1:2015. The process required all design choices to be systematically assessed by the users.

For this case study, a *cooperative design* methodology was chosen to benefit from the active participation of future users alongside other stakeholders. This methodology allowed future users to actively and creatively participate in device design [32].

In the cognitive ergonomics literature, many possible methods have been proposed to integrate users and designers in the dynamic process of system development [32]. The following data collection techniques were implemented here (as described in Figure 2): observations, participatory design through workshops (with Medtronic, Maatel,

**Figure 2.** Outline of the methodology used—designed by the authors. OR: operating room.



Commissariat à l'énergie atomique et aux énergies alternatives, and Grenoble-Alpes University), and formative evaluation through user tests (with Grenoble-Alpes University Hospital Erasmus and Grenoble-Alpes University).

This methodology was implemented from the beginning of the project, in parallel with the technical development of the device. The specificity of our intervention was that a first iterative loop



(observation, design, and formative evaluation) was completed before producing a functional prototype system.

This methodology aimed to address 2 important challenges at this stage of the project.

As the users of this device are potentially numerous (surgeons, OR nurses, and department nurses), the first challenge was to define how and when the different stakeholders could interact with the system, from the OR till the patient's discharge. The system should be smoothly integrated into the daily clinical practice.

The second challenge was to propose technical characteristics for the development of the system, such as the size, weight, and attachment system on the patient.

### **Analyses of the Existing State (January 2019 to February 2019)**

Analyzing the overall background of the industrial partner's project shed light on the key points to be addressed:

1. Commercial: market and competitive landscape study
2. Technical: work on biomarkers [24-27] and development of connected pH and lactic acid sensors
3. Use of the device: initial feedback from expert health professionals (voice of the customer) on the clinical needs and means to address them and storyboard presenting how the device will be used by experts
4. Literature review

From the first clinical needs identified, these documents helped to define a strategy for the technical deployment and wide adoption of the device, considering the future users and how the new device can be integrated into their practice. The knowledge at the beginning of the project was mainly provided by experts, without fully integrating the realities in the hospital setting. The initial focus of this case study was interest in the system, rather than its real future use and the corresponding challenges.

Thus, close observation of the actual work of future users should provide valuable knowledge, serving as a basis for the whole UCD.

### **Observations (March 2019 to May 2019)**

In all, 2 European hospitals were recruited as partners in the project, the Erasmus Medical Center in Rotterdam (the Netherlands) and Grenoble-Alpes University Hospital (France), to include complementary dimensions in the project (different countries and organizations; involvement in similar projects). Moreover, Erasmus Medical Center was involved in 2 clinical studies with Medtronic to determine the interest in biomarker use [24,32], and Grenoble-Alpes University Hospital is intensively committed to evaluate innovative medical devices, with a group entirely comprising experts in UCD approaches. As cultural and organizational differences were expected, observations were conducted at both sites. In Grenoble, observations were conducted by 2 usability engineers. In Rotterdam, they were performed by a usability engineer, a French surgeon, and a Dutch physician.

Several visits were made to observe routine practices and analyze the work of the various participants (surgeon, nurse manager, nurse, and nurse assistant in the operating theater and hospital ward). A total of 5 elective procedures (laparoscopy and laparotomy) were observed, 1 at Erasmus Medical Center and 4 at the Grenoble-Alpes University Hospital. Totally, 5 shifts (morning, afternoon, and night shifts) were observed in the digestive ward of the Grenoble-Alpes University Hospital. In addition to the data gathered during the course of these observations, interviews were conducted with several selected users.

The objective of these observations was to understand the use context, tasks to be completed, tools currently used, and how conditions vary from day to day. These observation times highlighted the needs and expectations of the target users and the potential difficulties and constraints they may face. This information was used to design a tool that would be easy to integrate into the health care professionals' daily practice.

### **Workshops (June 2019 to October 2019 and February 2020)**

Participative workshops with members of the development team were conducted to promote an efficient design of the medical device. They were facilitated by the presence of 2 usability engineers involved in the project. Industrial partners provided complementary expertise with new and integrative ideas on the development of the system [33]: Maatel for the development of the IoT module, Commissariat à l'énergie atomique et aux énergies alternatives for the development of the sensor module, Medtronic for the global vision and commercial strategy of the project, and usability engineers for the integration of the users' needs.

A total of 4 themed workshops were set up in the Grenoble area. The sessions were centered around the manipulation and handling of the device in simulated condition. Thus, a life-size mannequin's bust and several drains were available in each session.

The size and weight of the device were the subject of the first workshop. To ensure the efficacy of the session, a mock-up of the future device, electronic components similar to those that will be used in the future device, a balance, and a ruler were available. The manipulation of the objects provided support to overcome the unavoidable technical constraints regarding the needs of the users. Through exchanges and proposals, the technically viable size and weight were determined.

The first version of the device was 3D printed with the previously defined size and weight.

The second workshop was centered on connectivity between the sensor and the IoT modules. Each member manipulated different connection systems previously identified by the usability engineers. The session ended with the selection of a connection system that was both easy to handle, sufficiently safe to avoid involuntary disconnection of the 2 modules, and technically feasible.

The wireframe smartphone interface was the theme of the third workshop. The first version was created by the usability

engineers using Adobe Experience Design (Adobe). The aim was to test the interface through different scenarios to readjust the wireframe in preparation for user tests.

The final workshop was conducted after the usability tests (refer to the *Formative Evaluation Through Usability Tests* section) and focused on the device's attachment system to the patient.

To affix the system, a technical constraint was the length of the drain. The device should be placed at 10 cm from the abdomen (to avoid degradation of exudates along the drain), which limits the options for positioning the sensor module. As the system has significant weight, the risk of it pulling the sutures holding the drain in place as it exits the skin (major source of pain and infection) must be considered. Therefore, it is necessary to be able to attach it to the patient. During this workshop, attachment systems used on stoma and urinary pouch, camera pouch, and belt pouch were considered and manipulated to converge on an ideal solution.

Working with low-level equipment has the advantage of allowing the user to visualize how the device may be integrated into their daily practice without hindering imagination. Using systems that seem very mature or products that require high developmental cost often hinders creativity. These workshops

promoted the rapid development of a prototype system, which was tested with the expected users to obtain data from the clinical field.

### Formative Evaluation Through Usability Tests (November 2019 to December 2019)

A total of 5 usability tests were organized with 13 participants: 3 groups with nurses and nurse assistants (n=2, 67% in Grenoble and n=1, 33% in Rotterdam) and 2 groups with surgeons and surgical residents (n=1, 50% in Grenoble and n=1, 50% in Rotterdam), to compare views and analyze feedbacks. These tests were conducted by 2 usability engineers.

Tests were performed using low-level mock-ups (3D-printed model). They were sufficient at this stage of the study and perfectly allowed users to project themselves to future use of the tool. Thus, simple technical designs were developed, not going as far as anything sufficiently tangible to be presented as functional to future users.

To conduct the tests as efficiently as possible, a transportable *test kit* (Figure 3) was developed in addition to the mock-ups and wireframe smartphone interface. This kit included the test protocols, a camera, and a mannequin bust.

Figure 3. Usability test setup.



The aim of the Exucheck project was explained to all the participants before the start of the usability tests. Participants were free to ask questions, and all questions were answered. During the test, participants were asked to perform a set of tasks that they may be asked to perform in the future, using the whole prototype system (sensor, IoT modules, and wireframe smartphone interface). For example, they were instructed as follows:

*The patient (Mrs. de Groot Ann) is coming out of surgery. A drain was placed after the surgery. To analyse the exudates, the surgeon placed an*

*“Exucheck” sensor on the drain. You must now plug the IoT module into the sensor in order to get the exudate analysis. You have a Smartphone that will guide you through the different steps to install the IoT module. It's your turn now!*

Participants could stop any suggested task during the usability test. It was emphasized that it was the Exucheck system that was tested, not the participants. All participants provided their consent to participate in the usability tests and have the session recorded by video and audio for subsequent analysis.

The participants were able to comment on the size, shape, and weight of the mock-ups and the ease of navigation on the wireframe smartphone app.

User tests made it possible to do the following:

1. Present the concept to future users.
2. Gather early feedback to identify points that are not yet addressed.
3. Confirm or better understand clinical practice regarding the introduction of the system.
4. Identify cultural differences between Dutch and French practices.
5. Propose improvements to the system.

## Results

### Context in Which the Device Is Used

Field observations allow better understanding of the tasks, interactions, and constraints associated with the context in which the new system will be integrated. The aim of this case study was to propose transparent and seamless integration of the system into daily practice.

We initially assumed that the device would be fully deployed at the end of colorectal surgery. However, the end of a surgery corresponds to a phase in which the OR nurses are particularly busy. Each additional task linked to the introduction of this system can delay the operating schedule, which is undesirable for the just-in-time organization of the operating theater. Thus, another setup was proposed: only the sensor module must be calibrated in the OR. When the patient returns to the ward after surgery, a nurse and nurse assistant round occurs. Then, a few additional minutes can be taken to attach and activate the IoT module.

During hospitalization, and consistent with real hospital organization, the best time to monitor the sensor data is as part of standard nurse and nurse assistant rounds, when other biological parameters are recorded (temperature, blood pressure,

etc). Every minute is accounted for in a hospital environment. Over the course of observations and interviews, the fear of adding to the workload was mentioned several times. Thus, it is essential that the tool can be configured as quickly and automatically as possible. Owing to the many daily constraints faced by hospital staff, this device should not be seen as an additional hurdle.

Daily practices were not significantly different in terms of patient trajectory of care between the Grenoble-Alpes University Hospital and Erasmus Medical Center. However, 2 main distinctions were observed: lower frequency of nurse rounds in Rotterdam than in Grenoble and the role of a physician assistant to whom the nurses refer in Rotterdam. This role does not exist in France. However, at this stage of the project, these differences do not affect the integration of the medical device into daily clinical practice.

The results of this observation phase are valuable as they represent a rich source of information to refer to whenever a change is made to the product over the course of its design.

To conclude, the workflow was enriched and validated through the usability tests. The medical device was considered compatible with the normal daily practice and workload of health care professionals.

### Features of the Exucheck System

The overall feedback on the features of the system was good from all participants; they expressed interest in the concept.

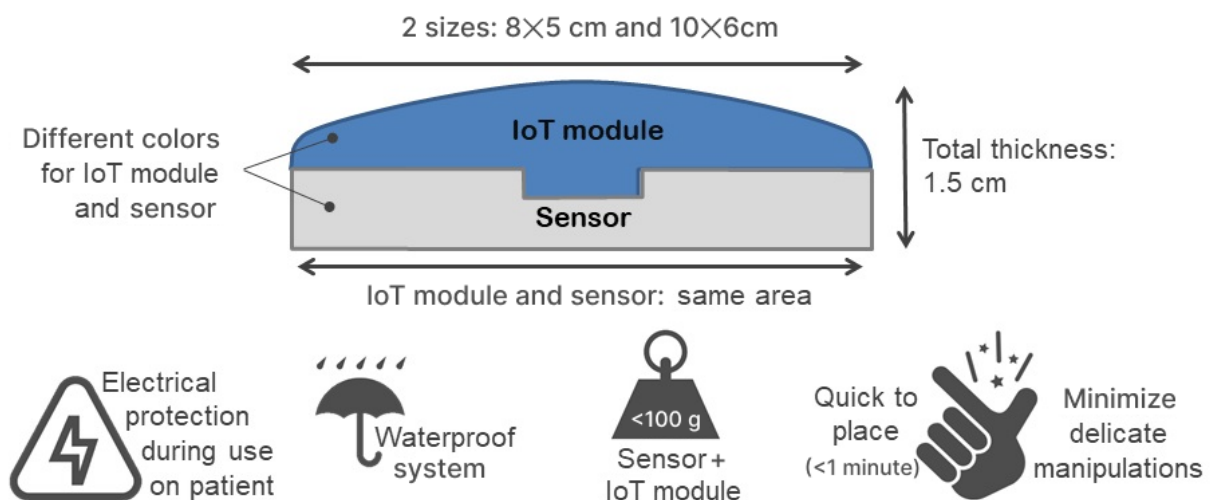
Most future users were willing to test it (“When do you think it will be available for clinical tests?” [surgeon]) and found the concept easy to use (“Good. It is intuitive. It is not complicated”).

Now, we present the features of each element of the system.

### The Sensor and IoT Modules

The following recommendations emerged from dedicated workshops and usability tests (Figure 4).

**Figure 4.** Main specifications of the sensor and Internet of Things (IoT) modules system.

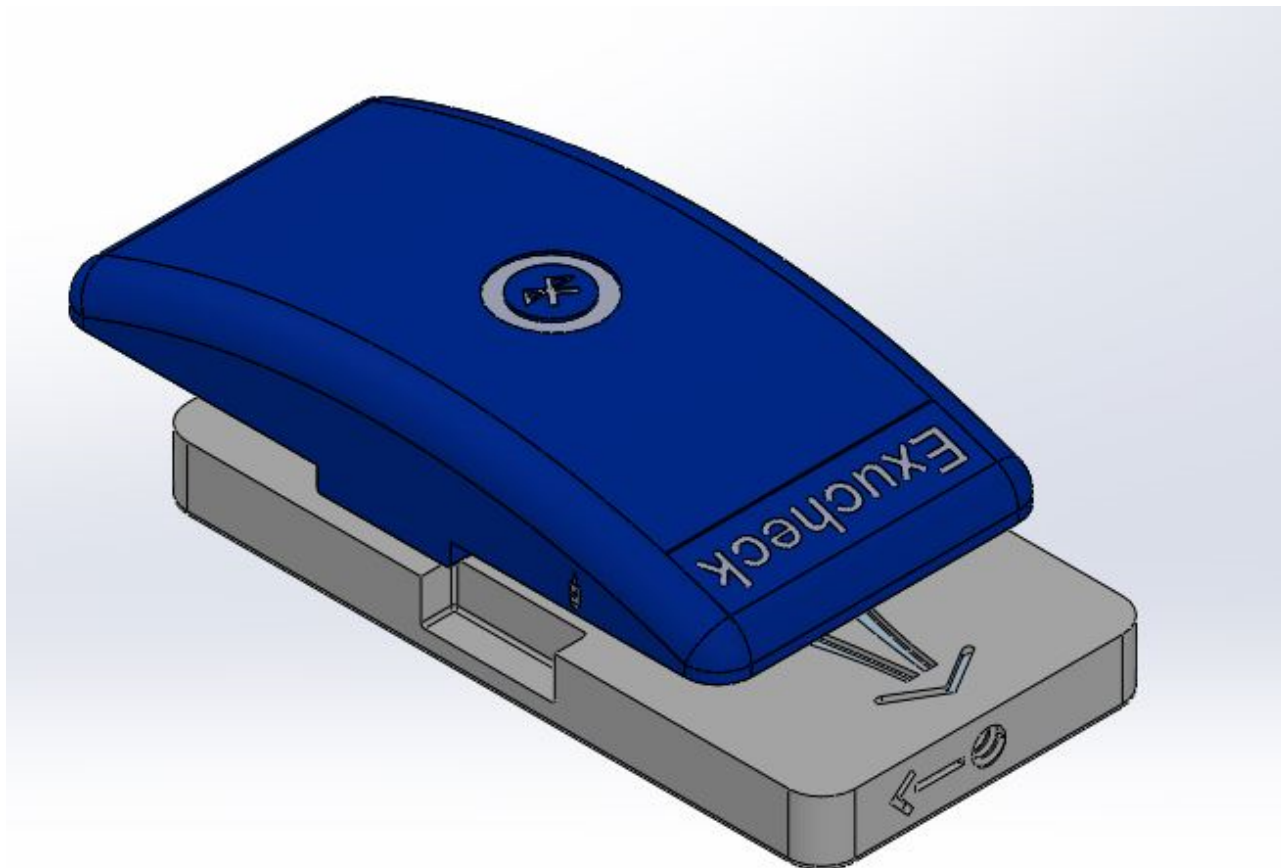


As the weight (maximum 100 g) of the device is a technical constraint (sum of the weight of the electronic board and estimated weight of the sensor module), the perception of load was studied. This perception depends on the density of the

device. Thus, the density can be modified to evenly distribute the weight, to reduce the impression of carrying a load.

The final design that was selected was curved (**Figure 5**) to reduce the impression of bulkiness that users mentioned about the previous 3D model (a parallelepiped).

**Figure 5.** Illustration showing the curved design.



Regarding the connection between the two modules, the participatory design led to the following:

1. Mechanical connection was made through the lateral buttons. Magnet will be used. Push buttons were recommended for the final design.
2. Electrical connection was made through a pin in the IoT module that activates the sensor module when the IoT module is plugged onto the sensor module.

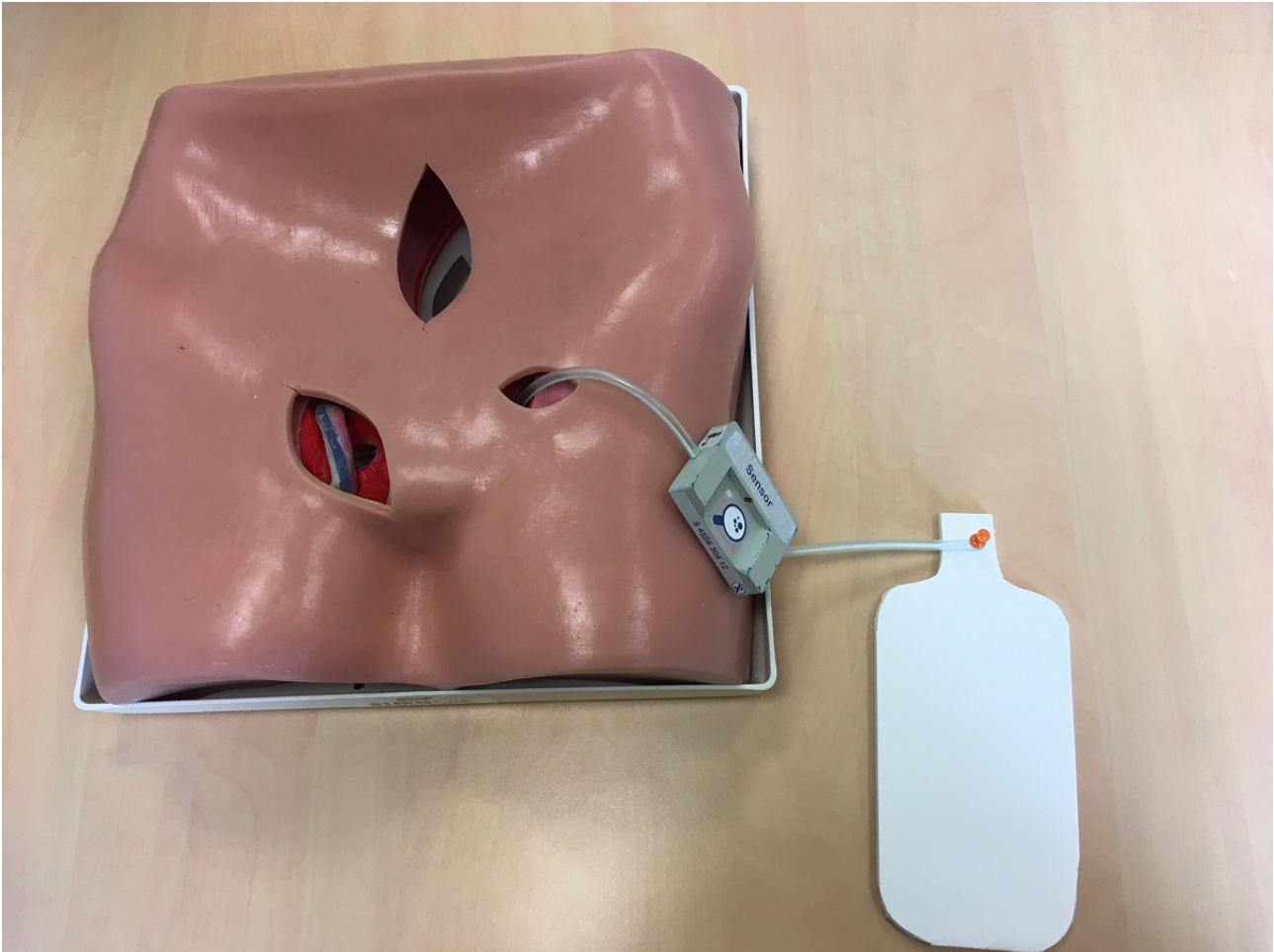
### Device Attachment

The main technical constraint for attaching the system was the length of the drain placed at 10 cm from the abdomen. Usability tests revealed the criticality of this issue, with differing views among the nurses, nurses' assistants, and physicians on *where and how* to affix the device. The workshop dedicated to this aspect also did not result in consensus on a potential placement and fixation of the system. It was concluded that more technical tests were required to remove certain constraints and ensure that the device met the practitioners' requirements.

Thus, how the system should be placed on the patient remains to be resolved. The following key parameters were identified: diameter and length (10 cm) of the drain between the sensor module and where the drain exits the skin (**Figure 6**). To progress on resolving this question, a functional prototype system is required. Currently, two strategies can be envisaged:

1. Seeking solutions and continuing the design iteration cycles. This strategy will allow clinical studies to begin with a more complete device that is close to the commercial device. The clinical study can be used as a support for the summative evaluation to complete the usability file for European Conformity marking [34].
2. Pursuing the proof of concept with a clinical study, despite this issue. This strategy will allow verification of the technical efficacy of the system. Furthermore, it can be used to identify key points to choose the most suitable solution. For example, if the measurements at 10 cm and 50 cm from the exit through the skin are similarly reliable, the sensor and IoT modules can be placed further from the patient's abdomen. This possibility will allow great freedom on where to place the system.

**Figure 6.** Illustration showing the issue regarding placement of the device on the drain attached to the patient's abdomen.



### The Display Module

A wireframe interface of the mobile app was created using Adobe Experience Design (Figure 7).

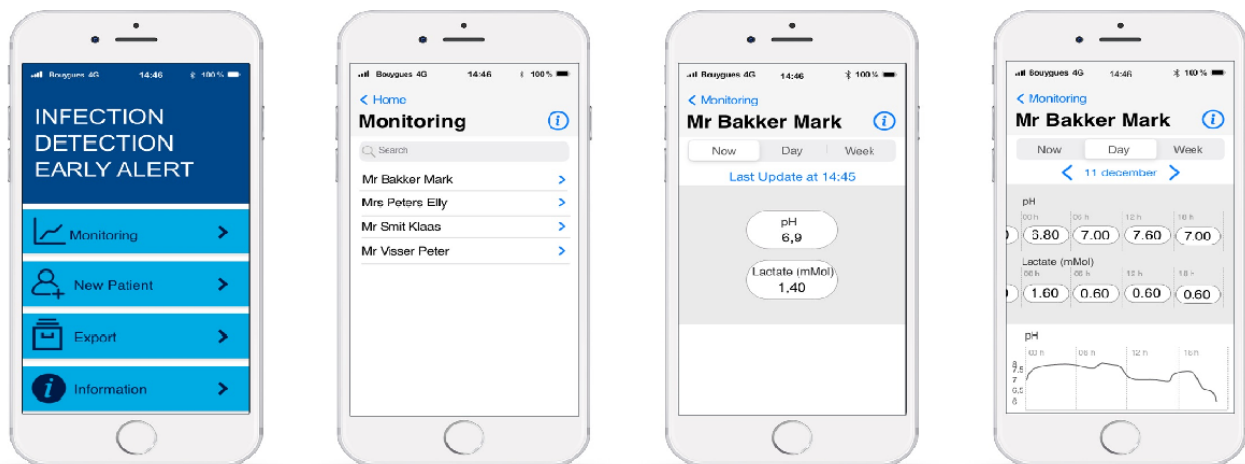
Over the course of discussions with nurses, issues with smartphone type, screen size, security, robustness, and risk of theft were discussed.

Regarding the mobile app, the feedback was positive, indicating that the handling was intuitive, even for professionals who are not particularly technically aware. However, it was

recommended that the font size be increased and access to the results be simplified by minimizing the number of clicks or even eliminating them. For example, the staff suggested that simply bringing the phone close to the sensor and IoT modules should trigger the display of results.

Regarding the use of a medical device based on a smartphone, the health care professionals are open to the idea of having a small touch-sensitive device. The main fear was theft or damage of the device. Therefore, it is important that it is robust and not very attractive to avoid being stolen.

**Figure 7.** Wireframe smartphone interface for the display module.



## Discussion

### Strengths of the Study

The implemented methodology, through observations, workshops, and usability tests, contributed to resolve the 2 challenges (integration into the daily practice and technical features) raised at the beginning of the study. The UCD enabled us to converge toward a common vision of a solution that best meets the requirements of the field and the technical constraints. At the end of this first stage of the project, we obtained a set of recommendations. This medical device will be developed according to feedback from technical tests and the next feedback from users.

The importance of implementing a UCD approach as early as possible in an innovative project was largely confirmed by the results obtained from this case study. Key points to be considered when working on a medical device are discussed below.

First, a UCD implemented at the earliest stage in the development of a medical device makes it possible to guide the design and plan the new technology such that it is consistent with the various users' (physician, surgeon, nurse, etc) daily practices, almost from the beginning. This type of approach guides toward a solution that will be easy to integrate into current care practices in an abdominal surgery department, while remaining technically feasible. Meetings and discussions with future users as early as possible ensure that strategic decisions are made appropriately, such as relating to the shape of the system and its operating mode. Beginning with technical developments can be counterproductive (loss of time and money) if they are not adapted to the reality in the field. By considering the end users' feedback from the earliest stages of the design process, it becomes possible to develop robust specifications for the technical partners within a limited time frame. The cycle of observations, workshops, tests, and new versions of the prototype systems was completed within 12 months, before the culmination of technical development.

Second, the techniques and tools selected were relevant to the context of this medical device and the time frame of the project.

In particular, when designing a medical device for use in a hospital environment, it is important to consider the entire life cycle of the system. In our case, observations began when the device was implemented during abdominal surgery (ie, preparation of the OR) and were continued till the patient was discharged from the hospital. Observation of all the steps allowed a systemic view of the patient's trajectory and helped to understand how the system can be integrated into the care trajectory. Multiple interactions around the patient were noted, which allowed us to envisage how the system will be managed by the distinct groups of health care professionals.

Workshops organized with industrial project partners created a real, dynamic environment around product design. For the case presented here, each workshop was dedicated to a specific developmental aspect: shape of the system, attachment system, and so on, making them attractive, concise, and effective. Each member of the project brought their own expertise based on their field experience and shed light on the expectations of future users based on the data collected during the observation phase. The workshop format was found to be particularly efficient. A wealth of results was obtained over a short period with minimal financial investment. Moreover, by remaining in touch with the needs of end users—medical staff and patients—the team maintained a realistic approach to the system's design, which gave great meaning to the project. Thus, this approach quickly reinforced synergies between partners by decompartmentalizing expertise.

From the beginning of the project, using low-level material made it easy to illustrate what was being said and develop the concept. In our project, a simple 3D print, a drain, and a mannequin bust allowed good projection, for both the future users and the project team. Touching and manipulating elements makes the experience more tangible and generates very rich feedback. In the early stages of a project, functional prototype systems are not necessary or even recommended. Proposing *handmade* prototype systems encourages users to modify them and propose improvements.

Finally, user involvement is central to a UCD approach and requires appropriate strategies for each situation and project, particularly, in a hospital environment. Significant responsibility

is involved, as patients' health depends on the work of the health care staff. Moreover, the health care team's time is precious, and their availability depends on their working hours, which are often staggered. To adapt to these constraints, it is necessary to do the following:

1. Anticipate the time and financial resources needed to facilitate the participation of nurses and physicians [10]. As this case study was conducted as part of the Exucheck project, associating the health care professionals as partners in the definition of the project was key to their involvement.
2. Be available. This made it possible to conduct observations throughout the nurses' and physicians' work, regardless of their working hours. When integrating a new medical device into a department, the atmosphere and tasks differ over the 24-hour period; this can have an impact on how a device is used and on nurses' and physicians' interactions with the system. By appointing 2 usability engineers to work together on the project, a large number of situations could be observed and the results could be compared.
3. Be reactive. An evaluation kit that was always ready and transportable was an asset when conducting user tests. This kit allowed rapid access to the field to exchange views with the team on a last-minute slot and bring the device evaluation tools as close as possible to the nurses' and physicians' workplace.
4. Adapt the organization of user tests. Nurse–nurse assistant pairs were involved, which helped their projection into conceptual innovations. As a result of shared awareness [35] between users, new ideas were more forthcoming and converged more rapidly toward a solution through a limited number of tests. A clinical team should share their practices to help in designing technologies for the team. However, bias can occur as a result of hierarchical relationships within the team conducting tests. The usability engineers must remain vigilant during tests to ensure that they are gathering all points of view.

### Limitations

One of the recognized limitations of UCD is that it considers only end user feedback for design choices and addresses technical constraints in parallel. The co-design approach that we used enabled us to remain as vigilant as possible on this point and to continually confront the needs and expectations of users regarding the technical constraints. However, we note that on certain aspects, notably the attachment of the system to the patient, our methodology has not yet succeeded in proposing a convincing solution. This shows that the user does not always have answers to the problems and that the proposed solutions are sometimes technically unfeasible. Therefore, it is important to set up new design loops involving the end user and the technical team in the design choices. This is especially true as users can evolve, change their minds, gain expertise, and transform their practice. Therefore, our role is to keep a critical eye on their feedback and be open to any request for change. It is also important to bear in mind that every technological advance can call an initial user need into question and vice versa.

Although patients are end users of the medical device, they were not consulted for this project. This was a conscious decision related to the level of progress of the development. In this first phase, the daily life of the patients was observed and analyzed in concertation with nurses and physicians. When a functional system is developed, feedback from patients will be essential. At this stage, there were several questions about the system and how it works to take full advantage of patient feedback.

Another limitation was that observations at both sites occurred only during elective surgical interventions. Thus, the results and recommendations do not consider the specificities of emergency surgery.

The study did not mention criteria such as safety (for the patient and health professional), sterilization or disinfection requirements, biocompatibility materials, antireflux system, and so on. By mutual agreement between the partners, these points have not been considered as priority in this early phase of the project and will be analyzed at a later stage in the mandatory process of risk analysis linked to usability engineering, when the first prototype is available.

### Conclusions

This paper presents the deployment over 12 months of a UCD methodology for the design of an innovative medical device during its early development phase.

The approach was implemented at the beginning of the project, from the concept of the medical device, and in parallel to overcoming technical barriers. The advantages of integrating the usability of the device during this step and in close collaboration with the technical teams, notably through workshops, were the following:

1. Identify valuable technical features (eg, shape, size, and weight) for hardware integration of the sensor module, IoT module, and software interface and avoid unnecessary generation of functional hardware that fails to meet needs. This approach promotes cost-effective development with minimized iterations.
2. Rapidly counterbalance user constraints with technical solutions.
3. Gather initial positive indications of future adoption of the system. This encourages continued technical development and financial investment.

The key to the success of our case study was the techniques implemented (observations, workshops, and usability tests); our adaptation to collecting user feedback in a hospital environment with constraints, particularly in terms of the availability of nursing staff; and finally, the active and enthusiastic involvement of the project team. The interest of the whole team in the results of the usability study and in the technical advances also facilitated their appropriation and integration over the course of the project.

The results show that involving various stakeholders around the notion of usability from the beginning of a project is possible through the implementation of immersive and collaborative techniques and through the very early manipulation of nonfunctional prototype systems.

The targeted objective was achieved. Technical and functional specifications were obtained within a few months. The UCD approach did not hamper technical development and, in contrast, optimized and enriched the development directions. The specifications consider future uses, needs of professionals, and technical constraints, while also facilitating future device integration within the hospital and as part of the patients' trajectory.

This study presents the first iterative loop within the framework of a UCD approach. This starts the usability engineering file according to standard IEC 62366-1:2015 to ensure compliance with European Regulation 2017/45. The approach will support the continuation of the project through other iterations until the final version of the system is produced.

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## Authors' Contributions

CR and CS set up, conducted, and analyzed the results of the usability study. PE, JFL, JLF, and BT contributed their clinical expertise during the study and substantively revised the manuscript. IM and YB substantively revised the manuscript. All authors read and approved the final manuscript.

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## Conflicts of Interest

None declared.

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## Abbreviations

**CAL:** colorectal anastomotic leakage  
**IEC:** International Electrotechnical Commission  
**IoT:** Internet of Things  
**OR:** operating room  
**UCD:** user-centered design

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Original Paper

# Integrating Natural Language Processing and Interpretive Thematic Analyses to Gain Human-Centered Design Insights on HIV Mobile Health: Proof-of-Concept Analysis

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## Abstract

**Background:** HIV mobile health (mHealth) interventions often incorporate interactive peer-to-peer features. The user-generated content (UGC) created by these features can offer valuable design insights by revealing what topics and life events are most salient for participants, which can serve as targets for subsequent interventions. However, unstructured, textual UGC can be difficult to analyze. Interpretive thematic analyses can preserve rich narratives and latent themes but are labor-intensive and therefore scale poorly. Natural language processing (NLP) methods scale more readily but often produce only coarse descriptive results. Recent calls to advance the field have emphasized the untapped potential of combined NLP and qualitative analyses toward advancing user attunement in next-generation mHealth.

**Objective:** In this proof-of-concept analysis, we gain human-centered design insights by applying hybrid consecutive NLP-qualitative methods to UGC from an HIV mHealth forum.

**Methods:** UGC was extracted from Thrive With Me, a web app intervention for men living with HIV that includes an unstructured peer-to-peer support forum. In Python, topics were modeled by latent Dirichlet allocation. Rule-based sentiment analysis scored interactions by emotional valence. Using a novel ranking standard, the experientially richest and most emotionally polarized segments of UGC were condensed and then analyzed thematically in Dedoose. Design insights were then distilled from these themes.

**Results:** The refined topic model detected K=3 topics: A: disease coping; B: social adversities; C: salutations and check-ins. Strong intratopic themes included HIV medication adherence, survivorship, and relationship challenges. Negative UGC often involved strong negative reactions to external media events. Positive UGC often focused on gratitude for survival, well-being, and fellow users' support.

**Conclusions:** With routinization, hybrid NLP-qualitative methods may be viable to rapidly characterize UGC in mHealth environments. Design principles point toward opportunities to align mHealth intervention features with the organically occurring uses captured in these analyses, for example, by foregrounding inspiring personal narratives and expressions of gratitude, or de-emphasizing anger-inducing media.

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## KEYWORDS

mHealth; mobile health; HIV; natural language; thematic analysis; human-centered design; human-centered; user-centered; user-generated content; proof-of-concept; user feedback; web-based; web app; men's health; peer support; informal support; support group; digital health; eHealth; sentiment; design insight; user insight; Python; model; machine learning

## Introduction

### Background

The advent of antiretroviral therapy (ART) marked an inflection point in the global AIDS epidemic, transforming HIV into a manageable chronic condition [1-3]. With people living with HIV who maintain undetectable viral loads incapable of passing the virus to their sexual partners, viral suppression by optimizing ART adherence is now a key tenet of population-level HIV-prevention planning [4,5]. However, ART adherence remains a challenge for many people living with HIV, endangering their health through viral rebound [6]. These challenges are attributable to a range of interlocking factors, many of them mirroring broader societal inequities in the United States: mistrust of medical providers, logistical and financial burdens of medical appointments, and stigma [7-10]. Unreliable transit, a lack of accessible brick-and-mortar services, and trauma can compound these challenges, particularly for many Black men who have sex with men (MSM) [11,12].

These persistent challenges suggest that traditional clinic-based treatment programs may be inadequate for fulfilling the needs of many MSM living with HIV. Mobile health (mHealth) interventions, which offer tools such as informational videos, hyperlocal service guides, and peer-support forums, have shown promise in this domain [13-17], including among MSM [15]. Many mHealth interventions include user-centered adaptations to bolster their appeal to user bases who inhabit intersecting identities (eg, Messages4Men for Black and Latino MSM [18]) or undertake specific risk behaviors (eg, APP+ for stimulant-using MSM [19]).

Traditional formative methods [20-23], often guided by the principles of user- and human-centered design (HCD [24-29]), aim to incorporate the insights of prospective mHealth user bases. Focus groups, user-experience interviews, and related in-person or virtual interactions are often undertaken to gain these insights. These methods can represent important contributions toward global health equity [30,31]. However, by relying on in-depth and often iterative interactions such as “think-aloud” usability tests [32], these methods can be burdensome to members of the communities they aim to empower, requiring time and logistical commitments akin to traditional study participation [33-35]. One alternative to these immersive approaches is mining user-generated content (UGC), comprising rich, unstructured, text-based data that end users themselves contribute to platforms, often in the form of social media posts or product reviews [36,37]. Across diverse sectors [37-39], UGC is increasingly recognized as an unmediated source of experiential data, through which consumers’, citizens’, and end users’ needs can be ascertained noninvasively at scale [40,41].

The scale of UGC data can introduce analytic challenges. The extraction of meaningful units of analysis among vast

unstructured data is the foremost among those challenges [42]. Natural language processing (NLP) approaches, which rely on machine-readable elements such as keyword frequencies and probabilistic distributions of keyword clusters [43], are often employed for UGC analyses [44,45]. One common NLP technique is topic modeling (TM), in which the likelihood of contextually meaningful terms to co-occur in relative proximity to each other and thus signify a discrete topic within an unstructured text is computed [46]. For example, the relative proximity of the terms “epidemic,” “antiretroviral,” and “suppression” in the opening paragraphs of this introduction would be highly unlikely to occur by chance alone. Instead, their likelihood to co-occur in those passages can be interpreted as a meaningful signifier of the topic in those passages, namely HIV treatment. The topic model itself is composed of these co-occurring terms [43]. Another widely employed NLP technique, sometimes used in concert with TM [47], is sentiment analysis (SA). SA refers to a variety of tools that map individual keywords and other syntactic units to a prevalidated human-rated lexicon, computing a crude but summative account of the prevailing emotional tenor of a text [45,48].

NLP techniques are typically incapable of preserving narrative, subtext, and nuance [49,50]. Within digital health research, recent attempts to address these shortcomings have integrated NLP with traditional qualitative methods. These methods, although fruitful, remain exploratory, and are often resource-intensive, with little evident standardization in methods. In health sciences, combined NLP and qualitative approaches have been applied, preliminarily, toward cross-validation of each respective approach. For example, Leeson et al [51] have shown that conceptual overlaps among the findings of probabilistic TM using the Gensim toolkit in Python, the neural network application Word2Vec, and open qualitative coding are broad but not uniform [51], demonstrating the value of a “both-and” versus an “either-or” approach to machine- versus human-optimized analyses of UGC. The clearest strength of the “both-and” approach is its ability to analyze very large textual data sets, while preserving important nuance. To this end, Guetterman et al [52] combined qualitative coding and an NLP semantic-similarity clustering technique to classify open-ended text message responses to the MyVoice national youth poll. Through a modified 2-arm crossover experiment, NLP, qualitative, and sequential NLP-qualitative and qualitative-NLP variations were compared. Although the latter sequential approaches proved most time-consuming, they were able to check the validity of exploratory qualitative work or cultivate more nuanced interpretations of NLP-applied topics, respectively [51]. Jones et al [53] used a sequential qualitative-NLP approach to model topics across 4,901,516 posts contributed to 5 breast cancer forums scraped (with permission) from the open web. Timimi et al [54], examining UGC from the Inspire online support communities, used a nested NLP-qualitative approach to generate “entities” (a clustering

technique) across more than 11 million unique posts. An inductive thematic coding analysis, applied to a subset of 246 posts, aided in developing a patient-centered lexicon to identify cognitive impairment side effects related to statin use.

Specifically, within mHealth, Petersen et al [55] integrated latent Dirichlet allocation (LDA) TM and SA with standard assessments of usability within a user-centered app design process. The sentiment of formative user interviews trended more positive as development progressed, which was reflected through improvements in the System Usability Scale (though not usefulness, satisfaction, and ease of use) scores. To our knowledge, no prior studies have applied a combined NLP-qualitative approach to textual UGC derived from an interactive mHealth environment. This is despite recent calls to bridge the respective strengths of data mining, at scale, with the richly realized insights provided by end-user narratives, to advance design practices in mHealth [56]. These detailed user-experience insights are necessary to advance mHealth design within the HCD paradigm [24,57,58]. If mHealth is to play a key role in the global HIV epidemic response, its persistent adoption will require deeply humanistic, yet scalable, strategies to guide user-centered adaptation. To this end, analyses of UGC in HIV mHealth must preserve the full range of human experiences and unique needs of multiply marginalized people living with HIV.

## Objectives

Recent findings point to the relative strengths of the sequential NLP-qualitative approach toward characterizing large-scale UGC, while preserving experiential nuance [51-55]. We applied a variation of this approach to UGC from the peer-support forum

of Thrive With Me, a web app tailored for gay and bisexual MSM living with HIV [59,60]. Blending the strengths of machine-optimized techniques using NLP analyses with the strengths of traditional qualitative analyses, our findings were guided by the following aims:

Aim 1: To demonstrate the viability of a novel, sequential, NLP-qualitative approach toward characterizing UGC contributed by the end users of Thrive With Me

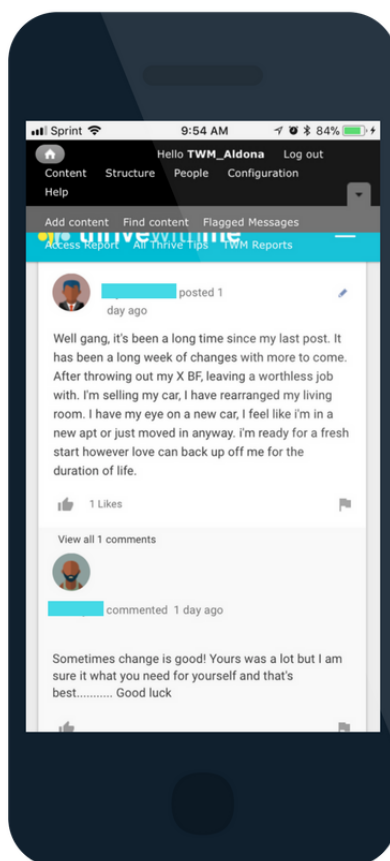
Aim 2: To examine the implications of the UGC-derived insights obtained in Aim 1 toward developing user-centered design adaptations for the next generation of HIV mHealth interventions

## Methods

### Study Intervention

Thrive With Me is a web app-delivered intervention that combines self-monitoring tools for ART adherence, informative multimedia covering ART adherence, and asynchronous peer-to-peer support within a pseudonymous forum with the aim of improving treatment adherence among MSM living with HIV. Its components are grounded in the Information-Motivation-Behavioral skills (IMB) model of health behavior change [61]. An early iteration of Thrive With Me demonstrated preliminary efficacy versus treatment as usual in a pilot randomized controlled trial [59]. A prospective 2-arm randomized controlled trial testing a refined version of Thrive With Me versus an information-only control condition finished in 2019, with outcome analyses presently underway [60]. A screenshot of the user interface on which Thrive With Me users interacted is shown in [Figure 1](#).

**Figure 1.** Illustrative screenshot of the Thrive With Me peer-support forum's user interface. Posts and comments in the screenshot were mocked up by the study staff for demonstration purposes.



## Study Population

Participants were eligible if they (1) were HIV seropositive, (2) identified as males, (3) had a self-reported detectable viral load or suboptimal (<90%) ART adherence in the past 30 days, (4) reported sex with another man in the past 12 months, (5) could read and write English, (6) resided in the New York City area, and (7) had access to the internet and SMS text messaging for the duration of the study [60]. This study analyzed UGC

contributed by participants randomized to the trial's active intervention condition (N=202), who were given access to the Thrive With Me web app for a period of 5 months at baseline. (Throughout, we use "UGC" to refer to unstructured text exclusively, distinct from paradata or usage analytics.) The subsample's sociodemographic attributes are shown in [Table 1](#). Full details of the Thrive With Me parent trial are available elsewhere [60].

**Table 1.** Baseline characteristics of Thrive With Me study participants in the intervention arm.

Demographics	Thrive With Me intervention arm (N=202)
Age, mean (SD)	40.1 (10.8)
Male, n (%)	202 (100)
<b>Race, n (%)</b>	
African American or Black	123 (61)
American Indian/Alaskan Native	1 (0.5)
Asian	1 (0.5)
Native Hawaiian or Pacific Islander	2 (1.0)
White	54 (27)
More than one race	12 (5.9)
Not reported	9 (4.5)
Hispanic, n (%)	62 (31)
<b>Education, n (%)</b>	
High school or less	59 (29)
Some college/associates/technical degree	90 (45)
College/postgraduate/professional degree	52 (26)
Not reported	1 (0.5)
<b>Employment status, n (%)</b>	
Full-time	41 (20)
Part-time	45 (22)
Unemployed	77 (38)
Disabled	35 (17)
Retired	2 (1.0)
Not reported	2 (1.0)
<b>Viral load (VL) measures</b>	
<b>VL (biological) (&lt;20), n (%)</b>	
Detectable VL	74 (37)
Undetectable VL	127 (63)
Not reported	1 (0.5)

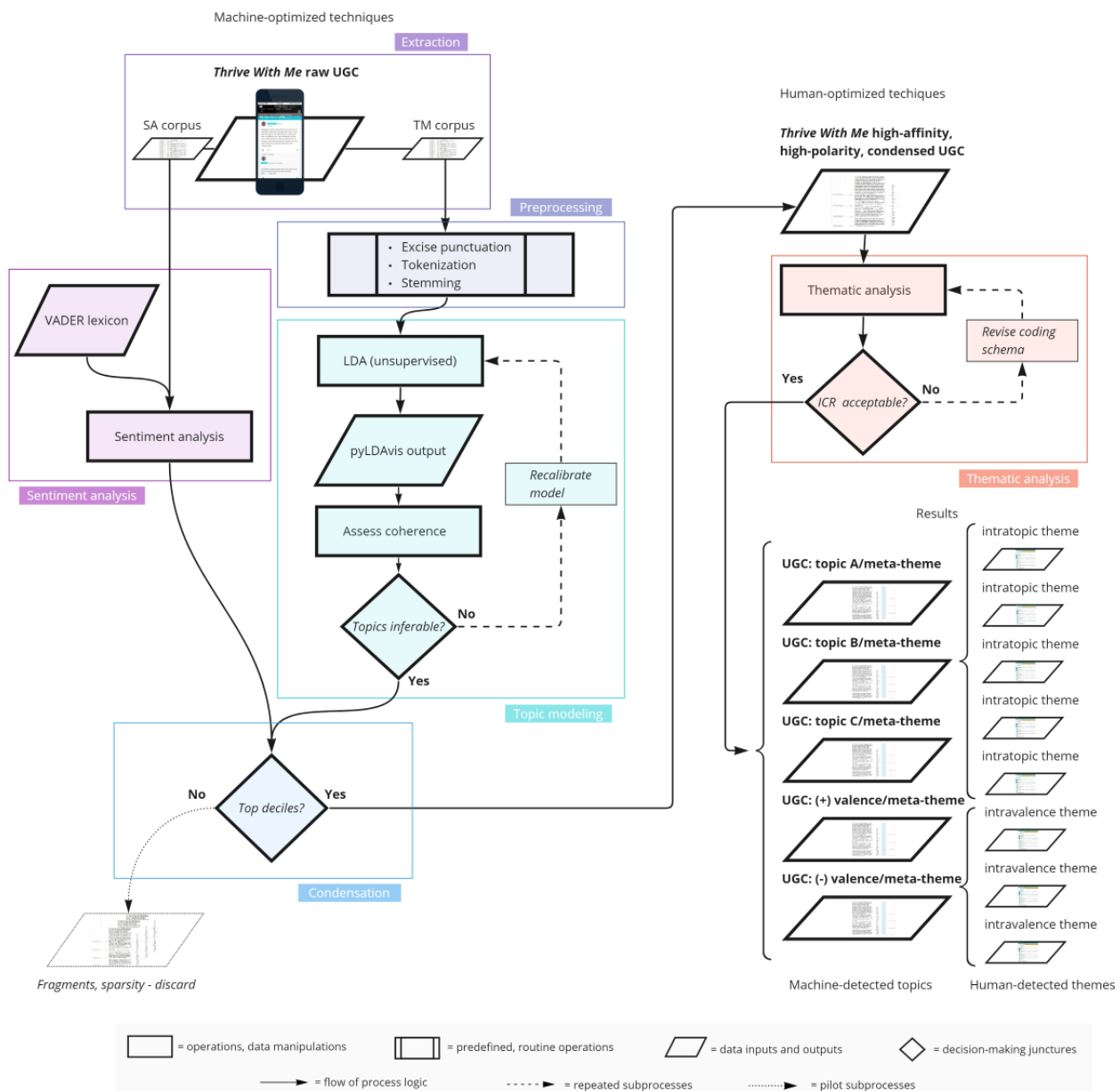
## Ethics Approval

All study procedures and the use of associated data for secondary analyses were approved by the ethics review boards of the University of Minnesota (#1504S69721) and Hunter College of the City University of New York (#2015-0641).

## Procedures

Initially, our procedures relied on the NLP techniques of unsupervised TM and rule-based SA to capture the semantic attributes of UGC drawn from Thrive With Me. We then employed a novel ranking technique to condense the richest and most emotionally polarized UGC. Finally, the detailed insights included in this condensed UGC were explored using the qualitative technique of interpretive thematic analysis. A flowchart of our complete procedure is shown in [Figure 2](#).

**Figure 2.** Flowchart of sequential machine- and human-optimized techniques. ICR: intercoder reliability; LDA: latent Dirichlet allocation; SA: sentiment analysis; TM: topic modeling; UGC: user-generated content; VADER: Valence Aware Dictionary for sEntiment Reasoner.



**Data Extraction**

Textual UGC from Thrive With Me’s peer-support forums were extracted by the web app’s developer, Radiant, as a structured .csv file using the Drupal content management system’s Entity Export CSV function. Original posts and the comments they accrued were handled uniformly (referred to as posts throughout) for the sake of analysis. Content generated by study staff during prelaunch testing was removed manually before preprocessing. With test content excised, the raw UGC corpus contained 4912 posts and 147,649 total words. To accommodate necessary differentiation in the preprocessing steps, 2 UGC corpora were created: the SA corpus and TM corpus.

**Data Preprocessing**

All subsequent data preprocessing and NLP analyses were undertaken in Python (version 3.7.10, Python Software

Foundation) on the Windows 10 (Microsoft Corporation) operating system.

In the TM corpus, first, unigram frequencies were calculated, and any unigrams occurring fewer than 3 times were discarded. The 571-term SMART (System for the Mechanical Analysis and Retrieval of Text) stop list was applied, excising all unigrams, such as “the” and “of,” terms whose co-occurrences are not typically indicative of the underlying topics from the raw TM corpus [62,63]. Capitalization and punctuation were removed throughout. All terms were converted to lowercase and then “split by whitespace” to ensure consonance in model inputs [43].

In the SA corpus, all semantic elements were preserved. In social media environments such as the Thrive With Me forum, peculiarities in syntax may amplify or even invert the intended sentiment of a text (eg, “so happy” versus “SOO happy!!! <3”



versus “sooo happy. /s”) and thus represent important model inputs to retain [64].

### TM Process

All steps in TM were applied to the TM corpus. We used the unsupervised LDA algorithm native to the scikit-learn (“sklearn”) Python library [65]. LDA is a generative probabilistic model that outputs a distribution of words (termed “tokens” [66]), which characterize the discrete topics within a text corpus [46].  $K$ , the number of topics an LDA model will detect, is a model input determined based on prior familiarity with a corpus, relevant domain expertise, and the results of exploratory analyses [43]. Replication scripts for LDA TM are provided in [Multimedia Appendix 1](#).

Each LDA model was evaluated for coherence by the first and second authors (SJS and SSJ) aided by the pyLDAvis tool. pyLDAvis plots modeled topics in 2 dimensions represented by circles, allowing for visual inspection of intertopic distances (how thematically distinct each topic is) and topic prevalence (how much content within a corpus each topic captures). A satisfactory  $K$  is characterized visually by circles with sufficiently large radii to capture a substantive share of a corpus and negligible overlap between circles, indicating discriminant interpretability across topics [67]. Detailed documentation on the use of pyLDAvis is available elsewhere [68]. We denote this preliminary LDA model as Model 1, which advanced to first-pass thematic analysis.

Finally, informed by Schofield and colleagues [62,63] and based on the coding schema developed inductively with Model 1, we removed high-frequency, non-topic-specific  $n$ -grams to generate a more intuitive set of tokens. This second pass was used to provide more self-evidently meaningful clusters of tokens for this proof-of-concept analysis. We denote this final model as Model 2.

Topic labels were developed based on domain knowledge, visual inspection of the top 30 per-topic tokens, and their particular distribution and contextual usage within the full series of posts assigned to each topic. Labels were finalized based on consensus between the first and second authors (SJS and SSJ).

### SA Process

All steps in SA were applied to the SA corpus using the vaderSentiment library in Python [69]. We used the human-validated VADER (Valence Aware Dictionary for sEntiment Reasoner) sentiment lexicon, which scores the valence and intensity of individual terms and their related semantic elements, such as emoticons (“(“:”) and abbreviations common to social media and web-based forums (“lol” and “wtf”). VADER outputs polarity (positive-neutral-negative, on a scale of  $-1$  to  $+1$ ) scores for each input string [64]. For this analysis, we generated sentiment polarity and compound scores per unique post. As the richest instances of neutral-sentiment UGC were thematically redundant with the posts examined via LDA, we focused on emotionally polarized UGC captured by VADER’s positive and negative polarity scores. This focus on polarized UGC allowed us to explore sources and expressions of distress, while highlighting organically occurring positive interactions among Thrive With Me users.

Replication scripts for VADER SA are provided in [Multimedia Appendix 1](#).

### Condensation

Data condensation strengthens an analytic sample by honing it to its richest, most illustrative cases [70]. To condense the raw 4912-post UGC corpora, we used a novel percentile-ranking standard, loosely informed by (and considerably simplified from) the work of Nikolenko and colleagues [49] to advance the most meaningful data toward thematic analysis.

In the TM corpus, we calculated a simple affinity score for each post by summing the number of topic-specific tokens that appeared within that post. In this context, affinity refers to the degree to which each post is representative of the topic to which it has been assigned [49]. Using the =PERCENTILE() function in Excel (Microsoft Corporation) [71], we identified the 90th percentile affinity score for each topic, discarding posts that contained fewer topic-specific tokens than the 90th percentile thresholds.

In the SA corpus, we relied on VADER-generated polarity scores for percentile ranking. Posts that fell below the 90th percentile polarity score for positive and negative valences were discarded.

The SA and TM corpora were percentile-ranked independently. LDA modeling, which relies on co-occurrence of terms, favors verbose UGC, whereas VADER, reliant on purer expressions of sentiment, favors concision; hence, no UGC was duplicated in the condensed TM and condensed SA corpora. Specifically, richer and verbose UGC was emphasized in the condensed TM corpus, whereas emotive and concise UGC was emphasized in the condensed SA corpus.

A 90th percentile cutoff was chosen to condense a data set such that it became compact enough to be handled by 2 human coders (SJS and CMC) for the following inductive thematic analyses.

### Interpretive Thematic Analyses

The condensed data set, comprising high-affinity and high-polarity UGC, was then subdivided into .csv files for thematic analysis by human coders. We used an inductive latent-level approach to examine the underlying concepts and discursive nuances intratopically [72]. Each stable topic and the strongest positively and negatively scored posts were thus handled as a meta-theme, each within a discrete .csv file. Human coders (SJS and CMC) undertook immersive close reads of these posts, identifying emergent intratopic themes and building pilot codes, first independently and then collaboratively, informed by the RADaR (rigorous and accelerated data reduction) technique in Excel [73]. Initially, we conducted open coding in Excel to leverage the accessibility of rapid matrix analysis techniques undertaken with nonspecialized software and to facilitate the necessary sorting and ranking of posts. Codes were applied iteratively and the overall coding schema was refined in conference, until unanimity in coding applications was obtained. Then, all data were migrated to Dedoose (SocioCultural Research Consultants) for final coding of the condensed data set that included LDA Model 1, where an overall pooled intercoder reliability of  $\kappa=0.78$  was achieved [70,74].

Finally, after obtaining the acceptable intercoder reliability, the first author independently applied the coding schema to the condensed data set that included LDA Model 2 in Dedoose, producing the final coding applications reported here.

## Results

### TM Process

The LDA model rated for optimal coherence comprised  $K=3$  topics, each composed of 30 co-occurring tokens. Topic A, disease coping [75], encompassed all posts in which the subject of living with HIV as a chronic condition predominated. Topic B, social adversities, covered those posts explaining the difficulties of navigating the interpersonal sphere as a person living with HIV. Topic C, salutations and check-ins, covered the broad array of brief greetings and personal updates routinely shared by users of the Thrive With Me forum. From the refined model, Model 2, our condensed data set included the 67 posts that contained more than 5 topic A-specific tokens (mean 7.31, SD 1.83), 118 posts containing more than 6 topic B-specific tokens (mean 9.43, SD 2.05), and 113 posts containing more than 4 topic C-specific tokens (mean 5.81, SD 1.14).

Altering the percentile split (whose primary rationale in this study was pragmatic) would have varied the size of the condensed UGC corpus considerably. In topic A, at the 75th percentile, at  $>3$  tokens per post, 188 posts would be carried forward to thematic analysis; at the 95th percentile, or  $>6$  tokens per post, 38 posts would be carried forward. In topic B, at the 75th percentile, at  $>4$  tokens per post, 270 posts would be carried forward to thematic analysis; at the 95th percentile, or  $>8$  tokens per post, 72 posts would be carried forward. Topic C, given the sparser nature of its UGC, was more dispersed. At the 75th percentile, at  $>2$  tokens per post, 522 posts would be carried forward to thematic analysis; at the 99th percentile, or  $>6$  tokens per post, only 20 posts would be carried forward.

The Model 2 tokens that characterize these topics, their labels and definitions, details of their condensation including the 90th percentile affinity score thresholds, and illustrative excerpts are shown in [Table 2](#).

The number of posts and the number of tokens detected in LDA modeling by topic and by user are tabulated in [Multimedia Appendix 2](#).

**Table 2.** Machine-detected topics, token n-grams, intratopic condensation, definitions, and illustrative examples.

Topic	Model 1 tokens	Model 2 tokens	Label	Definition	Model 2			Example high-affinity posts <sup>a</sup>
					Posts per topic, n (%) (N = 4912)	90th percentile threshold	High-affinity posts per topic, n (%) (N=1276)	
A	aids, care, com, doctor, don, effects, free, health, help, hiv, http, https, just, know, living, meds, need, new, people, positive, support, taking, thanks, time, took, treatment, undetectable, use, www, yes	aids, care, community, days, doctor, effects, feel, free, gay, health, hiv, living, know, meds, man, men, need, new, people, positive, really, sex, support, taking, think, time, took, treatment, undetectable, use	Disease coping	Portrayals of daily living with HIV, emphasizing serostatus awareness, ART <sup>b</sup> regimens, and other sociomedical topics	1028 (20.92%)	>5 topic-specific tokens per post	67 (5.25%)	I don't <i>think</i> disclosing an <i>HIV undetectable</i> viral load will persuade anyone who is <i>HIV</i> negative that we're less likely to infect them. It can be <i>useful</i> for potential partners that are also <i>HIV positive</i> because they are more likely to understand and accept that an <i>undetectable</i> viral load lowers the risk for re infection. Someone looking to avoid <i>HIV</i> or the risk of having <i>sex</i> with anyone <i>HIV</i> infected will likely not <i>care</i> or understand about <i>undetectable</i> viral loads.
B	blessed, cause, com, come, day, don, feel, gay, good, https, just, know, life, like, love, make, morning, men, real, really, people, person, sex, say, things, think, time, want, way, www	better, blessed, cause, come, day, feel, gay, good, hard, know, life, live, love, make, man, men, people, person, point, need, new, real, really, say, think, time, want, way, work, year	Social adversities	Portrayals of challenges and accomplishments in navigating sociality and sexuality as a sexual minority MSM living with HIV	1555 (31.65%)	>6 topic-specific tokens per post	118 (9.25%)	Truth b told.... what i am finding <i>hard</i> is to find guys that <i>want</i> more than a hook up....(they) <i>always</i> seem to <i>want</i> to sleep together <i>FIRST</i> (...) just sleeping with strangers right away doesn't turn me on like it used to... <i>makes</i> me <i>feel</i> kind of like a freak at <i>times</i> ..... if all i <i>wanted</i> to do was 'play'- I'd have NO problem finding guys to roll around with- even with my status- which i immediately and upfront disclose, both online and in <i>person</i> ..... It's finding guys who <i>want</i> conversation and dating and getting to <i>know</i> someone that has been <i>hardest</i> for me....
C	better, day, days, enjoy, feel, feeling, good, great, going, got, guys, happy, hey, hope, just, like, lol, man, morning, new, really, today, time, ve, welcome, year, years, week, weekend, work	best, better, day, doing, enjoy, feeling, going, good, got, great, guys, friday, happy, hello, Hey, hope, lol, luck, monday, morning, nice, really, sunday, thanks, time, today, week, weekend, welcome, wish	Salutations and check-ins	Greetings and brief personal updates	2329 (47.41%)	>4 topic-specific tokens per post	113 (8.86%)	<i>Morning</i> Thrivers! Can say much about my <i>weekend</i> cause I slept through it..... I just <i>wish</i> this holiday season would be over already so I can get back to some kind of normal being..... anyway I <i>wish</i> everyone a productive <i>week</i> and an <i>enjoyable</i> <i>thanksgiving</i> .....

<sup>a</sup>The topic-specific tokens are italicized.<sup>b</sup>ART: antiretroviral therapy.<sup>c</sup>MSM: men who have sex with men.

## SA Process

For the positively valenced ([+]Pos) posts, our condensed data set included the 488 posts assigned a polarity score  $>0.659$  by the VADER lexicon ([+]Pos intravalence mean 0.81, SD 0.12). For the negatively valenced ([-]Neg) posts, our condensed

sample included the 490 posts that were assigned a polarity score  $>0.196$  ([-]Neg intravalence mean 0.34, SD 0.16).

Details of the intravalence condensation of the strongly positive and negative posts, with illustrative examples, are shown in [Table 3](#).

**Table 3.** VADER (Valence Aware Dictionary for sEntiment Reasoner)-assigned sentiment polarity, intravalence condensation, and illustrative examples.

Sentiment polarity	90th percentile threshold	High-affinity posts per valence, n (%) (N=1276)	Example high-affinity posts (including polarity scores)
(+)Pos <sup>a</sup>	$>0.659$ (+) score	488 (38.24%)	<p>“Beautiful story, thanks for sharing” (0.828 Pos, 0.172 Neg)</p> <p>“I love you positiveness.....” (0.789 Pos, 0.000 Neg)</p>
(-)Neg <sup>b</sup>	$>0.196$ (-) score	490 (38.4%)	<p>“I hate trump (lower case)!!!” (0.000 Pos, 0.604 Neg)</p> <p>“Bad anxiety today. Even my blood pressure was high.” (0.000 Pos, 0.552 Neg)</p>

<sup>a</sup>Positively valenced.

<sup>b</sup>Negatively valenced.

## Thematic Analyses

The condensed data set contained 1276 posts: 298 associated with the 90th percentile of the affinity of topics A, B, and C from LDA Model 2, and 978 associated with the 90th percentile of positive and negative polarity. This data set was advanced to thematic analysis. The detected intratopic and intravalence themes, their operational definitions, code co-occurrences, and illustrative excerpts are displayed in a meta-matrix in [Multimedia Appendix 3](#).

Within topic A, most themes articulated the distinct, day-to-day obligations of living with HIV. The most frequently detected themes, which reflected informative prompts provided by the Thrive With Me web app, covered ART medications. These instances were rich enough to warrant the coding of dedicated subthemes capturing detailed adherence tips, personal antiretroviral regimens, and adverse effects. Issues of long-term survival were raised, as were various personal narratives and peer-to-peer recommendations for disclosing one's HIV serostatus to potential sexual partners. Further, a code (“Raising Awareness”) captured the many instances in which users shared details of activist events, local resources, and HIV-tailored public health messaging.

Within topic B, diverse personal narratives were shared, including all articulations of the specific challenges that sexual minority MSM living with HIV may encounter as they seek social and sexual bonds with other men. These included mismatched expectations around relationship longevity and extradyadic pairings, life chaos attributed to partners' alcohol and crystal meth use, and the roles of ex-partners. Trust, broken trust, discussions of self-confidence, and expressions of loneliness and isolation were emergent intratopic themes. The roles of support networks, including direct appeals to and provision of peer-to-peer social support among Thrive With Me users also emerged within this topic.

Within topic C, the overwhelming proportion of UGC was made of brief greetings. In posts where these greetings were expanded to include personal updates and peer check-ins, 2 intratopic

themes predominated; the first comprised substance use, misuse, and recovery, which included disclosures of relapse among Thrive With Me users; second, an emergent theme of personal triumph was also evident, which covered accomplishments such as new physical fitness regimens, career successes, and the attainment of treatment goals such as stable CD4 counts.

Strongly positive posts were characterized by gratitude, typically in response to peer-to-peer encouragements and affirmations occurring on the forum. Strongly negative posts were richer and more thematically heterogenous. Many of these posts were reactions to linked external news media, which overwhelmingly provoked anger. These media often covered acts of homonegativity and racism. Another (–)Neg theme encompassed the political climate in the United States during the period of the Thrive With Me trial, when the 2016 presidential election was decided. The final intravalence theme concerned mental health, typically through expressions of acute or ongoing struggles with depression, stress, and insomnia.

## Discussion

### Principal Findings

We combined common NLP techniques with traditional latent thematic analysis to classify UGC drawn from an interactive HIV mHealth environment. Through multiple iterations of LDA modeling, stable topics emerged: the day-to-day concerns of living with HIV; the social, romantic, and sexual tolls of aging with HIV as a sexual minority MSM; and routine greetings and daily affirmations. Using a 90th percentile cutoff, we condensed the UGC of which these topics were composed from a total of 4912 posts to a rich, illustrative subset of 1276 posts. By further analyzing this condensed UGC as a set of meta-themes, we identified latent discourses within them, through which experiential design insights could be mined.

Our work contributes to the diverse, cross-disciplinary literature exploring sequential NLP-qualitative methods [49,51-55,76], while responding to the call of Britt and colleagues [56] to explore the possibilities of integrated data mining and narrative analyses in mHealth. By sequentially combining NLP and

qualitative techniques, our work resembles recent analyses that demonstrated the ability of consecutive NLP-qualitative methods to create machine-generated meta-themes from web-based forum and text message data and, in turn, preserve narrative and context through qualitative coding [51-55]. In contrast to these analyses, we used UGC derived from an interactive mHealth environment, focusing on user-centered product adaptation as a potential application. In emphasizing design applications, our work resembles that of Petersen et al [55], who applied similar NLP techniques to interviews of prospective users of an exercise-promoting wearable technology, capturing improvements in sentiment and usability at 0-, 5-, and 10-week intervals. Unlike our own, this analysis [55] fulfilled the iterative criteria of a user-centered design cycle [22,26,27], forgoing the more labor-intensive aspects of qualitative analysis [70], while demonstrating its NLP-aided, user-centered approach.

To that end, the results reported here offer partial fulfillment of Aim 1. Although the sequential methods we demonstrated did successfully characterize the prevailing themes of the peer forum, the future viability of these methods will depend on their routinization. Our procedures included a number of transformations and cross-platform migrations, each of which introduces friction, which in turn disincentivizes adoption [77]. Routine NLP-enabled mHealth monitoring would, instead, require integrated text analytics [78,79] and graphical user interfaces to ensure accessibility for investigators without coding expertise [56]. Such “no-code” (a common industry term) solutions could aid in bridging the knowledge-translation gap through evidence synthesis and translation, a lasting challenge in implementation science [80], as well as in clinically integrating mHealth interventions [81]. Alternately, although our method demonstrates the value of maintaining human interpretability of NLP outputs, the very thematic codes we developed inductively might lend themselves, in future, to repurposing as target labels in training HIV-domain data sets for supervised deep-learning applications [82]. The inherent potential of such “both-and” approaches remains to be explored.

As for Aim 2, a range of actionable design insights surfaced from these findings to guide future iterations of Thrive With Me specifically and HIV mHealth generally. An HCD approach typically reframes these insights as “how might we” (HMW) prompts, a reframing we embrace here [24,26]. First, the seropositive MSM end users of Thrive With Me who engaged in the peer-support forum typically did so transparently and intimately, tapping their peers for encouragement, collaboratively navigating difficult subjects. These instances are most evident throughout topics A and B, specifically within the ART-related, “survivorship,” and “partnering challenges” themes and in the peer-to-peer affirmations surfaced via the (+)Pos UGC. Nevertheless, the forum was also, more problematically, a platform to express outrage at external news media. These media often recounted instances of homonegative violence and discrimination. These issues were, of course, clearly relevant to Thrive With Me users, as “reacting to media” codes, emergent within the (-)Neg condensed UGC (exclusively), occurred at twice the frequency of any other, with the exception of “partnering challenges” within topic B. However, their intrusive nature and negativity may have

dampened the overall emotional tenor of the forum. These appeals to outrage may have discouraged newly enrolled or “lurking” users from interacting with the forum or disproportionately consumed their attention. In either scenario, the intended benefits of the social support provided by the forum may have been undermined. As such, HMW 1 is “How might future iterations of Thrive With Me acknowledge the anger evoked by an oppressive society without compromising the supportive aims of the peer forum?” Active content moderation, dedicated channels for current events, or even an embargo on outbound links might accomplish such an aim; however, these solutions would require prototyping and prospective end-user feedback in an HCD cycle [24].

Another topic, with several related intratopic themes, concerned relationship difficulties. In addition to the abovementioned “partnering challenges” theme emergent within topic B, unmet relationship needs were evident throughout the “trust and betrayal” and social isolation-focused “voids in my life” themes. Thus, HMW 2 is “How might we support the interpersonal needs of seropositive MSM without imposing model drift into an ART adherence intervention?” The latent need is evident, and the deliberations of end users often touched on cross-cutting topic A and (-)Neg themes; the richest instances of intertopic cross-codings are shown among the “disclosing serostatus” (topic A), “partnering challenges” (topic B), and “substance use and misuse” (topic C) themes, illustrating the entanglement of these issues in Thrive With Me users’ lives. Dedicated informational modules might address these needs more directly, tying decision-making within this domain to specific triggers for illegal drug use or missed ART doses in a manner consistent with the IMB model in which Thrive With Me is grounded [60,61].

Finally, a desire to narrativize the personal triumphs of HIV survivorship is often evident across topics A and C, particularly within the “survivorship” and (in vivo) “other days I move mountains” codes. These narratives, which cover grief, coming out, and the lessons imparted by long-term survival, surface as an organically occurring form of UGC, pointing out their importance to Thrive With Me users, perhaps as validations of their personal resilience. Such strength-based, person-centered affirmations may hold the potential to constructively reauthor Thrive With Me users’ experiences of societal oppressions, while finding resonances within each other’s stories [83,84]. If implemented carefully, such reframing may redirect the negativity discussed in HMW 1 without invalidating the stressors that drive it, while simultaneously encouraging engagement with the peer forum. An appropriate HMW 3 is “How might we activate the potential of personal narratives toward the well-being of MSM living with HIV?” Asynchronous health recovery narratives, even those scraped from UGC on the open web, can enhance behavior-change self-efficacy and the likelihood of cancer screening [85,86]. The curation of these narratives in a dedicated portal, akin to innovations in digital psychiatry such as the NEON (Narrative Experiences Online) intervention [87], might represent an adaptable periphery of next-generation HIV mHealth [88].

## Limitations

These findings are subject to a range of limitations. As a proof-of-concept analysis, our methods are exploratory. Nevertheless, the abovementioned migrations and transformations built into our methods allow for the imposition of human error, while rate-limiting the rapidity with which results can be generated. In contrast, the adoption of a single alternative developer environment such as R (R Foundation for Statistical Computing), which permits qualitative analyses via the R qualitative data analysis package [89] would enhance efficiency considerably. We were also limited by our inability to member-check our LDA modeling and thematic coding schema with Thrive With Me users themselves, which would have bolstered transactional validity and laid the groundwork for a true HCD process, incorporating iterative prototyping, design sprints, and feedback elicited from the user base whose needs we attempt to fulfill. The use of domain-expert raters employed by Nikolenko and colleagues [49] to assure the coherence and human interpretability of LDA outputs offers a template for such a member-checking approach. A de facto tension exists between HCD, which is nimble, creativity-driven, and interactive, and UGC analysis, which is static and typically archival. Innovative solutions, such as real-time syndromic

surveillance on social media [90,91], point toward the possibilities of resolving this tension and toward potential innovations in interactive mHealth. Finally, through a design justice lens [31], we recognize that the approach we describe leverages analytic advancements undertaken in English, using English-language corpora, within an intervention context that requires users to receive information and interact in English [60]. Although the need for multilingual NLP is recognized within the field, progress remains limited [92]. Monolingual approaches toward capturing user-experience insights will, of course, remain narrow in scope amid the vast diversity of human speech.

## Conclusions

mHealth interventions that fulfill the needs of multiply marginalized MSM living with HIV must accommodate a diverse array of needs and experiences. The findings of this proof-of-concept analysis suggest that combined machine- and human-optimized techniques can capture actionable insights on these needs and experiences without adding to the burdens of prospective end users. By maintaining an empathic lens and focusing on refinements in method, techniques such as those demonstrated here can contribute to future innovations in HIV mHealth.

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## Authors' Contributions

SJS and SSJ designed and executed the analysis, with SJS leading the condensation, thematic analyses, and human-centered design (HCD) interpretations, and SSJ leading the preprocessing, topic modeling (TM), and sentiment analyses. CMC served as consensus coder in all rounds of thematic analysis and contributed toward the initial drafting of the manuscript. KJH designed the Thrive With Me intervention, led the development and parent trial from which these secondary analyses originated, and supervised all aspects of the work described herein. SJS wrote the initial draft of the manuscript, with SSJ, CMC, and KJH contributing to its refinement.

## Conflicts of Interest

SJS is a paid advisor to Waverider, which builds customizable dialectical behavior therapy eHealth tools. SSJ, CMC, and KJH declare no conflicts of interest.

### Multimedia Appendix 1

Text preprocessing, latent Dirichlet allocation topic modeling, and VADER (Valence Aware Dictionary for sEntiment Reasoner) sentiment analysis replication scripts in Python.

[[TXT File , 13 KB - humanfactors\\_v9i3e37350\\_app1.txt](#) ]

### Multimedia Appendix 2

Tokens detected per user, per topic (Model 2).

[[DOCX File , 49 KB - humanfactors\\_v9i3e37350\\_app2.docx](#) ]

### Multimedia Appendix 3

Human-detected intratopic (Model 2) and intravalence themes with definitions and illustrative examples.

[[DOCX File , 29 KB - humanfactors\\_v9i3e37350\\_app3.docx](#) ]

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## Abbreviations

**ART:** antiretroviral therapy  
**HCD:** human-centered design  
**HMW:** how might we  
**IMB:** Information-Motivation-Behavioral skills  
**LDA:** latent Dirichlet allocation  
**mHealth:** mobile health  
**MSM:** men who have sex with men  
(-) **Neg:** negatively valenced  
**NLP:** natural language processing  
(+) **Pos:** positively valenced  
**SA:** sentiment analysis  
**TM:** topic modeling  
**UGC:** user-generated content  
**VADER:** Valence Aware Dictionary for sEntiment Reasoner

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Original Paper

# Identifying Potential Gamification Elements for A New Chatbot for Families With Neurodevelopmental Disorders: User-Centered Design Approach

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## Abstract

**Background:** Chatbots have been increasingly considered for applications in the health care field. However, it remains unclear how a chatbot can assist users with complex health needs, such as parents of children with neurodevelopmental disorders (NDDs) who need ongoing support. Often, this population must deal with complex and overwhelming health information, which can make parents less likely to use a software that may be very helpful. An approach to enhance user engagement is incorporating game elements in nongame contexts, known as gamification. Gamification needs to be tailored to users; however, there has been no previous assessment of gamification use in chatbots for NDDs.

**Objective:** We sought to examine how gamification elements are perceived and whether their implementation in chatbots will be well received among parents of children with NDDs. We have discussed some elements in detail as the initial step of the project.

**Methods:** We performed a narrative literature review of gamification elements, specifically those used in health and education. Among the elements identified in the literature, our health and social science experts in NDDs prioritized five elements for in-depth discussion: goal setting, customization, rewards, social networking, and unlockable content. We used a qualitative approach, which included focus groups and interviews with parents of children with NDDs (N=21), to assess the acceptability of the potential implementation of these elements in an NDD-focused chatbot. Parents were asked about their opinions on the 5 elements and to rate them. Video and audio recordings were transcribed and summarized for emerging themes, using deductive and inductive thematic approaches.

**Results:** From the responses obtained from 21 participants, we identified three main themes: parents of children with NDDs were familiar with and had positive experiences with gamification; a specific element (goal setting) was important to all parents, whereas others (customization, rewards, and unlockable content) received mixed opinions; and the social networking element received positive feedback, but concerns about information accuracy were raised.

**Conclusions:** We showed for the first time that parents of children with NDDs support gamification use in a chatbot for NDDs. Our study illustrates the need for a user-centered design in the medical domain and provides a foundation for researchers interested in developing chatbots for populations that are medically vulnerable. Future studies exploring wide range of gamification elements with large number of potential users are needed to understand the impact of gamification elements in enhancing knowledge mobilization.

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## KEYWORDS

gamification; chatbot; neurodevelopmental disorders; engagement; mobile health; mHealth; eHealth; focus group; interview; user-centered design; health information technologies

## Introduction

### Background

Neurodevelopmental disorders (NDDs) include a wide range of disorders such as autism spectrum disorder, intellectual disability, cerebral palsy, and attention-deficit/hyperactivity disorder, affecting approximately 3% to 18% of the population worldwide [1-3]. The health and well-being of families with NDDs are significantly lower than that of non-NDD groups, as children with NDDs and their parents experience complex medical, social, and educational challenges [4]. Parents of children with NDDs face unique hardships, including managing communication between health care and social providers, implementing therapeutic recommendations, and maintaining their children's medical health records while constantly advocating for their best care [5-7]. The costs associated with the care of a child with NDDs are also substantial, which results in high rates of depression and anxiety symptoms in parents [8-10]. A significant challenge that parents often experience is navigating complex health information in a short period to care of their children. However, knowledge mobilization in NDDs is not achieved easily [11-13]. Thus, the advent of innovative technological tools that facilitate knowledge sharing, such as chatbots, can significantly benefit these families [14-17].

Chatbots are artificial intelligence-based tools with natural language processing capabilities that act as web-based conversational agents mimicking human interactions [18]. Although they are not yet used in NDDs, chatbots can provide much-needed support to parents. Chatbots can conduct health surveys; generate health-related reminders; communicate with clinical teams; schedule appointments; retrieve and analyze health data; and translate behavioral indicators such as physical activity, sleep, and nutrition into diagnostic patterns [19]. Chatbots also present several advantages in the health domain in general. They compensate for staff shortages; provide anonymity, convenience, and faster access to information; and lessen the reluctance to share sensitive (eg, emotional and factual) information [20]. For instance, chatbots used for sexual health and mental health settings showed that participants were more likely to disclose information needed for treatment with a bot rather than with a human [21]. Chatbots can be positioned in a web-based environment that is well known to families, such as social media messaging platforms (eg, WhatsApp and Facebook), making them more visible to most families living with NDDs [22,23]. Thus, health chatbots are generally seen positively by internet users [24], as they can increase access to

health care and improve physician-patient and clinic-patient communication [25,26].

A critical consideration when working with families living with NDDs is that it is important to engage in a sustained relationship (similar to coaching) with them to provide the best care. Their children will present different needs over time as their development emerges; therefore, we pondered whether implementing gamification can provide more sustained use of the chatbot, thus providing better care [27-29].

Gamification implements game-based mechanics such as social networks, customization, points, badges, and progress bars in nongame contexts [30-32]. Gamification has been used widely in web applications and mobile apps and assessed across various settings, including education [33] and health care [34], to increase user engagement [30,34-36]. In the health research community, gamification in mobile health applications has received considerable interest because of its potential to motivate behavior change [37-39]. Nevertheless, gamification elements have not yet been studied extensively in chatbots [40,41].

There are important caveats to consider when implementing gamification, because a product that uses gamification should not be assumed to increase user engagement [37,42,43]. Without careful consideration of the application context, user characteristics, and content quality, gamification can yield negative impacts in terms of behavior change [38,44].

### Objectives

Considering the existing knowledge gaps in gamification use in chatbots for the health domain and knowing that inappropriate gamification can potentially compromise the chatbot use [45], we aimed to (1) better understand if gamification will be considered positive for user engagement in a chatbot for NDDs knowledge mobilization and (2) discuss some commonly used gamification elements to evaluate whether they are beneficial from the perspective of parents of children with NDDs.

## Methods

### Design

Given the lack of studies on gamification in chatbots for health care, we first conducted a narrative literature review to identify potential gamification elements. We reviewed the literature from Google Scholar and PubMed, using the following keywords: “gamification,” “engagement,” “motivation,” “health care,” “education,” and “neurodevelopmental disorders” and the related diagnosis terms, “autism” and “intellectual

disability.” These terms were suggested by our teams of clinical and social sciences researchers. We did not identify any gamification elements that are specific to NDDs. Nonetheless, we found several meta-analyses discussing the most common gamification elements used in web applications [35,44,46,47]. As we intended to identify elements that can be implemented in our chatbot to inform, guide, and teach parents of children with NDDs, we also examined elements that have been used more specifically in education and health care [30,32]. Then, we compiled a list of the gamification elements identified in the literature and discussed it with our research team of computer scientists and health and education professionals with extensive expertise in interacting with families of children with NDDs. This was done to prioritize the elements that can be discussed in depth with the families.

Several gamification elements were concluded to be relevant and valuable, such as *goal setting* and *social networking* [48,49]

(which have been identified in clinical coaching programs and applications), *rewards* and *customization* [50], and *unlockable content* [23,24]. These elements are listed in [Table 1](#). *Goal setting* refers to the users’ ability to create specific goals for their children (eg, behavioral goals such as potty training and bicycle riding) to help make appropriate learning and training plans. *Social networking* refers to integrating a web-based space or forum for users to discuss and share their experiences. *Rewards* indicate intangible prizes being given to the users by the application every time they reach a goal or complete a task (eg, badge). *Customization* refers to the users’ ability to change the theme of the application interface, profile picture, notification frequency, and user avatar. *Unlockable content* suggests that certain content can be restricted to users until they reach a certain level of participation or use to encourage engagement. For all the elements, visual examples were also prepared to be shown to participants, ensuring better understanding of them.

**Table 1.** Gamification elements investigated in the study.

Gamification elements	Definition	Examples
Customization	Ability to change the features of the app	Notification, avatar, and theme
Rewards	Intangible prizes for every task completed	Badges and coupons
Goal setting	Users’ ability to create specific goals	Potty training and bicycle riding
Unlockable content	Restricting contents to users who reached certain levels of participation or use	Meditation and self-help articles
Social network	Integrating a web-based space to discuss and share experiences	Forum

For a product to succeed, users’ needs must be considered during the development and implementation of that product, and later evaluation must be performed to ensure that these needs are met. User participation is essential to reflect on the values, drivers, and goals of the chatbots that are to be developed. This is evident in previous studies that highlighted the importance of user participation when developing eHealth technologies, as seen in the Center for eHealth Research road map [51]. Thus, we considered different approaches to seeking feedback from families of children with NDDs regarding implementation of gamification elements in a chatbot for NDDs. We integrated two key product design approaches: user-centered design (UCD) and double diamond approach.

The UCD approach [52] consists of several methods that take end users’ needs into account, one of which is asking end users about the tasks and goals of the application. This approach allows users to influence how an app is developed and increases users’ acceptance. UCD can reduce the development time as usability problems are identified and resolved through frequent communication with users before the system is launched [53-55].

Similarly, according to the double diamond method, there are four design steps, with the first two steps involving discovering

and defining the problem before a product is developed and delivered [56,57]. Identifying which gamification features parents will find beneficial or deterring can ensure better reception of the application later.

We adapted the structures of the surveys used previously to evaluate user engagement in the postgamification application [58-60] and developed our guide for semistructured interviews and focus groups. The guide aimed to explore participants’ (parents of children with NDDs) previous experiences with technology and gamification, their opinions on the gamification elements being investigated, and their views on how they should be implemented ([Textbox 1](#)). We did not conduct a usability test as part of this project. Our goal was to identify the gamification elements that will be included in our chatbot prototype later. We will conduct usability tests in the future to test their impact on user experience.

The study was advertised with NDD-focused parent organizations, including Kids Brain Health Network, Canadian Autism Spectrum Disorder Alliance, and CanChild, via social media (Facebook and Twitter). Participants were recruited via convenience sampling [61].

**Textbox 1.** Questions and prompts that were used in the parent focus groups and interviews.

#### Main question 1

- Can you share with the group an experience you have had with an application that uses engagement mechanisms? If you have not had one, can you please outline what you have observed from other family or friends that have?
- Prompting questions
  - What did you like about your experience?
  - What did you dislike about your experience?

#### Main question 2

- When you think of *goal setting* to improve behaviors, what are the first thoughts that come to mind?
- Prompting questions
  - How do you feel about setting your own goals in an application, as opposed to an application setting a goal for you?
  - How would you feel about *customizing* the application to send you reminder notifications about your goal for the day? (If participants like the idea of reminder notifications, “how often would you like to receive these notifications?”)
  - Would it be rewarding to receive some form of *web-based rewards* for making improvements through goal setting (eg, a web-based badge)?

#### Main question 3

- What are your thoughts on including *unlockable content* in the Chatbot?
- Prompting questions
  - What kind of surprise content would you like to see, and how could this be done well or poorly (eg, color theme)?
  - Do you think you would find this engaging? Do you think unlockable content should be included in the Chatbot?

#### Main question 4

- What comes to mind when you think about the option of including a *social network* in the Chatbot?
- Prompting questions
  - What kinds of conversations would you want to have with other parents?
  - Let’s say we include a frequently asked questions board and a regular question board where parents could post their questions. How would you feel about parents policing the quality of the responses posted by other parents?
  - Would you use the questions section of the Chatbot if there was the potential for it to include fake news or information that was not validated by experts?
  - If we move forward with this, how would you like to *customize* the way you are represented (eg, logo, name, picture, and how much information would you like to reveal)?
  - Would you prefer for the Chatbot social network to be linked to another social networking platform such as Facebook or be independent?

#### Main question 5

- When we write up our report, what is one important point you think we should pay attention to from our discussion today?
- Prompting questions
  - What topics would you like us to talk about in the future?

## Ethics Approval

This project was approved by the research ethics board at the University of Alberta (study ID Pro00081113). All participants provided written informed consent before the sessions.

## Participants

We conducted 7 focus group sessions and 4 semistructured interviews, including a total of 21 participants, all of whom were parents of children with NDDs. Although our goal was to

follow the same session format for all participants, we followed a pragmatic approach to the session type to accommodate participants who had limited time availability and flexibility or, in rare cases, preferred to be interviewed alone. In all cases (21/21, 100%), we followed the same questions, as shown in [Textbox 1](#).

## Procedure

Owing to the COVID-19 pandemic, all sessions were conducted via the web using Zoom (Zoom Video Communications) and

recorded for both video and audio. Recordings were saved on our secure server (MedIT; University of Alberta). The identifiable information of the participants was stored in a secure encrypted manner. Similarly, the audio and video recordings of the interviews and focus groups were stored in our secure server and were available only to the research coordinators and assistants directly involved in data analysis. The participants agreed to have their data collected and stored as per our written consent form. The sessions ranged from 45 to 60 minutes and used a semistructured format, containing 5 main questions and 2 to 5 prompting questions (Textbox 1).

The focus group size ranged from 2 to 4 participants, whereas interviews had 1 participant each. Owing to time constraints, and because it is commonly not feasible to focus solely on individual views in a focus group, not all participants responded to every question in the focus groups, as seen in previous studies [62,63], but we ensured to cover all questions. We also analyzed the transcripts for common responses to each question. Then, we organized the results to represent 3 main themes, capturing the consensus among participants.

### Data Analysis

Videos were transcribed using Otter.ai, a tool that uses artificial intelligence to transcribe audio. Then, the transcripts were edited manually to correct errors, remove identifying information, and ensure that all the speakers were correctly labeled. Key answers and comments were extracted and analyzed using deductive and inductive thematic approaches [64-66]. The ratings for the

different gamification elements provided by participants were noted and compiled.

Open texts from the participants' responses are included in this paper. Participants' novel and impactful insights regarding the proposed gamification features were recorded. Participants were asked to comment on whether a gamification element was a *must-have*, *nice to have*, or *not needed* feature. Participants were not obliged to comment on every aspect. Then, the common statements from participants were used to generate the main themes using thematic analysis [67]. We followed some of the techniques of Guba and Lincoln [68], such as analyst triangulation, to establish credibility and confirmability for the study.

## Results

### Overview

A total of 21 parents of children with NDD agreed to participate, of whom 18 (86%) were White, 18 (86%) were women, and 16 (76%) were from Alberta, Canada (Table 2).

Findings from the focus groups (7 sessions; 17/21, 81% participants) and interviews (4 sessions; 4/21, 19% participants) were reviewed, which showed similar response trends; therefore, they were combined (Table 3).

The summary of parents' input, organized into 3 main themes, is presented in Table 4.

**Table 2.** Demographic characteristics of participants of the study (N=21).

Demographic characteristics	Participants, n (%)
<b>Sex</b>	
Female	18 (86)
Male	3 (14)
<b>Race or ethnicity</b>	
White	18 (86)
Asian	3 (14)
<b>Region</b>	
Alberta, Canada	16 (76)
British Columbia, Canada	1 (5)
Ontario, Canada	1 (5)
Quebec, Canada	3 (14)



**Table 3.** Participants' preferences toward including different gamification elements in a chatbot for neurodevelopmental disorders.

Gamification features	Participants' response, n (%)		
	"Must-have"	"Nice to have"	"Not needed"
Customization (n=11)	4 (36)	4 (36)	3 (27)
Rewards (n=17)	N/A <sup>a</sup>	11 (65)	6 (35)
Goal setting (n=19)	19 (100)	N/A	N/A
Surprise or unlockable content (n=19)	N/A	6 (32)	13 (68)
Social network (n=20)	12 (60)	5 (25)	3 (15)

<sup>a</sup>N/A: not applicable.

**Table 4.** Summary of parents' input, showing key themes about gamification elements (N=21).

Main themes and related key concepts	Participants, n (%)
<b>1. Parents of children with NDDs<sup>a</sup> were familiar with gamification</b>	
Participants had previous experience with gamification elements	21 (100)
Gamification elements are beneficial or moderately effective	12 (57)
<b>2. Specific gamification elements should be incorporated into a chatbot for NDDs</b>	
Goal setting is an important feature for the chatbot	19 (90)
A goal template that can be personalized is needed	15 (71)
Reminder frequency needs to be adjustable by users	21 (100)
Unlockable content (eg, resources) is deterring or off-putting	13 (62)
<b>3. The inclusion of social networking is favored and the topic of medical fact-checking is controversial</b>	
Social networks increase social support for parents	15 (71)
Social networks connect parents with similar experience	16 (76)
Social networks help parents to share good resources	21 (100)
Social networks should be implemented	17 (81)
Moderators are needed for social networks	14 (67)
Medical misinformation can be displayed on social networks	11 (52)
Medical misinformation should be filtered on social networks	9 (43)
Parents should have control over their representation on social networks	21 (100)

<sup>a</sup>NDDs: neurodevelopmental disorders.

## Parents of Children With NDDs Were Familiar With Gamification

The main goal of this study was to assess whether gamification will be perceived as being potentially useful in sustaining chatbot engagement and fostering use for better knowledge mobilization. We found that all the participants (21/21, 100%) had some experience with gamification in web applications and mobile apps, and 57% (12/21) of the participants reported from their experience that the tools were beneficial or moderately effective (Table 4).

## Specific Gamification Elements Should Be Incorporated Into a Chatbot for NDDs

Our next objective was to discuss some gamification elements that have been used previously in health or education domains and evaluated to be beneficial for populations with NDDs by our team of health and social science experts.

We found robust support for goal setting, which is one of the main tools used in clinical settings for families with NDDs [69,70]. Of 19 participants who commented on goal setting, 19 (100%) rated it (eg, for behavior management) as a *must-have* feature. Of the 21 participants, 19 (90%) noted that goal setting will be very important for the chatbot and 15 (71%) proposed the idea of having a *goal template* to choose from, which can be modified to fit their child's unique needs. When asked why a goal template is a *must-have* feature, they mentioned that goal setting will be important for new parents and recently diagnosed children:

*[P]arents that are newer...they would need that template because they wouldn't know what to do.*

*[H]aving some suggested goals for those people who can't think of their own goals. Because when you're at the end of your rope, you can't always think cohesively, actually, because a lot of our parents are*

*burnt out or have caregiver PTSD. So sometimes, it's hard to think of your own goals, and you already feel like you've tried everything. So having some suggestions that you can customize with at least as a starting point would be beneficial.*

Participants provided mixed responses regarding customization (eg, color theme and reminder frequency). All participants (21/21, 100%) wanted the ability to control the frequency of reminders being sent to them when a goal is completed. This is important because parents often feel overwhelmed and pressured, as mentioned previously. Among 11 participants who commented on customization, 4 (36%) stated that it is a *must-have*, 4 (36%) agreed that it is *nice to have*, and 3 (27%) said that it is *not needed*. We showed that although some parents have interest in customization, their main goal is to gain information for their children. Participants who answered that customization is *not needed* highlighted that reminders and notifications can bring a strong feeling of pressure:

*[H]aving customizable, so you can choose the frequency [notification], whether you want once a day or once a week, ...sometimes that nudge is needed. [I]f it's repeated, and it's not wanted, it could just be adding that pressure on that you're not doing- you already feel like you're failing your child. And when it's reminding you over and over again, and you don't want it to be then you're feeling the weight of that failure over and over again.*

*The parents should have...a snooze button...because it can be annoying if the parent feels pressured.*

*[W]hen I started...I need...daily, but after a while, I might want to change it. So I think that having it customizable will be very important. And each parent is going to have a different type of personality. And some parents might want more than one today and some parents might not want reminders at all.*

*[B]ecause I'm single mother, ...sometimes I just forget to check down my goals. If some apps or application could remind me to set up my goals and the follow up, ...that would be great.*

Parents who rated customization as *nice to have* stressed that they value the content more than the presentation or the option to customize the color theme and user interface:

*I think that you want to engage the parents to have a very visual and very easy...format...to be user friendly. And they pay attention to that...more so than...what color they can change...a lot of us parents are hungry for information, for references, links to research.*

*[Y]ou're coming from a place of nothing, a lot of the time and you're giving more than you even have, you would either feel it would add to the parental guilt, or...it would cause you to be like, disengaged. [E]ven the most willing participant who wants to change things and really wants help, you could be very overwhelmed if it was not messaged correctly.*

*They just want an answer. They just need help. They're so desperate for someone to help them and*

*find resources and access to things and the rest of it, while nice and might draw someone's eye in...isn't necessarily going to make or break.*

*[P]eople want to use this app, they're desperate. They need the information...concisely...and offering...a variety of colors across the rainbow isn't why someone's drawn to that app.*

Parents who said customization is a *must-have* feature commented on the need to have the app tailored to individual child, as each child has very different needs:

*It needs to be customizable, because parents are different, kids are different, even if they have the same diagnosis and situations are different. When you're trying to achieve a goal, some things will work for one kid, but not for another...It needs to be customized to the particular parent and child and situation.*

*[I]t needs to be customizable, if you have more than one child with the extra needs.*

Similarly, responses to using rewards such as badges were mixed. Of the 17 participants who commented on rewards, 11 (65%) rated it as being *nice to have*, but 6 (35%) said they would prefer not to have them. Of the 21 participants, 11 (52%) stated that web-based badges, which are a type of reward, are not rewarding, whereas 6 (29%) indicated that they are *nice to have*. The idea of the bot providing rewards may be perceived as focusing on the user (parents) and not the children with NDDs, which seems to trigger some negative feelings:

*I do it not because I want to be rewarded. My reward is to see my child doing well...when we see our children do well, that's already a reward.*

*I think it would be beneficial...but I think it has to make sure like it's really tailored to this audience of parents that are totally burned out...If it's too glossy and not meaningful...it won't mean anything and it won't resonate. It won't entice anyone to use it.*

*It's not...something that draws me to the app. I like the functionality of the app, not the awards. But I think that some parents, especially some younger parents might need those pats on the back.*

*[T]hey're not significantly motivating for me. For me, it's more about the personal engagement. So if I want to do what it is, whatever the activity is, then I'll do it and irrespective of things like badges or rewards. [F]or me, the engagement tool that's most successful is tracking, ...one where I can track my progress or my participation.*

However, for some parents, this can be a beneficial mode of reinforcement:

*[T]hat can be a good reinforcement. And then it can, it can show the options of the reinforcement, if you are getting 50 points, you will have this medal or this badge or if you get 100 points, you'll be getting a silver one or a gold or platinum, that is some positive reinforcement that the more we put our energy towards it and we get more successful. So the chances of success increase.*

Another frequently used gamification element in apps is unlockable content. Of the 21 participants, 13 (62%) did not support unlockable content, especially if helpful information or resources were being restricted. The main goal of parents was to identify trusted and relevant resources while working under time constraints. Thus, locked content was perceived as negative and detrimental to their journey:

*If I'm working on something like this, I don't want surprises.*

*[T]hose parents already are motivated. [T]he focus is not trying to how to motivate them, ...is to be able to help them even more with resources, ...and not to lock it out from where they can get access to. [T]hese parents deserve to be given as much as scientists and researchers can provide.*

*[I]f it was unlockable content, I'd be kind of annoyed I couldn't have it upfront if it was something I actually needed or had a question about.*

*I just think that if I need the information, I want to be able to access it. So making me jump through hoops to get it feels like something you'd be doing in the system, like in the public systems, jump through to get the information. I don't feel like that's user-friendly.*

*[U]nlockable content is like putting cookies on the highest shelf in the cupboard, it feels like it's a lack of trust and a lack of understanding where we're really coming from. [It's like] having...affirmation...locked.*

### The Inclusion of Social Networking Is Favored and the Topic of Medical Fact-Checking Is Controversial

The topic of social networks revealed the complexity of implementing a chatbot in the medical domain. Of 20 participants, 12 (60%) identified a social network as a *must-have*. Of the 21 participants, 15 (71%) agreed that a social network should be implemented in the chatbot to increase social support, 16 (76%) agreed to connect with others experiencing similar challenges, and 21 (100%) agreed to share helpful information (eg, recommended physicians and behavioral therapies):

*It could be from...experiences say toilet training...or just advice on things or suggestions...It's like a social platform.*

*[Y]ou get to meet new people. You get to learn about diagnosis, similarities in families, and that you're not alone.*

*[I]n this app, it might be easier to connect people in a safe space to ask questions...the big thing is like feeling like you're not alone.*

Of the 21 participants, 14 (67%) indicated that rules of participation and moderation must be established to provide a safe space for parents. Comments from parents indicated the potential for emotional discussion, and its regulation should be considered:

*[O]pen format for people to put comments, it can get into a heated conversation. [A]n administrator has to administer it...if there's any language or anything inappropriate, that has to be taken out.*

*[W]e're talking about a vulnerable sector; people are desperate to try something...There has to be some sort of filter or something that parents could get.*

*There are some extremely controversial topics that do come up in these conversations, and that's when we need somebody else to police it. The easiest one to come up with is vaccination. It's a very divisive topic...It's extremely inflammatory conversations.*

*[H]aving a report to admin button because with our kids, there are some great suggestions that parents give other parents but [i]t could be something very dangerous...because we've got...parents who are at the end of their rope.*

*Advice that some parents give is actually dangerous as well. And when parents are at the end of their rope, they will try absolutely anything.*

Opinions differed among participants regarding whether medical misinformation or anecdotal evidence should be allowed in such a network. Some participants preferred having unfiltered information displayed (11/21, 52%), including anecdotal advice posted by other parents, controversial topics, and information that has not yet been validated by experts. These participants reasoned that they preferred seeing all controversial comments and ideas and not being limited to only verified information. In contrast, others preferred being shown only scientifically verified information (9/21, 43%):

*[I]f it's posted there it needs to be validated...so the parents can see...it's been posted by the administrator, not by parents.*

Other major concerns included confidentiality, privacy, and security:

*First thoughts are privacy and confidentiality and the ability to use a nickname within it so you don't have to use your real name or divulge my personal identifiable details.*

*I'd probably want a little bit more anonymity than Facebook because [in] Facebook, I'm opting into...what I have revealed about myself...maybe, like demographics, like where you live, but not...the city...I don't think people need to necessarily, for the purpose of this, ...know exactly who you are...That's a problem that would be nicely solved in the chatbot...You'd have much more liberty to ask questions in a safer space.*

## Discussion

### Principal Findings

Our study revealed several informative points regarding the implementation of gamification elements in a chatbot that supports parents of children with NDDs. All parents (21/21, 100%) were familiar with gamification and showed overall

positive attitude toward integrating it into the chatbot. This is important, as such studies had not been conducted previously, despite NDDs having affected 3% to 18% of the population worldwide [1-3]. Our findings on goal setting aligned with the findings in the literature, showing that parents preferred having a customizable *goal template* for behavior management [28]. For the first time, our study showed that parents of children with NDDs found unlockable content to be deterring. This may be owing to the parents' long journey of constantly pursuing information, which underlines the importance of adopting a UCD approach when developing a chatbot. It will be important to evaluate whether this finding is generalizable to other health domains. Our findings on social networking showed varied responses, indicating that this is a complex topic and highlighting the necessity of closely working with end users when developing a chatbot for such a vulnerable population. Although some parents preferred being shown unfiltered information on social networks, which may contain medical misinformation, this will be challenging to implement, as it can cause detrimental consequences to other parents and the medical community. The complex questions raised about social networking highlighted the importance of including users in the designing process of health-specific chatbots.

From our literature review, we identified five gamification elements that may be important for increasing user engagement in a chatbot designed for parents of children with NDDs: *goal setting, customization, rewards, social networking, and unlockable content*. From interviews and focus groups with 21 participants, we identified 3 main themes: (1) parents of children with NDDs were familiar with and had positive experiences with gamification; (2) goal setting was considered as an essential feature for a chatbot for NDDs, whereas customization, rewards, and unlockable content received more diverse opinions; and (3) although social networking was viewed positively, it is a complex feature to implement owing to the issues pertaining to medical fact-checking.

Our use of a combination of interviews and focus groups was primarily owing to parents' limited availability. However, this allowed us to obtain distinct information. In focus groups, we were able to elicit common opinions and attitudes to form major themes, whereas interviews provided us with detailed information and unique perspectives on the same topics [71]. In addition, consulting with parents of children with NDDs, or the intended users, provided unique insight into the reasons why some gamification elements were suitable. For instance, in the case of social network, users mentioned that they would use this feature to identify other sources of information that may not be widely accessible on the web. The participants also warned about the potential negative impacts of emotional discussions on such sites.

Similarly, user consultation revealed an important aspect of creating NDD-focused chatbots. Although highly engaging in other spheres, unlockable content was overwhelmingly rated negatively. It was evident that withholding information from users, who described themselves as "desperate for information to help their children," will be damaging. It is unknown whether this remains true in other medical domains. To the best of our

knowledge, this is the first study on gamification and NDDs and one of the first studies on gamification in chatbots [41,72].

### Limitations

Our study was conducted during the COVID-19 pandemic [73-75], which, combined with the busy and fluctuating schedules of parents of children with NDDs [76-79], limited us to include only 21 parents. In addition, the convenience sampling method may have introduced a selection bias in our study. To assess the generalizability and transferability of our findings, studies in different countries and with more variable social determinants such as sex, gender, socioeconomic status, ethnicity, race, and age will need to be conducted in the future. Considering the unique vulnerability of the population interviewed, we refrained from pressuring any participant to respond to all questions. To obtain sufficient data, we included enough participants to reach a degree of saturation for each question. On the basis of our analysis, we were able to identify important themes with adequate certainty but would like to conduct further evaluation of the features identified as desirable in future prototypes or usability testing.

### Conclusions

Knowledge mobilization remains as a challenge in the medical domain [80]. This is especially true in situations of medical complexity such as public health or NDDs [81,82]. Parents of children with NDDs experience special social, medical, and financial burdens, which make it difficult for them to remain engaged in the usual knowledge mobilization tools. Gamification has been the subject of extensive research and interest, more recently in the medical field, and has been used for health professional education and patient self-management [83-85]. Chatbots have also been suggested to be used as a mental health assessment tool in the workplace [86].

Our study identified several gamification elements that should be used in a chatbot designed for parents of children with NDDs. As all our recruited participants (21/21, 100%) were parents of children with NDDs, this sample could provide a representation of the population's responses. Recruiting parents of children with NDDs can be challenging considering their background (eg, financial and social pressure and complex demands of raising a child with NDDs). Nevertheless, understanding their perspectives is crucial for identifying gamification elements that will best suit their needs.

For the first time, we showed that parents of children with NDDs support the use of gamification in a chatbot for NDDs. Our study illustrates the importance of adopting a UCD approach when determining the gamification elements needed to be included in a chatbot for NDDs. Some commonly used elements were perceived negatively by this specific group of users. Continuous incorporation of parents' feedback in the chatbot development will help to create a better-received application that can have positive impacts on the lives of these families. Although many studies have been conducted on using users' feedback to improve health-centered technology, our study is the first to assess the potential reception of gamification elements to enhance the experience of users of chatbots in the health domain and more specifically in the NDD domain. Using

health chatbots in the NDD domain is a practice that is still in its infancy. We believe that our study will help researchers in the same field gain a better understanding of this novel technology's design and applications. Future studies can include prototypes incorporating different elements of gamification, which can be correlated with their impact on usability and engagement.

Our study has two main implications: users' perception of 5 gamification elements and potential application of such elements in a chatbot that can be used as an assistant tool for families

living with NDDs. Participants indicated that chatbot has tremendous potential for educating users to increase their health literacy and improve their care for children with special needs. Their feedback and perception of the 5 elements will continuously guide us in our development of a prototype for this chatbot and conduct of interviews and focus groups in the near future. Given our special targeted population, our results also shed light on the design of health chatbots for populations with NDDs, specifically to improve user experience and increase user engagement, which can ultimately improve their quality of life tremendously.

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## Conflicts of Interest

None declared.

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## Abbreviations

**NDD:** neurodevelopmental disorder

**UCD:** user-centered design

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Original Paper

# Developing a Provincial Surveillance and Support System for Childhood Cancer Survivors: Multiphase User-Centered Design Study

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## Abstract

**Background:** Survivors of childhood cancer are at lifelong risk of morbidity (such as new cancers or heart failure) and premature mortality due to their cancer treatment. These are termed late effects. Therefore, they require lifelong, risk-tailored surveillance. However, most adult survivors of childhood cancer do not complete recommended surveillance tests such as mammograms or echocardiograms.

**Objective:** In partnership with survivors, family physicians, and health system partners, we are designing a provincial support system for high-priority tests informed by principles of implementation science, behavioral science, and design thinking.

**Methods:** Our multiphase process was structured as follows. Step 1 consisted of a qualitative study to explore intervention components essential to accessing surveillance tests. Step 2 comprised a workshop with childhood cancer survivors, family physicians, and health system stakeholders that used the Step 1 findings and “personas” (a series of fictional but data-informed characters) to develop and tailor the intervention for different survivor groups. Step 3 consisted of intervention prototype development, and Step 4 involved iterative user testing.

**Results:** The qualitative study of 30 survivors and 7 family physicians found a high desire for information on surveillance for late effects. Respondents indicated that the intervention should help patients book appointments when they are due in addition to providing personalized information. Insights from the workshop included the importance of partnering with both family physicians and survivorship clinics and providing emotional support for survivors who may experience distress upon learning of their risk for late effects. In our user-testing process, prototypes went through iterations that incorporated feedback from users regarding acceptability, usability, and functionality. We sought to address the needs of survivors and physicians while balancing the capacity and infrastructure available for a lifelong intervention via our health system partners.

**Conclusions:** In partnership with childhood cancer survivors, family physicians, and health system partners, we elucidated the barriers and enablers to accessing guideline-recommended surveillance tests and designed a multifaceted solution that will support survivors and their family physicians. The next step is to evaluate the intervention in a pragmatic randomized controlled trial.

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**KEYWORDS**

design; cancer screening; childhood cancer survivor; late effects; surveillance; cancer; cancer survivor; morbidity; mortality; cancer treatment; mammogram; echocardiogram

## *Introduction*

Approximately 80% of childhood cancer survivors will develop a serious, life threatening, or disabling late effect from their curative treatment by age 45 [1]. Cardiomyopathy and subsequent malignant neoplasms (particularly breast or colon cancer) are among the late effects with the greatest impact on both serious morbidity and premature mortality. North American guidelines [2,3] include recommendations for cancer surveillance (eg, mammography or breast magnetic resonance imaging [MRI] in women with a history of chest radiation and colonoscopy in survivors treated with abdominal or pelvic radiation) and echocardiographic assessment in survivors at risk for cardiac dysfunction due to exposure of the heart to radiation or anthracycline chemotherapy.

Unfortunately, most adult survivors of childhood cancer do not receive the recommended surveillance, placing them at risk for preventable harm [4-6]. Our recent study of over 10,000 North American adult survivors of childhood cancer revealed that only 13%, 37%, and 41% of high-risk individuals were currently adherent to recommended breast, colorectal, and cardiac screening, respectively.

A systematic review assessed the effectiveness of interventions promoting adherence to surveillance guidelines in adult survivors of childhood cancer [7]. Only 3 trials assessed interventions to improve uptake of our targeted tests (colonoscopy, breast imaging, and echocardiograms) in survivors of childhood cancer [8-10]. These interventions were found to be resource intensive and thus do not represent sustainable programs at a population level. Furthermore, interventions in these trials relied on survivors sharing educational materials with their primary care provider rather than purposefully educating primary care professionals on the needs of childhood cancer survivors [8,9]. This review, coupled with a recent review of interventions in routine risk populations to improve uptake of cancer screening [11], indicated that personalizing the invitation for surveillance [12], ensuring primary care endorsement [13], and providing reminders [14] could each play an incremental role in increasing completion

of recommended tests. In summary, a 2-pronged intervention that engages both survivors and their primary care clinician has the potential to significantly reduce morbidity and mortality by improving adherence to surveillance guidelines.

Therefore, working with cancer health system partners, we embarked on a rigorous design process for an intervention to address cancer surveillance for late effects among childhood cancer survivors. Our approach used behavioral science and design thinking. Behavioral science allowed us to employ relevant theories of behavior change to understand the factors that might influence surveillance adherence. We also used methods from design thinking, a “human-centered approach to innovation—anchored in understanding customer’s needs, rapid prototyping, and generating creative ideas” [15]. Design thinking has recently been applied in health care to address patient experiences, clinical outcomes, and health care spending [16-18]. We used these methods to gain a deeper, more empathic understanding of the experience of adult survivors of childhood cancer. This paper outlines how we used these 2 methodologies in a multistep process in the design of a provincial surveillance and support system for childhood cancer survivors.

## *Methods*

### **Overview**

We used a 4-step approach to design a childhood cancer surveillance and support system to facilitate completion of surveillance tests (echocardiograms, breast MRI, mammograms, and colonoscopy) among childhood cancer survivors (Table 1 and Figure 1). We chose a multidisciplinary method to incorporate different perspectives and approaches that were relevant to the design of an intervention. Our complementary approach can improve the fit between evidence-based theories (ie, behavioral theory like the Theoretical Domains Framework [19]), the strategies used to implement them (ie, implementation science [20]), and their implementation contexts (ie, using design thinking [15]). Furthermore, design thinking goes further than traditional barrier and facilitator assessment by embedding users more deeply in the process, thereby enhancing the usability and usefulness of the intervention.

**Table 1.** Stages of development of childhood cancer surveillance system.

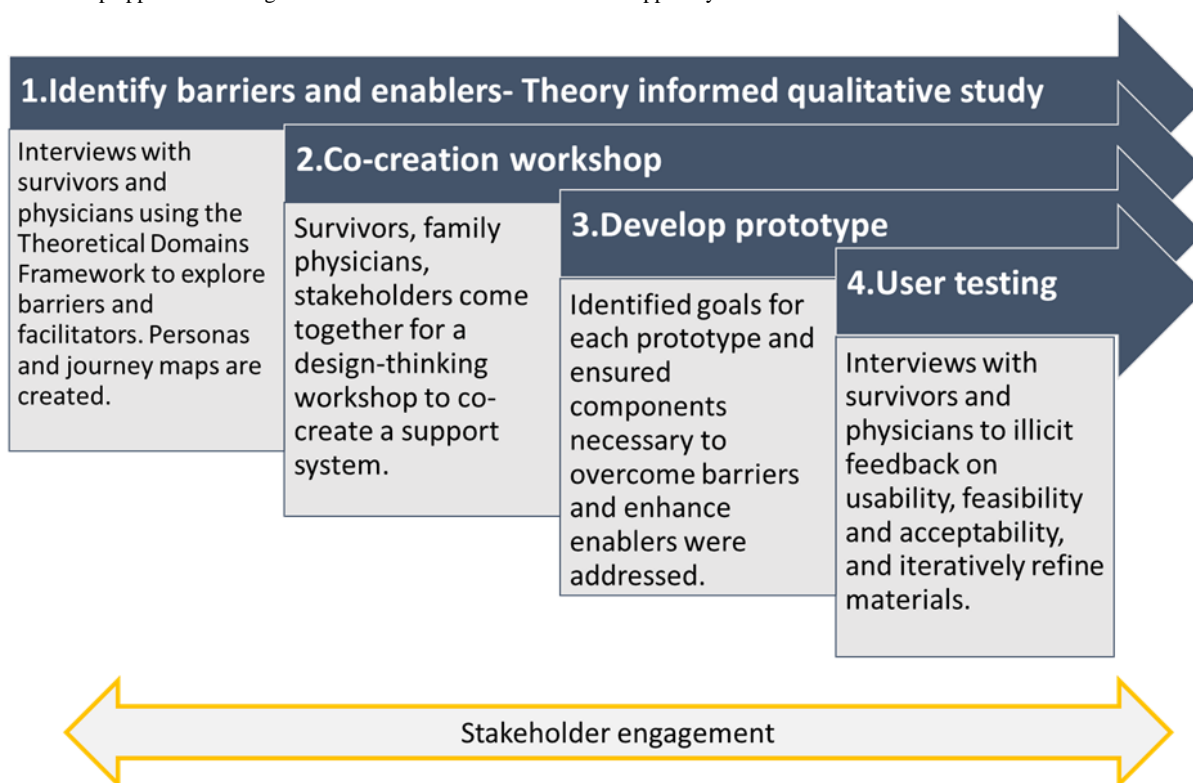
Intervention stage and description	Objective	Methods used	Products produced
Discover: theory-informed qualitative study [21]	<ul style="list-style-type: none"> <li>• Identification of key barriers, facilitators, needs, and challenges the intervention must address</li> </ul>	<ul style="list-style-type: none"> <li>• Qualitative interviews</li> <li>• Thematic analysis</li> <li>• Behavioral theory—Theoretical Domains Framework</li> <li>• Design thinking</li> </ul>	<ul style="list-style-type: none"> <li>• Personas and journey maps</li> <li>• Theoretical Domains Framework</li> <li>• Behavior change techniques to be addressed in intervention</li> </ul>
<b>Design and build<sup>a</sup></b>			
One-day workshop	<ul style="list-style-type: none"> <li>• Creation of guiding principles to help summarize and easily refer to features of the intervention identified as central to achieving its objectives</li> </ul>	<ul style="list-style-type: none"> <li>• Design thinking</li> </ul>	<ul style="list-style-type: none"> <li>• Personas and journey maps</li> <li>• Intervention components “worksheet”</li> <li>• Validation of concept</li> </ul>
Development of prototype	N/A <sup>b</sup>	N/A	<ul style="list-style-type: none"> <li>• Design of prototypes: survivor invitation letter; survivor information kit; website; survivor reminder letters; physician information letter</li> </ul>
User testing design <sup>a</sup>	<ul style="list-style-type: none"> <li>• All intervention components evaluated in detail and optimized from survivor and physician perspective</li> </ul>	<ul style="list-style-type: none"> <li>• Two rounds of iterative user testing</li> <li>• Think aloud methodology</li> </ul>	<ul style="list-style-type: none"> <li>• Iterative changes to prototypes developed with each round</li> <li>• Documented changes</li> </ul>
Evaluate: pragmatic randomized controlled trial <sup>c</sup>	<ul style="list-style-type: none"> <li>• Intervention evaluated in real-life context(s), modified to improve implementation in future contexts</li> </ul>	N/A	N/A

<sup>a</sup>We met regularly with stakeholders to review the emergent intervention design.

<sup>b</sup>N/A: Not applicable.

<sup>c</sup>To be completed in 2022-2023 (not reported in this paper).

**Figure 1.** Four-step approach to design a childhood cancer surveillance and support system.



In Step 1, we conducted a qualitative study of childhood cancer survivors and family physicians to explore intervention components that are essential regarding accessing evidence-based, high-yield surveillance tests. Semistructured interviews with adult survivors of childhood cancer who were eligible for 1 or more of the surveillance tests of interest (but had not attended a specialized survivor clinic in over 5 years) were completed. Survivors were asked to specify the details of their primary care provider or family physician, who were then invited to participate in an interview. We have reported on a previous analysis using the Theoretical Domains Framework (TDF) [22,23] and behavior change techniques [24,25] to identify influences on accessing surveillance tests among survivors [21]. The TDF proposes a comprehensive, theory-informed approach frequently used by implementation scientists to identify the determinants of behavior and behavior change in health care professionals and patients [23]. The TDF ensures that the full set of potentially important determinants of behavior, including those that may be especially relevant to the completion of surveillance, such as emotion, social norms, and beliefs about capabilities, are considered. Furthermore, it offers a strategy for mapping key determinants of behavior to relevant behavior change techniques to include in an intervention. In this way, the TDF can provide key insights into selecting the necessary intervention components and tailoring those components for different survivors [26].

In this study, we used thematic analysis [27] supported by the TDF to identify specific barriers and enablers to accessing and providing surveillance tests as they relate to intervention components. Transcripts were independently coded line-by-line by 2 research team members (authors JS and NS). Codes were then thematically analyzed and described in terms of how they could guide and shape the intervention. Next, initial themes were examined and refined to confirm that the themes characterized the data set as a whole and no themes were missed. Data collection and analysis continued iteratively until saturation was achieved—that is, until no new ideas were introduced during subsequent interviews [28]. To expand our knowledge of how our results can inform our intervention, we drew upon behavior change techniques associated with the TDF domains [24,25] that the intervention should address.

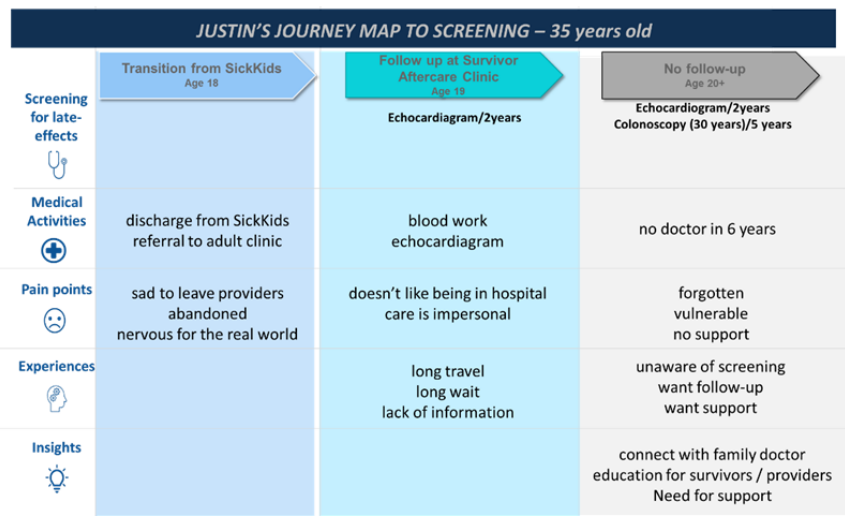
Then, using design thinking methodology, we created personas [29] and journey maps based on our interviews and analysis. Personas are fictional characters that represent an archetype character. They helped identify the user's needs and wishes and enabled the team to engage and empathize during the design process. Journey maps are a visualization of the process that a person goes through to accomplish a goal. We used this tool to dissect the process a survivor goes through from discharge from pediatric care to various life stages. It helped the team to think about the different moving parts of follow-up for a childhood cancer survivor and assisted with illuminating areas of potential interest. The personas guided the design and content decisions and addressed specific behavior techniques to be tackled in the intervention. For example, when addressing the behavior change technique “reduce negative emotions,” we ensured our ideas and content were consistent with the personas.

In Step 2, we organized a 1-day cocreation workshop in July 2020 that brought together childhood cancer survivors, primary care physicians, and cancer health system partners. The objective of the workshop was to validate findings from Step 1 and elicit ideas on the design and content of the surveillance system. Our team worked with Pivot Design Group, a design firm, to develop and facilitate the workshop. Select childhood cancer survivors and physicians who participated in Step 1 were invited to participate in this workshop. We purposively invited a diverse group of survivors who varied in age, location, and screening recommendations. After presenting the findings from Step 1, including personas and journey maps, we divided participants into 3 groups. Each group was assigned a persona and tasked with developing solutions regarding accessing surveillance for their persona (Figure 2). We wanted to evoke, understand, and overcome pain points through idea generation and develop a long-term solution together. At the end of the session, each group presented their solutions and then engaged in a discussion with the larger group. The session and breakout groups were recorded, and data was extracted into the following broad categories: (1) content, (2) functionality, (3) design, and (4) barriers. Data was then compared across the different breakout groups to identify similarities and differences.

In Step 3, upon consultation with survivors, physicians, and health system partners, our team developed the following prototypes: (1) survivor invitation letter, (2) survivor information kit, (3) website, (4) survivor reminder letters, and (5) physician information letter. Based on Steps 1 and 2, the following actions were taken to ensure the content was effective. First, we identified goals for each prototype and made sure that all components necessary to overcome barriers and enhance enablers (behavior change techniques [24,25] from Step 1) were addressed. We also incorporated principles of design, including decisions on font, colors, and logos. Finally, we made all decisions while considering the emotional impact that engaging with these materials would have on childhood cancer survivors.

In Step 4, we used the user-centered design methodology to iteratively refine the intervention materials and gain feedback on the usability, feasibility, and acceptability of the materials. Childhood cancer survivors who were eligible for the surveillance tests of interest (echocardiogram, mammogram/breast MRI, or colonoscopy) but had not attended a specialized survivor clinic in over 5 years were invited from 3 such clinics in Ontario (some survivors were reinvited for an interview from Step 1). Family physicians were recruited through social media and family medicine networks. In the first round, prototypes were low fidelity, and screen share technology was used to show the materials to participants. Materials were then updated based on feedback, and the design was improved with the help of a designer. In the second round of testing, materials were mailed to survivors and opened during the interview. We used the “think aloud” method wherein participants were encouraged to share thoughts, likes, and dislikes as they went through the materials. Interviews were recorded and data extracted, synthesized, and thematically analyzed to understand the user experience. The team then reviewed results and made design decisions iteratively.

Figure 2. Example of personas and journey maps.



**Ethics Approval**

This multistep and multisite study involved several components of research ethics approval. Step 1 of our study was approved by Clinical Trials Ontario (project ID 1906), with The Hospital for Sick Children's Research Ethics Board acting as the Board of Record. Steps 2 and 4 were conducted following the Women's College Hospital's Quality Improvement approval process. Institutional approvals were sought at all relevant participating sites where applicable. All survivors and physicians gave informed consent to participate in the study.

**Results**

**Step 1: Qualitative Study**

We interviewed 30 survivors and 7 family physicians (Table 2). Childhood cancer survivors were keen to learn more about their risk for late effects and surveillance recommendations. Concurrently, it was deemed crucial that survivors' emotions, including cancer-related anxiety, would be addressed in the intervention. We learned that information on late effects and accessing surveillance could help empower survivors with the knowledge and tools necessary to complete tests but that the intervention must also reduce the burden of remembering when tests are due and scheduling appointments. Based on the barriers

and enables identified, as well as the experience and knowledge of our team, we developed 4 survivor personas, 1 family physician persona, and corresponding journey maps (see Figure 2 for an example). Personas differed regarding their family context (single versus married with children), location (small town versus city) and emotional state (anxious versus not). The survivors' personas included a grading on a scale of traits such as feeling unwell versus well, unaware of late effects versus aware, avoidant of health care versus engaged, and anxious versus relaxed.

Our analysis of interviews with family physicians revealed that barriers to supporting childhood cancer survivors in their practice included physicians' unfamiliarity with long-term follow-up care guidelines for childhood cancer survivors, time constraints in each patient interaction, and limited support in unpacking the unique needs of childhood cancer survivors. Physicians vocalized that personalized information about their patient's needs would ensure that they could support their patient in accessing surveillance tests. Based on these interviews, we developed a surveillance concept that involved 3 components: (1) help reconnect childhood cancer survivor to the health system; (2) provide information on recommended screening tests; and (3) remind survivors of upcoming screening tests (Figure 2).

**Table 2.** Characteristics of childhood cancer survivors (N=30) and family physicians (N=7).

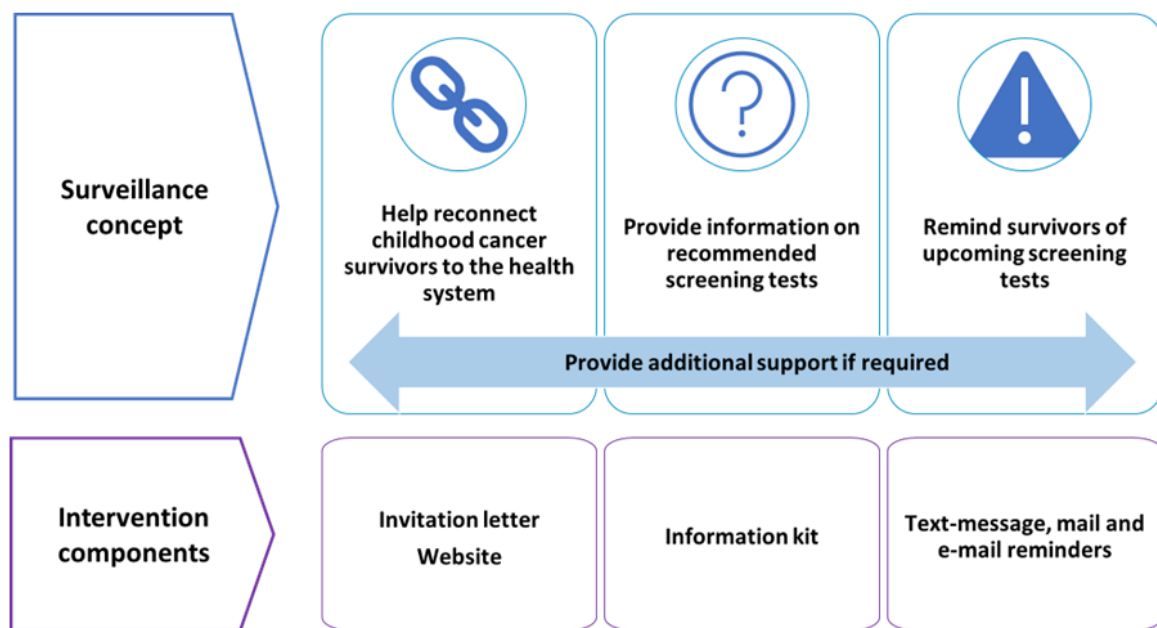
Respondents and their characteristics	Values
<b>Childhood cancer survivors</b>	
Age (years), mean (SD)	41 (10.5)
<b>Frequency of doctor visits, n (%)</b>	
≤Once a year	27 (90)
>Once a year	1 (3)
Undetermined/very infrequently	2 (7)
<b>Location, n (%)</b>	
Urban	22 (73)
Rural	8 (27)
<b>Gender, n (%)</b>	
Female	18 (60)
Male	12 (40)
<b>Highest level of education attained, n (%)</b>	
Less than high school	1 (3)
High school	1 (3)
College/university/graduate	28 (94)
<b>Type of cancer, n (%)</b>	
Lymphoma	10 (33)
Leukemia	7 (24)
Neuroblastoma	2 (7)
Wilms tumor	3 (10)
Bone tumor	5 (16)
Liver tumor	3 (10)
<b>Family physicians</b>	
Age (years), mean (SD)	45 (14)
Years in practice, mean (SD)	17 (4)

## Step 2: Workshop

A total of 6 childhood cancer survivors, 3 family physicians, and 3 health system partner stakeholders attended the workshop. Stakeholders represented relevant provincial health system partner organizations. The workshop validated our surveillance concept (Figure 3) and provided key insights regarding the development of the intervention components. In terms of the invitation letter, we learned from survivors that receiving a letter regarding their cancer could be stressful and anxiety provoking. Interestingly, survivors were not concerned about privacy in receiving a letter identifying them as a childhood cancer survivor

in the mail. The importance of involving the family physician in the intervention was highlighted. Family physicians expressed a desire to receive concise, clear information regarding the individual patient's history and the next steps required. Survivors preferred different options regarding methods of communication (ie, mail, email, text message). Survivors communicated the importance of additional information, if required, and a website for more information. Finally, survivors appreciated the idea of an “opt-in” program where the initial outreach only had general information and then they could choose if they wanted to receive personalized information regarding their risks and screening recommendations, including periodic reminders.

**Figure 3.** Childhood cancer survivor surveillance concept and corresponding intervention components.



### Step 3: Prototype Development

Prototypes were developed by establishing goals for each prototype, ensuring the content addressed the specific barriers and enablers from the qualitative study, the behavior change techniques identified [21] were implemented as intervention components (Table 3), and the intervention components from the workshop were incorporated. For example, in the introductory letter and information kit for the survivors, we addressed the following: (1) personalized information on how to complete surveillance tests and information about health consequences of late effects, delivered in a impactful manner; (2) prompts/cues to perform the required tests and supports to

enable surveillance while conserving mental resources; (3) persuasive information on the health benefits of surveillance; and (4) supports to reduce fear of cancer and negative emotions linked to surveillance.

In recognition that survivors may feel anxiety or fear when receiving a letter about their childhood cancer, it was important to choose a color scheme that would help survivors feel at calm and safe. We chose a blue as a dominant color because it has been shown to be associated with trust and confidence [30,31]. To ensure buy-in from survivors, we knew it would be important to include recognizable logos. Therefore, to lend credibility to the program, we included logos to link it to an already established and recognized organization.



**Table 3.** Prototype development.

Item	Goals	Discovery phase Domains of the Theoretical Domains Framework [19,22]	Behavior change techniques mapped from the Theoretical Domains Framework that were addressed <sup>a</sup> [24]	Design choices
Survivor invitation letter	<ul style="list-style-type: none"> <li>• Generate awareness of late effects and surveillance guidelines</li> <li>• Reconnect childhood cancer survivors to the health system</li> <li>• Confirm identity</li> <li>• Offer personalized information</li> <li>• Determine preferred method of contact (email, mail, text message)</li> <li>• Confirm primary care provider</li> </ul>	<ul style="list-style-type: none"> <li>• Knowledge (of late effects)</li> <li>• Emotion (fear of cancer)</li> </ul>	<ul style="list-style-type: none"> <li>• Biofeedback</li> <li>• Instruction on how to perform behavior</li> <li>• Information about antecedents</li> <li>• Information about health consequences</li> <li>• Information about social and environmental consequences</li> <li>• Reduce negative emotions</li> </ul>	<ul style="list-style-type: none"> <li>• Include information on how to obtain surveillance</li> <li>• Include information about health consequences of late effects</li> <li>• Advise on ways to reduce fear of cancer and negative emotions linked to surveillance</li> </ul>
Survivor information kit	<ul style="list-style-type: none"> <li>• Provide tailored information</li> <li>• To enlist action: share with primary care provider</li> </ul>	<ul style="list-style-type: none"> <li>• Beliefs about consequences (of surveillance)</li> <li>• Intention (to complete surveillance tests for late effects)</li> </ul>	<ul style="list-style-type: none"> <li>• Information about health consequences</li> <li>• Salience of consequences</li> <li>• Information about social and environmental consequences</li> <li>• Anticipated regret</li> <li>• Information about emotional consequences</li> <li>• Goal setting (behavior)</li> <li>• Information about health consequences</li> <li>• Self-incentive</li> </ul>	<ul style="list-style-type: none"> <li>• Provide information on health benefits of surveillance in an effective and memorable manner and awareness of possible regret if surveillance is not performed</li> <li>• Provide information about emotional benefit of completing surveillance and tips regarding self-incentive if surveillance is performed</li> </ul>
Website	<ul style="list-style-type: none"> <li>• Increase legitimacy of program</li> <li>• A place to find more information if desired</li> </ul>	<ul style="list-style-type: none"> <li>• See knowledge, emotion, beliefs about consequences</li> </ul>	N/A <sup>b</sup>	N/A
Survivor reminder letters	<ul style="list-style-type: none"> <li>• Ensure survivors do not forget about surveillance test</li> <li>• To enlist action: reach out to physician to book test</li> </ul>	<ul style="list-style-type: none"> <li>• Memory, attention, and decision-making (reminders)</li> </ul>	<ul style="list-style-type: none"> <li>• Prompts/cues</li> <li>• Conserving mental resources</li> </ul>	<ul style="list-style-type: none"> <li>• Include prompts/cues to perform surveillance</li> <li>• Enable surveillance completion while conserving mental resources</li> </ul>
Physician information letter	<ul style="list-style-type: none"> <li>• Education on patient history and surveillance recommendations</li> <li>• To enlist action: contact survivor and use their electronic medical record to schedule reminders</li> </ul>	<ul style="list-style-type: none"> <li>• Knowledge (of late effects)</li> </ul>	<ul style="list-style-type: none"> <li>• Instruction on how to perform behavior</li> <li>• Information about antecedents</li> <li>• Information about health consequences</li> <li>• Information about social and environmental consequences</li> </ul>	<ul style="list-style-type: none"> <li>• Include information on patient's cancer history, risk of late effects, and surveillance recommendations</li> </ul>

<sup>a</sup>An international consensus project identified a list of 93 behavior change techniques as elemental components of interventions. It was developed to help intervention designers, researchers, and theorists in the development and evaluation of theory-based interventions. Published linkage of behavior change techniques to Theoretical Domains Framework domains is based on triangulating relationships found in published studies and by expert consensus (see [32]).

<sup>b</sup>N/A: not applicable.

## Step 4: User Testing

### Round 1

In the first round of user testing, we interviewed 5 survivors and 2 physicians (Table 4). Key insights and areas for improvement are highlighted regarding each prototype.

#### Invitation Letter

Survivors did not find the letter overwhelming and were glad to learn about late effects. They appreciated our acknowledgment that learning this information could be stressful

and that we provided a point of contact for additional support. There was some confusion related to the program flow (ie, how to access surveillance tests), for which adjustments were made. Survivors expressed hesitancy in joining the surveillance program, with our analysis suggesting that this could stem from the survivor lacking a family physician, not feeling at risk for late effects, feeling uncertain of the benefits of the program, or experiencing fear related to surveillance tests. In the next iteration, we addressed these issues by highlighting benefits (physical and emotional benefit) and clear information on accessing a family doctor.

**Table 4.** Characteristics of the participants in user testing (N=11).

Characteristics	Round 1 (n=5)	Round 2 (n=6)
<b>Gender, n (%)</b>		
Male	3 (60)	2 (33)
Female	2 (40)	4 (66)
Age (years), mean (SD)	35 (8)	37 (10)
<b>Location, n (%)</b>		
Urban	3 (60)	3 (50)
Rural	2 (40)	3 (50)

#### Website

Survivors were glad to have a website with more information on late effects and the program. However, some were uncertain about how to sign up. Survivors also found the website stale and boring; thus, in the next iteration, we strove to make the website aesthetically pleasing while maintaining a sense of importance and urgency.

#### Information Kit

Survivors' interest in the program increased after they saw the information kit. This demonstrated that it would be beneficial for survivors to have a better understanding of the information kit when then received the introductory letter. There was a range of desire for information; therefore, we decided that the website would be a good forum to include additional information. There was also some confusion on what to do next and the role of the survivor in the program. Changes were made to highlight the program flow, and we highlighted the importance of bringing this information kit to their family doctor. Some survivors felt overwhelmed by the responsibility of taking on these surveillance tests. In the next iteration, we included empowering language and emphasized that their family physician would help them through the process.

#### Reminders

Survivors wished to receive reminders via email. They also wanted more information on when their test was due instead of a simple message that they were due for a test. They felt that these reminders looked official and would encourage them to book a test. Some expressed that they wished that these tests could be booked without a family doctor, but that was not something we could address in the confines of this provincial health system in Ontario.

#### Physician Information Letter

We interviewed 2 physicians in the first round, and the information letter was well received by both. These physicians were glad to know that the survivors would also be receiving their screening recommendations. They found the letter clear and concise but requested additional information on accessing tests and what to write on the requisition. They requested reminder letters to ensure that they could help their patients keep on track with their surveillance tests, and this was developed for the next round of testing. It was important for them to see the logos of provincial health organizations on the letter.

### Round 2

In the second round of interviews, we spoke with 6 childhood cancer survivors and 6 family physicians (Table 4). Overall, the design of the materials was well received and there were minimal suggestions for changes.

#### Invitation Letter

Survivors appreciated the opportunity to choose to learn more information on late effects and screening recommendations. They felt empowered with the new knowledge and supported to complete the recommended surveillance. They were enthusiastic to learn more through the program website and felt that this gave the program legitimacy. Some survivors questioned the credibility of the program and wondered how their personal health information was collected. Changes were made to explain the organizations that were supporting this program and why they had access to their personal information.

#### Information Kit

Survivors found the kit clear and concise and felt it would be useful to bring in to show their family physician.

## Reminders

Reminders were appreciated and thought of as an essential component of the program.

## Physician Information and Reminder Letter

Some physicians found the tone of the letter to be prescriptive rather than collaborative. They also requested more information on their patient's cancer diagnosis and treatment history so they could have a more informed conversation with their patient. Physicians highlighted that the possibility that survivors did not receive information on late effects and surveillance should be made clear. It was important for physicians that the patient was also engaged in the program and received a letter. They wanted the patients to be partners in their care and share responsibility of initiating contact with the physician to order the surveillance tests.

Finally, the feasibility of this study was carefully considered in the context of the infrastructure of our stakeholders in this phase. For example, some users wanted a highly tailored information kit that included many follow-up recommendations, but this was not feasible with existing data sets that were leveraged for this intervention. Survivors also requested an online portal where they could view their screening recommendations; however, stakeholders were concerned with privacy and were not interested in creating and maintaining a website with this type of information.

## Discussion

Our design process used both behavioral theory and design thinking to develop a complex intervention aimed at increasing adherence to surveillance guidelines for late effects among childhood cancer survivors. We began with a discovery stage, where we identified important barriers, such as the burden of managing care and lack of knowledge among both survivors and physicians through a behavioral theory-led process. Survivors' emotions, including cancer and surveillance-related anxiety, required careful consideration. It was further emphasized by survivors that the support system must help with reducing the burden of remembering when tests are due and scheduling appointments. Personas and journey maps enabled our team to empathize and design with different types of survivors in mind (eg, different stages of life and geographical location). During our design and build phase, we tailored the prototypes to best empower survivors, give them sufficient and clear information, address their fears, and provide them with necessary support, directions, and reminders to promote access to surveillance tests.

The result of this process is a design of a centralized system to identify high-risk survivors and provide them and their family physicians with personalized information about recommended surveillance and periodic reminders. Our surveillance and support system builds on existing recommendations put forth by the National Cancer Policy Board of the Institute of Medicine and the National Research Council to design systems of care that are responsive to the long-term needs of childhood cancer survivors as they transition from pediatric to adult care, improve awareness of late effects and their implications among survivors,

and augment professional education and training regarding late effects for primary care clinicians [33]. Our next step is to implement and evaluate this intervention in a pragmatic randomized controlled trial with an embedded process evaluation.

Our discovery and iterative design process described in this paper led to new insights for this population and may help the development of other surveillance systems aimed to increase screening. For example, our discovery process highlighted the importance of engaging both physicians and patients simultaneously in the intervention so they can both be partners in care, a component missing from most previous interventions for childhood cancer survivors [7]. We also demonstrated that by addressing and supporting emotional needs and empowering individuals to take control of their health, outreach to a population with a complex health history is not only feasible but also welcomed. This barrier has not been thoroughly described or addressed in previous interventions aimed at improving adherence to surveillance guidelines in survivors of childhood cancer [7].

This study adds to the growing literature on the design of interventions using user-centered methodology and behavioral [34-38] and psychological [39,40] theory. As per our experience, we found these 2 methodologies to be compatible and beneficial. We were able to design for childhood cancer survivors in a user-centered empathetic fashion while also infusing rigor and systematic thinking by incorporating behavioral theory. There is growing need to address complex system problems in a manner that is compassionate and user-focused while also relying on insights from behavioral science at the various stages of design and evaluation.

To maximize the likelihood of implementation, we made sure to engage relevant stakeholders who will ultimately be rolling out the intervention if it is shown to be effective when tested in a pragmatic controlled trial. Therefore, during the design and build phase, we had to ensure that the design of our intervention would be compatible with operationalization. For instance, survivors voiced preference on which organization they would prefer to receive surveillance information from; however, we had constraints based on privacy and could not align our design with this preference. We also had to rely on the existing outreach infrastructure; therefore, we could not accommodate physicians' preference to receive information on late effects and surveillance recommendations via fax. Other elements that were expressed as important during the cocreation workshop, such as a nurse navigator, were removed from the design because they were costly and incompatible with creating a sustainable intervention. This process has highlighted the importance of designing an intervention in tandem with ongoing conversations with necessary stakeholders who will be delivering the program.

This work highlights the feasibility and value of using behavioral science and design thinking in the development of a scalable and long-term health system approach to address the surveillance needs of childhood cancer survivors. However, there are some limitations to our work. First, using a design thinking approach enabled us to develop a deeper understanding of survivors' and primary care clinicians' needs and communicate them in an

actionable way, but it also had constraints. For example, we had to balance survivors' and physicians' wishes with the capacity and infrastructure of our health system partners. Additionally, this methodology was not straightforward; at times, it was challenging to prioritize divergent feedback from user groups, and multiple rounds of feedback and iterations can be time consuming. Additionally, since feedback was gathered during user testing, we had to be mindful of carefully considering implications before adding new features. Finally, we were only able to work with survivors who responded to our invitations, and the extent that these insights are

generalizable to the general childhood cancer survivor community is unknown.

In this article, we present an example of intervention design using behavioral theory and design thinking. In partnership with survivors, family physicians, and health system partners, we have elucidated actionable barriers and enablers related to completion of guideline-recommended surveillance by adult survivors of childhood cancer and designed a multifaceted solution that will support survivors and their family physicians. Further directions include evaluating this intervention through a pragmatic randomized controlled trial.

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## Conflicts of Interest

None declared.

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## Abbreviations

**CIHR:** Canadian Institutes of Health Research

**MRI:** magnetic resonance imaging

**POGO:** Pediatric Oncology Group of Ontario

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Review

# Strategic Guidance and Technological Solutions for Human Resources Management to Sustain an Aging Workforce: Review of International Standards, Research, and Use Cases

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## Abstract

**Background:** New technologies offer opportunities to create a healthy, productive, and capable aging workforce. There is little research from an organizational perspective about how technology can help create a sustainable aging workforce.

**Objective:** This study aims to (1) explore how technological solutions in organizations can help create and maintain a healthy, productive, and capable aging workforce; and (2) provide recommendations and strategic guidance that benefit both the aging worker and the organization.

**Methods:** International standardization practices, ethical frameworks, collaborative research, and use cases are used to demonstrate how technological solutions can be translated into practice and formed the basis for the development of a set of recommendations to create and maintain a sustainable aging workforce.

**Results:** Organizations need to look at aging through different lenses to optimize an age-inclusive workforce rather than viewing it by chronological age alone. International standards in technology, human resources management, and aging societies can form part of the solution to improve aging workforces. Digitalization of workplaces, digital literacy, innovation, intergenerational collaboration, and knowledge management form important elements of the international standard on age-inclusive workforce. Using internationally agreed ethical frameworks that consider age bias when designing artificial intelligence-related products and services can help organizations in their approach. Age bias in artificial intelligence development in the workplace can be avoided through inclusive practices. No blockchain application was found yet to improve the aging workforce. Barriers to blockchain adoption include fear of layoffs, worker resistance and lack of blockchain competence, worldwide adoption, support, and funding. Integrating blockchain into the internet of things may allow for improved efficiencies, reduce cost, and resolve workforce capacity problems. Organizations could benefit from implementing or funding wearable technologies for their workers. Recent tools such as the Ageing@Work toolkit consisting of virtual user models and virtual workplace models allow for the adaptation of the work processes and the ergonomics of workplaces to the evolving needs of aging workers. Lastly, selected use cases that may contribute to sustaining an aging workforce are explored (eg, the Exposure-Documentation-System, wireless biomedical sensors, and digital voice notes).

**Conclusions:** The synergy of international standardization and ethical framework tools with research can advance information and communication technology solutions in improving aging workforces. There appears to be a momentum that technological solutions to achieve an age-inclusive workforce will undoubtedly find a stronger place within the global context and is most likely to have increased acceptance of technological applications among aging workers as well as organizations and governments.

International standardization, cross-country research, and learning from use cases play an important role to ensure practical, efficient, and ethical implementation of technological solutions to contribute to a sustainable aging workforce.

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## KEYWORDS

workforce; HR; aging; older people; standards; international standards; occupational health; blockchain; AI; ICT; strategy

## Introduction

### Aging and Working Population Changes

In many developed and developing countries, the aging population is increasing due to advances in medicine and public health as well as socioeconomic developments. The number of people aged 65 years or over in the global population will double from 703 million in 2019 to 1.5 billion in 2050 [1].

This demographic change represents a challenge for the working environment as the workforce is aging [2]. In 2018, 20% of the working population in the European Union was aged 55 and over, with one-third of them being over 60 years [3]. In the United States, it is estimated that by 2024, 25% of the workers will be 55 years and older. One-third of them will be over 65 years [4]. The old-age dependency ratio (OADR) is also expected to rise sharply. The OADR describes the ratio of people aged 65 and over (old ages) to people aged 20-64 years (working ages). In Europe and North America, the OADR is projected to rise from 30 in 2019 to 49 in 2050 per 100 working age persons. By 2050, many Asian and Latin American countries are projected to join European countries in having high OADRs [1]. For example, Japan is expected to have the highest OADR in the world of 81, followed by the Republic of Korea at 79, and Spain at 78, while China and Taiwan will have an OADR of 71 per 100 working age persons.

### Aging Workforce and Technological Changes

Simultaneously with demographic changes, the fourth industrial revolution (Industry 4.0) is rapidly developing. Organizations aim to exploit developments in the field of artificial intelligence (AI), the internet of things (IoT), and collaborative robots. With changing market demands, and the shift from mass production to increasingly specialized and customized products, the complexity in production and work tasks will increase. Work will increasingly take place in automated factories with cyber-physical production systems, where machines, products, and workers will be interconnected [5]. Work tasks and processes will become increasingly complex such as supervision of machines, and will increasingly require problem-solving skills. Good knowledge management and information and communication technology (ICT) become increasingly important as new work tasks require a higher level of knowledge and information processing ability.

While some jobs may disappear due to technology, new ones will emerge [6]. Furthermore, new organizational business models, such as platform work (eg, Uber), and evolving worker preferences, such as remote work [6], have led to technological changes in the workplace. COVID-19 has also demonstrated the “forced innovation” such as the implementation of telehealth [7], increased use of videoconferencing, and technological

solutions created during COVID-19 to support an aging workforce [8].

### Benefits and Downsides of Technological Advances and an Aging Workforce

An age-inclusive workforce can increase the competitive advantage through increased engagements and performance [9]. Conversely, there is a stream of thought that age diversity is harmful for organizational productivity, which was confirmed in a Belgian sample of 2431 organizations in the private sector [10]. However, van Ours and Stoeldraijer [11] did not find any relationship between increasing age and a pay-productivity gap in the Dutch manufacturing industry. And, more recently, a 2019 Estonian study demonstrated that older workers are as productive as younger workers [12]. Overall, the evidence appears conflicting [13] and a meta-analysis has demonstrated that the relationship between productivity and workers’ age is not yet clearly established empirically [14].

Broadly, quality work means that people can be productive at work, add value to the organization, have a decent income, feel secure in the workplace and socially included, and are able to participate in decisions that affect their working environment.

Provided that work is quality work, additional benefits of prolonging working lives for older people include work being good for health [15], allowing social participation, and providing financial independence. When workers age, some physical and mental capabilities (such as visual or reaction time) decline [16], while professional knowledge and experience increase. ICT can play a role to ensure quality work for aging workers. To date, technology has mostly replaced both physical and cognitive repetitive tasks through computer programming, whereas it has become complementary to the performance of nonroutine cognitive tasks for humans [14].

On the one hand, ICT can improve working conditions, for example, by reducing loads, shortening commuting time, or assisting in activities. ICT can compensate for some of the decreasing capabilities of older workers or reduce risks in terms of hazardous tasks, and protect older workers during pandemics by allowing remote working [7]. Ergonomics plays an important role in creating aging-appropriate work designs to meet the needs of workers. Including aging workers in the design process can contribute to achieving this goal [17]. On the other hand, traditional jobs may be lost, continuous and more rapid upskilling in technology is needed, and workers may have difficulties in the use of new technologies. Furthermore, technology may decrease autonomy at work [6], which is an important determinant for quality work. Currently, the literature is inconclusive about the negative aspects of technology on working conditions [6].



Another consideration is that younger workers' knowledge about new ways of working and new technologies is often perceived to be more explicit. But the tacit knowledge of older workers gained through experience is equally important, especially for performing complex tasks. Research has shown that older people perform more consistently on cognitive tasks than younger people [18]. Older workers have competencies that younger workers may not have developed yet. Thus, the skills of younger and older workers complement rather than substitute each other [19].

Nagarajan and colleagues [17] conducted a systematic review of 122 studies (1990-2018) to identify organizational factors that contribute to sustaining an aging workforce. Notably, they found that technological tools were the least researched factor that contributes to a sustainable aging workforce. Only 4.9% (6/122) of the research focused on technology compared with the other 4 main factors, including human capital (40/122, 32.7%), institutions (32/122, 26.2%), human resources management (29/122, 23.7%), and health (15/122, 12.3%). The authors suggested future work is needed in the area of technological tools to improve productivity in an aging workforce [17]. Our paper seeks to address this gap by exploring how technology can be used to improve the aging workforce.

## Objectives

This paper aims to (1) explore how ICT solutions in organizations can help create and maintain a healthy, productive, and capable aging workforce; and (2) provide recommendations and strategic guidance that benefit both the aging worker and the organization.

## Methods

Different sources of data are drawn upon that point to the benefits of and how ICT can help create and maintain a healthy, productive, and capable aging workforce that adds value to both the organization and the aging workforce. The focus of attention was on using different lenses on aging, international standardization, ethical frameworks, international collaborative research, and practical use cases. Information was gathered on international efforts in the field of aging workforce based on research in technical literature, professional journals, and internet articles. We searched the International Organization for Standardization (ISO) browsing platform [20] and contacted international experts.

A brief literature review was conducted in Web of Sciences (2010-2021) using the following keywords: information communication technology and (human resources or workforce or employee or worker) and (aging or older or old or aging or mature). Searches were restricted to English publications.

Following this, several distinct areas of aging workforce and ICT were further explored. First the importance of using different lenses toward aging was examined, and a multidimensional perspective to optimize an age-inclusive workforce was presented. Second, international standards directories were examined to determine how international standardization contributes to a sustainable aging workforce. Third, increased digitalization leads to an increased need to

understand the ethical requirements and implications of these changes in the workplace. It also requires us to understand how ethics can contribute to a sustainable aging workforce. Therefore, ethical frameworks and standards that deal with ethics in relation to ICT and an aging workforce were examined. Fourth, novel research in the area of aging workforce and ICT solutions were examined to demonstrate how international collaborative research can contribute to a sustainable aging workforce. Lastly, several use cases were studied to show how ICT solutions can be translated into practice and applied.

Based on the steps above, a set of recommendations was developed for organizations to provide strategic guidance and practical solutions to improve the aging workforce.

## Results

### Context of an Aging Workforce and ICT

A Web of Science literature search between 2010 and 2021 identified 324 papers; of these, 27 abstracts were selected for further review and 13 were finally included in this review. Themes that emerged centered around the impact of age and ICT on health-related outcomes (n=6); the impact of technology on the demand for older workers (n=3); the relationship between aging, ICT investment, and productivity (n=1); age and the use of social media for work purposes (n=1); and lastly the impact of ICT on the rise of nontypical employment and associated occupational health and safety (OHS) consequences (n=1).

Six papers focused on the impact of age on ICT and health-related outcomes. Overall, studies found no relationship between age, ICT, and health. Berg-Beckhoff et al [21] conducted a systematic review and concluded that although ICT leads to more burnout, there was no linear relationship between age and technostress and burnout. Arvola and colleagues [22] also found that there is no difference in well-being and mental health between older workers who do tele-work and those who do not. Borle and co-workers [23] also reported that, among German workers, ICT does not negatively affect the health and social life of older workers, but they did find that digital work intensification overall is associated with worsening mental health and work ability but not physical health.

By contrast, Hauk et al [24] reported that increasing age led to reduced technostress, based on longitudinal data among 1216 employees. The authors explain that this relationship is influenced by the level of work engagement, and that because older workers tend to have higher work engagement compared with their younger counterparts, they have less technostress. Setyadi and colleagues [25] went a step further and explored how different concepts of aging, including cognitive age and chronological age, influence the effect of technostress on work satisfaction, performance, and intention of long-term ICT use. They concluded that the higher the cognitive age (coined as "young spirited workers"), the less technostress the worker experienced. This highlights the need for organizations to look at different dimensions of aging. Furthermore, technostress was mainly influenced by techno overload, uncertainty, and insecurity as well as workers' intention to continue to use technology. Carlotto et al [26] found among Brazilian ICT

workers that professionals aged between 35 and 60 years reported a greater identity with their career, higher satisfaction with life, and less technostress. In summary, it appears that age influences one's career identity and work engagement in a positive manner, and therefore can possibly lead to reduced technostress.

Three papers examined the impact of technology on the demand for older workers, with 2 focusing on high-income countries [27,28] and one on a lower-income country (Pakistan) [29]. Peng et al [27] found that in 9 European countries between 1970 and 2007, ICT led to a decrease in the demand for older workers. The authors reported that some deskilling of older workers took place, which influences the demand of these older workers and suggests that these trends can be alleviated somewhat through activities such as wage settings and collective bargaining agreements [27]. This may require government-level support. Similarly, Blanas and co-workers found, in 10 high-income countries and 30 different industry sectors, that software and robots reduced the demand for young, lower-skilled, and female workers, notably in the manufacturing industry [28], whereas it increased the demand for older, high-skilled, and male workers, particularly in the service industry. Both studies confirm that lower-skilled and routine human tasks are replaced by ICT. Lastly, Hanif et al [29] looked at 295 older workers in the ICT sector in Pakistan and found that age, gender, and lower health status are barriers to sustainable employability, while technical qualifications facilitate sustainable employability.

A 2020 Japanese and Korean study explored the complex relationship between aging, ICT investment, and productivity, and found that in Japan and Korea aging has a positive effect on labor productivity in organizations with a high level of ICT capital investments [30]. However, compared with younger workers, in Japan a higher proportion of lower-educated older workers have a positive impact on productivity, whereas in South Korea a larger proportion of higher-educated older workers have a positive impact on productivity. The study's analyses also demonstrated that the combined effect of ICT investments and older workers led to an increase in productivity

in Japan for high- and low-educated workers, but in Korea only for low-educated workers. The authors concluded that organizations can alleviate productivity decline due to aging by increasing ICT investments. This means that investing in ICT capital and technologies can potentially increase productivity and extend the working lives of older people.

In a rapidly changing world knowledge sharing is essential. One paper looked at generational differences and the use of social media for work purposes and found that beyond age, organizational rank, knowledge needs, enthusiasm, and personality played a role in influencing workers attitudes to use social media for knowledge sharing [31].

Min and colleagues [32] argued that Industry 4.0 has led to nonstandardized employment globally, such as gig work and short-term contracts, which makes OHS more difficult to implement and monitor. Overreliance and trust in new technology run the risk of large-scale and new types of accidents. The authors call for the development of new concepts of decent work, organizing of networks among independent workers to allow for OHS monitoring, and standardization of OHS regulations.

### **A Multidimensional Perspective to Optimize an Age-Inclusive Workforce**

Traditionally, aging is viewed by chronological age. However, organizations should think beyond the traditional concept that aging equals chronological age and instead employ a wider multidimensional perspective in the workplace. North [13] argues that generation, age, tenure, and experience must be integrated together to improve our understanding of aging workforce. The American Association of Retired Persons (AARP) uses the following lenses of aging at work: organizational tenure, career stage, life events, generation, accessibility, and chronological age (Table 1) [9]. The AARP did not include experience, like North [13] suggested, in their multidimensional perspective of aging. Examples of how this can be applied in practice are presented in Textbox 1.

**Table 1.** Multidimensional lenses of aging workforce.

Perspective	Explanation	Example
Organizational tenure <sup>a,b</sup>	Time spent within the same organization	2 years
Career stage <sup>b</sup>	Stages may include entry, establishment, advancement, maintenance, transition, and maturity (ISO <sup>c</sup> 30400:2016) [33], or simply early, mid-, and late career.	Mid-career
Life events <sup>b</sup>	Age-related life events such as studying, getting married, having a child, becoming a carer for spouse or parents, being a grandparent or death of partner.	Carer for parents and children
Generation <sup>a,b</sup>	Specified birth cohort. Determines world views, experience of historical and economic events	Gen X
Accessibility <sup>b</sup>	Physiological or mental changes that impact the ability to work	Back problem and early onset dementia
Chronological age <sup>a,b</sup>	Years since birth	45 years
Experience <sup>a</sup>	Experience acquired in specific skills overtime	Years of online teaching

<sup>a</sup>Adopted from North et al [13].

<sup>b</sup>Adopted from American Association of Retired Persons (AARP) [9].

<sup>c</sup>ISO: International Organization for Standardization.

**Textbox 1.** Practical examples of different lenses of aging at work applied in practice.

<p><b>Generation</b></p> <ul style="list-style-type: none"> <li>Consider the different usage patterns of social media by different <i>generations</i> to ensure a wide pool of suitable applicants during recruitment [31].</li> </ul> <p><b>Organizational Tenure and Experience</b></p> <ul style="list-style-type: none"> <li>An organization plans an expansion of an existing digital decision-support system. It is likely that those who have been longer with the organization or who have more <i>experience</i> with the system require less training, and hence, tailoring the training to specific needs may prove beneficial.</li> </ul> <p><b>Experience</b></p> <ul style="list-style-type: none"> <li>During the initial outbreak of COVID-19, academic teaching staff with online teaching experience had less anxiety and required less training in transitioning their entire study units to online teaching than people who had less experience. The experience of seasoned online teachers was used to assist novices and was certainly not reflective of just age.</li> </ul> <p><b>Others</b></p> <ul style="list-style-type: none"> <li>Other lenses that can be considered are biological, psychosocial, functional, and social aging [34]. Using different lenses when considering the aging workforce will ensure solutions are tailored to achieve optimum outcomes.</li> </ul>
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## How Can International Standardization Contribute to a Sustainable Aging Workforce?

### What Is the International Organization for Standardization?

The ISO produces voluntary international standards. Its members are national standards bodies representing each country. ISO works closely with the International Electro Technical Commission (IEC). A standard is defined as a document that “provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.” [35].

The economic benefits of international standards are global harmonization of products and services, which increases trade, efficiency, and productivity. It also creates trust that products are safe and reliable among consumers, organizations, and governments. Each standard clearly identifies which Sustainable

Development Goals it contributes to, thus reflecting their social and ethical benefits.

International experts contribute to working groups, which form part of technical committees. Working groups prepare the international standards. International standards go through several global commenting and voting stages to ensure consensus and practice-based solutions are reached. Experts are nominated by their national standards body and represent various stakeholder views including industry, small business, unions, academics, governments, consumers, or not-for-profit organizations.

The most relevant standard in relation to aging workforces will be presented below, while other standards will be listed where appropriate.

### Technical Committee 314 on Aging Societies

Aging workforce was identified as a priority by the Technological Committee 314 on Aging Societies, resulting in

the establishment of the first working group: *Working Group 1—Guidelines for an Age-Inclusive Workforce*. Approximately 16 countries from Europe, North America, Asia, Africa, and the Pacific participated. This international standard provides guidelines that allow organizations and other stakeholders to develop, implement, maintain, and support an age-inclusive workforce, while adding value to the organization, the older workers, communities, and other stakeholders [36]. Organizations can use this guideline as a stand-alone document or as part of their management systems, human resources activities, corporate social responsibility, or diversity and inclusion programs.

Digitalization of workplaces, digital literacy, and innovation form important elements. Recommendations in relation to digitalization and digital literacy focus, for example, on policies and procedures, remote working, training, resources, access, and mechanisms for evaluating technical opportunities.

Innovation recommendations encourage, for example, age-inclusive cocreation and co-design initiatives, where older workers are involved in workplace design, co-design, and create new products and services such as health apps. The rapidly aging demographic brings new, large, and untapped market opportunities. The added benefit of being creative at work is that evidence shows it also improves work engagement [37]. Tasks needing creativity, social intelligence, and human contact will remain and likely not be replaced by automation processes. Importantly, these tasks can be performed by people, regardless of their age [14].

The standard also addresses knowledge management and intergenerational collaboration. Both are relevant for an aging workforce to allow knowledge transfer between different generations and ICT skill building. Knowledge management systems not only include organizational knowledge management culture, structure, governance, and leadership but also roles and responsibilities, technology, processes, and operational matters [38]. ICT plays a relevant role in knowledge management systems.

### **Corporate Social Responsibility**

Organizations that wish to operate in a socially responsible way and demonstrate commitment to sustainability can use the popular ISO 26000 standard guidance on social responsibility [39] as a guide to integrate social responsibility into their values and practices. Interestingly, there is a lack of organizations that have focused specifically on age from a diversity and inclusion strategic perspective. A 2015 PricewaterhouseCoopers CEO Global Survey found that 63.9% (549/858) of organizations had diversity and inclusion strategies, yet only 7.9% (68/858) had an age-inclusive strategy [40]. Organizations aiming to develop their aging workforce can capitalize on this by defining this goal as a corporate social responsibility activity, increasing their market competitiveness.

## **How Can Ethics Contribute to a Sustainable Aging Workforce in the Area of Technology?**

### **Overview**

The rapid changes in technology and aging workforce require a continuous rethink in ethical principles and applications. For example, how do organizations act in a socially responsible way? How do we make AI systems trustworthy and how do we deal with their risks? How can organizations adapt their governance and consider these new risks?

### **Ethical Frameworks**

Several ethical frameworks have been developed based on user group (eg, older users) or technology type such as AI, and these can help organizations manage their risks. Globally agreed standardized ethical principles are important to reduce trade barriers, allowing for exporting and importing of technology, and to build confidence in the ethical use of technology systems. Organizations will benefit from identifying an ethical framework relevant to their context and needs. Two examples are provided below, followed by the description of the trustworthiness of AI systems for an aging workforce.

First, an ethical framework for standardization of product and services in ICT and active and healthy aging consists of the following principles: accessibility and usability, affordability, autonomy and empowerment, beneficence and nonmaleficence, care protection and support, equality/equity and justice, inclusion/nondiscrimination and social impact, interoperability, and privacy/safety and security [41]. These ethical principles could easily be used to further guide aging workforce technological developments to reduce risks.

Second, leading technology companies and several international standardization bodies such as the ISO, the Institute of Electronic and Electronic Engineers (IEEE), and the Organization for Economic Cooperation and Development (OECD) [42] have recently developed AI ethical frameworks to deal with the risks surrounding AI. Of particular note is the G20 (a multilateral forum of the top 20 major economies in the world) adopted human-centered AI Principles in June 2019 [42], which were derived from the OECD AI Principles and include (1) inclusive growth, sustainable development, and well-being; (2) human-centered values and fairness; (3) transparency and explainability; (4) robustness, security, and safety; and (5) accountability.

### **Trustworthiness of AI Systems for an Aging Workforce**

ISO has a Technical Committee (ISO/IEC Joint Technical Committee 1/Subcommittee 42 Artificial Intelligence) that produces AI-related standards. To make AI systems trustworthy and deal with their risk, organizations should adapt their governance and consider newly emerging risks. An example of such a new risk is unfair bias toward older workers based on age. This may take the form of agism in search engine algorithms or this may occur when unrepresentative training sets are used for machine learning systems [43] or AI-assisted decision making (eg, if only younger workers' training records are used to predict performance). If there is an unfair bias, this is going to be exacerbated by AI systems. Therefore,

organizations that use tools that consider bias when designing products and services may be able to rethink their approach concerning vulnerable populations. One such tool has been developed by the ISO and the IEC in 2020 as an international standard that can be used to guide organizations in ensuring their AI systems are trustworthy [44] and reduce bias: *ISO/IEC Technical Report 24028:2020: Information technology—Artificial intelligence—Overview of trustworthiness in artificial intelligence*. Trustworthiness can include, for example, reliability, availability, resilience, security, privacy, safety, accountability, transparency, integrity, authenticity, quality, and usability. The standard discusses approaches to establishing trust in AI systems “through transparency, explainability, controllability, etc.” Potential mitigation techniques and methods to combat engineering pitfalls and threats and risks to AI systems are also discussed in this standard.

Another available tool on the market is the P7000 standard, developed by the Institute of Electrical and Electronics Engineers (IEEE). This standard includes a process model that engineers and technologists can use to tackle ethical considerations when initiating, analyzing, and designing a system. The standard addresses the following *process* requirements: “management and engineering view of new IT product development, computer ethics and IT system design, value-sensitive design, and, stakeholder involvement in ethical IT system design.” [45].

Age bias in AI development in the workplace can further be avoided through inclusive practices. A system’s bias can emerge in perception, information processing, decisions, and through the design [43], and organizations should be aware of this when implementing ICT systems. For example, the design of robots mimicking characteristics of toddlers or young children (eg, big open eyes, voice). By using age-inclusive practices, the needs of aging workers can be included in the development and use of AI systems.

## How Can Blockchain and IoT Contribute to a Sustainable Aging Workforce in the Area of Technology?

### *Blockchain Data Management and the Aging Workforce*

A 2019 systematic review has highlighted the different types of blockchain applications and identified human resources data management as an area of application [46]. More advanced forms of data protection in the form of blockchain are already tested [46]. Blockchain is an information recording system that has the potential to provide secure, pseudonymized, and immutable records of distributed information and is thought to potentially have a large positive social impact such as reducing age bias during recruitment processes or learning and development targets in an organization to ensure equal training opportunities across ages. To prevent misuse of the technology, blockchain should also be designed with ethical considerations in mind, and especially what impact it has on aging workforces and vulnerable and marginalized populations. While blockchain is able to restore personal control over data, it could also be misused to exert power over people and information. Therefore,

blockchains should be intentionally designed by an ethical approach including reflections on governance, identity, verification and authentication, access rights, and ownership of data [47]. It is important to be age inclusive when developing such systems.

A 2019 systematic review reported that the use of blockchain has clearly enhanced data management and hence audibility because all operations can be verified [46]. However, full operability to allow cross-organizational management is still in its infancy but some prototyping of cross-organizational management of workflow is in development. Furthermore, there is still concern about its use due to data being stored on a public ledger and more research is needed to demonstrate real-world blockchain application [46]. We suggest that aging workforce and blockchain management form part of this research agenda. To this effect, Salah and co-workers [48] investigated blockchain applications in human resource management by interviewing human resources management experts. They identified potential applications may be useful for performance appraisal; recruitment; and verification of references, medical records, criminal records, or trainer credentials [48]. Other proposed blockchain-based credentialing are health care provider data management and directory systems [49]. The latter example attempts to match health care provider details with their national medical licenses. However, perceived blockchain adoption challenges are, for example, fear of layoffs, employee resistance due to lack of blockchain competence, worldwide adoption, support, and funding [48]. Overall, no application was found to improve the aging workforce and blockchain has yet to find its way into human resources management and thus aging workforces.

### *Integration of Blockchain With the Internet of Things and the Aging Workforce*

Beyond blockchain, Mackey and colleagues [49] argue that in Japan’s case, integrating blockchain into the IoT ecosystem will be a future use case that will improve delivery of home care and telehealth services, particularly because of the growth of connected medical devices and smartphone apps. This may have 2 implications for our aging workforce. First, this integration will be essential to improve efficiencies and reduce cost for organizations that wish to support workers health and well-being and will also resolve health care workforce capacity problems [49]. Second, the integration will allow for improved self-management of chronic diseases, which has a direct impact on the aging workforce. For example, continuous glucose monitoring wearables for patients with diabetes or flash glucose sensor technology, which do not require a fingerpick to measure insulin levels, will allow people to manage their diabetes more efficiently, and thus increase their ability to continue to work. It is expected that wearable technology will continue to improve the aging workforce. Organizations could benefit from considering implementing or funding wearable technologies for their workers, for example, in the form of benefits as part of an employee contract.

## How Can Aging Workforce ICT Research Contribute to a Sustainable Aging Workforce?

### Overview

The synergy of international standardization and ethical framework tools with research can advance the work in improving aging workforces. We present an example of an international research project below.

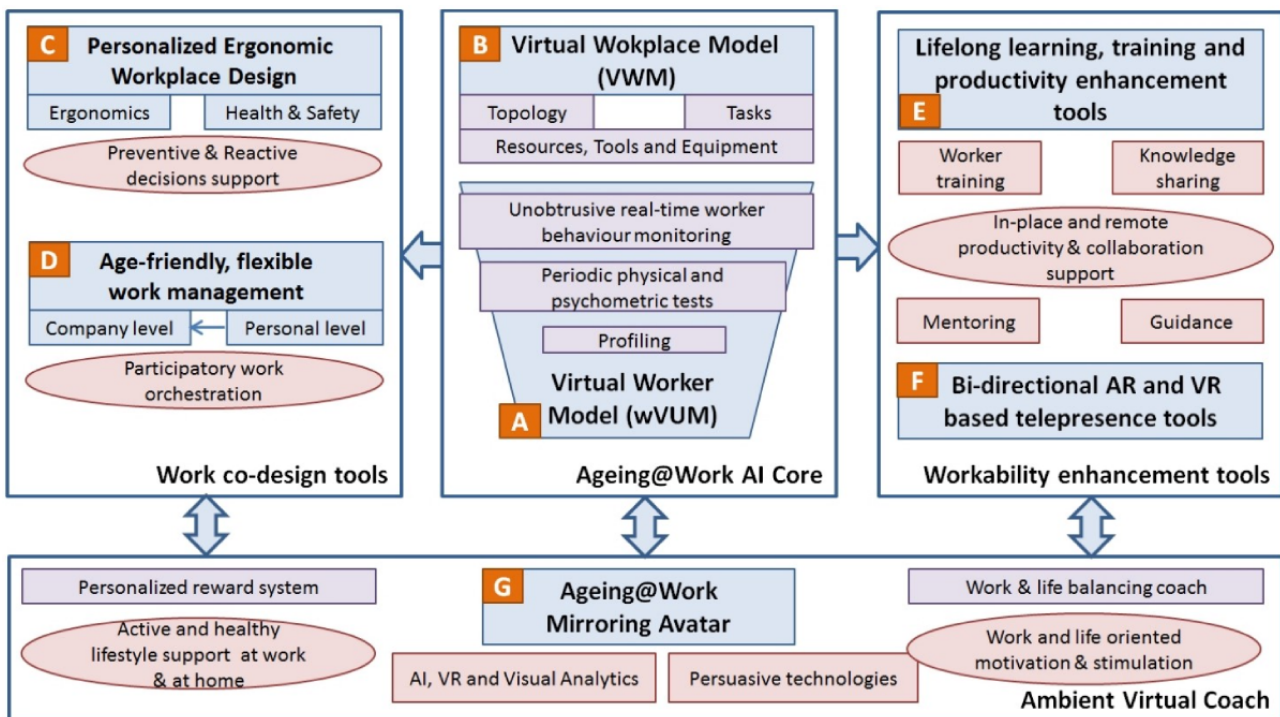
### Ageing@Work Vision of AI-Enabled ICT Solutions

Ageing@Work is a European Union-funded international research project that aims to develop a set of adaptive and personalized ICT tools to help aging workers to maintain their work ability and enable them to be active and age healthily. An aging-appropriate work design will be created through the use of AI, augmented reality, virtual reality, and virtual assistant systems. The Ageing@Work toolkit will be developed through user-centered design and pilot tested in 2 sites in core Industry 4.0 processes [50]. The first pilot is a German indoor, machining factory. The workplaces are located in an industrial hall at different machines, which need to be equipped with tools, programmed, and observed. Normally, the worker must observe

several machines simultaneously. The second pilot is a Spanish outdoor, mining factory. The workers of the quarries and treatment factory have to handle heavy machinery in outdoor conditions. They also carry out physically demanding maintenance work on the machinery.

The toolkit builds upon an AI core consisting of virtual user models and virtual workplace models that allow to adapt the work processes and the ergonomics of workplaces to the evolving needs of aging workers (see A/B in Figure 1). The virtual user models will include an activity monitoring system based on unobtrusive sensors such as smartphone apps or wearable sensors that will provide well-being data. As the system contains sensitive health data, it is subject to strict data protection rules. The virtual workplace models represent a virtual mapping of the work environment, that is, the arrangement of machines and equipment. Based on the data collected from aging workers and their workplaces, the system will be able to inform the workers about possible individual interventions. The system will also inform the organization about general improvement possibilities in work processes and task assignments as well as in ergonomics and health and safety of the work environment.

Figure 1. Ageing@Work concept [50]. AI: artificial intelligence; AR: augmented reality; PPE: personal protective equipment; VR: virtual reality.



To adjust the workplace to the changes in the functional capabilities of aging workers, a personalized ergonomic design tool will be developed. This is intended to help minimize health risks by simulating improvement potential based on the virtual workplace models and enabling an ergonomic workplace design (see C in Figure 1). The work processes will be improved by a work decision-support tool that makes recommendations for the task assignment that are flexible and adjusted to the worker’s needs. Based on the collected data from the worker and the work processes, the system makes personal recommendations to individual workers for optimized task scheduling and informs managers about possible improvements to the entire process

(see D in Figure 1). The system guarantees that managers will not receive personal data on individuals, but only an aggregated evaluation.

A range of productivity enhancement tools developed based on virtual and augmented reality will support the productivity and work ability of the aging workers. These include extended telepresence tools that enable older workers to collaborate remotely with younger workers and support virtual demonstration of work tasks. In addition, knowledge management tools for lifelong learning and knowledge sharing will be provided, which allow both older and younger workers

to acquire knowledge for learning new tasks and to keep the experience of older workers in the organization and pass it on to younger workers (see E/F in [Figure 1](#)).

Furthermore, a virtual assistant tool, the Ambient Virtual Coach, will provide an easy-to-use interface consisting of an empathetic, mirroring avatar that makes recommendations on the work processes and the workers behavior based on the information from the virtual user and workplace models (see G in [Figure 1](#)). Combined with a personalized reward system, the Ambient Virtual Coach will motivate positive behavior at work and home by promoting work-life balance and quality of life.

The Ageing@Work project integrates novel ICT tools in core Industry 4.0 and is multidisciplinary, covering ergonomics, psychology, and behavioral research. It combines the design of aging-appropriate work systems with the role of motivation among aging workers in improving their positive behaviors and perceptions about work. Using a wide range of advanced technology in combination with a virtual avatar, Ageing@Work pursues the goal of a highly personalized support for active and healthy aging in the context of an improved workplace's adaptation and productivity [50].

## Use Cases to Sustain an Aging Workforce

### Overview

To assist organizations in creating good working conditions and identifying suitable technology to enable adaptation to an aging workforce, several use cases will be discussed below. Some cases to sustain an aging workforce have been in use for several decades and have been continuously developed and adapted to changing conditions, such as the Exposure-Documentation-System, and some cases describe newer technologies, which have just recently found their way into organizations or are still in testing stage.

### Exposure-Documentation-System

The multilingual "Belastungs-Dokumentations-System (Exposure-Documentation-System)" is an ergonomic assessment tool that allows organizations to systematically assess work-related exposures of aging workers, derive preventive measures, and subsequently design aging-appropriate work systems. It has been successfully implemented in operational practice for many years and supports companies in creating jobs, independent of age, that can be performed by aging workforces [51].

The Exposure-Documentation-System is based on the occupational science procedure "Beurteilung Arbeitsbedingter Belastungen (Assessment of work-related exposures)," which has been continuously refined since 1977. It has been adapted to validated ergonomic findings and current needs of organizations in many industrial sectors such as iron and steel, glass and ceramic, trade and goods logistics, forwarding agencies and port handling, and chemical and automotive

industries as well as small- to medium-size enterprises. It supports companies in occupational health management, occupational integration management, the simulation of future work systems and the assessment and design of working conditions, demographic change, and the retaining of skilled workers in the company.

Work-related exposures can be assessed on the basis of workplace observations and measurements to derive appropriate design measures. Physical and mental workloads, environmental conditions, and occupational safety are recorded by trained personnel and scientifically analyzed by the Exposure-Documentation-System. The workplace analysis is process oriented, that is, the data collection is based on individual work tasks and collected during a workers' shift. The individual workload assessments are combined by the Exposure-Documentation-System to form a workplace profile that reflects the worker's exposures over the entire shift ([Figure 2](#)).

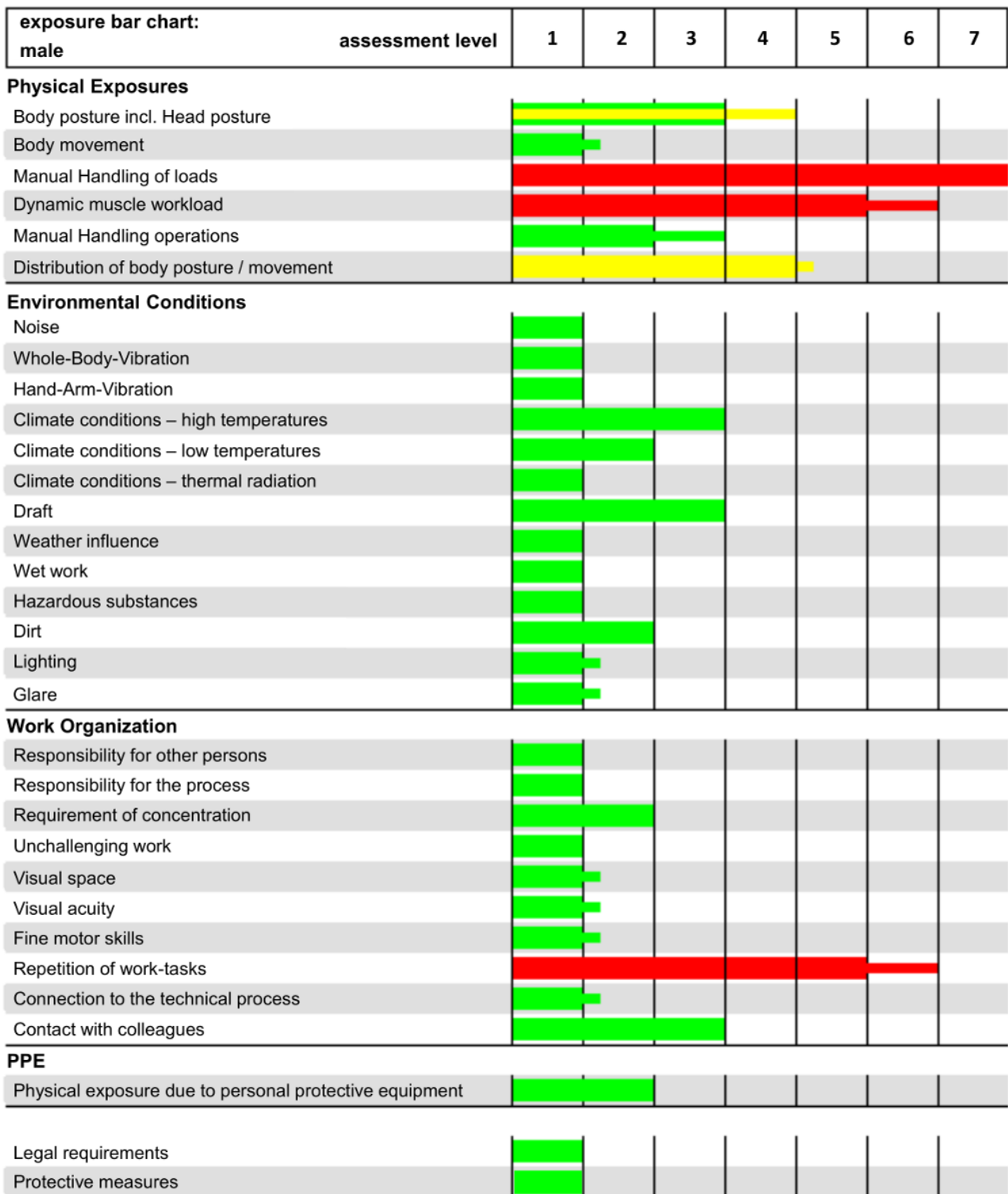
The systematic analysis of physical and mental exposures can identify ergonomic improvements. The system enables a standardized exposure assessment to measure ergonomic quality with more than 30 items on a 7-point scale ranging from 1 (very low exposure) to 7 (overload very likely). The results are displayed in a traffic light system to illustrate the strengths and weaknesses of the analyzed work system. A green bar means that overall the exposures are harmless to the worker's health. A yellow bar shows the maximum acceptable exposure value, that is, the workplace is only suitable for appropriately trained and healthy workers. A red bar means that the limit of acceptable exposure is exceeded and therefore requires action.

Design measures can be identified based on the assessment. The Exposure-Documentation-System also allows the tracking and verification of the effectiveness of the measures taken. This may help organizations to find appropriate technical tools for sustaining an aging workforce, for example, by determining the possible applications of collaborating robots in the workplace and their impact on the working conditions of aging workers.

Based on scientific findings, the Exposure-Documentation-System evaluates the higher bodily exposure of older workers and younger workers resulting from the same workload. The differences in the assessment are reflected in the workplace profile, with the thin bars representing the stress levels for older workers ([Figure 2](#)). Aging workers will have a higher total dose of exposure [52]. However, it is recommended that this be considered equally for younger workers.

Beyond the prescribed health and safety requirements in the workplace, the Exposure-Documentation-System enables organizations to create attractive jobs for aging workers. This supports them in increasing work motivation and satisfaction and has a positive effect on the organizational competitiveness.

**Figure 2.** The Exposure-Documentation-System workplace profile with demographic analysis for aging workers. Incl: including; PPE: personal protective equipment.



**Wearable Technology for Older Workers**

Wearable technology is increasing in popularity. A gray literature review conducted by the Aged Care Industry Information Technology Council reported that wearable technology in the aged care sector is on the rise [53], which presents new opportunities for the aging workforce. A substantial proportion of the older population or people with a chronic condition are at an increased risk of COVID-19, and

this has serious workforce implications such as people being required to work from home or at-risk people being directed to change roles or work in a different department. Wearable technology allows at-risk workers or those currently under quarantine or self-isolation to self-monitor for symptoms remotely, thereby protecting the health of the workers.

For example, the LifeSignals Biosensor 1AX [54] is a wireless medical biosensor and COVID-19 personal symptom monitoring device that when placed on the patient’s chest monitors



symptoms and reports these (in real time) to the LifeSignals App. The biosensor is linked with a smartphone app and allows for continuous monitoring of COVID-19 symptoms. It is for single-use only and can be used for 5 days for the early detection and monitoring of COVID-19 symptoms [55]. The patch records 2-channel electrocardiogram, heart rate, respiration rate, skin temperature, and motion (via an accelerometer). The app shows and tracks the vital signs in real-time, using easy-to-follow traffic light charts, similar to the Exposure-Documentation-System. The app provides health trends and alerts so the person can contact a health care provider if required. The technology is interoperable and can be integrated into other platforms, systems, and apps. The app is also compliant with the international standard ISO 13485:2016 Medical devices—Quality management systems—Requirements for regulatory purposes [56].

It is expected that wearable technology will continue to improve the aging workforce, depending on the application. Despite the potential of wireless biosensors, the acceptance by an aging workforce remains to be seen and the concerns around ethics discussed above remain. However, organizations could consider offering wearables, such as a biosensor, for those who wish to use it. Organizations could benefit from considering implementing or funding wearable technologies for their workers, for example, in the form of benefits as part of an employee contract. Additionally, the workers can choose not to share the data from the app with their employer yet still improve their health.

### ***Digital Voice Notes Across Applications for Aging Workers***

Another opportunity for aging workers is the digital voice technology. It enables quick communication with co-workers via real-time voice chat and allows for leaving messages across different applications [57]. This is useful for faster communication, decision making, having fewer meetings, and better understanding the voice tone of the sender of the message, which improves mutual understanding. This technology is specifically beneficial for aging workers for several reasons. First, it is specifically useful for aging workers who may have trouble typing messages fast due to dexterity issues or who simply forgot their reading glasses. Instant voice chat can resolve this issue instantly. Second, verbal fluency remains at a high functional level until advanced ages [14], therefore the use of digital voice notes benefits especially aging workers. Third, for lower-educated older workers the transition to digital technology by using voice notes rather than requiring to type notes will potentially increase acceptance of such technology at a faster rate and thereby their employability to remain in the workforce as digitalization of workplaces continues.

### **Recommendations**

Based on the review of international standardization practices, collaborative research projects, and uses cases, we propose the following ICT-related recommendations (Textbox 2) that organizations could consider to get started in improving their aging workforce.

**Textbox 2.** Recommendations.**Perspectives**

- Apply a multidimensional perspective to optimize an age-inclusive workforce in your organization (eg, organizational tenure, career stage, life events, generation, accessibility, chronological age, and experience).
- Identify how the skills of younger and older workers complement each other rather than substitute each other.

**International Standards**

- Investigate which international standards are relevant to your organization or your project to improve an aging workforce from a human resources management or information technology perspective.

**Human Resources–Related International Standards**

- Be a leader in becoming an age-inclusive organization
  - Become involved with the ISO (International Organization for Standardization) TC (Technical Committee) 314 Aging Societies community [58].
  - Follow the International Standard ISO 25550:2022 Aging societies—General requirements and guidelines for an age-inclusive workforce [34].
- Promote sustainable employability among all staff.
  - Consider using the following international standard as a guide: ISO/TR (Technical Report) 30406:2017 Human resource management—Sustainable employability management for organizations [59].
- Promote knowledge management and intergenerational collaboration to allow knowledge transfer between different generations in the aging workforce.
  - Consider using the following international standard: ISO 30401:2018 Knowledge management systems—Requirements [38].
- Promote age diversity in the workplace.
  - Operate in a socially responsible way and demonstrate commitment to sustainability through the ISO 26000 Standard guidance on social responsibility [39] or ISO 30415:2021 Human resource management—Diversity and inclusion [60] with a focus on being an age-inclusive organization.

**Technology-Related International Standards**

- Understand risk, such as age bias, and risk-mitigation practices of emerging technologies by consulting international standards. For example,
  - ISO/IEC (International Electro Technical Commission) Technical Report 24028:2020 Information technology—Artificial intelligence—Overview of trustworthiness in artificial intelligence [44].
  - P7000 Engineering methodologies for ethical life-cycle concerns [45].
  - ISO 13485:2016 Medical devices—Quality management systems—Requirements for regulatory purposes [56].

**Ethics**

- Benefit from identifying an ethical framework relevant to organizations' context and needs. Many frameworks are available as either general or specific guidelines based on user group (eg, older people) or technology used.
- Choose and implement new technologies carefully and identify ethical and legal issues and take appropriate technical and organizational measures in advance of data collection or processing.
- When designing technology to improve your aging workforce, apply universally agreed ethical principles based on aging principles or technology principles. For example,
  - The ethical principles of standardization in information and communication technology (ICT) and active and healthy aging: Accessibility and usability, affordability, autonomy and empowerment, beneficence and nonmaleficence, care protection and support, equality/equity and justice, inclusion/nondiscrimination and social impact, interoperability, and privacy/safety and security [41].
  - The G20-adopted human-centered artificial intelligence principles [42]: (1) inclusive growth, sustainable development, and well-being; (2) human-centered values and fairness; (3) transparency and explainability; (4) robustness, security, and safety; and (5) accountability.
- Avoid age bias in ICT development and implementation.
- Involve older people in the planning, development, and implementation of ICT applications.

**Research**

- Consider using new technologies to create an aging-appropriate work such as artificial intelligence, augmented and virtual reality, and virtual assistant systems.
- Ensure technologies are developed through user-oriented design, and consider the needs of aging workers and the changes in functional capabilities before implementing new technologies.
- Promote work ability of aging workers by adapting the work processes and the ergonomics of workplaces to the evolving needs of the aging workers and encouraging healthy behavior.
- Enable older workers to collaborate remotely with younger workers so that they can work from home.
- Provide knowledge management tools for lifelong learning and knowledge sharing, which allow both older and younger workers to acquire knowledge for learning new tasks and to keep the experience of older workers in the organization and pass it on to younger workers.
- Multidisciplinary research is needed to identify opportunities and challenges for blockchain use and other technologies in the area of aging workforce.

#### Use Cases

- Systematically assess work-related exposures of aging workers and derive preventive measures to design aging-appropriate work systems.
- Consider higher-workload exposures of older workers equally for younger workers, due to the higher total dose of exposure.
- Track and verify the effectiveness of measures taken (before implementing new technologies) to identify whether there has actually been an improvement for aging workforces.
- Consider promoting, implementing, or funding wearable technologies for aging workers, for example, in the form of benefits as part of an employee contract.
- Consider promoting or implementing digital voice notes across applications for aging workers.

## Discussion

### Principal Findings

This paper outlined the implications of aging on working populations in the context of Industry 4.0. Technology has known downsides such as job losses but can also have benefits such as keeping people at work through assisting older workers in undertaking physically demanding tasks. Understanding aging through different lenses, beyond simply age, is important to make real changes in an organizational and digital context. ISO has various existing or emerging standards that tackle the area of aging workforce and ICT applications, which are based on best practice and international consensus. These standards can guide organizations in identifying a way forward to manage their workforce [61] and the challenges brought on by ICT. These standards can also inform training institutions in curriculum development and competency training relevant to aging workforces, which, to our knowledge, is not commonly used currently, such as human resources management, ergonomics, and health informatics. Standards can also be used to train new types of workforces such as the rise in the telehealth workforce [7]. Organizations and governments should consider using the newly introduced international standards that focus on ICT and aging workers so they can improve and prolong working life of people, which may also lead to reduced organizational costs and an increase in retirement age. The following question remains though: “How ready the aging workforce is in embracing technology?” To answer this question, in 2020, the Aged Care Industry Information Technology Council Australia [62] conducted a national benchmark analysis of the technology readiness of the aged and community care sector. The authors found no good specific examples of ICT implementation to assist the older workforce; instead their research found a real need for better digital inclusion and digital

workforce improvements across the board. The authors concluded that at a sector level, there is a need to address the significant variability in technology capabilities in terms of infrastructure as well as workforce expertise, and attitudes to technology-enabled care.

Furthermore, AI, robotics, digital voice notes, blockchain, IoT, and wearable technology can serve our aging workforces as has been described above. But when designing or implementing technology to improve aging workforces, organizations should always strive to improve the ergonomics of work systems and apply universally agreed ethical principles to manage associated risks. Additionally, organizations can leverage their identity as being an age-inclusive workforce through linking this to corporate social responsibility and be an employer of choice.

Building relationships with key stakeholders across disciplines, industries, government, industry, and research will also lead to increased identification of evidence-based solutions such as the Ageing@Work project described above or the MAIA project (Models and Methods for an Active Aging workforce: an International Academy), which has started in 2020 [63]. MAIA is a research and innovation staff exchange funded by the European Union’s Horizon 2020. The academy concentrates on the problems and needs of the aging industrial workforce. The academy is multidisciplinary including aging, psychosocial, ergonomics, manufacturing system design, robotics, assistive technologies, and economics. These projects can form the blueprint for other international collaborations to find common solutions to common problems.

Finally, we have provided a set of recommendations on how international standardization can be used to improve aging workforce productivity, health, and competitiveness through the use of ICT when designing work for aging populations.

It is recommended that age-inclusive practices, international standards, and research are combined to further improve the aging workforce. For example, a recent study measured emotional exhaustion among regional doctors in training and the application of international standard guidelines on sustainable employability management in a hospital. All criteria from the ISO sustainable employability guidelines that were measured were significantly associated with emotional exhaustion, demonstrating the applicability of the guideline. There is potential to incorporate standards that relate to aging workforce into future aging research to further improve the credibility and application of standards in practice. Given the rise of nonstandardized employment globally, such as gig work and short-term contracts, governments play a crucial role in ensuring the OHS of workers, through developing new concepts of decent work, organizing of networks among independent workers, and standardization of OHS regulations [32]. A recent study [8] reported case studies from 15 countries to address the impact of COVID-19 on aging workers and included many technological solutions such as next-generation age-inclusive manufacturing systems in Germany or an AI system run by a large Korean telecommunications company (SK Telecom) that continuously tracks the health of service users to reduce workload for health care staff.

In the wake of inadequate pension systems, reduced savings and low interest rates, a global financial crisis, pandemic, and increased divorce rates, many older people do not have sufficient income to retire and may be required to continue to work to

survive. Currently, there is a lack of good road maps on how organizations can capitalize on their aging workforce and deal with the risks. Current business and employment models, practices, and policies are slowly changing to adopt to the new way of working. ICT has proven it plays a pivotal role in this area. Governments will play a role in assisting the adaption and implementation of technology, ethical frameworks, and international standards that support the aging workforce.

## Conclusions

Applying a multidimensional lens on aging in organizations such as organizational tenure, career stage, life events, generation, accessibility, chronological age, and experience will improve sustainable employability among aging workers. The synergy of international standardization and ethical framework tools with research and use cases can advance the work in improving aging workforces. Technological developments can support achieving an age-inclusive workforce, such as AI, virtual assistants, wearable technology, or blockchain solutions coupled with IoT. These developments will undoubtedly find a stronger place within the global context and is most likely to have increased acceptance of ICT applications among aging workers as well as organizations and governments. International standardization, using ethical frameworks and standards, cross-country research, and learning from use cases play an important role to ensure practical, efficient, and ethical implementation of ICT solutions to contribute to a sustainable aging workforce.

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## Authors' Contributions

AKW and SWP contributed equally. AKW, SWP, and HG designed the research. AKW and SWP drafted the manuscript and analyzed the content. HG and PS provided critical analyses of the content. SWP finalized the manuscript. All authors reviewed and approved the final version of the manuscript.

## Conflicts of Interest

AKW, PS, and HG are active participants in the Ageing@Work research project and are co-developers of the Exposure-Documentation-System. SWP is a work, health, and aging consultant. SWP and HG have an interest in international standardization processes. SWP was the Convenor of the ISO TC 314 Aging Workforce Working Group Age Inclusive Workforce and HG was an expert member. The authors declare no further conflict of interest in relation to the companies mentioned in the paper.

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## Abbreviations

**AARP:** American Association of Retired Persons

**AI:** artificial intelligence

**ICT:** information and communication technology

**IEC:** International Electro Technical Commission

**IEEC:** Institute of Electrical and Electronics Engineers

**IEEE:** Institute of Electronic and Electronic Engineers

**IoT:** internet of things

**ISO:** International Organization for Standardization

**MAIA:** Models and Methods for an Active Aging workforce: an International Academy

**OADR:** old-age dependency ratio

**OECD:** Organization for Economic Cooperation and Development

**OHS:** occupational health and safety

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Review

# The Role of mHealth Interventions in Changing Gender Relations: Systematic Review of Qualitative Findings

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## Abstract

**Background:** The rapid and widespread growth of mobile technologies in low- and middle-income countries can offer groundbreaking ways of disseminating public health interventions. However, gender-based inequalities present a challenge for women in accessing mobile technology. Research has shown that mobile health (mHealth) interventions can affect gender relations in both positive and negative ways; however, few mHealth programs use a gender-sensitive lens when designing, implementing, or analyzing programs.

**Objective:** This systematic review aims to identify and summarize the findings of qualitative research studies that explore the impact of mHealth interventions on gender relations as a result of participating in such initiatives in low- and middle-income countries.

**Methods:** We performed a systematic literature review to examine empirical evidence of changes in gender relations attributed to participation in an mHealth intervention in low- and middle-income countries. Peer-reviewed articles were included based on whether they evaluated an mHealth intervention and were published between 2013 and 2020. Articles using mHealth that solely targeted health workers, did not assess a specific intervention, used mobile technology for data collection only, or were formative or exploratory in nature were excluded. The search terms were entered into 4 key electronic databases—MEDLINE, EMBASE, PsycINFO, and Scopus—generating a comprehensive list of potentially relevant peer-reviewed articles. Thematic analysis was used to identify, analyze, and report the themes that emerged from our data.

**Results:** Of the 578 full-text articles retrieved, 14 (2.4%) were eligible for inclusion in the study. None of the articles appraised gender from the outset. The articles uncovered findings on gender relations through the course of the intervention or postprogram evaluation. Most studies took place in sub-Saharan Africa, with the remainder in South and Southeast Asia. The articles focused on maternal and child health, HIV diagnosis and treatment, and reproductive health. This review found that mHealth programs could enhance spousal communication, foster emotional support between couples, improve women's self-efficacy and autonomy in seeking health information and services, and increase their involvement in health-related decision-making. Despite the positive impacts, some mHealth interventions had an adverse effect, reinforcing the digital divide, upholding men as gatekeepers of information and sole decision-makers, and exacerbating relationship problems.

**Conclusions:** These results suggest that given the rapid and persistent upscale of mHealth interventions in low- and middle-income settings, it is imperative to design interventions that consider their impact on power dynamics and gender relations. Future research is needed to fill the evidence gaps on gender and mHealth, acknowledging that women are not passive beneficiaries and that they need to actively participate and be empowered by mHealth interventions.

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**KEYWORDS**

mobile health; mHealth; gender relations; systematic review; low- and middle-income countries; mobile phone

## *Introduction*

The rapid and widespread growth of mobile technologies, especially in low- and middle-income countries (LMICs), offers an innovative mechanism for disseminating public health interventions [1-3]. The extensive use of mobile devices can reduce the geographical barriers often faced in rural and regional areas, encouraging their inclusion in health care and health-related interventions [1,4]. Mobile phones offer the potential to improve health care by providing accessible, sustainable health care for underserved communities, contending with underresourced health care systems in low- and middle-income settings [5,6]. Over 750 million people, or 10% of the global population, still do not have access to a mobile broadband network [7]. This primarily affects those living in rural and remote areas of LMICs [7]. A further 3.3 billion people who live within the reach of a mobile broadband network do not use mobile internet because of financial barriers, lack of awareness of mobile internet and its potential benefits, and lack of skills or confidence in using mobile internet [7]. Many digital-based health programs aim to improve women's health in LMICs, often focusing on maternal and child health [8-11]. However, gender-based inequalities pose a challenge for women, who experience lower literacy rates and less access to mobile technology, inhibiting the uptake and impact of health interventions delivered via digital platforms [12-14].

Mobile health (mHealth) is defined by the World Health Organization as any "medical and public health practice supported by mobile devices" [15]. Evidence suggests that mHealth interventions effectively enhance treatment adherence and appointment compliance and can be used as a tool to assist with data collection [2,4]. Research has also shown that mHealth interventions can transform gender relations positively by improving access to health resources, increasing women's decision-making ability, and supporting spousal communication [12]. mHealth interventions have the potential to increase women's autonomy in seeking health services and health information, thus enhancing their health-related decision-making [16]. This is because mHealth interventions alter traditional mechanisms for communication with health care professionals and, as such, can reduce or eliminate women's reliance on spousal approval and financial support to access health services and afford confidentiality and anonymity.

A systematic review by Jennings and Gagliardi [16] revealed the need for a further rigorous investigation into mHealth in terms of implementation and evaluation to establish whether mHealth programs transform rather than reinforce gender inequalities, and this review builds upon these findings [16]. The review highlighted that women face multiple barriers to participating in mHealth interventions, including social, financial, and digital literacy and the need for spousal approval [16]. Research on the effect of mHealth interventions on men's and women's interactions highlighted that when scaling up mHealth interventions, it is critical to ensure that the intervention

targets the transformation of gender relations and does not reinforce existing gender inequities [16].

The term gender refers to the socially constructed characteristics of women and men and the behavioral norms, relationships, and roles associated with identifying as female or male [17]. Gender relations can be defined as how "a culture or society defines rights, responsibilities, and the identities of men and women in relation to one another" [18]. The relationships between men and women are also influenced by political, economic, religious, environmental, and sociocultural constructs [19]. Therefore, gender significantly affects people's experiences of and access to health care [17].

It is becoming increasingly evident that mHealth can improve the lives of many; however, there is limited research examining the influence of these interventions on gender-based power dynamics and existing inequalities and their impact on women's access to health resources [16,20]. However, evidence supports the use of a gender equity lens in designing and analyzing digital programs [20]. In their review of findings from a cohort of implementation research projects in LMICs, Sinha and Schryer-Roy [20] argued that gender and power analyses are essential when designing and implementing digital interventions [20]. Although researchers have noted several positive impacts of mHealth interventions on gender relations, including increased communication between opposite-sex partners, enhanced female autonomy, improved female social status, and increased access to health resources [16], evidence has also suggested that these programs may unintentionally perpetuate the digital divide and enhance pre-existing power imbalances, exacerbating gender inequalities [12,16,21]. Evidence suggests that a lack of gender analysis and health equity when designing, implementing, and evaluating digital interventions can exacerbate or create new health inequity and gender inequalities [20]. However, the absence and low quality of available literature limit analysis on this issue [16]. As the number of mHealth interventions continues to increase, further research is required to illuminate their impact on gender relations, particularly in low- and middle-income settings.

This systematic review aimed to identify and summarize the findings of qualitative research studies that explore the impact of mHealth interventions on gender relations as a result of participating in such initiatives. Are gender relationships adequately assessed when implementing mHealth interventions? This paper examines empirical evidence of changes in interactions between women and men attributed to their participation in an mHealth intervention in an LMIC. In doing so, it aimed to illuminate the risks and benefits of using mHealth interventions in the context of gender relations in LMICs.

## *Methods*

### **Inclusion Criteria**

In our review, we included research studies published in peer-reviewed journals that met the following criteria: (1) the

study used qualitative research methods to evaluate an mHealth intervention; (2) the study documented findings on the impact of an intervention on gender relations for intervention participants; (3) the study was published in English between January 2013 and December 2020; and (4) the mHealth intervention was conducted in an LMIC, as defined by the 2020 World Bank classification [22].

Studies were excluded if they were conducted in upper- or upper-middle-income countries, published in a language other than English, gray literature, and non-peer-reviewed or unpublished reports (dissertations and conference abstracts). We also excluded publications that did not specifically assess an mHealth intervention, studied mHealth interventions that solely targeted health workers, used mobile technology for data collection only, and were nonintervention studies such as formative research or exploratory studies.

**Textbox 1.** Search strategy for electronic databases.

**Search category and search terms (searched using Boolean operator AND)**

**Mobile phones**

“Mobile phone(s),” “cell phone(s),” “cellular phone(s),” “mobile,” “phone,” “mobile-based,” “mobile applications,” “SMS,” “text,” “text-message,” “audio message,” “smartphone,” “eHealth,” “mHealth,” and “mobile health”

**Maternal health-related and child health-related interventions**

“Health,” “maternal,” “child,” “birth(s),” “delivery,” “child,” “obstetric,” “pregnancy,” “neonatal,” “antenatal,” “anaemia,” “pre-eclampsia,” “HIV,” “AIDs,” “malaria,” “abortion,” “tuberculosis,” “postpartum,” “family planning,” “sexual,” and “reproductive”

**Gender relations**

“Gender,” “women,” “female,” “relation,” “interaction,” “equity,” “inequity,” “equality,” “inequality,” “men,” “male,” “participation,” “empower,” “sex roles,” “women’s role,” “men’s role,” “gender role,” “autonomy,” “violence,” “gender-based violence,” “intimate partner violence,” “domestic violence,” “safety,” “literacy,” “economic,” “mobility,” “status,” “access,” “capacity,” and “communication”

**Title, Abstract, and Article Screening**

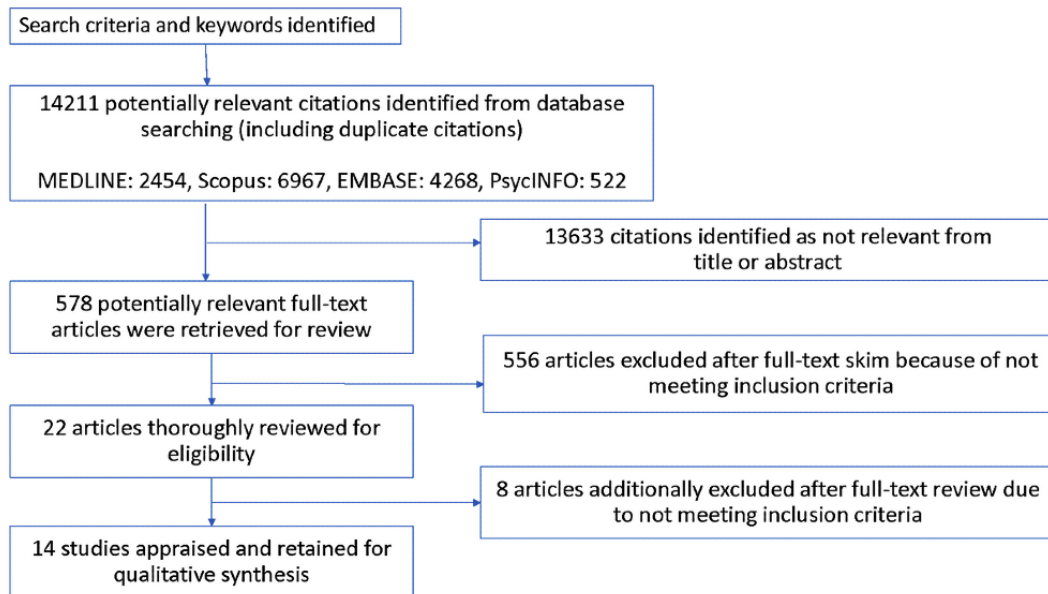
The research team independently reviewed titles and abstracts obtained from the initial results of the electronic databases. The researchers compiled a list of all potentially relevant articles. If the title and abstract did not provide sufficient information, the full-text article was retrieved, saved in Endnote, and assessed for eligibility. Full-text articles were independently skim-read by 4 research team members and included or excluded as per

The systematic review is registered with PROSPERO (International Prospective Register of Systematic Reviews; CRD42021218001).

**Search Strategy**

The research team conducted a preliminary literature search to identify appropriate search terms relevant to the scope of our review. The electronic search of the Scopus database was the primary means of collating the initial list of appropriate terms. All authors compiled and agreed on relevant search terms and expanded the list to include synonyms and variations in spelling classified under 3 key areas: mHealth, maternal health-related and child health-related terms, and gender relations, as listed in [Textbox 1](#). The key search terms (using Boolean operators) were then entered into 4 key electronic databases—MEDLINE, EMBASE, PsycINFO, and Scopus—generating a comprehensive list of potentially relevant peer-reviewed articles.

the criteria. The research team shared a Microsoft Excel spreadsheet containing citations and their findings and discussed their results. Any inconsistencies were examined and adjusted based on the consensus of all authors, resulting in a finalized list of publications for review. The search and screening process is outlined in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) [23] flow diagram in [Figure 1](#).

**Figure 1.** Search screening and flowchart. mHealth: mobile health.

## Study Appraisal

The final list of the selected studies is shown in the *Characteristics of Included Studies* section. All authors systematically appraised each study, and information was extracted and recorded under the following categories: article number, author, journal, year of publication, description of mHealth intervention, country, study's primary objective, study design, sample size (qualitative and quantitative), and findings on gender relations.

## Quality Assessment

Each study was independently reviewed by the research team. We assessed qualitative studies using the Critical Appraisal Skills Programme Qualitative Research Studies checklist [24]. Each paper was appraised to grade the quality of evidence using the 10 questions listed in the *Characteristics of Included Studies* section. A score was assigned for each study. The research team debated any discrepancies in scores until all team members agreed to all scores represented. For question 7 regarding ethical considerations, the paper was awarded a score if the research was approved by an institutional ethics committee or review board. Overall, the literature was of high quality and used appropriate methodologies, recruitment strategies, and research designs. All the articles discussed the value of the research and provided a clear statement of the aims and findings. Most of the literature includes appropriate methods for data collection and analysis; however, very few articles discussed reflexivity. The results are presented in the *Characteristics of Included Studies* section.

## Synthesis Process

Each researcher independently reviewed the findings on the influence of mHealth on gender relationships. Data from each publication were coded manually by all 4 researchers, identifying key text that captured the effect of mHealth on gender relations and aligned with our research question. Each researcher read each article several times, made preliminary notes to document and analyze the initial findings, and provided

a framework for emerging themes. We reviewed the results using thematic analysis to identify, analyze, and report themes within our data set [25]. The researchers met to share emerging themes to decide how to present the key thematic synthesis findings.

We present our findings based on the framework by Jennings and Gagliardi [16] and report our results under 3 key themes: positive transformative influences, negative transformative influences, and nontransformative influences. Positive transformational influences on gender relations empower women and enhance gender relations. Negative transformational influences disempower or adversely affect relationships. Nontransformative influences perpetuate rather than challenge gender-based disparities [16].

## Results

### Literature Search and Review Process

A total of 14,211 articles were retrieved using our search terms, and the titles and abstracts were reviewed for relevance. Of these 14,211 articles, 578 (4.07%) full-text and peer-reviewed articles were retrieved for review. The articles were skimmed and reviewed for eligibility, with 96.2% (556/578) of articles being excluded because of the absence of an evaluation of an mHealth intervention, the mHealth intervention targeting health workers, lack of reported findings on gender relations, or the study not being conducted in an LMIC. Additional screening of the remaining 22 articles led to a further 8 (36%) articles being excluded because of insufficient information, unclear methodology, or general information regarding mHealth interventions.

### Characteristics of Included Studies

A total of 14 publications were included in the final list of articles [26-39]. Of these 14 studies, 3 (21%) were conducted in Bangladesh, 1 (7%) in Vietnam, and 1 (7%) in India. The remaining interventions were conducted in sub-Saharan Africa, including 29% (4/14) of studies in Kenya, 21% (3/14) of studies

in Uganda, 7% (1/14) of studies in Ghana, and 7% (1/14) of studies in Malawi. All selected studies were sourced from electronic databases and found in peer-reviewed journals. The mHealth interventions focused on several health areas, including agriculture and nutrition counseling; maternal, neonatal, and infant health care; sexual and reproductive health; HIV or AIDS and antiretroviral treatment; intimate partner violence (IPV); and health-linked unconditional cash transfers. The mHealth apps used in these studies involved SMS text messages, automated SMS text messages, automated voice messages, access to hotlines and counseling call centers, and interactive voice response (IVR) technology. All studies focused on assessing barriers to and facilitators of mHealth interventions, such as feasibility, acceptability, accessibility, and appropriateness. All studies described short-term findings, with no studies examining the long-term ramifications of the intervention. Approximately half of the studies included

interviews with both women and their male partners. In-depth interviews were the most commonly used method for data collection; however, few studies used focus group discussions (the data collection methods are detailed in Table S1 in [Multimedia Appendix 1](#) [8,26-32,34,36-39]). A summary of the characteristics of the 14 included studies is shown in [Table 1](#) (see [Multimedia Appendix 1](#) [8,26-32,34,36-39] for the detailed characteristics of selected studies). [Table 2](#) provides summary of quality scores for selected articles based on Critical Appraisal Skills Programme checklist. Table S2 in [Multimedia Appendix 1](#) provides details for each of the CASP questions and answers for each paper. Table S3 illustrates each paper by thematic coding - positively transformational, negatively transformational and non-transformational. Table S4 and S5 illustrate end-user involvement from each intervention and data collection methods.

**Table 1.** Characteristics of selected studies.

Study	Journal	Description of mHealth <sup>a</sup> intervention	Primary objective	Sample	Key findings on gender relations
Alam et al [26]; Bangladesh	International Journal of Environmental Research and Public Health	Provided women with nutrition counseling, support, and information for home gardens and an unconditional cash transfer delivered on a mobile platform	To assess the feasibility and acceptability of the intervention that aims to improve the health of women and children in rural Bangladesh	Qualitative: 20 women and 6 project workers; quantitative: 58 women	<ul style="list-style-type: none"> <li>Positive transformative: increased spousal communication, further enhanced by mobile phone (received from the project), and cash transfer strengthened independent financial decision-making by women, as well as joint financial decision-making</li> <li>Nontransformative: some women were not free to go to the market to withdraw funds or open a mobile banking account</li> </ul>
Alam et al [27]; Bangladesh	JMIR mHealth and uHealth	Pregnant women, new mothers, and their family members accessed weekly voice or SMS text messages and used a 24-hour hotline to contact physicians who provided support on maternal and child health care	To describe the experiences of subscribers and the perceptions of physicians who provided consultations through the <i>Aponjon</i> service, focusing on access, acceptability, usability, benefits, and challenges	Qualitative: 8 women, 8 husbands of female subscribers, and 11 medical physicians; quantitative: 3894 subscribers	<ul style="list-style-type: none"> <li>Positive transformative: increased women's autonomy in seeking health services; women were not as reliant on men to arrange medical advice or appointments; increased involvement of male partners in health care, resulting in informed decision-making and increased joint health-related decision-making</li> </ul>
Atukunda et al [28]; Uganda	AIDS and Behavior	SMS text messages were sent to nominated social support persons of individuals who were HIV positive to help adherence to antiretroviral treatment	To examine individual characteristics and socio-cultural dynamics that explain trends in social support and adherence to an SMS text message-based antiretroviral intervention	Qualitative: 10 social supporters; quantitative: 63 participants who were HIV positive and 45 patient-identified social supporters	<ul style="list-style-type: none"> <li>Positive transformative: improved relationships between participants, particularly if the support person was of a different gender</li> <li>Negative transformative: SMS text messages were sometimes a trigger for relationship problems; the response to the intervention was highly sensitive to existing relationship issues, with support person efforts being perceived negatively, particularly if the support person was the married partner</li> </ul>
Brinkel et al [29]; Ghana	Tropical Medicine and International Health	Parents or caregivers accessed health information via an mHealth interactive voice response system to support them in caring for children who were sick	To evaluate user experiences with the interactive voice response system	Qualitative: 37 mothers; quantitative: 37 mothers	<ul style="list-style-type: none"> <li>Positive transformative: increased women's health-related knowledge, thus increasing their decision-making ability to make informed decisions regarding the health of their children</li> </ul>
Brown et al [30]; Kenya	AIDS and Behavior	Automated SMS text messages were sent to new mothers to notify them of infants' HIV test results and when infants who were HIV negative were eligible for retesting	To evaluate mothers' experiences receiving HIV Infant Tracking System-enhanced early infant diagnosis services (acceptability, benefits, and areas for improvement)	Qualitative: 137 women	<ul style="list-style-type: none"> <li>Positive transformative: increased women's autonomy in seeking health services because of reduced financial costs, and travel time increased male involvement</li> <li>Negative transformative: reinforced gender divide for women who were illiterate as it increases reliance on the husband to read the message</li> <li>Nontransformative: women's burden of work and competing responsibilities, and limited resources made it difficult to attend the clinic</li> </ul>

Study	Journal	Description of mHealth <sup>a</sup> intervention	Primary objective	Sample	Key findings on gender relations
Campbell et al [31]; Uganda	AIDS and Behavior	SMS text messaging-based intervention that sent messages to individuals who were HIV positive requesting a return to the clinic after abnormal test	To document the experiences of participants who were HIV positive regarding the SMS text messaging-based intervention in rural Uganda and propose a framework for acceptance of mHealth apps	Qualitative: 43 women and men who were HIV positive	<ul style="list-style-type: none"> <li>Positive transformative: new means of engaging partners in communication; SMS text messages fostered a sense of closeness and appreciation of emotional support from the partner</li> </ul>
Decker et al [32]; Kenya	BMJ Global Health	Women at risk of IPV <sup>b</sup> used the myPlan app, a safety decision-making and planning mHealth app tailored to the Kenyan context for prevention and response to gender-based violence	To evaluate the efficacy of the app on safety and health outcomes of the myPlan app and intervention	Qualitative: 30 women; quantitative: 352 (n=177 intervention and n=175 control in a 2-arm RCT <sup>c</sup> )	<ul style="list-style-type: none"> <li>Positive transformative: increased women's knowledge on safety and rights concerning IPV; enhanced feelings of confidence and resilience; and enabled women to make informed decisions related to their safety, mitigate violence, and deescalate potentially harmful situations with their partners</li> </ul>
Hazra et al [33]; India	Journal of Health Communication	Voice messages sent to husbands covering topics such as antenatal care, postnatal checkups, early initiation of breastfeeding, clean cord care, and delayed bathing	To examine whether the distribution of information on maternal and child health to husbands would enhance men's knowledge and result in the adoption of healthy behaviors	Qualitative: 10 male participants and their wives and 2 FGD <sup>d</sup> with health care workers; quantitative: 881 husbands	<ul style="list-style-type: none"> <li>Positive transformative: increased male knowledge of women's health, thus increasing informed decision-making and communication between couples</li> <li>Negative transformative: reinforcement of traditional gender roles as men alone were provided messages and did not always share information with female partners</li> </ul>
Huda et al [34]; Bangladesh	JMIR mHealth and uHealth	Pregnant women and new mothers were provided with a free mobile device and received interactive voice messages, direct nutrition counseling from a call center, and an unconditional cash transfer via mobile banking	To determine the feasibility, acceptability, and appropriateness of the intervention designed to improve nutrition during pregnancy and the first year of life for women and children in rural Bangladesh	Qualitative: 21 participants; quantitative: 340 pregnant or recently delivered women	<ul style="list-style-type: none"> <li>Positive transformative: increased women's ability to translate health-related information into practice; increase in spousal communication</li> <li>Nontransformative: traditional duties and gender-based roles were noted as a barrier to access (restricted movement outside the house and lack of ability to go to the marketplace to access cash)</li> </ul>
Ilozumba et al [8]; Uganda	JMIR mHealth and uHealth	SMS text messaging platform designed to provide participants with information regarding upcoming antenatal care visits and recommendations on reproductive health practices	To outline the assumptions of the program designers and contrast their assumptions with empirical data to better understand facilitators and barriers related to the outcomes of the program	Qualitative: 15 female participants, 11 male participants, FGDs with 50 village health team members, and interviews with 6 health service providers	<ul style="list-style-type: none"> <li>Positive transformative: increased male involvement in maternal health decision-making (men own phones); increased women's ability to demand health services, enhancing joint health-related decision-making</li> <li>Negative transformative: male partners were noted as a barrier by some, as they were not intended primary beneficiaries, thus reinforcing gender differentials in women's decreased levels of mobile phone ownership and lower rates of female literacy</li> </ul>
McBride et al [36]; Vietnam	Journal of Public Health	mMom is an mHealth platform that sends SMS text messages to improve women's health during pregnancy by encouraging their use of health services	To determine whether implementation of a low-cost mHealth intervention could increase ethnic minority women's access to maternal, newborn, and child health services	Qualitative: 60 female participants and 8 individual interviews with community health workers	

Study	Journal	Description of mHealth <sup>a</sup> intervention	Primary objective	Sample	Key findings on gender relations
Nyemba-Mudenda and Chigona [37]; Malawi	Information Technology for Development	The Mobile System for Safe Motherhood is a toll-free hotline, interactive voice response, and SMS text messaging system designed to provide pregnant women with maternal health-related information, tips, and appointment reminders	To assess whether the use of mobile phones in maternal health can enable capability outcomes and outline the factors that facilitate and restrict the outcomes from being enabled	Qualitative: 46 (26 female participants, 4 community volunteers, 4 midwives, 4 health facility managers, and 4 stakeholders; 32 IDIs <sup>e</sup> and 2 FGDs)	<ul style="list-style-type: none"> <li>Positive transformative: increased husbands' interest and engagement in maternal and infant health, increased health-related joint decision-making, and enhanced women's empowerment to make informed decisions about health care</li> <li>Positive transformative: women empowered by health information gained the support of husbands, spousal communication improved as they listened to messages on the shared phone, and male knowledge of and involvement in maternal care and support of women's access to health services increased</li> <li>Negative transformative: increased arguments with male partners; women could not adapt all recommendations as gender roles prohibited the woman from resting when pregnant</li> </ul>
Shelus et al [38]; Kenya	International Perspectives on Sexual and Reproductive Health	mHealth app designed to assist women in tracking their menstrual cycles to plan or prevent pregnancy	To explore women's experiences with using the CycleBeads app and how this experience varied based on how the participant learned about the app	Qualitative: 28 female app users; quantitative: 185 female app users	<ul style="list-style-type: none"> <li>Positive transformative: increased women's knowledge of fertility and tracking of the menstrual cycle, enhanced confidence in preventing pregnancy, improved communication with their sexual partner, and increased health-related joint decision-making</li> </ul>
Velloza et al [39]; Kenya	MHealth	Tablet-based app developed for use by providers during consultations with couples who were HIV serodiscordant, which derives data from, women via SMS text messages to assist health workers in providing counseling on safe conception options	To assess the acceptability and feasibility of the Safer Conception Intervention for Partners app	Qualitative: 19 couples who were HIV serodiscordant and 5 health care providers; quantitative: 74 couples who were HIV serodiscordant	<ul style="list-style-type: none"> <li>Positive transformative: increased women's knowledge, which enabled more informed decisions regarding health, strengthened communication with partners, and increased health-related joint decision-making between partners</li> <li>Negative transformative: a report of verbal and physical abuse was related to a misconception about the source of SMS text messages</li> </ul>

<sup>a</sup>mHealth: mobile health.

<sup>b</sup>IPV: intimate partner violence.

<sup>c</sup>RCT: randomized controlled trial.

<sup>d</sup>FGD: focus group discussion.

<sup>e</sup>IDI: in-depth interview.



**Table 2.** Summary of quality scores for selected articles based on Critical Appraisal Skills Programme checklist (N=14).

Item number	Items	Articles, n (%)
1	Clear statement of aims	14 (100)
2	Appropriate methodology applied	14 (100)
3	Appropriate research design	14 (100)
4	Appropriate recruitment strategy	14 (100)
5	Appropriate data collection methods	11 (79)
6	Reflexivity noted by researchers	1 (7)
7	Ethical issues are taken into consideration	10 (71)
8	Sufficiently rigorous data analysis	13 (93)
9	Clear statement of findings	14 (100)
10	Discusses the value of research	14 (100)

### Measuring Influence on Gender Relations

None of the studies we reviewed specifically appraised gender relationships from the outset. However, 21% (3/14) of studies examined relationships between women and men: the study by Campbell et al [29] on the acceptance of an SMS text message-based intervention for people living with HIV asked questions about how the intervention affected relationships; the examination by Decker et al [30] of a safety decision-making app for women at risk of IPV studied relationship quality and changes in self-efficacy; and the study by Hazra et al [33] considered the change in the relationship between husband and wife when the husband was the recipient of SMS maternal and child health voice messages. The remaining 79% (11/14) of studies uncovered findings on gender relations through the course of the intervention or postprogram evaluation and did not assess long-term changes that occurred because of the intervention. Half of the evaluated studies interviewed women only, and the other half interviewed women and men (sexual partners and spouses).

Half of the studies included in this review interviewed both women and men. Recent studies have highlighted the value of interviewing both partners as responses can often differ [40,41]. The inclusion of both partners in the interviews is a *hotly debated* topic in family studies. Dyadic interviews can lead to richer information and more evidence gathered as couples feed off each other, provide more information, and offer different perspectives. However, one partner can dominate the discussion and may limit the freedom of the other to respond truthfully. Using participant observation and observing the interaction between men and women in the interview itself may provide results in decision-making, gender relations, and negotiations between couples.

### Positive Transformative Influence on Gender Relations

#### Spousal Communication

This review of the literature revealed several positive ways in which mHealth interventions could transform gender relations. Our findings showed improved spousal communication on an everyday basis when learning together and regarding health-related information. Several studies reported an increase

in everyday communication [26,31]. During the postprogram analysis, the study by Alam et al [26] assessing the feasibility of a nutrition intervention that used mHealth and provided women in rural Bangladesh with a mobile phone showed that daily communication with their spouse increased. Women spoke of the benefits of communication: “I can call [my husband] in case of any problem using this mobile phone. I have been benefited as my husband has one mobile phone that he always keeps with him and carry wherever he goes. Now, if my husband goes outside, he calls me in my phone if necessary, isn’t it good for me?” [26]. In a trial of an SMS text messaging-based intervention for people living with HIV in rural Uganda, Campbell et al [31] also found that the intervention fostered a new means of engaging partners to communicate regularly by phone.

When the mHealth intervention contained a training component, gender relations transformed as couples spent time learning together (agricultural and nutrition training), which would not usually occur in many countries because of the gendered division of labor. The study by Alam et al [26] observed that women worked with their husbands to create homestead gardens, fostering collaboration and communication. Spousal communication increased as couples discussed the health information provided by the mHealth intervention [33,36,37]. In India, Hazra et al [33] found that male participants, recipients of voice messages on maternal and child health, said they would discuss how to follow health-related instructions with their wives, as per the intervention’s recommendations. One of the fathers would record the messages and play them back to discuss healthy practices with his wife [33]. In Vietnam, McBride et al [36] also found that ethnic minority women shared SMS text messages on maternal and child health with their husbands, thus enhancing communication between couples. According to the study by Nyemba-Mudenda and Chigona [37], couples in Malawi would read SMS text messages and listen to interactive voice messages on maternal health together, share and discuss information, and report enhanced communication on health-related topics. In addition to discussing health information, women in several studies reported an increased ability to communicate openly with male partners on sexual and reproductive health topics [38,39]. Increased communication between partners improved their ability to cooperatively use

contraceptive choices [38,39]. In Kenya, an mHealth app called CycleBeads was designed to assist women in tracking their menstrual cycles to plan for or prevent pregnancy [38]. Women using the app described improved communication with their sexual partners, saying, “He thinks I don’t want to have sex with him. But after showing him this application, even he knows it’s unsafe to have unprotected sex” [38]. Another study in Kenya used SMS text messages to promote safer conception for couples who were HIV serodiscordant and reported similar outcomes, affirming that male reproductive health knowledge improved mutual communication with their partners regarding conception strategies [38].

### ***Emotional Support From Partner***

The literature also showed that mHealth interventions enhanced emotional support between couples [30-33,37]. Brown et al [30] presented findings from their SMS text messaging-based intervention in Kenya, which aimed to improve the early diagnosis of infants who were HIV positive. SMS text messages sent to women provided new opportunities for male partners to communicate emotional support to their partners. The study by Campbell et al [31] found that individuals who were HIV positive in rural Uganda stated that the SMS text messages fostered a sense of closeness and appreciation of emotional support from their partners. Interaction with partners and family members altered; when one husband was asked whether the messages brought any changes to his relationship with his wife, he replied that they fostered a sense of trust: “We got to love each other more...we keep communicating on the phone...and this change of heart started with the message” [31]. In Malawi, women using an SMS text messaging and toll-free hotline on maternal health said that the discussion of information provided a sense of support from their husbands [37]. Decker et al [32] reported that the myPlan mHealth app in Kenya, an interactive tool that survivors of IPV can use to aid in safety decision-making, reduced decisional conflict within relationships. Women became more resilient and learned to mitigate violence and abuse from their partners [32]. Modes of spousal communication were transformed as women learned how to de-escalate potential violence: “now when he comes home, I study his mood so that I know how to handle him in order to avoid the chaos” [32].

### ***Decision-making***

Numerous studies revealed that men were becoming more involved in maternal and child health, which is traditionally seen as a domain of women [30,35,36]. The study by McBride et al [36] revealed that men in Vietnam exhibited a new interest in maternal and child health and supported their wives in attending neonatal health services. The study by Ilozumba et al [35] reported similar findings, stating that men’s involvement had an unintended positive consequence in Uganda, and by receiving SMS text messages, they became more involved in maternal health care. By participating in mHealth interventions, men increased their health-related knowledge associated with women’s and children’s health [33,42]. This knowledge enhanced informed decision-making on the part of men and fostered health-related decision-making between partners [26,33,35,36,42]. Owing to the gendered divide in mobile phone

ownership, several studies reported having to enroll men in maternal and child health programs as women did not own phones [33,35]. In India, Hazra et al [33] ascertained that mHealth messages sent only to men improved joint decision-making with their partners. Alam et al [42] also observed enhanced health-related joint decision-making between couples in Bangladesh following the use of the *Aponjon* maternal and child health care hotline [42]. In Uganda, when men enrolled in a maternal SMS text messaging-based intervention intended for women, their increased involvement led to an increase in joint health-related decision-making [35].

### ***Increased Male Involvement: Resource Allocation***

On the basis of gender roles, men are often the primary household decision-makers and have greater access to resources. However, male partners provided additional financial support to women when provided with information regarding women’s and children’s health [29,30,36,37]. The study by Alam et al [26] combining nutrition and agricultural counseling with an unconditional cash transfer reported that women made decisions, either on their own or in conjunction with their husbands, about how the cash transfer would be spent, thus altering gender roles. A phone-based intervention supporting parents to care for children who were sick in Ghana was perceived as a mechanism of reducing the barrier of women not having control over financial resources and not making decisions without their husbands’ support [29]. The intervention provided women with information and allowed them to participate in health-related decision-making [29].

In rural Bangladesh, 14% (2/14) of mHealth studies provided unconditional cash transfers to women and revealed barriers to receiving cash. The obstacles included women having no national identity card to open a web-based banking account or not being able to go to the market (prohibited or culturally unacceptable) to withdraw money. However, the studies by Alam et al [26] and Huda et al [34] found that women received support from husbands, male family members, or children to open accounts or collect money from mobile banking agents in the marketplace. The funds received through this program provided women with cash that they could spend on food, medicine, and other supplies, with most women deciding how to spend the money themselves [34]. Women and men cooperated and made decisions jointly about expenditure, whereas, previously, they would not necessarily have had such inputs. These mHealth interventions demonstrate that they can economically empower women, overcome obstacles, use mobile banking, and access financial resources.

### ***Autonomy in Seeking Health Information and Access to Services***

The literature showed that, overall, mHealth interventions have the capacity to increase women’s autonomy in seeking access to health care and improve access to health information. mHealth interventions can reduce gender-based barriers, such as spousal permission, lack of freedom of movement, the necessity for male accompaniment, and requiring financial support [26,29,30,35,37-39,42]. Studies suggest that when women have increased health-related knowledge, they become more

empowered to demand essential health services and quality care [35,37].

In Bangladesh, based on interviews with both women and men after the intervention, Alam et al [42] found that when women could access an mHealth hotline independently, it increased their autonomy in seeking health services. Women found the hotline convenient, could act independently, and make calls on their own; they were no longer reliant on men to arrange medical advice or appointments. In Kenya, where women used the myPlan IPV prevention app, this was also the case as women reported building resilience and confidence in discussing IPV and gaining support, knowledge, and access to the available services [32]. Men are often the key decision-makers in rural Ghana, with women not always having access to reliable health information and services or control over household resources. Women participating in an IVR system in Ghana reported that the IVR provided them with trustworthy information, which enabled them to have more control over their health care and that of their children and empowered them to make independent health-related decisions [29].

### *Self-efficacy*

Our findings also revealed that mHealth programs increased women's independence in seeking access to health services and led to positive changes in women's self-efficacy. Despite the low rates of female phone ownership, Nyemba-Mudenda and Chigona [37] reported that women gained self-confidence and skills by communicating via mobile phones, reducing the gendered digital divide [37]. In gaining health-related knowledge, women found that their confidence was enhanced, as was their capacity to put this knowledge into practice [34,37-39,43]. Women in Vietnam who participated in an SMS text messaging-based program on maternal and child health felt empowered by this newfound knowledge, made informed decisions about health care, and were more confident in their interaction with community health workers [36]. In Malawi, women were provided with maternal health knowledge and support and subsequently empowered to request a health service or attention from a health care worker; in contrast, before the intervention, they would "settle for whatever assistance was given" [37]. In Ghana, Brinkel et al [29] found that health information contributed to empowerment, altered gender relations, and challenged women's low decision-making abilities. In Kenya, an IPV safety app motivated a woman to sell clothes [32]. As a result of earning additional income, the woman could buy food for her children and no longer had to wait for her partner, thus providing autonomy in financial decision-making, when previously her husband would beat her if she asked for money for food [32].

### **Negative Transformative Influence on Gender Relations: Relational Conflict and Decision-making**

Despite the improvements discussed so far, mHealth interventions have the potential to exacerbate or ignore the persistent gender-based barriers that women face [30,31,33,35,37]. In Uganda, the study by Atukunda et al [28] reported an increase in conflict between couples while taking part in an SMS text messaging-based HIV support program. The trial used SMS text messages sent to a nominated social

support person of an individual who was HIV positive and aimed to improve antiretroviral adherence [28]. Although the authors noted that the relationship turmoil was not a direct result of the intervention itself, the SMS text messages may have been a trigger as relations between some of the couples either stalled or became turbulent, exemplified by feelings such as lack of trust, unsupportive behavior, resentment, suspicions of infidelity, stigma, or fear of disclosure of HIV status. One of the women reported, "He shouts at me for constantly asking him about his medicines every day, so I stopped asking about them. He doesn't listen to me at all and says I nag him" [28]. The intervention proved to be a catalyst, exacerbating relationship problems, particularly if the support person was the spouse of the person who was HIV positive. Velloza et al [39] recounted an instance of verbal and physical abuse in an SMS text messaging intervention in Kenya, which supported a safer conception for couples who were serodiscordant and living with HIV when a male partner believed that the SMS text message was from a former partner. In Malawi, community attitudes toward a maternal and child mHealth intervention were suspicious as they thought the intervention was "a satanic gimmick to get blood from pregnant mothers' bodies and kill the babies," which led to conflict between husbands and wives [37]. Some men forbade or stopped their wives from using the service, forcing them to leave the intervention [37]. Women would obey their husbands out of fear and respect or run the risk of being forced out of the house [37].

### **Nontransformative Influence on Gender Relations**

#### *Gender Gaps in Literacy*

Evidence also indicates that mHealth programs could be nontransformative and reinforce gender-based inequalities. An mHealth trial in Kenya used SMS text messages to remind mothers to take their babies to the clinic for HIV testing; however, some women were illiterate and unable to read or understand the SMS text messages [30]. When literacy rates are lower among women, reliance on SMS text messages reinforces gender divisions and women's dependence on husbands to enable access to information.

#### *Men as Gatekeepers of Technology and Information*

A maternal and child health app in India sent SMS text messages to only men, reinforcing the role of men as gatekeepers of information and decision-makers in the family [33]. Although some men shared and discussed the information, a substantial number of men did not. Some men stated that they "did not feel the need" to discuss the messages; others said they were busy at work or just not interested in such messages, which was thought of as women's business and knowledge that the mother should already know [33]. One of the studies indicated that low female ownership of mobile phones could reinforce reliance on men and the conduit a woman must go through to obtain mHealth information. In Uganda, men were enrolled to receive SMS text messages on maternal and child health targeted at women; although for some, this increased male involvement in reproductive health decisions, it also proved to be a barrier for some women. A Ugandan woman enrolled in a study reported not receiving any antenatal care until the seventh month of pregnancy as "her husband had not given her permission,"

illustrating that her husband had been a barrier to her seeking health services [35].

## Discussion

### Principal Findings

We reviewed the impact of mHealth interventions on gender relations in LMICs based on studies published between 2013 and 2020. Our results demonstrate that mHealth interventions have the potential to improve women's health, enhance digital literacy, positively affect women's empowerment, and enhance gender relationships. The findings also revealed that mHealth programs could reinforce gender divisions, exacerbate domestic conflict, and reinforce the dominance of men as key decision-makers and gatekeepers of knowledge and mobile technology. Gender-based digital divide, women's lack of access, and digital literacy have been well documented. However, despite the increase in the use of mHealth apps, most studies continue to focus on the feasibility and acceptability of such interventions, with none of the reported studies explicitly assessing the positive or negative impact of the intervention on gender relations.

Despite these data limitations, several key findings emerged. The studies revealed that mHealth interventions could positively affect spousal relationships and enhance communication and decision-making on health-related topics. Messages on maternal and child health sent via mHealth platforms to either the woman or man's phone were listened to and shared between couples. The new knowledge gained was discussed, and communication between couples improved. Several studies reported starting a dialogue on sexual and reproductive health, topics traditionally seen as "women's business." In Kenya and Uganda, mHealth programs targeting people living with HIV found that communication and emotional support between couples were enhanced [31,39]. Another program in Kenya, targeting safety for women at risk of IPV, was reported as being transformative for relationships as women gained skills to communicate with their partners in new ways and mitigate the risk of IPV [32].

The review found that mHealth interventions improved men's health-related knowledge associated with women's and children's health, and this knowledge increased informed health-related decision-making on the part of the men and fostered health-related decision-making between partners. Men either received the messages or were the owners of the phone that their partners needed to access, and therefore, the sometimes unintentional inclusion of the husband had the positive effect of accelerating access to health care. Our findings also suggest that mHealth interventions have the ability to increase male partners' understanding of women's health, thus enabling them to act as facilitators to increase women's access to health services and information by providing either financial or emotional support. Mobile phone ownership is still low in some parts of Malawi and particularly so for women. Many women in this intervention relied on their husbands' phones to receive the messages, with this male involvement being described as a "paradigm shift" [37].

Engaging men in mHealth interventions can increase their ability to make informed decisions related to their female partners' or children's health [44]. Furthermore, male participation in mHealth interventions can increase joint health-related decision-making between partners and enhance health-related communication, translating into better health practices. Participants in a mobile phone-based messaging service in maternal and newborn health in Afghanistan reported that involving fathers was beneficial, and joint decision-making between wives and husbands increased [45]. The "Super Abbu" (Super Dad) pregnancy and infant hotline in Pakistan was inundated with calls from fathers, with approximately 40,000 calls within the first 2 months, illustrating the need to include fathers and engage men for optimal health outcomes for women and children [46].

In many households, men are the primary household decision-makers and have greater access to income. Several studies reported changes in power dynamics over financial matters, particularly if the intervention incorporated cash transfers [26,34]. Women gained financial autonomy and control over income as recipients of cash transfers. Women were no longer as reliant on men for financial support for health and nutrition decision-making, enhancing control over financial resources and input into decisions regarding expenditure.

This review established that mHealth interventions can increase women's autonomy in seeking access to health care and improve access to health information. mHealth interventions can reduce gender-based barriers, such as requesting financial support, gaining spousal approval, and the need for male accompaniment. The literature also suggests that women's participation in mHealth interventions can increase women's autonomy in accessing health services and health information. Furthermore, these interventions can empower women to translate their knowledge into practice. Thus, mHealth interventions can enhance women's active care-seeking behavior, increase their ability to adopt healthier practices, and enhance their confidence to demand better quality care. In Nepal, research has found that telemedicine could overcome gender-based barriers to accessing health services in rural Nepal [47]. These conclusions concur with our findings, revealing that women's participation in mHealth interventions could increase women's autonomy in seeking health services through reduced travel restrictions, time, and financial costs [47]. Our findings also revealed that women reported an increased sense of self-efficacy with health-related knowledge and were more empowered and confident in their decision-making ability [44]. Increasing evidence suggests that digital health positively influences health equity [20].

Despite these positive impacts, we reported on several gender-based barriers. mHealth interventions can have an adverse effect, reinforcing the digital divide and upholding men as gatekeepers of information and sole decision-makers. Interventions can reflect and reinforce existing gender-based inequities such as the digital divide or hinder access to resources or information. mHealth can emphasize women's reliance on men to access technology [44]. A recent study on an mHealth maternal nutrition intervention from Burkina Faso revealed that although the researchers did not focus their research on gender at first, it proved to be highly relevant to their study [48].

Mothers who took part in the nutrition intervention stressed that they were “not empowered to make nutrition-based decisions that incur costs...nutrition-related request can spark marital strife” [48]. This illustrates the risk that mHealth interventions can pose in increasing women’s reliance on men for economic resources.

When mHealth interventions strengthen the role of men as gatekeepers, controlling access to mobile phones and information received, as women have lower literacy rates than men, this increases a woman’s dependency on men and can lead to conflict. Previous studies have shown that mHealth interventions can lead to increased tension between couples and domestic disputes and precipitate IPV [16,49]. However, few studies have evaluated or reported on its potential harm. Unintended consequences can occur when gender dynamics are not assessed. An mHealth intervention promoting contraceptive use in rural Bangladesh noted an increase in reports of IPV linked to participation in the program, a conflict that may have resulted from women receiving phone calls from an unknown number [49]. Another study from Ghana assessed the impact of family planning on gender relations and reported increased tension in relationships, with men reporting that they feared that their wives would be unfaithful as they now used contraception [50]. These findings highlight the need to monitor the intended and unintended consequences of mHealth interventions on gender relationships.

The findings of this review have several limitations. Qualitative data are largely context specific, making these findings nongeneralizable to broader settings. Similarly, as gender relations are highly dependent on sociocultural factors,

generalizability and transferability may be further limited. In addition, it is possible that some literature was overlooked as the search was limited to journal articles published in English and to those available electronically. Furthermore, this search did not include any gray literature or unpublished sources. Despite these limitations, our research team applied a comprehensive and robust search strategy to enhance the rigor of this review.

### Program

Given the rapid, persistent upscale of mHealth interventions in low- and middle-income settings, it is imperative for intervention teams to design these interventions while considering their impact on health equity, power dynamics, and gender relations. Efforts should be made to promote positive impacts while mitigating negative effects. To promote the positive impact of mHealth interventions on gender relations, rigorous formative research is needed to assess the context-specific requirements of the intervention and the participants. The key to this is involving the end user to inform and co-design interventions to ensure that they are appropriate, feasible, and safe in the context in which they are implemented. Thorough monitoring and evaluation throughout the course of the intervention are also recommended. Researchers must design gender-transformative mHealth interventions to truly affect change and not exacerbate existing gender inequalities [12,51]. Future research is required to fill the evidence gaps in gender and mHealth, acknowledging that women are not passive beneficiaries and need to actively participate and be empowered by mHealth interventions. These interventions require rigorous assessment from a gender perspective, from design and implementation to evaluation, to explore their impact on women and men from the outset.

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### Conflicts of Interest

None declared.

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Multimedia Appendix 1  
Supplementary material.

[DOC File, 150 KB - [humanfactors\\_v9i3e32330\\_app1.doc](#) ]

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## Abbreviations

**IPV:** intimate partner violence

**IVR:** interactive voice response

**LMIC:** low- and middle-income country

**mHealth:** mobile health

**PRISMA:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses

**PROSPERO:** International Prospective Register of Systematic Reviews

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Review

# The Challenges Toward Real-world Implementation of Digital Health Design Approaches: Narrative Review

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## Abstract

**Background:** Digital health represents an important strategy in the future of health care delivery. Over the past decade, mobile health has accelerated the agency of health care users. Despite prevailing excitement about the potential of digital health, questions remain on efficacy, uptake, usability, and patient outcome. This challenge is confounded by 2 industries, digital and health, which have vastly different approaches to research, design, testing, and implementation. In this regard, there is a need to examine prevailing design approaches, weigh their benefits and challenges toward implementation, and recommend a path forward that synthesizes the needs of this complex stakeholder group.

**Objective:** In this review, we aimed to study prominent digital health intervention design approaches that mediate the digital health space. In doing so, we sought to examine the origins, perceived benefits, contrasting nuances, challenges, and typical use-case scenarios of each methodology.

**Methods:** A narrative review of digital health design approaches was performed between September 2020 and April 2021 by referencing keywords such as “digital health design,” “mHealth design,” “e-Health design,” “agile health,” and “agile healthcare.” The studies selected after screening were those that discussed the design and implementation of digital health design approaches. A total of 120 studies were selected for full-text review, of which 62 (51.6%) were selected for inclusion in this review.

**Results:** A review identifying the 5 overarching digital health design approaches was compiled: user-centered design, person-based design, human-centered design, patient-centered design, and patient-led design. The findings were synthesized in a narrative structure discussing the origins, advantages, disadvantages, challenges, and potential use-case scenarios.

**Conclusions:** Digital health is experiencing the growing pains of rapid expansion. Currently, numerous design approaches are being implemented to harmonize the needs of a complex stakeholder group. Whether the end user is positioned as a person, patient, or user, the challenge to synthesize the constraints and affordances of both digital design and health care, built equally around user satisfaction and clinical efficacy, remains paramount. Further research that works toward a transdisciplinarity in digital health may help break down friction in this field. Until digital health is viewed as a hybridized industry with unique requirements rather than one with competing interests, the nuances that each design approach posits will be difficult to realize in a real-world context. We encourage the collaboration of digital and health experts within hybrid design teams, through all stages of intervention design, to create a better digital health culture and design ethos.

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**KEYWORDS**

digital health; end users; user experience; health behavior; intervention; co-design; mobile health; mobile phone

## Introduction

### Background

With an estimated 1.7 billion smartphone users downloading health care apps in 2018 [1], digital health represents an important strategy in the future of health care delivery [2]. The field represents an emerging sociotechnical [3] design space that fuses together health care, the digital industry, and academia. The rapid growth of digital technologies has shifted digital health from internet-based apps for medical content, commerce, and connectivity to a broad spectrum of emerging, always-on technologies such as genomics, artificial intelligence, wearables, mobile apps, and telemedicine [4]. Self-management is becoming a cornerstone of the health system [5]. With this, the complexity of digital health interventions (DHIs) has increased [6], presenting vast variance in use-case scenarios that reach beyond typical health validation or technical usability approval. Digital health poses the unique design challenge of digital and health professionals collaborating in a multistakeholder environment with very disparate methodologies on how to design a solution. This new ecosystem brings new and complex challenges to the design ethos.

The importance of new approaches to digital health is highlighted by the Food and Drug Administration requirement for end-user involvement in validating the design process for usability and human factors [7]. In addition, in 2018, the World Health Organization developed a detailed taxonomy of digital health [4], accentuating its rapid expansion. Despite receiving US \$6 billion in funding in 2017 [4], concerns regarding uptake [8], usability [9], and patient outcomes [6] continue to confound digital health.

### Context

To address these concerns, numerous design approaches are being proposed today. However, a key challenge to overcome is the variance in perspective among health experts, user experience (UX) designers, patients, academics, etc. Where designers may lack a theoretical basis and clinical foundation, health experts may lack knowledge of agile development methodologies and UX design [10] and academics often navigate both spaces, seeking to develop common ground. Dovetailing various specialists from 2 distinctly different mindsets is at the root of the challenge [11]. Simply layering on industry agile design approaches to traditional health care intervention design has proven problematic. The definition of measurable outcomes [12] is a lengthy process in health care. By contrast, validating outcomes in the digital industry is an iterative process that is not bound to a long-term expansive data set. From a digital perspective, usability is premised on user validation and satisfaction; from a health care perspective, usability is premised on safety and clinical efficacy. The merging of digital and health into one ecosystem challenges the incentivization of both partners [12]. Therefore, in spite of technologies that have given rise to exciting new forms of health interventions (ie, sensory apps and wearables), patient outcomes are difficult to measure because of the disparity in the evaluation methods of slow, safe, and scientific evaluation in health care and rapid, lean, and iterative evaluation in the digital industry [1]. For example, a

health app may be validated on UX design principles evaluating qualitative feedback regarding user efficacy. However, it may be invalidated by health safety and clinical efficacy trials, showing no therapeutic benefit. Similarly, a health app may pass rigorous, quantitative health-based trials but receive no uptake because of a failure to validate the UX based on sound design principles. Furthermore, there is the additional layer of variance in health regulation at federal and local levels. Understanding that designing positive patient outcomes in digital health is a blend of both health improvement and successful user engagement is part of the path forward.

### Objectives

In seeking to resolve this problem, a better understanding of digital health design approaches is needed for improving use-case effectiveness, for potential hybridization of methods, and overall to reduce polarization [13] of the digital and health industries. Although digital health is still in its nascent stages [14], today's youth are technology natives [15], making the increasing transition to the digital delivery of health care inevitable. An improved social framework for design collaboration is critical for improving outcomes to facilitate better adoption, acceptance, and sustained use of DHIs [16]. Moving away from the tug-of-war between health care and digital design and instead toward a collaborative coproduction of digital health would represent a paradigm shift toward a truly transdisciplinary field [16]. In essence, the dualism of competing interests (digital and health) must give way to holistic design approaches that account for the constraints and affordances of health care and digital design collectively.

To better understand digital health design approaches, we reviewed 120 papers in the digital health space spanning qualitative, mixed methods, and case studies that present various co-design approaches to DHIs. We identified 5 overarching design approaches, examining the nuances in approaches and recommending their suitability for various industry use-case scenarios. This spanned traditional user-centered design (UCD) approaches to nuanced person, human, and patient-centered design approaches that seek to tailor various health care use-case scenarios. In doing so, we sought to examine the nuances in the approaches and recommend their suitability for various industry use-case scenarios. We hope that this research contributes toward the transdisciplinary evolution of digital health.

With the future of health care delivery becoming increasingly digital—more independent, self-managed interventions are being facilitated. Our research identifies the complexity of the sociotechnical arena that is digital health, one where 2 worlds with 2 different approaches are merging together to deliver health care. By examining the history, evolution, advantages, and challenges of industry implementation, we sought to identify growing pains in a hybrid industry that is in its adolescence.

## Methods

### Review Framework

This narrative literature review provides a descriptive and contextual detail on emerging digital health design approaches. Performed between September 2020 and April 2021, it maps a

broad range of research domains, topics, strategies, experiments, and observations. The flexibility of the review approach is important, considering the broad stakeholder base in digital health from quantitative to qualitative research (inclusive of various perspectives: health care, engineering, computer science, human-computer interaction, psychology, design, etc). In this light, a narrative review allowed us to incorporate a broad spectrum of studies (and viewpoints) that would be difficult to facilitate in a systematic review. The broad range of findings were analyzed, compared, and contrasted for the synthesis and contextualization of key findings.

**Search Strategy**

A literature search was conducted using the following electronic databases: MEDLINE, PsycINFO, CINAHL, Scopus, and Web of Science. In addition, the searches were supplemented with findings from Google Scholar and JMIR. Key search terms included “digital health design,” “mHealth design,” “e-Health design,” “agile health,” and “agile healthcare” in various combinations.

**Eligibility Criteria**

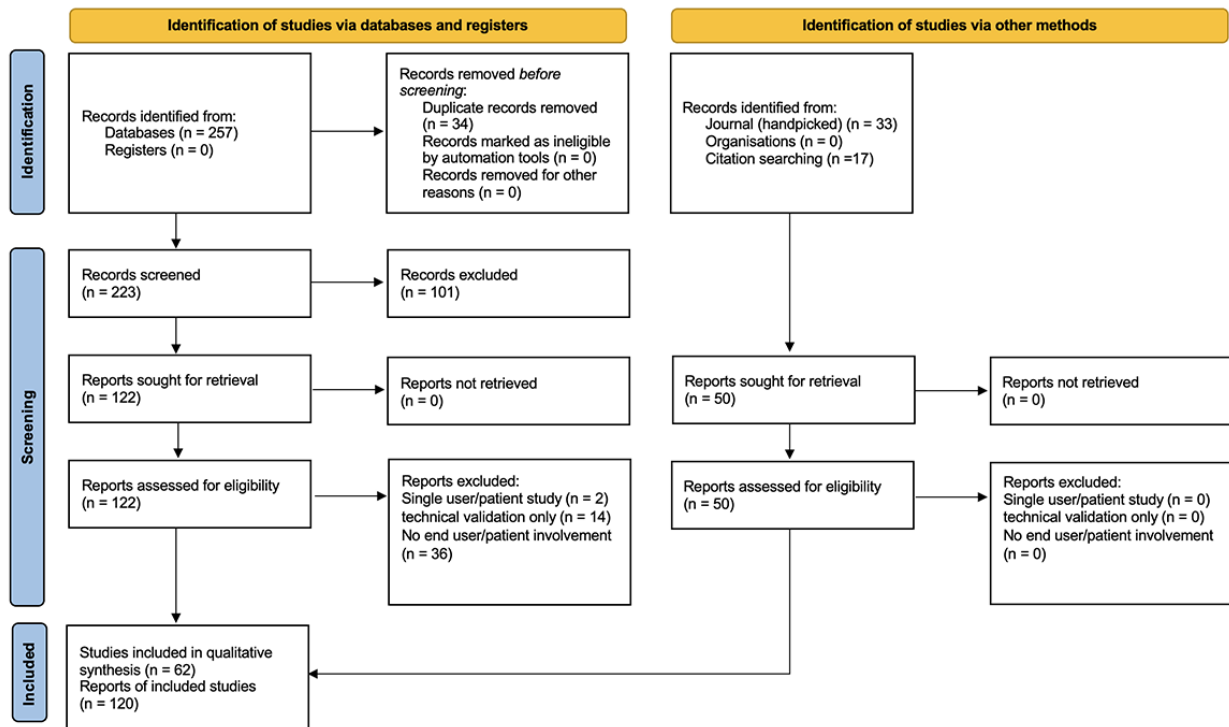
The search strategy resulted in title and abstract retrieval based on any of the following inclusion criteria: (1) the study described an evaluation or protocol for a DHI; (2) the study described or evaluated an observational study (ie, design workshop); (3) the study detailed a case study (single or multiple) involved a digital health design approach; (4) the study proposed or described a digital health design methodology or methods; (5) the study provided a viewpoint or commentary on digital health design (ie, framework, policy, design, or evaluation); (6) the study was

published between September 1, 2015, and December 31, 2020; and (7) the study was published in English. Studies were excluded if they (1) involved single user or patient studies; (2) focused solely on technical validation (ie, automated testing); and (3) did not discuss or evaluate end-user involvement in the study (ie, in design, development, usability, framework, or strategy).

**Data Collection and Analysis**

The first author completed the searches with assistance from librarians at Simon Fraser University, who reviewed search strategies, reference lists, and the relevancy of results. The identified titles and abstracts were downloaded and organized using Paperpile (Paperpile LLC). The first author independently screened all titles and abstracts against the defined eligibility criteria. After title and abstract reviews, full papers were assessed for inclusion by all authors. Considering the broad spectrum of design approaches and use-case scenarios in the emerging digital health space, studies from a wide variety of journals and sector vantage points were included. This included experimental, observational, methodological, case studies, and commentary-based studies. From this investigation, we extracted the 5 most prominent, most frequently occurring design approaches for analysis. A total of 120 studies were analyzed in full text. After full-text analysis, 62 studies that satisfied the inclusion criteria were included in this study. A visual overview of the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram is presented in Figure 1. Additionally, prominent findings from the literature review are presented in Table 1.

**Figure 1.** PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.



**Table 1.** Foundational publications on digital health design approaches.

Study	Type	Focus	Summary
<b>Digital health intervention design</b>			
Blandford et al [13], 2018	Commentary	Interdisciplinary research	Seven lessons on the multidisciplinary approach of health and HCI <sup>a</sup> to identify user needs and co-design interventions. The rupture between formative evaluation (HCI) and summative evaluation (health) is ever present in the cultures, values, and design assumptions presented.
Shaw et al [17], 2018	Commentary	Implementation	The potential impact of a service-design approach for improving the triple aim of health services (enhance patient experience, improve health outcomes, and reduce costs). A perspective on shifting from traditional implementation to an interactive cycle of value proposition design.
Thabrew et al [18], 2018	Review	Children and young adults	A summary of the core principles of agile co-design (the collective creativity of all stakeholders throughout a design project) in eHealth interventions for children and young people.
Hekler et al, 2016 [19]	Commentary	Behavior intervention	An adaptation of agile science principles for real-world behavior change in health care. Adapting and adjusting evidence-based research to specific individuals and contexts.
Birnbaum et al [20], 2015	Commentary	Patient engagement	Digital health intervention design has shifted away from top-down implementation models to seeking to bridge the gap between health products and patient needs. A discussion on the evolution of UCD <sup>b</sup> to (PCD <sup>c</sup> ) and (PLD <sup>d</sup> ) as a health-centric response to this challenge.
Poole [9], 2013	Commentary	Interdisciplinary research	A call for interdisciplinary cooperation among technologists, health researchers, and HCI experts to address user acceptance and adoption in mobile health. The research highlights the barriers to successful collaboration.
<b>User-centered design</b>			
Duque et al [21], 2019	Review	Older adults	A systematic review (2013-2018) of UCD approaches with older adults, including discussion on the challenges in better involving older patients in a UCD process.
Wysocki et al [22], 2018	Observational (design process)	Parent (caretaker)	A mixed methods study of parents of children aged <6 years with a chronic disease. The research describes the UCD process, illustrates the reach of crowdsourcing for design inputs, and summarizes the results of a randomized controlled trial.
Villardaga et al [23], 2018	Observational (design process)	Mental health	A stage-by-stage walk-through of applying a UCD process in the design of a mobile health smoking cessation app; from the rationale, ideation, prototyping, design, and user research to the final feature set. Learnings are systematically reported from each stage.
Azimi et al [24], 2017	Review	Older adults	A discussion on the Internet of Things and its propensity to assist care for older adults and remote monitoring. An exploration of current UCD approaches in care for older adults is examined along with recommendations for future development.
Lyles et al [25], 2016	Observational (design process)	Primary care	An exploration of a UCD approach including patients, providers, and health stakeholders to improve primary care tools in iterative stages.
Lyon and Koerner [26], 2016	Commentary	Implementation	A report on using a UCD approach for psychosocial interventions as a supporting exploratory approach to evidence-based treatment. The “fail fast” mantra of agile development is weighed against empirical approaches in traditional health care.
Curtis et al [27], 2015	Observational (design process)	Caretaker	A blended approach of the behavior change wheel, UCD, and commercial approaches to systematically design a childhood weight management app. Parents were primary stakeholders through the process.
<b>Person-based design</b>			
Devlin et al [3], 2016	Review	Implementation	Examining the implementation lessons from a large-scale deployment of a person-centered assisted living program. The challenges to work with heterogeneous groups, the resilience to break through barriers, the tensions in co-design processes, and the inherent market pressures to deliver products are all explored.
Yardley et al [28], 2015	Commentary	Methodology	3 illustrations of how person-based design can be used to improve acceptability and feasibility in the formative design stages.

Study	Type	Focus	Summary
Yardley et al [28], 2015	Feasibility study	Behavior intervention	An understanding of the person-based design approach through the initial stage of planning, feasibility testing and implementation, and the second stage of identifying guiding principles to inspire and inform more context-specific behavioral issues. The perspectives of the people who use the solution are central, beyond the typical user-based analysis and validation.
<b>Human-centered design</b>			
Wheelock et al [29], 2020	Commentary	Methodology	An overview of (HCD's <sup>e</sup> ) overarching philosophy and its methods and practical implementation in health care. The analysis discusses the challenges to build trust within a complex stakeholder group and a call for better co-design methods to navigate this challenge.
Chancellor et al [30], 2019	Review	Mental health	A systematic literature review of human-centered machine learning exploring the human in HCD. The study resulted in 5 key findings on how the human is understood: (the specific) disorder, social media, the scientific, the data or machine learning, and the person.
Ragouzeos et al [31], 2019	Observational (design process)	Patients	An experiment to observe the collaboration of patients, designers, IT experts, and clinicians in an HCD process to prototype a rheumatoid-arthritis intervention.
Holeman and Kane [32], 2019	Review	Implementation	A contextualization of HCD for global health equity, and the unique offerings of HCD over traditional health care approaches to research and innovation. The research tracks over 70 HCD driven digital health initiatives.
Mumma et al [33], 2016	Framework	Implementation	IDEAS (integrate, design, assess, share), a framework strategy to design, develop and evaluate digital interventions and health behavior change incorporating a wide swathe of human-centered factors.
Harte et al [7], 2017	Framework	Implementation	A 3-phase methodology that blends use-case scenario, expert usability analysis and user testing in a <i>connected health</i> format that is iterative, seeking to improve human factors in collaboration.
<b>Patient-centered design</b>			
Grisot et al [34], 2020	Case study	Implementation	An examination of designing for recombability in health care. A total of 2 case studies are studied to better understand the blending of patient-centered approaches into health care design.
Boissy [35], 2020	Viewpoint	Implementation	A proposal for <i>operationalized empathy</i> , redesigning patient experience measurement and developing organizational readiness for patient-centeredness.
Espay et al [36], 2019	Review	Implementation	A discussion on how to road map a hybridized patient-centered and clinical outcome in the digital space for Parkinson disease.
Carter et al [37], 2018	Viewpoint	Implementation	A conceptualization of "clinician-innovators": the merging of technology-enabled innovation and patient-centered care to bridge the implementation gap in digital health.
Van den Bulck et al [38], 2018	Cross-sectional study	Health informatics	An implementation road map for patient-centered digital outcome measures that considers patients characteristics, benefit-to-burden ratio, integration actualization and regulatory approval within the digital health system.
Tang et al [39], 2016	Viewpoint	Implementation	A discussion on the effectiveness of patient-centered information systems considering social and economic factors as well as disparity in multisector health outcomes.
<b>Patient-led design</b>			
Kempner and Bailey [40], 2019	Case study	Patient engagement	A case study examining 2 websites on collectivizing self-experimentation and crowdsourcing in patient-led approaches.
Stolk-Vos et al [41], 2018	Feasibility study	Patient engagement	Feasibility study for the design of a patient-led hospital checklist to promote patient engagement and broader collaboration with health care professionals.

Study	Type	Focus	Summary
Leese et al [42], 2017	Case study	Patient engagement	A case study walk-through on a patient-led collaboration that discusses the practical, ethical, and sector disconnect issues in negotiating a patient-led approach.

<sup>a</sup>HCI: human-computer interaction.

<sup>b</sup>UCD: user-centered design.

<sup>c</sup>PCD: patient-centered design.

<sup>d</sup>PLD: patient-led design.

<sup>e</sup>HCD: human-centered design.

## Results

What follows is a narrative synthesis of the historical context of the health care and digital industries, respectively, and the subsequent emergence of prominent digital health design approaches are discussed, including origins, advantages, disadvantages, challenges, potential use cases, and nuances.

### Health Industry

The health industry's *do no harm* [43] approach centers intervention design on systematicity, transparency, and rigor. Methods must be provable and reproducible [13]. This approach is built upon a pharmacological intervention mindset that posits randomized control trails (RCTs) as the gold standard for health intervention evaluation. The health outcome of an intervention is the key metric of concern [9].

Ironically, the rigorousness of clinical evaluation is also what challenges its implementability in digital health. RCTs tend to take many years to present outcomes, whereas digital production cycles spin iteratively in a matter of months. This mismatch in pace [14] challenges the boundaries of an evaluation framework. Clinical studies are also not designed to account for usability testing that could evaluate patient safety [4]. The nuances that affect patient uptake, the UX that fuses the sociotechnical domain, are often not considered in the health industry approach. A key challenge to the waterfall model [13] of systematic research in the health domain is the rinse-and-repeat rapidity of iterative design in the digital industry.

### Digital Industry

The digital industry's *fail fast, fail often* mantra [43] is premised on rapidity, iteration, and an overall understanding that the solution will emerge organically. This approach is rooted in the belief that it is impossible to fully understand the user's needs ahead of time [13]. Therefore, rather than front-loading research, it is evenly distributed and prioritized during an agile evolution of ideation, prototyping, and testing alongside user participation and evaluation. This approach lends itself to innovative projects by reducing costs [26] and interacting with potential users [33] early and often. Broadly interdisciplinary, the digital industry often prioritizes a qualitative approach with flat management teams that consider human factors, computer science, information systems, psychology, sociology, and visual design [9].

Nonetheless, the digital industry's swift production cycles are incompatible with paradigmatic long-term health evaluation [13]. Although the digital industry can succeed in bringing a

product to market within a short time frame, its rapidity and lack of rigor cannot satisfy the clinical depth of research of health validation, one that is inclusive of a more long-term, data-driven quantitative analysis.

## Emergence of Digital Health

### A Clash of Cultures

It is within this clash of cultures that the digital health industry is rapidly emerging. Despite overlap in interests [9] and a mutual desire to improve health outcomes, the industry has experienced the growing pains of harmonizing what a design approach entails to be both *digital* and *health* collectively. Digital professionals often view health research as too time-consuming and *straight-laced*, whereas health professionals often view digital research as *scruffy* and unreliable [13]. The digital push for rapid innovative solutions is pulled back by the desire for long-term safety and efficacy in health care. The implementation gap can be bridged by a more transdisciplinary approach that binds together health care operations, clinical informatics, and digital design in a more fluid process [37].

To do this, optimized design approaches are needed that position cocreation as a fundamental pillar of the digital health value proposition [17]. For adoption, acceptance, and sustained use [16] of DHIs to be improved, a paradigmatic shift toward a participatory silo-less domain is required. A transformational [37] approach that requires digital professionals to weave health requirements into the affordances and constraints of intervention design, and for health professionals to embrace design thinking [44], can better orient DHI design around human factors and user experiences. Product design and health care design can no longer be demarcated. The bidirectional relationship between patient and health care service is omnipresent in today's digital world [45].

While curating a DHI, there are a number of key areas of conflict to overcome.

### Design

While the digital industry considers a user-centric process that defines an intervention by the needs of the target user in a narrow, fast-paced goal orientation, the health industry is expert-driven, and considers a broader, more complex design framework that begins long before software development and extends long after its rollout [13].

### Evaluation

While the digital industry focuses on UX in the form of qualitative feedback, such as user testing and analysis, health

experts look to evaluate the effects and impact of an intervention as a successful or unsuccessful health outcome [13]. The former method can occur over a short period with a limited sample size, whereas the latter is expansive, is detailed, and can occur over years.

### **Validation**

The digital industry values technical validation to ascertain usability and user validation to ascertain positive UX and potential uptake. The health industry conducts clinical validation to understand whether the intervention provides efficacy for a condition-specific content [43]. In addition, it conducts system validation, which considers a wider scope of patients, providers, and the health care system as a larger network of health care delivery [43], a broader marker of the overall success of the health intervention.

### **Implementation**

The digital industry understands this to be the final layer in the product timeline, the release, and handoff of a digital health product. In the health industry, implementation is a complex systematic process of strategic planning and expert consultation, guided by clinical governance. It is not an end point but an ongoing research into health care efficacy. A digital health product would be but one factor of the whole implementation [13].

The variance in designing, evaluating, validating, and implementing interventions forms the core problem space for digital health stakeholders. To reduce this complexity and improve intervention quality and uptake, a number of design approaches mediate the digital health space. In our review of the following 5 design approaches (summarized in Table 2), we weigh their strengths and weaknesses and evaluate their challenges toward industry implementation.

**Table 2.** A comparison of the advantages and challenges of 5 key design approaches.

Design approach	Advantages	Challenges
UCD <sup>a</sup>	<ul style="list-style-type: none"> <li>• A large research community to draw upon with broad use in human-computer interaction and related fields.</li> <li>• User-validated process directly addresses uptake concerns in DHIs.</li> <li>• Broad approach is adaptable to all categories of DHIs.</li> </ul>	<ul style="list-style-type: none"> <li>• Defining the end-user in health care interventions is difficult because of the complex collaboration of stakeholders in DHI<sup>b</sup> facilitation (ie, clinicians, caregivers, and patients) who may all be end-users of the DHI.</li> <li>• Aligning preferences to patient end-users may conflict with health policy based on expert-led evidence-based practices.</li> <li>• Largely qualitative feedback often represents a small sample size that opposes the rigors of traditional longitudinal health metrics.</li> </ul>
PBD <sup>c</sup>	<ul style="list-style-type: none"> <li>• Psychoanalytical approach that contextualizes improved well-being as a design outcome is well suited to behavior changing DHIs.</li> <li>• Empathetically guided “sensitive design” process broadens stakeholder focus beyond active users to also include passive users and collaborators in the DHI as a whole person network approach.</li> </ul>	<ul style="list-style-type: none"> <li>• Behavior change metrics from PBDs may not be transferable to other types of DHI designs.</li> <li>• Psychoanalytic “sensitive design” may create an expert-led barrier to entry for other collaborators in the DHI (developers, designers, etc) and add scope.</li> </ul>
HCD <sup>d</sup>	<ul style="list-style-type: none"> <li>• Highly adopted and International Organization for Standardization-recognized approach for system design, already has health care provider backing (Mayo Clinic, Kaiser Permanente).</li> <li>• Combining approaches of user-centered design, human-computer research, anthropology, and sociology under the banner of “social innovation” has broad appeal to unite a wide swathe of DHI collaborators.</li> </ul>	<ul style="list-style-type: none"> <li>• An “umbrella term” that approaches design ethos and policy framework from many fields of research, there is a lack of unified guidelines, thus there is a need for a demonstrable lightweight framework for DHI design and facilitation.</li> <li>• Project scope is challenged by the breadth of collaborators (patients, clinicians, designers, developers, and academics) which may expand timelines in a fast-paced design environment.</li> </ul>
PCD <sup>e</sup>	<ul style="list-style-type: none"> <li>• Pivoting focus from user to patient (commercial to health care) creates better alignment with health care infrastructure policy, allowing for better buy-in from health care stakeholders.</li> <li>• Empowering patients to take leadership of their health care management is a leading metric in DHI retention and advocacy (particularly in wearables and sensor-based DHIs).</li> </ul>	<ul style="list-style-type: none"> <li>• Positioning patients as primary stakeholders (or as experts) oversimplifies the complexity of health safety and clinical efficacy guidelines and may lead to undesired patient outcomes.</li> <li>• Crowdsourcing DHI preferences may lead to misdiagnosis by popular convention, democratized data sets will still need to be weighed against medical best practices.</li> </ul>
PLD <sup>f</sup>	<ul style="list-style-type: none"> <li>• Self-tracking, self-analysis PLD approach is positioned well for today’s emerging personalized health care marketplace.</li> <li>• Machine learning-backed “citizen science” approach offers large quantitative data sets for better triangulation of patient preferences.</li> </ul>	<ul style="list-style-type: none"> <li>• Patient-led approach may lack the holistics of HCD or PBD and the safety and efficacy of traditional health care methods, this may limit the focus to preferences rather than clinical health outcomes</li> <li>• Scalability is questionable because of limited stakeholder base (lack of consensus) and self-experimentation approach (lack of clinical validation).</li> </ul>

<sup>a</sup>UCD: user-centered design.

<sup>b</sup>DHI: digital health intervention.

<sup>c</sup>PBD: person-based design.

<sup>d</sup>HCD: human-centered design.

<sup>e</sup>PCD: patient-centered design.

<sup>f</sup>PLD: patient-led design.

## Design Approaches

### *User-Centered Design: 12 Studies*

UCD is a qualitative design framework with roots in the human-computer interaction community dating back to the early 1980s [21]. It builds validation and satisfaction around the end user [13] by understanding personas, preferences, and environments through an iterative design approach. The goal is to output purposeful design, with the understanding that the intuition of experts alone is often insufficient for user validation [9].

Therefore, UCD focuses on the routine everyday needs of users and their circumstances, resulting in a design philosophy that guides the development phase iteratively [13]. By appealing to the conscience of users, situating them as primary stakeholders, and involving them in the design process, usability can be proposed, tested, and verified in a cyclical process, prioritizing the needs of the users in real-world situations [25]. A result of the UCD process is to determine why a design in a given environment with certain constraints and affordances is successful in one instance with a given set of users but unsuccessful in another, and how to mediate these design challenges [9].



The shift to a UCD approach in health care converts the traditional patient-physician relationships to a more reciprocal collaborative space, particularly in the development of self-monitoring and self-management apps [1]. The implementation of UCD approaches in health care is very much in its infancy [24] but holds the propensity for greater patient empowerment. Involving users in ideation and using a visual storytelling approach that involves workshops and gamification may invoke rich emotional feedback that helps feed health application design. These metrics are mutually important for the advancement of broader scientific research on efficacy, usability, and safety [23].

Positing the user as the primary stakeholder is not without limitations. Traditional approaches to health intervention design that are rooted in evidence-based practices or theory-based principles of change [23] may oppose the user-centricity of intervention design, seeing that user validation is not the sole desired output of a health intervention. In health care, a variety of expert viewpoints exist specific to the type of intervention. This often involves physicians, health experts, government, nonprofits, and other stakeholders who are part of a holistic health intervention. Positioning the user as the expert [13] may challenge long-standing traditions of clinical expertise in the health industry.

An example of this conflict is a *stop smoking* application that offers users advice and notifications on how to quit smoking. In a UCD approach, the input, ideas, and feelings of users would be central to the application design. Research conducted by Cheong et al [46] showed that smokers (users) widely believed that cutting down on cigarette use is the path to quitting smoking. Validated data from health experts showed the contrary, that stopping outright was statistically the most successful approach [46]. In this context, a challenge exists: academic research and expert analysis are not automatically factored into a UCD simply because neither may be end users.

Despite the disparity in approaches, the value of exploring UCD in digital health is driven by the inexorable link between technology and health care delivery [27] in the form of mobile health (mHealth). UCD is being used to facilitate lifestyle and self-management of chronic conditions such as diabetes [22]. The mutual interest of the physician and patient in the metrics produced by users exemplifies the rich potential of UCD in health care, one where agency is inevitably shifting to the end user [5]. In both the collaborative ideation phase and in postdeployment observation, the UCD identifies both challenges and trends in end-user behavior.

In summary, UCD is one approach that helps shift the evaluation of DHIs from postrelease [25] to the design phase, with an eye toward pivoting intervention designs according to user feedback. Rather than front-loading research and delaying evaluation, research and evaluation are fluid processes happening throughout the life of the design. It is hoped that, in doing so, design flaws are reduced or eliminated, and simultaneously, user engagement is increased. Despite the rupture a UCD approach may cause to traditional health care approaches, a key buy-in is the potential for scientific discovery through the multidisciplinary nature of design ideation. Improved contextual

design, particularly in complex health interventions, can address both efficacy and cost concerns [26]. In seeking to smoothen the edges of UCD in health care, a number of emerging approaches have been developed that center on human-, person-, or patient-centered design (PCD). These nuances offer a tailored approach to traditional UCD.

### ***Person-Based Design (4 Studies)***

Person-based design (PBD) is a new space [3] that seeks to humanize the design approach, neither framing participants as users or patients [8] but more generally as the people who use the intervention [13]. Building on UCD, it layers on mixed methods qualitative research in the form of behavioral theory and analysis [28]. Building the intervention around the stages of planning, optimization, and implementation, it seeks to enhance feasibility and acceptability through an intervention design that is sensitive to the lives of the people who use them. A broader psychoanalytic method, self-determination theory [8] is cited as a reason to expect improved uptake when people feel a sense of *acted user agency* in the design process. It is also understood from this approach that a variety of people contribute to a holistic solution as stakeholders, not just users, patients, or experts specifically [8]. PBD aims to help intervention designers understand how people (patients, health care workers, family members, etc) experience and implement a given intervention; these nuances create unique insights for the design process, beyond the user or patient perspective alone [8].

PBD separates itself from user-centered and patient-oriented designs by focusing on motivation, enjoyment, informativeness, and convincingness. This approach is more empathetically rooted than traditional UCD metrics built around usability, acceptability, and user satisfaction [8]. Enhancing the well-being of the person, rather than validating the experience of the user, is the differentiator. An example of the advantageousness of PBD is in the contextualization of sensor data interpretation. From a data-centric viewpoint, restaurant app users were tracked to see when they were near fast food restaurants, and then prompted with a notification. The context sensing at play would seem logical from a mapping viewpoint. However, in a PBD study, it was found that users were skeptical or annoyed about notifications raising trust concerns. This psychoanalytic approach contextualizes emotionless data points that do not speak to the feelings and behaviors of people [8].

While UCD maps a user's knowledge and skills, validating them on a basis of user satisfaction, PBD uses health psychology to validate a person's responses wholly [8]. Similar to UCD, PBD also faces the challenge of contrasting research methods with traditional health approaches [13]. PBD approaches often form an iterative workshop base [3] similar to many agile UCD practices. Person-based advocates position it as a complement to existing theory-based and evidence-based approaches [8], although being focused on behavior change [8], questions exist as to how broadly or narrowly it can be used in health care [8]. Therefore, a key consideration is how to blend the PBD framework into the industry-practiced agile ideation and prototyping cycle, leveraging the advantages of both methods.

### ***Human-Centered Design (8 Studies)***

Human-centered design (HCD) has evolved over the last 3 decades from human factors, human-computer interaction, anthropology, sociology, and UCD. It is an interdisciplinary approach to create social innovation in the health domain [32]. HCD is recognized by the International Organization for Standardization as a standard for interactive system design [33]. It has been adapted by the Mayo Clinic Center for Innovation and by global health care provider Kaiser Permanente [29]. The “human” in HCD signifies a broader social and organizational construct, prioritizing the aspirations and experiences of people holistically [30]. The foundational layer of the HCD is empathy. Before turning to traditional UCD phases, such as defining, ideating, prototyping, and testing, empathy is used to understand the underlying barriers, conflicts, and root causes related to pain points [37]. Although UCD may pivot design based on end-user pain points, HCD first asks [33], “Why is there a pain point and where did it come from?” In this regard, it may align more suitably with mainstream behavioral health practices [33], potentially increasing buy-in and reducing the rigidity of porting tech industry UCD practices into health care.

HCD seeks to create a deeper, more meaningful involvement of end users, observing and interviewing patients, clinicians, and various members of the health care team. The holistic approach seeks out a “right time, right place” method of capturing the collective experiences of the human who is mediated by the intervention [31]. This real-time intervention adaptation [36] binds together the collective brain of diverse stakeholders around the human. The focus on HCD shifts the lens from building technologies to building a framework to interpret and resolve complex DHIs at their core [32]. As an umbrella term [32], it can be difficult to define explicitly; nonetheless, it differentiates itself from UCD by pre-emptively aligning the technological intervention with people’s values, concerns, and day-to-day needs. This includes documenting the participation of potential users, supporting cooperation with them, and augmenting human skills in the design approach [32]. By collaborating to specify the context of the intervention [29] from a human and health behavior context, there is an element of design before the (digital) design. The HCD approach provides empirical evidence that may satisfy both clinical concerns over UCD brushing over holistic health research and designer concerns over articulating purposeful design for end users. HCD may serve as a bridge between health care and digital approaches, fostering greater trust among stakeholders [29].

Among the challenges for HCD to overcome is the fact that, unlike most health care processes, it is not systematic [33] with clear guidelines. In some circles, it is seen as a buzzword [32] with vague demarcation points among design, development, engineering, and health care. Arguably, this is exactly the juxtaposition desired to drag out empathetic insights for a more holistic design approach. Research conducted from a singular, siloed vantage point may struggle to provide the wholeness of HCD. In contrast, HCD provides a voice to humans [36] who will depend on the given DHI, through the broader lens of the collective interpretation of a digital health team. Another challenge is that HCD can sometimes be viewed as superficial

[32] and impractical. Gathering patients, clinicians, designers, developers, and academics under one tent is fine in theory but difficult to implement in reality. This is further complicated by the desire for pace (from the digital side of the room) [7] and the desire to move slowly and cautiously (from the health side of the room). Development teams may not be eager to add scope before the scope in the form of empathetic discovery sessions [32]; physicians may not see the value in various theoretical approaches to medical or pharmaceutical interventions. HCD practitioners will argue that no amount of expertise built upon abstract assumptions substitutes the deep intuitive data points from observing and collaborating with all stakeholders [32], from patients to experts, in the wild. HCD may not offer the fixity of a systematic health protocol [32], but instead it offers a theoretical framework for the interpretation of complex DHIs free of bias that may skew the intervention design away from the needs of the humans who use them. Moving forward, the ability to scale up an HCD for a more policy-driven rollout will be challenging [32]. Considering that HCD is vastly open to interpretation, the continued cross-functionality of digital health teams will be pivotal for developing emerging rubrics.

### ***Patient-Centered Design (12 Studies)***

PCD nuances HCD, specifically pivoting to the needs of the patient. The British National Health Service’s motto, “no decision about me, without me” emphasizes the need for patient-centered shared decision-making [38]. In 2001, the Institute of Medicine authored a report calling for 6 improvements to health care delivery, among which was a patient-centered approach that is responsible for individual patient needs and values, guiding clinical decisions [35]. By 2006, the Picker Institute issued a guide that was built upon the Institute of Medicine report, citing the need for better education and shared knowledge, more collaborative approaches, and more consideration of patient needs and preferences [35]. This backdrop coincides with the emergence of DHIs over the past 15 years that can enhance patient engagement, but with that is the fear that “tools are not enough” [38], that the needs of the patient should guide the design approach. The concept being that patient validation maximizes acceptability and usability [47].

The PCD approach targets patient-facing technologies such as personal health records, patient portals, and mHealth apps [39]. In this regard, it hopes to provide a digital pathway to the triple aim in health care of improving patient experience, reducing costs, and improving health [17]. PCD seeks the patient to take leadership roles in their care, rather than being empowered by professionals [48], through qualitative patient perspective workshops that are interesting and enjoyable [47]. It pivots the UCD approach to user needs and wants, reframing them as patient needs centered on achieving therapeutic benefits and patient wants being intervention designs that guide retention [47]. In doing so, it shifts traditional industry UCD approaches from consumer oriented to patient focused. This logic aligns better with health care infrastructure and policy [34]. Borrowing from HCD, PCD operationalizes patient empathy [35], seeking out metrics that show a patient trajectory moving from passive to active participation [34], a key indicator of more knowledgeable, more empowered patients.

PCD is proving influential in wearable, sensory-based technologies that quantify the self. An explosion in digital health technologies (DHTs) that are lifestyle interventions—self-tracking, self-experimenting in diet, exercise, and sleep [49]—has demonstrated the valuation of more human or patient-centered interventions. By their nature, wearables provide a bilateral relationship between the end-user and the health care industry. This real-time data demonstrates not only the needs and wants of users, but also their behavioral interaction with DHIs. In another example, Johns Hopkins Hospital created an app for discharge that shifts from paper to digital, reengineering, and expediting the process, putting the agency in the hands of the patient [10]. This process still requires constraints; however, the positioning of the patient in a proactive role accentuates the National Health Service's call for more engaged patients [34].

Although patient empowerment and personal agency are undoubtedly factors in improved design and uptake, centering the patient as a primary stakeholder is not without challenges. A patient may desire a DHI design that is discordant with proven clinical efficacy [31]. For example, an app that manages the dispensary of medications may need clinical checks and balances to avoid side effects or abuse. This may not fit the preferences of the patients centering on the design. Overconfidence or social crowdsourcing of ideas may incorrectly influence patient mindsets. The diagnostic accuracy of PCD can be easily questioned. In this regard, it is difficult to imagine this as a standalone design approach [36]. In addition, PCD as a broad approach can be seen as an oversimplification of the complex and intricate domains of health care [34]. Disease management and urgent care often have very specific and time-sensitive approaches that cannot be opened to popular opinions. Also, the qualitative, rapid approach to PCD data points is difficult to correlate with gold standard RCT data sets that are quantitatively vast [36]. With smaller data sets, PCD approaches often bring into question who the patient is, how diverse the demographic is, and why they were chosen [36]. This is not to say that PCD is not impactful but rather that it has a particular scope and context to better understand patient thoughts and preferences for intervention design [36]. This scope is challenged when patients contradict medical best practices. Regardless of its influence in clinical decisions, PCD provides insights into patient preference and behavior that other design approaches may not uncover.

### **Patient-Led Design (5 Studies)**

Furthering the patient-centric approach is patient-led design (PLD), a design approach that considers patients as partners [42]. Taking an example from the web 2.0 phenomena of prosumerist crowdsourcing, the approach understands that patients themselves are proactively taking the lead in curating their own health care through digital means, a health care 2.0 [40]. This approach resonates with the transition from “sick care” to health care, one where personalized health care is built around the patient’s self-tracking and self-analysis [48]. Preliminary research, ideation, and design all function within the discovery of patient-led initiatives to equip, enable, and empower patients [20].

A key advantage of PLD is the ability to rapidly garner results from large samples of the population [40]. This crowdsourcing approach, coupled with advancements in machine learning, can provide rich data sets, a quantitative means to triangulate results in other qualitative studies in design approaches (HCD, UCD, etc). In addition, the self-experimentation of patients that occurs during the curation of DHIs leverages a form of citizen science such that innovative treatments may evolve from the process [40]. Similar to PCD, buy-in is easier to attain when patients are treated as the primary stakeholders. This approach can be particularly useful for startups and low-budget projects seeking new and innovative DHIs.

Similar to PCD, PLD is challenged by the shifting balance of power dynamics between patients and clinicians [41]. As more agency is given to the patient in the design and curation of an intervention, less is given to the traditional health care base, raising questions regarding safety and efficacy. Weighing it against HCD, questions remain about the holisticity of the approach, one that could benefit from a richer group of stakeholders in the formation of digital health solutions [40]. Self-experimentation juxtaposes the standardization of medical treatments. Health literacy is not a prerequisite for PLD.

In counterbalancing the constraints and affordances of PLD, it can be argued that more patient participation can lead to increased health literacy, greater understanding of safety, and a shared responsibility in balancing power [41], something of interest to patients and clinicians alike. It is hoped that PLD reveals new types of patient engagement in the highly participatory digital space [42]. Considering that Reddit-like digital coffeehouses are only likely to increase with augmented reality and machine learning technologies, the goal of leveraging these data points and mixing them with qualitative findings opens up an avenue for more robust research methods. Increasingly, DHTs will provide more tailored interventions that develop diverse data points around the patient’s feedback. The physician of tomorrow may increasingly be oneself [48], mediated by algorithmic deep learning. Ignoring this transition would be unwise. Nonetheless, understanding the context of when PLD is resourceful versus when it may be harmful within a DHI design remains a question moving forward.

### **The Golden Thread of Collaboration: Participatory Design, Co-design, and Cocreation**

Each of the aforementioned design approaches shares the general values of participatory design, co-design, or cocreation. This approach is supported by the UK National Institute for Health Research [50], with the foundation being that the intersection of various sciences and learned experiences harmonizes DHIs [3] in the form of *social innovation* [51]. The cultural shift [52] to more autonomous, pervasive [53] DHTs has enhanced value cocreation in digital health as a strategy of increased patient involvement, reduced costs [54], and better uptake. Participatory co-design methods mesh industry toolkits and workshops with a wider swath of human- and patient-centered strategies [55]. This involves collaborating with end users and a diverse array of professionals in preideation research, ideation, prototyping, testing, and postlaunch retrospectives, synthesizing the understanding of health, technology, and design experts,

anchored upon the insights of the user [53,56]. This approach has been referred to as a *golden thread* that runs through every stage of the intervention, looking through the lens of the target user throughout [18,56].

This equal partnership approach [57] studies what the end user says about the DHI, does with the DHI, and makes from the DHI [18]. The nuances in each of the aforementioned design approaches shift the focus from user to human to patient, each pivoting the mission statement slightly in search of new and groundbreaking approaches. However, they each share the essence of the co-design ethics of mutual learning, democratization of power relations through shared ownership, and use tools and techniques to facilitate better collaboration [58]. Designing innovative health solutions *with* and not *for* end users is the desired outcome [43].

In doing so, closing the gap among clinical, technical, and design perspectives is oriented around not *what is* but what *could be* [51]. This can be an uncomfortable process in health care as it questions traditional practices and favors a new, broader body of knowledge [57,59]. While it may increase the sense of belonging [60] in patients, it may also decrease the sense of worth in clinicians. Nonetheless, co-design seeks to shift the voice [13] of DHIs to an interdisciplinary domain that is more reflective of the digital ecosystem today.

There are a number of key challenges in this shift. Moving digital health design approaches from theoretical to practical involves resolving the cultural differences between health care and complementary domains involved in DHIs. Nonlinear, more agile pathways to DHI design need to be embraced. Co-creation methods as a project valuation are not widely understood in health care [61]. Co-creation rethinks health care delivery that impacts both the macro and micro level of the health ecosystem [61], a top-to-bottom cultural change that understands the shifting agency of increasingly digital health care facilitation. This is also difficult in practice because of the layered levels of bureaucratic governance, from regional to federal to international regulation [15], each having its own perspectives, priorities, and ethics. The fact that there are so many variations in how to deliver DHIs further complicates upstream changes to health care policy. Becoming comfortable with the uncomfortable [57] is part of the adolescence of digital health.

## Discussion

### The Promise of Digital Health

Digital health is emerging as an industry that gives promise to a more personalized health care experience. The demand for health care apps doubled between 2011 and 2015, reaching 165,000 apps [1]. In response, mHealth investment grew from US \$4.4 billion to US \$6 billion between 2016 and 2017 alone [43]. The digitization of health care delivery is increasing the autonomy of health care users. With this, a paradigm shift is emerging, wherein the agency of users is rivaling traditional health care practice that is primarily expert-based. There is a wider acceptance of pivoting the intervention design toward the user, person, patient, or human, part and parcel because of an emerging landscape of digital natives. Clinical professional

assessment is becoming increasingly supplemented by self-analysis and self-management apps that shift agency toward the health care user. This is creating greater access with more robust data points, which curates personalized real-time data. This contributes to a faster, more intuitive health care delivery. Emerging design approaches are seeking to port digital and design best practices into health care solutions. Simultaneously, the rigors of health care safety and efficacy are in need of being compressed into digital delivery timelines. This dichotomy has created friction on how design, evaluation, and implementation are understood from the digital and health care sides of the room.

Among the key challenges identified in this research is the disparity between intervention design in traditional health care and digital settings. The hybrid ecosystem that is digital health faces a multiplicity of design approaches and countless use-case scenarios. These approaches have exposed a silo disconnect among various stakeholders and methodological differences in intervention design. Despite each nuance in the design approach shifting the vantage point of the primary stakeholder, it is often unclear how these design approaches can be tailored for rapid app development while balancing the safety and rigor of health standards. Although a PCD may prove effective in large stakeholder projects such as mHealth self-tracking diet apps, a patient-led approach may have fewer constraints, allowing for more crowdsourced experimentation in the development of innovations in DHTs. In contrast, person- and human-based design may appeal to psychoanalytic interventions for depression and mood disorders. There are no hard demarcation points between the design approaches, as they borrow and overlap techniques under the broader umbrella of co-design. This lack of systematicity accentuates both the promise and the challenge of digital health. The implementation gap [37] is the space that is allowing new, collaborative approaches to emerge. It is also the flashpoint of methodological differences.

### Improving the Future of Digital Health Design

Looking to the future, reducing the polarization of the 2 cultures (digital and health) [13] is paramount. As digital health matures, interdisciplinary approaches can become transdisciplinary and free of sector boundaries such that digital and health are undemarcated. On the part of digital experts, a better understanding of distal outcomes from a health perspective would be enlightening. Similarly, health experts would do well to understand the value of proximal user research and rapid iteration. Health concepts, such as efficacy and safety, can become hybridized with digital concepts, such as UX and usability. For example, a “user efficacy” can blend clinical and design principles that target both effectiveness and positive experience. Safety and usability can blend health constraints with technical affordances.

In addition, there is the value proposition challenge of absorbing the additional cost of design infrastructure and digitally upskilling stakeholders [62] in a co-design environment. Owing to this study being focused on defining and critiquing design approaches, we have not addressed this *elephant in the room*. However, financial challenges exist to justify these design approaches as part of a business-as-usual approach. Further

studies should be considered to weigh the unique value proposition of a given design approach for a given health care sector or use-case scenario. For digital health collaborators to reduce friction and pain points, focusing on a value proposition design that establishes a digital application of the triple aim in health care is important. Considering that a 2019 survey found that only 57% of patients felt that physicians acted in their best interest [29], the digital agency of health care users can only serve to improve trust and uptake. In doing so, a value chain can emerge that keeps stakeholders across multiple disciplines—clinicians, academics, designers, and developers—mutually invested in an approach that is transparent, is effective, and, most of all, creates true digital health affinity.

To address these challenges from a research perspective, we recommend the following three steps:

1. Triangulation of the common challenges that bleed through all design approaches to help distinguish overarching pain points in digital health. To that end, a systematic review focused on the key challenges in incorporating end users in the design of DHIs would be instrumental.
2. User studies that illustrate collaboration with industry partners to blend various design approaches into agile workflows would demonstrate pragmatic implementation in health care app development. This will help with proof of concept, providing real-world analysis and value proposition. It will also explore and resolve issues of practicality and scalability because of real-time industry constraints.
3. Case studies that involve digital experts spending time in health care environments to understand what efficacy and validation implies in a health care context. Similarly, a study of health experts who reach beyond consultancy, instead fully participating in agile development cycles, from

ideation to product release, is needed to increase our understanding of purposeful design and user validation.

Although the hybridization of digital health may feel forced, the aforementioned steps may encourage a more organic and unified approach to design.

## Conclusions

The future of health care is becoming increasingly digital. The proliferation of artificial intelligence [45] in the form of machine and deep learning [30] offers limitless real-time [1] insights that promise to further fuse together digital and health into the mid-21st century. In its infancy, this interdependent relationship has been strained. The various approaches to manage differences in digital and health care design center around various forms of collaborative co-design. The goal of bringing together 2 vastly different industries (digital and health) under one umbrella is a complex challenge that is being explored using various design approaches. Although each of the studied approaches offers a nuanced take on how to create purposeful design in digital health, positing the challenge around the user, person, or patient shifts the vantage point of the primary stakeholder only slightly. Of greater concern is how to create a truly transdisciplinary environment in which a culture of digital health emerges that is less tribal and more agile, reducing the friction of competing interests. To accomplish this, a demonstrable value proposition that proves faster, better-quality, more efficient, and more user-empowered solutions is needed. In doing so, there is the potential for better buy-in from all stakeholders. Further research is needed to analyze the pragmatic and cost-effective demonstration of each design approach in a real-world context. Finally, piloting these design approaches within robust design teams that expand the usual array of project managers, designers, and developers to include clinicians and health experts—from ideation through to deployment—can lay the foundations of an emerging digital health culture, an ethos that balances the needs of health care and design equitably.

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## Authors' Contributions

The study protocol was conceived by AD, GJC, and SM. AD prepared and drafted the manuscript. All authors provided input into the design, edits, and revision of the manuscript. All authors read and approved the final manuscript. AD is the guarantor of the review.

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## Conflicts of Interest

None declared.

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## Abbreviations

**DHI:** digital health intervention

**HCD:** human-centered design

**PBD:** person-based design

**PCD:** patient-centered design

**PLD:** patient-led design

**PRISMA:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses



**UCD:** user-centered design

**UX:** user experience

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Original Paper

# Electronic Diagnostic Support in Emergency Physician Triage: Qualitative Study With Thematic Analysis of Interviews

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## Abstract

**Background:** Not thinking of a diagnosis is a leading cause of diagnostic error in the emergency department, resulting in delayed treatment, morbidity, and excess mortality. Electronic differential diagnostic support (EDS) results in small but significant reductions in diagnostic error. However, the uptake of EDS by clinicians is limited.

**Objective:** We sought to understand physician perceptions and barriers to the uptake of EDS within the emergency department triage process.

**Methods:** We conducted a qualitative study using a research associate to rapidly prototype an embedded EDS into the emergency department triage process. Physicians involved in the triage assessment of a busy emergency department were provided the output of an EDS based on the triage complaint by an embedded researcher to simulate an automated system that would draw from the electronic medical record. Physicians were interviewed immediately after their experience. Verbatim transcripts were analyzed by a team using open and axial coding, informed by direct content analysis.

**Results:** In all, 4 themes emerged from 14 interviews: (1) the quality of the EDS was inferred from the scope and prioritization of the diagnoses present in the EDS differential; (2) the trust of the EDS was linked to varied beliefs around the diagnostic process and potential for bias; (3) clinicians foresaw more benefit to EDS use for colleagues and trainees rather than themselves; and (4) clinicians felt strongly that EDS output should not be included in the patient record.

**Conclusions:** The adoption of an EDS into an emergency department triage process will require a system that provides diagnostic suggestions appropriate for the scope and context of the emergency department triage process, transparency of system design, and affordances for clinician beliefs about the diagnostic process and addresses clinician concern around including EDS output in the patient record.

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**KEYWORDS**

electronic differential diagnostic support; clinical reasoning; natural language processing; triage; diagnostic error; human factors; diagnosis; diagnostic; emergency; artificial intelligence; adoption; attitude; support system; automation

## Introduction

Diagnostic error is common in emergency departments [1-4], prolonging encounter times [5] and the length of stay [3] and increasing morbidity and mortality [2,3,5]. When systematically studied, cognitive factors (ie, how clinicians think) are frequently cited as an underlying cause [6]. When a diagnosis is missed, simply “not thinking of it” tops the list for causes [7]. The use of electronic differential diagnostic support (EDS) has emerged as a solution. EDS systems are decision aids that suggest a differential diagnosis (ie, a list of potential diagnoses) based on inputted data, allowing clinicians to be primed to potential diagnoses, thereby reducing the chance that they “do not think of it” [8-11]. Multiple studies have shown small but significant increases in diagnostic accuracy, using a variety of different EDS systems, with clinicians of different experience levels [8,11-14]. EDS increases the number of diagnostic hypotheses and the probability of the correct diagnosis being in the differential [8,11,13-15]. These benefits were present regardless of whether the EDS was used before or after the clinician had a chance to examine all of the available information [11].

In the emergency department, embedding EDS within a physician triage process holds promise to maximize the benefits of EDS. First, EDS flags relevant life-threatening diagnoses to clinicians, allowing a “must-not-miss list” to be at the top of their mind. Although clinicians are often trained to think about worst case scenarios, these life-threatening diagnoses are still occasionally missed or delayed. Prompting by EDS around multiple life-threatening diagnoses could facilitate timely intervention where delays matter (eg, antibiotics for potential meningitis in a patient presenting with altered consciousness). Second, physician triage directs up-front investigation, where EDS prompting may improve the range of investigations [13] with the potential to decrease emergency department visit time and improve the specificity of discharge diagnosis.

However, clinician adoption of EDS has been limited [10]. Prior work exploring attitudes about the feasibility and acceptability of EDS has identified that the additional time required to use an EDS was a deterrent [16]. Automating EDS data entry is a promising but untested approach, especially if the system can access data streams from the electronic medical record [17,18]. Such automation is possible within emergency department triage processes, where information collected by a triage nurse can be fed into an EDS system capable of natural language processing, providing subsequent clinicians with an EDS-supplied differential diagnosis.

However, it is unclear whether clinicians would be accepting of this type of approach, even if it were convenient. A human factors review highlights the critical influence of clinician perception and trust of tools such as EDS as being important in their adoption within health care contexts [17]. Clinician perception around the perceived quality of EDS suggestions could influence their willingness to use it. Similarly, trust in the EDS system and the relative control over data fed into the EDS system also shapes the acceptance of the technology. In fact, recent evidence raises concern that clinicians who are

mistrusting of EDS systems do not appear to benefit from them [12]. To assess the acceptability of integrating EDS within the triage process, we conducted a qualitative study of emergency department triage physicians to identify their perceptions and concerns with this approach.

## Methods

We conducted a qualitative study, interviewing physicians involved in an EDS-aided emergency department triage process.

### Setting

This study was conducted at a tertiary care emergency department of an academic teaching hospital with a physician-supported triage process. In this setting, patients were assessed in a triage process that includes a triage nurse and a triage physician, before being assigned to a zone for a more thorough assessment. Patients were registered by a triage nurse who noted the chief complaint and vitals. Patients were subsequently assessed by a triage physician who performed and documented an abbreviated history and physical examination. The triage physician assigned patients a zone within the emergency department based on the severity of illness, established a working diagnosis or differential diagnosis, and ordered initial investigations and time critical interventions. Patients were subsequently moved to a different area of the emergency department based on the triage physician’s decision, to be assessed by the most responsible emergency department physician within the assigned zone. This process allowed initial investigations and management to start even if the physician assigned to the patient’s zone is busy. The triage physician process is not meant to be comprehensive; the full history and physical examination and all subsequent investigations, management, and disposition determinations are performed by the most responsible physician. Triage physicians work quickly to keep up with the emergency department volumes, typically assessing 12-15 patients per hour. Trainees are not involved in the triage process given the need to keep pace with the volume of patients presenting to the emergency department. All triage physicians are fully qualified, independently practicing emergency department physicians.

### EDS-Aided Emergency Department Triage Process

We developed a rapid human prototype, using a research associate, to simulate automated EDS integration into the triage process of a busy emergency department. This approach allowed triage physicians participating in the triage process to access EDS without having to input data themselves into the system. We chose the Isabel system (Isabel Healthcare) as it was one of the most frequently studied EDS platforms, with minimal time investment required for use [10,11,16]. A research associate (BA), who is a medical doctor with emergency department training, entered data from the triage nurse note into the EDS system using a tablet. The Isabel system accepts patient age, gender, travel history, and symptoms, which are entered into textboxes. The system uses natural language processing to provide lists of potential diagnoses, flagging the diagnoses that are life-threatening. The research associate provided the triage physician with the EDS output via the tablet before the physician assessed each patient complaint in person. This process

mimicked automated access to the EDS output based on the triage record within the electronic medical record.

### Recruitment

All emergency department physicians were involved via a rotating schedule with the triage process. All were invited to participate by email. Written consent was obtained. Participants were provided with a simulated EDS integration into the electronic medical record for the last hour of their triage shift. Each participant took part in a semistructured interview at the end of their triage shift.

### Interviews

Semistructured interviews were conducted by a research associate (BA), which were then transcribed verbatim from recordings. The interview guide included questions around the perceived role for EDS integration into the triage process, potential and actual advantages and disadvantages, any impact the system had on patient management decisions, opinions on how to best integrate the system into the workflow, and whether it would be advantageous for trainees to use the system.

### Analysis

We performed a direct content analysis of the semistructured interviews of emergency department physicians who had access to the EDS during a triage shift. Analysis was anchored within a human factors paradigm, highlighting the role of perception, usability, workload, and trust in automated electronic approaches [19]. Using the principles of direct content analysis [20], the analytic team (MS, JS, SM, AK, and BA) read the transcripts and engaged in a process of iterative open coding, followed by group discussion to inform subsequent coding. Following open coding, we engaged in axial coding to establish linkages between the data, informed by the human factors paradigm. The team met regularly during the analytic process to revise the interview guide and discuss interim analyses and emerging themes. Theoretical saturation was determined through analytic consensus, where empiric evidence supported themes of sufficient depth to advance understanding while maintaining practical relevance.

**Table 1.** Participant demographics.

Demographic	Participant (N=13), n (%)
<b>Years of experience</b>	
<5	5 (38)
5-10	4 (31)
11-20	1 (7)
>20	3 (23)
<b>Gender</b>	
Female	2 (15)
Male	11 (85)
<b>Specialty</b>	
Family medicine with emergency medicine training	6 (46)
Emergency medicine	7 (54)

### Rigor

The research team consisted of varied perspectives including clinicians (MS, BA, and JS), educational scientists (MS, SM, and GN), and an educator (AK). We adopted a realist stance, recognizing that participant and contextual factors would influence our data set. We enhanced rigor through a purposeful sampling of practicing clinicians at a single busy center. The interviews were completed by a physician with sufficient content knowledge to understand usability challenges but without knowledge of the emergency department workflow to avoid in-group assumptions around technology adoption and mitigate social desirability bias that might moderate opinions. The interviewer kept field notes and a reflective diary. Transcripts were transcribed verbatim to avoid losing word choices and tone and were anonymized prior to analysis to preserve confidentiality and avoid bias from the analytic team. Throughout the analysis, the analytic team declared biases and assumptions and actively sought contrasting opinions from others involved in the analytic process.

### Ethics Approval

This study was approved by the Hamilton Integrated Research Ethics Board (#13926). All participants provided written informed consent.

## Results

### Participant Demographics and Themes

We conducted 14 interviews from 13 emergency department physicians, as described in [Table 1](#).

One participant used the EDS for 2 shifts and underwent 2 interviews. Of the 13 physicians, the years in practice varied: 5 (38%) were within the first 5 years of practice, 4 (31%) within 5-10 years, 1 (7%) within 11-20 years, and 3 (23%) with greater than 20 years. In all, 6 (46%) physicians were certified as family medicine specialists with subspecialization in emergency medicine, and 7 (54%) were certified as emergency medicine specialists. In total, 4 themes were identified in the analytic process, as described in [Table 2](#).

**Table 2.** Themes identified by clinicians around incorporating electronic differential diagnostic support (EDS) systems in the emergency department.

Theme	Relevant human factors construct <sup>a</sup>	Description	Number of clinicians who made statements that supported this theme (N=13), n (%)
1. The quality of the EDS was inferred from the scope and prioritization of the diagnoses.	Perception and usability	Participants linked the value of the EDS to the types of diagnosis being suggested. Diagnoses that did not seem appropriate or were outside of the physician's range of practice were suggested, which prompted clinicians to doubt the value of the EDS.	9 (69)
2. Trusting EDS differential diagnoses was linked to varied beliefs around the diagnostic process and potential for bias.	Trust and usability	Participants were concerned about the unintended and untested benefits of EDS. Some worried that it might introduce bias, whereas others wanted to see more evidence of its benefit.	10 (77)
3. Who benefits? Not me.	Perception and trust	Participants acknowledged that EDS could add value but found it hard to imagine that they would make an error that the EDS could correct.	13 (100)
4. Information flow between EDS and the electronic medical record	Usability and workload.	Participants believed that EDS should be able to use information in the medical record to provide a differential diagnosis, but that the differential diagnosis output of the EDS should not be automatically incorporated into the medical record. Including the EDS output could prompt an over investigation of diagnostic suggestions even when they are not appropriate to the context.	8 (62)

<sup>a</sup>Adapted from Asan and Choudhury [19].

### Theme 1: The Quality of the EDS Was Inferred From the Scope and Prioritization of the Diagnoses

*A lot of [the suggested diagnoses] seemed very extraneous, I'm not totally sure where they got them from. There were a couple where...I don't see a world that that's what's going on with this patient.* [Participant #6]

Participants passed judgment on the quality of the EDS based on whether the diagnostic suggestions were relevant to their context and scope of practice in the emergency department.

*This could be Goodpasture's [disease]...But do I think that that patient actually had any of those things? Absolutely not...Should I do a bunch of blood work? I don't think that's really my role.* [Participant #13]

The suitability of diagnostic suggestions was even tied to the patient's location in the emergency department.

*It was telling me, intestinal ischemia in a 25-year-old with abdominal pain...we would be able to see that within the first couple of seconds by looking at them. And they sure as hell wouldn't be seen at triage, I'm sure they'd be in the resuscitation bay.* [Participant #10]

Similarly, participants assumed that the ordering of diagnoses on the list was related to probability, as this is a common clinical convention. The system's utility was questioned when the ordering of the diagnoses did not align with participants' clinical impression: "either that the most likely diagnosis was not even on the list or it was really far down, and they had very unlikely diagnoses closer to the top" (Participant #8).

Of note, EDS was used early in the emergency department visit where there was only limited information available based on the triage nurse's intake process. This process was not readily

apparent to participants, occasionally leading to poor perception of the EDS quality, particularly when patients were unable to articulate their symptoms well, presented with misleading or vague complaints, or did not disclose relevant past medical history up-front.

### Theme 2: Trusting EDS Differential Diagnoses Was Linked to Varied Beliefs Around the Diagnostic Process and Potential for Bias

Participants were skeptical about EDS adoption within the triage process, voicing concern around trusting the accuracy of the outputted differential diagnosis. These concerns were both around how EDS would influence the diagnostic process, as well as how EDS generated a differential diagnosis.

#### Subtheme 1: Influence on the Diagnostic Process

Participants were concerned about the potential for EDS to bias them: "it would actually be more useful if it told me stuff after I'd seen the patient to jog my memory, rather than going in biasing me a little bit" (Participant #10). They had strong, but divided, beliefs about whether the EDS should be used early or late in the diagnostic process to mitigate bias. The use of EDS up-front concerned some participants that their judgment would be "clouded," "anchored," or "biased," whereas others saw it as a mechanism to "combat confirmation bias," "think outside the box," and "avoid tunnel vision." Interestingly, the need to reduce bias was given as a justification for both positions.

#### Subtheme 2: Transparency Around How the EDS Generated a Differential Diagnosis

Many participants wanted to understand more about how the system created a differential diagnosis before adopting it in their practice or advocating for it to be embedded within the triage system: "I did not really find it that helpful, to be honest with you...First of all...I have no idea how the software works" (Participant #8). There were calls from participants to make

explicit the algorithms used as well as a desire for empiric evidence that the algorithms improved the diagnostic process and reduced diagnostic error.

### Theme 3: Who Benefits? Not Me

Most participants did not see a personal benefit but endorsed the use of the EDS for less experienced colleagues. A small number of participants acknowledged that experienced clinicians might derive benefit, either through episodic use in situations where clinicians faced diagnostic uncertainty or through consistent use to identify situations where a diagnosis was simply overlooked.

*I think it would be a great thing for learners or less experienced docs...sometimes it's helpful...for someone who has experience in that, some of the differential diagnoses are things that might not have popped into my mind. [Participant #1]*

Participants had strong divergent opinions around whether learners would benefit from the EDS, with some believing that learners need to practice generating diagnoses on their own to avoid “spoon feeding them” and others believing that it would “overwhelm” them, which is in contrast with those believing it to be a good learning tool to “develop diagnostic acumen” and a way of reducing “cognitive overload” for learners. Opinions also diverged on whether it made learners safer: “It can help them to make sure they’re keeping a broad differential instead of narrowing in on and prematurely closing” (Participant #8) versus “If they’re being supervised, then I don’t see a reason for it...from a patient safety point of view” (Participant #5).

### Theme 4: Information Flow Between EDS and the Electronic Medical Record

Participants did not react adversely to the EDS drawing data from the electronic medical record. In fact, extracting data from the electronic medical record to automate EDS output was desirable, as long as the click burden was low. Participants wanted some control over this process to understand the data that were being fed to the EDS and, in some cases, wanted the system to only use the data that they personally collected or vetted.

However, participants had substantial concerns around the output of EDS being a part of the medical record. Uniformly, clinicians opposed the EDS output being documented in the medical record, citing medicolegal implications.

*I think you could run into problems if there's an AI-generated differential and your clinical gestalt disregards a couple of the points because you don't think they're likely. And then if there's a bad outcome...being held liable because the AI-generated differential told you to consider such and such. [Participant #8]*

## Discussion

### Principal Findings

In this study, we provided EDS to emergency department physicians doing triage assessment using a researcher to simulate an automated system. We found that emergency department

physicians were hesitant about adopting this approach with 4 themes emerging. First, quality was inferred by the scope and prioritization of the EDS output, which was not customized to the emergency department triage setting. Second, trust in the EDS was linked to participant beliefs and assumptions of the diagnostic process and would benefit from transparency and evidence around EDS function and outcomes. Third, participants were disinclined to consider themselves to be in the group of clinicians that would benefit from EDS, with divergent opinions on whether the EDS should be a tool for learners. Finally, participants wanted the ability to draw from the medical record to feed the EDS but insisted that the EDS output be kept out of the patient record.

This study adds to the literature as interventions aimed at reducing diagnostic error are rarely assessed in the workplace [21,22]. A recent narrative review highlighted that most interventions are studied under experimental circumstances and called for more investigation of interventions within the workplace settings [21]. Within the emergency department setting, second opinions, decision aids, guided reflection, and focused education have all been proposed to reduce diagnostic error, although most of these interventions have been evaluated in experimental settings [21]. Some data is available regarding the perceived benefit of checklists in a clinical workplace setting [21,22]. One study conducted by Graber et al [22] used a rapid cycle design process to iterate the checklist content in primary care settings. Clinicians identified situations where the checklist had changed the working diagnosis, unlike in this study of EDS where clinicians only hypothesized a benefit. Interestingly, both interventions involved similar content (eg, the specific checklist for chest pain is highly similar to the output provided by the EDS of a middle-aged man with chest pain). However, clinician exposure to the checklists was over a 2-month period, far greater than the single shift used in this study.

The clinician uptake of EDS was low in a different 3-month pilot, with the authors calling for the customization of the platform to better suit the primary care environment [23]. In particular, the platform suggests a level of diagnostic precision that may not be realistic for initial illness presentations with differential diagnoses being constructed with different precisions over the course, context, and type of clinician assessing the patient [24]. These concerns raised in the primary care setting are equally applicable to the emergency department. Diagnostic labels such as “chest pain not yet diagnosed,” “chest pain query pulmonary embolism,” and “rule out acute coronary syndromes” are common in the triage process. Similarly, discharge with the “test of time” using guidelines around when to return to the emergency department is a frequent strategy to avoid over investigation while allowing a serious illness to declare itself [25]. These approaches suggest that clinicians accommodate diagnostic uncertainty, with an incremental approach to diagnostic labeling and subsequent testing, which does not neatly fit the EDS platform used.

For those involved in EDS design, this study highlights areas where the EDS platform could be modified to facilitate clinician adoption in the emergency department. Clinicians seemed to lose faith in the EDS system when diagnostic suggestions did not fit the context or scope of their practice. This finding leaves

open the possibility of greater clinician trust of EDS systems if suggestions were customizable to their environment and scope of practice. Similarly, the ergonomics of use were frequently highlighted. Attempts to automate EDS within the triage process or embed it within the electronic medical record should prioritize the transparency of the data being entered and allow single-click access at different stages of the diagnostic process, as clinicians are unlikely to agree on a common strategy for use.

For those advocating for EDS use in practice, several considerations are warranted. First, clinicians' underlying beliefs and assumptions about the diagnostic process influenced their willingness to use the EDS and perceptions around its benefits. In some cases, these beliefs seemed to conflict with evidence that experienced clinicians can benefit from EDS [10] and that benefit is present both with early and late use in the diagnostic process [11]. Second, clinicians have a need to understand how the EDS works and the evidence for its effectiveness in practice. Although evidence of EDS improvements in diagnostic accuracy exists in controlled settings [10], it is unclear whether it is justified to subject EDS to the same level of evidence required for diagnostic tests or therapeutic strategies, as evidence in either of these paradigms is limited [26]. At minimum, increasing

transparency around how an EDS generates a differential may enhance clinician adoption.

### Limitations

We highlight 2 important limitations. First, this study took place in a single setting, with a limited sample size and a single approach to embedding EDS within the triage process. This process allowed the uniformity of experience but limited generalizability to other settings. Second, the opinions and perceptions of clinicians can deviate from their behavior in practice, thus limiting the inferences that can be drawn.

### Conclusions

Using a research associate to mimic the integration of EDS into the triage process proved feasible. However, clinicians remain skeptical about the value of the EDS output in the triage process. Those interested in facilitating EDS adoptions should consider (1) whether the diagnostic suggestions provided are appropriate for the scope and context of the emergency department triage process, (2) how much transparency of the EDS system's inner workings is required to earn the trust of clinicians, (3) addressing clinician beliefs about the diagnostic process, and (4) addressing clinician concerns around including EDS output in the patient record.

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### Conflicts of Interest

None declared.

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## Abbreviations

**EDS:** electronic differential diagnostic support

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Original Paper

# Electronic Co-design (ECO-design) Workshop for Increasing Clinician Participation in the Design of Health Services Interventions: Participatory Design Approach

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## Abstract

**Background:** Participation from clinician stakeholders can improve the design and implementation of health care interventions. Participatory design methods, especially co-design methods, comprise stakeholder-led design activities that are time-consuming. Competing work demands and increasing workloads make clinicians' commitments to typical participatory methods even harder. The COVID-19 pandemic further exacerbated barriers to clinician participation in such interventions.

**Objective:** The aim of this study was to explore a web-based participatory design approach to conduct economical, electronic co-design (ECO-design) workshops with primary care clinicians.

**Methods:** We adapted traditional in-person co-design workshops to web-based delivery and adapted co-design workshop series to fit within a single 1-hour session. We applied the ECO-design workshop approach to codevelop feedback interventions regarding abnormal test result follow-up in primary care. We conducted ECO-design workshops with primary care clinicians at a medical center in Southern Texas, using videoconferencing software. Each workshop focused on one of three types of feedback interventions: conversation guide, email template, and dashboard prototype. We paired electronic materials and software features to facilitate participant interactions, prototyping, and data collection. The workshop protocol included four main activities: problem identification, solution generation, prototyping, and debriefing. Two facilitators were assigned to each workshop and one researcher resolved technical problems. After the workshops, our research team met to debrief and evaluate workshops.

**Results:** A total of 28 primary care clinicians participated in our ECO-design workshops. We completed 4 parallel workshops, each with 5-10 participants. We conducted traditional analyses and generated a clinician persona (ie, representative description) and user interface prototypes. We also formulated recommendations for future ECO-design workshop recruitment, technology, facilitation, and data collection. Overall, our adapted workshops successfully enabled primary care clinicians to participate without increasing their workload, even during a pandemic.

**Conclusions:** ECO-design workshops are viable, economical alternatives to traditional approaches. This approach fills a need for efficient methods to involve busy clinicians in the design of health care interventions.

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**KEYWORDS**

clinicians; community-based participatory research; web-based design; delivery of health care; health intervention; physicians; primary health care; videoconferencing

## Introduction

### Problem Description, Significance, and Previous Work

Participatory design describes practices for cocreating products and services with users. The co-design approach places stakeholders as peers to the intervention planners and system designers. Co-design methods have been shown to improve the development, usability, and rollout of health services interventions [1]. Co-design methods also benefit health services researchers by improving the relevance of research, showing high sustainability, and increasing subsequent collaborations [2]. Co-design has a long history of health services applications. Recent examples with health care staff include improving hospital palliative care [3], primary care decision support for antibiotics prescribing [4], and primary care artificial intelligence-based documentation assistants [5].

Traditionally, co-design workshops are conducted in person [6]. This enables prototyping with low-tech or rudimentary materials to maximize accessibility and engagement. However, traditional co-design is difficult. Barriers include transportation, retention, and for staff, reluctance in using personal time to attend workshops [7]. The COVID-19 pandemic made some of these barriers more severe after organizations activated safety protocols that effectively ended colocated meetings. The COVID-19 pandemic also increased the use of online meetings, supporting a potential adaptation of the co-design workshop format for distributed work groups.

Online meetings have increased participation from hard-to-reach patient stakeholder populations [8] and demonstrate potential for reaching clinicians whose experiences may be underrepresented [9]. Web-based co-design provides flexibility in location, which addresses the barrier of transportation of people to a central physical location. Time commitment remains a major barrier to recruitment and retention; clinicians were busy even before the present pandemic. An abbreviated method for co-design, however, may overcome such time-related barriers.

### Objective

There is a pressing need to adapt traditional methods of co-design workshops, including delivery, facilitation, materials, activities, and duration, to increase clinician participation in the design of health care interventions [8]. Our objective was to adapt co-design workshops to encourage primary care clinicians' participation with special consideration of their increased workload and safety during the pandemic.

### Application to a Health Services Problem: Case Study

Clinicians in ambulatory care services, including primary care, usually order diagnostic tests for their patients to investigate patient symptoms. Clinicians are expected to see the results, interpret them, plan a treatment if needed, and communicate results to the patient (even if test results are not available until after the patient has left the health care facility). Failure to

follow up on abnormal test results leads to delayed and missed diagnoses. These failures happen in approximately 7% of abnormal lab results and 8% of abnormal imaging results [10,11]. As indicated in the National Academies of Sciences, Engineering, and Medicine's Report—Improving Diagnosis in Health Care—diagnostic testing is a key part of the information gathering process within the diagnostic process [12]. Failure to follow up on key pieces of information gathered in this process (ie, abnormal test results) can lead to diagnosis and treatment delays [13,14]. To combat this problem, the health care system operated by the United States Department of Veterans Affairs (VA) requires that test results requiring no action to be communicated to patients within 14 days after availability and results requiring an action to be communicated within 7 days (based on Veterans Health Administration Directive 1088).

Missed follow-up of test results occurs due to several sociotechnical factors [15]; interventions to deliver feedback to improve test result follow-up also need to be sociotechnical [16]. We used participatory methods involving clinicians, including co-design workshops, to identify possible interventions to deliver feedback that could improve follow-up of test results in VA primary care.

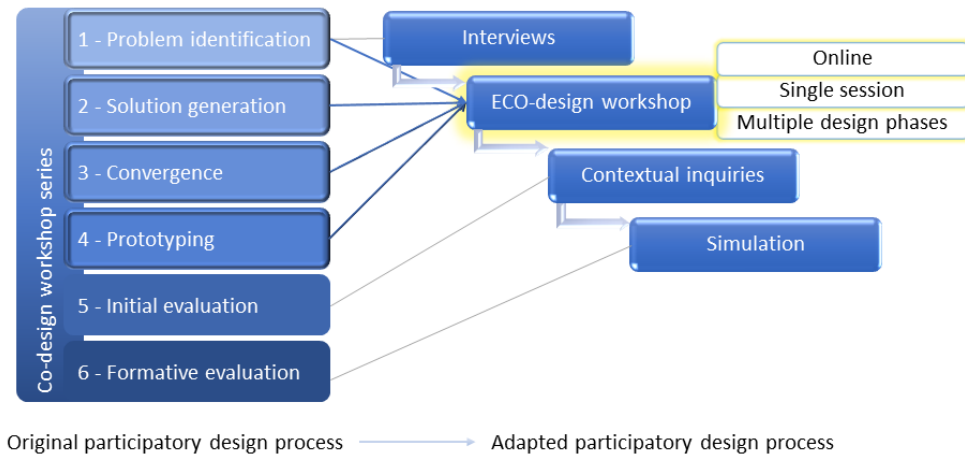
## Methods

### ECO-design Workshop

Our adaptations were intended to create an economical and electronic (ECO) version of traditional co-design workshops, allowing remote (ie, in their own ecosystem, minimizing the need for travel) and efficient (ie, brief, minimizing time burden) physician participation. Our ECO-design workshop can also be conceptualized as an eco-mode for traditional co-design workshops. We modeled our approach on Reddy et al's approach [2], which included clinician stakeholders (pharmacists) in the design of a health services intervention. Reddy et al's approach [2] included detailed descriptions of a co-design process with the following 6 steps: "(1) problem identification, (2) solution generation, (3) convergence, (4) prototyping, (5) initial evaluation, and (6) formative evaluation." We adapted this 6-step process (Figure 1) for distributed groups with limited availability for participation. Our process adaptations were driven by the COVID-19 pandemic's constraints on primary care clinicians. The most impacted aspect of Reddy et al's published design process [2] was the in-person co-design workshop. Their process involves 6 co-design workshops to be attended by all participants. Each workshop lasts about 2 hours, and workshops are expected to be scheduled 4-6 weeks apart to permit analysis of completed sessions and planning of future sessions [2]. During the pandemic, clinicians were less available to participate in any type of research activity that lasted more than an hour, nonessential travel was prohibited for clinicians and researchers, and there was a limit on the number of people in any given room, consistent with social distancing policies. Therefore, our adaptations to the co-design workshop were

needed to enable a large group of clinicians to participate in workshops lasting 1 hour or less.

**Figure 1.** Structure of an adapted co-design (ECO-design) process.



### Recruitment: Setting, Sampling, and Ethics

We used convenience sampling with an emphasis on homogeneity [17]. Participants were recruited from the primary care clinics of a large medical center in Southern Texas. Any clinician in this department was considered a possible participant. Recruitment was done via email, with assistance from a senior primary care clinician at the medical center. We offered each potential participant a medical textbook as an incentive. We were permitted to use a recurring meeting time, which was normally reserved for a department-wide journal club, for the co-design workshops. Because potential participants were already scheduled to attend this meeting of the journal club, we avoided adding to their daily loads. Participants indicated their consent to recording via spoken response to the facilitator.

### Ethics Approval

This study received expedited approval (protocol H-44363) by the Institutional Review Board at Baylor College of Medicine and the Research and Development Committee at Michael E DeBakey VA Medical Center.

### Logistics: Data Collection Methods, Instruments, and Technologies

#### Technology

The workshops were organized using the medical center's primary videoconferencing software—Microsoft Teams (Microsoft Corp). Microsoft Teams provided scheduling reminders (through the medical center's calendar software, Microsoft Outlook), included automatic log-in for participants on work-furnished devices, offered a method for sharing files via the chat space, and offered a method for recording audio and video from the workshops. Closed captioning and autotranscription were not available with this software at the time of the workshop. Participants were able to mute and unmute their cameras and microphones. Names of signed-in participants were displayed onscreen; phone numbers were shown for those who dialed in to the telephone bridge.

### Materials

We created an electronic workbook for the ECO-design workshops. The workbooks were emailed to participants before the workshops and posted in the chat during the session. The contents of the workbook (Multimedia Appendix 1, part A) were organized to align with the workshop agendas and contained writing prompts for each intervention type to support group activities. The workbooks were designed to capture participants' individual thoughts before engaging in group discussions. With the workbooks, participants were able to elaborate on ideas independently before, during, and after discussion. The chat function provided a secondary method for collecting participant contributions.

### Virtual Rooms

To minimize participants' time burden, the workshops took place during a regularly scheduled meeting time. We started the ECO-design workshops in one virtual room, where the topic and relevant background information related to the problem we were trying to solve was introduced (ie, failure to follow up on abnormal test results). When the workshops were conducted, Microsoft Teams' breakout room feature was new and potentially unfamiliar to some users and unavailable to others, so we emulated breakout rooms by creating 4 additional Microsoft Teams meetings and inviting participants to leave the main room and enter their assigned breakout room.

Participants in each room were asked to work on one of 3 feedback interventions we developed from the literature in the problem domain [18-22]. For purposes of our project, we labeled each of the 3 intervention types as follows: "social" (ie, a conversation guide for one's supervisor), "technical" (ie, an electronic data dashboard), and "sociotechnical" (ie, an email message or template). The separate rooms enabled focused exploration of all the intervention types simultaneously and encouraged participation within smaller groups [8].

### Research Team and Roles for the ECO-design Workshops

Workshops were facilitated by a multidisciplinary research team, whose members all held advanced degrees in relevant fields: DrPH in management, policy and community health

(US), PhD in cognitive psychology (ANDM), PhD in social work (TDG), PhD in industrial engineering with emphasis on human-computer interaction (AS), PhD in informatics (HP), and MPH in health promotion and health education (ADO). There were 9 team members in total, 2 per breakout room (eg, 1 facilitator and 1 notetaker) and 1 person assisting participants in the main room.

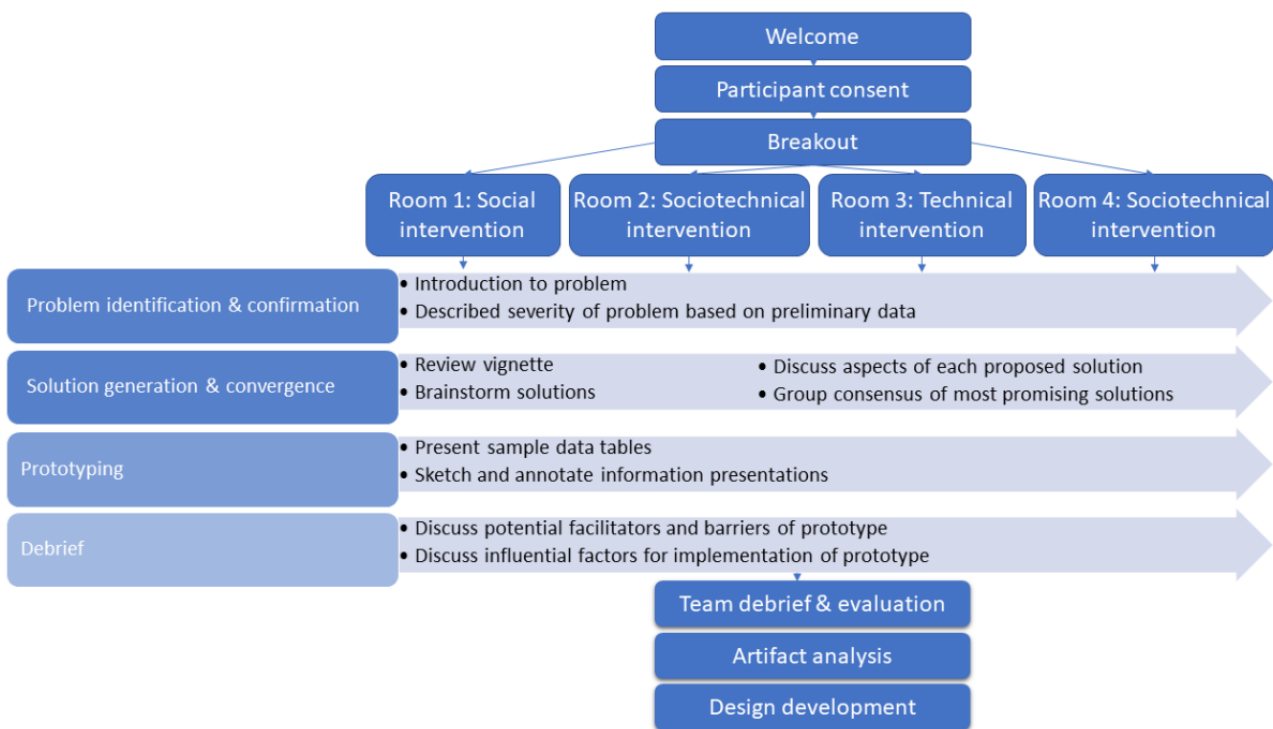
**Communication**

A group text message via team members’ cellular phones was critical to the success of the workshop because the technology did not support communication across breakout rooms. Text messaging was used to ensure the leads of each room completed all segments of their workshops in the allotted time.

Workshop segments (Figure 2) were timed as follows: welcome and consent (3 minutes), problem identification and confirmation (4 minutes), solution generation and convergence (13 minutes), prototyping (35 minutes), and debrief (5 minutes). During the workshops, facilitators read from an annotated slide deck (Multimedia Appendix 1, part B). Participants were encouraged

to turn on their cameras, but it was not required. First, one facilitator (AS) introduced the research team members, described the aims of the study, and the objective of the ECO-design workshops. Second, spoken consent was sought for recording audio and video from the main and breakout sessions. Third, from the list of attendees, we assigned participants to four workshops by surname. After posting hyperlinks to four breakout rooms in the chat window of Microsoft Teams, we instructed participants to enter the breakout session assigned to their surname. Each breakout session was assigned either the social, technical, or sociotechnical intervention. Each breakout session was facilitated by a coauthor with experience in research interviewing (AS, TDG, US, and HP). A second facilitator in each session began audio and screen recording, took notes, and monitored chat content. Both facilitators shared their screens at various points in the session to display notes and enable viewing, annotating, and manipulation of the prototype. Another team member stayed in the main room to help participants with technical issues and to prompt team members in each room regarding when to move on to the next topic or end the session (ANDM).

**Figure 2.** ECO-design procedure.



In each virtual room, the session started with the following prompt:

*Consider this: your supervisor walks into your office and says, “a number of your patients have abnormal test results with no documented follow-up. You will need to address these delays.” What is your initial reaction?*

Participants were asked to respond to this prompt in their workbooks. Next, participants were asked to design the subsequent interaction using an assigned mode (Figure 2; Table 1). One room was assigned to a dashboard visualization (facilitated by AS), another to a conversation guide (facilitated by TDG), and the remaining two to email template (facilitated by US and HP). The workbooks supported participation throughout the phases, steps, and tasks in the ECO-design workshops.

**Table 1.** ECO-design workshop tasks and complementary workbook prompts.

Workshop tasks	Workbook prompts
<b>Problem identification and confirmation</b>	
	<ul style="list-style-type: none"> <li>• What is your initial reaction?</li> <li>• What would be your response?</li> <li>• What would be the first thing you do after your supervisor left the room?</li> </ul>
<b>Solution generation and convergence</b>	
Conversation guide	<ul style="list-style-type: none"> <li>• How would you improve the conversation or supervisor dialogue?</li> <li>• How would you improve the conversation started in the scenario?<sup>a</sup></li> <li>• Discuss tone, language, and communication mode.<sup>a</sup></li> <li>• Who should be the one initiating the conversation?<sup>a</sup></li> <li>• What information would best support the conversation?<sup>a</sup></li> </ul>
Email template	<ul style="list-style-type: none"> <li>• What should be the subject?</li> <li>• What needs to be communicated in this text?</li> <li>• When should this email be sent?</li> <li>• Should anyone be CC'd?</li> <li>• What should be the subject?<sup>a</sup></li> <li>• What needs to be communicated in this text?<sup>a</sup> <ul style="list-style-type: none"> <li>• Tone</li> <li>• Links</li> <li>• Attachments</li> </ul> </li> <li>• When should this email be sent?<sup>a</sup></li> <li>• Messaging frequency.<sup>a</sup></li> </ul>
Dashboard prototype	<ul style="list-style-type: none"> <li>• If a dashboard existed, where would you expect to find it (ie, necessary navigation)?</li> <li>• How would you like to be notified of updates or new information?</li> <li>• Where would you like to see this dashboard?<sup>a</sup></li> <li>• How would you expect to navigate to it?<sup>a</sup></li> </ul>
<b>Prototyping</b>	
	<ul style="list-style-type: none"> <li>• How would this help you understand and address the problem?</li> <li>• How would you redesign this table?</li> <li>• How would this help you understand and address the problem?<sup>a</sup></li> <li>• What would be your first step or question after seeing these data?<sup>a</sup></li> <li>• How would you redesign this table?<sup>a</sup> <ul style="list-style-type: none"> <li>• Add</li> <li>• Delete</li> <li>• Rearrange</li> </ul> </li> <li>• What would be the most helpful time frame?<sup>a</sup></li> </ul>
<b>Debriefing</b>	
	<ul style="list-style-type: none"> <li>• How does this compare to existing performance data that are available to you?</li> <li>• How would you like to gain access to this type of data?<sup>a</sup></li> </ul>

<sup>a</sup>Optional prompts.

Then, while still within the breakout sessions, participants were asked to review the content of tables corresponding to a summary data presentation across many patients and data presentations for individual patients. We prepared these tables before the workshop. In both sections, participants were encouraged to add, remove, or reorganize the data to aid in understanding and facilitate appropriate action ([Multimedia Appendix 1](#), part C).

At the end of the workshop, participants were asked to send their completed workbooks either via Microsoft Teams to the breakout room facilitator or via email to the study coordinator. Finally, after being asked to share their completed workbooks with their facilitators, participants were dismissed. Recordings of the main workshop and breakout sessions were stopped here and processed using Microsoft Teams. Workbooks and recordings were stored securely on an access-controlled network file server.

### Workshop Evaluation and Analysis

A team debriefing session occurred 2 days after the ECO-design workshop. The meeting was held via Microsoft Teams for 1 hour. The agenda items included ideas for improvement regarding logistics (eg, what went well, how engaged the participants were, some weaknesses of the methods, and where we can refine the methods), major themes and ideas, debriefing details according to breakout room, initial thoughts about the data, and next steps for the team. Notes were taken during the meeting and shared with the research team.

## Results

### Participants

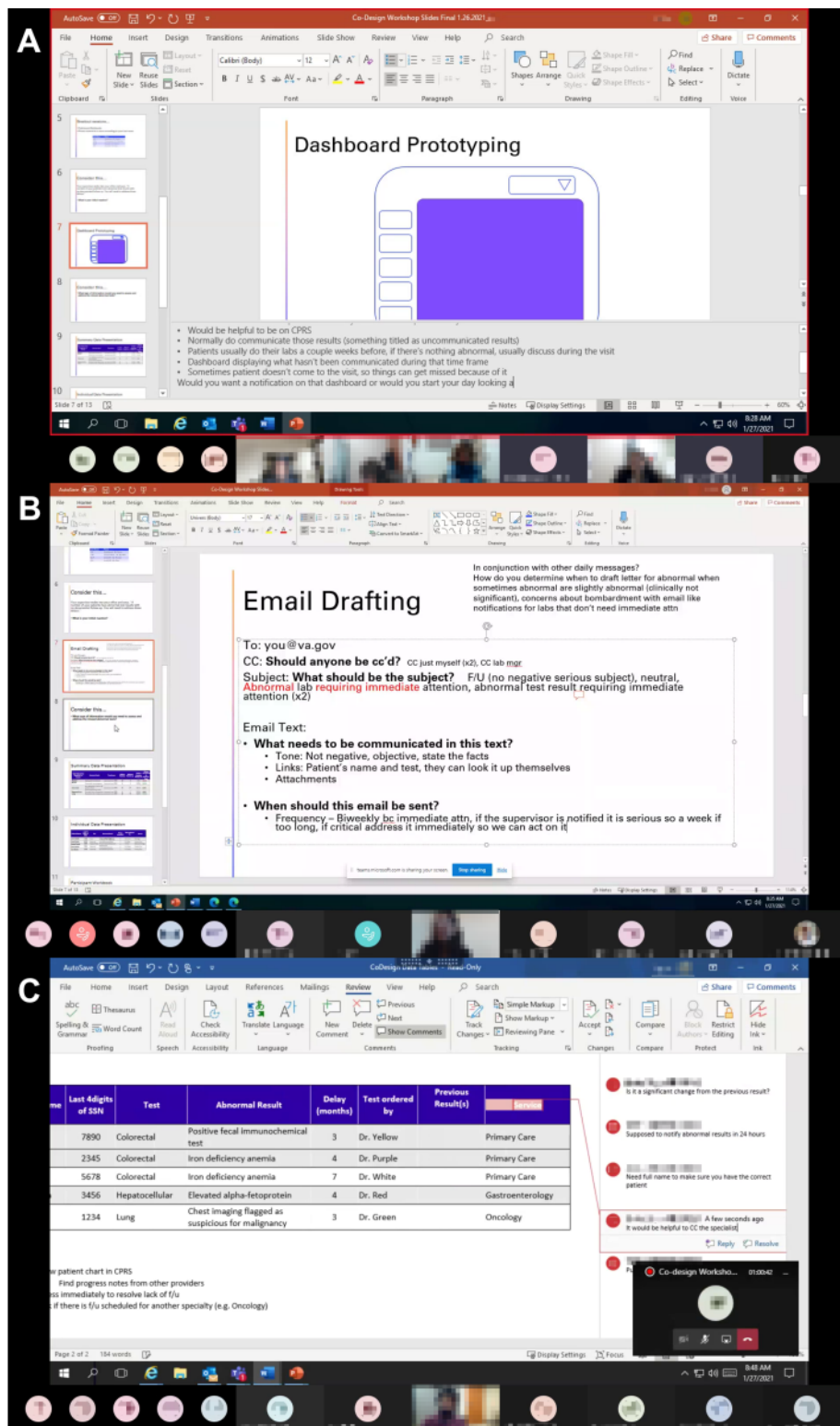
We were provided with the names of 49 people (of those, 1 was later identified as a nonclinician and was excluded). A total of

28 clinicians responded to our invitation, and all 28 attended the workshop. We assigned 8 people to the dashboard intervention workshop, 5 to the conversation guide intervention workshop (including the nonclinician), and 6 and 10 to the first and second email workshops, respectively. The workshops were conducted in January 2021.

### Outcomes

Figure 3 shows examples of ECO-design from the parallel workshops. Participants in the technical intervention workshop laid out a data dashboard (Figure 3A), while participants in one of the sociotechnical intervention workshops proposed the content of a supervisor's email message (Figure 3B). In the other sociotechnical intervention workshop, participants marked up tables indirectly through the second facilitator (Figure 3C).

**Figure 3.** Part A: ECO-design workshop participants lay out a technical intervention (data dashboard) to improve test-result management. Part B: workshop participants co-create a sociotechnical intervention (email message) to improve test-result management. Part C: workshop participants mark up a hypothetical table of unresolved results.



The ECO-design workshops provided data and artifacts similar to traditional co-design workshops. We were able to perform traditional analysis and next steps that led to the development of an empathy map (ie, a graphical description of clinician stakeholders). The workshops also informed user interface prototypes with varying fidelity levels. The sociotechnical intervention and social intervention workshops contributed to

high-fidelity prototypes of email and script templates. The technical intervention workshop attributed to a medium-fidelity prototype of a dashboard.

### Debriefing and Evaluation

We held a debriefing meeting after the ECO-design workshop. In the meeting, we discussed ideas for improvement in logistics, such as assigning a dedicated person to Microsoft Teams



troubleshooting, ensuring participants used the organization's current version of Microsoft Teams, helping participants join their assigned breakout room in a timely manner, and adding expedited introductions at the beginning of the workshop. Most participants did not use their cameras during the workshop, which we agreed should be addressed for the next workshop. However, no specific solution was reached during the debriefing meeting. Some participants were more active than others, whether speaking aloud or contributing to the chat or both. Finally, only 5 participants returned workbooks from the ECO-design workshops, with an average of 3.6 questions answered completely; therefore, finding a way to ensure completion and timely receipt of the workbooks is needed.

We identified several challenges related to facilitation. In traditional workshops, a brief introduction of all participants, optionally with an icebreaker activity, can help participants

build on each other's strengths. We omitted this step with regard to our time limit. However, most clinicians knew each other as coworkers. Moderating the sessions in a way where we ask individual participants about their thoughts and suggestions instead of waiting for the respondents to jump in and reply may encourage broader participation. We could not see whether participants were filling out the workbook as we were moving forward with the slides; future workshops should periodically remind participants to fill out their workbooks throughout the workshop. For the future, we plan to incorporate tools like digital whiteboards or live polling to verify or encourage individual and group participation.

### **Recommendations for Future ECO-design Workshops**

**Table 2** summarizes our observations and corresponding recommendations.

**Table 2.** Recommendations for implementing ECO-design workshops.

Workshop aspect or dimension	Observation or lesson (facilitator or barrier)	Recommendation
Recruitment and scheduling	<ul style="list-style-type: none"> <li>Breakout rooms allowed exploring ideas in parallel (facilitator).</li> <li>No travel required (facilitator).</li> <li>Reduced time burden on clinicians (facilitator).</li> <li>No peer introductions or icebreaker activities (barrier); acceptable if participants already know each other.</li> <li>Invitees via digital recruitment may not be from the desired stakeholder group, owing to outdated or missing information (barrier).</li> </ul>	<ul style="list-style-type: none"> <li>Take advantage of existing meetings; this will help with recruitment opportunities because adding another appointment to primary care clinicians' schedules will increase their workload.</li> <li>We advise group sizes of 5 for a small group to 10 for a large group.</li> <li>Have a plan for excusing excluded participants or removing their data afterward.</li> </ul>
Technology or videoconferencing software	<ul style="list-style-type: none"> <li>Flexible teleconferencing means some people can dial in (facilitator).</li> <li>Too many dial-in users or users with no camera or disabled cameras make it difficult to read the room, that is, assess nonverbal communication (barrier).</li> </ul>	<ul style="list-style-type: none"> <li>Use videoconferencing software with a breakout room feature.</li> <li>Explicitly encourage participation via video if participants are able to do so.</li> <li>Collaborative editing tools (eg, a digital whiteboard) should be integrated in the videoconferencing software.</li> <li>Games using these tools can foster interactive creation of solutions (eg, semantic environment [23]).</li> <li>Audio and video recording sessions; ensure software allows recording of breakout rooms in addition to the primary room.</li> </ul>
Facilitation	<ul style="list-style-type: none"> <li>Participants prompted or self-identified as experts or as having more experience to weigh in more at different points of the workshop (facilitator).</li> </ul>	<ul style="list-style-type: none"> <li>Assign at least three people to facilitate the session (moderator, notetaker, and technical facilitator).</li> </ul>
Time and activities	<ul style="list-style-type: none"> <li>Established relationship among participants that allowed us to save time on introductions (facilitator).</li> </ul>	<ul style="list-style-type: none"> <li>Allocate time in the co-design workshop to describe and confirm the problem only (the problem identification portion has potential to run long. Use other methods to define the problem before the co-design workshop).</li> <li>Participant and team debriefs are essential.</li> <li>Allow time for participants to evaluate the session (present participants with a short web-based survey or at least a rating scale with a section for free-text comments).</li> </ul>
Data collection	<ul style="list-style-type: none"> <li>More difficult to engage participants in completing workbooks or other tasks in online meetings (barrier).</li> </ul>	<ul style="list-style-type: none"> <li>Electronic workbooks can be used as a data collection tool.</li> <li>Collect workbooks before the end of the session whether they are finished or not. Most likely, participants will not have time to edit before or after the session. If they leave with the file, do not expect it to be sent later.</li> <li>Save the chat text, as it is a great source for data analysis.</li> </ul>

## Discussion

### Summary

This is one of the first published studies to explore a web-based participatory design with primary care clinicians. Having an effective approach to conducting design workshops in primary care is important in addressing ongoing primary care concerns and priorities, from care coordination delays to clinician burnout [24]. When the COVID-19 pandemic limited clinicians' participation in participatory design, we adapted traditional in-person co-design workshops to web-based delivery and

adapted co-design workshop series to fit within a single 1-hour session. Implementing the ECO-design workshop approach, clinicians codeveloped 3 different types of feedback interventions. Our results demonstrate the feasibility of ECO-design workshops and describe fundamental considerations for future ECO-design workshops with clinicians.

### Lessons Learned

Similar to web-based participatory design series conducted in other contexts or domains (eg, [8,25]), we found advantages, disadvantages, and opportunities for improvement related to recruitment, software, and facilitation. Some of our findings

were tied to specific workshops or interventions, while other findings were more universally applicable. In addition, working with clinicians invoked considerations that are unique to the health care context.

The ECO-design format may attract more participants. Recruitment may have been aided by the ease of accepting invitations to online meetings. Due to policies at the health care institution, the incentives offered to clinicians were limited and not enticing, even for the condensed online workshop. We could offer books but not money or food. Alternatives should be considered. During the workshops, we noticed varying impacts of technology, intervention, and clinician characteristics on participation.

The participants' ability to maneuver, edit, or manifest prototype ideas easily is essential. Our web-based platform was more challenging for clinicians than expected and was a major trade-off that needs to be considered for future ECO-design workshops. Adding collaborative software to the workshop would have provided more opportunities for participants to manipulate the prototypes. However, there were potential disadvantages, including additional costs, learning curve or familiarity with new software, and increased window switching among software programs. In the health care context, additional safety considerations include information security and related approvals for software due to privacy concerns.

Among the workshops and intervention types, participation and facilitation differed. In the technical (ie, dashboard) and sociotechnical (ie, email template) intervention workshops, we witnessed the most active participation. Despite limitations with the software, it appeared that the direct manipulation of onscreen elements encouraged participation. In contrast, we observed lower participation or engagement in the social (ie, conversation guide) intervention workshop, which may have been the most emotionally evocative. Clinicians discussed similarities to other difficult professional conversations. We were unable to determine the location or physical environments (eg, home office, team workroom, or clinic) of participants. Even if the meetings are online, it is important that participants are in safe, trusted physical and virtual environments to better support these types of activities.

Lastly, we found that a group of 10 participants was too large for small group discussions and activities, especially for a 1-hour session. There was not enough time to give everyone a chance to comment (albeit some participants preferred not to comment). Given the ease of being able to log in and only observe, engagement levels in online meetings might be decreased compared to traditional formats across contexts. Clinician participation varied as expected. Although some clinicians spoke dominantly, others used the chat functionality to contribute to the workshop. Established relationships and knowledge of expertise among clinicians aided facilitation, as participants explicitly asked particular colleagues to speak up on certain topics.

Overall, ECO-design workshops demonstrated an economical alternative to traditional co-design workshops. Specifically, we

were able to minimize physician time burdens and travel costs for both participants and researchers. To maximize the level of engagement and manipulation of low-tech or physical tools, traditional co-design workshops may still be preferred when participants are colocated and technology is limited. Nonetheless, ECO-design workshops could serve as a complementary approach to traditional co-design workshops. Therefore, we recommend ECO-design or hybrid co-design workshops for the added benefit and cost-effectiveness (including time cost) of participants from multiple sites and institutions.

### Limitations and Future Work

All participants were from a single site of a single health care institution and were members of the same journal club. Although the use of the journal club enabled the workshops to occur without adding additional meetings to primary care clinicians' schedules, this potentially introduced selection bias. For the next phase of our participatory design process, we will include primary care clinicians from other sites. Moreover, some people participated more than others in our workshops; this, however, is likely to happen in traditional co-design workshops as well and should be addressed similarly (ie, by asking questions of the quieter individuals throughout the meeting). Future workshops may include gamification to increase participation. It can be hard to motivate participation from everyone, and some may not be attending fully to the workshop because of multitasking.

We tested only one videoconferencing software platform. Other software that may have been helpful in group or collaborative editing (eg, a digital whiteboard) was not yet available in the organization or would have incurred additional costs. Future studies could conduct ECO-design workshops with other videoconferencing software and compare outcomes and experiences.

During the COVID-19 pandemic, certain aspects of traditional research design were not feasible. Pandemic restrictions and increased clinician workload prohibited additional data collection or evaluation (eg, comparative evaluation with a traditional workshop or postworkshop participant surveys). Future studies should implement the aforementioned aspects to inform the next iteration of ECO-design workshops.

### Conclusions

The ECO-design workshop enabled primary care clinicians to participate in the design process of multiple types of interventions for obtaining feedback about test result management. Our adaptations provided data and artifacts that supported a participatory design process within the amplified time constraints of primary care clinicians and safety protocols imposed by the COVID-19 pandemic. From our adapted co-design workshop, we were able to develop a prototype for each intervention type. Therefore, the ECO-design workshop is a feasible alternative to traditional in-person co-design workshops.

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## Authors' Contributions

AS, TDG, and ANDM proposed the study, and AS was its guarantor. AS and HP drafted the manuscript with critical input from TDG, US, ADO, ANDM, and HS. AS, TDG, US, HP, ADO, and ANDM facilitated the workshops. US analyzed workshop recordings.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Workbook, workshop script, and data tables for discussion.

[[DOCX File, 30 KB - humanfactors\\_v9i3e37313\\_app1.docx](#)]

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## Abbreviations

**HSR&D:** Health Services Research and Development

**VA:** Department of Veterans Affairs

**VHA:** Veterans Health Administration

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Original Paper

# Acceptability of an In-home Multimodal Sensor Platform for Parkinson Disease: Nonrandomized Qualitative Study

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## Abstract

**Background:** Parkinson disease (PD) symptoms are complex, gradually progressive, and fluctuate hour by hour. Home-based technological sensors are being investigated to measure symptoms and track disease progression. A smart home sensor platform, with cameras and wearable devices, could be a useful tool to use to get a fuller picture of what someone's symptoms are like. High-resolution video can capture the ground truth of symptoms and activities. There is a paucity of information about the acceptability of such sensors in PD.

**Objective:** The primary objective of our study was to explore the acceptability of living with a multimodal sensor platform in a naturalistic setting in PD. Two subobjectives are to identify any suggested limitations and to explore the sensors' impact on participant behaviors.

**Methods:** A qualitative study was conducted with an inductive approach using semistructured interviews with a cohort of PD and control participants who lived freely for several days in a home-like environment while continuously being sensed.

**Results:** This study of 24 participants (12 with PD) found that it is broadly acceptable to use multimodal sensors including wrist-worn wearables, cameras, and other ambient sensors passively in free-living in PD. The sensor that was found to be the least acceptable was the wearable device. Suggested limitations on the platform for home deployment included camera-free time and space. Behavior changes were noted by the study participants, which may have related to being passively sensed. Recording high-resolution video in the home setting for limited periods of time was felt to be acceptable to all participants.

**Conclusions:** The results broaden the knowledge of what types of sensors are acceptable for use in research in PD and what potential limitations on these sensors should be considered in future work. The participants' reported behavior change in this study should inform future similar research design to take this factor into account. Collaborative research study design, involving people living with PD at every stage, is important to ensure that the technology is acceptable and that the data outcomes produced are ecologically valid and accurate.

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**KEYWORDS**

sensor; Parkinson disease; wearables; cameras; acceptability; smart home; behavior change; multimodal home-based; qualitative

## Introduction

### Background

Parkinson disease (PD) is a slowly progressive neurodegenerative disease that leads to multiple potential movement-related and non-movement-related symptoms, such as muscle rigidity, slowness of movement, tremors, and sleep disturbance [1].

PD symptom progression is currently measured using clinical rating scales [2], which have flaws, including a *snapshot* nature that misses the hour-by-hour fluctuations of PD symptoms and a suboptimal capture of in-home symptoms that differ from those in the clinic [3-5]. Recent work has focused on continuous, longitudinal *passive* (not requiring any active input from the participant) monitoring with technological sensors to produce very frequent objective measurements of specific parameters (eg, gait and tremor). Digital sensors have the potential to measure PD movement-related symptom fluctuations and, potentially, disease progression while a person lives their life freely without external intervention (*free-living*). However, the acceptability (the extent to which the target population considers an intervention to be appropriate based on their cognitive and emotional responses to it [6]) of various types of passive technological sensors for free-living at home has not been widely explored in PD.

### Prior Work

#### *Passive Sensors*

Ideally, any outcomes being measured by technological devices would be clinically relevant, associated with health-related quality of life [7], and developed in collaboration with the patient population under study [8,9]. We have limited knowledge about the perspectives of people with PD regarding the acceptability of multimodal sensors, including cameras, in the home environment.

Wearable devices (devices equipped with sensors used to measure, process, or analyze health indicators from the person wearing them [10]) have received significant research interest in the study of PD [11-14]. Worldwide, multiple groups have used wearables to detect symptoms of PD, such as bradykinesia and dyskinesia, in a free-living setting [15-17]. They can be worn on different locations on the body, including the wrist, lower back, and lower limbs.

Thus far, the development of wearables to measure PD symptoms has largely focused on the ability of devices to measure symptoms, with relatively few quantitative or qualitative studies exploring the acceptability of the devices [18-21]. Qualitative research methodology, such as the use of interviews or focus groups, can complement other types of intervention development work such as pilot studies [22] by allowing opportunities for a deeper understanding of factors that could impede or facilitate the implementation of an intervention. Acceptability work examining wearables has found that they are acceptable for periods of several days to a few weeks [23], especially if study participants perceive that they will benefit from the provided results [24] or if there is a high

caregiver burden associated with their PD [25]. However, one of the groups used questionnaires with free-text responses to explore the experience of 1 week of bilateral wrist-worn wearables at home and found that comfort and wearability decreased over this period [26]. Compliance with wearable device use over periods of several months can be relatively high [23,27]; however, concerns have been raised through qualitative work that social acceptability [18,19] and issues with usability [20] are barriers to wearable sensor use in PD. AlMahadin et al [21] conducted semistructured interviews followed by focus groups with people with PD (who had not been required to have experience in wearable research) to scope the patient perspectives related to the preferences and requirements of wearable device design. They found that the body location felt to be most acceptable for wearable use over longer periods was the wrist and that the participants did not have concerns related to the device visibility or data privacy [21]. The mentioned studies examined various aspects of wearable acceptability in PD; however, this study is unique in that it examines the acceptability (through qualitative work or otherwise) of wearables alongside other sensors at home in PD.

In addition to wearables, other sensors such as cameras can be used to quantify PD symptom parameters. Video data, processed in such a way as to reduce identifiability (eg, Open Pose [28]), have been used to measure symptoms such as resting tremor, finger tapping [29], and sit-to-stand [30]. Many people with PD already have passive smart home-type technologies in their homes [31]. Cameras and other sensor modalities can be used in multiple heterogeneous sensor systems (described for the purposes of this paper as *multimodal* sensor platforms, meaning multiple different types of sensors) providing data from various sources in a range of formats. Multimodal sensing has been shown to be more accurate in distinguishing between PD and control based on common activities of daily living [32,33] than unimodal sensing, which has been used to distinguish different severities of PD [34], predict medication status [35], and detect symptoms such as freezing of gait [36]. Multimodal sensor platforms are also being increasingly used to detect and quantify activities of daily living in-home settings [37]. Given these uses, multimodal sensing presents an opportunity to better understand how the multiple fluctuating symptoms of PD interact with the (at times, complex [38]) daily life in PD compared with unimodal sensing. However, there is an as of yet unmet need for studies exploring how participants with PD feel about living with privacy-preserving cameras or multimodal sensor platforms in their daily lives.

Our group developed a multimodal sensor platform using (1) *ambient sensors* (embedded in the environment) such as appliance sensors, mains electricity use detection, water pipe use quantification, environmental sensors detecting humidity and temperature, and others (Figure 1 shows the device layout in the study setting, and Table 1 shows the details of sensor capabilities); (2) wearable devices; and (3) cameras producing privacy-preserving video data. By *privacy preserving*, for the purposes of this paper, we imply a privacy-enhancing silhouette-based obfuscation method [39] for preprocessing video data to reduce identifiability. The platform of relatively inexpensive multimodal sensors can be scaled to multiple homes.



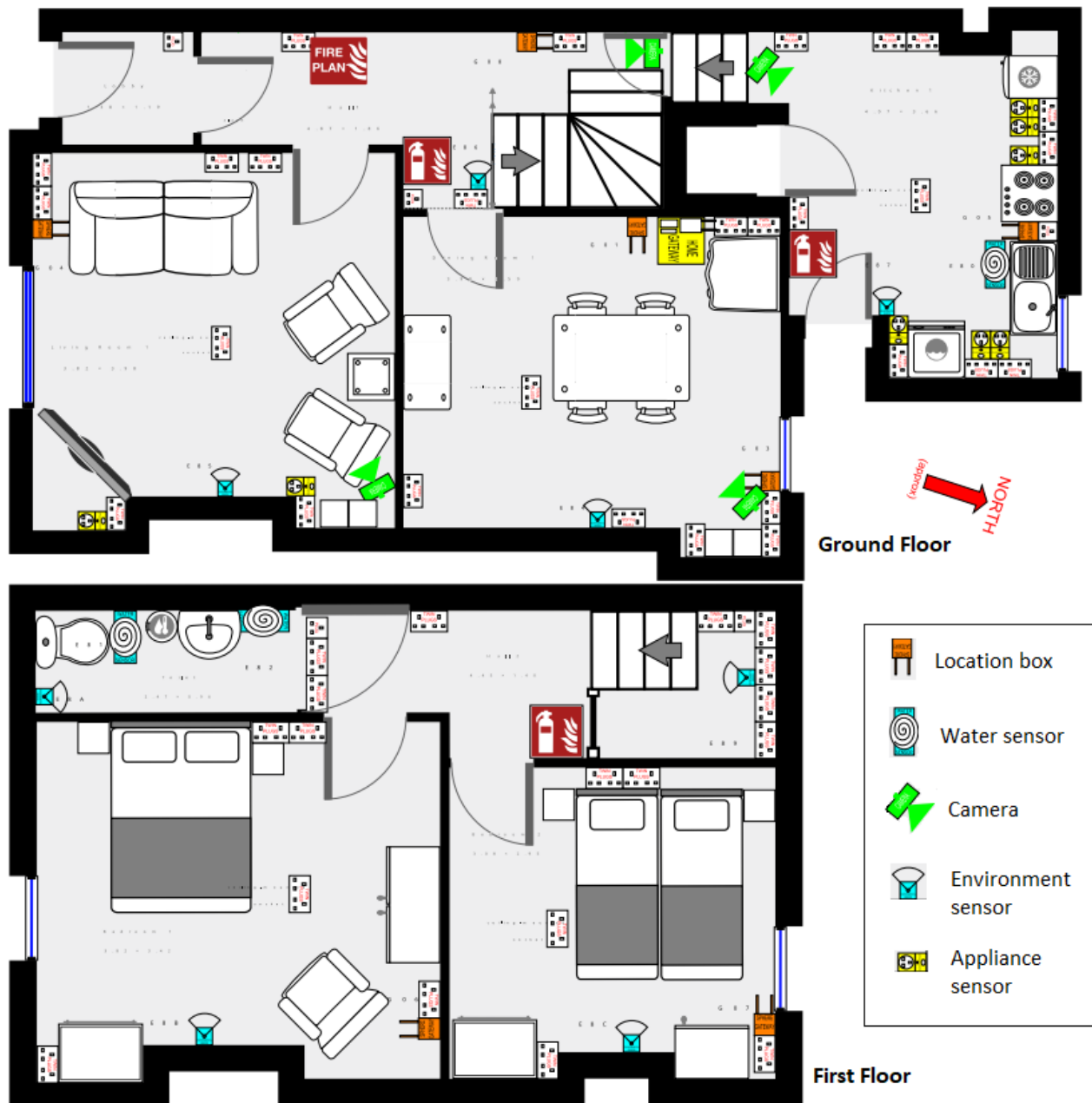
Its use has been found to be acceptable in the general population [40] and in specific medical conditions [41]; however, no work has been conducted to investigate acceptability in PD. Exploring multimodal sensor acceptability could deepen our understanding of how people with PD interact more widely with technology [42].

Living with new technology may lead to conscious or subconscious adjustments in users' behaviors or activities [43];

however, currently, there are few studies investigating this in PD, with a limited number of studies focusing on specific aspects, such as the wearables' impact on daily activities [18].

Understanding the impact of a multimodal sensor platform on the behavior and lives of people with PD can help design such platforms that limit sensor-derived behavior changes to enable accurate measurement of symptoms and activities in one's own home.

Figure 1. Sensor layout in the study setting.



**Table 1.** Sensors used in this study and their sensing capabilities.

Sensor	Sensing capabilities	Details of placement
Wearable (triaxial accelerometer)	<ul style="list-style-type: none"> <li>• Movement</li> <li>• Indoor localization</li> </ul>	One worn on each wrist
Received Signal Strength Indicator sensors	<ul style="list-style-type: none"> <li>• Movement</li> <li>• Indoor localization</li> </ul>	On walls usually behind furniture
Privacy-preserving video cameras	<ul style="list-style-type: none"> <li>• Silhouette outline</li> <li>• 2D and 3D bounding boxes around participant</li> </ul>	On walls of downstairs communal rooms above the eye level
Environmental sensors	<ul style="list-style-type: none"> <li>• Humidity</li> <li>• Temperature</li> <li>• Light</li> <li>• Pressure</li> </ul>	On walls above the eye level
Passive infrared sensors	<ul style="list-style-type: none"> <li>• Detecting movement</li> </ul>	On walls above the eye level
Appliance sensors	<ul style="list-style-type: none"> <li>• Use of kettle, toaster, television, washing machine, refrigerator, and microwave</li> </ul>	Attached to appliance plug and plugged into an electrical socket
Main electricity use sensor	<ul style="list-style-type: none"> <li>• Use of mains electricity</li> </ul>	Attached to an electricity meter
Mechanical flow sensors	<ul style="list-style-type: none"> <li>• Use of toilet and taps in bathrooms</li> </ul>	Attached to water pipes inside cupboards

### High-Resolution Video

High-resolution video data can be used to add additional objective evidence about a symptom at the time when another passive sensor is collecting data, evidence that is called *ground truth*. Understanding how someone experiences high-resolution video capture, including how it may alter behavior, could inform design choices in future ground-truthing work for PD. There is some evidence of positive attitudes toward high-resolution video capture at home in PD, where examples of cameras that could be used were discussed [44]; however, minimal further acceptability studies have been conducted with patients with PD who have directly experienced free-living high-resolution video recording.

### Goals of This Study

In this study, a cohort of participants with PD and healthy volunteer controls stayed in a home-like setting equipped with a multimodal sensor platform (described previously). Throughout their stay, they were passively sensed by the sensor platform. The ground truth was obtained at prespecified and limited times using high-resolution video cameras. The participants mostly lived freely during this time. We then explored this experience in depth using interviews and set the comments in the context of the participants' prestudy attitudes toward technology, as well as their age, disease stage, and other characteristics.

The primary objective of this study was to explore the acceptability of in-home multimodal passive sensors, as well as intermittent high-resolution video data capture, in people living with PD.

Two further subobjectives were as follows: (1) to identify any proposed limitations, controls, or other suggested alterations to the multimodal sensor platform, with a focus on PD; and (2) to

specifically identify any self-reported behavior changes resulting from the use of technological sensors in this study.

## Methods

### Setting

A fully furnished 2-bedroom terraced house was embedded with a wide range of passive and unobtrusive sensors (described in Table 1). The wrist-worn wearables used in the sensor platform comprised a triaxial accelerometer with a medium-width strap made from blue- or yellow-colored silicone rubber and a pin buckle clasp, and one device was worn on each wrist. The participants wore a second device on each wrist as part of the research team's collaboration with IXICO, a UK-based imaging and digital biomarker analysis company. However, for this qualitative work, only the impact of our group's colored devices was explored. The other sensors were mounted statically (eg, on walls), with no interaction required between the participant and these devices. The cameras were wall mounted above the eye level in each of the 4 communal rooms in the house: kitchen, hall, dining room, and living room. This house has been used in many previous studies involving human participants.

Participants were recruited to live freely in this house for a period of 5 days and 4 nights while they were passively sensed. They were able to come and go from the house and continue their activities of daily living. Between 1 and 3 prearranged hours per day, high-resolution video data were recorded from the communal rooms of the house. They were visited by a researcher on only 1 occasion between arrival and departure (apart from the 2 pairs who were visited twice for technical reasons). The study data were collected between October 2020 and June 2021; during this time, several COVID-19-related national lockdowns took place in the United Kingdom, and thus,

in some cases, participants were obliged to spend almost all their time in the house.

The participants were given an electronic tablet device that they could use to pause sensor data collection temporarily or permanently or delete data already collected.

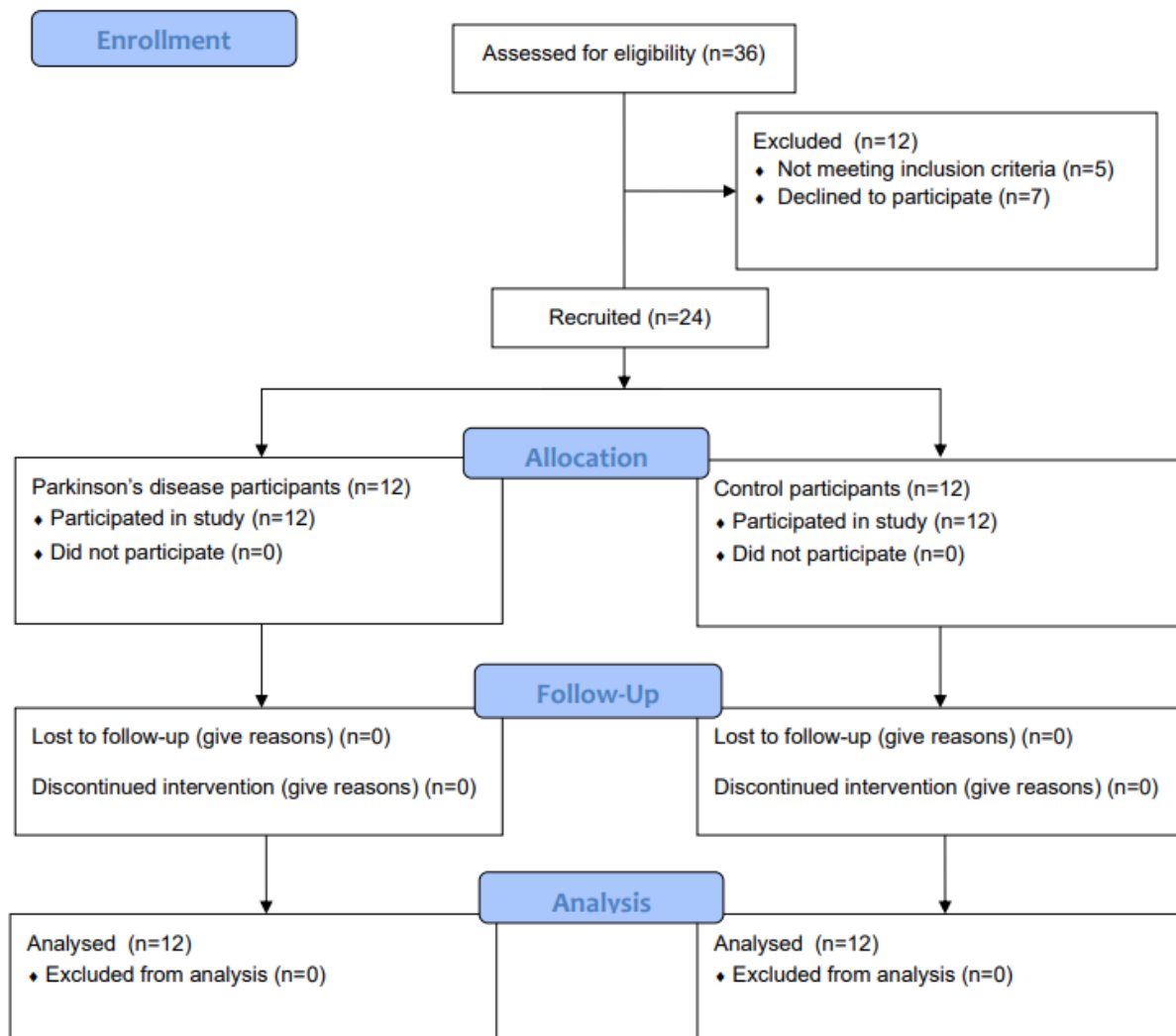
Written information was provided to each participant before the study data collection, detailing what the study would involve, which sensors would be used, and what they measured. The participants had at least two telephone or video-conferencing calls with a researcher before participation, during which they had the opportunity to ask questions and discuss their thoughts.

### Participants

A total of 24 participants were recruited, 12 (50%) with PD and 12 (50%) healthy volunteer controls (called *control participants* for the purposes of this paper). The CONSORT (Consolidated Standards of Reporting Trials) flow diagram of participant recruitment and attrition is shown in Figure 2.

The participants stayed in pairs in the house, and thus, data were collected from 12 separate 5-day periods. Participants were recruited through convenience sampling, Movement Disorders clinics in the participating National Health Service Trust, our partner charity Cure Parkinson’s, our local Movement Disorders patient and public involvement group, or word of mouth. Written consent was provided by all participants.

Figure 2. CONSORT (Consolidated Standards of Reporting Trials) flow diagram of study recruitment and attrition.



### Data Collection

Sensor data were collected continuously (or episodically for high-resolution video data), as described previously.

Semistructured interviews were conducted by a single researcher (CM [MD], a female neurology specialty registrar trained in qualitative interview methodology) in the house on the final day of the study. The participants met and spent time with the researcher on at least two separate occasions before the interview

and once in person. They were aware of the research goals of the study and the aim of the interviews. All participants reported that they were comfortable participating in the interviews in their pairs. The interviews lasted between 25 and 56 minutes. The interview topic guide is shown in Textbox 1 and was discussed with the participants before the interviews commenced. Interviews were recorded on a secure encrypted audio-recording device and transcribed verbatim post hoc

(transcripts not returned to participants), with field notes made during the interview by the researcher.

**Textbox 1.** Interview topic guide.

1. Experience of staying in the study setting
2. Thoughts about the sensors and sensor platform
3. Discussion of the high-resolution video camera data collection
4. Thoughts about the data collected
5. Specific focus on Parkinson disease and the discussion around the sensors in relation to Parkinson disease

A total of 3 subscales of the Media Technology Usage and Attitudes Scale [45] were completed by all participants to better understand how they viewed sensors and technology in their own lives. These subscales included 12 questions related to Positive Attitudes Toward Technology (6 items), Anxiety About Being Without Technology or Dependence on Technology (3 items), and Negative Attitudes Toward Technology (3 items). Each item, listed in [Multimedia Appendix 1](#), comprised a statement scored using a 5-point Likert scale: 5=strongly agree, 4=agree, 3=neither agree nor disagree, 2=disagree, and 1=strongly disagree.

This tool was designed to measure media and technology involvement across a variety of research studies, either as a whole scale or using any subset of the 15 subscales.

### Data Analysis

The audio recordings were listened to multiple times to familiarize ourselves with the data. The transcripts were open coded systematically line by line by CM (using NVivo [QSR International] software [46]) following a flexible and inductive methodological approach. The open codes were reviewed and refined and then grouped into subcategories, which were subsequently grouped into themes without a preexisting coding framework [47,48]. The themes were then reviewed and refined by splitting, combining, and examining the relationships between themes. The final themes were reviewed and agreed upon with a second researcher.

The participants were allocated a study identification for this study according to whether they had PD (*PWP*) or were a control (*C*) participant, alongside a number for their pair, randomly selected from 1 to 12. For example, a person from pair 3 with PD was coded as *PWP3*.

### Philosophical Approach

This study sought to understand participants' opinions on the sensor platform's acceptability, recognizing that the results were best understood when set in the participants' social and experiential contexts. This relativist ontological stance [49] was chosen to reflect the research team's belief in the subjectivity of reality—that each participant may experience the sensor platform differently and that this experience is best understood by considering contextual factors such as their prior attitudes toward technology and demographics such as age and severity stage of PD (or status as a control volunteer).

Furthermore, to explore the subjective reality experienced by the participants, an interpretivist epistemological approach [50] was used to prioritize the research goal of understanding what

the individuals' views were over an explanation of why they were expressed. The interviews followed a loose topic guide; open-ended questions with no right or wrong answers were used to initiate discussions around the chosen topics ([Textbox 1](#)). This approach to the interviews was designed to create an interactive relationship between the researcher and participant, where the multiple potential realities of their experience were explored to produce a detailed, rich, and complex data set. The interview design, combined with the iterative inductive data analysis approach [47] described previously, also aimed to enhance the validity of the data by exploring individuals' opinions as opposed to solely focusing on what was general and average in the cohort. However, in addition to this individual-level approach [51], some cohort-level quantitative results were produced to illustrate comparative themes and patterns for the reader.

The trustworthiness [52] of this research was carefully considered. Credibility was promoted using interviews of substantial length, where persistent observation from the researcher aimed to deeply prove opinions. Some direct quotes were checked with individual participants to determine the accuracy of their content. In addition, debriefing questions after study participation were designed to triangulate the findings of the interviews using sources collected at different times and in different settings (study setting and participants' homes) from each participant. This source triangulation of qualitative data, along with the complementary quantitative study results, aimed to reduce individual researcher bias. The collection of demographic and questionnaire data as part of the detailed description of individual participants could enhance the applicability of the study findings to other contexts [53].

### Ethics Approval

Ethics approval was granted by the National Health Service Wales Research Ethics Committee 6 on December 17, 2019, and approval from the Health Research Authority and Health and Care Research Wales was confirmed on January 14, 2020 (reference 19/WA/0051).

Participation in this study was voluntary; participants had the right to withdraw at any stage without the decision affecting their medical care or legal rights. Participants gave informed consent to participate, explicitly agreeing to participate in study interviews that were audio recorded and to the publication of anonymous quotations. Each participant was anonymized by being assigned a unique study identification number, and all directly identifying details were removed from the interview scripts. Data were held securely and processed in line with the

General Data Protection Regulation. To avoid issues related to undue influence from one person in the pair toward the other, a separate or joint interview choice was offered.

## Results

### Participant Demographics

The 24 participants were divided into 9 heterosexual spousal pairs (n=18, 75%), 1 pair of close friends (n=2, 8%), and 2 parent-child pairs (n=4, 17%). Each pair comprised 1 participant with mild to moderate PD and 1 healthy volunteer control participant (participant demographics are included in [Multimedia Appendix 2](#)). All participants were of White British ethnicity. The cohort with PD had a mean age of 61 years, with the control cohort's mean age being 59 years. The mean number of years since the PD diagnosis in the cohort with PD was 8.4 years.

[Multimedia Appendix 3](#) demonstrates the participants' scores on the Media Technology Usage and Attitudes Scale subscale on attitudes; the relevant subscale questions are illustrated in [Multimedia Appendix 1](#).

### Acceptability

#### Privacy-Preserving Cameras

There was a universal sense from the participants that, with informed consent, the collection of privacy-preserving video data from the communal rooms in this setting was acceptable. Indeed, there was a general feeling, articulated by PWP4, that the privacy-preserving video data crossed an acceptability threshold (compared with high-resolution video) for collection in more private rooms:

*I wouldn't mind something monitoring my silhouette in that [the bedroom], but you wouldn't want color cameras on in the bedroom. I think it's making sure that it's not too intrusive.*

Sensor acclimatization occurred relatively quickly according to all participants. PWP2 felt "the first day you are more cautious...but within hours you get used to them"; however, for C2 it was "literally five or ten minutes until you get used to it."

#### Wearables

Overall, the (wrist-worn) wearables were the least acceptable of all the sensors, both in terms of the frequency of issues mentioned by the participants and the noted intrusiveness on free-living. PWP10 mentioned the following:

*The only ones [sensors] I was aware of were the ones on my wrist. I, kind of, never even gave the other ones a second thought.*

PWP6 went further to say the following:

*If there was a system that I didn't have to do that [wear wearables], that would be better, but, yeah, because the data you're collecting is important, then, yeah, I would.*

In relation to PD symptoms, there were concerns about wearable usability and comfort issues, for example, related to sensitive skin:

*I can imagine putting on the wearables when you've got the shakes would be a complete nightmare.* [PWP7]

*Put the blue one on too tight, and I woke up with an itchy rash.* [PWP8]

The participants felt that it would be helpful for them to choose their own strap and device to suit their preferences.

There were mixed feelings about how the wearable devices made the participants feel psychologically. C3 noted the following:

*I don't know how I would've felt outside [wearing the wearables]. I think, personally, I would've covered them over."*

It was noted that improved aesthetics would be likely to encourage compliance. However, others did not find wearable aesthetics an issue:

*I went out in a short-sleeved dress at one point and it just didn't bother me.* [C1]

Interestingly, PWP5 felt that the wrist-worn wearables empowered him and that he "felt like James Bond." He said that if someone asked him about the wearables, he would "put some story to it"; he actively enjoyed the sense of feeling different from others by wearing devices for research.

How people outside the study viewed the wearables and their impact on the participants were discussed. PWP8 said that in a regular group she attended, she "had to pull my sleeve up and show them what I'd got on my wrist." However, the idea of worrying about what others thought of the research wearables had not occurred to PWP3:

*I've got a lot more other things that I'd be more worried about showing someone rather than the wearables.*

Multiple participants commented on their experience of wearing the wearables overnight. There were anxieties from 8% (2/24) of participants about the fit of the wearables affecting the data's usefulness. PWP2 was concerned that one of her wearables had "slipped around and was facing down, practically all night I guess," and thus, the data may be inaccurate. For some, the wearables themselves disturbed sleep "when you're turning, because you're trying to find a way of being comfortable, then the wearables are more noticeable." However, for some, the wearables at night were more tolerable than they had anticipated:

*I thought they would really annoy me...but it didn't.* [PWP7]

#### Other Ambient Sensors (Environmental, Appliance, Mains Electricity, Water Pipe, and Passive Infrared)

These sensors were universally found to be acceptable in the context of the study, and all participants anticipated that they could live with these sensors for several months in their own homes. C7 articulated this by saying "I mean, we looked at them when we came in, and thought, 'Oh, that's where they all are,' and carried on."

### Whole Sensor Platform

Approximately 96% (23/24) of the participants found the sensor platform acceptable to live with and would be happy for it to be deployed to their own homes for long periods of up to a year.

The one participant who was uncomfortable with the idea of sensor deployment to his own home, PWP11, had quiescent but long-standing obsessive-compulsive disorder before entering the study, which was reactivated around the time of participation. He felt that completing the diaries and being sensed by technological devices reminded him that he had PD. He said the following:

*I think what is not a problem for a few days or for a week would be a different kettle of fish if you were looking at weeks or months on end. And, also, well, it would be a strange feeling to know that your decline into illness is being charted on an ongoing basis. Sometimes it's good not to dwell on it, not to be too—not to get obsessed about your own health.*

However, he also emphasized the importance of appropriate informed consent before deployment:

*If you make it clear what's on the menu, then people can opt in on that.*

He also acknowledged the conflict between data impact and research benefit and his discomfort related to the sensors:

*Well, it's balancing its usefulness against its intrusion, isn't it?*

### Privacy

Approximately 96% (23/24) of the participants stated that they had no significant privacy concerns about the passive sensor data, and the overwhelming response was expressed by PWP10, who said the following:

*It comes down to if it's helpful and useful, then it's in my own best interests, isn't it, you know, to say, "Do with it as you wish."*

The reasoning behind this broad acceptance of privacy risks was varied. PWP3 felt that "Me getting out of bed and getting dressed as a silhouette wouldn't be interesting to anybody anyway." PWP11 noted that personal data was collected in other circumstances with more limited consent than in this study:

*In terms of personal information, you can walk down any street in city A and you've got CCTV recording your movements without asking your permission and digging a lot less anonymous data out.*

PWP12 made the point that he perceived that the sensor data of the nature collected in this study would be difficult to use in a negative way against the participants, in contrast to, for example, genetic profiling and the impact on insurance premiums:

*I think it's completely different than DNA or blood types, or...I think, now, if you could connect those two together, then that might be more of a problem.*

However, one of the participants (C3) expressed concerns about video data getting into the wrong hands and being disseminated via the internet:

*The only problem is that, and it's me being neurotic, I suppose, the fact that you hear all these things on the internet, people putting videos, and things, on the internet, and I know they're [directly-identifiable study data] not on the internet, and I know they're secure, and all this, but that's always been in the back of my mind.*

### Intermittent High-Resolution Video Data Capture

When directly questioned, all participants found the high-resolution video data acceptable during this study. Before participation, some participants were nervous about it:

*We heard about the cameras, and we weren't quite sure how intrusive they would be. So, we probably were more guarded than we are now, you know, we're more at ease now [having finished the study]. [PWP6]*

However, PWP12 noted that they found the high-resolution video recording "less intrusive than I thought it was going to be, which is good, yeah."

### Optimizing Sensor Platform Design

#### Limitations

All participants were happy with the privacy-preserving cameras in the communal rooms—kitchen, dining room, living room, and hall.

Regarding other camera locations, of the 24 participants, 16 (67%; n=8, 50% with PD, and n=8, 50% controls) were happy to consider having privacy-preserving video data captured in the bedroom. Approximately 31% (5/16) made the caveat that they would ideally have some control over such collected data (eg, to be able to switch the data collection off). The positives of collecting sensor data in bedrooms were noted by several participants (eg, capturing important bedroom-specific symptoms and activities):

*There is a lot, lot to capture for a person with Parkinson's that happens in the bedroom. So, that's where the person gets dressed, that's where the person has their nightmares. [C5]*

For those not wanting cameras in bedrooms, reasons given were related to privacy around dressing, personal hygiene, and sexual activity, where a camera was felt to be "too invasive...I'd feel too worried about that" (C9).

PWP9 mentioned that he felt the bedroom cameras would not capture interesting data from him:

*I agree with the thing about that first 45 minutes or hour, or whatever, can be quite difficult, but I think, for us, we tend to get up and go downstairs into the kitchen, and get our breakfast.*

He felt that whether cameras were deployed in bedrooms or bathrooms should be managed on a case-by-case basis, depending on how people lived and used the rooms in their houses.

Interestingly, 21% (5/24) of the participants would consider cameras deployed in bathrooms in their own homes. This was a controversial topic, with the remaining 79% (19/24) of participants feeling that it was not acceptable.

*I think that personal hygiene is your personal hygiene, and I think it should be done behind closed doors.*  
[C5]

There were acknowledgments of the conflict between data usefulness and privacy; for example, PWP12 felt the following:

*If it's limiting the research not doing it [collecting data from bedroom or bathroom], or it's helpful to do it, then I think as long as you have the ability to control it [then it may be acceptable]*

Some participants discussed ways of mitigating the privacy invasion of cameras. For instance, C5 said they would be happy for researchers “to do it [record sensor data from bedroom or bathroom] on specific nights, so that you [participants] had a break away from it.” Interestingly, this was countered by C9, who felt that she would be happier with continuous data collection if she could gain a fuller understanding of the data; she wanted first to “have a look to see what that [sensor data] looks like so I could now how invasive it feels, I think it wouldn't make a difference whether there was a holiday [sensor-free period] or not.”

Some participants were categorical in that at least some sensor-free space in the house was needed for in-home deployment:

*I think if there was a case of the cameras were in every room of the house, people would be very uncomfortable.* [PWP3]

*You then wouldn't get people acting normally.* [C3]

### Sensor Controls

Of the 24 participants, 10 (42%; n=6, 60% with PD) felt that participant-operated sensor data collection controls were appropriate for the following reasons: participant-led control would be better than predefined *camera-free times* so that the episodes of worse symptoms would not be missed, to collect data of specific activities that participants perceived to be important for researchers to capture (“you could switch it on and off as and when you felt it's something valuable”), and to turn the sensors off at important times to the individual:

*If I was being completely honest, I think taking my clothes off in front of a camera that was on would possibly make me feel quite vulnerable, I wouldn't be comfortable with it, but once I'd then got my pyjamas on, then it wouldn't bother me again* [C5]

The nature of such a control device was discussed by 8% (2/24) of participants, and both felt that having a handheld device would be ideal for periods of poor mobility:

*Some sort of control which was on your person, because in our bed, this morning, particularly, I was, to get out of bed is a real struggle sometimes.* [PWP3]

PWP3 and C3 noted that the touch screen interface of the electronic study diary did not suit them: C3 found touch screens

difficult to use, in part because she is left-handed, and they both felt that “touch screens and Parkinson's don't really make sense” because of the impact of having tremors and reduced fine motor dexterity. They suggested that the sensor control device should have a large “button, really, because people can't manage with the remote controls [with small buttons], can they?”

Notably, none of the participants paused or deleted any sensor data during this study.

Interestingly, there were some strong opinions held by the 8% (2/24) of participants who preferred sensor controls to be held by the researchers. PWP5 felt this because of the following:

*I think if you're [researchers] in control of it, I think that's better, yeah, because it's going to get done, isn't it? If I'm in control of it, I might not film it.*

PWP12 made the additional comment that he would not want to unwittingly introduce bias in the data captured:

*You could become in the habit of always controlling it on, I don't know, when you're cooking, or whatever, just as an example, so it becomes a really skewed view of what you're doing, if you're not careful.*

PWP9 made the point that being able to control the sensor data collection may increase awareness of the sensors and reduce the unobtrusiveness of the platform:

*Wouldn't want to control—I'd want them just to be there, because then I think I'd just forget that they were there, and that—I wouldn't want to have it on my mind the whole time.*

In particular, the idea of having a control mechanism to delete data after it had been captured was not seen as important by C3, who said that the ability to “delete information, and stuff, which, to me, is silly, because if you've recorded it, you keep it in.”

### Practicalities

At least 2 participants raised concerns about their occupations, which would not allow wrist-worn devices while at work (health care professional and construction industry).

The look and sound of the nonwearable sensors were discussed on several occasions. To acclimatize to the sensors and reduce the reminders that they were being sensed, there was a desire for the devices to blend into the background of the room. PWP6 mentioned the following:

*There's no light that tells you it's on, and I think that's an important thing...if they suddenly went—lit up, you'd think, “Oh, the camera's on,” and you'd change, but you tend to forget about it.*

However, C8's view of the light was that it felt normal:

*You've got all sorts of alarms in houses these days with little red lights in the corner, and sensors, you know, the odd little red light up there doesn't seem—it's just normal these days.*

The possibility that sensors might emit sound was also identified as a possible barrier to acceptability by PWP10, who found the lack of noise from the sensors to be positive:

*It's all silently in the background, you're not aware of it. It's not as if there's whirring and clanging machines, or anything, is it?*

The location of the cameras in the corners of rooms above the eye level was mentioned as positive for acceptability and as having a low impact on free-living by PWP8, who said the following:

*It's not evident, is it? You haven't got a great big camera staring you in the face.*

### **Focus on PD Outcomes**

Some participants had recommendations for specific symptoms or times in the day that should be prioritized for data collection in future research. These included sensing both day and night as “The night-times are the times where you can get a truer picture of what's going on...” (C4), and over multiple days to weeks as opposed to intermittently:

*It varies how good you are...You don't want a good day, in a way, you want a bad day so you can see how people manage. [PWP5]*

Other outcomes that participants felt should be a focus of future research were the ability to climb stairs, outdoor activity, and the impact of menstruation on PD.

### **Behavior Change**

Although all participants asserted that they had not consciously changed their actions for the passive sensors, it became evident from the unsolicited interview responses that behavior changes had occurred.

The participants felt a sense of responsibility toward capturing “good” data, which, at times, translated into behavior change. For example, PWP7 mentioned the following:

*Did take my watch [wearable] off this morning, I think it was, then realised I'd left something in the bedroom, so I picked it up and carried it with me...because I had three on and one off.*

They worried the data would not be complete, and C10 mentioned they were more “conscious of how long we were out [of the house]” so as not to reduce the amount of data captured. Generally, there was also a heightened awareness of the activities that would be helpful for the research team. For example, C3 said the following:

*My concern was we weren't doing enough for you, actually physically moving around.*

On a more human level, the perception of being sensed had subtle impacts on the participants' interpersonal and private behaviors. C3 felt that they and PWP3 felt less free to be tactile with each other in the study:

*We're more touchy/feely normally, and cuddly, and things, which we didn't do.*

PWP5 said that they “made sure I didn't go around with no clothes on.”

However, none of the 24 participants felt that they had to escape from or *trick* the sensors during the study, and they largely felt able to live as they would normally. For example, C4 stated that

they were “really just transposing our life from our own house into, more or less, what we're doing in this situation...we were, more or less, oblivious to being recorded, I think.”

Participation in this study led participants to wonder what the researchers would think of their behavior from the sensor data. The reactions ranged from the severity of their PD symptoms, with PWP10 “trying to open something and it wouldn't come open. I think I was thinking ‘This'll look bad. I can't even open a paper bag,’” to a more general sense that researchers may query or misinterpret their activities of daily living. For example, PWP4 said the following:

*There was one evening when [C2] was giving my back a massage upstairs, and I said, “God, what's this going to look like on the sensors?”*

However, the use of intermittent, preagreed times of high-resolution video data capture introduced a marked difference in the awareness and behavior of some participants compared with the continuously used *background* sensing. C11 articulated the following:

*You're more hyperaware if you're being observed [by cameras capturing high-resolution data]. It almost makes you on your best behavior.*

They were backed up by others, including C12 who felt they “certainly wouldn't have a disagreement if you thought the cameras were on you, I don't think.” Several participants mentioned that they would try to capture data that they perceived to be helpful to the research team during these 2-hour epochs. PWP4 said that “if anything, you want to put a show on, rather than just sitting inert,” and C5 felt that they made “sure that it was PWP5 [their study partner] that was doing the activities so that you were capturing their movements.” The prearranged times of high-resolution data capture were intrusive enough that participants appeared wary that the cameras were filming at other times:

*There's been a couple of times where PWP5's gone right up to the cameras and, “They are, they're filming, they are filming, C5.” And I'm like, “No, they're not, PWP5, don't worry about it.” [C5]*

However, conversely, PWP8 denied any impact on their behavior:

*I just knew they were there and just forgot about them. even forgot about the times when I was supposedly being videoed.*

## **Discussion**

### **Principal Findings**

This work has found that it is acceptable to use multimodal sensors, including wrist-worn wearables, cameras, and other ambient sensors passively, in free-living patients with PD but that the least acceptable sensor was the wearable device. There were several suggested controls and limitations related to future sensor deployment in people's own homes, especially for camera use. Behavior changes during this study were noted by the study participants, which may have been related to being passively



sensed. Recording high-resolution videos in a home setting for limited periods was considered acceptable.

## Acceptability

### **Multimodal Sensor Acceptability, Including Privacy-Preserving Cameras**

There were very few concerns related to data confidentiality or security, largely as the participants judged that the benefits of advancing research into PD outweighed any personal concerns about data misuse, which is in line with other research looking at the motivations behind providing personal data for research [54]. The person who expressed concern about the privacy of camera sensors, C3, felt that she had always been more aware than other people she knew about the possibility of covert video recording, for example, when she visited hotels. Beyond this, she did feel that she trusted the security of the data management by our research group. Interestingly, C3 gave the highest score on the *negative attitudes* subscale of the Media Technology Attitudes and Usage Questionnaire; therefore, she placed herself as feeling very negative toward technology. Her *anxiety/dependence* subscale score was very low, indicating that she felt not at all dependent on technology in her day-to-day life. These attributes may have contributed to the articulation of stronger views about privacy than the other participants.

This is the first qualitative study to compare wearable acceptability with that of other sensors. Compared with the other devices, wearables were the least acceptable sensor type in this platform, both in terms of the frequency of issues identified and the intrusion on free-living activities. This was related to practical issues around comfort, aesthetics, usability with PD symptoms, and the impact of the devices on sleep. This contrasts with some of the literature on the experience of using wearables in PD, where other groups have reported good acceptability of wrist-worn devices [21,55], albeit with reports that wearable acceptability decreased over time [26]. An important finding from this study was the variation in the wearables' psychological impact, with reports varying from positive descriptions of a sense of empowerment or a willingness to show them off to negative feelings, including a desire to conceal them from other people. The fear of wearables socially identifying someone's age, disease, or disability has been found by other groups [18,20,27] and should be a factor in device design, for example, concealing research-grade sensors in a wrist-watch (eg, off-the-shelf devices such as the Apple Watch [56]). It is possible that wearables were the least well tolerated as they are the only sensors that require direct participant interaction—increasing the intrusion on free-living compared with ambient sensors—and that further work toward a more seamless transition between digital sensing and physical wearable use [57] could help improve wearable acceptability in PD. The inclusion of health-tracking features in wearables has been found to improve their acceptability related to passive sensing [58,59]. This is possibly related to moving away from a reliance upon, or conversely, a suspicion of, technology and toward a relationship of trust through confidence in technology as a helpful instrument with which to visualize symptoms and therefore better understand our bodies [60].

One of the participants (PWP11) had a strongly negative response toward the entire sensor platform, which reminded him of his identity as a patient. He did not feel it would be tolerable to live with for longer than a few days, partly because of the impact on his mental health. This contrasts with the generally positive impressions of other participants. PWP11 had conflicting results on the Media Technology Attitudes and Usage questionnaire, with a low average score on the *positive attitudes* subscale (indicating that he was not overly positive about technology) but a high average *anxiety/dependence* and low average *negative attitudes* subscale scores (suggesting that he is more dependent on and not very negative toward technology); therefore, this questionnaire was not helpful in interpreting his experience. Psychiatric comorbidity alters how someone interacts with technology, and conversely, trends in the use of technology can predict whether someone has specific psychiatric disorders [61]. When designing a platform for people with PD, it is important to take special care to consider how its sensors may influence psychiatric symptoms such as depression, apathy, anxiety, and cognitive dysfunction (as well as how data may be affected by these factors) as these are all possible symptoms of PD. The potential utility of in-home sensing needs to be balanced against the risks to individual participants.

This is the first study to examine how people with PD experience video data collection while living freely in a home-like environment. Interestingly, the *privacy-preserving* cameras, which we imagined the participants may have felt negatively about, were well-accepted by our participants, and a high level of trust in the research team may have facilitated camera acclimatization. The reported time taken to acclimatize to cameras varied between minutes and hours, which is an important consideration as the time when behavior may be altered may need to be removed from the final data analysis of future studies. The person who reported acclimatizing quicker (C2) had a more positive attitude toward technology than the person who took longer (PWP2), adding weight to the importance of evaluating an individual's technological attitudes when designing further similar studies.

Obstacles to camera deployment to homes included instances where fellow home-dwellers cannot give informed consent for this data collection (eg, children or people with cognitive impairment). In such cases, it would be important to unpick both the acceptability and appropriateness of the use of any sensor, particularly those devices whose data outputs are not fully anonymous.

The ambient sensors (environmental, water pipe, appliance, mains electricity use, and passive infrared sensors) were well tolerated and posed no acceptability issues to our participants, indicating that their deployment to people's own homes would be reasonable.

### **Acceptability of Intermittent High-Resolution Video Data Recording**

Intermittent high-resolution video recording was found to be acceptable to all participants while they were free-living in this setting, although some participants had been wary of how they would feel before the study.

Given the need to ecologically validate sensor data findings in the real world [62], we anticipate more camera sensors will start to be used for this purpose; this study lends support that this is an acceptable study design choice if full informed consent is gained from participants.

### ***Design Adaptations Suggested for Home Sensor Deployment***

To increase the acceptability of home-based use of these sensors, several controls and limitations were suggested by our participants, especially for camera use. This included the following: camera-free time, especially related to recording in the bedroom; no cameras in bathrooms (according to 19/24, 79% of participants); and some camera-free space in the house.

Two-thirds of the participants were happy to consider cameras in their bedrooms for research purposes, largely driven by the motivation to understand symptoms that occur in bedrooms, which are currently poorly quantified. This finding is supported by other studies exploring the acceptability of home-based video recording [44]. When considering camera placement within these more *private* (bed or bath) rooms, it is important to recognize the potential risks to human dignity, especially related to vulnerability and sense of self [63], and efforts should be made to minimize the amount and identifiability of the data collected in these rooms. It should be noted that the methods used to produce silhouette video data are ways of working to protect the privacy of participants through camera use. Other methods have been described by Li et al [39], including the use of a body avatar or a point-light representation.

The question of whether sensor data collection control was needed (or not), as well as who should operate it (participant or researcher), drew mixed responses from our study participants. A bespoke system whereby participants were offered the option of who, if anyone, would control sensor data collection, including how to pause or delete data, may be a future route for free-living passive data-sensing studies.

The participants were interested in how the sensor platform design could be optimized to minimize intrusion in day-to-day life. Perhaps unsurprisingly, they generally wanted devices that would blend into the background of their homes without sounds or lights to highlight that they were there. They were concerned about how their friends and family would interact with and feel about the sensors in the homes they shared with study participants. This is echoed in similar findings from another group that highlighted the importance of social acceptability and aesthetics of technological sensors in PD [64]. A key point was that some participants simply would not be able to wear wrist-worn wearables during the day because of their occupations. To ensure the generalizability and inclusion of the younger working population of people with PD, these kinds of limitations need to be considered in future sensor platform design.

### **Participant Behavior Changes**

#### ***Related to Passive Sensors***

The semistructured interviews drew out several different behavior change examples from participants regarding passive

sensors. There was feedback that the participants were aware of how they may be viewed, or even judged, by the research team for their symptoms or what they did in the house. This awareness of how others perceived themselves is important to recognize when trying to capture naturalistic behavior: a heightened awareness may have caused some of the conscious or subconscious behavior modifications described in the results and may also affect how the participants view themselves [65]. The aim of our group and many others was to record natural free-living behavior; however, if our passive sensors alter subconscious (or conscious) behaviors, this needs to be carefully considered in future study design and data interpretation.

#### ***Related to High-Resolution Video Recording***

Our results showed how the use of intermittent video changed some of our participants' behaviors in a seemingly marked way at time, so the use of video ground truthing in real world settings should be judicious and targeted to symptoms which are accurately evaluated by clinicians watching the videos. Perhaps it should also be agreed that participants will either not be informed when high-resolution video is being recorded, or recording could be done over longer periods for participants to acclimatize to the sensors and normalize their behavior as much as possible.

### **Needs and Opinions Related to PD**

Unmet needs related to the quantification of particular PD symptoms and daily activities identified by this study's participants included a 24-hour view of symptom fluctuations; nighttime symptoms, including nocturia and sleep; the impact of menstruation on symptoms; activities outside the house; and mobility on ascending and descending stairs. The everyday management of PD symptoms and daily activities is complex and fine-tuned, and others have called for a technology-assisted outcome measure design to address this complexity [38]. We echo this and advocate that people with PD be involved in the design of any system measuring free-living home-based technology platforms to measure aspects of their disease.

### **Study Limitations**

This study included a small group of people with mild to moderate PD who had a relatively wide age range (46-74 years), all of whom were of White British ethnicity. The sample size, lack of candidates with severe PD, and absence of ethnic diversity indicate that we cannot generalize the study results to the wider population of people living with PD. In addition, a selection bias is likely to be present; those who offered to participate in a study such as this may be more positively disposed toward technology, and thus, we cannot assume that the largely positive opinions on technology acceptability reflect the views of all people living with PD. The study population's education level and prior experience with digital or assistive technology should be collected in future studies. Living alongside someone with PD is likely to influence the control participants' opinions related to sensors, and thus, it is important to bear this context in mind and not to assume that *control* opinions are entirely independent of PD; rather, they are more reflective of the next of kin and carers of people with PD. The study location in a home-like setting was different from one's

own home. One could speculate that being in such a location heightens awareness of being sensed, thus affecting behavior and activities more than being in one's own home. Furthermore, the relatively short duration of 5 days may not have been enough time for the sensors to feel *normal* to the participants; thus, the amount of behavior change may diminish in studies over longer periods.

### Conclusions

This study showed that it is broadly acceptable to live with multimodal sensors, including wrist-worn wearables and cameras, for 5 days in a free-living environment and that most study participants would be happy to consider these sensors' deployment in their own homes. However, the least well-tolerated of the sensors were the wearables, and the participants suggested several limitations on passive sensor use at home, including sensor (especially camera)-free time and

space. A significant subset of the study participants wanted to see the ability to control home-based sensor data collection, for example, in the form of being able to pause the sensors. Participants reported a range of behavior and activity changes during the study, some of which may have been related to the passive sensors used. When considering the validation of sensor data in a home environment, the use of high-resolution video cameras to provide a ground truth was found to be acceptable in this study. A future direction of qualitative work could be to evaluate how people living with PD feel about the sensor platform in their own homes.

These findings, in the context of other research in this field, should help inform design choices for studies involving passive sensing in-home environments. People living with PD should play an active role in developing such sensor platforms and studies, especially when choosing symptoms that should be measured.

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### Authors' Contributions

CM was the study's principal investigator, and she drafted the study protocol, collected the quantitative and qualitative data, conducted the interviews, and collected the questionnaires. CM performed the qualitative data analysis and produced the results of the study. ELT advised on data management and gave ongoing input in relation to qualitative data collection and analysis. IC and ALW supervised the studies and work of CM; ALW was the study's chief investigator; IC was the principal of Sensor Platform for Healthcare in a Residential Environment - Interdisciplinary Research Collaboration; and both had a major influence on the study's direction. All authors have reviewed and approved the manuscript for publication.

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### Conflicts of Interest

None declared.

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#### Multimedia Appendix 1

The Media Technology Usage and Attitudes Scale subscale questions on attitudes and anxiety about dependence on technology. [[DOCX File, 13 KB - humanfactors\\_v9i3e36370\\_app1.docx](#) ]

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#### Multimedia Appendix 2

Participant demographics and details about Parkinson disease. [[DOCX File, 16 KB - humanfactors\\_v9i3e36370\\_app2.docx](#) ]

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#### Multimedia Appendix 3

Results of the Media Technology Usage and Attitudes Scale subscale scores for each participant.

[DOCX File , 14 KB - [humanfactors\\_v9i3e36370\\_app3.docx](#) ]

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**Abbreviations****CONSORT:** Consolidated Standards of Reporting Trials**PD:** Parkinson disease

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Original Paper

# The Perceived Effectiveness of Secure Messaging for Medication Reconciliation During Transitions of Care: Semistructured Interviews With Patients

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## Abstract

**Background:** Medication discrepancies can lead to adverse drug events and patient harm. Medication reconciliation is a process intended to reduce medication discrepancies. We developed a Secure Messaging for Medication Reconciliation Tool (SMMRT), integrated into a web-based patient portal, to identify and reconcile medication discrepancies during transitions from hospital to home.

**Objective:** We aimed to characterize patients' perceptions of the ease of use and effectiveness of SMMRT.

**Methods:** We recruited 20 participants for semistructured interviews from a sample of patients who had participated in a randomized controlled trial of SMMRT. Interview transcripts were transcribed and then qualitatively analyzed to identify emergent themes.

**Results:** Although most patients found SMMRT easy to view at home, many patients struggled to return SMMRT through secure messaging to clinicians due to technology-related barriers. Patients who did use SMMRT indicated that it was time-saving and liked that they could review it at their own pace and in the comfort of their own home. Patients reported SMMRT was effective at clarifying issues related to medication directions or dosages and that SMMRT helped remove medications erroneously listed as active in the patient's electronic health record.

**Conclusions:** Patients viewed SMMRT utilization as a positive experience and endorsed future use of the tool. Veterans reported SMMRT is an effective tool to aid patients with medication reconciliation. Adoption of SMMRT into regular clinical practice could reduce medication discrepancies while increasing accessibility for patients to help manage their medications.

**Trial Registration:** ClinicalTrials.gov NCT02482025; <https://clinicaltrials.gov/ct2/show/NCT02482025>

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**KEYWORDS**

medication reconciliation; patient portals; telemedicine; pharmacist-patient relationship; medication errors

## Introduction

Medication discrepancies are associated with unintended consequences for patients, including adverse drug events (ADEs), rehospitalizations, and emergency department visits [1-3]. Medication discrepancies, defined as unintended differences between documentation in a patient's medical record and what the patient reports taking [4], commonly include omissions, commissions, and incorrect dose or frequency. Identifying medication discrepancies during transitions from hospital to home—a time of increased risk for discrepancies—can benefit patients and save costs via decreased rehospitalizations and less emergency department utilization [3].

Nearly 60% of patient records contain at least one medication discrepancy [5]; therefore, identifying discrepancies is a crucial step to reduce ADEs. Medication reconciliation is a process by which the medications that a patient reports taking are compared with the medications listed in their health record with subsequent resolution of any identified discrepancies. The final step of the medication reconciliation process involves communicating the corrected list to the patient, caregivers, and clinical teams [6]. Medication reconciliation *prior* to hospital discharge is known to decrease patient readmissions and emergency department visits [7]. However, less is known about effective and efficient medication reconciliation processes that occur during the care transition *after* hospital discharge.

There has been substantial advancement in the integration of information technology into the electronic health record (EHR) to identify and resolve medication discrepancies during hospital admissions [8,9] and in the outpatient setting [1,9-12]; however, little research has focused on health information technologies to identify and address medication discrepancies during patient transitions between care settings.

One potentially useful technology to address medication discrepancies in the postdischarge period is a web-based patient portal. These portals are integrated into a health system's EHR and allow patients to have greater access to and control of their health information. Common features include the ability to request prescription refills, manage appointments, and send secure electronic messages (ie, secure messaging) with health-related questions to their health care clinicians [13-15]. The development and advancement of secure messaging within patient-facing platforms has allowed for greater communication between health care clinicians and patients [16,17]. Secure messaging within patient portals may allow for improved health outcomes [18,19]. Several tools now leverage secure messaging to address health concerns, such as diabetes, hypertension, and weight management [20,21].

Previously, our group developed and tested the Secure Messaging for Medication Reconciliation (SMMRT) tool [22] as a solution for patients to use secure messaging asynchronously to help identify medication discrepancies after being discharged from an inpatient setting to home. We

conducted a formal usability evaluation of SMMRT with patients in a human-computer interaction laboratory [23]. In this study, our objective was to characterize how patients perceived the ease of use and effectiveness of the SMMRT intervention after using SMMRT in a real-world setting. We sought to identify features of SMMRT that patients perceived as most and least effective and to assess how this tool could be improved for patients in the future.

## Methods

### Trial Setting, Participants, and Intervention

This research is part of a larger study [23,24] that included a randomized controlled trial of SMMRT [25], which was conducted at 1 tertiary Veterans Affairs (VA) Medical Center to analyze the effectiveness of asynchronous, patient portal-based communication via secure messaging, between patients and clinicians for medication reconciliation. Briefly, the trial recruited patients from acute hospital settings or subacute rehabilitation centers who were prescribed 3 or more medications, were being discharged home (as opposed to a rehabilitation facility), passed the Callahan Six-Item Screener for cognitive impairment [26], and had a home computer and internet access. Patients randomly assigned to the intervention group were asked to use SMMRT for medication reconciliation once they returned home; control patients received usual care [25].

### SMMRT Trial Intervention

SMMRT is an interactive PDF that allows for a patient and clinician to conduct medication reconciliation after hospital discharge using secure messaging. Each SMMRT form contains the medication names, dosages, directions, and images of all active, expired, and pending medications documented in the patient's EHR. Patients can review their medication list and select from options in a dropdown menu to indicate whether they are taking the medication as directed, as shown in [Figure 1](#).

Within 3 business days of hospital discharge, all patients enrolled in the intervention arm of the trial were sent a SMMRT form to review. Prior to hospital discharge, research assistants (RAs) trained patients on how to use the patient portal and SMMRT by helping the participants log into their patient portal account and allowing patients to use a sample SMMRT for practice. This training was intended to prepare patients so they could use SMMRT later at their home. Technical support was available to patients after discharge via the study's contact. Patients were instructed to use SMMRT to review their medications on their own and return it to the study's clinical pharmacists via secure messaging within 10 days of receipt. If a patient did not return SMMRT within 10 days, one of the study's clinical pharmacists contacted the patient via telephone and talked with the patient to complete SMMRT together. This allowed patients to view SMMRT at home while discussing their medications with the clinical pharmacist. Once SMMRT

was complete, either by the patient via secure messaging or by the clinical pharmacist completing SMMRT with the patient over the phone, the clinical pharmacist reviewed SMMRT information and updated the EHR documentation (eg, by

removing or adding medications to the patients' records) to reconcile any discrepancies. Analyses of medication reconciliation accuracy was outside the scope of qualitative interviews, which were focused on patients' perceptions.


**Figure 1.** Example of the Secure Messaging for Medication Reconciliation Tool (SMMRT).

This is the Secure Messaging for Medication Reconciliation Tool (SMMRT). This tool allows patients and pharmacists to make sure the medication list is accurate.

Please note this list of medications only includes medications you take yourself at home.

### ● Active Medications

A prescription that can be filled at the local VA pharmacy. If you have refills, you may request a refill of this prescription from your VA pharmacy.

Comments from Pharmacist on left		Patients, please complete the information on the right
<p>Pharmacist comments, if any:</p> <hr/>	<div style="text-align: center;"> <h4>● ACETAMINOPHEN 325MG TAB</h4> <p>RX #: 12120560                      Quantity: 100 Refills left: 10                      Start: 2018-02-05</p> <p><small>No Image Available</small></p> <p>Instructions: TAKE 1 OR 2 TABLETS BY MOUTH EVERY SIX HOURS AS NEEDED FOR PAIN                      Prescriber: Prescriber, Doctor 1</p> </div>	<p>Taking this medication as prescribed?</p> <div style="border: 1px solid red; padding: 2px;"> <p>Yes, I am taking as prescribed ▾</p> <p>Yes, I am taking as prescribed</p> <p>No, I am taking differently</p> <p>No, I am NOT taking</p> <p>Unsure</p> </div>
<p>Pharmacist comments, if any:</p> <p>Our records show you are getting this medication from multiple VA facilities. Which facility would you like to get this prescription from Providence, Rhode Island or Boston?</p>	<div style="text-align: center;"> <h4>● CETIRIZINE HCL 10MG TAB</h4>  <p>RX #: 5917308                      Quantity: 120 Refills left: 4                      Start: 2018-07-05</p> <p>Instructions: TAKE ONE TABLET BY MOUTH EVERY 6 HOURS FOR ALLERGY ###                      Prescriber: Smith, Doctor</p> </div>	<p>Taking this medication as prescribed?</p> <div style="border: 1px solid red; padding: 2px;"> <p>▾</p> <p>Comments about this drug:</p> <div style="border: 1px solid red; height: 40px; width: 100%;"></div> </div>

### Study Participants, Recruitment, and Procedures

Participants who were enrolled in the intervention arm from April 2019 to September 2019 were eligible to participate in an interview, regardless of SMMRT completion status. We contacted potential participants sequentially, according to the date of their study enrollment, and invited them to participate via a mailed invitation with up to 2 follow-up phone calls until we reached our goal of 20 patient interviews. Due to project time constraints, sequential sampling was conducted. A total of 29 participants were invited to participate, with 8 nonrespondents, 1 participant declining to participate with no response given, and 1 participant who became ineligible since he was readmitted to the hospital. Participants were involved in 30-minute semistructured phone interviews; they received US \$50 for their time if they completed any portion of the interview.

Semistructured interviews were conducted between July 2019 and September 2019, within 2 months of the patient's

participation in the SMMRT trial intervention arm. All interviews with participants were conducted via phone by 1 of 2 RAs, both with master's degrees and prior experience conducting qualitative interviews (JEB, KY). No new themes were identified after 10 participants, indicating adequate data saturation [27]. To minimize personal bias, the primary RA who conducted the patient interviews and individuals who served as qualitative analysts were not involved in the initial development of SMMRT, patient recruitment for the clinical trial, or patient training on SMMRT. Interviews were audio-recorded with the permission of the participant and transcribed verbatim.

### Ethical Approval

All study procedures and documents were approved by the VA Boston Healthcare System Institutional Review Board on 21 May, 2018 (protocol number: IRB#3156).

### Interview Content

The primary objective of interviews was to characterize patients' perceptions of the ease of use and effectiveness (ie, ability to

identify and reconcile medication discrepancies) of SMMRT. We also explored perceptions of the VA patient portal, MyHealthVet, as it related to the use of secure messaging and completion of medication reconciliation. Interview questions ([Multimedia Appendix 1](#)) were developed under the guidance of 2 research physicians (AML and SRS), a research psychologist (AR), and a PhD scientist with extensive experience in qualitative methods (ALRJ). Questions were developed to probe patients about their experiences using SMMRT and MyHealthVet and to discuss features of SMMRT that emerged as most effective and those features that patients felt were unnecessary or counterproductive. We also sought to understand why patients did not complete or return SMMRT. The interview guide was pilot tested within the research team and refined for clarity.

### Analysis

We followed a qualitative analysis approach described by Bradley et al [28] for health services research. We did not have any preconceived themes prior to analysis; rather, interview transcripts were analyzed using an inductive, qualitative analysis

approach to identify emergent themes [28]. To begin, 2 transcripts were randomly selected, read, and analyzed independently by 2 members of the qualitative team (ALRJ, JEB). They discussed potential themes until reaching consensus on an initial list [28]. The analysts then independently re-analyzed the same initial 2 transcripts using the initial list of themes ([Table 1](#)) and then again reviewed and revised themes and discussed coding discrepancies until consensus agreement was reached [28]. The remaining 18 transcripts were then coded by JEB, who discussed any potential newly identified themes or coding difficulties with ALRJ until consensus was reached to minimize personal bias [28]. To ensure quality, a total of 5 (25%) transcripts were independently analyzed and discussed by these 2 analysts on an iterative, periodic basis over the course of the data analyses [28]. Coding of all transcripts was documented using NVivo qualitative analysis software [29]. Frequencies and proportions of responses were calculated based on interviewee responses and relevant baseline data collected as part of the larger trial. This manuscript was prepared based upon the Standards for Reporting Qualitative Research (SRQR) [30].

**Table 1.** Key themes used for coding, along with example quotes from patients.

Theme	Definition	Example quote(s)
Barriers to use of asynchronous communication platform	Barriers the participant faced while using components of MyHealtheVet (MHV) software that were also needed for SMMRT <sup>a</sup> form study process. This can include difficulties related to logging into MHV, the use of the secure messaging platform, downloading SMMRT, uploading SMMRT, and internet connection issues. Exclusions: This does not include barriers of difficulties relating to using SMMRT from pdf once downloaded.	<ul style="list-style-type: none"> <li>“I did have a problem [with MyHealtheVet] because they had to [do] something so I could send the messages...”</li> </ul>
Ease of use of asynchronous communication platform	Ease of use of using the MHV platform in the context of the SMMRT study. This can include comments about ease of use of logging into MHV, the use of the secure messaging platform, downloading SMMRT, and attaching SMMRT to the secure message. Exclusion: This does not include comments about using SMMRT once downloaded.	<ul style="list-style-type: none"> <li>“I couldn’t remember my login or my password, so I had to keep going back and getting a new one.”</li> </ul>
Barriers to using SMMRT	Difficulties the patient experienced while using SMMRT PDF once downloaded off of the MHV patient portal. This can include difficulty filling out SMMRT and saving SMMRT. This can also include sociotechnical obstacles barriers to completing SMMRT (eg, patient’s health).	<ul style="list-style-type: none"> <li>“I had a problem [with SMMRT] because I couldn’t save the stuff anyway... I went over each of the prescriptions and it asked what my dosage was, was I taking it, and stuff like that. When we did [complete] that, the ‘submit to save’ [option] never worked”</li> </ul>
Ease of use of SMMRT	Positive comments about using SMMRT PDF once downloaded. This includes ability to use drop down boxes, ability to use free text boxes, text size, and readability of the PDF.	<ul style="list-style-type: none"> <li>From a caregiver: “It was quite easy. It was very easy, and I think the form was pretty good to verify [the patient’s] medication.”</li> </ul>
Training and technical support	Comments about perceptions of the education, instructional materials, and technical support offered to participant with regards to SMMRT study process. This includes in-person training in the hospital, written “help guide” sent home with participant, and phone calls with study team for technical help.	<ul style="list-style-type: none"> <li>“It was fairly easy. [The RA] basically explained pretty clearly and [in] very easy terms what the task at hand was, and pretty much once I logged in, that was very clear. She also gave me some handouts. It was pretty easy for me to comprehend and follow.”</li> </ul>
Effectiveness of SMMRT	Benefits of using the SMMRT PDF. This can include comments about medication clarifications that occurred as a result of using SMMRT PDF, other secondary benefits experienced by the participant (eg, increased MHV use), and positive overall thoughts and feelings about the study. This can also include comments about follow up from study pharmacists.	<ul style="list-style-type: none"> <li>“...even though I thought there was no way I could do that [ie, make an error], I had misinterpreted the one of the instructions on my medications and your [SMMRT] program caught it.”</li> <li>“The SMMRT study itself I think is kind of long overdue... this could become a regular practice or a regular part of MyHealtheVet or somehow incorporated in the whole experience, I think it will be very helpful for people. I found it was for me.”</li> </ul>
Facilitated SMMRT form completion	Comments about completing SMMRT over the phone with extensive assistance from a pharmacist or study staff (eg, pharmacist completes SMMRT during the call based on conversation with the patient). Exclusion: This does not include comments relating to technical support completing SMMRT or comments relating to follow-up calls from pharmacist to reconcile identified medication discrepancies.	<ul style="list-style-type: none"> <li>“I had already had [SMMRT completed] on my computer anyway so it was really easy for me to translate it to him that way [when he called]”</li> </ul>
Medication pictures on SMMRT	Comments about the value (good or bad) of the medication pictures included on the SMMRT PDF.	<ul style="list-style-type: none"> <li>“Pictures of medications? No, I don’t remember any pictures.”</li> <li>“I think it would be good if there were pictures on every one of them. Only because when [patients] have their pill box, and if they have the picture of it, even though some are the same color and shape, they might have an idea of which one is which if it’s all in a pill box.”</li> </ul>
Future directions	Comments about future development and use of SMMRT. This includes whether the participant would recommend it to other veterans and whether addition training tools, such as YouTube would be beneficial. This can also include suggestions of changes to the design and use of SMMRT PDF.	<ul style="list-style-type: none"> <li>“Well, I guess if they have computer knowledge... [and] they’re comfortable using the computer, I don’t see why anybody would object to doing this.”</li> </ul>

<sup>a</sup>SMMRT: Secure Messaging for Medication Reconciliation Tool.

## Results

### Study Sample

There were 20 interviewees, who were all male, and the majority were white (13/20, 65%). They had a mean age of 62.5 (SD 9.5) years and had completed a mean of 13.8 (SD 2.4) years of education. Demographics of the sample for these interviews were consistent with the demographics of the overall study sample. Participant characteristics are displayed in [Table 2](#). Most (16/20, 80%) patients had registered for a MyHealtheVet account prior to enrollment in the trial, and 15 (15/20, 75%) self-reported previous secure messaging use. Among those who reported regular daily computer use (16/20, 80% of total sample), most also reported prior secure messaging experience (14/16, 88%). One participant reported that a caregiver used secure messaging on his behalf and the patient himself had no computer experience. Thus, we recruited the caregiver to use

SMMRT in collaboration with the patient, and both participated in the interview.

Interviews were conducted at an average of 34.8 (SD 19) days following the participants' completion and submission of SMMRT. Self-reported viewing of SMMRT was analyzed and used to categorize participants into viewed (n=17) and did not view (n=3) SMMRT on a home computer. We also assigned SMMRT return status based on data collected in the larger clinical trial: returned SMMRT via secure messaging (n=9), completed SMMRT via telephone with a clinical pharmacist (n=10), and did not complete SMMRT (n=1).

During the qualitative analysis process, we identified findings related to 7 themes, which included Training and Technical Support, Medication Pictures, Technology-related Barriers, Pharmacist-Facilitated SMMRT Completion, SMMRT Completion, Perceived Effectiveness of SMMRT, and Future Development.

**Table 2.** Characteristics of patient participants (n=20).

Characteristics	Results
Age (years), mean (SD)	62.5 (9.5)
Male, n (%)	20 (100)
<b>Race, n (%)</b>	
White	13 (65)
Other	7 (35)
<b>Education level, n (%)</b>	
Completed grades 8-11	2 (10)
High school/general educational development (GED)	5 (25)
Some college	7 (35)
College graduate or higher	6 (30)
<b>Employment status, n (%)</b>	
Full time	6 (30)
Part time	2 (10)
Retired	6 (30)
Unemployed	1 (5)
Disability	5 (25)
<b>Self-reported computer use, n (%)</b>	
Never <sup>a</sup>	1 (5)
A few times	4 (20)
Regularly	12 (60)
Expert	3 (15)
Prior patient portal experience <sup>b</sup> , n (%)	16 (80)
Prior secure messaging experience, n (%)	15 (75)
SMMRT <sup>c</sup> viewing status: viewed SMMRT on home computer (self-report), n (%)	17 (85)
<b>SMMRT completion status, n (%)</b>	
Completed and returned via secure messaging	9 (45)
Completed with pharmacist via telephone	10 (50)
Not completed or returned	1 (5)
Number of active medications in the EHR <sup>d</sup> , mean (SD)	15 (6)
Days between SMMRT completion and interview, mean (SD)	35 (19)

<sup>a</sup>One participant reported relying on the assistance of a caregiver when completing SMMRT and while using the patient portal, MyHealtheVet.

<sup>b</sup>The portal was MyHealtheVet.

<sup>c</sup>SMMRT: Secure Messaging for Medication Reconciliation Tool.

<sup>d</sup>EHR: electronic health record.

## Training and Technical Support

Participants with no previous secure messaging experience (n=5) reported the training session was very valuable, with 1 participant reporting “Without it, I wouldn’t have been able to get the job done.” A user that had previous MyHealtheVet experience endorsed the benefits of the training, saying the “[RA] made some small suggestions for me so I could understand it a little better. It was great and beneficial as a refresher course.”

## Medication Pictures

Although SMMRT contained sample pictures of each medication listed, few participants reported favorable opinions relating to this detail, with many not recalling the medication pictures on SMMRT. Importantly, no participants reported issues with incorrect picture images (eg, a picture of a generic form of the medication vs a picture of the name-brand medication).

## Technology-Related Barriers to Returning SMMRT Electronically via Secure Messaging

Of the 20 participants, 11 (55%) did not return SMMRT via secure messaging. Barriers were primarily related to technology and included 3 main subthemes: (1) difficulties with using a PDF (eg, saving the completed SMMRT to the computer prior to upload), (2) patient portal access issues (eg, difficulty logging into the portal and problems attaching SMMRT to the secure message), and (3) internet bandwidth issues. Participants also described difficulty with downloading SMMRT from the patient portal. For instance, “it wouldn’t let me download all the [SMMRT] pages.” Some of these issues were also raised by participants who were able to overcome these barriers to return SMMRT via secure messaging. In some situations, participants contacted the study team for technical support, while other barriers were resolved by the participant using the user guide provided during study training. A limited number of participants reported contacting the study team for help troubleshooting issues relating to downloading SMMRT and sending SMMRT back to the appropriate person.

The level of internet connectivity required for use of the patient portal and SMMRT was also discussed by participants. Participants reported difficulty with downloading and sending SMMRT due to limited internet connectivity, with 1 participant reporting, “I live in the mountains with no internet hardly. I have to get [internet] through a satellite,” which then led to decreased internet bandwidth speed. This highlights the access issues some rural veterans may experience when trying to access the patient portal to complete SMMRT.

## Pharmacist-Facilitated SMMRT Completion

Due to difficulty returning SMMRT via secure messaging, 10 participants (10/20, 50%) reported completing SMMRT over the phone with a clinical pharmacist. Participants reported this collaboration with the pharmacist to be smooth and efficient, with most participants reporting it took less than 15 minutes to complete SMMRT over the phone. Patients who completed SMMRT over the phone with assistance from a pharmacist ( $n=10$ ) had a mean age of 63.7 (SD 9.5) years compared with a mean age of 60.4 (SD 11.7) years for patients who completed SMMRT via secure messaging ( $n=9$ ). Of the patients completing SMMRT with the pharmacist, 6 reported their computer expertise as a “regular” or “expert” user, with the other 4 patients reporting limited computer experience. In contrast, all 9 patients who returned SMMRT via secure messaging reported their computer expertise as a “regular” or “expert” user.

## SMMRT Completion

Of those who viewed SMMRT in the patient portal, most participants reported that SMMRT was easy to navigate, with participants reporting “it was pretty easy to comprehend and follow” and “everything was great and very clear, very straightforward.” Participants who returned SMMRT via secure messaging reported that the directions were clear, allowing for a seamless completion of SMMRT and emphasized the benefit of completing SMMRT in the comfort of their own home with their home medication list, without the stress of being in a medical setting. Of participants who were able to complete

SMMRT ( $n=9$ ), the mean self-reported time to complete SMMRT per participant was 13.6 (SD 3.23) minutes. Participants expressed that SMMRT was timesaving in comparison with the usual medication reconciliation process they commonly experience postdischarge.

## Perceived Effectiveness of SMMRT

The perceived effectiveness of SMMRT by the participants was discussed in the context of 2 key categories: (1) reconciling medications that were previously discontinued by a medical provider but were never removed from the patient’s “active” medication list in the EHR and (2) clarifying medication dosages or frequencies. Overall, the majority of patients who completed SMMRT via secure messaging or in collaboration with the clinical pharmacist reported that the use of SMMRT helped remove at least one medication from the patient’s health record that was erroneously listed as “active” but had been previously discontinued by a medical provider. Additionally, participants reported that SMMRT helped clarify an issue relating to medication directions or dosages. One participant stated, “[The pharmacist] deleted what was necessary, and by the time we had the [trial follow up call], [my medication list] was clean.” Participants reported feeling “more in tune” to their medications after completing SMMRT.

## Future Development

Nearly all patients who viewed SMMRT stated they would recommend it to other patients transitioning from hospital to home. Participants suggested adaptations, such as providing delivery via a smartphone app, online video tutorials, and increased availability of on-demand help via the internet. Participants explained that these resources could better assist individuals who have limited computer knowledge and thus advance the ease of using the patient portal, secure messaging, and therefore SMMRT. Overall, participants endorsed the need for a tool like SMMRT, stating that this type of medication management technology is “long overdue.”

## Discussion

### Principal Findings

In this study, we examined the perspectives and preferences of patients who used SMMRT to conduct medication reconciliation from home after a recent hospitalization. We captured patients’ perspectives on the effectiveness of SMMRT and its ability to help uncover medication discrepancies, the visual display of SMMRT, the barriers faced when completing SMMRT, and the potential future use of SMMRT in routine patient care. To our knowledge, this is one of the first studies to specifically assess patients’ user experiences with secure messaging for medication reconciliation after hospital discharge.

Most patients completed SMMRT via secure messaging or in collaboration with the clinical pharmacist. More than one-half of patients in our sample identified a medication discrepancy via SMMRT, highlighting its clinical effectiveness. If patients perceive that digital technologies are effective, it often increases the likelihood that the technology will be utilized [31]. This may have promoted patients’ overall favorable opinions of SMMRT, despite the barriers experienced when returning

SMMRT via secure messaging. Recent literature reports that patients can identify medication discrepancies in their own personal health record with comparable accuracy to a pharmacy technician, supporting the assertion that patients can be closely involved in the medication reconciliation process [32,33], as they were in the SMMRT intervention. SMMRT has the potential to reduce the risk of ADEs and rehospitalizations by providing a mechanism for patients to help identify medication discrepancies.

Our study revealed insights on the visual display of SMMRT, which can inform future medication reconciliation technologies for patients. For example, we found that the medication pictures did not hold significant value for the patients. This study finding is in contrast with prior usability research from our group during SMMRT development that indicated strong support for including medication pictures [23,34]. Additionally, interviewed patients did not indicate any confusion regarding the presence of the pictures, even though this was reported to be an issue during the initial usability testing of SMMRT [23]. Together, these findings indicate that the medication pictures did not benefit nor harm patients' user experience. Thus, our findings indicate that the resources needed to include accurate medication pictures on SMMRT may exceed their value to patients.

Despite our overall positive findings, patients' ability to return SMMRT electronically was impeded by many barriers, with patient portal-related usability problems among the most prominent obstacle. This is likely due to the portal's file uploading process, which involves multiple critical steps. In addition, barriers related to geographic infrastructure, such as patients with poor or no internet connection, also created a disadvantage for patients living in more rural or remote areas. Alternative options for medication reconciliation during transitions of care may be needed for that population. One way to reduce some barriers is by adapting SMMRT for use on a smartphone. This adaptation may further increase patient uptake given the role that smartphones play in many day-to-day activities, possibly leading to fewer barriers faced. Patient portal use may increase with the perceptions that increased use may result in increased long-term independence [35], possibly explaining older patients' willingness to learn, troubleshoot, and use this new tool despite the difficulties experienced. Improving overall usability of patient portals and associated secure messaging technologies may increase the adoption of SMMRT and medication-related tools for patients of all ages and technology-related abilities.

Overall, patients endorsed SMMRT to be a valuable medication reconciliation tool and indicated they would use SMMRT again. Similar to our findings, prior research has found secure messaging to be beneficial and useful for regular communication [17,36]. Nevertheless, adoption of medication reconciliation technologies remains low [37]. When reviewing the literature, we found studies that examined several other types of medication reconciliation tools [12,34,38], such as clinician-facing medication reconciliation tools for use in the hospital setting [9] or kiosks for patients to review and comment on their medications prior to their clinical appointment [9,34]. Other studies evaluated secure messaging, primarily for purposes other than medication reconciliation [20,21]. Thus, it is difficult

to contrast our findings with others due to the novelty of our research and lack of published research on medication reconciliation with a similar clinical process (postdischarge), technology (secure messaging), and study setting (patient's home use). Importantly, our findings provide evidence that patients are willing to engage with medication reconciliation technologies in the home setting, after hospitalization, and find them useful for medication management.

### Limitations

This study was conducted with 1 patient portal, which although used for veteran patients across the United States, may differ in some ways from other commonly used patient portals. In addition, although both men and women were eligible to participate in the interviews, only men were interviewed, reflecting much of the patient population of the VA health care system. The high mean age of the patients in this sample may have influenced the findings. Patient age may influence patient portal use, with research showing older patients experience greater barriers [39] to use than younger patients. We used sequential sampling due to project constraints, but the use of random sampling would have been a stronger approach.

Although the follow-up interviews to the larger clinical trial included aspects of usability, they were not specifically focused on usability; thus, a usability framework was not used. Incorporating a usability framework to the interview guide or analysis process could provide increased value. The use of a usability questionnaire as part of the interview could have also yielded additional insights.

We also only examined the perspectives of patients, not clinicians, who are also instrumental in medication reconciliation processes. Lastly, qualitative interviews were conducted up to 2 months after patients completed SMMRT, which may have affected recall; however, patients had the option to view SMMRT while completing the interview. Future research is warranted to further enhance the design and usability of SMMRT, secure messaging systems, and patient portals.

### Conclusion

Our findings offer insight into the usability of an at-home medication reconciliation tool—SMMRT. Overall, this tool was viewed as a positive and valuable experience by most patients. Patients perceived SMMRT to be an effective mechanism to conduct medication reconciliation after a recent hospitalization, and nearly all patients stated they would recommend SMMRT to other patients. Importantly, for more than one-half of patients in our study, the use of SMMRT uncovered at least one medication discrepancy. Digital health tools such as SMMRT offer increased ownership for patients over their own personal health information and may lead to greater overall health compliance, highlighting the need for continued development of SMMRT. If widely implemented, SMMRT has the potential to improve medication safety on a much larger scale. Nonetheless, we identified several barriers that should be addressed, with barriers relating to the patient portal being the most prominent. Additional efforts are warranted to improve the usability of SMMRT and secure messaging platforms for patients.



Our results are expected to be valuable to health care organizations, software developers of patient portals and secure messaging platforms, and patients themselves. Implementing

SMMRT into routine clinical practice could allow for greater patient involvement and enhanced medication safety during the vulnerable transition from hospital to home.

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## Conflicts of Interest

None declared.

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Multimedia Appendix 1

Semistructured interview guide.

[\[DOCX File , 15 KB - humanfactors\\_v9i3e36652\\_app1.docx \]](#)

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## Abbreviations

- ADE:** adverse drug event  
**EHR:** electronic health record  
**HSR&D:** Health Services Research and Development  
**RA:** research assistant  
**SMMRT:** Secure Messaging for Medication Reconciliation Tool  
**SRQR:** Standards for Reporting Qualitative Research  
**VA:** Veterans Affairs

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Original Paper

# Patients' and Publics' Preferences for Data-Intensive Health Research Governance: Survey Study

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## Abstract

**Background:** Patients and publics are generally positive about data-intensive health research. However, conditions need to be fulfilled for their support. Ensuring confidentiality, security, and privacy of patients' health data is pivotal. Patients and publics have concerns about secondary use of data by commercial parties and the risk of data misuse, reasons for which they favor personal control of their data. Yet, the potential of public benefit highlights the potential of building trust to attenuate these perceptions of harm and risk. Nevertheless, empirical evidence on how conditions for support of data-intensive health research can be operationalized to that end remains scant.

**Objective:** This study aims to inform efforts to design governance frameworks for data-intensive health research, by gaining insight into the preferences of patients and publics for governance policies and measures.

**Methods:** We distributed a digital questionnaire among a purposive sample of patients and publics. Data were analyzed using descriptive statistics and nonparametric inferential statistics to compare group differences and explore associations between policy preferences.

**Results:** Study participants (N=987) strongly favored sharing their health data for scientific health research. Personal decision-making about which research projects health data are shared with (346/980, 35.3%), which researchers/organizations can have access (380/978, 38.9%), and the provision of information (458/981, 46.7%) were found highly important. Health data-sharing policies strengthening direct personal control, like being able to decide under which conditions health data are shared (538/969, 55.5%), were found highly important. Policies strengthening collective governance, like reliability checks (805/967, 83.2%) and security safeguards (787/976, 80.6%), were also found highly important. Further analysis revealed that participants willing to share health data, to a lesser extent, demanded policies strengthening direct personal control than participants who were reluctant to share health data. This was the case for the option to have health data deleted at any time ( $P<.001$ ) and the ability to decide the conditions under which health data can be shared ( $P<.001$ ). Overall, policies and measures enforcing conditions for support at the collective level of governance, like having an independent committee to evaluate requests for access to health data ( $P=.02$ ), were most strongly favored. This also applied to participants who explicitly stressed that it was important to be able to decide the conditions under which health data can be shared, for instance, whether sanctions on data misuse are in place ( $P=.03$ ).

**Conclusions:** This study revealed that both a positive attitude toward health data sharing and demand for personal decision-making abilities were associated with policies and measures strengthening control at the collective level of governance. We recommend pursuing the development of this type of governance policy. More importantly, further study is required to understand how governance policies and measures can contribute to the trustworthiness of data-intensive health research.

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## KEYWORDS

data-intensive health research; big data; data sharing; patient and public preferences; health data sharing conditions; ethics; governance; policy; patient and public involvement; research participants; trust

## Introduction

Various proposals exist for an ethical governance framework for data-intensive health research [1,2]. However, lessons learned point out that no fit-for-purpose governance framework currently exists [3,4]. At the same time, oversight in large, big data-driven research projects cannot be achieved by simply collecting and synthesizing existing governance elements of databases that participate in the project [3,5]. In addition, there is growing awareness of the need for a so-called social license to ensure patients' and publics' support, cooperation, and trust with data-intensive health research [5-8]. These governance challenges are echoed in the current preparatory developments of a European Health Data Space, which is part of the European Strategy for Data [9-11]. Therefore, it has become evident that we need to understand patients' and publics' preferences about what such a governance framework should look like. In this context, we use the plural "publics" to stress the diversity contained within the singular "public at large" [12,13].

Previous empirical research on patients' and publics' views revealed that they are generally positive about data sharing. Nonetheless, their support for data-intensive health research is not unconditional [5,8,14]. Moreover, when conditions are met, people tend to be more supportive of data sharing for data-intensive health research [5,8,14-18]. Protecting patients' privacy and safeguarding confidentiality and security of personal health data are important conditions for support of data sharing [5,8,14,19,20]. The possible risk of harm induced by health data research plays an important role in these conditions and impacts overall support in the long run [5,8,14,18]. More specifically, the possibility of abuse or misuse of data carries important weight in patients' risks perceptions [5,8,14,17-19,21]. Whereas the status of data-intensive health research as a common good that contributes to public benefit is widespread, this status needs to be guaranteed to gain and retain support [8,15,22,23]. In light of this, empirical findings point out that it is crucial to strike an appropriate balance between benefits and risks across the stakeholders involved in health data research [6,14,18,24,25]. Secondary use by commercial parties, such as pharmaceutical companies, complicates maintaining such a balance. Commercial involvement is considered to be accompanied by motivations that severely diminish the perceived public benefit of data use, such as profit-seeking [14,18,19]. Therefore, personal control plays an important role in patients' and publics' views on governance [8,17,18], such as requirements for specific informed consent [20,22,26,27]. Yet, the feasibility of specific informed consent within the context of data-intensive health research has been questioned [8,18]. Alternatives in which ethics and governance frameworks warrant trust in different ways are increasingly seen as viable and appropriate [6,28]. One example is to entrust data access committees with a more prominent role in controlling data sharing and research [19,22,23]. Still, low levels of awareness and understanding of research, oversight, and governance practices by laypeople currently form obstacles

to pursuing this path [8,14,17]. As the distance between research and patients and publics increases [5,17-19], seeking transparent and engaged forms of communication is pivotal [8,12]. Moreover, relevant information regarding the context of data use, particularly *by whom*, and the content of research should be provided [1,20,23,29].

The notion of personal control still plays an important role in patients' and publics' attitudes to data-intensive health research governance [8,17,18]. However, empirical research increasingly points to governance as a means of garnering trust in research, research organizations, and data-sharing practices [5,6,17,18]. The empirical literature reveals some valuable insights about conditions that are important for patients' and publics' support for data-intensive health research. Yet, much less is known about which types of governance policies and measures are desired [5]. In this study, we build upon these insights as well as prior conceptual work on elements for socially sanctioned governance [5], to further operationalize governance and seek empirical input by asking patients and publics. Therefore, the aim of this study was to gain further insight regarding how conditions for support of governance can be put into practice in a governance framework. Accordingly, we used a structure involving 3 themes: (1) views on conditions for health data sharing, (2) preferences for health data sharing policies and governance measures, and (3) the role and implementation of patient and public involvement.

## Methods

### Aim and Design

The aim of this survey was to establish patients' and publics' preferences for data-intensive health research governance. The first version of the questionnaire was pilot tested twice with patient panels from the European Heart Network and its Dutch member organization Harteraad. Following this, minor changes were made to phrasing of the questions. The final questionnaire consisted of 17 questions distributed over 5 pages, taking respondents approximately 10 minutes to complete. Respondents were able to review and change their answers. In addition to the English version, the questionnaire was translated to Danish, German, French, Dutch, Swedish, Finnish, Spanish, Portuguese, Romanian, and Slovenian to make it easier for people to participate and increase widespread uptake. We used 5-point, Likert-item questions as well as multiple-choice questions (see [Multimedia Appendix 1](#)). Duplicate entries were avoided by using cookies that expired after 6 months, preventing users from accessing the survey twice.

### Ethical Considerations

Approval from an ethical committee was not necessary for this type of unobtrusive, nonmedical scientific research. Under Dutch law, this research is exempt from review by a medical research ethics committee (Medical Research Involving Human Subjects Act [WMO]; Central Committee on Research Involving Human

Subjects). Participants gave their informed consent for the use of their answers for scientific research prior to the start of the questionnaire.

### Setting

The survey was conducted online among a purposive sample by digital distribution via the European Heart Network, a partner of the BigData@Heart project. The European Heart Network is a European alliance of foundations and associations dedicated to preventing cardiovascular diseases, supporting and representing patient interests throughout Europe. Distribution was facilitated by the European Heart Network itself, its 27 member organizations, and its participation in the European Commission's Health Policy Platform. The survey was distributed via patient panels; email and online newsletters; and calls for participation in web items, email, and various social media platforms (Twitter, Facebook, LinkedIn). The survey was administered using the Qualtrics XM survey tool. The only inclusion criterion was age 18 years and older. Participation was voluntary and without incentives. The survey was accessible from February 9, 2021, until May 10, 2021.

### Analysis

We analyzed both complete and incomplete questionnaires. Analysis focused on descriptive statistics and exploring patterns within and between the thematized variables. Data were analyzed using SPSS version 26 (IBM Corp, Armonk, NY). For Likert-item ordinal variables, we report descriptive statistics including response percentages for each category, the median, and IQR. For multiple-choice categorical variables, we report frequencies and percentages for each category as well as the mode. For the descriptive statistics, we report valid percentages.

Using inferential statistics, we compared groups and tested for associations between preferences for data sharing conditions as well as policies and measures. We employed nonparametric chi-square tests of independence, Mann-Whitney *U* tests, Kruskal-Wallis tests, and Spearman rank order correlations since the assumptions underlying parametric statistics were violated. More fundamentally, nonparametric statistics were more appropriate due to the ordinal and categorical levels of measurement of the survey variables [30-33].

We used an  $\alpha$  level of .05 to determine significance for all statistical tests. All tests were 2-tailed. For all tests reported, the (nonparametric) assumptions were met. Since missing data were diffuse, specific missing data patterns were not apparent, and <5% of data were missing for all variables, missing data have been assumed ignorable. We treated missing data in the nonparametric statistical tests via customary pairwise deletion of cases, which is robust for large sample sizes with diffuse and small amounts of missing data [34,35]. As a result, sample sizes varied slightly across tests. To infer the direction of associations for chi-square tests of independence, dependent variables were dummy coded.

## Results

A total of 987 respondents took part in the survey: 81.7% (788/964) of the respondents identified as being cardiovascular disease patients, and 58.9% (576/978) of the respondents were male. Respondents were relatively old, and 80.5% (782/972) of the respondents came from the Netherlands. See [Table 1](#) for an overview of the background variables.

**Table 1.** Frequencies of background variables (n=987).

Variables	Results, n (%) <sup>a</sup>
<b>Gender<sup>b</sup></b>	
Female	400 (40.9)
Male	576 (58.9)
Other	2 (0.2)
<b>Age range (years)<sup>b</sup></b>	
18-30	25 (2.6)
31-40	32 (3.3)
41-50	83 (8.5)
51-60	188 (19.2)
61-70	339 (34.7)
≥71	311 (31.8)
<b>Country of residence<sup>c,d</sup></b>	
Belgium	9 (0.9)
Finland	10 (1.0)
Germany	68 (7.0)
Ireland	5 (0.5)
Netherlands	782 (80.5)
Portugal	7 (0.7)
Sweden	7 (0.7)
United Kingdom	68 (7.0)
<b>Education level<sup>e</sup></b>	
Less than secondary/high school	18 (1.9)
Secondary/high school	212 (21.9)
Vocational/professional qualifications	343 (35.4)
Bachelor degree	168 (17.4)
Master degree	146 (15.1)
Postgraduate degree	58 (6.0)
Other	23 (2.4)
<b>Identification as a patient<sup>f</sup></b>	
Yes	788 (81.7)
No	176 (18.3)

<sup>a</sup>Percentages given are valid percentages; n varies per variable.

<sup>b</sup>n=978.

<sup>c</sup>Countries with a percentage >0.5% are shown.

<sup>d</sup>n=972.

<sup>e</sup>n=968.

<sup>f</sup>n=964.

## Views on Conditions for Health Data Sharing

We asked participants about their general attitudes to sharing their health data for scientific health research purposes. Generally, 62.7% (615/981; median 5, IQR 4-5) of participants in the survey indicated they *strongly favored* sharing their health

data for health research. This was followed by 23.8% (233/981) who *somewhat favored* health data sharing. A total of 86.5% (848/981) was in favor of sharing their health data. Several aspects of conditions for health data sharing were considered important. Respondents (458/981, 46.7%; median 5, IQR 3-5) found receiving information about research projects *highly*

important, while 38.9% (380/978; median 5, IQR 2-5) of the respondents found it *highly important* to be able to decide which researchers or organizations have access to their data. Moreover, 35.3% (346/980; median 5, IQR 2-5) saw being able to decide which research projects had access to their data as *highly important*, and 23.1% (226/980) found this *highly unimportant*. Choosing which types of health data are shared was considered *highly important* by 33.3% (325/977; median 5, IQR 1-5) of respondents. Conversely, 26.7% (261/977) indicated this was *highly unimportant* to them.

Sharing data anonymously was preferred by 33.3% (328/985; mode 2), whereas 22.9% (226/985) indicated anonymity should be required. Pseudonymous data sharing was preferred by 26.1% (257/985) of the respondents. Respondents indicated that researchers or organizations having a relevant research question

(423/983, 43.0%; mode 1) and researchers from government or not-for-profit organizations (423/983, 43.0%) should have access to their data. See Table S1 in [Multimedia Appendix 2](#) for the detailed descriptive results.

We tested whether the background variables of age, gender, education level, and identification as a patient were associated with participants' willingness to share their health data for health research (see [Tables 2](#) and [3](#)). Higher education levels were significantly, positively associated with higher levels of willingness to share health data ( $\rho=0.096$ ,  $n=962$ ,  $P=.003$ ). However, all education levels strongly favored sharing their health data (median 5), except for those with less than a secondary or high school education. We therefore additionally tested the dependent variables for associations with education level.

**Table 2.** Association between background variables and willingness to share health data, assessed using the Kruskal-Wallis test and Spearman rank order correlation.

Variables	Statistic	P value
<b>Kruskal-Wallis test (n=972)</b>		
Age	$\chi^2_5=4.2$	.52
Gender	$\chi^2_2=2.5$	.28
<b>Spearman rank order correlation (n=962)</b>		
Education level	$\rho=0.096$	.003

**Table 3.** Association between background variables and willingness to share health data, assessed using the Mann-Whitney U test.

Variable	Median	Mean rank	U	z	P value
<b>Identification as a patient (n=958)</b>					
Yes (n=784)	5	486	62914	-1.87	.06
No (n=174)	5	449			

Participants' willingness to share health data was significantly associated with anonymity preferences ( $\chi^2_{12}=134.5$ ,  $n=979$ ,  $P<.001$ ,  $\phi_c=0.214$ ); 32.9% (279/848) of participants in favor of health data sharing preferred anonymity, followed by 28.2% (239/848) of participants who preferred pseudonymization. In contrast, 72% (31/43) of participants who opposed health data sharing required anonymity. Participants' level of education was also significantly associated with preferences for anonymity ( $\chi^2_{18}=44.5$ ,  $n=966$ ,  $P<.001$ ,  $\phi_c=0.124$ ). However, preferences for anonymity followed the same pattern across education levels, as with willingness to share health data.

We found that respondents who are more willing to share data are less interested in choosing which of their health data are shared, for which projects, and with whom (see [Table 4](#)).

In addition, willingness to share health data was significantly associated with which types of researchers should have access to participants' data ( $\chi^2_{12}=34.9$ ,  $n=977$ ,  $P<.001$ ,  $\phi_c=0.109$ ); 43.2% (366/847) of those favoring health data sharing preferred access to their data by all researchers and organizations with a relevant research question. Slightly less (355/847, 41.9%) wanted only researchers from government or not-for-profit organizations to have access to their data.



**Table 4.** Spearman rank order correlations ( $\rho$ ) between willingness to share health data and views on conditions for health data sharing.

Variable	1. In general, how do you feel about sharing your health data for health research?	2. How important is it that you can decide for which research projects your health data are shared?	3. How important is it that you are informed about the research projects for which your health data is shared?	4. How important is it that you can decide for yourself which researchers/organizations your health data is shared with?	5. How important is it that you can choose which health data is shared and which is not?
<b>1. In general, how do you feel about sharing your health data for health research?</b>					
$\rho$	1	-0.187	-0.034	-0.179	-0.276
<i>P</i> value	— <sup>a</sup>	<.001	.28	<.001	<.001
<b>2. How important is it that you can decide for which research projects your health data are shared?</b>					
$\rho$	-0.187	1	0.539	0.634	0.638
<i>P</i> value	<.001	— <sup>a</sup>	<.001	<.001	<.001
<b>3. How important is it that you are informed about the research projects for which your health data is shared?</b>					
$\rho$	-0.034	0.539	1	0.555	0.482
<i>P</i> value	.28	<.001	— <sup>a</sup>	<.001	<.001
<b>4. How important is it that you can decide for yourself which researchers/organizations your health data is shared with?</b>					
$\rho$	-0.179	0.634	0.555	1	0.713
<i>P</i> value	<.001	<.001	<.001	— <sup>a</sup>	<.001
<b>5. How important is it that you can choose which health data is shared and which is not?</b>					
$\rho$	-0.276	0.638	0.482	0.713	1
<i>P</i> value	<.001	<.001	<.001	<.001	— <sup>a</sup>

<sup>a</sup>Not applicable.

## Preferences for Health Data Sharing Policies and Governance Measures

Study participants expressed their views on data sharing policies and governance measures for researchers sharing or using health data from databases: 80.6% (787/976) considered it *highly important* that databases are highly secure and difficult to get into (median 5, IQR 5-5). The possibility to have health data deleted at any time was considered *highly important* by 60.6% (589/972; median 5, IQR 4-5) of participants, while 55.5% (538/969; median 5, IQR 4-5) deemed it *highly important* to be able to decide on conditions for health data sharing, such as limitations for international data sharing or commercial use. Last, researcher reliability checks before gaining data access were judged *highly important* by 83.2% (805/967; median 5, IQR 5-5) of participants.

Moreover, we asked participants which 3 of 7 governance measures they favored most. Having sanctions for data misuse was chosen most often by 23.5% (637/2708; mode 6) of the participants. Also, 22.4% (607/2708) favored having data access requests evaluated by an independent data access committee. See Table S2 in [Multimedia Appendix 2](#) for the detailed descriptive results.

Being more willing to share health data was associated with 2 data sharing policies (see Table S3 in [Multimedia Appendix 2](#)). The possibility to have health data deleted at any time ( $\rho=-0.118$ ,  $n=967$ ,  $P<.001$ ) and being able to decide on conditions under which health data can be shared ( $\rho=-0.173$ ,  $n=964$ ,  $P<.001$ ) were significantly associated with being less

willing to share health data. In addition, higher education levels were significantly associated with greater preference for database security ( $\rho=0.145$ ,  $n=957$ ,  $P<.001$ ).

Willingness to share health data was significantly associated with several data sharing governance measures: 63.4% (538/848) of participants who favored sharing health data favored an independent committee to evaluate health data access requests ( $\chi^2_4=11.8$ ,  $n=981$ ,  $P=.02$ ,  $\phi_c=0.110$ ). Also, 66.2% (561/848) of those favoring health data sharing preferred subjecting those who misuse data to sanctions ( $\chi^2_4=7.9$ ,  $n=981$ ,  $P=.096$ ,  $\phi_c=0.090$ ). Conversely, 70.0% (594/848) of participants in favor of health data sharing did not deem it important that researchers should ask for consent each time data are used ( $\chi^2_4=26.4$ ,  $n=981$ ,  $P<.001$ ,  $\phi_c=0.164$ ). Obtaining approval from representatives on behalf of patients to use their data was not preferred by 74.8% (634/848) of participants in favor of health data sharing ( $\chi^2_4=10.4$ ,  $n=981$ ,  $P=.03$ ,  $\phi_c=0.103$ ). Additionally, education level was significantly associated with preference for having an independent committee for data access requests ( $\chi^2_6=26.9$ ,  $n=968$ ,  $P<.001$ ,  $\phi_c=0.167$ ). Notifying patients and citizens that their health data will be re-used was also significantly related with education level ( $\chi^2_6=19.5$ ,  $n=968$ ,  $P=.003$ ,  $\phi_c=0.142$ ).

We furthermore found that being able to decide on conditions under which data can be shared was positively and strongly associated with the possibility of having health data deleted at any time. A highly secure database and researcher reliability

checks before data access were also strongly related with being able to decide on conditions under which health data can be shared (see Table S4 in [Multimedia Appendix 2](#)). Moreover, 62.4% (455/729) of those preferring to decide on data sharing conditions favored sanctions for misuse. However, informing patients or citizens about results of research studies that used their health data was not judged important by 81.6% (595/729)

of participants. Similarly, allowing researchers to use health data only for a pre-approved period of time was not deemed important by 63.5% (463/729) of participants. Asking consent each time data are used (450/729, 61.7%) and notifying patients of reuse (441/729, 60.5%) were also not considered important by those preferring to decide on data sharing conditions. See [Table 5](#) for a detailed overview.

**Table 5.** Chi-square tests of independence for association between preference to decide on conditions and health data sharing governance measures (n=969).

Chi-square test of independence	Chi-square (df)	P value	Cramér V	Moderately/slightly important, n (%)
Requests for access to health data should be evaluated by an independent (data access) committee (1)	7.2 (4)	.14	0.086	445 (61.0)
Researchers should ask for consent of the patients/citizens from whom these data originate each time their health data will be used (2)	65.6 (4)	<.001	0.260	279 (38.3)
Researchers should notify patients/citizens that their health data will be re-used (3)	14.8 (4)	.005	0.124	288 (39.5)
Researchers should obtain approval from representatives on behalf of patients/citizens to use their health data (4)	11.8 (4)	.02	0.111	161 (22.1)
Researchers should only be allowed to use the health data for a pre-approved period of time. After this period, the health data can no longer be used (5)	16.6 (4)	.002	0.131	266 (36.5)
If health data is misused, those concerned must be subject to sanctions (6)	10.5 (4)	.03	0.104	455 (62.4)
Researchers should only inform patients/citizens about the results of the research studies for which their health data was used (7)	15.1 (4)	.005	0.125	134 (18.4)

## The Role of Patient and Public Involvement in Health Data Sharing

We asked participants about their opinion on patient participation, which we defined as research conducted by talking to, rather than about, patients. About one-half (466/987, 47.2%; mode 1) of the respondents had ever heard of patients being involved in health research. A smaller group had ever participated in patient and public involvement activities, such as participation in review committees or sounding board groups (214/987, 21.7%; mode 2). Most of the participants considered each patient and public involvement role in health data research important. Specifically, 40.3% (383/951; median 4, IQR 3-5) deemed it *fairly important* that patients and publics are involved in choices about consent and providing information about health data use, and 31.4% (299/951) deemed this *extremely important*. Involvement in evaluating health data sharing requests was considered *fairly important* by 39.3% (362/921; median 4, IQR 3-4) and *extremely important* by 21.4% (197/921) of participants. Involvement in choices about which research questions are relevant in medical science was judged *fairly important* by 38.8% (361/931; median 4, IQR 2-4), while 35.4% (330/931; median 4, IQR 2-4) thought so about making choices about how to conduct research using health data. Slightly fewer (292/949, 30.8%; median 4, IQR 3-4) considered patient and public involvement in choices about disseminating research results *fairly important*. See Table S5 in [Multimedia Appendix 2](#) for the detailed descriptive results.

Awareness of and having participated in patient and public involvement activities were significantly related with greater willingness to share health data (see [Table 6](#)). In addition, respondents with (less than) secondary or high school education were significantly less aware of patient and public involvement ( $\chi^2_{12}=52.1$ ,  $n=968$ ,  $P<.001$ ,  $\phi_c=0.164$ ).

Low willingness to share health data was significantly associated with greater importance for 3 patient and public involvement roles (see Table S6 in [Multimedia Appendix 2](#)). The importance of involvement in making choices about consent and providing information decreased when health data sharing was favored. We observed the same decrease in importance for involvement in evaluating data sharing requests and the dissemination of research results. Additionally, lower education levels were significantly related with greater importance of involvement in making choices about research questions ( $\rho=-0.103$ ,  $n=913$ ,  $P=.002$ ) and how to conduct health data research ( $\rho=-0.148$ ,  $n=193$ ,  $P<.001$ ). Patient and public involvement in evaluating health data sharing requests ( $\rho=-0.089$ ,  $n=903$ ,  $P=.007$ ) and disseminating research results ( $\rho=-0.189$ ,  $n=931$ ,  $P<.001$ ) was also considered more important by those with lower education levels. What is more, the importance of patient and public involvement roles was significantly greater for participants who had ever heard of patients and publics being involved in health research. This was not the case for involvement in disseminating research results (see Table S7 in [Multimedia Appendix 2](#)).

**Table 6.** Association between willingness to share health data and awareness of and having participated in patient and public involvement activities, assessed using a Mann-Whitney *U* test.

Variable	Median	Mean rank	<i>U</i>	<i>z</i>	<i>P</i> value
<b>Awareness of patient and public involvement (n=902)</b>					
Yes (n=462)	5	471	92429	-2.75	.006
No (n=440)	5	431			
<b>Having participated in patient and public involvement activities (n=905)</b>					
Yes (n=212)	5	507	71603	-2.19	.03
No (n=738)	5	467			

## Discussion

### Principal Findings

In this survey of patients' and publics' views about data-intensive health research governance, respondents were very much in favor of sharing their health data for scientific health research. Nevertheless, in correspondence with the literature [8,14], our findings indicate that support for data-intensive health research is not unconditional. People require additional means of exercising control. Control is desired at the individual level as well as at the collective level of governance in the form of various policies and measures.

In terms of privacy, anonymous data sharing was preferred most, whereas it was required far less. Instead, pseudonymous health data sharing was favored to a greater extent. Further analysis revealed that those favoring health data sharing had a more lenient stance on anonymity. Conversely, an overwhelming majority of those opposing health data sharing considered anonymity to be a requirement. This is in line with previous research, which indicates that anonymization is an important factor for support of health data sharing governance [15,20,36]. De-identification is important for privacy but also functions as a form of data security at large. However, there are different views on what would be feasible and desirable approaches to implement de-identification in practice [4]. Moreover, what should be "default" for safeguarding confidentiality and health data security remains a topic of discussion [8,36,37]. By pointing out the acceptability and desirability of pseudonymity, our findings provide further input in this debate. Our findings dispute that anonymization still forms a salient approach in the discussion around data de-identification. Moreover, this highlights the importance of exploring both technical and legal possibilities in practice, so that pseudonymous data sharing can be pursued as a way forward for researching health data [38,39].

Participants in our study were of the opinion that all researchers or organizations having a relevant research question should have access to their data. This goes against restricting data access to public or not-for-profit researchers or organizations, which is commonly preferred. Moreover, our findings point out that those opposing health data sharing preferred access by public or not-for-profit researchers or organizations only to a far greater extent. This corroborates that pursuing collective or public benefit leads to greater support for health data sharing and research [8,22,29]. In particular, our findings specify how providing warranties can contribute to maintaining support.

Foremost, warranties of public benefit need not necessarily be limited to health data access by government, public, or not-for-profit researchers only. Rather, more attention should be paid to how the relevance of research purposes can be explicated in such a way that conditions for support of health data sharing are fulfilled. At its core, this necessitates researchers and participants to articulate together what makes research purposes relevant in the first place.

Our findings confirm that private use of shared health data is detrimental to support and willingness to partake in data-intensive health research, as it is often accompanied by a profit motive. This confirms previous links between commercial involvement and motivations for data use that were seen as undesirable [8,14,17-19]. As public-private cooperation increases in data-intensive health research, rebalance should be sought by addressing the social relevance of research questions for patients and publics. Ascertaining what contributes to the relevance of research questions and practices from the perspective of patients and publics would provide a promising way forward.

We distinguish 2 types of policies and measures that are considered important in relation to governing data-intensive health research. First, at the individual-level, personal control over participants' health data is strongly preferred. This is in line with previous insights that revealed that participants want to have greater control over the entire data research process [14,27,29,40]. Thus, our findings reinforce the current understanding about the importance of personal control over health data sharing for research [8,17,18]. Examples are demanding that researchers should ask for consent each time data are used as well as make it possible for participants to decide which researchers can use particular types of data and for which research projects.

Yet, participants value personal control far more than simply and only the practice of giving up-front informed specific consent. Our findings highlight that personal control should be understood and can be put to practice more broadly than the specific forms of control with which we are familiar. In addition to traditional and conventional ethical requirements like consent, personal control can comprise less conventional means to empower participants [22,23,29]. They can be given opportunities to audit who has used their data as well as how their data have been used. Nevertheless, strengthening personal control is far less important as people are more favorable to health data sharing. This emphasizes current insights about the

importance of conditions that build trust in data-intensive health research [8,14,21,41]. Our findings support the hypothesis that ethics requirements and governance policies establish the trustworthiness of research organizations and data-sharing practices [5,6,17,18]. Hence, they are crucial to warrant greater trust by patients and publics [6,14,28].

A second type of policies and measures that were deemed important is located at the collective level of governance. Current insights recognize that governance policies and measures strengthen transparency and engender responsible conduct, which are important for accountability and trustworthiness [8,14,18,29,42,43]. Our findings point out that governance policies and measures are considered valuable since they strengthen possibilities for participants to exercise control on health data sharing. Governance raises the level of control over health data research to that of the collective. In large-scale health data research, this leap facilitates building transparency and trustworthiness beyond the limitations faced by individual research participants.

In addition to corroborating previous insights, our findings put more flesh on the bones of what governance policies and measures could look like. We highlight that this type of governance fulfills a performative function since it shapes a clear and consistent framework on which trust can be built. Having such a framework clarifies the consequences of data misuse and neglect of responsibility. This exemplifies that participants feel the need for hard-and-fast safeguards, measures, and policies. Sanctions can serve to demarcate the boundaries of permissibility in health data research, as the purposes to which data are put are called into question and uncertainty prevails [8,18].

Our findings underline how relevant awareness of patient and public involvement is for willingness to partake in data-intensive health research. Expanding patient and public involvement roles in governance particularly requires attention. This substantiates suitable and meaningful patient and public involvement as an important way of increasing trust, since it fosters greater mutual understanding and a more open research process [8,12,27,44]. See Table 7 for an overview of the main points and key takeaways from the discussion.

**Table 7.** Table summarizing the main points and key takeaways of the discussion.

What was known before	What this study adds	Implications for practice
Protecting patients' privacy and the confidentiality and security of personal health data are important concerns in patients' attitudes to data sharing and linkage [5,8,14,19,20].	Respondents <i>prefer</i> anonymous data sharing, closely followed by the option of pseudonymous data sharing.	It is important to explore possibilities for utilizing pseudonymous data sharing in governance policies.
Data-intensive health research's status as a common good is widespread, which contributes to gaining and retaining support [8,15,22,23].	A research (question)'s relevance is more important than restricting data access to not-for-profit researchers or organizations only.	Warranties that can explicate public benefit and contribute to maintaining support should be developed further as an integral part of governance.
Data use by commercial parties seeking profit, like pharmaceutical companies, diminishes its perceived public benefit [14,18,19].	Shared health data perceived to be used by private parties for the purpose of commercial gain is detrimental to patients' and publics' support and willingness to partake in data-intensive health research.	Establishing relevance is crucial to public-private cooperation in research, yet more insight is needed into how such relevance can be strengthened and secured.
Research participants want to be facilitated to have greater control over the process of health data sharing and research [8,17,18].	Respondents prefer being enabled to exercise various specific forms of individual-level, personal control.	Research participants should be able to decide who can gain access, to which types of data, and for which endeavors.
Personal control plays an important role in patients' and publics' views on how governance should be shaped [20,22,26,27].	Personal control should go beyond conventional roles of research participants, such as giving consent.	Research participants should be empowered via unconventional and innovative tools, such as participant-initiated data auditing.
Beyond personal control, patients and publics prefer governance arrangements to garner trust in data-intensive health research [5,6,17,18].	People in favor of health data sharing require less means of exercising personal control.	Establishing trustworthiness of research organizations and data sharing practices should be a central goal of designing governance.
Governance strengthens transparency and engenders responsible conduct, which are important for accountability and trustworthiness [8,14,18,29,42,43].	Governance measures are considered valuable since they strengthen possibilities to exercise collective control on health data sharing.	Raising control to a collective level allows going beyond the limits of individual control in large-scale health data research.
Participants experience uncertainty about what are permissible purposes for data use and require hard-and-fast safeguards [8,18].	Shaping a clear and consistent framework of consequences for data misuse and neglect of responsibility is crucial in governance.	Governance should create and demarcate normative boundaries, backed by repercussions such as sanctions when not respected.
Meaningful patient and public involvement is important to foster mutual understanding and a more open research process [8,12,27,44].	Patient and public involvement in governance contributes to willingness to partake in research.	Patient and public involvement should be expanded and assigned various roles as part of governance.

Comparing individual-level, personal control to control at the collective level of governance, the latter stands out. Implementing such policies and measures facilitates establishing

clear-cut governance frameworks, which can merit conditions that need to be met for patients and publics to support data-intensive health research. Various policies and measures

need to be pursued to ensure trust in proper purpose, use, and protection of health data. Policy requirements that safeguard the security of databases should be developed. Measures to impose sanctions for data misuse need to be implemented. Finally, reliability checks for researchers should be incorporated.

### Strengths and Weaknesses

The purposive sampling strategy that we employed precludes straightforward generalization of our findings. This means that we must be careful in interpreting the findings in the context of a wider population. The results of this study are likely to represent patients' and publics' preferences that tend to patient advocacy since distribution was facilitated by the European Heart Network. Additionally, the study population overrepresented older age groups, men, and residents of the Netherlands. Most respondents had completed vocational education or possessed professional qualifications. Moreover, they identified as patients. Yet, these characteristics are in line with what is expected from the population of patients and publics involved with cardiovascular diseases from which we sampled. Our sample and findings seem to be representative of this group. Additionally, as education level was significantly associated with several dependent variables, the role of this background variable in the results needs to be stated. Further research could benefit from a systematic, probability, stratified or cohort sampling approach. Doing so would forestall limitations of population diversity and facilitate generalization to a broader population of patients and publics. These factors may have contributed to more positive tendencies in preferences and slightly stronger associations between variables. However, they were unlikely to have strongly distorted the findings, such as changes in positive versus negative distributions, or the direction of associations.

We should be cautious about qualitative interpretation of our results. The quantitative methods we employed only provide limited means of doing so. Future research on patients' and publics' preferences for data-intensive health research governance could benefit from employing qualitative methods. Conducting interviews or focus groups facilitates painting a

richer picture of the motivations and reasons for the preferences we found. Mixed method approaches such as sequential explanatory designs could provide interesting insights by triangulating quantitative and qualitative methodologies in this field of inquiry.

### Conclusions

Policies and measures are crucial for governing data-intensive health research and building trust. The findings of this study point out that greater attention should be directed to patients' and publics' preferences for control at the collective level of governance than has hitherto been recognized. This confirms the slow but steady shift to understanding conditions for support of data-intensive health research to operationalize governance policies and measures. Our findings further entrench that governance functions by building on conditions for support and furthers trustworthiness of data-intensive health research. This resonates with preparatory developments that are part of establishing the European Health Data Space [10,11].

We recommend that future research explores patients' and publics' meaning-making and interpretation of control at the collective level of governance for data-intensive health research. Future research needs to address how specific varieties of governance policies and measures can be shaped in practice in accordance with conditions for support of health data sharing and research. Sanctioning data misuse is one policy that requires exploration in greater detail. We described data misuse as attempting to trace anonymous health data back to one's identity, yet it remains opaque what patients and publics exactly see as data misuse. This is a critical topic for policy making that needs to be addressed. What types of sanctions for data misuse would be regarded as appropriate and required to warrant trust needs to be studied further. The development of reliability checks for researchers and under what conditions an independent evaluation committee should be pursued need further study as well. Attaining insight in the views of research participants, publics, and professionals is crucial to establish provisional fixed points for the governance of data-intensive health research.

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### Conflicts of Interest

None declared.

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### Multimedia Appendix 1

Questionnaire to capture patients' and publics' preferences for data-intensive health research governance.

[[DOC File , 128 KB](#) - [humanfactors\\_v9i3e36797\\_app1.doc](#) ]

## Multimedia Appendix 2

Results tables.

[\[DOC File , 142 KB - humanfactors\\_v9i3e36797\\_app2.doc \]](#)**References**

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## Abbreviations

**IMI2:** Innovative Medicines Initiative 2 Joint Undertaking

**EFPIA:** European Federation of Pharmaceutical Industries and Associations

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Original Paper

# Implementing a Virtual Emergency Department: Qualitative Study Using the Normalization Process Theory

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## Abstract

**Background:** COVID-19 necessitated the rapid implementation and uptake of virtual health care; however, virtual care's potential role remains unclear in the urgent care setting. In December 2020, the first virtual emergency department (ED) in the Greater Toronto Area was piloted at Sunnybrook Health Sciences Centre by connecting patients to emergency physicians through an online portal.

**Objective:** This study aims to understand whether and how ED physicians were able to integrate a virtual ED alongside in-person operations.

**Methods:** We conducted semistructured interviews with ED physicians guided by the Normalization Process Theory (NPT). The NPT provides a framework to understand how individuals and teams navigate the process of embedding new models of care as part of normal practice. All physicians who had worked within the virtual ED model were invited to participate. Data were analyzed using a combination of inductive and deductive techniques informed by the NPT.

**Results:** A total of 14 physicians were interviewed. Participant experiences were categorized into 1 of 2 groups: 1 group moved to normalize the virtual ED in practice, while the other described barriers to routine adoption. These groups differed in their perception of the patient benefits as well as the perceived role in the virtual ED. The group that normalized the virtual ED model saw value for patients (coherence) and was motivated by patient satisfaction witnessed (reflexive monitoring) at the end of the virtual appointment. By contrast, the other group did not find virtual ED work reflective of the perceived role of urgent care (cognitive participation) and felt their skills as ED physicians were underutilized. The limited ability to examine patients and a sense that patient issues were not fully resolved at the end of the virtual appointment caused frustration among the second group.

**Conclusions:** As further digital integration within the health care system occurs, it will be essential to support the evolution of staff skill sets to ensure physicians are satisfied with the care they are providing to their patients, while also ensuring the technology and process are efficient.

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**KEYWORDS**

virtual care; emergency department; Normalization Process Theory

## Introduction

Canadian emergency departments (EDs) endure overcapacity and significant resource constraints [1]. Visits to EDs in Ontario, Canada's most populous province, have grown by 24.8% in the last decade, rising from 5.1 million in 2009 to 6.5 million in 2019 [2,3]. As ED visits increase and wait times to physician assessment lengthen, resources are increasingly stressed while patient satisfaction decreases [4]. As a result, there is growing attention toward finding alternative patient care options to improve system sustainability [5-7].

Virtual care utilization has increased across health care yet remains underutilized in the ED setting. Virtual care had limited uptake in EDs prior to COVID-19 due to various factors including limited financial compensation, licensure restrictions, and lack of connectivity to resources required to build the system [8]. The COVID-19 pandemic markedly altered patterns of health care utilization in Canada with the introduction and expansion of virtual care. Canadians are accessing physicians through digital technology, and virtual care increased from 1.6% in 2019 to 70.6% in 2020 [9]. Surveys have found that virtual care saves time, improves access, and can be easy to use [10]. In a Canadian survey in May 2020, those who connected with their doctor virtually during COVID-19 reported a 91% satisfaction rate with 46% indicating a preference toward a virtual visit as the first point of contact with their doctor [11].

COVID-19 prompted many emergency care facilities to operationalize virtual care services [12]. The number of Ontario ED visits decreased by 25% in March 2020, indicating that people who should be seeking ED care were not [13]. In response to these trends, Sunnybrook Health Sciences Centre, an academic tertiary/quaternary care hospital in Toronto, Ontario, piloted a virtual ED in December 2020 that connected patients directly to ED physicians. As the first virtual ED to launch in the Toronto area, the design, planning, and implementation were informed by patients and providers of virtual care services in other specialties and emergency services in other regions. To support iterative developments and sustainability, an embedded evaluation was included alongside the pilot launch to address our understanding of whether and how the virtual ED—a complex health care intervention—is actually adopted and sustained as routine practice. The Normalization Process Theory (NPT) [6,14] is a widely used theory of implementation for achieving this understanding and is often used to understand the implementation of eHealth applications [15]. The aim of this study was to use the NPT to understand ED physician experiences of virtual ED implementation and whether and how they were able to integrate a virtual ED alongside in-person operations.

## Methods

### Design

We conducted an NPT-informed qualitative study to explore the implementation of a virtual ED (ED services delivered virtually).

### Normalization Process Theory

Normalization is defined as the embedding of a technology as a routine and taken-for-granted element of clinical practice and focuses on the “work” of implementation. The NPT defines implementation as the “translation of strategic intentions into everyday practices” through collective action and collaborative work. The NPT identifies, characterizes, and explains the mechanisms that motivate and shape implementation processes. In this analysis, we considered the role of 4 implementation mechanisms—coherence (what is the work), cognitive participation (who does the work), collective action (how does the work get done), and reflexive monitoring (how is the work understood) [6,16].

### Context and Setting

Sunnybrook Health Sciences Centre is an adult academic tertiary/quaternary care hospital in Toronto, Ontario, fully affiliated with the University of Toronto. It is a regional trauma, cancer, high-risk maternal, neonatal, neurosurgical, interventional cardiology, and stroke center. The hospital sees 1.3 million patient visits annually with approximately 60,000 ED visits annually. ED visits are funded through an alternate funding agreement with the Ontario Ministry of Health and Long-Term Care.

### The Intervention

In December 2020, Sunnybrook Health Sciences Centre launched a 6-month virtual ED pilot which was continued. From December 2020 to December 2021 the virtual ED had a total of 1987 virtual visits, with a median of 150 visits per month (SD 25). The virtual ED is staffed by ED physicians weekday afternoon and evenings in parallel to the in-person ED. Physicians that worked in the virtual ED voluntarily signed up for the program and completed these shifts in addition to their regular in-person clinical requirements (these shifts were not replacements for their previously agreed to clinical load). Patients self-triaged using a web form via the Sunnybrook Health Sciences Centre website. Patients are advised of potentially appropriate and inappropriate conditions for a virtual visit along with advice of when to consult their family physician as their primary contact for lower acuity concerns. Patients registered online for a same-day appointment at the virtual ED.

A dedicated patient administrative assistant confirmed demographic information and valid health card and created an appointment that was emailed or texted to the patients (based on their stated preference). The assistant also emailed a calendar invitation to the ED physician's secure hospital email to alert him/her of a new appointment. The patient met with the ED physician via Zoom video and discussed the concern and a plan for moving forward. The administrative assistant helped patients navigate technological difficulties, communicated written instructions and any follow-up investigations or referrals directly with patients, and coordinated patient experience surveys. The ED physicians and administrative assistants used phone, SMS text messaging, and secure email to support their workflow.

Four possible care pathways can result from a virtual ED visit: (1) the patient's care can be managed during the virtual appointment including potential prescriptions faxed directly to

their preferred pharmacy, (2) the patient may be reassured that their issue can be managed through their family physician and does not require urgent care, (3) the patient is scheduled for follow-up for diagnostic imaging such as x-rays or ultrasounds or blood work at the outpatient area of the hospital for the same or next day, or (4) the patient may need to come to the ED for urgent in-person assessment and further investigations.

### Data Collection

Physicians who participated in the virtual ED received an invitation via email from JNH, implementation lead of the virtual ED. Interested physicians contacted the study coordinator who explained the study, provided a study information sheet, and obtained consent. All interviews were conducted by DS and were recorded and transcribed verbatim. We collected descriptive information such as demographic details (ie, gender and age) and data on their ED experience (ie, number of shifts worked per month). The interview guide was structured around the 4 constructs of the NPT to enable exploration of physicians' experiences of implementing the virtual ED. It was also revised to include issues that emerged as important in early interviews ([Multimedia Appendix 1](#)). For example, we began to ask questions around the ED physician's sense of role and identity as that impacted their sense of legitimation and buy-in into the intervention. Interviews were recorded and transcribed. All physicians received a CAD \$50 (US \$38.5) e-gift card in remuneration for dedicating their time to an interview.

### Data Analysis

#### Overview

Thematic analysis using inductive and deductive coding was used to describe the manifest and latent content [17]. This approach complemented the research questions by allowing the NPT domains to be integral to the process of deductive thematic analysis while allowing for themes to be derived directly from the data using inductive coding.

#### Directed Content Analysis

A codebook was prepared a priori ([Multimedia Appendix 2](#)) and involved adapting the NPT framework to the context of virtual ED and was agreed upon by the study team. All transcripts were coded independently line-by-line by 2 research team members (JS and DS). Deductive codes were compared for the first 3 interviews to achieve consensus and the remaining interviews were coded independently. The first level of coding was deductive based on the NPT domains.

#### Thematic Analysis

Inductive coding was considered on a case-by-case basis. Subsequent levels of coding involved re-examining the content

of the codes and narrowing in on more specific elements discovered in the data during coding. Initial themes were then reviewed and refined to ensure that the themes represented the data set as a whole and that no themes were missed or overrepresented.

### Integrative Analysis

NVivo 12 (QSR International) was used to manage the data set. An initial thematic framework was drafted and was discussed in data analysis workshops among all the authors. The framework underwent several iterations as new issues emerged in the meetings. The final synthesis and interpretation involved considering each theme and subtheme in the context of the whole set of interviews.

The trustworthiness, or credibility, of the study was enhanced by having 2 researchers (JS and DS) working closely together on data analysis. A detailed codebook was produced to ensure uniformity of coding. Meetings with the larger research team throughout the analysis process provided additional insights from experts in emergency medicine, qualitative research, implementation science, and the NPT. This process provided feedback, allowed any shortcomings in the analysis to emerge, and verified the data analysis and interpretation processes [18].

### Ethics Approval

Ethical approval was received from The Research Ethics Board of Sunnybrook Health Sciences Centre (2021-0040-E). All participants consented to participate.

## Results

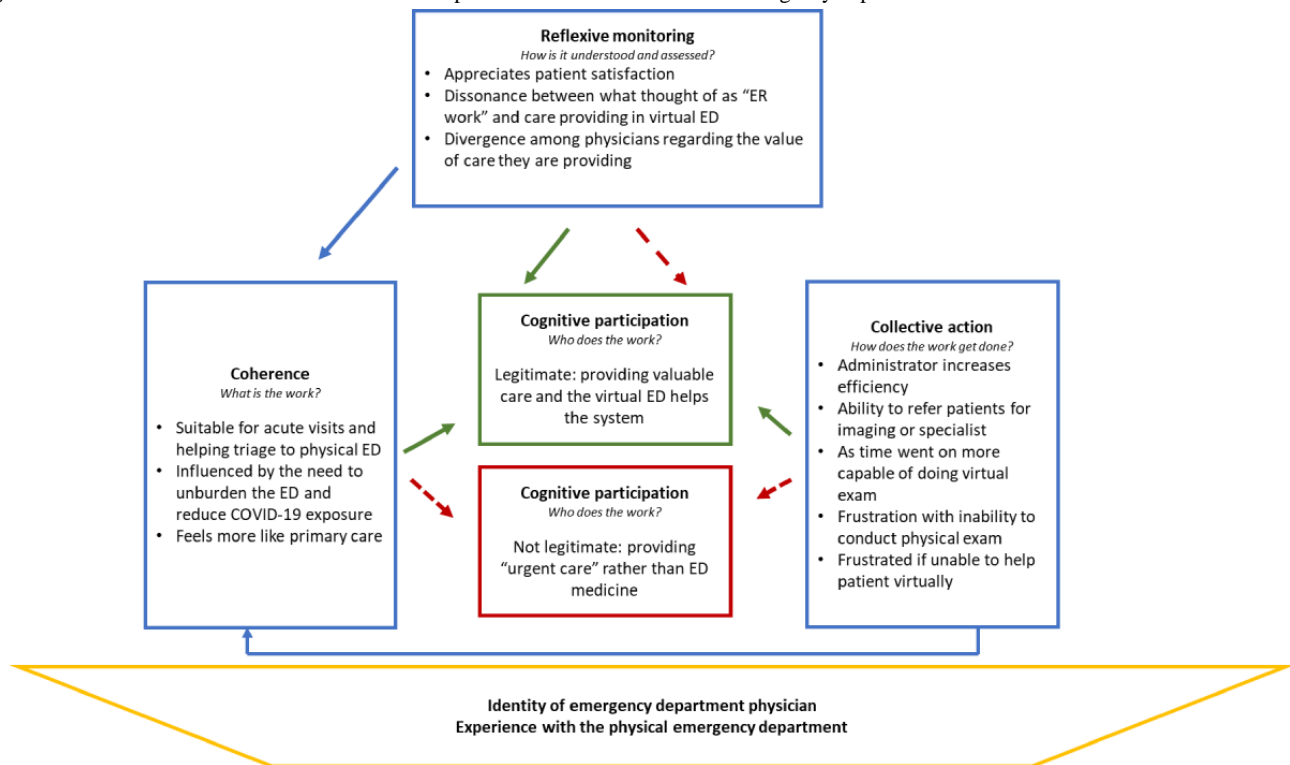
### Physician Demographics

We reached out to all physicians who had completed a virtual ED shift (21 physicians) and 14 agreed to be interviewed. Of these, 7 (50%) were female with an average of 16 years of experience (range 6-41 years; [Table 1](#)). Our analysis describes 2 pathways for physicians in our study, with 1 group moving to normalize the virtual ED in practice (10/14, 71%), while the other elected to not fully adopt it (4/14, 29%). The first group saw value for patients (coherence) and was motivated by patient satisfaction and the relief witnessed (reflexive monitoring) at the end of the virtual appointment. By contrast, the other group did not find virtual ED work reflective of urgent care (cognitive participation) and felt their skills as ED physicians were underutilized (a denormalization of their role). For them the virtual ED more closely resembled the role of primary care ([Figure 1](#)).

**Table 1.** Characteristics of emergency department physicians (n=14).

Characteristics	Value
Age (years), mean (range)	46 (31-67)
<b>Gender, n (%)</b>	
Male	7 (50)
Female	7 (50)
Experience (years), mean (range)	16 (3-41)
<b>Number of emergency department shifts per month, n (%)</b>	
1-8	4 (29)
8-15	7 (50)
15+	3 (21)
<b>Prior experience with virtual care, n (%)</b>	
Yes	6 (43)
No	8 (57)

**Figure 1.** Thematic framework of the normalization process of the virtual ED. ED: emergency department.



**Coherence: Providing Valuable Care to Patients**

Coherence involves the sense-making work that individuals undertake to bring meaning to a practice. It was reflected in how ED physicians understood the value, responsibilities, tasks, and objectives of the virtual ED. A central value reported by physicians was the support the virtual ED provided for patients on deciding whether an in-person ED visit was necessary. This refers to the work of *differentiation*, where participants sorted and classified the elements of the virtual ED in comparison to the standard in-person model to make sense of whether and how it fits within their understanding of ED care:

*I've sent a fair number of people to the [physical] emergency department to get evaluated. And what I hear from them mostly is reassurance because they don't want to go to the emergency department unless they need to. And so, when I talk to them and say, look, here are my concerns...that has been something that the patients have expressed appreciation for, because they don't want to wait eight hours in the emergency room if they don't have to. [Physician 11]*

Physicians described which patient scenarios they felt were most fitting for a virtual ED model, including follow-up from a diagnostic test, mental health issue, or supporting episodic care. While all physicians believed the virtual ED was an

efficient and patient-centered model, those who normalized the practice saw value in providing this care themselves while others felt like this was not the best use of their skill set. Physicians described the downstream benefit to the system of easing the burden of in-person care within an already stressed environment, which reduced the psychological pressures on ED physicians.

*So the mental health of the people working at the Emergency is going to be better if there's less people there, because you can't really focus on the emergencies, rather than thinking, "Oh my goodness, there's no way I'm going to get through my night shift because there's 40 people in the waiting room." Psychologically – that's a very, very tough hill to climb...that's easing my mental suffering about the stress of being on that shift. [Physician 3]*

Some also described how they appreciated being able to see a patient in a more intimate environment without the commotion of the physical ED and the additional context this provided during a care interaction.

While many physicians had concerns around the quality of care within a virtual ED model in its early stages, these were alleviated when the value for patients and physicians became clear. Specifically, patients who were reluctant to seek medical care during the pandemic due to concerns about the risk of in-person exposure now had a mechanism to safely connect with the health system.

*I feel stronger about it, now that I see that people are calling in. They have trust in the care that we're giving. Some people are calling just to get reassurance that they're OK to stay at home. Some people are calling to get treatment over the virtual emergency care platform...we're providing successful care and people are pleased with the care they're receiving. So, we should be doing it. [Physician 2]*

The group of physicians who elected not to normalize the virtual ED model described how the virtual shifts felt more like delivering primary care. They believed in the value of the care being provided but felt that they were no longer providing ED medicine. Some also speculated that patients were using the virtual ED as a substitute for their family physician to gain quicker access to specialists.

*I think what's happening is that the emergency physician is now turning into a family doctor. I think you have to be careful. You're giving patients the impression that you are doing family doctor services. I think some people do it because they can then get an appointment with a specialist in the hospital. [Physician 1]*

### **Cognitive Participation: Legitimate Emergency Work for Some But Not for Others**

*Cognitive participation* refers to the relational work that people do to engage and commit to a new intervention. We explored how physicians work with others, drive implementation, and see the virtual ED as part of their role. We found that for some engaging in the work of the virtual ED and witnessing the value firsthand was a key element to overcoming initial skepticism

and legitimating their role. This *legitimation* involves the work of reflecting on and deciding whether the virtual ED is the right thing to do and a meaningful use of their time and should therefore become part of their routine work.

*Initially I was quite sceptical as to how it would work, I've never really done virtual care before, and I couldn't envision patients that I would be able to treat virtually. I thought that any patient would wind up being sent into the emergency department for an evaluation...But now having done it, I actually like it a lot and it does seem useful for patients. [Physician 15]*

Physicians described that they were able to help patients by advising on the need for an in-person visit, booking a diagnostic test, or a referral to a specialist. This was a shift from their experience of providing value in the physical ED, where they were able to physically examine patients and provide complex care. These care pathways and decision points increased the legitimacy of the virtual ED model among those who normalized it.

However, those physicians who elected not to normalize the virtual ED had concerns over the legitimacy of their role, often feeling that this work was not aligned with the perceived role of an ED physician—a perception that was informed by their training and their prior experiences in providing in-person ED care. These physicians described their belief that any health issue that did not require in-person care was an issue meant for a primary care physician. The virtual model limited their ability to utilize the resources of the ED which led some to feel unfulfilled.

*I don't think that what we're doing is specific to emergency medicine. Like the job that we signed up for, for emerge is more the acute things that day-to-day stuff with resources. So even being called – like one time I was called on an airplane, is there a doctor on the plane for this patient? And without resources it was quite difficult to take care of the patient because of the nature of our jobs...I don't feel that the virtual emerge is fulfilling to me in terms of being an emergency physician. [Physician 8]*

A key distinction was the function of triaging patients versus providing emergency treatment. Where patients required treatment that could be achieved virtually, physicians who elected not to normalize the virtual ED believed these interactions to be within the scope of primary care.

*Yeah, it's a lot more like primary care, than emergency care, in what we're providing. It's sort of replacing – emergency triage. We decide if the patient, needs an emergent assessment, but we're not providing any emergency care, but I guess we're using our emergency expertise. Does this person need emergent assessment? But if we're truly treating the patient virtually, it's something that I think is in the realm of primary care, which we also do in the ER, I guess, sometimes. When patients come in with more primary care complaints, we still manage them. [Physician 9]*

## Collective Action: Physicians Adapted to the Limitations of a Virtual ED Environment

*Collective action* explores how the work of implementing new interventions into practice is done. Both groups needed to navigate a new virtual work environment and consider how to adapt their skill sets and resources to a virtual model. They were able to adapt and learn how to work within the limitations of a virtual care appointment (eg, asking a patient to help with range of motion or a caregiver to support a strength test). Physicians described the efficiency of being able to prepare for the visit by viewing the chief complaint (and sometimes the patient history) prior to initiating the virtual consult. The administrative assistant played an essential function in helping with technological issues, or sending prescriptions or referrals:

*The support by the administrative staff that are on, and helping, has been excellent. I have had a couple of different people fulfil that role. And I found in both cases they were very helpful at keeping things running and answering questions.* [Physician 3]

Physicians also described that their access to the same diagnostic testing or referrals that they were accustomed to in the physical ED was crucial to providing care. This enabled them to practice and provide value as if they were in the physical ED.

*So, [in the beginning] the piece that I felt was missing was the comprehensive bloodwork and radiology. So, diagnostic imaging that we hadn't been offering previously but we've started doing that. And so, I feel that really allows them to "come" to the Virtual Emergency Department and we can say to them, "Yeah. We're going to order this diagnostic imaging today. Yes, we're offering bloodwork.* [Physician 2]

## Reflexive Monitoring: Reflecting on Value From Patient Interactions

*Reflexive monitoring* refers to how individuals work together to appraise the intervention and how it is working. Physicians described evaluating success and impact through feedback from their patient interactions. For those who normalized the virtual ED, the feedback they received from patients was formative of how they viewed their role in the virtual ED. The immediate feedback provided by patients gave them the assurance that they were providing valuable care and reinforced the legitimization of their role. For example, some physicians were surprised by the great value of providing patients guidance on whether in-person ED visit was warranted.

*Do I need to go to the Emerge for this? Can this wait? Should I make an appointment?" And that advice – I don't think we realize how valuable it is.* [Physician 4]

This immediate positive feedback reinforced the coherence of the virtual ED physicians and their views of how this work aligned with their role as an emergency physician. They also saw value in providing patients with access to emergency services without having to send them into the physical ED and connecting them directly with outpatient follow-up. Although they recognized that the care they were providing was different than what they were used to, the physicians who normalized

the virtual ED were reinforced by the positive impact they were having on patients.

*All the patients I've seen, they've pretty much all given me positive feedback saying what a wonderful service this is and I think we've also added things to the virtual service that has made it be more applicable to emerge, like being able to order an X-Ray for a patient virtually so they can go and get an X-Ray done or get an ultrasound done the next day rather than just sending them into the emerge for a visit to do that is really useful. And being able to have access to our regular outpatient follow up options.* [Physician 14]

The physicians who elected not to normalize the virtual ED still recognized its positive impact; however, this value was not strong enough to overcome the perception that the virtual ED was not a legitimate use of their emergency skills.

*I'm not offering a lot of extra value, seeing them in the [virtual] Emergency Department. So, there is a bit of skepticism around the sustainability of whether emergency physicians will continue to have a role here or whether we should think of expanding primary care for these types of problems.* [Physician 3]

## Discussion

### Principal Findings

Our work explored the dynamic implementation process of a virtual ED to identify the elements that contributed to the virtual model becoming normalized for some physicians but not others. We found that cognitive participation and legitimization played a key role in normalizing the virtual model. For some, the satisfaction of providing quality and beneficial care for patients overshadowed any concerns of not using their skills as an emergency physician to their fullest potential. For others, the limited ability to examine patients and a sense that patient issues were not fully resolved at the end of the virtual appointment caused frustration. These physicians signed up for fewer shifts and did not experience the continuously evolving model and capabilities of the virtual ED platform. The virtual ED was normalized as an organizational operating model, as it was routinely incorporated into practice. However, some participants saw that their professional roles and skills as being denormalized. This resulted in *relational restructuring*—where there was a discordance between value for patients and their professional identity—which led them to opt out of the virtual ED model as participation was voluntary. Other physicians adapted to the *normative restructuring* by shifting their perspective on whether and how their unique skills set added value amid shifting standards and workflows within the virtual ED as compared with the in-person model (eg, saw value in helping with triage to the in-person ED).

For those physicians who elected not to normalize the virtual ED, relational pathways between legitimization and coherence were not present. These physicians felt the care they were providing did not fit with their identity as an emergency physician, highlighting the influence of social norms in the successful uptake of a virtual ED model. Social norms theory

posits that individuals are characterized by a variety of context-dependent connections, social roles, and rules in the form of norms and conventions [19,20]. Therefore, to promote virtual emergency medicine, we found that it was important to consider the importance of the culture and norms of physicians' professional identity and ensure that in-person care translates to the virtual shift. Similarly, research has shown that predictors of physicians' intention to use telemedicine in their clinical practice are influenced by their perception of what the social groups to which they belong expect from them [21-23].

It is not surprising that the pivot to a virtual ED model is very dramatic for a specialty that is trained and habituated to working in a fast-paced and high-stakes environment. The virtual ED required ED physicians to restructure their behavior and how they practiced medicine. Their professional identities as ED physicians felt incongruent with the care they were providing in the virtual ED. This had a great impact on legitimation, and the value created for patients was not sufficient to overcome the perceived shift in professional identity for a subset of physicians. The role of professional identity in the normalization of complex interventions may be rooted in a perceived threat of professional traditions, which has been a driver of physician resistance to virtual care more broadly [24-26]. Similarly, ensuring staff are supported in developing the necessary skill sets for virtual models is an important element of supporting normalization [27].

The COVID-19 pandemic has transformed the way health care is delivered, with various sectors providing more care through technology. Emerging evidence has documented physician views about the challenges of rapidly implementing telemedicine [28-31]. A survey among nephrologists reported increased access for patients, but concerns with proper physical examination, monitoring, and education of patients. They also reported less job satisfaction and sense of connection with patients [32]. Many studies focused on family physicians and generally, primary care clinicians have found virtual care acceptable, improves access and quality of care [33-36], and provides them with flexibility [36]. Studies have also reported that physicians felt it was a useful addition, saves time, and can enhance patient care. Further, some even preferred to provide follow-up for their patients by telemedicine rather than face-to-face clinics [35]. However, they have also noted changes to physician-patient interactions [34]. This physician population

was generally positive and did not have the same concerns regarding a shift in professional identity or the type of medicine they were practicing.

### Limitations

This evaluation took place as iterative improvements to the virtual ED were taking place and therefore experiences of the virtual ED were different for some physicians (eg, unavailability of ordering diagnostic imaging). Participation in the virtual ED was voluntary and physicians were interviewed at a single point in time, limiting our ability to explore whether experience over time shifted engagement with or perceptions of the virtual ED model. Also, we interviewed 67% (14/21) of emergency physicians and we do not know how the experiences of those we did not interview would impact our findings. The study included physicians from a single ED and it is unclear whether or how these results would generalize to other settings. Finally, while the COVID-19 pandemic was the catalyst for the virtual ED model, it has created artificial circumstances under which the model initially operated. Future work should explore whether and how the model and its use evolve under normal operating conditions.

### Conclusions

The rapid implementation of an innovative model for urgent care delivery provided an opportunity to understand how ED physicians integrate virtual care and the factors that influence uptake. Understanding the implementation of complex interventions is an important challenge for health care administrators and policy makers who must make decisions regarding the intervention and eventually scale and spread. The NPT is useful for exploring a greater understanding from participants as to how they make sense of and internalize a new technology, which in turn may help address and mitigate resistance from health professionals. Specifically, it highlighted the need to communicate how a new intervention aligns with professional identity and to communicate whether and how the creation of value is different from current experiences. As further digital integration within the health care system occurs, it will be essential to support the evolution of staff skill sets to ensure physicians are satisfied with the care they are providing to their patients, while also ensuring the technology and process are efficient.

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### Availability of Data and Materials

Data collected in this study are interview transcripts and excerpts and are available upon request, as per Research Ethics Board ethics.

## Conflicts of Interest

CRM has authored many key papers developing Normalization Process Theory and its constructs.

### Multimedia Appendix 1

Interview guide.

[[DOCX File, 15 KB - humanfactors\\_v9i3e39430\\_app1.docx](#)]

### Multimedia Appendix 2

Normalization process theory coding framework.

[[DOCX File, 15 KB - humanfactors\\_v9i3e39430\\_app2.docx](#)]

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## Abbreviations

**ED:** emergency department

**NPT:** Normalization Process Theory

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Original Paper

# Patient Experience and Feedback After Using an Electronic Health Record–Integrated COVID-19 Symptom Checker: Survey Study

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## Abstract

**Background:** Symptom checkers have been widely used during the COVID-19 pandemic to alleviate strain on health systems and offer patients a 24-7 self-service triage option. Although studies suggest that users may positively perceive web-based symptom checkers, no studies have quantified user feedback after use of an electronic health record–integrated COVID-19 symptom checker with self-scheduling functionality.

**Objective:** In this paper, we aimed to understand user experience, user satisfaction, and user-reported alternatives to the use of a COVID-19 symptom checker with self-triage and self-scheduling functionality.

**Methods:** We launched a patient-portal–based self-triage and self-scheduling tool in March 2020 for patients with COVID-19 symptoms, exposures, or questions. We made an optional, anonymous Qualtrics survey available to patients immediately after they completed the symptom checker.

**Results:** Between December 16, 2021, and March 28, 2022, there were 395 unique responses to the survey. Overall, the respondents reported high satisfaction across all demographics, with a median rating of 8 out of 10 and 288/395 (47.6%) of the respondents giving a rating of 9 or 10 out of 10. User satisfaction scores were not associated with any demographic factors. The most common user-reported alternatives had the web-based tool not been available were calling the COVID-19 telephone hotline and sending a patient-portal message to their physician for advice. The ability to schedule a test online was the most important symptom checker feature for the respondents. The most common categories of user feedback were regarding other COVID-19 services (eg, telephone hotline), policies, or procedures, and requesting additional features or functionality.

**Conclusions:** This analysis suggests that COVID-19 symptom checkers with self-triage and self-scheduling functionality may have high overall user satisfaction, regardless of user demographics. By allowing users to self-triage and self-schedule tests and visits, tools such as this may prevent unnecessary calls and messages to clinicians. Individual feedback suggested that the user experience for this type of tool is highly dependent on the organization's operational workflows for COVID-19 testing and care. This study provides insight for the implementation and improvement of COVID-19 symptom checkers to ensure high user satisfaction.

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## KEYWORDS

COVID-19; patient portals; digital health; diagnostic self evaluation; medical informatics; internet; telemedicine; triage; feedback; medical records systems; San Francisco; user experience; user satisfaction; self-triage; symptom checker; health system; workflow; feedback; integration; electronic health record

## Introduction

### Background

During the COVID-19 pandemic, symptom checkers have become an essential tool for providing patients with on-demand access to triage recommendations [1-5]. These tools take patients through self-guided questions about demographics, symptoms, exposures, and past medical history and suggest a diagnosis or recommend a disposition. They employ algorithms and automation to connect patients to care without requiring intervention from clinical staff. COVID-19 symptom checkers have a variety of potential benefits. When used for triage, they may reduce the risk of COVID-19 transmission [4,5] and provide patients with care advice more quickly and efficiently than other methods (ie, telephone hotlines) [6,7]. When used for daily entry screening, they greatly reduce the need for staffing to conduct manual screens [8-10].

### Symptom Checkers

Symptoms checkers are widely considered to be popular with patients because they provide them with 24-7 access to health information, risk assessments, and in some cases, test and appointment scheduling. A handful of studies have reported moderately high user satisfaction ratings for COVID-19 symptom checkers. One study of 296 patients who were predominantly health care workers reported 56% found their institution's internal web-based symptom checker tool useful [11]. Symptom checkers for conditions other than COVID-19 have also reported positive user experiences, including 1 study reporting high satisfaction in 70%-80% of users [9]. In a study of 22 college students, qualitative factors related to the decision to use publicly available symptom checkers included presence and knowledge of COVID-19 symptoms; fear of in-person health care services; awareness, paranoia, and curiosity; technical literacy; and acceptability [10]. Reported negative characteristics of symptom checkers included doubting accuracy, limited symptom submission possibilities, and unclear logic model of symptom checker [10].

While these studies suggest that users may positively perceive web-based symptom checkers, they are insufficient to understand the patient and tool characteristics that contribute to user experience. Furthermore, no studies have quantified user feedback after the use of an electronic health record (EHR)-integrated COVID-19 symptom checker with self-scheduling functionality. Symptom checkers that are EHR-integrated and offer self-scheduling may have higher user satisfaction because they decrease the time it takes for patients to be scheduled for necessary appointments or tests [6].

As symptom checkers become more ubiquitous for COVID-19 and other use cases, it is important to understand user perceptions and to know which features make them attractive. This type of user feedback can inform product development and

improvement for these symptom checkers and any other digital health tools. In addition, it is important to understand whether there are demographic differences that drive user perceptions of the tool, as these may impact health disparities.

### Patterns of Symptom Checker Usage

At the University of California, San Francisco (UCSF), in March 2020, we launched one of the first COVID-19 symptom checkers with self-triage and self-scheduling capabilities. We designed a survey to collect feedback and user experience upon use. This is the first known study to conduct user research on an EHR-integrated symptom checker with self-scheduling functionality. Our primary aims in this analysis are to examine patterns in user experience and user satisfaction by demographic characteristics, determine what patients view as alternatives to symptom checker use, and gather actionable feedback for symptom checker improvements.

## Methods

### Setting

UCSF Health is a large academic health system providing approximately 1.7 million outpatient visits annually. The UCSF primary care practices serve approximately 90,000 empaneled patients. As of January 2022, approximately 95% of adult primary care patients were enrolled in UCSF's EHR-tethered patient portal.

In early March 2020, UCSF established a COVID-19 telephone hotline, which became the primary telephone intake point for all UCSF patient and employee inquiries regarding COVID-19, including general questions, exposures, symptom assessments, and test scheduling requests.

### Symptom Checker Tool

The UCSF COVID-19 Symptom Checker was developed as an EHR-tethered portal-based self-service option for patients with symptoms of or exposure to COVID-19 or those who are requesting a COVID-19 test. After answering a series of branched logic questions about exposures, symptoms, and comorbidities, patients are directed to the appropriate disposition based on their predicted risk level. The triage algorithm used in this tool was identical to the one used on the telephone hotline. UCSF uses a commercially available EHR from Epic Systems. In early March 2020, we used our EHR vendor's configuration tools to design, configure, and deploy our UCSF COVID-19 Symptom Checker, which launched on March 12, 2020 [6]. Patients could access the tool by logging into the patient portal on a smartphone, tablet, or computer and were directed to the tool from the hotline, primary care phone tree, and UCSF websites. The tool was available in English and Spanish—the two languages currently supported by our patient portal. The Symptom Checker was available to all adult patients at UCSF with active patient portal accounts [1].

If appropriate based on their responses, patients could self-schedule SARS-CoV-2 RNA tests, video visits, or in-person appointments directly through the tool, as described previously [6]. When patients chose to schedule their test or visit online, a scheduling tool opened within the Symptom Checker, displaying available appointments and allowing the patient to select one. If no appointments were available, patients were directed to call the telephone hotline.

### User Feedback Survey

The optional, anonymous user feedback survey for the UCSF COVID-19 Symptom Checker was built on Qualtrics and consisted of 12 total questions (Multimedia Appendix 1). The survey link was embedded in the final screen of the tool, where patients were shown their care recommendation. The survey was optional, and there were no reminders or prompts to promote survey completion. Patients who did not complete the tool were not able to access the survey.

We designed the survey to be lightweight and easy to complete. Questions were a combination of slider-style rating questions, multiple-choice, select-all-that-apply, and optional open-ended questions. Only the first question, in which patients were asked about their overall rating of the tool, was required. The patients were then asked to assess their agreement on Likert scale with statements describing their experience and about how they would have sought care had the tool not been available. Additionally, the participants were asked about the most important features to them and were able to comment on any technical difficulties experienced. The respondents were asked optional demographic questions on age, gender, ethnicity, and race.

### Study Population

For this analysis, we included all adults who responded to the Qualtrics feedback survey from December 16, 2021, until March 28, 2022. A subanalysis of the peak of the omicron surge (December 16, 2021, to January 28, 2022) and its effect on patient satisfaction and experience was conducted. We defined the peak as the period during which the tool averaged over 200 unique users a day.

### Ethics Approval

This study was approved by the UCSF Institutional Review Board (20-30903).

### Evaluation and Statistical Analysis

Data were exported from the Qualtrics survey and analyzed using R 3.5.1 (The R Foundation). The participants' longitude and latitude at the time of response based on Qualtrics estimation using respondent IP addresses were matched to respective census block tract and area deprivation index national percentile as a

proxy for socioeconomic status [12]. Descriptive statistics were used to analyze user responses. Differences in the user cohort based on responses were analyzed using the 2-tailed chi-squared test for categorical variables and the two-sample, 2-tailed *t* test for continuous variables. Visualizations were created using the *ggplot2* library. A multivariate linear regression analysis was performed with a primary outcome of user overall rating and the demographic questions of the survey. For the purposes of multivariate analysis, respondent ethnicity was stratified as non-Hispanic and Hispanic, and race was stratified as White and non-White. To assess the collinearity of covariates, variable inflation factors were calculated with a cutoff of <10. Moreover,  $P < .05$  was considered significant.

Constructive open-ended responses were assigned 1 of 10 categories by a physician reviewer who was familiar with the ambulatory COVID-19 care structure. We did not categorize responses that were purely complementary or that did not offer specific feedback.

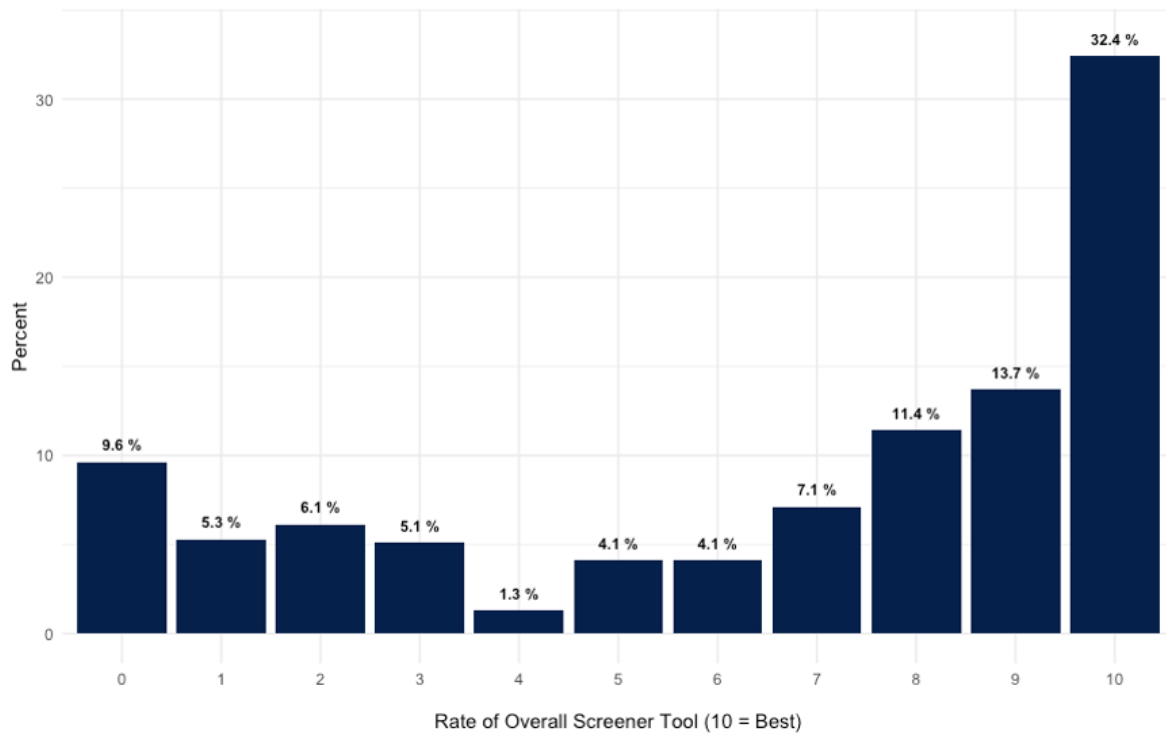
## Results

### Survey Response Data

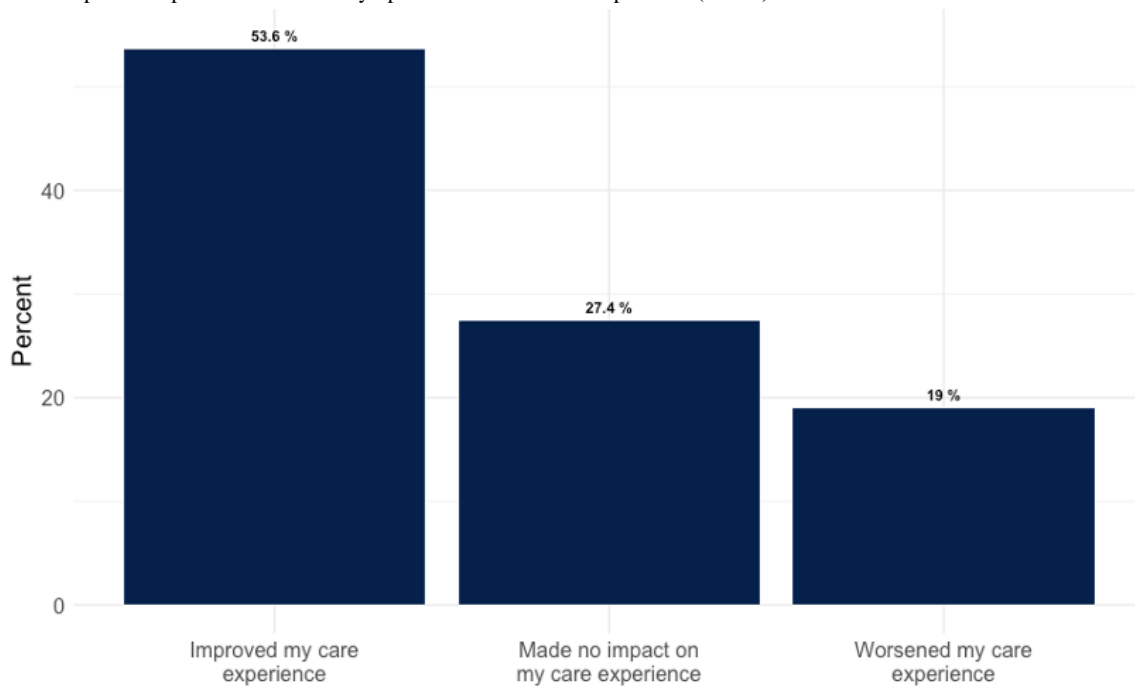
From December 16, 2021, until March 28, 2022, there were 395 total responses to the experience survey (Figure 1). During that time, the Symptom Checker was used 29,384 times for a response rate of 1.6%. The median 1-10 rating was 8 (IQR 3-10). In total, 182 users (46.1%) rated their overall experience 9 or 10. When asked how the Symptom Checker affected the overall care experience, about half of the users ( $n=178$ , 53.6%) responded that the COVID-19 Testing and Care Tool "improved my care experience," 91 users (27.4%) responded that the tool "made no impact on my care experience," and 63 users (19.0%) said the tool "worsened my care experience" (Figure 2). Most users strongly agreed (162/332, 48.8%) or agreed (44/332, 13.3%) that the tool "helped them get the care I needed," while 23.1% (77/332) strongly disagreed.

When asked about the most important feature of the tool, over half of the users ( $n=254$ , 64.3%) cited the ability to schedule their COVID-19 test online. The second most popular feature was 24-7 access to triage advice if they had COVID-19 symptoms or exposure ( $n=129$ , 32.6%; Figure 3). Most respondents (253/331, 76.4%) reported no technical difficulties while using the tool. The most commonly reported technical difficulty was problems with visit or test scheduling. When asked about usability, 52.4% (174/332) of users strongly agreed with the statement that "this tool was easy to use," while 10.2% (34/332) of respondents strongly disagreed. Most respondents (208/332, 62.7%) strongly agreed with the statement that "questions were easy and clear to understand," while 7.2% (24/332) strongly disagreed.

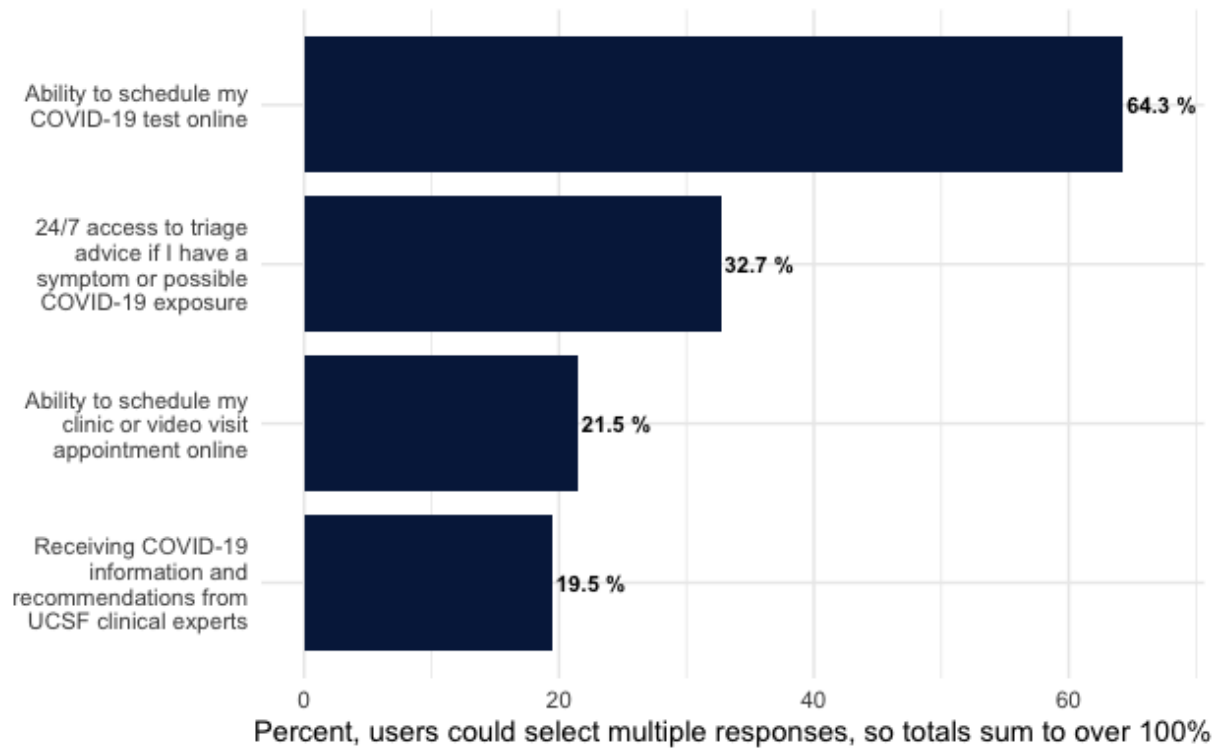
**Figure 1.** Overall user ratings of COVID-19 Symptom Checker (n=395).



**Figure 2.** Patient-reported impact of COVID-19 Symptom Checker on care experience (n=332).



**Figure 3.** Most important COVID-19 Symptom-Checker features (n=395). UCSF: University of California, San Francisco.



### Omicron Surge Subanalysis

There were 288 responses during the omicron surge from December 16, 2021, to January 28, 2022. The median 1-10 rating during that time was 8 (IQR 4-10), and 139 (48.2%) users gave the tool a rating of 9 or 10. There was no difference in overall rating for responses during the Omicron surge compared with before or after the Omicron surge ( $P=.86$ ).

### Demographics

Patient demographics of the survey respondents are summarized in [Table 1](#). There were no significant differences in the user-reported care experience (“improved,” “made no impact,” or “worsened my care experience”) between cohorts by age, race, ethnicity, sex, or socioeconomic status ([Table 2](#)). A multivariate linear regression analysis similarly found no significant associations between user rating and respondent demographics and time frame of use. A subanalysis during the omicron peak found similar results.

**Table 1.** Patient demographics (N=395).

Variable	Value
Average rating, median (IQR)	8 (3-10)
<b>Age (years), n (%)</b>	
18-39	45 (11.4)
40-59	123 (31.1)
>60	158 (40)
<b>Race, n (%)</b>	
White	222 (56.2)
Black or African American	11 (2.8)
Asian, Native Hawaiian or Other Pacific Islander	51 (12.9)
American Indian or Alaska Native	5 (1.3)
Other or prefer not to answer	37 (9.4)
<b>Ethnicity, n (%)</b>	
Hispanic	33 (8.4)
Non-Hispanic	227 (57.5)
Prefer not to answer or unknown	49 (12.4)
<b>Sex, n (%)</b>	
Male	94 (23.8)
Female	221 (55.9)
Prefer not to answer	9 (2.3)
<b>Time frame, n (%)</b>	
Omicron	288 (72.9)
Before or after Omicron	107 (27.1)
Area deprivation index national percentile (IQR)	3 (2-9)

**Table 2.** Multivariable linear regression model to identify predictors of user rating.

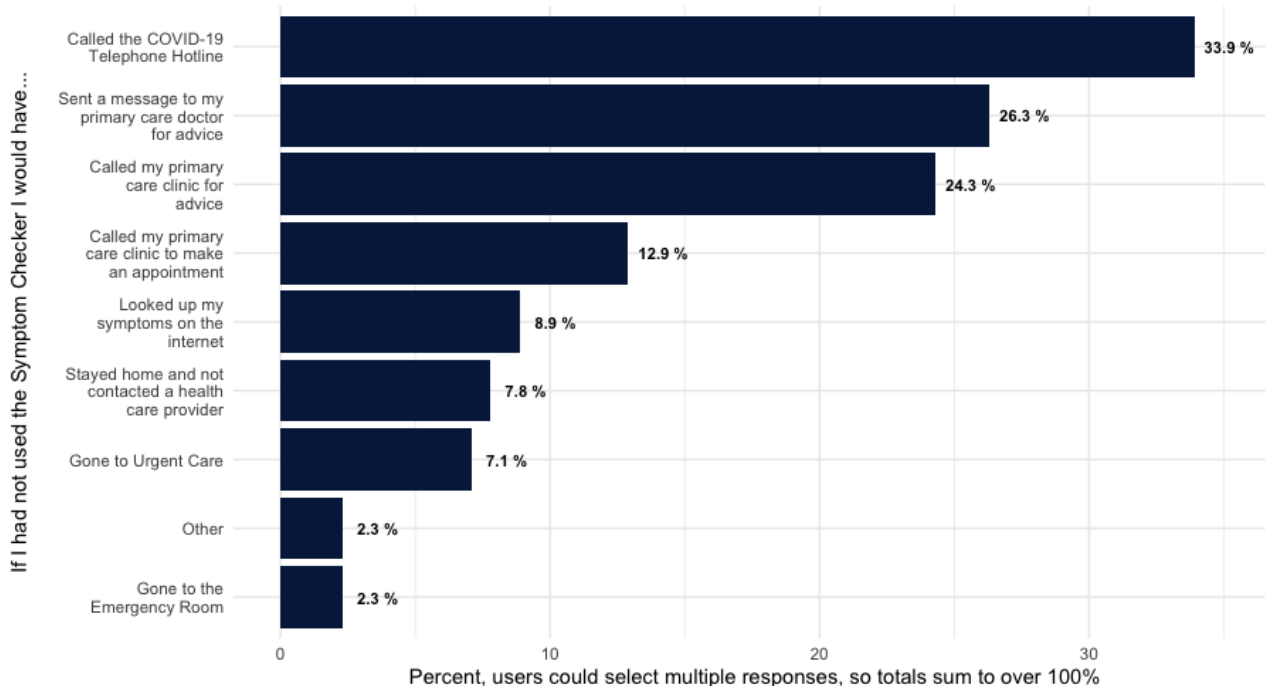
Variable	Estimate	95% CI	P value
<b>Age (vs 18-39)</b>			
40-59	-0.65	-2.02, 0.72	.35
>60	0.13	-1.25, 1.52	.85
Male (vs female)	0.08	-0.91, 1.08	.87
Non-White (vs White)	0.79	-0.23, 1.82	.13
Non-Hispanic (vs Hispanic)	-0.15	-1.58, 1.28	.84
Area deprivation index	-0.02	-0.04, 0.00	.09

### Alternatives to Care

Respondents gave a wide variety of answers when asked what they would have done if they did not have access to the web-based tool (Figure 4). The most common response was

calling the COVID-19 telephone hotline (n=134, 33.9%), followed by sending a patient portal message to their physician (n=104, 26.3%) and calling their primary care clinic for advice (n=96, 24.3%).



**Figure 4.** Patient-reported alternatives to COVID-19 Symptom Checker use (n=395).

### Open-ended Feedback

The most common categories of open-ended feedback were as follows: (1) requested changes to other COVID-19 services (eg,

telephone hotline), policies, or procedures; (2) request for additional tool functionality; and (3) lack of appointment availability (Table 3). This feedback was used to inform updates and upgrades to the tool.

**Table 3.** Patient feedback categories, counts, and examples.

Category	Count	Examples and quotations
Requested changes to other COVID-19 services (eg, telephone hotline), policies, or procedures	24	<ul style="list-style-type: none"> <li>• “Should do covid testing 24 hours.”</li> <li>• “Would be nice if you had MORE testing locations.”</li> <li>• Long wait times when calling the hotline during surges</li> <li>• Desire to be able to schedule preoperative or preadmission COVID-19 tests online</li> </ul>
Request for additional functionality	19	<ul style="list-style-type: none"> <li>• “Would be good to see possible appointment times upfront and then opt to continue entering all one's personal info. Many people are first looking for an available time slot that can work for them.”</li> <li>• Same-day cancelation or rescheduling of a visit online</li> <li>• Ability for the tool to recall prior responses</li> </ul>
Lack of appointment availability	12	<ul style="list-style-type: none"> <li>• Lack of availability of same- or next-day test appointments during Omicron surge</li> <li>• “There are literally no appointments available even though it recommended I have one.”</li> </ul>
Difficulty navigating patient portal	8	<ul style="list-style-type: none"> <li>• Confusion in differentiating this tool from a distinct, “schedule a visit” tool on the patient portal</li> <li>• “I couldn't find the link to schedule a test. I began at ‘Schedule an appointment.’”</li> <li>• Link to this tool not prominent enough</li> </ul>
Request for more personalized health information	6	<ul style="list-style-type: none"> <li>• “How do I find out what ‘Your Value=Not Detected’ means? Does this mean I do not have Covid?”</li> <li>• Request for quarantine advice personalized to individual circumstance</li> </ul>
Outdated information or wording	6	<ul style="list-style-type: none"> <li>• Recommendation page listed an outdated clinic phone number</li> </ul>
Difficult to understand care directions	4	<ul style="list-style-type: none"> <li>• “Didn't go through with scheduling a visit/test because 1) it wasn't clear if I had to have a video visit before the test; &amp; 2) I didn't know where I could get tested (for example, at primary care facility in ****?). So I aborted testing tool.”</li> </ul>
Technical difficulties	4	<ul style="list-style-type: none"> <li>• “I did not get confirmation that the test was scheduled.”</li> <li>• Network or connectivity problems</li> </ul>

## Discussion

### Principal Findings

This study is the first, to our knowledge, to conduct user research on an EHR-integrated COVID-19 symptom checker with self-scheduling functionality. In this analysis, users generally perceived the symptom checker positively and usually reported that the tool improved their care experience. The most popular features were the ability to self-schedule a COVID-19 test online and 24-7 access to triage advice. Constructive or negative feedback on the tool was often a reflection of the larger ecosystem of care delivery for COVID-19, particularly during times of high demand, rather than related to the digital tool itself. This points toward the need for systems to develop robust, high-quality services in conjunction with usable and functioning digital health tools to aid in access.

### Comparison With Other Studies

This analysis supports existing literature [10,11,13] that COVID-19 symptom checkers are generally popular with users. It is well known that there are disparities in access to and ability to use digital tools [14-16]. However, we observed no differences in overall experience by age, sex, race, ethnicity, and socioeconomic status for those who successfully completed

the tool. This suggests that disparities in the use and satisfaction of digital tools like this one may be primarily an issue of access to the tool itself, since those who successfully used the tool reported deriving an equivalent degree of benefit regardless of demographics. This finding can be extended to other patient portal-based tools such as self-scheduling and automated prescription refill services.

### Strengths and Weaknesses of the Study

This survey was completely optional, and we observed a low response rate, so there may be a risk for nonresponse bias. However, recent research suggests that the trends observed may accurately represent attitudes of the population despite low response rate [17,18]. Furthermore, we looked not only at quantitative trends but also at written feedback and noticed that most themes were mentioned in several responses, arguing that we may have reached saturation for likely responders or users with high digital literacy [19]. To keep the survey concise and anonymous, we were limited in the demographic information we could analyze and had no clinical information about the respondents. For that reason, we were unable to stratify the results based on clinical outcomes, comorbidities, or other patient factors. However, the anonymity of the survey likely promoted more open and honest feedback and responses. Finally, because we embedded the survey at the end of the tool,

we were limited in our ability to assess technical barriers to tool use, since those who were unable to use the tool never saw the survey. However, we chose to locate the survey at the end of the tool because our primary goal was to receive timely and actionable user feedback. We chose not to conduct the survey by phone, email, or mail, out of concern that patients would confuse their Symptom Checker experience with other digital and telehealth tools (eg, video visits and remote monitoring) that they may use in the course of an illness, and because we wanted to avoid nonclinical patient communications during times of acute illness.

### Implications

This analysis may be useful to health systems that are trying to weigh the benefits of developing or integrating a COVID-19 symptom checker or similar tool with potential costs. In addition to the other established benefits, high patient satisfaction may make investment in COVID-19 symptom checkers worthwhile. Second, this tool may help to prevent front-line staff and physician burnout [20] by decreasing the volume of calls and patient portal messages. In total, this tool has been used over 80,000 times since it was introduced in March 2020. Based on the proportion of patients who responded that if they had not used this tool, they would have called or messaged their clinicians, the tool may have prevented over 20,000 calls and over 8800 patient messages to date. To our knowledge, this is the first study to assess patient alternatives to use of a symptom checker in the United States. It is consistent with literature from Switzerland and France that most users would have contacted health care systems in the absence of a self-triage tool, and that the use of these tools decreases call center volume [21,22]. Our results may also be generalizable to chatbots, which are widely used in health care to automate triage, connect patients, and reduce provider burden.

Several of the qualitative trends we observed may be useful to health systems and developers for the design and improvement

of symptom checkers and other patient self-service tools. First, the most common category of written feedback was pertaining to the COVID-19 services, policies, and procedures, as well as appointment availability at the health system, rather than an intrinsic aspect of the tool. For that reason, it is essential that health systems first optimize their operational workflows and rightsize their capacity for tests and visits prior to or in conjunction with implementing such a tool. Second, users frequently requested software features that were beyond the current capabilities of the platform we used. Developers of these tools must therefore weigh the benefit of more nimble tools with user-friendly features (eg, transparency of visit availability) with the cost of their development and integration into the EHR. Third, users rarely reported technical challenges, suggesting usability of simple patient-portal-embedded tools. Fourth, the most popular feature of the symptom checker was the ability to self-schedule a COVID-19 test online, suggesting that EHR-integrated tools with the ability to offer self-scheduling of tests, screening exam, or imaging may be perceived more positively by patients compared with those without such features. Finally, our experience from reviewing continuous user feedback reinforced the notion that embedding a simple user feedback survey into a digital tool is a helpful way to promote iterative development.

### Conclusions

COVID-19 symptom checkers have effectively aided health systems in handling high volumes of triage and scheduling requests during the COVID-19 pandemic. We report high user satisfaction and user experience across demographic groups. Furthermore, patient-reported alternatives to the use of this tool suggest it may have saved thousands of phone calls and patient messages. COVID-19 symptom checkers are likely to remain in use for the near future in a diverse array of settings, and an examination of characteristics of use provides insight to improve the patient experience.

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### Conflicts of Interest

ABN has received research grants from Eli Lilly, Pfizer, Royal Philips, Commonwealth Fund, and Cisco; has served as advisor and received consulting fees from Roche, Sanofi, Medtronic, Eli Lilly, Steady Health, and Intuity Medical; is a medical advisor of Tidepool (for which he has received no compensation); and has received author and speaker honoraria from TCOYD, Medscape/WebMD, and AcademyHealth. RG Exercised stock options with Phreesia, Inc. TJJ has served as an advisor to Assure Health and received consulting fees and equity.

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### Multimedia Appendix 1

Qualtrics survey questions embedded into electronic health record-integrated COVID-19 self scheduling and triage tool.

[DOCX File , 17 KB - [humanfactors\\_v9i3e40064\\_app1.docx](#) ]

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## Abbreviations

**EHR:** electronic health record

**UCSF:** University of California, San Francisco

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Original Paper

# Participants' and Nurses' Experiences With a Digital Intervention for Patients With Depressive Symptoms and Comorbid Hypertension or Diabetes in Peru: Qualitative Post–Randomized Controlled Trial Study

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## Abstract

**Background:** Depression is one of the most prevalent mental disorders and a leading cause of disability, disproportionately affecting specific groups, such as patients with noncommunicable diseases. Over the past decade, digital interventions have been developed to provide treatment for these patients. CONEMO (Emotional Control in Spanish) is an 18-session psychoeducational digital intervention delivered through a smartphone app and minimally supported by a nurse. CONEMO demonstrated effectiveness in reducing depressive symptoms through a randomized controlled trial (RCT) among patients with diabetes, hypertension, or both, in Lima, Peru. However, in addition to clinical outcomes, it is important to explore users' experiences, satisfaction, and perceptions of usability and acceptability, which can affect their engagement with the intervention.

**Objective:** This study aimed to explore the RCT participants' experiences with CONEMO in Peru, complemented with information provided by the nurses who monitored them.

**Methods:** In 2018, semistructured interviews were conducted with a sample of 29 (13.4%) patients from the 217 patients who participated in the CONEMO intervention in Peru and the 3 hired nurses who supported its delivery. Interviewees were selected at random based on their adherence to the digital intervention (0-5, 10-14, and 15-18 sessions completed), to include different points of view. Content analysis was conducted to analyze the interviews.

**Results:** Participants' mean age was 64.4 (SD 8.5) years, and 79% (23/29) of them were women. Most of the interviewed participants (21/29, 72%) stated that CONEMO fulfilled their expectations and identified positive changes in their physical and mental health after using it. Some of these improvements were related to their thoughts and feelings (eg, think differently, be more optimistic, and feel calmer), whereas others were related to their routines (eg, go out more and improve health-related habits). Most participants (19/29, 66%) reported not having previous experience with using smartphones, and despite experiencing some initial difficulties, they managed to use CONEMO. The most valued features of the app were the videos and activities proposed for the participant to perform. Most participants (27/29, 93%) had a good opinion about the study nurses and reported feeling supported by them. A few participants provided suggestions to improve the intervention, which included adding more videos, making the sessions' text simple, extending the length of the intervention, and improving the training session with long explanations.

**Conclusions:** The findings of this qualitative study provide further support and contextualize the positive results found in the CONEMO RCT, including insights into the key features that made the intervention effective and engaging. The participants' experience with the smartphone and CONEMO app reveal that it is feasible to be used by people with little knowledge of technology. In addition, the study identified suggestions to improve the CONEMO intervention for its future scale-up.

**Trial Registration:** ClinicalTrials.gov NCT03026426; <https://clinicaltrials.gov/ct2/show/NCT03026426>

(*JMIR Hum Factors* 2022;9(3):e35486) doi:[10.2196/35486](https://doi.org/10.2196/35486)

## KEYWORDS

mobile intervention; depression; diabetes; hypertension; comorbidity; qualitative research; mobile phone

## Introduction

### Background

Depression is one of the most prevalent mental disorders worldwide, affecting >322 million people, and it is the leading cause of global disability [1]. Depression is more prevalent in specific groups, including patients with chronic noncommunicable diseases, such as diabetes and hypertension, negatively affecting their treatment adherence and health outcomes [2]. Despite this, there is still a significant treatment gap for mental disorders, particularly in Latin America [3].

There have been increasing efforts to improve this situation over the last decade, including digital and internet-based interventions for mental disorders [4], which have proven to be effective in reducing depressive symptoms [5]. However, they also come with their own set of challenges, particularly for older populations, who are more likely to be affected by comorbid depression and diabetes or hypertension. Issues such as physical disabilities and low technology literacy negatively affect their experience with and adherence to digital interventions. In contrast, positive experiences and perceived benefits improve engagement and adherence to them [6-9].

Randomized controlled trials (RCTs) are the most rigorous method to assess the effectiveness of an intervention [10], and several digital and internet-based interventions have proven to be effective in treating depression [11,12]. Although RCTs usually focus on the clinical outcomes, it is also important to explore the users' experiences, as poor usability and low acceptability can lead to low engagement with the intervention and user errors and ultimately reduce the potential effectiveness of the digital intervention [13,14]. Consequently, assessing the users' experiences can help researchers to better understand the key features of engagement with a digital intervention, what needs improvement, and which benefits are more relevant, to further inform changes to improve its design. The assessment of users' experience with digital interventions is complex but usually focuses on 2 key components: usability and acceptability [13-16], and they are usually explored through qualitative methods [16].

This paper presents the findings of a qualitative study conducted by the Latin American Treatment and Innovation Network in Mental Health [17] as part of the evaluation of the CONEMO (Emotional Control in Spanish) RCT. CONEMO is a 6-week low-intensity psychoeducational digital intervention designed to reduce depressive symptoms among people with diabetes,

hypertension, or both, delivered through a smartphone app and minimally supported by a nurse.

### The CONEMO RCT

The aim of the RCT was to assess the effectiveness of the CONEMO intervention in reducing depressive symptoms among individuals with diabetes, hypertension, or both, attending public health care facilities in Lima, Peru, and São Paulo, Brazil [17]. The RCT was preceded by pilot studies in both cities, which showed that the trial was feasible to be conducted in public services and presented promising results for the intervention, specifically, a trend in the reduction of depressive symptoms and improvements in disability levels [18].

The RCT results showed that the intervention was effective in reducing the baseline Patient Health Questionnaire-9 (PHQ-9) score by at least 50% at the 3-month follow-up compared with the enhanced usual care group [17]. In addition, there were improvements in disability, quality of life, and activity levels in the intervention group at 3 months. At the 6-month follow-up, only the improvement in activity levels was statistically significant [17].

### Objectives

This qualitative study aimed to explore the RCT participants' experience with CONEMO in Peru, complemented with information provided by the 3 nurses who monitored them. Specifically, the study aimed to provide insights into (1) the participants' satisfaction and acceptability of CONEMO, (2) the perceived benefits of its use, (3) their experience with the study nurses, (4) their experience with the usability of the smartphone and app, (5) the problems they encountered with technology, and (6) their suggestions to improve the intervention.

## Methods

### Design

This was a qualitative study, conducted after the 6-month follow-up assessment of the participants of the CONEMO RCT in Lima, Peru (ClinicalTrials.gov NCT03026426).

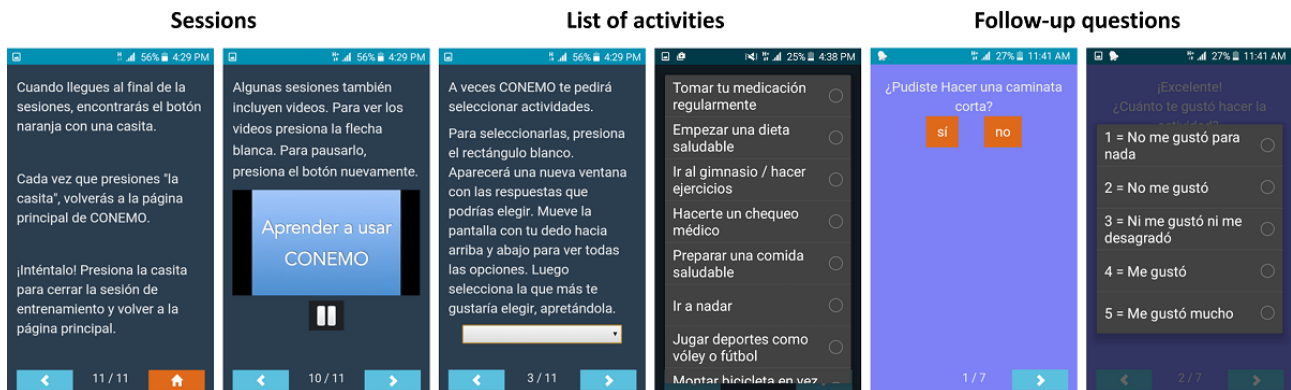
### Description of the CONEMO Implementation in Peru

In Peru, 217 participants were randomly assigned to the digital intervention arm. They received a loaned smartphone with the app installed. The app had a basic interface, which allowed reading the latest session and checking previous completed sessions, and a *request help* button to use in case they encountered difficulties while using the app. The sessions

consisted of texts, and some had videos in which a psychologist talked to the participants about the topic of the session based on the principles of behavioral activation [19]. Participants received 3 sessions per week for 6 weeks, completing up to 18 sessions in total. The sessions focused on promoting pleasant activities, healthy activities, and tasks (Figure 1). At the end of each session, participants were presented with a list of activities that they could aim to complete until the next session. At the

beginning of the next session, the app presented follow-up questions asking the participants if they had completed the previously selected activity and how they felt about it. If the participant had not completed the activity, they received a message within the app, motivating them to complete it. Participants with high PHQ-9 score received a recommendation to seek specialized mental health care in their health facilities at inclusion in the RCT.

**Figure 1.** CONEMO app interface.



The intervention was supported by 3 nurses, hired full time for the project, who conducted an in-person 1-hour training with the participants on the use of the smartphone and app, monitored their adherence to the sessions, and provided technical support, if necessary. Participants received a manual describing the use of the app. For monitoring, nurses made 2 mandatory monitoring phone calls in the initial 3 weeks and additional phone calls if the participants had low adherence (defined as not completing 2 consecutive sessions) or requested help. To monitor their assigned participants, nurses used a dashboard, which displayed the sessions completed by the participants and the help requests. At the end of the 6-week period, the nurses and participants had a final meeting in the health clinic to return the smartphone. During the RCT in Peru, each study nurse had between 72 and 74 participants assigned to them over a period of 9 months. The nurses' activities are described in further detail in another publication [20].

### Setting and Informants

In Peru, the RCT was conducted in 3 public hospitals and 4 public primary health care centers located in Lima, the capital city. The RCT procedures and inclusion criteria are described in the main paper [17].

The information for the qualitative study was collected from two types of informants: (1) participants who received the CONEMO intervention and (2) nurses involved in the intervention delivery during the RCT. The participants were adults with diabetes, hypertension, or both and depressive symptoms as measured using PHQ-9 at the time of inclusion in the RCT (score  $\geq 10$ , which indicates moderate depressive symptoms). For this qualitative study, 2 hospitals and 2 primary

health care centers were selected, where 312 (72.2%) of the 432 RCT participants were recruited.

We aimed to interview between 24 and 36 participants (6-9 participants per facility) and all the study nurses (3/3, 100%). To ensure representation of participants across levels of engagement with the digital intervention, 3 groups were predefined according to their adherence to the digital intervention during the RCT: low (0-5 sessions completed), medium (10-14 sessions completed), and high adherence (15-18 sessions completed). On the basis of the number of participants in each of these adherence groups, a sample of potential interviewees proportional to the strata was selected. Owing to the high adherence of the participants to the intervention during the RCT (169/217, 77.9% completing all sessions), most participants (24/29, 83%) were from the 15-18-sessions category. The participants to be interviewed were selected at random by an independent statistician. Participants who were not able to be contacted were replaced by another participant from the same group, also selected at random. All the nurses (3/3, 100%) participated in the study.

### Data Collection Tools

Semistructured interviews were conducted to collect information. The interview guides were based on topics developed for a research project by the National Institute of Mental Health Collaborative Hubs [21] and locally adapted by the Latin American Treatment and Innovation Network in Mental Health research team to make them relevant to the participants and nurses' experiences with the CONEMO intervention. The topics covered in the 2 interview guides are listed in Table 1.



**Table 1.** Topics included in the interview guides.

Informants	Topics
RCT <sup>a</sup> participants	<ul style="list-style-type: none"> <li>• Expectations of their participation in the RCT</li> <li>• Satisfaction with their participation</li> <li>• Acceptability of the intervention</li> <li>• Perceived benefits of the intervention</li> <li>• Experience with usability of the smartphone and app</li> <li>• Difficulties found while using the smartphone or app</li> <li>• Relationship with the study nurse</li> <li>• Experience with the training and monitoring</li> <li>• Suggestions to improve the intervention</li> </ul>
Nurses	<ul style="list-style-type: none"> <li>• Experience with participants' training</li> <li>• Relationship with the participants</li> <li>• Supervision of participants</li> </ul>

<sup>a</sup>RCT: randomized controlled trial.

## Procedures

Data were collected from September 2018 to December 2018, upon completion of the 6-month evaluation of the RCT. Both interviewers and participants were blinded to the results of the RCT throughout data collection and analysis. Potential informants were contacted via phone and invited to participate in the study. After providing informed consent, informants were interviewed face-to-face by the RCT's fieldwork coordinator (MT; male) or fieldwork supervisor (VC; female), 2 bachelors in psychology, with experience in conducting in-depth interviews. The interviewers discussed the interview guides and standardized their procedures. Individual interviews were conducted in Spanish, at the health facility in which the participant was recruited for the RCT. Interviews with nurses were conducted at the research team's offices. The duration of interviews was, on average, 52 (SD 19) minutes for RCT participants and 71 (SD 18) minutes for nurses. All interviews were audio recorded and transcribed verbatim.

## Data Analysis

All interviews were analyzed using NVivo (version 12; QSR International), and content analysis was conducted [22]. A coding book was developed for each type of informant in advance, based on the interview guides. In total, 2 researchers

(MT and VC) conducted the coding process after a standardization process. During coding, emerging codes were discussed between the coders to decide if they were to be added to the coding book. After coding was completed, quotes and codes were summarized using a coding matrix [23].

## Ethical Considerations

The protocol of the RCT, including this qualitative study, was approved by the National Institute of Mental Health Data and Safety Monitoring Board and locally by the institutional review board at the Universidad Peruana Cayetano Heredia (Constancia 345-16-16). Participation was voluntary and all the informants signed an informed consent form before the interview. All the research team members completed ethical training in good clinical practices and human participants' research.

## Results

### Participants' Characteristics

Overall, 32 semistructured interviews were conducted with 29 people, who participated in the CONEMO intervention during the trial, and the 3 hired nurses, who supported its delivery. Participant demographics are shown in Table 2, and nurse demographics are shown in Table 3.

**Table 2.** Participants' demographics (n=29).

Characteristics	Value
Age (years), mean (SD)	64.4 (8.5)
<b>Sex, n (%)</b>	
Male	6 (21)
Female	23 (79)
<b>CONEMO<sup>a</sup> sessions completed, n (%)</b>	
0-5	2 (7)
10-14	3 (10)
18	24 (83)
<b>Recruitment location (health facility), n (%)</b>	
1	8 (28)
2	9 (31)
3	6 (21)
4	6 (21)

<sup>a</sup>CONEMO: Emotional Control in Spanish.

**Table 3.** Nurses' demographics (n=3).

Characteristics	Value
Age (years), mean (SD)	33 (5.2)
Sex (female), n (%)	3 (100)
Working experience (years), mean (SD)	8 (1.7)

## Participants' Expectations and Satisfaction With CONEMO

The participants' main expectations of the CONEMO intervention were to receive help to "feel better," learn how to cope with their emotions, be motivated to try new things, better organize their activities throughout the day, communicate more with their children, learn more about how to deal with their diabetes, hypertension, or both, or do more exercise.

Most of the interviewed participants (21/29, 72%) stated that CONEMO fulfilled their expectations, which included feeling better and trying new things. In contrast, a few participants mentioned that their expectations were partially met or not met at all. For example, one of them said that he expected something "deeper" and more useful, but the intervention was mainly asking how he was feeling and to do things he already did, such as exercise and eating healthy:

*Interviewer: "Okay, and do you consider that the study met your expectations, the expectations that you had at the beginning when you decided to participate?"*

*Participant: "No, because everything they said there, to eat vegetables, to do exercise, I have been doing that before, so just normal [activities], did not helped me much." [Male participant; aged 68 years; high adherence]*

When asked if they would recommend CONEMO to other people, most interviewees (20/29, 69%) said that they would, some even stated that they had recommended it to their relatives or friends. The main reasons they recommended it were because it had helped them to feel better or improved their health or because they believed it can help other people. Some participants mentioned specific aspects of CONEMO that will be beneficial to others, for example, learning how to feel better and take care of themselves, receiving step-by-step instructions and advice, monitoring and attention received from the nurse, and recommendations to see a psychologist or psychiatrist:

*I would recommend [CONEMO] to patients like me, who sometimes lose our memory, we forget, I forget one thing or another. And then, it makes you remember, because it tells you: take out your pen, write, do this, it makes you remember, it gives you very nice advice, that's why I would perhaps advise another patient, that this is beautiful, it's beautiful. Also, as I said, at our age no one pays attention to us and there was a nurse and a cellphone that they gave us and they were aware of me. [Female participant 1; aged 59 years; high adherence]*

## Perceived Benefits of Using CONEMO

Most participants (26/29, 90%) reported perceiving changes in themselves after using CONEMO, which helped them to feel better. Some of these changes were related to their thoughts and feelings, whereas others were related to their routine and habits.

### Changes in Thoughts and Feelings

Regarding their thoughts and feelings, many interviewees (11/29, 38%) mentioned that they began to think differently or became more optimistic, and a participant mentioned that she stopped thinking about dying:

*I thought about...what am I in this world for, right? My role is over, my children are already grown up, they can be on their own, like, my life no longer [had purpose]. I didn't try to take my life, but I have thought about that. For example: "Oh, God, take me," things like that, but no, I haven't tried it. And I felt that I was falling down, but not now. Now I don't think about it (laughs). Now I'm thinking that I have to travel (laughs) and now I'm doing it, right? And I feel better.* [Female participant 2; aged 59 years; high adherence]

*In my case, I was depressed, I said: "what will happen to my life?" I tried to improve, thanks to CONEMO, thanks to the nurses, to the videos, ...reading it and practicing it, I tried to improve, that's why I'm fine here, I feel good, I no longer feel depressed as before.* [Male participant; aged 53 years; high adherence]

Some participants mentioned feeling calm and more peaceful (8/29, 28%), whereas others said they felt more confident, paid more attention to themselves, and felt that they were important to other people (7/29, 24%). Another change mentioned was their interaction with others, including being less moody, listening more to others, and arguing less (5/29, 17%):

*[CONEMO] calmed me down a lot, I felt safe, I felt that I was not, how do you say, a piece of furniture that is no longer used, because I was convinced that nobody cared about me, that I only mattered when they needed me. And [CONEMO] made me come out of all those things, all those doubts, all that concern and it helped me a lot.* [Female participant; aged 69 years; medium adherence]

*There were a lot of changes in me, more independence, more confidence in myself and there are several things that I have achieved with CONEMO.* [Male participant; aged 71 years; high adherence]

### Changes in Routine and Habits

Similarly, when asked about changes to their routines or habits, one of the most common changes was going out more (12/29, 41%). Some participants described their previous routines as being isolated and always staying at home, either owing to lack of motivation or physical difficulties, but after using CONEMO, they felt motivated to go out more often:

*I started doing sports to feel better, right? Because it is good to walk, not to stay locked in the house. Sometimes you have problems and just stay locked in, so it is better to go out for a walk, walk, walk, be distracted, not overwhelmed with problems.* [Female participant; aged 57 years; high adherence]

Other changes perceived by the participants were developing new hobbies, including reading, listening to music, sewing, and knitting (6/29, 21%). Some participants developed interest in technology, and after they returned the smartphone provided by the study, their relatives bought them one to continue using it (4/29, 14%). Some participants also mentioned visiting or spending time with friends and family more often (5/29, 17%):

*I knew sewing a bit and like it, so I made patterns and started drawing and taking measures, and out of the three [patterns] I made two blouses that I liked, and I still use them now. They are for summers but I use them, so all of that made me change.* [Female participant; aged 76 years; medium adherence]

Another important change mentioned by some participants was improving their health-related habits, such as taking care of their diabetes, hypertension, or both and being more consistent with taking their medication or eating healthy (4/29, 14%). Other participants mentioned doing more exercise (8/29, 28%), which was also perceived as a distraction, with a participant reporting having lost 25 kg since using CONEMO:

*It was positive, yes, because it helped me with its questions, it also helped me to be more responsible with myself, with my medicines because I also forgot, I forgot to use my insulin on time...it supported me in that, it helped me.* [Female participant; aged 57 years; high adherence]

## Participants' Experience With the Intervention

### Experience With the Study Nurses

The study nurses were in charge of training the participants on how to use the smartphone and CONEMO app and provided monitoring to solve technical difficulties. Approximately two-thirds of the participants (18/29, 62%) considered the training clear and sufficient to learn how to use the smartphone and CONEMO app. However, nurses mentioned that this session was long and that some participants felt nervous about using the smartphone.

A few participants said that the training session with the nurse was not long enough to learn how to use the CONEMO app. They also sought help from a relative, and a participant mentioned learning through trial and error:

*It was not enough, it was only one appointment with her, but no, I think it was very little time...like I told the nurse, I am a little bit dumb about learning this stuff, I have to practice a lot, the nurse told me if anything happens to call her, to let her know or ask for help, but I did not ask her because I thought "If I broke it?" but I asked help from my granddaughter.* [Female participant; aged 76 years; medium adherence]

Some participants reported experiencing some difficulties after the training, feeling that they initially understood the nurse's instructions and information received, but forgot them later (6/29, 21%). Some participants scheduled a second training session with the nurse, whereas others asked a relative for help:

*When she taught me, it seemed easy, but when being back at home, I forgot it, I did not know how to use it or anything.* [Female participant 1; aged 59 years; high adherence]

Regarding nurses' phone monitoring, most of the interviewed participants (27/29, 93%) had a positive opinion, with some highlighting aspects such as feeling supported by the nurse, feeling important, and feeling that someone was interested in them. Other participants mentioned that the calls were useful either to reinforce continuing completing the sessions or as reminders to complete them:

*I liked it because it showed an interest in me, and that is what I wanted, because I like to be listened to, to be taken care of, to have interest in me, and I felt that way, that they were interested. And I liked to be called.* [Female participant 3; aged 59 years; high adherence]

*I usually forgot [the session], but [the nurse] called me so I remembered.* [Male participant; aged 53 years; high adherence]

Nurses agreed with this, stating that most of the participants were satisfied with the monitoring calls and only a few were reluctant to answer the phone or busy with other responsibilities:

*I had a patient who blocked my number, she knew it was my number, so with the clinical coordinator we had to call her from public phones or another number to schedule [the monitoring], and I also had two, three patients who did not answer the calls or cancelled the appointment because they had to attend meetings with their children.* [Nurse; aged 30 years]

### **Experience With the Smartphone and App**

Most of the interviewed participants (19/29, 66%) reported not having previous experience with using smartphones. Overall, approximately one-third of the interviewed participants (11/29, 38%) reported some difficulties at the beginning in learning how to use the smartphone provided by the study. They required some time to become familiar with the technology, but, eventually, they learned to use it. Nurses confirmed this, especially in the case of older adults:

*At the beginning it was [difficult] to use the smartphone, just that, everything else was okay...a little bit difficult because I did not understand it, but then, little by little, reading the manual, I learned it all and I used it.* [Female participant; aged 64 years; high adherence]

In contrast, a few participants had a more negative opinion about their experience with the smartphone and considered it to be very difficult to use:

*I do not like it. I have one [smartphone] given to me by my son, and I prefer this [basic] phone.* [Female participant; aged 60 years; high adherence]

Regarding the CONEMO app, most participants (28/29, 97%) had a good opinion, with most of them highlighting features such as the videos (19/29, 66%) and list of suggested activities for the participant to engage in (15/29, 52%). The videos were

described as "educational" and "helpful," and were clear and understandable to most participants (19/29, 66%). The activities proposed in the app were perceived as an opportunity to try new things or, through the app's follow-up questions, to remind them to perform some activities. The participants compared these suggestions with having someone who cares about them:

*It was good because [when] I started [with the study], I used to be secluded at home, but [then] I read, and went to visit my cousin, my friend. I went out to the beach to sit for a while and distract myself, I liked a lot that [CONEMO] told us to do these things.* [Female participant; aged 74 years; low adherence]

Some participants also liked reading the contents of the sessions and advice provided (10/29, 34%) and considered the contents to be "motivational." Finally, another aspect of the app highlighted by 7% (2/29) of the participants was the frequency of the sessions (ie, 3 sessions per week), which was considered to be appropriate to take the time to perform the activities selected in each session:

*It was ideal because it wasn't every day, it was Monday, Wednesday, Thursday, I got a notification and with that I had a chance to make some time when I finished what I was doing to read and apply it.* [Female participant 3; aged 59 years; high adherence]

### **Problems Found While Using the Smartphone and App**

Approximately half of the interviewed participants (15/29, 52%) reported having experienced some difficulties either with using the smartphone or the app. Regarding smartphone, the most common difficulties were related to not remembering how to perform certain basic tasks, such as using the touch screen, turning the smartphone on or off, or connectivity issues. Nurses noted that a common issue among participants was not remembering how to unlock the phone. Nurses also mentioned that at the beginning, they had difficulties in understanding their patients' descriptions of problems with the phone during the calls because their explanations were not very clear. However, as the nurses became more familiar with those problems, they could help patients solve them more quickly:

*Some patients had difficulties handling the phone, so I gave them options, like steps, so they can enter the phone easily...Practicing with them, taking the time to explain step by step, repeating it again and again, in the end they did understand what it was about.* [Nurse; aged 39 years]

Similarly, the most common difficulty found while using the app was not remembering how to use it. In addition, 7% (2/29) of the participants mentioned that they had difficulties in understanding the content of the sessions.

When queried about who they asked for help when encountering these difficulties, the most common answer was a young relative, followed by the study nurse. Other participants mentioned that they solved the issue by themselves through trial and error, reviewing the manual provided by the research team, or trying to remember the information provided by the nurse:

*You know who helped the most? My granddaughter...I told her "Teach me because you know" I saw how she used her phone, so I told her "Teach me" and she said to me: "look, these pictures, messages, look, my uncle sent you a message." Through her I did [learn]. [Female participant; aged 76 years; medium adherence]*

### Suggestions to Improve the Intervention

When asked about their suggestions to improve different aspects of the intervention, only a few participants provided feedback, mostly centered on the app and its use. The most common suggestion was to add more videos and make them long, as this was the favorite feature of the app. Overall, 7% (2/29) of the participants suggested making the text of the sessions simple, because sometimes they found it difficult to understand. Others said that it should include more information, particularly about activities or hobbies that older people can do.

Other suggestions mentioned less frequently were to make the app more user-friendly, because some participants had to ask for help; increase the frequency of the app sessions; include more information and questions in them; and increase the font size. Some other suggestions were focused on the intervention design, with a few participants wanting the intervention to last long and include in-person meetings among the participants or to be able to interact with other participants through chat.

Very few participants had suggestions to improve the nurses' activities. Some participants suggested having more contact with the nurse, either with more calls or more meetings. Others suggested improving the training with long explanations. Finally, a participant suggested receiving in-person help from the nurse to perform the activities proposed by the CONEMO app.

## Discussion

### Principal Findings

This study aimed to explore the experience of participants when using a digital intervention (CONEMO) while conducting an RCT to test this intervention in Lima, Peru. CONEMO was considered as an acceptable intervention by users, with most participants (26/29, 90%), including those with low adherence to the intervention sessions, reporting significant benefits for their mental and physical health and improvements in their habits and behaviors. In addition, regarding the usability of the technological components of the intervention, participants felt comfortable using the app; they experienced only a few difficulties, especially at the beginning, which they were able to solve with help from relatives or nurses. Collecting the participants' experiences and opinions allowed a better understanding of the most valued aspects of the intervention and how they may have contributed to their engagement with the app during the RCT. In addition, this qualitative study provides important lessons that can guide the design of future digital mental health interventions, considering the feedback received from the participants.

During the RCT in Peru, the adherence rates for the CONEMO sessions were very high, with 92% of the participants completing more than half of the sessions and 78% completing all the 18

sessions [17]. The interviewed participants in the qualitative study acknowledged their satisfaction with the intervention, with most of them (21/29, 72%) mentioning that CONEMO fulfilled their expectations and that they would recommend it to other people. Furthermore, the participants elaborated on the perceived benefits of using CONEMO on their mood, thoughts, and behaviors, which provides context to the positive RCT results [17].

CONEMO was developed under the principles of behavioral activation [19], and the sessions invited participants to engage in different activities. In the RCT, participants in the intervention arm significantly improved their disability outcomes (as measured by the World Health Organization Disability Assessment Schedule-II) and levels of activity (as measured by the Behavioral Activation for Depression Scale Short Form) [17]. The qualitative interviews confirmed that CONEMO motivated the participants to engage in the proposed behavioral activation activities and introduced significant changes to their daily routines. We collected clear examples of the types and variety of activities they performed to be more vital and improve their physical and mental health. The study findings support the use of digital interventions based on behavioral activation to treat patients with depressive symptoms. In addition, it is aligned with existing evidence regarding the use of digital interventions to introduce lifestyle changes, particularly for older adults [24].

It is important to consider that the intervention included interaction with the project nurses. Despite the nurses' role being centered on providing technical support related to the smartphone and CONEMO app, the interviewed participants stated feeling supported by the nurse and mentioned that they felt someone was interested in them. The participants were also particularly impressed with the videos in which they were able to see another person talking to them. It can be speculated that the feeling of support described by the participants owing to the interactive components of the intervention could have contributed to their engagement with CONEMO and the improvement in their emotional well-being. This finding is particularly relevant because the intervention is aimed toward people with noncommunicable diseases, who are mostly older adults and at great risk of experiencing social isolation [25,26], as described by some of the interviewees. Interactivity between the users and digital interventions has been reported as an important feature with a positive impact on the engagement with the intervention, particularly in mental health apps [13,27,28]. In addition, feedback and support have been reported as motivators for older adults using digital health interventions [29]. Digital interventions targeting older populations can include peer support, through chat or calls, as a feature of the app, as suggested by some interviewed participants.

Usability is a key component that influences the adoption of apps, particularly for people with little experience and knowledge of technology, and can influence engagement and symptom reduction [15]. In the case of CONEMO, although most participants (19/29, 66%) lacked experience in using a smartphone and encountered initial difficulties in becoming familiar with its use, most of them (24/29, 83%) were able to complete the sessions successfully and without great difficulties. This result highlights CONEMO's good usability and confirms

that older adults with no previous experience with technology are able to engage with digital interventions.

Considering the participants' positive feedback regarding acceptability and usability, CONEMO can be easily adapted and implemented within the health system for patients with other health conditions or multimorbidity. The positive feedback has been echoed by other stakeholders who were interviewed, who consider CONEMO to be feasible to implement within the local health system [30]. In the current context of the COVID-19 pandemic, the population had to adapt relatively quickly to the use of technology to communicate with other people, work, and study, among other activities. Similarly, health systems also had to adjust quickly and implement telemedicine procedures where there were none. Particularly, within the Peruvian health system, the COVID-19 pandemic forced the health system to swiftly develop and implement telemedicine services and protocols [31]. This scenario makes the health system more open to introducing digital and technology-based interventions and provides an opportunity for CONEMO to be implemented on a wide scale. In addition, there is an ongoing mental health reform aimed to strengthen the provision of mental health services within the public health system [32,33]. CONEMO can be implemented in community mental health centers, which are increasing in number each year in Peru, and the study nurses' role can be easily adopted by the available staff or other people extensively available in low-income and middle-income settings, such as community health workers, can be included.

Despite the success and positive feedback received from the participants, there are some improvements that can be made to the design of CONEMO for future interventions or deployment, and the interviews provided a few suggestions.

First, they suggested including more videos that were rated very favorably by the participants during the pilot study [18]. The similarity in the findings shows that the CONEMO videos are still highly valued by the participants and adding more will increase the satisfaction and engagement with the intervention.

Second, a few participants suggested reviewing the contents of the sessions to make them easy to understand and including further information on the types of activities they can perform and how to perform them. As a next step, it will be useful to conduct a validation process of the sessions' content with a wide range of participants to make the sessions understandable and inclusive for all.

Finally, there is a perception among some participants that the training session for participants at the beginning of the intervention was not sufficient to fully understand how to use the smartphone and app, and a few participants suggested increasing the time for this activity. The revised training session can include an extra session to resolve doubts and allow time for more practice to foster familiarity with the device. In

addition, the training should involve, when possible, a participant's relative, as they were the main resource to solve the technical difficulties faced, and not the study nurses, as intended initially. Furthermore, as videos were a highly valued feature of the intervention, the training can also include videos to reinforce the content provided during the in-person training. Videos stored in an archive can be accessed at any time by participants or their relatives. These improvements will not only provide sufficient sources to solve technical difficulties but also optimize the use of the scarce human resources within the health systems of low-income and middle-income settings.

### Strengths and Limitations

The participant sample included people with different levels of adherence to the intervention and from different health facilities. In addition, we included study nurses to complement the information provided by the participants and compare their points of view. Given the high adherence to the intervention by most participants (200/217, 92.2% completed at least 9 sessions and 169/217, 77.9% completed all the sessions), it was difficult to include people with very low adherence. Another strength of this study is that everyone (ie, participants and evaluators) was blinded to the results of the trial, thus providing a less biased view of the intervention. A limitation of the study is the time at which the interviews were conducted. They were conducted approximately 4.5 months after the end of the 6-week intervention, and it is possible that their recollection of experiences may not be as accurate as one would expect when questions are asked immediately after completion of the intervention. It was not possible to conduct these interviews close to that time because the primary outcomes needed to be assessed 3 months after completion of treatment. However, the trained interviewers were instructed to ask additional questions and explore when the answers were very superficial or vague, and the data collected were sufficiently rich to capture the experiences of the participants.

### Conclusions

The findings of this qualitative study not only support but also enrich and complement the results found in the CONEMO RCT regarding improvements in the participants' mental and physical health and the positive changes in their habits and daily behaviors. The participants' experiences with the smartphone and CONEMO app showed that it is not only feasible to be used by people with little knowledge of technology but also, with minor adaptations, can be implemented at a large scale. In addition, the study identified suggestions to continue improving the CONEMO intervention and provided insights into the key features that made the intervention engaging and effective. Furthermore, these results provide further evidence that it is possible to implement digital mental health interventions with high rates of acceptability and adherence in low-income and middle-income countries.

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### Authors' Contributions

RA, PRM, DCM, and JJM contributed to study conceptualization, funding acquisition, study supervision, and critical revision of the manuscript. FDC, MT, and VC contributed to data collection, analysis, draft preparation, manuscript revision, and editing. All authors have read and approved the final manuscript for submission.

### Conflicts of Interest

DCM has accepted honoraria and consulting fees from Otsuka Pharmaceuticals, Optum Behavioral Health, Centerstone Research Institute, and One Mind Foundation and royalties from Oxford Press and has an ownership interest in Adaptive Health, Inc.

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## Abbreviations

**CONEMO:** Control Emotional in Spanish  
**PHQ-9:** Patient Health Questionnaire-9  
**RCT:** randomized controlled trial

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Original Paper

# Automated Decision Support For Community Mental Health Services Using National Electronic Health Records: Qualitative Implementation Case Study

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## Abstract

**Background:** A high proportion of patients with severe mental illness relapse due to nonadherence to psychotropic medication. In this paper, we use the normalization process theory (NPT) to describe the implementation of a web-based clinical decision support system (CDSS) for Community Mental Health Services (CMHS) called Actionable Intime Insights or AI<sup>2</sup>. AI<sup>2</sup> has two distinct functions: (1) it provides an overview of medication and treatment history to assist in reviewing patient adherence and (2) gives alerts indicating nonadherence to support early intervention.

**Objective:** Our objective is to evaluate the pilot implementation of the AI<sup>2</sup> application to better understand the challenges of implementing a web-based CDSS to support medication adherence and early intervention in CMHS.

**Methods:** The NPT and participatory action framework were used to both explore and support implementation. Qualitative data were collected over the course of the 14-month implementation, in which researchers were active participants. Data were analyzed and coded using the NPT framework. Qualitative data included discussions, meetings, and work products, including emails and documents.

**Results:** This study explores the barriers and enablers of implementing a CDSS to support early intervention within CMHS using Medicare data from Australia's national electronic record system, My Health Record (MyHR). The implementation was a series of ongoing negotiations, which resulted in a staged implementation with compromises on both sides. Clinicians were initially hesitant about using a CDSS based on MyHR data and expressed concerns about the changes to their work practice required to support early intervention. Substantial workarounds were required to move the implementation forward. This pilot implementation allowed us to better understand the challenges of implementation and the resources and support required to implement and sustain a model of care based on automated alerts to support early intervention.

**Conclusions:** The use of decision support based on electronic health records is growing, and while implementation is challenging, the potential benefits of early intervention to prevent relapse and hospitalization and ensure increased efficiency of the health care system are worth pursuing.

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## KEYWORDS

implementation; computerised clinical decision system; decision system; decision support; participatory action framework; psychotropic medication; psychotropic; nonadherence; monitoring; medication adherence; algorithms; algorithm; electronic health records; EHR; health record; normalization process theory; automated alerts; automated alert; mental health; mental illness; adherence; medication; eHealth; web-based

## Introduction

A high proportion of patients with severe mental illness relapse due to nonadherence to psychotropic medication [1-5]. Psychotropic medications, including antipsychotics, antidepressants, and mood stabilizers, are routinely used in the treatment of severe mental illness such as schizophrenia and bipolar disorder [6-8]. Regular attendance at medical services and adherence to the timing, dosage, and frequency of prescribed medication is important in the long-term management of these chronic mental health conditions to avoid the risk of relapse and hospitalization [9]. A recent meta-analysis showed that for patients who discontinued medication after clinical remission, the risk of relapse was 78% at 24 months and 84% at 36 months [10].

In Australia, Community Mental Health Services (CMHS) provide community-based specialized care for people living with severe mental illness as part of a stepped care model [11]. Clinical decision support systems (CDSS) can assist CMHSs in the early detection of nonadherence to facilitate a more proactive model of care to help break cycles of preventable relapse and thus improve health outcomes for people with serious mental illness [12]. In current practice, medication adherence is only routinely monitored for the high-risk medication clozapine [13].

One of the challenges of developing systems for monitoring medication adherence is the siloed nature of health care data in Australia, resulting from the way in which health care funding is managed. Health care funding is split between federal and state governments, resulting in siloed data. Broadly speaking, states fund acute care services, which include CMHS, and the commonwealth funds Medicare universal health insurance coverage, which includes general practitioners (GPs), medication, radiology, and pathology [14]. The development of Australia's national electronic health record, My Health Record (MyHR), has made it possible to improve data sharing across the health care system. Actionable Intime Insights (AI<sup>2</sup>) is an innovative application using MyHR data for automating service disengagement and nonadherence risk monitoring.

In this paper, our objective is to evaluate the implementation of the AI<sup>2</sup> application to better understand barriers and enablers to implementing a web-based CDSS to support medication adherence and early intervention in CMHS. To do this, we adopt an approach that combines participatory action research (PAR) with normalization process theory (NPT) [15]. PAR includes the voice of the researchers and captures the collaboration between researchers and clinicians over the course of the pilot implementation [15,16]. NPT has emerged as a framework for understanding complex health care interventions and the implementation of health technologies and electronic health records [17-21]. Underpinning the structure of NPT is the pragmatic need to understand the challenges of introducing CDSS into health care settings [22,23].

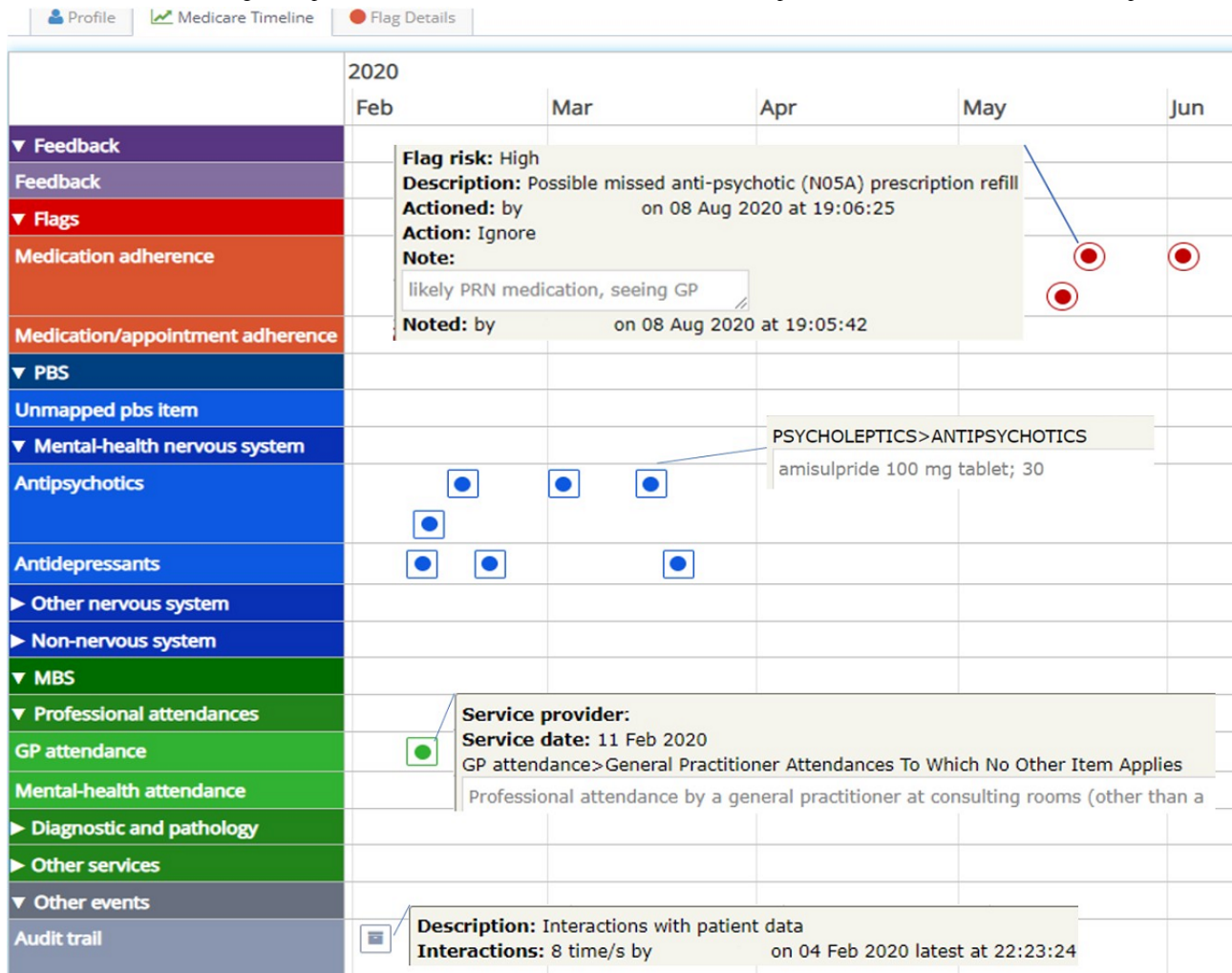
## Methods

### Actionable Intime Insights Application

Actionable Intime Insights (AI<sup>2</sup>) is a web-based software that synthesizes data from Australia's national My Health Record (MyHR) system in near real-time to determine whether patients' records of attendance for medical appointments and prescription refill records reflect treatments appropriate for their condition [24]. Algorithms in the software generate alerts when prescriptions have not been refilled and when 6-month appointments for mental health care plan reviews with the GP have not occurred at the expected times. These alerts are visually presented in a dashboard along with a time line visualization of all previous claims (Figure 1). The decision rules for generating alerts are derived from best practice guidelines for the treatment of schizophrenia, bipolar disorder, and major depression [25,26]. The development of the software, algorithm details, and clinical outcomes of implementation were previously published [24,27,28].

The AI<sup>2</sup> dashboard lists all clients in the clinic and has a search function to retrieve individual patient data and filters that which can be used to target specific client groups based on episode status (open or closed), risk of nonadherence (high, moderate, or low), and time since last alert. Patient data can be individually reviewed using the time line view (Figure 1).

**Figure 1.** Time line view. GP: general practitioner; MBS: Medicare benefits schedule. PBS: pharmaceuticals benefits schedule; PRN: pro re nata.



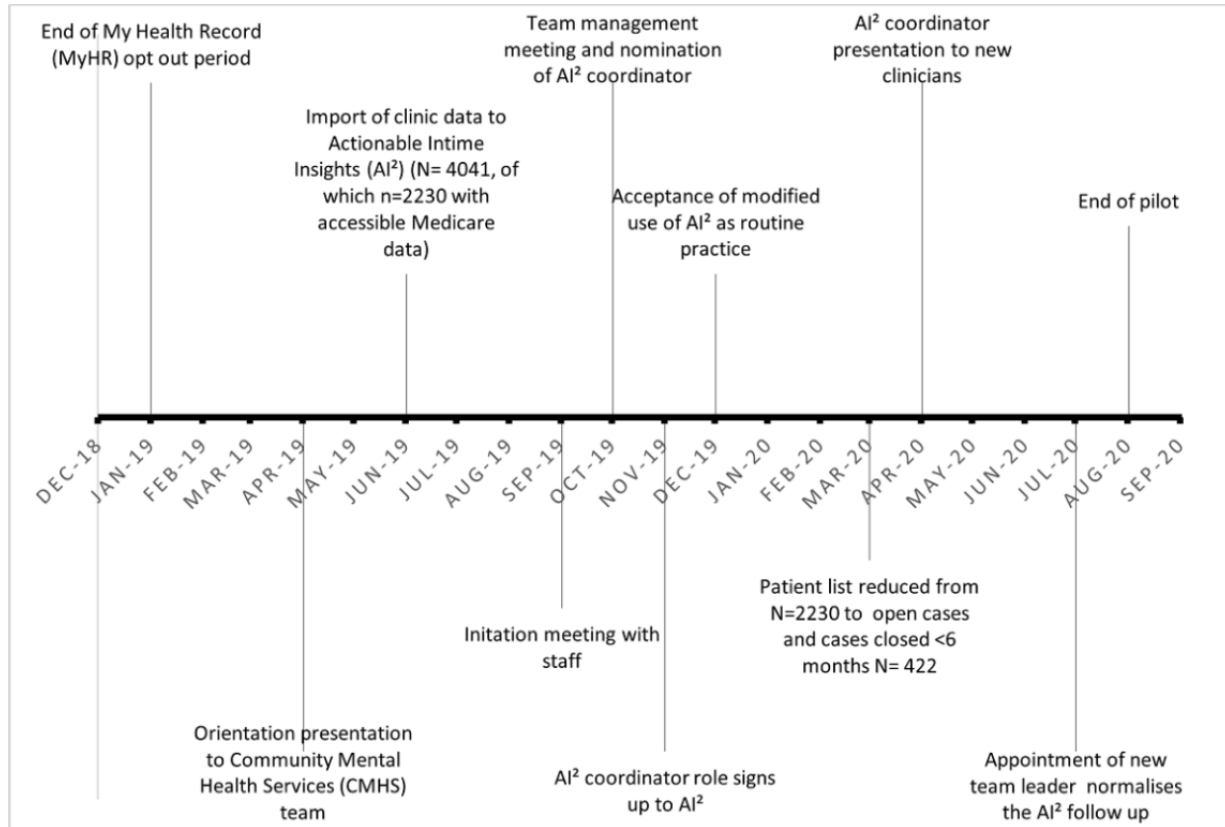
**Implementation Site**

The pilot implementation of AI<sup>2</sup> was conducted in 2019-2020 in a CMHS in South Australia. The site care team consisted of 9 mental health clinicians from multidisciplinary backgrounds, including 2 on-site psychiatrists (0.4 full-time equivalent [FTE] and 0.2 FTE), 2 nurse consultants, a youth clinician, and a team leader. The service catchment has a highly itinerant population. At the time of implementation, the CMHS was managing 60 case coordination clients, 30 clozapine clients, and around 13 new referrals weekly. Care was provided using a consultation liaison model with psychiatrists consulting with patients on an as-needed basis. Patients were referred for psychiatric care by their GPs or case managers for assessment and advice regarding treatment and services (eg, pharmacotherapy, psychological treatment, anger management, relationship counselling, financial counselling, etc). Following consultation, a written summary

of the recommendations including medication advice was sent to the patient and their GP. Case managers provided care coordination for patients within their service, and weekly case review meetings were held with the treating psychiatrist. Patients being treated with clozapine were reviewed every 6 months as per protocol, with all other patients reviewed only as requested (by the case managers or GPs), typically <1/year. A time line of key milestones is captured in Figure 2.

Patient lists including first name, surname, gender, date of birth, and Medicare number were imported to AI<sup>2</sup> in June 2019. The AI<sup>2</sup> software uses the patient identifiers to automatically contact the Healthcare Identifiers Service to obtain the patient’s Individual Healthcare Identifier (IHI). Once a patient has an IHI, the server connects to MyHR and downloads Medicare claims data from MyHR to AI<sup>2</sup>. Data are updated on a weekly basis. A minimum of 2 years of Medicare data are downloaded.

Figure 2. Implementation timeline.



**Participants**

Participants (N=18) in the research are shown in Table 1.

Table 1. Participants (N=18) in this study.

Participants by type	Values, n
<b>CMHS<sup>a</sup> participants</b>	
Psychiatrist	1
Social worker	4
Nurse	2
Nurse practitioner	1
Admin officer	1
Occupational therapist	2
Peer review worker	1
<b>Research team</b>	
Psychiatrists	2
Computer scientists	2
Implementation researchers	2

<sup>a</sup>CMHS: Community Mental Health Services.

**Data Collection**

Consistent with participatory action research, data collection was a 16-month process from start to end of the pilot. The principal site psychiatrist (0.4 FTE) was also a member of the research team and attended weekly research meetings over the

course of the pilot implementation. Data were collected throughout the implementation. Data included in the final analysis are shown in Table 2. Transcripts from team meetings and other work products were used to inform timing and context and provide clarification [29].

**Table 2.** Data used in the analysis by type.

Data type	Number of documents
On-site discussion group	2
Emails	15
One-on-one interviews	3
LHN <sup>a</sup> emails and docs	3
Research team meetings	1
Total	24

<sup>a</sup>LHN: Local Health Network.

## Ethics Approval

This research was approved by the Southern Adelaide Clinical Human Ethics Research Committee (Ref 177.17) and the Country Health SA governance committee and was granted site approval for the use of AI<sup>2</sup>. Clinicians provided online consent for the use of the software. The research team and participating site clinicians also provided written consent for the audio recording of meetings and interviews as well as for the incorporation of work products related to the use of AI<sup>2</sup> to be included as data.

## Analysis

Transcripts and documents were uploaded to NVivo software and coded using a deductive thematic analysis approach using the following NPT framework constructs: coherence, cognitive participation, collective action, and reflexive monitoring (Table 3) [30,31]. The problem of overlapping constructs in NPT was challenging [32,33]. Several iterations of coding were required to confirm that the coding was consistent with the NPT framework. Agreement on coding was reached between authors YvK and EL. Team members involved in the implementation reviewed the overall results for accuracy and fidelity.

**Table 3.** Four generative mechanisms of the normalization process theory (adapted from Lloyd et al [34], which is published under Creative Commons Attribution 2.0 International License [35]).

Generative mechanism	Description
Coherence	The sensemaking work that people do individually and collectively when they are faced with the problem of operationalizing some set of practices.
Cognitive participation	The relational work that people do to build and sustain a community of practice around a new technology or complex intervention.
Collective action	The operational work that people do to enact a set of practices, whether these represent a new technology or complex health care interventions.
Reflexive monitoring	The appraisal work that people do to assess and understand the ways that a new set of practices affect them and others around them.

## Results

### Coherence: Sensemaking

Coherence describes the sensemaking work done both individually and collectively by clinicians and administrators, as they worked to integrate AI<sup>2</sup> into their everyday practice [36]. Sensemaking is a process of understanding and rationalization that impacts subsequent actions and roles [36]. The site psychiatrist worked closely with the researchers on the implementation plan. As part of the implementation process, the site psychiatrist and the research team made 2 presentations to staff, an orientation presentation in April 2019 and a more detailed initiation meeting in September 2019. Author YvK also participated in a team management meeting in October 2019 to discuss and plan the rollout (Figure 2).

### Investigating Medication Adherence

An important part of the work Community Mental Health clinicians do is understanding patients' medication and adherence. Clinicians in CMHS use multiple databases to both

investigate and manage patients. As one participating clinician (referred to as CL in the quotes) confirmed:

*So, when we have a client referred to us, we will often refer to not just our database. [CL9]*

However, prior to the development of MyHR, CMHS did not have access to Medicare data, which includes pharmacy prescription data as well as Medicare claims data for GP attendance, radiology, and pathology. Clinicians, including both social workers and nurses, routinely make calls to patients GPs and family to investigate medication adherence and GP attendance.

*We would normally talk to GPs to try and get a sense of whether people have been compliant...talking to family members, talking to clients themselves and talking to GPs is how we get that information. [CL9]*

### Change to Care Model

The detection and flagging of nonadherence using AI<sup>2</sup> were problematic because it represented a change to the existing care

model and specifically a change from a reactive to a more proactive model of care.

*We are very, very, very used to only managing clients who are open to us or new referrals...[but] alerting us to someone who might be relapsing, who used to see us but hasn't for some time, we're just not used to thinking in that way.* [CL9]

Nonetheless, clinicians were able to draw parallels between AI<sup>2</sup> and the systems used for monitoring depot injections and clozapine and were able to recognize the value of early intervention. However, they were concerned about extending monitoring to all patients:

*So, we have voluntary clients who might be late for a depot, and we're alerted to that, and we give them a call and say, "Hey, have you forgotten your depot?"...We see that as a part of relapse prevention...although...[AI<sup>2</sup>] does take it to the next level...monitoring...everybody.* [CL10]

Nurses were more accepting of AI<sup>2</sup> than social workers. Nurses are used to working with patients under community treatment orders, clozapine management, and depot injections, whereas social workers have a more supportive role and a different relationship with patients of CMH.

*A lot of our clients are voluntary. It is based on trust...if I'm checking the [AI<sup>2</sup>] data, then making that phone call and saying, "...I'm aware that you haven't been back to your GP. I don't feel comfortable around that...I think that changes your relationship with your client.* [CL12]

### **Cognitive Participation: Onboarding**

Cognitive participation describes the way in which clinicians engage with AI<sup>2</sup> and what motivates their use of the software [37,38].

#### **Legitimation of Patient Monitoring**

Monitoring patients' adherence was viewed as more acceptable for case-managed (open) patients than for closed patients:

*This is all right with clients [who are] case managed...ones [who are] not case managed?...They've been discharged back to their primary carer, which is the GP. So, do we still [get] involved with contacting these people saying, "You didn't go for your script?"* [CL1]

It also raised concerns about jurisdiction:

*Some ethical considerations here also. [For example], I had a red alert for a client that I had transferred to another mental health team some months earlier. I felt obligated to notify the current treating team in the event that client was deteriorating.* [CL9]

Consistent with the negative media coverage of MyHR leading up to the implementation pilot, several clinicians viewed AI<sup>2</sup> by association as:

*A breach of patient confidentiality, or patient ethics in terms of patients' rights.* [CL9]

Clinicians were also concerned about the specific use of AI<sup>2</sup> for surveillance, with one reference to "Big Brother." Several clinicians also felt that patients would not expect their MyHR data to be used to detect nonadherence:

*It's a bit of a surprise that that information might be used in that way. Yeah. So, when people opted in to have their records shared, this was one of the things that, maybe, wasn't on the agenda.* [CL3]

### **Medicolegal Concerns**

While the use of a system based on MyHR data was a concern, clinicians were more troubled by the risk of moral hazard. Other than the site psychiatrist, clinicians refused to sign up to AI<sup>2</sup> out of concern for the potential medicolegal implications of alerts.

*The dilemma really is...a moral hazard...if you find out something, what is your obligation to do with that information?...If I don't look at them, it's not [a moral hazard].* [CL11]

### **Collective Action: Enacting**

Collective action refers to integrating new practices into existing workflow [34]. It also includes understanding how a new practice impacts interactions between clinicians and patients [39].

#### **Phase 1: Getting Started**

The original vision for the pilot implementation was that all clinicians would sign up to AI<sup>2</sup> and use the alerts on the dashboard to provide early intervention, which involved 3 actions: (1) triaging patients with alerts to identify the need for further follow-up; (2) following up on patient alerts identified through the triage process by making phone calls to the patient, the GP, carer, or other listed contacts; and (3) entering follow-up feedback into the software (Figure 3).

Figure 3. Alerts view.

Profile Timeline Alert Details

Successfully created

Unactioned Alerts in the last 3 months

Alert description	Date of alert	Risk	Action to choose	Notes
Possible missed anti-psychotic (N05A) prescription refill	09 Dec 2019	●	Ignore Action	Optionally enter a note (maximum 250 characters)

Actioned Alerts History

Alert description	Date of alert	Risk	Action	Follow-up notes
Possible missed anti-psychotic (N05A) prescription refill	10 Oct 2019	●	Actioned	Optionally enter a note (maximum 250 characters) case manager informed case manager informed I checked with as well as with Gp surgery case manager's response: he due again on 7th November
Possible missed anti-epileptic (N03) prescription refill	23 Sep 2019	●	Ignored	Optionally enter a note (maximum 250 characters)
Possible missed anti-Parkinson (N04) prescription refill	27 Jul 2019	●	Ignored	Optionally enter a note (maximum 250 characters)

Clinicians were initially reluctant to sign up to AI<sup>2</sup>. Therefore, a workaround was devised to get the pilot implementation underway. The psychiatrist agreed to triage the alerts initially. When approaches to the emergency triage and liaison service and a level 4 nurse with a quality and safety portfolio acting at a regional rather than team-based level failed, the psychiatrist continued to triage alerts for the duration of the pilot. The number of alerts generated when patient data were initially uploaded onto AI<sup>2</sup> was overwhelming. This was because the clinic patient list included both case-managed patients (open) and closed patients. Closed patients were included because they are the primary target for early prevention. Open patients were already receiving care. Another reason for the high number of alerts was that the Medicare data uploaded by AI<sup>2</sup> contained 2 years of data, creating a backlog of alerts. To make the task more manageable, the psychiatrist made the decision to use dashboard filters to develop a use case focusing on the management of open cases and cases closed within the last 6 months.

The task of following up on alerts was delegated to site-based clinicians, and the psychiatrist encouraged staff and leadership to come up with a workable solution. Resistance to change in practice and the additional work resulting from the introduction of AI<sup>2</sup> caused ongoing delays in implementation, initially attributable to workload and managing resources.

*We were at one point 7.4 FTE down. We're now sitting at 2.3, 2.4 just over two at the moment...to me it's...a resource matter. Who is the resource? Where is the resource going to come from within the team? [W]hat impact will that have on the rest of our duties and our tasks? [CL8]*

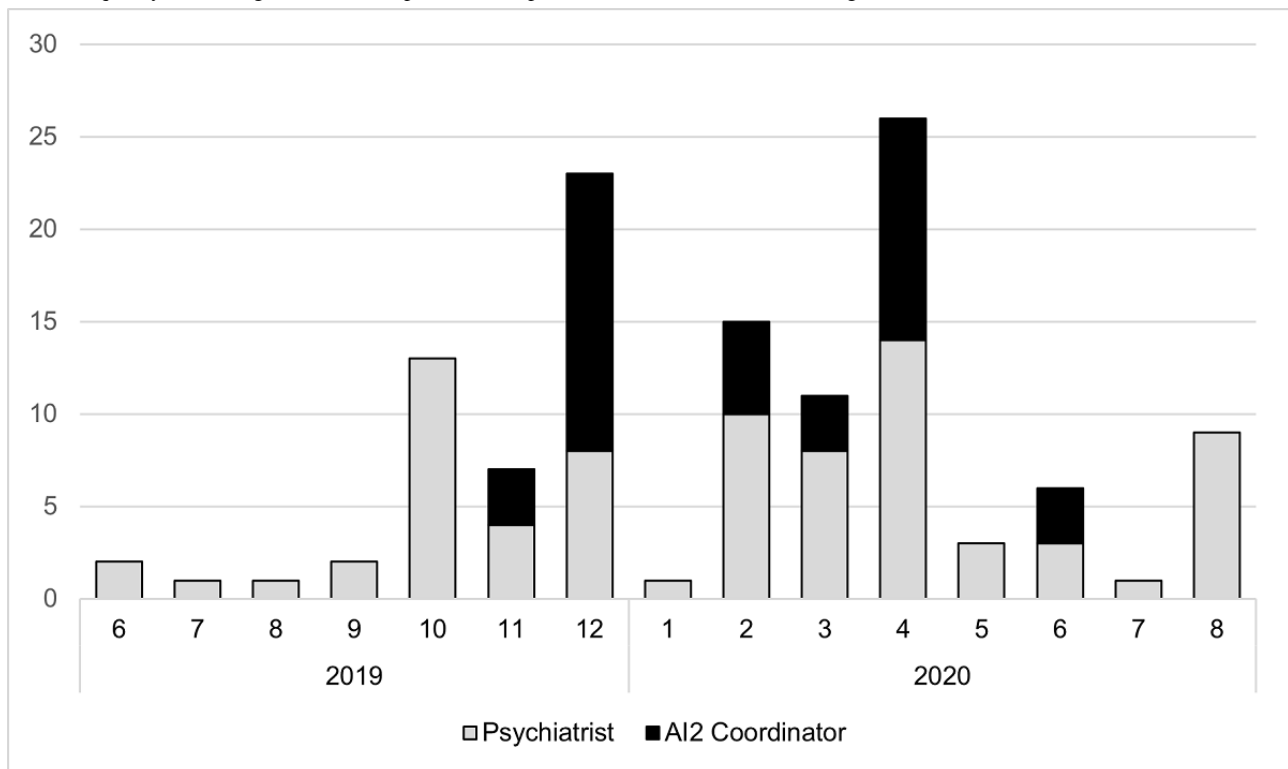
### Phase 2: Role of the AI<sup>2</sup> Coordinator

While acknowledging the benefits of AI<sup>2</sup>, the team leader's priority was to maintain routine work at a time of low staffing levels and competing demands, which resulted in slow progress being made. At a management meeting in October 2019, at which point staffing levels were back to normal, it was decided to appoint an AI<sup>2</sup> coordinator to assist the psychiatrist and manage patient follow-up. The AI<sup>2</sup> coordinator was to be a clinician with some availability and flexibility who was able to perform complex work independently and was willing to take AI<sup>2</sup> on as a portfolio. An additional time allocation of 0.2 FTE was discussed but never implemented due to resourcing priorities set outside the team.

A level 3 nurse at the management meeting agreed to take on the role of AI<sup>2</sup> coordinator and signed up to AI<sup>2</sup> in November 2019. With only the psychiatrist signed up to AI<sup>2</sup>, the psychiatrist would log onto AI<sup>2</sup>, triage patients with alerts, and identify patients in need of further follow-up. Since no one else was signed up to AI<sup>2</sup>, the psychiatrist would take a screenshot of the patient's time line view and email it to the AI<sup>2</sup> coordinator along with brief notes. The email and time line conveyed the history and the essential information required by clinicians to make follow-up calls with the patients.

However, without additional FTE, the AI<sup>2</sup> coordinator was not always able to follow-up with the patients, so the process was adapted to distribute the follow-up responsibilities to the respective case managers, leaving the coordinator to follow-up on any unassigned patients. The coordinator collated the feedback and entered that into AI<sup>2</sup>. Figure 4 shows the frequency of access to AI<sup>2</sup> over the course of the pilot. A total of 242 patients were contacted, or attempts to contact them were made.



**Figure 4.** Frequency of use (log in) over the implementation period. AI<sup>2</sup>: Actionable Intime Insights

### Procedure

Importantly, clinicians agreed on how to document AI<sup>2</sup> activities in the clinic's electronic record database. A local work site instruction was developed to document the use of AI<sup>2</sup> in the clinic (Multimedia Appendix 1). Staff created "referral episodes" for closed patients to document activities resulting from AI<sup>2</sup> alerts in the main clinical system. Referral episodes are used in the clinical software to document events such as calls from the police or neighbors.

### Training Needs

The training mainly focused on how to communicate with patients. Initially, clinicians were concerned about patients' reactions to cold calls based on alerts received from AI<sup>2</sup>. Making cold calls is part of routine practice when information is received from people in the community or for patients on clozapine, depot, and community treatment orders, but in the wake of negative media coverage of MyHR, clinicians were concerned about patient reactions to calls based on data from MyHR.

*Concerns around confidentiality and that this person would be really angry with the call...were the concerns of a number of team members. [CL9]*

Based on her own experience, the AI<sup>2</sup> coordinator trained clinicians on making AI<sup>2</sup> follow-up calls to patients. This training was important for overcoming clinician concerns.

*I was... standing with them, looking at the screen shot that [the psychiatrist] had sent...I was saying, if I was to ring this client, I would say—and then I would tell them what I would say. [CL9]*

### Normalization

Making follow-up calls became more routine over time.

*I don't think the team believed me until they started making the phone calls themselves and could see that...the client was okay with receiving that call. [CL9]*

Moreover, despite initial concerns, follow-up calls were well received by patients and viewed as another touchpoint in the trajectory of care, giving patients the feeling of having a safety net.

*[Patients] felt reassured that there was an extra layer of protection in a sense of support or monitoring. [CL9]*

Toward the end of the implementation in July 2020, there was a significant change of attitude in staff and acceptance of AI<sup>2</sup> as business as usual. Two factors may have contributed to this: (1) growing awareness of the patients' acceptance of the monitoring and follow-up phone calls and (2) a change from a collaborative leadership style to a more directive leadership.

*I think people still hold those views, but the fact that we now have...a team leader who's quite directive...[and] they've now had some exposure and have realized that actually their patients don't mind the phone call. Those...things lining up together has been what's, I think, turned things around. [CL9]*

At the meeting, it was also decided that the task of follow-up on alerts should be spread equally across the team rather than being passed onto the patient's case manager. This was determined to be a more equitable approach.

## Reflexive Monitoring: Reviewing

Reflexive monitoring refers to the work of appraising change and its impact [17].

### Time Line View

The reluctance of clinicians to sign up to AI<sup>2</sup>, especially in the earlier stages of the pilot, prevented clinicians from benefitting from the time line view, which provides a valuable history of patients' medication and attendance at medical appointments and that is not available on the clinic's Electronic Health Record (EHR). A routine and often time-consuming part of CMHS clinical work is making calls to patients, carers, GPs, and pharmacists to understand patient medication history and adherence.

*Being able to check this on the...dashboard instead [of making calls] will save that time for everyone.* [CL9]

Having AI<sup>2</sup> as a separate application to use was not viewed as a problem. Clinicians were accustomed to using multiple databases to research patient history, especially for new referrals.

*So, whenever a client is referred to us, it's helpful to have the information, and people will often refer to those 3 databases to gather collateral.* [CL9]

The AI<sup>2</sup> coordinator found that using AI<sup>2</sup> to investigate adherence was time saving:

*We've got to ring up the GPs. The GPs don't always answer because they're not always there. So, we're doing a hell of a lot of chasing around and it can—four about three patients, three to four patients—it can take the best part of half a day to do all this, so it's very time consuming.* [CL1]

Clinicians also acknowledged that information from GPs is generally limited to what scripts were issued, whereas Medicare data indicates when medications were collected and is a better proximal surrogate indicator of adherence.

*Although AI<sup>2</sup> cannot guarantee compliance with...oral medication, it can certainly give a more accurate representation about what may have been happening.* [CL9]

Clinicians also discussed the potential of the time line view as a way to:

*lead to better conversations with the client about future care planning and how to prevent relapse.* [CL9]

The value of the time line view was recognized by the Local Health Network who introduced the mandatory use of the time line to inform consumer care planning and service delivery decision making at the 90-day clinical review and the discharge review to supplement information that would otherwise be used in a clinical review process.

### Missing Data

While all the clinic's patients are displayed on the dashboard, not all patients' Medicare data were able to be uploaded. MyHR

was designed to give patients control over their MyHR, so patients may have opted out of the MyHR Record or blocked access. There were also systemic issues related to health care funding. Data may not have been uploaded due to invalid or missing Medicare numbers or errors in the date of birth or spelling of the name. CMHS are state funded and do not use Medicare for claims, so patients' Medicare details can be incomplete. To address this issue, the clinic reception began to routinely ask patients for their Medicare details, a common practice in Medicare based-services such as GP practices.

### Improving Software

The alerts on AI<sup>2</sup> are generated by algorithms based on best practice guidelines. Based on clinician feedback on alerts, the pilot testing of these algorithms identified issues that could be improved with further refinement.

### Follow-up Alerts

Data on AI<sup>2</sup> is near real-time, meaning that delays in pharmacy uploads to Medicare or Medicare updates to MyHR can appear temporarily as alerts for missing medication; while these alerts are overridden by the system once an upload occurs, they can add to data noise.

*Pharmacies, specifically the ones which a lot of our patients get supply from, don't update the PBS record in a timely way; thus their delayed reporting to MyHR is leading to an alert.* [CL11]

In the alerts that were passed onto the clinicians for follow-up, there were also several false positives and false alerts.

*There were some clients who had stopped taking their medication, but the case manager...already knew that that was likely to have been the case. So that wasn't new information for them, as such...others were false alerts, like, oh yes, the client just told me they have been taking their medication, so I'm not sure why it's come up on the system.* [CL9]

Of the alerts followed up on, only a few indicated unsupervised discontinuation of medication. Others indicated that the person was in hospital or in remand, where an alert was generated because medication prescribed in these settings was not funded by Medicare.

*[There is] a growing sense among case managers that there is very little return for the effort to chase the alerts, and many people's time is wasted in the process.* [CL11]

Without a positive case study, the impact of preventative care was difficult for staff to appreciate, but the AI<sup>2</sup> coordinator remained pragmatic.

*Yes, there is another task, but ultimately, it might prevent you from having to do another 10 tasks if this person gets sick and needs detaining and needs to end up in hospital, they would see the value in that. But at the moment, it's just another sort of task that we're adding.* [CL9]

Arguably, the patients reviewed over the course of the trial received improved quality of care, benefitting from a clinical

review that would otherwise not have happened. Several patients also received an outreach call from Community Mental Health clinicians.

## Discussion

### Principal Findings

This study evaluates the implementation of an innovative clinical decision support system to support early intervention for Community Mental Health Services using data from Australia's national electronic record, MyHR. The use of data from MyHR for clinical purposes became a reality in February 2019 at the end of the opt-out period, when MyHRs were automatically created for people who chose not to opt out. At the end of the opt out period, 90.1% of Australians had a MyHR [40].

Medicare data in MyHR are increasingly being used in emergency departments by clinicians and pharmacists because they provide valuable information that is not available to clinicians in hospital databases due to the siloed nature of health care in Australia [41]. AI<sup>2</sup> is an application designed for CMHS to automate risk monitoring and detection of nonadherence using Medicare data from MyHR to facilitate early intervention and prevent relapse and hospitalization for people living with severe mental illness.

The implementation was a series of ongoing negotiations and compromise resulting in a staggered rollout. At the beginning, we observed significant resistance to restructured work practices as a result of implementing the intervention. The substantial workarounds required to move the implementation forward highlights having the capacity to adapt as an important aspect of implementation. Clinicians' reluctance to sign up to AI<sup>2</sup> was attributed to not wanting to be exposed to alerts that potentially create an obligation to act. Clinicians have a duty of care, both ethically and in common law and legislation, whereby they must avoid omissions that could result in harm to others. It could be argued that alerts in AI<sup>2</sup> are potential early indicators of nonadherence to treatment and medication, which, if not followed up, could result in harm. The pilot implementation allowed researchers to better understand the challenges of implementation and the resources and support needed to implement and sustain a model of care based on early intervention.

### Coherence

The pilot implementation was overshadowed by the negative press coverage leading up to the end of the opt-out period for MyHR, reflecting the impact of broader external influences on implementation [42]. Clinicians struggled with sensemaking in the initial change from explicit to implied consent for clinician access to patient MyHR data [43-45]. Clinicians who routinely make calls to patients based on alerts raised by police or other members of the community expressed real concerns about how patients would react to calls based on alerts from MyHR data. Similarly, clinicians also expressed concerns about the addition of early prevention work in addition to the existing workload, but they were not prepared to use the time line view to save the time involved in ringing around GPs to verify medication

adherence, suggesting that the source of the data was likely more challenging than the activities needed to support the implementation. The most significant challenge for clinicians was the concern over the moral hazard associated with the alerts. Exposure to alerts creates a dilemma for clinicians, balancing an opposing ethical/moral duty to follow-up to prevent harm with the management of existing duties, resulting in clinicians refusing to sign up to the software.

Negotiations regarding how to operationalize and proceed with the implementation were protracted, opposing key supporters and detractors. Persistence and persuasion from the psychiatrist were necessary but insufficient to start the implementation. Reluctance by the initial team leader and significant resistance from one team member negatively impacted the attitudes of others, resulting in prolonged delays. Negotiations were resolved with the nominal appointment of the AI<sup>2</sup> coordinator to work with the psychiatrist and provide direction and leadership from within the Community Mental Health team. While the AI<sup>2</sup> coordinator was able to monitor and support clinicians to make the follow-up calls, the work was later normalized with a change of team leader.

### Collective Action

Workarounds were needed to operationalize the software. As has been the case in other EHR implementations [46], negative resistance, in the form of clinicians refusing to sign up to AI<sup>2</sup>, resulted in a hindrance workaround [47], whereby the psychiatrist triaged alerts, and the AI<sup>2</sup> coordinator managed follow-up by allocating the task to others, collected and entered alert feedback on the software and the main clinic database, and provided the necessary training and support. The overwhelming number of alerts generated by the system was also daunting but made more manageable with the development of a specific use case focusing on case-managed (open) and closed patients (<6 months) reflecting the "easy in, easy out" nature of the CMHS.

### Reflexive Monitoring

Like other national EHRs, the aim of MyHR was to support secure patient data sharing across the health care system to improve patient outcomes and reduce the time clinicians spend gathering clinical information [27]. However, despite the potential for change, the uptake and use of MyHR data in acute services has been slow [41,48]. The use of CDSS based on EHRs is growing, and while implementation can be challenging, the potential benefits are improved outcomes for patients through early intervention to prevent relapse and hospitalization and increased efficiency for the health care system. Importantly, for implementation to succeed, a top-down approach is unlikely to work. It is important to have leadership within the team implementing the software to actively support and address issues and concerns of the staff doing the work [33].

### Strengths and Limitations

While this study involved only 1 site, it was important to aid our understanding of the impact of a fundamental change to the Australian health care system and the challenges that lie ahead for the increased use of digital data to enable proactive care. As others have found, pilot implementations are valuable for

understanding and ameliorating implementation issues [31]. The strength of the project was in combining use of normalization process theory and participatory action research to drive change, focus on problem solving, and work collaboratively toward achieving an outcome [16]. Working closely with the implementation site and key members of the CMH team also made it possible to gain insight that focus groups or interviews alone would not have afforded.

A weakness of the implementation is the relatively small size of the implementation site, making it potentially more difficult to replicate in larger services. Considerations for future implementations should be to focus on how to manage the very different tasks of triaging and follow-up. Combining triaging and follow-up may result in a duplication of effort in a larger Community Mental Health team. The task of triaging alerts requires a certain level of medical expertise and experience, and while the task is not onerous, it needs to be done routinely to support any given use case. The underlying issues of reluctance to change from proactive to reactive care will always be problematic and is likely best resolved in the medium term with dedicated staff and in the short term with additional resourcing. The underlying concern of moral hazard also needs to be addressed. The easy in, easy out approach to CMHS also means that there is an expectation that closed patients will return, so there is a duty of care that exists between CMHS and their

clients, whether they are currently open or closed clients [49]. AI<sup>2</sup> potentially offers a solution to provide early intervention for closed patients that could reduce relapse and rehospitalization [47].

## Conclusions

The NPT framework has provided a useful structure that clearly identifies the challenges of implementation in a way that can facilitate future improvement. While changes to practice are always challenging, clinicians' attitudes toward MyHR in the wake of the negative press leading up to the opt-out period impacted the implementation more than we anticipated. Increasing the use of MyHR in emergency services and other areas where siloed data has been an issue will normalize it, allowing clinicians to benefit from having access to data that can make a difference to the lives and well-being of patients. The aim of this pilot implementation was to understand the implementation challenges and test the application design. The pilot was useful in addressing issues with the software and elucidating the challenges of implementing a disruptive software into CMHS [50]. Further trials are needed to determine whether applications like AI<sup>2</sup> that support early intervention can help reduce overall demand on the already overburdened Community Health Services, but this may require a period of transition that involves additional work for existing staff [51,52].

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## Conflicts of Interest

EL is a staff member of Health Translation SA, which provided funding for this project through the Medical Research Future Fund Rapid Applied Research Translation funding scheme.

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Multimedia Appendix 1

Local work site instruction.

[[DOCX File, 95 KB](#) - [humanfactors\\_v9i3e35403\\_app1.docx](#) ]

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## Abbreviations

**AI<sup>2</sup>**: Actionable Intime Insights  
**CDSS**: Clinical Decision Support System  
**CMHS**: Community Mental Health Services  
**EHR**: Electronic Health Record  
**FTE**: full-time equivalent  
**GP**: general practitioner  
**IHI**: Individual Healthcare Identifier  
**MyHR**: My Health Record  
**NPT**: normalization process theory  
**PAR**: participatory action research

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Original Paper

# Telehealth Perceptions Among US Immigrant Patients at an Academic Internal Medicine Practice: Cross-sectional Study

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## Abstract

**Background:** The use of telemedicine has increased dramatically through the COVID-19 pandemic. Although data are available about patient satisfaction with telemedicine, little is known about immigrant patients' experience.

**Objective:** We sought to investigate patients' experiences with telehealth compared to in-person visits between immigrants and nonimmigrants. We wanted to identify and describe next visit preferences within the Farmington University of Connecticut Internal Medicine practice to ultimately guide suggestions for more equitable use and accessibility of visit options.

**Methods:** A total of 270 patients including 122 immigrants and 148 nonimmigrants were seen by 4 Internal Medicine providers in an in-person (n=132) or telemedicine (n=138) university practice setting. Patients were queried between February and April 2021, using an adaptation of a previously validated patient satisfaction survey that contained standard questions developed by the Consumer Assessment of Healthcare Providers and Systems Program. Patients seen via in-person visits completed a paper copy of the survey. The same survey was administered by a follow-up phone call for telemedicine visits. Patients surveyed spoke English, Spanish, or Arabic and were surveyed in their preferred language. For televisits, the same survey was read to the patient by a certified translator. The survey consisted of 10 questions on a Likert scale of 1-5. Of them, 9 questions assessed patient satisfaction under the categories of access to care, interpersonal interaction, and quality of care. An additional question asked patients to describe and explain the reasons behind next visit preferences. Survey question responses were compared by paired t tests.

**Results:** Across both immigrant and nonimmigrant patient populations, satisfaction with perceived quality of care was high, regardless of visit type ( $P=.80$ ,  $P=.60$  for televisits and  $P=.76$ ,  $P=.37$  for in-person visits). During televisits, immigrants were more likely to feel providers spent sufficient time with them ( $P<.001$ ). Different perceptions were noted among nonimmigrant patients. Nonimmigrants tended to perceive more provider time during in-person visits ( $P=.006$ ). When asked to comment on reasons behind next televisit preference, nonimmigrant patients prioritized convenience, whereas immigrants noted not having to navigate office logistics. For those who chose in-person visits, both groups prioritized the need for a physical exam.

**Conclusions:** Although satisfaction was high for both telemedicine and in-person visits across immigrant and nonimmigrant populations, significant differences in patient priorities were identified. Immigrants found televisits desirable because they felt they spent more time with providers and were able to avoid additional office logistics that are often challenging barriers for non-English speakers. This suggests opportunities to use information technology to provide cultural and language-appropriate information throughout immigrants' in-person and telemedicine visit experience. A focus on diminishing these barriers will help reduce health care inequities among immigrant patients.

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**KEYWORDS**

telemedicine; immigrant patient; immigrant; ethnic minority; cultural minority; patient satisfaction; telehealth; satisfaction; health care; health equity; digital health; patient experience

## Introduction

Telemedicine, defined as the remote diagnosis and treatment of patients by means of telecommunication technology, is an aspect of the broader entity telehealth. Telehealth refers to the delivery and facilitation of health and health-related services via digital communication technologies [1]. Methods to assess telehealth and telemedicine quality include measures of patient experience as well as patient satisfaction. Patient experience includes the range of interactions patients have with the health care system, including the care they receive, access to information, and communication. Patient satisfaction, on the other hand, is a narrower term defined as how well a patient's expectations about a health encounter are met [2].

Telemedicine has been well studied and shown to enhance access to care in remote populations [3-6]. In rural settings, telemedicine is associated with decreased travel costs and increased access to social support [7]. Studies of video visits in subspecialty care have demonstrated the benefits of convenience and increased accessibility to cardiovascular, wound, and home care [8-14]. The use of telemedicine is increasing due to these benefits; but most of our knowledge of patient satisfaction and experience is gleaned from disease-specific, subspecialist, or rural settings. The impact of telemedicine on primary care is less studied.

A study of MinuteClinic consumers reported high satisfaction with telemedicine visits, naming convenience and high quality as drivers of satisfaction [15]. Studies of patients' perceptions of telemedicine in the primary care setting have shown mixed results. One study assessed video visits with primary care physicians immediately followed by in-person visits with the same provider; patients found video visits were less desirable [16]. Another study of interviews of patients following video visits with primary care providers suggested patients were quite satisfied with video visits, prioritizing convenience and privacy when assessing visit type [17].

Beginning in 2020, the use of telemedicine expanded so patients could safely seek health care during the COVID-19 pandemic. Concerns persist that despite these efforts to increase access, telemedicine may increase the health care equity divide [18]. The increased use of telemedicine for health care delivery has dropped from the initial surge but continues at higher than pre-pandemic levels, primarily in urban, higher-income, and White populations [19]. The increased number of patients using telemedicine, whether it is their preferred method or the only option available, serves as an opportunity to investigate patient satisfaction and equitable use of telemedicine. Previous research suggests most patients and clinicians report no difference in the overall quality of a video visit as compared to an office visit. Patients rate tele-visits highly and find them desirable due to saved travel time and costs [20].

There are not many studies on whether the quality of telehealth care patients receive is impacted by additional challenges of

navigating cultural and language differences present in the telemedicine setting. A Canadian study found that in health care interactions, immigrant patients are often concerned about communication barriers due to cultural and language differences [21]. Previous work looking at attitudes toward telemedicine by minorities in the United States found that Latinos and African Americans were satisfied with the increased access and reduced wait time provided by telemedicine but had concerns about confidentiality, privacy, and physical absence of the provider [22]. Data from the 2011-2015 National Health Interview Survey assessed the use of eHealth services including making appointments and filling prescriptions via the internet as well as using patient portals among US natives, naturalized citizens, and noncitizens. Researchers found that naturalized citizens and noncitizens were less likely than US natives to access eHealth. The underutilization of eHealth among immigrants was linked to English proficiency [23].

Patient satisfaction is traditionally linked to access to care, improved interpersonal interactions, and perceived quality of care [20]. Whether these outcomes apply equally to telemedicine visits across immigrant and nonimmigrant populations is unclear. Given that the University of Connecticut Farmington Internal Medicine practice serves a large immigrant population, we were interested in investigating patient experiences with telehealth compared to in-person visits across immigrant and nonimmigrant patient populations. We sought to identify and explain the reasons behind immigrant visit preferences to ultimately guide recommendations to encourage equitable use and accessibility of visit options. A cross-sectional study design was used to allow researchers to compare populations in real time and quickly assess the acceptance of a relatively novel telemedicine service.

## Methods

### Study Setting

The Farmington Internal Medicine practice of UConn Health serves a 72% Medicare and Medicaid population, many of whom are non-US natives. Patients were seen from February to April of 2021 by 4 participating internists.

### Intervention

In March of 2020, in response to the COVID-19 pandemic, UConn Health deployed telemedicine to all outpatient practices. At the time of this study, telephone, video, and in-person visits were offered to all patients simultaneously based on staff screening criteria. Criteria for video visits included mild COVID-19 complaints not requiring inpatient evaluation or a chief complaint that the provider agreed could be adequately addressed by a limited patient-facilitated exam. Telephone visits were used primarily for complaints that providers felt did not require an exam. Telemedicine visits were conducted via video and telephone. Video visits were conducted via Zoom embedded in Epic. Medical assistants scheduled tele-visits, and a call center

scheduled in-person visits. Medical assistants provided detailed telephone instructions in patient's preferred language about how to join the televisit.

### Participant Recruitment and Patient Characteristics

Survey data were collected for both in-person and telemedicine visits. Participants were recruited if scheduled with the participating providers and if they spoke English, Spanish, or Arabic. Visits were deemed by providers to be appropriate for in-person visits versus televisits based on patient's preference and the chief complaint.

### Survey Development

Patient experience [24] was assessed through the administration of a survey ([Multimedia Appendix 1](#)), using some dimensions adapted from an instrument developed by the Consumer Assessment of Healthcare Providers and Systems consortium [25] and validated in a study [20]. Patients were asked to describe their experience with their present telemedicine or in-person visit by rating their agreement on statements about access to care, interpersonal interaction, and quality of care as 1 (definitely agree), 2 (disagree), 3 (neutral), 4 (somewhat agree), and 5 (definitely agree). An additional question asked patients to describe and explain the reason behind their next visit preferences. Patients were asked to explain if their choice was based on convenience, time off from work, time with the provider, visit quality, or another reason.

### Survey Administration

During the study period, all patients seen by participating providers were offered participation in the study. For in-person visits, medical assistants obtained verbal consent and passed a paper copy of the survey to patients in their preferred language at the beginning of the visit. Patients then completed the survey. For televisits, the investigating medical students made a

follow-up call, using a university language line interpreter. After obtaining verbal consent, the same survey was read to telemedicine participants in their preferred language.

### Statistical Analysis

Results include quantitative and descriptive subgroup comparisons. For survey questions on patient satisfaction (questions 1-9), 2-tailed paired *t* tests (at  $P < .05$  significance) were calculated in Microsoft Excel and used to compare numbers of individual Likert scale question responses. Although opinions differ on how to best analyze Likert data, consensus exists that parametric tests are appropriate [26]. The satisfaction survey responses did not follow a normal distribution; therefore, percentages of individual responses rather than means were compared. For the question on next visit preference (question 10), some patients left the question blank, others provided some combination of multiple selections and write-in responses. Therefore, this question was analyzed without any formal statistics.

### Ethical Considerations

For Spanish or Arabic surveys, a translation to the appropriate language by a native speaker and then a back translation to English by a separate native speaker was performed to ensure accurate translation. Surveys were deidentified and blinded to providers. The study was approved by the University of Connecticut Institutional Review Board (21X-132-1), and translation protocols were followed.

## Results

Survey data were collected from 138 televisits and 132 in-person visits. These responses came from 122 immigrant and 148 nonimmigrant patients ([Table 1](#) and [2](#)).

**Table 1.** Patient characteristics (N=270).

Characteristics	Participants <sup>a</sup> , n (%)	Televisits (n=138), n (%)	In-person visits (n=132), n (%)
<b>Female immigrant<sup>b</sup></b>			
Total	72 (51.1)	39 (28.3)	33 (25)
Aged 18-29	24 (17)	15 (10.9)	9 (6.8)
Aged 30-35	47 (33.3)	24 (17.4)	23 (17.4)
Aged >56	1 (0.7)	0 (0)	1 (0.8)
<b>Female, US born</b>			
Total	69 (48.9)	37 (26.8)	32 (24.2)
Aged 18-29	39 (27.6)	18 (13)	21 (15.9)
Aged 30-35	26 (17.4)	15 (10.9)	11 (8.3)
Aged >56	4 (2.7)	4 (2.9)	0 (0)
<b>Male immigrant</b>			
Total	50 (38.7)	24 (17.4)	26 (19.7)
Aged 18-29	21 (16.3)	10 (7.2)	11 (8.3)
Aged 30-35	29 (22.5)	14 (10.1)	15 (11.4)
Aged >56	0 (0)	0 (0)	0 (0)
<b>Male, US born</b>			
Total	79 (61.2)	38 (27.5)	41 (31.1)
Aged 18-29	46 (35.6)	24 (17.4)	22 (16.7)
Aged 30-35	30 (23.3)	14 (10.1)	16 (12.1)
Aged >56	3 (2.3)	0 (0)	3 (2.3)

<sup>a</sup>Total female participants: n=141, 52.2%; total male participants: n=129, 47.8%.

<sup>b</sup>Born outside of the United States.

**Table 2.** Participant characteristics based on the country of origin (N=270; in-person visits: n=132, 51%; televisits: n=138, 49%).

Country of birth and preferred language <sup>a</sup>	In-person visit (n=132), n (%)	Televisit <sup>b</sup> (n=138), n (%)
<b>Argentina</b>		
Spanish	1 (0.7)	4 (1.5)
<b>Colombia</b>		
English	2 (1.4)	2 (1.5)
Spanish	0 (0)	10 (7.6)
<b>Costa Rica</b>		
Spanish	4 (2.9)	2 (0.8)
<b>Dominican Republic</b>		
Spanish	2 (1.4)	2 (1.5)
<b>Ecuador</b>		
Spanish	3 (2.2)	4 (3.0)
<b>El Salvador</b>		
Spanish	2 (1.4)	3 (1.5)
<b>Guatemala</b>		
Spanish	3 (2.2)	2 (1.5)
English	3 (2.2)	0 (0)
<b>Peru</b>		
Spanish	1 (2.9)	3 (2.3)
English	1 (0.7)	6 (4.5)
<b>Venezuela</b>		
Spanish	4 (2.9)	3 (1.5)
<b>Afghanistan</b>		
Arabic	4 (2.9)	3 (1.5)
<b>Iran</b>		
Arabic	0 (2.2)	2 (1.5)
English	3 (2.2)	0 (0)
<b>Jordan</b>		
Arabic	3 (2.2)	2 (1.5)
<b>Morocco</b>		
Arabic	3 (2.2)	1 (0.8)
<b>Pakistan</b>		
Arabic	4 (2.9)	4 (3.0)
English	4 (2.9)	2 (1.5)
<b>Qatar</b>		
Arabic	0 (0)	1 (0.8)
<b>Somalia</b>		
Arabic	2 (1.4)	1 (0.8)
<b>Syria</b>		
Arabic	6 (4.3)	5 (3.8)
<b>Turkey</b>		
Arabic	2 (1.4)	3 (2.3)
<b>United States (nonimmigrant)</b>		

Country of birth and preferred language <sup>a</sup>	In-person visit (n=132), n (%)	Televisit <sup>b</sup> (n=138), n (%)
English	75 (54.3)	73 (55.3)

<sup>a</sup>Patients were surveyed in their preferred language.

<sup>b</sup>Of the visits, 63 were via video and 75 via telephone.

### Patient Experiences With Telemedicine And In-Person Visits

Survey response rates for in-person visits and televisits were 89% and 78%, respectively. During televisits, immigrants were more likely than nonimmigrants to feel providers spent enough time with them ( $P<.001$ ), whereas nonimmigrants felt providers

spent more time with them during in-person visits ( $P=.006$ ). There were no significant differences between immigrant and nonimmigrant perceptions of quality of care between visit types ( $P=.80$  and  $P=.60$  for televisits;  $P=.76$  and  $P=.37$  for in-person visits). All but 2 patients preferred next visits to be congruent visit types (Tables 3 and 4).

**Table 3.** Summary of responses by those who participated in telemedicine visits (n=138), characterized by immigrant (n=63) and nonimmigrant (n=75) experiences.

Survey domains, items, and patient type	Definitely disagree, n (%)	Disagree, n (%)	Neutral, n (%)	Somewhat agree, n (%)	Definitely agree, n (%)	P value <sup>a</sup>
<b>Access to care</b>						
• I was able to schedule today's visit soon enough						.21
Immigrant	0 (0)	0 (0)	1 (2)	7 (11)	55 (87)	
Nonimmigrant	0 (0)	0 (0)	2 (2)	14 (19)	59 (79)	
• I saw the provider I wanted to see today						.007
Immigrant	0 (0)	0 (0)	2 (3)	3 (5)	58 (92)	
Nonimmigrant	0 (0)	0 (0)	12 (16)	6 (8)	57 (76)	
• I got the type of visit I wanted today						.003
Immigrant	0 (0)	0 (0)	1 (2)	3 (5)	59 (93)	
Nonimmigrant	0 (0)	0 (0)	6 (8)	14 (19)	55 (73)	
<b>Interpersonal interaction</b>						
• My provider spent enough time with me						<.001
Immigrant	0 (0)	0 (0)	0 (0)	4 (6)	55 (94)	
Nonimmigrant	0 (0)	0 (0)	4 (5)	24 (32)	47 (63)	
• My provider listened to me						.09
Immigrant	0 (0)	0 (0)	0 (0)	3 (5)	60 (95)	
Nonimmigrant	0 (0)	0 (0)	0 (0)	10 (13)	65 (87)	
• My provider addressed all my concerns						.53
Immigrant	0 (0)	0 (0)	0 (0)	3 (5)	60 (95)	
Nonimmigrant	0 (0)	0 (0)	2 (3)	2 (3)	71 (94)	
<b>Quality of care</b>						
• My provider showed me respect						.74
Immigrant	0 (0)	0 (0)	0 (0)	3 (5)	60 (95)	
Nonimmigrant	0 (0)	0 (0)	2 (3)	2 (3)	71 (94)	
• The quality of care was excellent						.80
Immigrant	0 (0)	0 (0)	1 (2)	4 (6)	58 (92)	
Nonimmigrant	0 (0)	0 (0)	2 (3)	2 (3)	71 (94)	
• I would recommend the provider I saw today to my family						.60
Immigrant	0 (0)	0 (0)	0 (0)	2 (4)	61 (96)	
Nonimmigrant	0 (0)	0 (0)	1 (1)	2 (3)	72 (96)	
<b>Next visit preference</b>						
• (If today was a televisit) I prefer a televisit for my next visit						.07
Immigrant	0 (0)	0 (0)	0 (0)	0 (0)	63 (100)	
Nonimmigrant	2 (3)	0 (0)	0 (0)	0 (0)	73 (97)	

<sup>a</sup>Paired *t* test comparing responses between immigrants and nonimmigrants.

**Table 4.** Summary of responses by those who participated in in-person visits (n=132), characterized by immigrant (n=59) and nonimmigrant (n=73) experiences.

Survey domains, items, and patient type	Definitely disagree, n (%)	Disagree, n (%)	Neutral, n (%)	Somewhat agree, n (%)	Definitely agree, n (%)	P value <sup>a</sup>
<b>Access to care</b>						
• I was able to schedule today's visit soon enough						.83
Immigrant	0 (0)	1 (2)	1 (2)	5 (8)	52 (88)	
Nonimmigrant	0 (0)	2 (3)	2 (3)	4 (5)	65 (89)	
• I saw the provider I wanted to see today						.20
Immigrant	0 (0)	0 (0)	0 (0)	0 (0)	59 (100)	
Nonimmigrant	0 (0)	0 (0)	0 (0)	2 (3)	71 (97)	
• I got the type of visit I wanted today						.27
Immigrant	0 (0)	0 (0)	0 (0)	1 (2)	58 (98)	
Nonimmigrant	0 (0)	0 (0)	0 (0)	0 (0)	73 (100)	
<b>Interpersonal interaction</b>						
• My provider spent enough time with me						.006
Immigrant	0 (0)	0 (0)	0 (0)	1 (2)	39 (66)	
Nonimmigrant	1 (1)	0 (0)	0 (0)	0 (0)	69 (95)	
• My provider listened to me						.11
Immigrant	0 (0)	0 (0)	0 (0)	4 (7)	55 (93)	
Nonimmigrant	0 (0)	0 (0)	0 (0)	1 (1)	72 (99)	
• My provider addressed all my concerns						.15
Immigrant	0 (0)	0 (0)	0 (0)	5 (8)	54 (92)	
Nonimmigrant	0 (0)	0 (0)	0 (0)	2 (3)	71 (97)	
<b>Quality of care</b>						
• My provider showed me respect						.37
Immigrant	0 (0)	0 (0)	0 (0)	0 (0)	59 (100)	
Nonimmigrant	0 (0)	0 (0)	0 (0)	0 (0)	73 (100)	
• The quality of care was excellent						.76
Immigrant	0 (0)	0 (0)	0 (0)	1 (2)	58 (98)	
Nonimmigrant	0 (0)	0 (0)	1 (3)	0 (0)	72 (99)	
• I would recommend the provider I saw today to my family						.37
Immigrant	0 (0)	0 (0)	0 (0)	2 (4)	59 (100)	
Nonimmigrant	1 (1)	0 (0)	1 (1)	2 (3)	72 (99)	
<b>Next visit preference</b>						
• (If today was a televisit) I prefer a televisit for my next visit						.37
Immigrant	0 (0)	0 (0)	0 (0)	0 (0)	59 (100)	
Nonimmigrant	0 (0)	0 (0)	0 (0)	0 (0)	73 (100)	

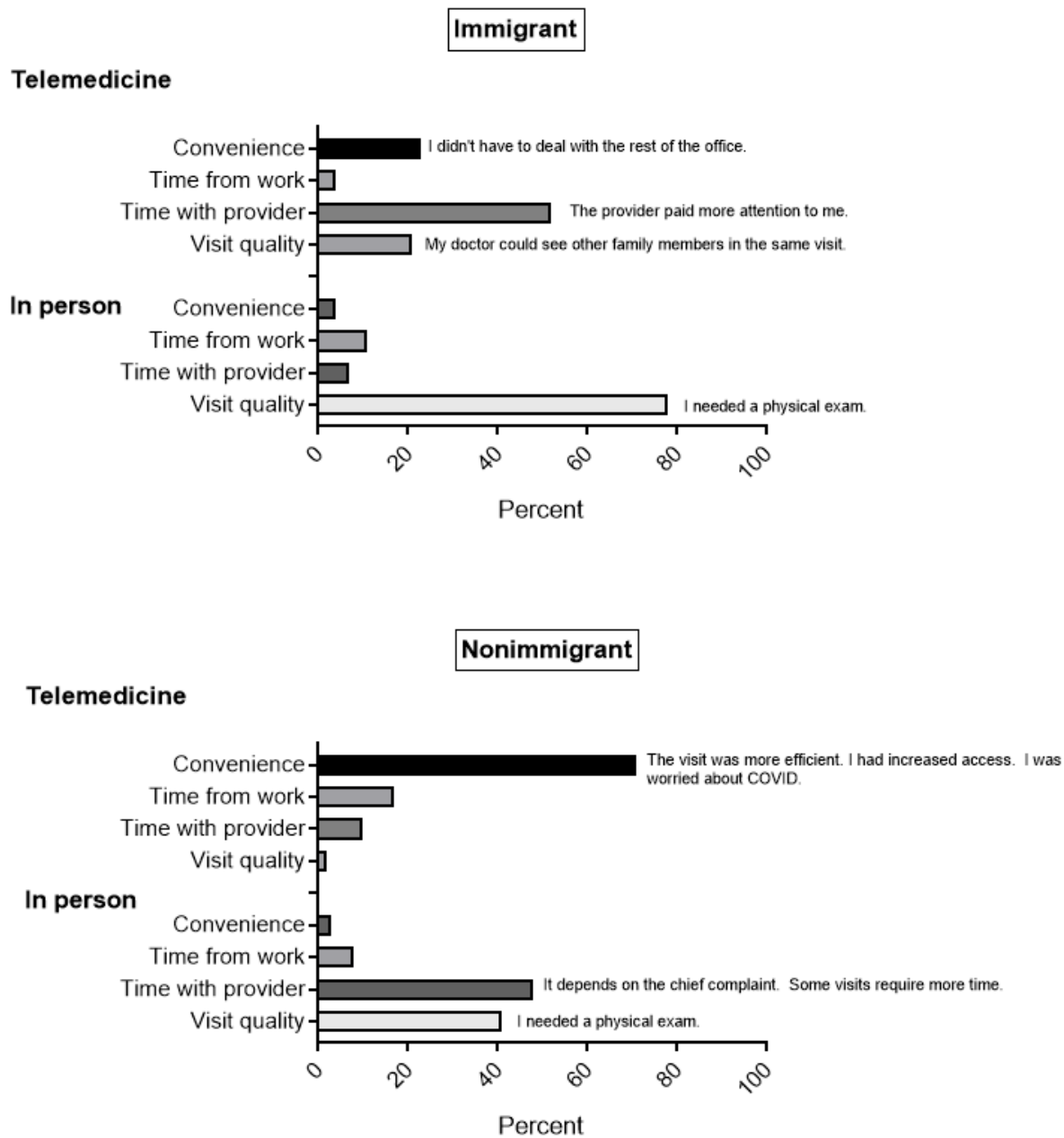
<sup>a</sup>Paired *t* test comparing responses between immigrants and nonimmigrants.

### Reasons Behind Next Visit Preference

When asked to describe and explain the reason for preferring a telemedicine or in-person visit, nonimmigrants prioritized convenience when choosing televisits. Convenience was explained as a more efficient visit as well as an option to obtain

a timelier appointment. Immigrants, on the other hand, prioritized time with the provider when preferring telemedicine visits, explained as the advantage of not having to navigate the rest of the office. Common reasons across patient groups for preferring in-person visits included visit quality, explained as the perceived need for a detailed physical exam (Figure 1).

Figure 1. Reasons behind next visit preferences.



## Discussion

### Principal Findings

We sought to investigate patient experience and describe and explain the reasons behind telehealth visit preferences compared to in-person visits between immigrants and nonimmigrants. We hoped to use these preferences to guide suggestions for a more equitable use and accessibility of visit options. In terms of rating

the patient experience of access to care, both patient groups felt that they were able to schedule a soon enough appointment regardless of the visit type (televisits:  $P=.21$ ; in-person visits:  $P=.83$ ). Immigrants were more likely to feel they saw the provider they wanted in a televisit, whereas both patient groups felt they had access to the provider they wanted in an in-person visit (televisits:  $P=.007$ ; in-person visits:  $P=.20$ ). In assessing access to the preferred visit type, immigrants were more likely to feel they got the type of visit they originally wanted when



the visit was a televisit. When the visit was an in-person visit, both patient groups felt they received the visit type they wanted (televisit  $P=.003$ ; in-person visit:  $P=.27$ ). Immigrants were more likely to feel providers spent enough time with them when the visit was a televisit ( $P<.001$ ), whereas nonimmigrants felt they had more time with their providers during an in-person visit ( $P=.006$ ). This difference did not seem to depend on other interpersonal cross-cultural communication factors. There seemed to be no differences perceived in listening (televisits:  $P=.09$ ; in-person visits:  $P=.11$ ), showing respect (televisits:  $P=.74$ ; in-person visits:  $P=.15$ ), or addressing concerns (televisits:  $P=.53$ ; in-person visit:  $P=.37$ ) across immigrant and nonimmigrant patient populations. An explanation for immigrants' perception of additional time with providers during televisits included not having to navigate additional office logistics. Nonimmigrants seemed to have different priorities in visit preferences. They seemed to prioritize convenience in telemedicine visits described as less time off from work and increased efficiency and access. Nonimmigrants also prioritized time with providers but for seemingly different reasons, including when the need for a physical exam or a more complex chief complaint arose.

### Comparison With Previous Studies

Previous studies have described favorable patient experience with video visits when applied to disease-specific conditions in rural settings [27-29]. One study found disease-specific video visits in rural settings favorable because they were associated with decreased travel costs, less time off from work, and a greater ability to tailor care to patient and family needs [7]. These findings are consistent with the nonimmigrant subset of our population who found telemedicine visits favorable primarily for the reasons of convenience and less time off from work. Although telemedicine visits have been used at increasing rates in primary care settings, studies are largely limited to nonimmigrant patient populations. In nonimmigrant populations, a variety of methods have been used to assess patient experience with telemedicine, including patient surveys and interviews [24]. A mixed survey and interview study [30] reported increased satisfaction with telemedicine based on convenience and the ability to access care safely during the pandemic. Telehealth was felt by patients to be most appropriate for routine follow-ups when a physical exam was not necessary, especially when there was already an established patient-provider relationship [30]. The fact that all our patients were seen by their primary providers may have increased their acceptance of televisits. Both immigrant and nonimmigrant populations prioritized the need for a physical exam in evaluating in-person visits. The fact that immigrants found televisits desirable seems to somewhat conflict with previous work that has shown immigrants are less likely to access eHealth services including scheduling appointments via the internet and using electronic patient portals [23]. However, these tasks may be inherently more complex to navigate for a non-US native than having a telemedicine appointment. The fact that our medical assistants, with the aid of a translator, walked immigrants through the process of joining a televisit likely increased immigrants' access to these appointments and their acceptance of them. As telemedicine visits were typically scheduled by medical

assistants rather than our call center, medical assistants may have been protective of patients whom they knew had difficulty navigating the system, and they likely pushed a little more to get immigrant patients in with their primary providers. Our immigrants' acceptance of telemedicine may also be due in part to having a more tech-savvy immigrant population, as many were refugees and as such had recently successfully navigated incredibly complex logistics. Telehealth videoconferencing has been successfully used to coordinate care for immigrants with chronic conditions such as hepatitis C and latent tuberculosis. The advantage and acceptance of this visit type was linked to the ease of coordinating care between provider, patient, and subspecialist [31]. Similarly in our study, immigrants noted that an advantage of the telemedicine visit was the ability of the provider to see multiple family members simultaneously. Our study conflicts in part with previous work that shows Latinos question the absence of providers in televisits [22]. Investigators point to a concern about privacy and digital access for Latinos based on income, insurance, and documentation status. Our patients were insured, documented, and may have had more digital access.

### Study Limitations

A limitation of the generalizability of this study is the inability to segregate data by English proficiency. The immigrant population in this study included primarily newly arrived immigrants. Although the countries of origin represented in this study are numerous, participant numbers from individual countries are small. The survey used in the study was validated in English and administered according to the Institutional Review Board's back translation protocols. However, given the small numbers of individual countries represented, it is impossible to draw culturally specific conclusions. Finally, detailed patient interviews might have more fully uncovered reasons behind patient preferences.

### Conclusions

Although nonimmigrants preferred televisits because of their convenience, immigrant patients preferred televisits due to the perceived time spent with providers. This preference was found in the absence of any perceived differences in other interpersonal communication factors and supported by additional write-in responses suggesting a possible reason for this preference, namely that the telemedicine environment seems to eliminate some of the inherent barriers found in navigating the office. This study suggests that multiple opportunities exist to use information technology to provide cultural and language-appropriate information throughout immigrants' health care experience.

As we continue to expand telemedicine, it is important to understand the different priorities and unique barriers experienced by immigrant populations. Although university practices often have access to robust telephone translation services, these services are less accessible outside of the in-person visit encounter. Resources within the electronic medical record to communicate in other languages could be developed and applied to additional aspects of the patient experience, including visit scheduling, appointment reminders, portal use, patient instructions, and telephone reminders. Patient

navigators and a wider array of language options in web-based instructions might also be used to help ensure scheduling and follow-ups. Provider education to optimize telemedicine examination techniques and support alternative scheduling

models may expand provider uptake [32]. Advocacy for broader reimbursement of telephone visits might also improve immigrant access to telemedicine when video visits are financially less accessible.

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## Authors' Contributions

All listed authors contributed substantively to this study and approved the final manuscript.

## Conflicts of Interest

None declared.

Multimedia Appendix 1

Patient experience survey.

[PDF File (Adobe PDF File), 186 KB - [humanfactors\\_v9i3e36069\\_app1.pdf](#) ]

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Original Paper

# Evaluation of a Health Information Exchange System for Geriatric Health Care in Rural Areas: Development and Technical Acceptance Study

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## Abstract

**Background:** Patients of geriatrics are often treated by several health care providers at the same time. The spatial, informational, and organizational separation of these health care providers can hinder the effective treatment of these patients.

**Objective:** This study aimed to develop a regional health information exchange (HIE) system to improve HIE in geriatric treatment. This study also evaluated the usability of the regional HIE system and sought to identify barriers to and facilitators of its implementation.

**Methods:** The development of the regional HIE system followed the community-based participatory research approach. The primary outcomes were the usability of the regional HIE system, expected implementation barriers and facilitators, and the quality of the developmental process. Data were collected and analyzed using a mixed methods approach.

**Results:** A total of 3 focus regions were identified, 22 geriatric health care providers participated in the development of the regional HIE system, and 11 workshops were conducted between October 2019 and September 2020. In total, 12 participants responded to a questionnaire. The main results were that the regional HIE system should support the exchange of assessments, diagnoses, medication, assistive device supply, and social information. The regional HIE system was expected to be able to improve the quality and continuity of care. In total, 5 adoption facilitators were identified. The main points were adaptability of the regional HIE system to local needs, availability to different patient groups and treatment documents, web-based design, trust among the users, and computer literacy. A total of 13 barriers to adoption were identified. The main expected barriers to implementation were lack of resources, interoperability issues, computer illiteracy, lack of trust, privacy concerns, and ease-of-use issues.

**Conclusions:** Participating health care professionals shared similar motivations for developing the regional HIE system, including improved quality of care, reduction of unnecessary examinations, and more effective health care provision. An overly complicated registration process for health care professionals and the patients' free choice of their health care providers hinder the effectiveness of the regional HIE system, resulting in incomplete patient health information. However, the web-based design of the system bridges interoperability problems that exist owing to the different technical and organizational structures of the health care facilities involved. The regional HIE system is better accepted by health care professionals who are already engaged in an interdisciplinary, geriatric-focused network. This might indicate that pre-existing cross-organizational structures and processes are prerequisites for using HIE systems. The participatory design supports the development of technologies that are adaptable to regional needs. Health care providers are interested in participating in the development of an HIE system, but they often lack the required time, knowledge, and resources.

**KEYWORDS**

electronic health records; health information exchange; geriatrics; community-based participatory research; technical acceptance; usability; health information network; postacute care; patient-centered care

## Introduction

### Background

Advanced age is associated with a higher morbidity risk and a higher risk for multiple comorbidities. Older patients are more likely to be affected by functional limitations and lose their independence and autonomy [1]. Morbidity, functional limitations, and symptoms in patients of geriatrics can vary widely. Thus, these patients are often treated by several health care providers with different tasks and competencies [2,3].

In Germany, the geriatric services of different health care professions, levels of health care provision (general and specialized care), and inpatient and outpatient health care are distinctively separated from each other with respect to planning, service implementation, access, and reimbursement. Specialized geriatric health care is provided by a variety of professions and includes inpatient and outpatient services [4,5].

As a consequence, there are significant communication and co-operation requirements associated with the provision of geriatric care. Especially in rural federal states such as the study region, Mecklenburg-Western Pomerania, specialized geriatric health care is rare and the distances are large, limiting close co-operation between health care providers and, hence, a comprehensive case management of the patients [6].

In rural areas, there is usually less access to health care for older people, and it is of lower quality compared with that available to urban patients even when considering the inconsistent definition of *rural* and possible interferences with other sociodemographic aspects [7,8]. As a result of demographic change, predominantly rural communities are often both declining in size and aging faster [9]. At the same time, the work environment in rural areas is often not very attractive to health care providers (eg, because of economic issues or working conditions). In addition, long distances are a major barrier to access to geriatric health care for older adults with multimorbidity and reduced mobility [7,9-11].

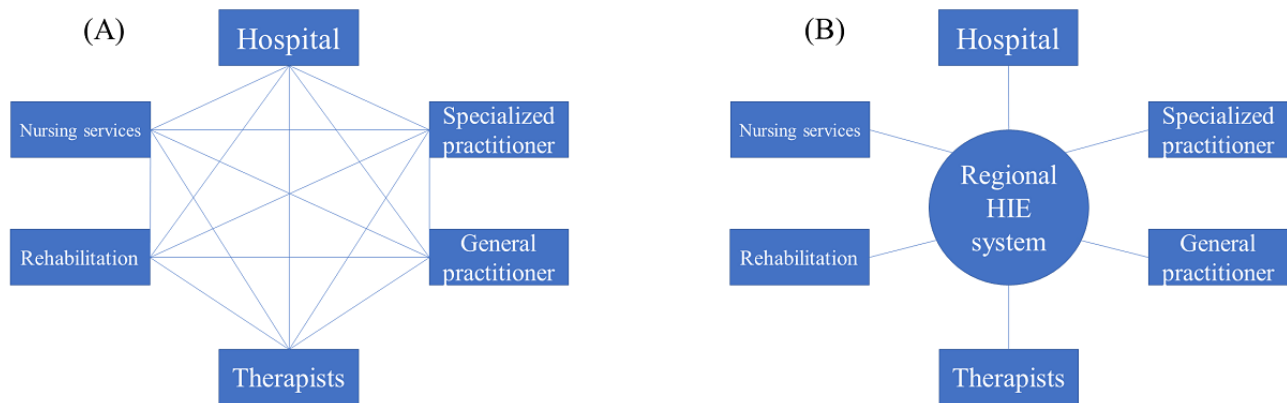
An analysis of problems and preferred solutions based on a questionnaire for German health care providers showed that the organizational and spatial separation of cotreating providers is

one of the most urgent problems in rural areas. The respondents mostly preferred cross-professional networking to meet this challenge [12]. A study in the United States on older patients with comorbidities who needed a surgical procedure showed that information exchange between primary care providers and surgical providers is often discordant during transition, particularly the communication of the functional and social status of the patients [13]. Facilitating cross-institutional communication is a promising way to improve the quality and efficiency of geriatric health care. Information and communication technologies (ICTs) in health care such as electronic health records (EHRs) or health information exchange (HIE) systems jointly managed by all health care providers who are involved in the treatment of patients of geriatrics can be an option to support regional geriatric health care [3,14].

EHRs have a broad range of technical approaches and functionalities. The International Organization for Standardization defines the term EHR as a “repository of information regarding the health status of a subject of care, in computer processable form” [15]. For the International Organization for Standardization, facilitating continuous, efficient, and quality integrated health care is the primary goal of an EHR [15]. In addition to EHRs, an important key area is HIE, which allows health care providers to share and access clinical patient health information electronically across settings. HIE approaches have a number of benefits for health care, especially for patients with chronic illnesses, such as safer care, a reduction in the patients’ length of stay, fewer laboratory and imaging orders [16], and reduced mortality and serious adverse event incidence [17]. However, the resistance of health care providers [18,19], the difficulty of implementation in existing workflows [20], or a lack of interfaces with other digital patient documentation and information systems [21,22] can prevent the sustainable implementation of ICTs in practice.

Figure 1 shows how the communication processes between geriatric health care providers can be streamlined through the use of a regional HIE system. The effectiveness of an HIE system, measured by the reduction in the quantity of potential communication and data transfers, is expected to increase with the number of providers engaged in the care of a patient.

**Figure 1.** (A) The status quo: unilateral exchange of health information between practitioners who are typically involved in geriatric care in the status quo (eg, by mail or telephone). (B) Multilateral exchange via the regional health information exchange system. The links between the practitioners represent potential communication processes to share patient health information.

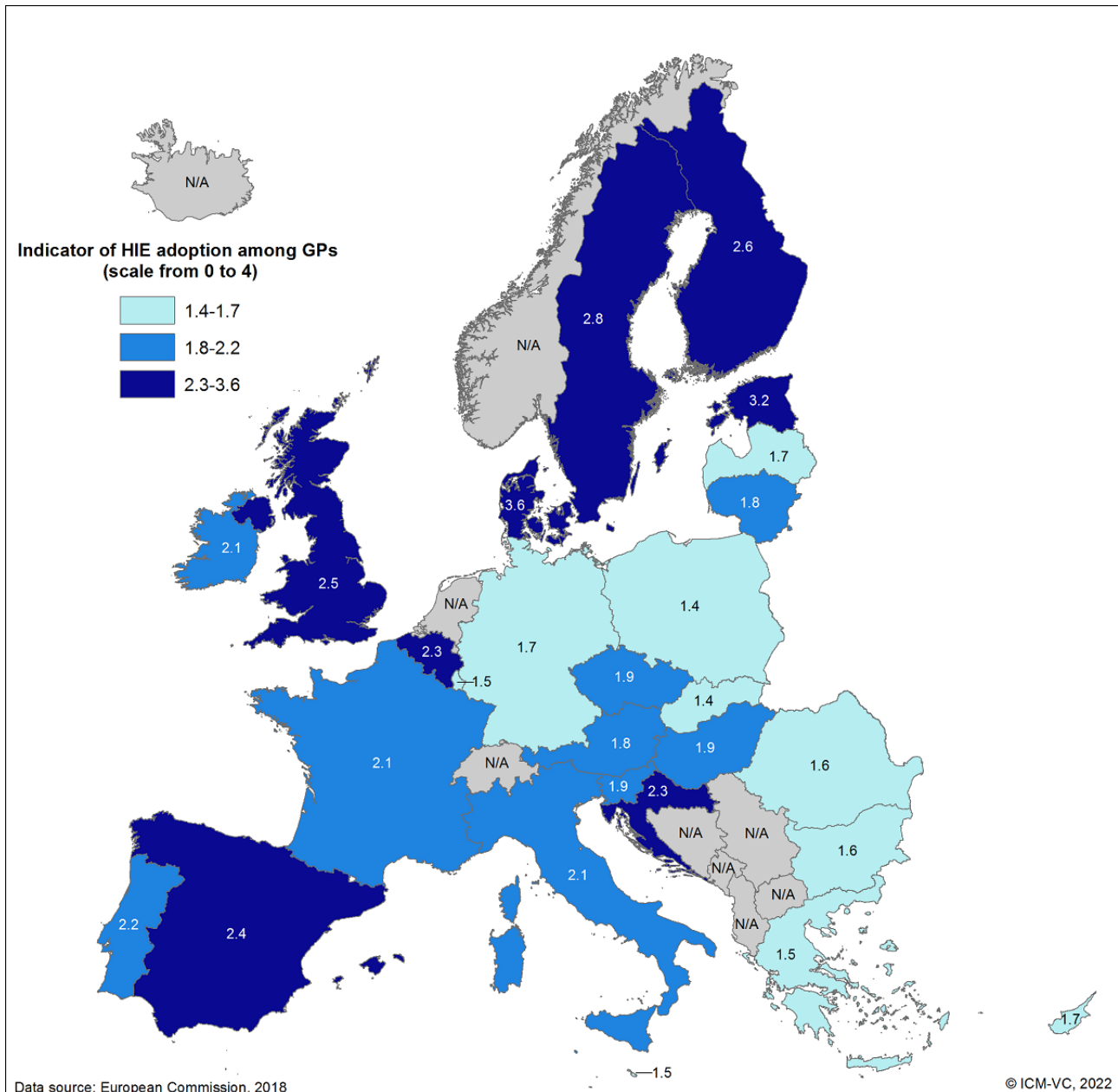


### Research Questions

Recently, Germany passed several laws to foster the use of ICTs, such as the *eHealth Gesetz* (Act for Secure Digital Communication) in 2016 or the *Krankenhauszukunftsgesetz* (Act for a Future Program on Hospitals) in 2020. Particularly noteworthy is the *Patientendaten-Schutz-Gesetz* (Act for Protecting Electronic Patient Data) from 2020, which obliged statutory health insurance companies in Germany to provide EHRs for their members by 2021 at the latest. Health care providers are able to save patient health information,

prescriptions, medical reports, and results in those EHRs, which can be accessed by patients via an app. However, Germany is lagging behind other European countries regarding the use and dissemination of ICTs (eg, in terms of the adoption of HIE systems by general practitioners [GPs]; [Figure 2](#)) [23] or the use of health IT (HIT) applications in hospitals [24]. Although approximately 89% of German GPs' practices are connected to the telematics infrastructure, which enables HIE and the use of other HIT applications [25], the communication between GPs and hospitals is still mainly paper-based [24].

**Figure 2.** Health information exchange (HIE) adoption by general practitioners (GPs) in the European Union (EU) [23]. The scores reflect the share of GPs (n=5,793) who indicated the following state of HIE use in their practice: 0=not aware; 1=do not have it; 2=have it but do not use it; 3=use it occasionally; 4=use it routinely. ICM-VC: Institute for Community Medicine, Section Epidemiology of Health Care and Community Health; N/A: not applicable, because not a member state of the EU or no data available (eg, the Netherlands).



A study on an HIE system in combination with automated clinical event notifications supporting multidisciplinary care coordination for patients of geriatrics has shown that the system can reduce potentially avoidable admissions and duplicate testing [26]. However, in the United States, between 2012 and 2014, a decline in planning and operating efforts was observed in the field of HIE systems [27].

A study on users' acceptance of an HIE system to coordinate the care of patients with chronic illnesses and mental comorbidities has shown that contextual factors, such as various motivational factors, the level of trust between patients and physicians, or incomplete transmission of information, may reduce the willingness of individuals to use HIE systems [28]. However, only a few studies have examined the efficiency and effectiveness of HIE systems [29].

Therefore, the aim of this study was to develop and evaluate a regional HIE system that supports information exchange in rural geriatric care. To counter the aforementioned barriers to implementation, the development followed a community-based participatory research (CBPR) approach that sought to identify and incorporate specific needs as well as the practical knowledge of the affected geriatric health care providers.

Considering the development of the regional HIE system, the research questions were as follows: (1) How can the quality of co-operation between health care providers and between health care providers and researchers be described? (2) What motivates the participating health care providers to engage in the development of the regional HIE system? (3) What barriers and facilitators can be identified with regard to the use of the regional HIE system? (4) What practical feasibility issues can



be observed? (5) What use cases can be supported by the regional HIE system? (6) What functions should the regional HIE system provide to support regional geriatric health care involving all relevant regional health care providers? (7) How is the users' acceptance of the regional HIE system and what factors may affect it?

## Methods

### Overview

Following the CBPR approach, this study used a flexible, iterative, and open-ended mixed methods approach [30] to integrate the knowledge and practical insights of the participating health care providers into the development of the regional HIE system [31,32]. The following stages were conducted: identification of suitable geographic regions for implementing the regional HIE system, identification of regional stakeholders, compilation of specific regional problems of geriatric health care, development of a common workflow, definition of the specific needs of the stakeholders, development of the regional HIE system, and usability testing. [Multimedia Appendix 1](#) depicts the development and research activities in detail. Qualitative methods were applied during the entire course of development. At the end of the project, a survey was conducted.

### Ethics Approval

The ethics board of the University Medicine Greifswald reviewed and approved this study (BB 083/18).

### Qualitative Phase

#### *Participants and Recruitment*

The first step was the identification of suitable regions within Mecklenburg-Western Pomerania. Preferred regions were those with geriatric facilities that were already co-operating in a network of health care providers. Health care providers in each region were recruited based on an open-ended, casual sampling strategy, including snowball sampling, as this allows for a sampling of natural interactional units [33]. At the beginning, health care providers identified as central to regional geriatric health care were invited to jointly develop an EHR. This initial group was then asked to bring in further interested co-operation partners from different health care professions and sectors.

To organize and conduct the meetings between researchers and participating health care providers, CBPR principles according to Israel et al [34,35] were followed. These principles aim to reconcile the interests of the researchers with those of the users, such as building on strengths and resources within the community, recognizing the participating networks as units of identity, sharing decision-making, jointly disseminating the results, and presenting the regional HIE system to other interested health care providers.

For the usability tests of the regional HIE system, patients of the participating geriatric health care providers were included after they provided informed consent. Following the definition of patients of geriatrics of the German expert associations for geriatric care, eligible persons were patients aged >70 years and who had at least two geriatric-typical syndromes or who were

aged >80 years [36]. Geriatric-typical characteristics include, for example, frailty, decubitus, and tendency to fall [36,37].

### Setting

The study took place between January 2018 and October 2020 in the northeast of Germany (federal state of Mecklenburg-Western Pomerania). The setting included inpatient as well as outpatient geriatric care. In Mecklenburg-Western Pomerania, geriatric rehabilitation clinics and acute stationary hospitals are allowed to provide inpatient geriatric care. Outpatient geriatric care can be provided by GPs with or without special training in geriatric care working together with therapists' practices.

### Data Collection and Analysis

During the initial workshops in each focus region, the participants were asked to identify the relevant functions of HIE in geriatric care (eg, electronic case report forms [eCRFs] on diagnoses, medication history, or certain assessment instruments). The results of the workshops were used to design the regional HIE system based on a pre-existing system, the so-called eHealth platform of the University Medicine Greifswald.

Before the participants started testing the regional HIE system, they received training at the workplace on how to use its basic functions. Each partner received a personal client certificate and an individual user account. The participants were asked to test the functions and notify the researchers regarding which adjustments should be made and which additional functions they would need for use in practice. This process was repeated iteratively several times until the regional HIE system provided a comprehensive set of functions that met the needs of geriatric care. User acceptance and usability aspects were simultaneously assessed using the regional HIE system for the HIE of representative (ie, geriatric) cases of the participating health care facilities for test purposes. Usability issues were identified based on the feedback of the users after these tests.

Qualitative data were collected by means of participant observation and informal interviews during the workshops and other meetings to characterize the co-operation within each focus region; identify barriers to and facilitators of HIE in geriatric care; and evaluate the participants' acceptance of the regional HIE system, which included usability aspects. Moreover, qualitative data on the participants' motivation to engage with the regional HIE system were gathered using free-text items in a questionnaire. Especially for obtaining insights into workflow and usability issues of HIE systems, qualitative methods such as observations and interviews were seen as useful [38]. An approach using observations in combination with informal interviews is relatively unobtrusive and, therefore, was easy to integrate into workshops and meetings with practice partners. It also had the advantage of preventing participants from perceiving themselves as study objects, thereby offering the opportunity to observe actions or opinions under everyday conditions. Observation is a promising method to evaluate complex objects of investigation such as interactions within a group of different people over a certain

period as other methods would not or would only indirectly provide answers to the research questions [38].

Owing to the coincidental nature of observations and informal interviews [39], no interview transcripts exist. Observations and interview notes were taken by the researchers right after the contacts in a project diary for each focus region, with information about the time, participants, and content of the contacts. To report the qualitative data in our research, we adhered to the SRQR (Standards for Reporting Qualitative Research) [40].

Following the guidelines of the SRQR, the qualitative findings and results of the standardized questionnaire were cross-checked to ensure the trustworthiness of the qualitative data. To increase reliability, the following means were used: if more than one researcher attended a project meeting with the participating health care providers, the observations were discussed afterward. After the data collection phase, the project diaries were checked for incoherencies by two other researchers (AB and PP) involved in the project. Furthermore, all email correspondence and phone contacts with the participants were documented, which served as an audit trail for the research activities.

Project diary entries were categorized using inductive content analysis. The data were analyzed using MAXQDA (version 10; VERBI Software Consult).

### Quantitative Phase

#### Sampling

Convenience sampling was used to select the survey participants. As the study was interested in the participants' acceptance of the regional HIE system, participants had to attend at least one regional HIE workshop or meeting with the research team. Furthermore, the participants had to be involved in geriatric care. However, there were no restrictions with respect to their profession (medical, therapeutic, and nursing staff) or sector of the health care system (eg, practices or hospital).

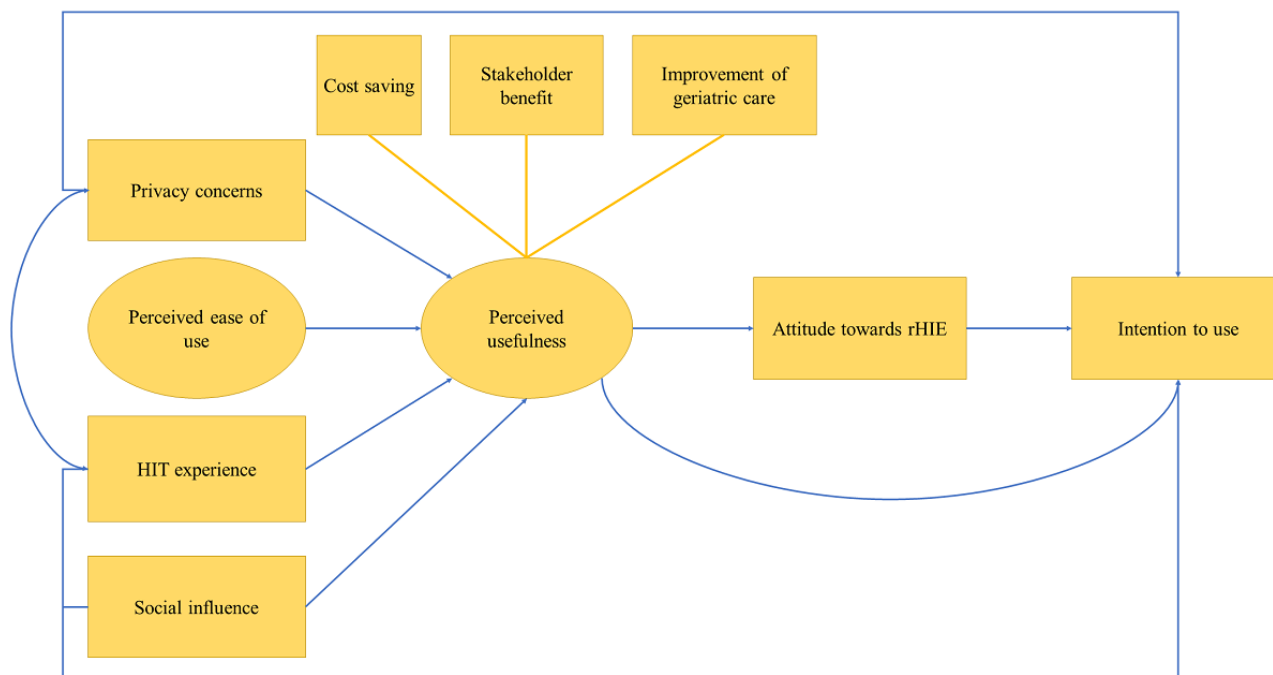
#### Setting

The survey was conducted in health care facilities that are usually involved in geriatric care and that participated in the development of the regional HIE system. Inpatient as well as outpatient facilities were included.

#### Data Collection and Analysis

The questionnaire sought to evaluate the satisfaction of the participants with the developmental process, their motivation for participating, their attitude toward the regional HIE system, and the factors affecting their intention to use it in their working practice. To evaluate the participants' acceptance of the regional HIE system, items from an adjusted technology acceptance model (TAM) [41] were used. This is an adapted model specifically describing influential factors for the acceptance of a shareable EHR, which focuses on the intention to use rather than on actual use. Thus, it is a suitable model for considering technologies that are still in the preprototype stage. This model is shown in Figure 3.

**Figure 3.** Adapted and tested technology acceptance model for health ITs (HITs), own illustration, based on Steininger and Stiglbauer [41]. rHIE: regional health information exchange.



The survey, as a quantitative method, was seen as a suitable means to objectively determine the aforementioned variables and cross-check the results of the qualitative survey.

The questionnaire included 35 questions regarding the status quo of communication in geriatric care (eg, the current quality of communication, perceived communication costs, frequent communication partners, frequently missing patient health

information, current communication means, and local electronic medical record [EMR] systems in use). This was followed by a set of statements on the acceptance and perceived usability of the regional HIE system according to the TAM (Figure 3) and the assessment of the CBPR co-operation. The statements were to be evaluated using a 5-point Likert scale (“strongly agree”-“strongly disagree”). The last section consisted of questions asked to obtain demographic details about the participants (eg, occupation, affiliation to a health care facility, membership status in medical networks, age, and sex). The questionnaire was pretested by 5 research colleagues. A descriptive analysis of the quantitative data was conducted, and the results were presented both in total numbers and in relative percentages. Free-text answers were categorized using inductive content analysis.

### Technical Infrastructure

The so-called eHealth platform of the University Medicine Greifswald served as the technical basis for the development of the regional HIE system. The eHealth platform includes a user interface (c37.CaseBoard by celsius37.com AG) and a database back end consisting of an Orchestra server (Orchestra eHealth Suite; version 18.2.1; x-tention) supporting Integrating the Healthcare Enterprise standards, such as Cross-Enterprise Document Sharing, which allows for cross-organizational exchange of medical documents and information; Patient Identifier Cross-Referencing for cross-organizational patient identification; Cross-Enterprise User Assertion for

cross-organizational user authorization; and Audit Trail and Node Authentication, which allows for an audit trail and node authentication.

X-tention Orchestra structures and merges data, including record linkage, in the main database, whereas c37.CaseBoard, as the user interface, enables health care professionals to edit and manage patient health and treatment information. The original intention of the project was to use the eHealth platform for exchanging patient health information between subsidiary facilities affiliated with the university hospital (eg, radiological images taken by an affiliated walk-in clinic).

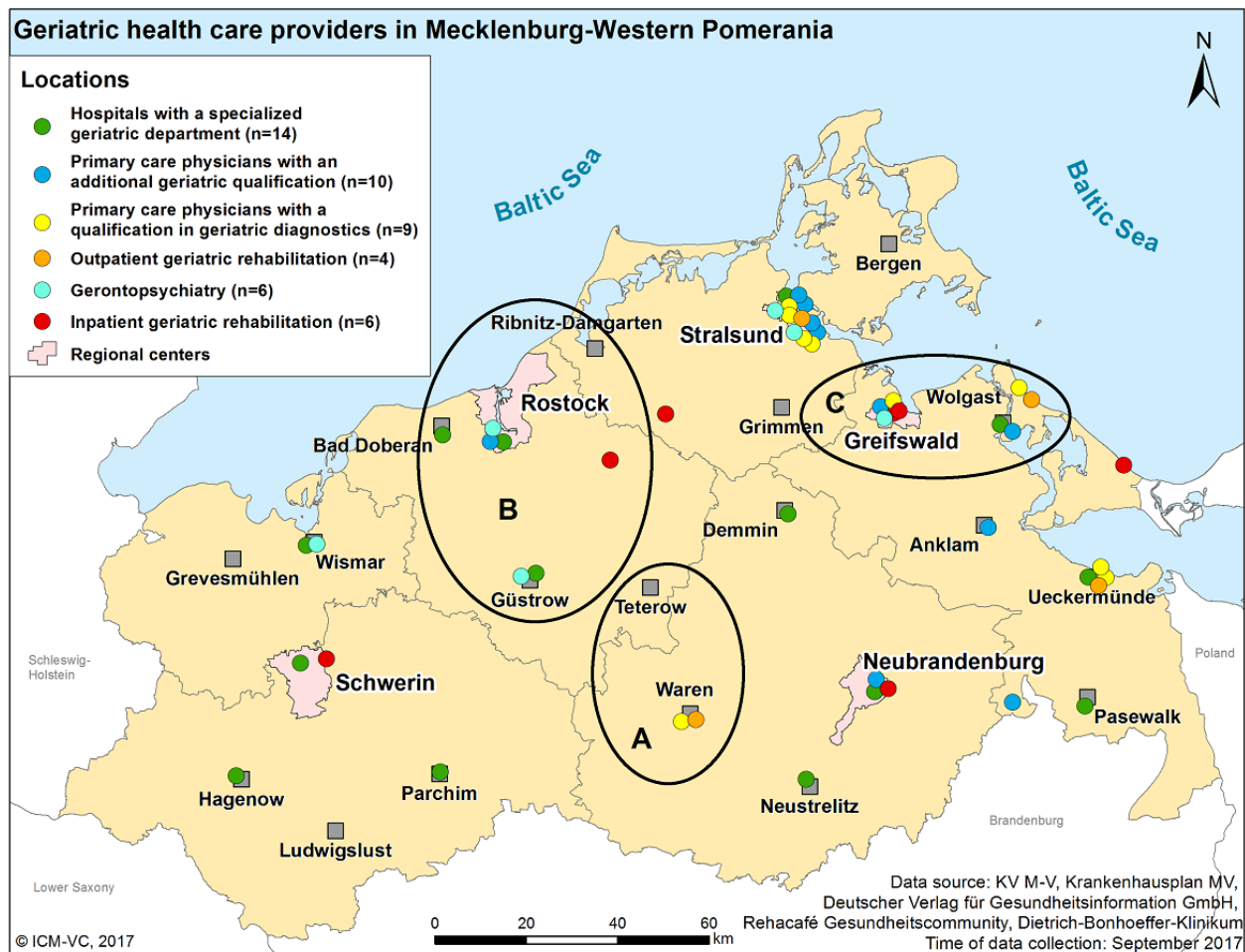
## Results

### Qualitative Results

#### *Characterization of Participants and Focus Regions*

Health care providers from 3 focus regions participated in the development and implementation of the regional HIE system (Figure 4). In region A, local GPs, a specialized GP (a primary care physician with a qualification in geriatric diagnostics or an additional qualification in geriatric care), and an acute inpatient hospital without a specialized geriatric department were involved. In region B, GPs, a specialized geriatric GP, a hospital with a specialized geriatric department, and an inpatient geriatric rehabilitation clinic participated. In region C, a hospital with a specialized geriatric department collaborated with a geriatric day clinic and local GPs.

**Figure 4.** The three focus regions (A, B, and C) involved in the development of the regional health information exchange system. ICM-VC: Institute for Community Medicine, Section Epidemiology of Health Care and Community Health ; KV M-V: Association of Statutory Health Insurance Physicians in Mecklenburg-Western Pomerania; MV: Mecklenburg-Western Pomerania.



In total, 22 people from all 3 focus regions participated in CBPR activities on developing the regional HIE system. All 22 were included in the participant observations and informal interviews. [Multimedia Appendix 2](#) characterizes the 3 participating focus regions in detail and shows that different health care professions and facilities participated in the workshops and meetings on the regional HIE system during the developmental process. Each region contributed geriatric qualifications and specializations to a different extent. The extent of networking within each region also varied. The networks in regions A and B had a formal co-operation agreement (which also included joint activities beyond the scope of mere patient care), whereas the network in region C was of an informal nature and, thus, solely restricted to the joint care of patients that is typical in the health care system (eg, because of the transfer of patients between different sectors or health care facilities). One of the formal networks had a focus on geriatric care (region B), and the other had a focus on general care with mainly GPs as members. The network from region B was the only network with a network coordination office, which organizes multi-professional task forces on certain issues of cross-organizational health care in the region.

A total of 12 workshops were conducted between January 2018 and October 2020. [Multimedia Appendix 3](#) depicts how many

workshops were conducted in each region and what achievements could be made.

To test usability, 50 patients were recruited between June 2019 and October 2020 in region B. In regions A and C, practitioners used test data sets for usability testing of the regional HIE system.

### ***Relationship Between Participants and Between Participants and Researchers***

On the basis of observational data, [Multimedia Appendix 4](#) characterizes the relationship between the participating health care providers in the 3 focus regions and the relationship between the participants and the researchers considering the CBPR principles. It was found that co-operation with the network in region B was the best with regard to continuity, trustworthiness, and the strategic orientation of the collaboration.

### ***Health Care Providers' Motives for Participation***

[Table 1](#) shows the CBPR partners' most important reasons for participating in the regional HIE project. The improvement of the quality of care, promotion of cross-sectoral co-operation, and reduction of administrative costs for patient documentation were the strongest motives for participating. Quality of care refers to patient-related outcomes, including rehospitalizations,

adverse drug effects, or need for nursing services. Promoting cross-sectoral co-operation means the general improvement of communication and information exchange between different health care facilities treating the same patients. Lower

communication and documentation costs refers to the expectation of the participating facilities that they will be able to reduce their administrative costs associated with sharing or documenting patient health information.

**Table 1.** The project partners' motives for participation in the regional health information exchange project. Respondents' free-text answers from the questionnaire (categorized; N=11).

Motive	Partners, n (%)
Quality of care	6 (55)
Promoting cross-sectoral co-operation	6 (55)
Lower communication and documentation costs	5 (45)
More efficient use of resources in health care	3 (27)
Better availability of information	2 (18)
Proxy co-operation (eg, improvement of business relations)	1 (9)
Uniform cross-divisional discharge management	1 (9)
Patient-centered focus on overall health	1 (9)
Other	1 (9)

### **Identified Use Cases and the Extension of the eHealth Platform**

A total of 3 use cases of the regional HIE system were identified (Textbox 1).

The following functions were identified and implemented into the regional HIE system: assessment eCRFs (specific geriatric assessment instruments such as the Barthel Index, Mini-Mental State Examination, and Mini Nutritional Assessment), diagnosis eCRFs (International Classification of Diseases, 10th Revision,

and German codes for principal and secondary diagnoses), medication eCRFs (prescribed substance, dose, dosing time, and purpose), an eCRF for contact persons (contact information of the responsible nursing service, GP, caregiver, and relatives), assistive device eCRFs (assistive devices already used by the patient and those newly prescribed), and an eCRF on powers of attorney and the living will of the patient. In addition, users can share any medical documents (eg, medication plans, physician's letter, and discharge letters) by scanning and uploading them as PDFs to the regional HIE system.

**Textbox 1.** Use cases of the regional health information exchange (HIE) system.

#### **Use cases**

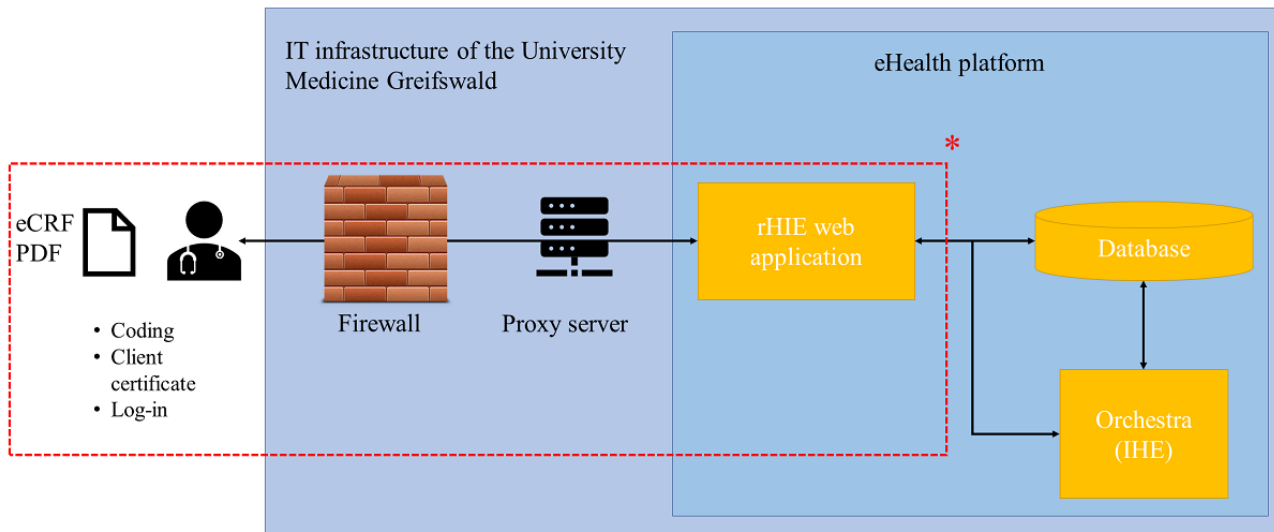
- Discharge management: the regional HIE system should provide treatment information (eg, diagnoses and results) of an inpatient stay for other involved health care professionals as soon as this information has been collected. Hence, general practitioners (GPs) will be able to coordinate the subsequent treatment of their patients more effectively and at an early stage of care.
- Outpatient geriatric treatment: GPs or practitioners specialized in geriatrics should be able to share information on assessment results, prescribed medications, assistive devices, therapies, care needs, and social medical information.
- Emergency care: previously recorded patient health information would be accessible in an emergency independent of time and location.

After the extension of the former eHealth platform, authorized geriatric health care providers are able to access the regional HIE system for exchanging health information of their patients with other health care providers involved in the treatment but not with the patients themselves.

In this project, digitized documents were only exchanged as scanned PDFs, but a structured data exchange based on Fast

Healthcare Interoperability Resources standards is theoretically possible if the local EMRs of the participating health care facilities support Fast Healthcare Interoperability Resources and have the required interfaces. All the involved practitioners can communicate directly by using a comment function. Figure 5 depicts how the technical infrastructure of the eHealth platform has been extended.

**Figure 5.** Technical infrastructure of the eHealth platform. Authorized users can exchange patient health information via electronic case report forms (eCRFs) or as digitized documents (eg, PDFs). IHE: Integrating the Healthcare Enterprise; rHIE: regional health information exchange. \*New components of the rHIE system added to the pre-existing eHealth platform.



Screenshots of the functions of the regional HIE system are provided in [Multimedia Appendix 5](#).

### **Barriers to and Facilitators of the Use of the Regional HIE System**

On the basis of the observational data, the following barriers to and facilitators of the use of the regional HIE system were identified.

A total of 13 barriers were identified ([Multimedia Appendix 6](#)). Major barriers were as follows: some users considered the regional HIE system to be a comprehensive EHR rather than a pure HIE platform; therefore, they found it too laborious to use the regional HIE system in parallel with their local and mainly paper-based patient records. A participant criticized that the parallel structures of local patient records and the regional HIE system meant that the availability of information for other collaborating facilities still depended on when health care providers actually transferred data to the regional HIE system. Thus, whether the patient health information on the regional HIE system was available in time still depended on local workflows. In addition, 9% (2/22) of the participants proposed improving the regional HIE system by adding a notification function that informs other health professionals involved in the treatment if patient information is updated or new documents are uploaded.

Moreover, users complained about ease-of-use aspects and technical issues that negatively affected the use of the regional HIE system, such as bad internet connectivity, unnecessary mandatory fields in the eCRFs, problems with browser settings, or the overly complex registration process.

The fact that there is not yet region-wide use of the regional HIE system and a lack of trust among users were seen as further barriers to the implementation of the regional HIE system. Owing to the patients' right to choose their practitioner freely on the one hand and the complex user registration process on the other, it was not always possible to share patient health information with all health care professionals actually involved

in the treatment. Finally, 14% (3/22) of the participants did not want to use the regional HIE system as they feared too much transparency in terms of their working procedures and outcomes.

In total, 5 facilitators were identified ([Multimedia Appendix 7](#)). One of the main facilitators was the adaptability of the regional HIE system to local needs by using a modular structure and customizable eCRFs. In contrast to EHRs of different statutory health insurance companies, which have been developed recently, the regional HIE system is open for all patients regardless of their membership of certain insurance companies, which makes adoption of the regional HIE system to support local information exchange easier. Moreover, the web-based design enables facilities to exchange information via the regional HIE system regardless of their individual technical infrastructure. Furthermore, participants who saw the regional HIE system as an HIE system for transferring only certain information relevant to treatment rather than a comprehensive EHR of patient health information were more open-minded about the use of the regional HIE system in practice. Trust among the participants within their local health care networks also increased the use of the regional HIE system. Finally, high computer literacy of the users was seen as helpful in the implementation of the regional HIE system.

## **Quantitative Results**

### **Survey Participants**

All 22 participants in the CBPR workshops were asked to complete a questionnaire at the end of the project. A total of 12 questionnaires were filled out (12/22, 55% response rate). There were several reasons for nonresponse. A total of 14% (3/22) of the participants filled out the questionnaire together with another colleague from their team and did not send back their own questionnaires. In 18% (4/22) of the cases (all from region A), the head of the network insisted on performing the testing as a representative of the other participating GPs. Therefore, the other GPs did not feel responsible or were not able to answer the questions asked in the questionnaire. In 14% (3/22) of the cases, the reasons for not answering were unknown.

In region A, 100% (3/3) of the participants were aged between 51 and 60 years. In region B, 60% (3/5) of the participants were aged between 41 and 50 years, and 20% (1/5) were aged between 21 and 30 years. In region C, 25% (1/4) of the participants were aged between 41 and 50 years, 25% (1/4) were aged between 31 and 40 years, and 25% (1/4) were aged >60 years. A total of 17% (2/12) of the respondents (1/2, 50% from region B and 1/2, 50% from region C) did not provide their age. Thus, participants from region A were, on average, older than the other participants. Region B was the region with the youngest participants on average.

### ***Status Quo of HIE Processes in Regional Geriatric Health Care***

Of the 12 respondents, 8 (67%) often or always depended on information from other health service providers in the treatment of their patients, and 1 (8%) did not respond. The respondents indicated that the following health care facilities were central for the cross-sectoral HIE in geriatrics (multiple choices were possible): hospitals (9/12, 75%), nursing care services (9/12, 75%), GPs (8/12, 67%), speech and occupational therapists (7/12, 58%), and geriatric rehabilitation and day clinics (4/12, 33%).

Information and patient data that were often not (immediately) available but needed for further treatment of patients of geriatrics were as follows (multiple choices were possible): information about prescribed assistive devices (5/12, 42%), vaccination (4/12, 33%), social situation (4/12, 33%), self-medication of the patient (4/12, 33%), geriatric assessments, and discharge letters (3/12, 25%).

Furthermore, the questionnaire respondents were asked to assess the quality of the current HIE. Of the 12 participants, 5 (42%) rated the quality of information exchange as good, 5 (42%) rated it as neutral, 1 (8%) rated it as bad, and 1 (8%) did not answer.

Of the 12 participants, 8 (67%) considered the effort and expenses involved in the current cross-institutional HIE as high to very high, and 3 (25%) felt that the demands were reasonable.

A total of 67% (8/12) of the participants stated that they were using paper-based records supported by electronic data processing. A total of 33% (4/12) of the participants (1/4, 25% from region A and 3/4, 75% from region B) answered that they were using comprehensive digital records. Of those 4 participants, 1 (25%) from region B was using a digital record with the ability to share patient data with other facilities.

Considering the means currently used for exchanging patient health information, 12 participants, with 1 missing, responded as follows (multiple responses were allowed): 10 (83%) were using mail or fax, 9 (75%) were using phones, 5 (42%) were using email, and 1 (8%) was using WhatsApp or similar apps. No participant used SMS text messaging or HIE systems. In all regions, half of the participants (2/3, 67% from region A; 3/4, 75% from region B; and 1/5, 20% from region C) were using only conventional, nondigital means of communication (mail, fax, or phone) for exchanging medical information.

### ***Acceptance of the Regional HIE System***

**Multimedia Appendix 8** shows different aspects of the TAM 2 and to which extent the participants agreed that the regional HIE system could fulfill these aspects in practice. The participants were mostly skeptical regarding technical (3/12, 25%) and organizational integrability (3/12, 25%) and being able to provide the necessary human resources needed to use the regional HIE system in practice (5/12, 42%).

The participants mostly agreed that they were appropriately informed of the advantages and disadvantages of the regional HIE system (7/12, 58%). Most believed that the regional HIE system was able to improve different aspects of the provision of geriatric health care (quality of care: 8/12, 67%; availability, completeness, and timeliness of important medical information: 7/12, 58%; and continuity of care: 5/12, 42%). The regional HIE system was also considered by 42% (5/12) of the participants to reduce the expenses incurred for documentation and communication in comparison with the status quo of HIE.

Nearly half of the participants agreed that the regional HIE system guaranteed an appropriate level of privacy protection for both patient (5/12, 42%) and provider (5/12, 42%) data. The same proportion of participants agreed that colleagues from their own and other facilities found the regional HIE system useful (5/12, 42%). Half of the participants planned to continue using the regional HIE system after the project ended (6/12, 50%). Nearly half also agreed that they would recommend the use of the regional HIE system to other colleagues (5/12, 42%).

The participants from region A were the most critical about using the regional HIE system in practice after the end of the project. A total of 67% (2/3) of the participants from region A indicated that they would not use the regional HIE system in practice. However, in region B, 60% (3/5) of the participants and, in region C, 50% (2/4) of the participants agreed that they would use the regional HIE system in practice. The other participants from regions B and C gave a neutral response.

Although the regional HIE system was developed by involving the regional geriatric experts, after finishing development, only 2 of them agreed that the regional HIE system had appropriate functions to support HIE in geriatric care.

## ***Discussion***

### ***Principal Findings***

Regarding the use of the regional HIE system in practice, the following barriers were identified: lack of trust owing to the implicit disclosure of own treatment methods to other users, missing regional geriatric network structures, time constraints, limited human resources, differences in computer literacy, and some ease-of-use issues. An overly complicated registration process for health care professionals and the patients' free choice of the treating health care provider can, in turn, result in an incomplete exchange of patient health information via the regional HIE system. Among the participants, acceptance of the regional HIE system was high but varied between the 3 focus regions. The status quo of pre-existing HIE systems was at a low level in all regions.

According to the observational data, a concern was that the use of the regional HIE system could result in an increased workload for the participants instead of reducing the effort required for documentation as there is no automatic data transfer between the regional HIE system and the local EMR yet. Chronaki et al [42] also found that, because of individual resistance to innovations, changes in workflow related to the implementation of an EHR could lead to a heavier workload for health care professionals at the beginning. Switching from one system to another, insufficient financial resources, and the absence of computer skills were also identified as barriers in a study on factors that affected the uptake of an EHR by GPs in Ireland [43]. In addition to a lack of technical support, a lack of support at the management, colleague, or even political level can be a barrier to the implementation of an EHR [44,45].

The exchange of information between practice and hospital information systems and a regional HIE system is generally a challenge in Germany as there are >110 different practice management systems and also a variety of hospital information systems. In addition, most respondents (10/12, 83%) still mainly used paper-based records, albeit in combination with electronic data processing such as practice management software products. As a consequence, full integration of the regional HIE system into local EMRs is challenging. However, the amount of time saved by using an EHR increases with the level of interoperability of the EHR system [46], so further development of the regional HIE system should focus more intensively on interoperability and building up interfaces with other systems.

Some participants (2/22, 9%) were unsatisfied with the development of the regional HIE system as it took too much time. Moreover, they felt that they had too little influence on the development. However, the same participants had very high expectations (eg, automatic synchronization between the different local EMRs and the regional HIE system) and were generally skeptical of the project. It is known that staff skepticism, a lack of clinical leadership, a vendor whose products are not ready on time [47], and unfulfilled expectations are barriers to the implementation of EHRs [48]. Pagliari et al [49] outlined that clinicians' mistrust of e-communications could also be a barrier.

Some participants (1/22, 5%) were concerned about patient and provider privacy. Rosen et al [50] suggested that physicians fear there might be a quality assessment based on their EHR use data, which might lead to a low uptake among physicians who, for instance, stick to more traditional referral processes. Hackl et al [51], based on interviews with Austrian physicians, concluded that there are serious concerns that EHR data could be used against the participating physicians. Ford et al [52] recognized a threat to physician autonomy and concluded that, despite an existing EHR system, this could result in a lack of information sharing. Therefore, a role- and rights-based access policy should be integrated into the regional HIE system, which allows the owners of the patients' medical documents or records to release them to predefined subsets of health care providers, for example, exclusively to nursing services, only family physicians, or to a combination of these user groups. By contrast, the patient should be able to grant and control health care providers' individual access to the regional HIE system (eg,

using a personal identification number or managing access settings via the patient's own account). This would also solve the problem that not all relevant health care providers can be added to the HIE system in advance.

The following facilitators of the use of the regional HIE system were identified: adaptability and modular structure of the regional HIE system, web-based design, use of the regional HIE system as an HIE system, trust among the users of an HIE system, and computer self-efficacy. Although the web-based design does not solve the interoperability problem of a scattered HIT landscape, it was identified as a facilitator of the use of the regional HIE system as it allows health care providers with different technical resources to exchange health information. It helps overcome the problems associated with the existence of various kinds of patient records and IT systems (eg, paper-based vs electronic records). Another study also highlighted that the federated web-based design is a facilitator as it presupposes less trust among the participating users because each user retains the control of their own data [53].

Another facilitator was that the regional HIE system, in contrast to EHRs offered by statutory health insurance companies, can be used by all patients regardless of their individual insurance company. The regional HIE system also allows for HIE between health care providers involved in the treatment without it being restricted to certain medical information and results or by whether the patient uses the EHR function provided by their health insurance company. In contrast to EHRs, clinical data transferred via HIE systems follow the patient electronically across delivery settings and, thus, HIE systems are more able to improve care coordination [14].

Moreover, the participatory design can be seen as a facilitator of the adoption of the regional HIE system as it enables health care providers of a certain region to adapt the HIE system to the specific local geriatric health care needs.

Comparing the individual focus regions, it is remarkable that the collaboration with participants from region B was the best in terms of continuity of co-operation, strategic planning, network identity, engagement in participatory activities, and other CBPR aspects. In contrast, collaboration on the development of the regional HIE system was the worst in region A and average in region C. Most of the participants from region B (3/5, 60%) were also convinced of the benefits of the regional HIE system for local geriatric care and indicated that they would use it in practice after finishing the project, whereas participants from region A (2/3, 67%) in particular were more skeptical and mainly indicated that they would not continue to use the regional HIE system. A reason seems to be that practitioners trained in geriatrics and geriatric-focused networks were more open-minded about participatory designs and more often saw the urgency of cross-organizational information exchange to improve geriatric care outcomes. Moreover, the presence of a network coordination office, a nonhierarchical organization, and the leadership of a geriatric-focused clinic in region B could have facilitated development and implementation in the region.

Participants engaged in a network that seeks to develop and improve regional interdisciplinary geriatric concepts seem to be more interested in the regional HIE project than those who



are going at it alone. A reason for this could be that these participants are more sensitized to the communication problems in the current health care system. Another reason may be that they already have a clear concept of what is needed to improve cross-sectoral communication. Mostashari et al [54] showed that already existing team-based care strategies were a good prerequisite for a successful implementation of EHRs.

Participants' individual characteristics, such as age or computer literacy, could have been important factors affecting the acceptance of the regional HIE system as participants in region B were, on average, the youngest and a participant from region B had high computer literacy, whereas a participant from region A had doubts about using HIT innovations in his practice. Another study showed a significant negative correlation between health care workers' age and their perception of telemedicine's significance [55]. Moreover, previous studies have identified computer anxiety as a barrier [56] and computer self-efficacy [57] as a facilitator of the adoption of EHRs [58].

The technical state of HIE seems to be at a low level in all regions, which would be consistent with the general relatively low level of HIE adoption in Germany compared with other European countries. The participants had mainly used nondigital means for exchanging medical information, such as mail, phone, or fax, or used less secure and unilateral means of communication that made it difficult to verify the authenticity of the content and the sender, such as email or WhatsApp. Another survey on outpatient care providers' electronic exchange of health information identified partner readiness and clinicians' previous familiarity with HIT systems as the most important predictors for HIE system use [59]. Thus, the fact that the intention to use the regional HIE system was at a lower level in regions A and C might be explained by the participants having less previous experience using HIT systems.

### Strengths and Limitations

Especially for gaining insights into issues related to workflow and the acceptance of the regional HIE system, observations in combination with informal interviews proved to be a relatively unobtrusive approach and could easily be integrated into workshops and meetings with the practice partners. The mixed methods approach was also suitable for the evaluation of complex objects of investigation such as interactions within a group of different people over a certain period.

Furthermore, the CBPR approach helped address technical as well as organizational issues of implementation that came up during the course of development. Moreover, the participative design helped create functions that were adequately adapted to the regional needs of the providers. The CBPR strategies also seemed to have a positive effect on the users' acceptance.

With the support of the participating health care providers, the development of the regional HIE system was effective. Participants brought in their social capital, reputation, and

knowledge. In addition, researchers and practitioners used mutual symposia and workshops to leverage the synergies between research and practice.

This study has some limitations. It was based on a small number of very heterogeneous health care providers. The results are not representative of the entire community of geriatric health care providers or the health care system in general. Variances in the EHR and HIE infrastructure between the included focus regions are not known. Although a survey collecting quantitative results was conducted, the small sample did not allow for any inferential analysis of the results. However, the results provide a good picture of the regionally different structures of health care provision and associated facilitators of and barriers to the implementation of a regional HIE system.

Even though the CBPR approach seeks to involve all affected stakeholders equally, this was not always possible during the workshops and meetings because of the time constraints of certain participating health care providers. However, the participants represented a comprehensive and inclusive sample of health care providers who were usually involved in geriatric treatment. Observation data were cross-checked with survey data. This enabled a comprehensive and in-depth understanding of communication processes in regional geriatric care, the EHR functions needed, and the users' acceptance issues.

### Conclusions

In summary, the time and effort required to build the necessary trust for a CBPR approach can be seen as the greatest barrier to the participatory design of a regional HIE system. Participative processes and communication efforts (eg, feedback groups, workshops, and training of participants) and the recognition of nonscientific institutions as eligible co-operation partners are necessary for a successful project.

In regions where CBPR collaborations could be established, the development of the regional HIE system was successful as the use cases for it could be identified directly based on the needs of the regions, the functions of the regional HIE system could be adequately designed, and there was a higher degree of acceptance among the users than in other regions. Meta-analyses of a larger sample of studies aiming to develop and implement HIE could provide more evidence to determine whether CBPR approaches are generally more suitable for increasing users' acceptance.

In the future, further stakeholders should be involved in the implementation and further development of the regional HIE system. In addition, more research is needed on questions such as how to adequately remunerate HIE use, which legal adjustments are needed, and how to facilitate cross-sectional co-operation in a fragmented health care system. Finally, the regional HIE system should be evaluated when used with a more general purpose such as a multi-setting environment for more generalizable results on its usability and acceptance.

## Acknowledgments

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## Authors' Contributions

All authors were involved in the conception of the regional health information exchange system. NP, AB, and NvdB analyzed and interpreted the data from the questionnaires, interviews, and participant observations and were the major contributors to the writing of the manuscript. NP, AB, and PP collected data during workshops with the local health care networks and professionals. AB, PP, FR, and ML checked the data sets generated during this study for any incoherencies and were responsible for the representation of the data. All authors revised and approved the final manuscript.

## Conflicts of Interest

None declared.

### Multimedia Appendix 1

Details and timeline of the developmental process. HIE: Health information exchange; rHIE: regional health information exchange system; CBPR: Community-based participatory research; eCRF: electronic case report forms.

[\[PDF File \(Adobe PDF File\), 90 KB - humanfactors\\_v9i3e34568\\_app1.pdf \]](#)

### Multimedia Appendix 2

Characterization of participating focus regions and their representatives during the development of the regional health information exchange system. The table represents the results from the questionnaire as well as the findings from the participant observations and informal interviews.

[\[PDF File \(Adobe PDF File\), 77 KB - humanfactors\\_v9i3e34568\\_app2.pdf \]](#)

### Multimedia Appendix 3

Chronology of the community-based participatory research (CBPR) workshops in each focus region and the achievements that were made during the workshops. rHIE: regional health information exchange system.

[\[PDF File \(Adobe PDF File\), 137 KB - humanfactors\\_v9i3e34568\\_app3.pdf \]](#)

### Multimedia Appendix 4

Community-based participatory research aspects of the collaboration between the participating health care facilities and the researchers according to the observational data in the 3 different focus regions. Source: project diaries.

[\[PDF File \(Adobe PDF File\), 79 KB - humanfactors\\_v9i3e34568\\_app4.pdf \]](#)

### Multimedia Appendix 5

Screenshots of the regional health information exchange system: (A) an example of a geriatric assessment electronic case report form, tandem stand, and (B) the comment function that supports free communication between the authorized health care providers.

[\[PDF File \(Adobe PDF File\), 165 KB - humanfactors\\_v9i3e34568\\_app5.pdf \]](#)

### Multimedia Appendix 6

Barriers to the use of the regional health information exchange system from the perspective of the users according to the results of the content analyses of the project diaries.

[\[PDF File \(Adobe PDF File\), 120 KB - humanfactors\\_v9i3e34568\\_app6.pdf \]](#)

### Multimedia Appendix 7

Facilitators of the use of the regional health information exchange system from the perspective of the users according to the results of the content analyses of the project diaries.

[\[PDF File \(Adobe PDF File\), 91 KB - humanfactors\\_v9i3e34568\\_app7.pdf \]](#)

### Multimedia Appendix 8

The participants' agreement with certain statements categorized by various aspects of the technology acceptance model 2. To express their agreement, respondents could use a 5-point-Likert scale (n=12). HIT: Health IT.

[PNG File , 52 KB - [humanfactors\\_v9i3e34568\\_app8.png](#) ]

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## Abbreviations

- CBPR:** community-based participatory research
- eCRF:** electronic case report form
- EHR:** electronic health record
- EMR:** electronic medical record
- GP:** general practitioner
- HIE:** health information exchange
- HIT:** health information technology
- ICT:** information and communication technology
- SRQR:** Standards for Reporting Qualitative Research
- TAM:** technology acceptance model

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Original Paper

# Defining Recommendations to Guide User Interface Design: Multimethod Approach

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## Abstract

**Background:** For the development of digital solutions, different aspects of user interface design must be taken into consideration. Different technologies, interaction paradigms, user characteristics and needs, and interface design components are some of the aspects that designers and developers should pay attention to when designing a solution. Many user interface design recommendations for different digital solutions and user profiles are found in the literature, but these recommendations have numerous similarities, contradictions, and different levels of detail. A detailed critical analysis is needed that compares, evaluates, and validates existing recommendations and allows the definition of a practical set of recommendations.

**Objective:** This study aimed to analyze and synthesize existing user interface design recommendations and propose a practical set of recommendations that guide the development of different technologies.

**Methods:** Based on previous studies, a set of recommendations on user interface design was generated following 4 steps: (1) interview with user interface design experts; (2) analysis of the experts' feedback and drafting of a set of recommendations; (3) reanalysis of the shorter list of recommendations by a group of experts; and (4) refining and finalizing the list.

**Results:** The findings allowed us to define a set of 174 recommendations divided into 12 categories, according to usability principles, and organized into 2 levels of hierarchy: generic (69 recommendations) and specific (105 recommendations).

**Conclusions:** This study shows that user interface design recommendations can be divided according to usability principles and organized into levels of detail. Moreover, this study reveals that some recommendations, as they address different technologies and interaction paradigms, need further work.

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**KEYWORDS**

user interface design; usability principles; interaction paradigm; generic recommendations; specific recommendations

## Introduction

In the context of digital solutions, user interface design consists of correctly defining the interface elements so that the tasks and

interactions that users will perform are easy to understand [1]. Therefore, a good user interface design must allow users to easily interact with the digital solution to perform the necessary tasks in a natural way [2]. Considering that a digital solution is

used by an individual with specific characteristics in a particular context [3-7], when developing a digital solution, designers must pay attention to a high number of components of user interface design, such as color [8] typography [1], navigation and search [9], input controls, and informational components [10].

Digital solutions and their interfaces must be accessible to all audiences and aimed at universal use in an era of increasingly heterogeneous users [3,4,11-17]. Therefore, designers should also be aware of broad and complex issues such as context-oriented design, user requirements, and adaptable and adaptive interactive behaviors [5]. The universal approach to user interface design follows heuristics and principles systematized by different authors over the years [18-20], but these are generic guidelines, and examples of how they can be operationalized in practice are scarce.

The literature presents many user interface design recommendations for varied digital solutions and users [21-25]. However, the absence of a detailed critical analysis that compares, evaluates, and validates existing recommendations is likely to facilitate an increasing number of similar recommendations [12,26-29]. Although existing recommendations refer to specific technologies, forms of interaction, or end users, the content of some recommendations is generic and applicable to varied technologies and users, such as “always create good contrast between text and page background” [30]; “color contrast of background and front content should be visible” [23]; “leave space between links and buttons” [30]; and “allow a reasonable spacing between buttons” [31]. These illustrative examples highlight the need to aggregate, analyze, and validate existing recommendations on user interface design. Accordingly, this study aimed to synthesize existing guidelines into a practical set of recommendations that could be used to guide user interface design for different technologies.

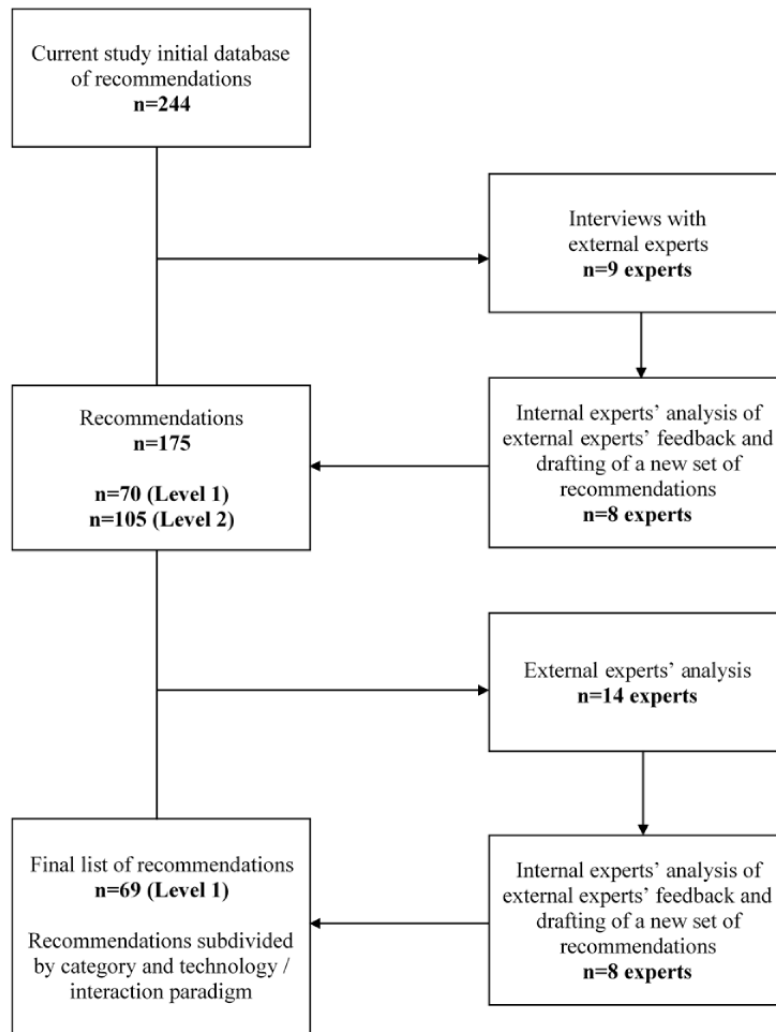
This is important because it contributes to the standardization of good practices and will conceivably allow for better interface design achieved at earlier stages of product development.

## Methods

### Background

In a previous work, 244 interface recommendations were identified, and they formed the basis for this study [32]. The identification of the 244 recommendations combined multiple sources: (1) our previous work [33], (2) a purposive search on Scopus database, and (3) inputs provided by experts in the field of interface design. The references identified through all 3 steps were extracted into an Excel (Microsoft) database with a total of 1210 recommendations. We screened this database and looked for duplicated recommendations. During this analysis, very generic recommendations were also deleted, and recommendations addressing similar content were merged. The resulting database, with 194 recommendations, was analyzed by 10 experts in user interface design recruited among SHAPES (Smart and Health Ageing through People Engaging in Supportive Systems) [34] project partners, who added another 62 recommendations, resulting in 256 recommendations. A further analysis identified 12 duplicated references that were deleted, resulting in a final list of 244 recommendations. The large number of recommendations was deemed impractical, and further action was necessary. Building on this prior research, a set of recommendations on user interface design were engendered following 4 steps: (1) interview with user interface design experts, (2) analysis of the experts’ feedback and drafting of a set of recommendations, (3) reanalysis of the shorter list of recommendations by a group of experts, and (4) refining and finalizing the list. Each of these steps is detailed below, and the whole process is illustrated in Figure 1.



**Figure 1.** Steps of analysis of the user interface design recommendations.

### Interview With User Interface Design Experts

An Excel file with the 244 user interface design recommendations was sent to external experts in the field of user interface design. For an individual to be considered an expert, they had to meet at least 1 the following criteria: (1) have designed user interfaces for at least 2 projects/digital solutions or (2) have participated in the evaluation of user interfaces for at least 2 projects/digital products.

An invitation email was sent to experts explaining the objectives of the study, along with a supporting document with the 244 recommendations. They were asked to analyze the recommendations and report on (1) repetition/relevance, (2) wording, (3) organization, and (4) any other aspect they felt relevant. They were given approximately 4 weeks to analyze the 244 recommendations and send their written analysis and comments back to us. Subsequently, they were asked to attend a Zoom (Zoom Video Communications) meeting aimed at clarifying their views and discussing potential contradictory comments. The written comments (sent in advance by the experts) were used to prepare a PowerPoint (Microsoft) presentation where recommendations and respective comments (anonymized) from all experts were synthesized. This presentation was used to guide the Zoom meeting discussion.

To maximize the efficiency of the discussion, recommendations without any comments and those that received similar comments from different experts were not included in the presentation. For recommendations with contradictory comments, the facilitator led a discussion and tried to reach a consensus. For recommendations with comments from a single expert, the facilitator asked for the opinion of other experts. The Zoom meeting was facilitated by one of the authors (AIM) and assisted by another (author CD) who took notes. The facilitator encouraged the discussion and exchange of opinions from all experts participating in each meeting. The Zoom meetings were recorded, and the experts' arguments were transcribed and analyzed using content analysis by 2 authors (AIM and AGS) with experience in qualitative data analysis. Written comments sent by the experts as well as comments and relevant notes made during the meeting were transposed into a single file and subject to content analysis. After transcription, the notes were independently read by both the aforementioned authors and grouped into themes, categories, and subcategories with similar meaning [35]. Themes, categories, and subcategories were then compared, and a consensus was reached by discussion.

## Analyzing Experts' Feedback and Drafting a Set of Recommendations

The authors of this manuscript (internal experts), including individuals with expertise on content analysis and on user interface design and usability, participated in a series of 6 meetings that were approximately 2 to 3 hours in duration each. These meetings, which took place between January and April 2021 and were held online, aimed to analyze the comments made by external experts in the previous step. Based on the experts' comments, each recommendation was either (1) not changed (if no comments were made by the experts), (2) deleted, (3) merged with other complementary recommendations, (4) rewritten, or (5) broken up into more than 1 recommendation. The decisions were based on the number of experts making the same suggestion, alignment with existing guidelines, and coherence with previous decisions for similar recommendations. In addition, based on external experts' suggestions, the recommendations were organized as follows: (1) hierarchical levels according to level of detail and interdependency, (2) usability principles, and (3) type of technology and interaction paradigm.

## Reanalyzing the Shorter List of Recommendations

To further validate decisions made by the internal panel and explore the possibility of reducing the number of recommendations, the set of recommendations resulting from the previous step (and its respective organization according to hierarchical levels and principles) was reanalyzed by an additional external panel of experts. Once again, to be considered an expert, individuals had to meet the previously identified criteria for experts (have designed user interfaces for at least 2 projects/digital products or have participated in the evaluation of user interfaces for at least 2 projects/digital products). An online individual interview was conducted in May 2021 with each expert by one of the authors (CD). Experts had to answer 3 questions about each of the recommendations: (1) Do you consider this recommendation useful? (Yes/No); (2) Do you consider this recommendation mandatory? (Yes/No); and (3) Do you have any observation/comment on any recommendations or on its organization? The first question was used to determine the inclusion or exclusion of recommendations, and the second one was used to inform on the priority of recommendations through the possibility of having 2 sets of recommendations: 1 mandatory and 1 optional. The third question aimed to elicit general comments on both individual recommendations and their organization. Consensus on the first 2 questions was defined as 70% or more of the experts signaling a recommendation with "Yes" and less than 15% of experts signaling the same recommendation with "No." Qualitative data from the third question was independently analyzed by 2 authors (CD and AGS) using content analysis, as previously described.

## Refining and Finalizing the List of Recommendations

The internal panel of experts (the authors of this study) had an online meeting in which findings of the previous step were presented and discussed, and amendments to the existing list

of recommendations were decided to generate the final list of user interface design recommendations.

## Ethical Considerations

This study focused on the analysis of previously published research and recommendations; therefore, ethical approval was considered unnecessary.

## Results

### Interview With User Interface Design Experts

A total of 9 experts participated in this step of the study: 5 females and 4 males with a mean age of 39.1 (SD 4.3) years. The participants were user interface designers (n=3, 33%) and user interface researchers (n=6, 67%) who had a background in design (n=6, 67%), communication and technology sciences (n=2, 22%), or computer engineering (n=1, 11%). A total of 3 meetings with 1 to 3 participants were conducted with a mean duration of 2 hours. Of the 244 recommendations, 166 (68%) were commented on by at least 1 expert.

Regarding the analysis of the interviews and written information sent by the experts, it was possible to aggregate commentaries into 2 main themes: (1) wording and content of recommendations and (2) organization of recommendations. The first theme was divided into 5 categories: (1) not changed (if no comments were made by the experts); (2) deletion of recommendations (because they were not useful or were contradictory); (3) merging of recommendations (to address complementary aspects of user interface design); (4) rewriting of recommendations (for clarity and coherence); and (5) splitting recommendations into more than 1 (because they included different aspects of user interface design). Of the 244 recommendations, external experts suggested that 108 should be merged (usually pairs of recommendations but could also include more than 2 recommendations), 29 should be rewritten, 4 should be split into more than 1, and 44 should be deleted. Among the recommendations, 78 received no comment. For 19 recommendations, it was not possible to reach consensus in the interview phase.

The second theme (organization of the recommendations) was divided into 2 categories: (1) hierarchization of recommendations and (2) grouping of recommendations. This last category was subdivided into 2 subcategories: (1) grouping of recommendations according to usability principles and (2) grouping of recommendations according to whether they apply to digital solutions in general or to specific digital solutions/interaction paradigms. Examples of quotations that support these categories and subcategories are presented in [Table 1](#). Regarding the grouping of recommendations according to usability principles, the categories proposed by 5 experts ([Table 1](#)) were reorganized and merged into 12 categories: feedback, recognition, flexibility, customization, consistency, errors, help, accessibility, navigation, privacy, visual component, and emotional component. The mapping of the categories proposed by the experts and the 12 categories (named principles) are presented in [Multimedia Appendix 1](#).

**Table 1.** Categories and subcategories of the theme “organization of recommendations,” quotations supporting the categories, and number of experts that made comments in each category/subcategory.

Categories	Subcategories	Citations (examples)	Experts, n (%)
Hierarchization	N/A <sup>a</sup>	<ul style="list-style-type: none"> <li>• There are recommendations with different levels of detail, and they are all placed at the same level; some recommendations correspond to guidelines, others are practical design indications. [E<sup>b</sup>6, male]</li> <li>• It would be interesting to organize the recommendations based on the relationship between them. A high-level recommendation contains low level recommendations. [E8, male]</li> <li>• It makes sense to split into layers. I suggest dividing them into recommendations applicable to all and into standards, with a very high level of detail (button size, space between buttons etc). [E1, female]</li> </ul>	4 (44)
Grouping of recommendations	Design principles	<ul style="list-style-type: none"> <li>• During our analysis, we organized the requirements into categories to assist us. [E7, female]</li> <li>• To be able to do the analysis, I had to code each recommendation to more easily identify the ones that could be grouped according to that category and thus detect repetitions and redundancies. [E6, male]</li> <li>• To make it easier, I created categories according to Nielsen's 10 usability heuristics and 5 design principles. [E3, female]</li> </ul> <p>Of the 9 experts, 5 suggested categories for grouping recommendations:</p> <ul style="list-style-type: none"> <li>• Feedback; users/confusion, errors; human-computer dialogue; system behavior; navigation; presentation; system; users; instruction/information; user control; personalization; system; screen reader; users/cognitive load; system/devices; instructions; user/emotions; design considerations; gamification; users/sensory. [E7, female]</li> <li>• System status; feedback; task execution; navigation/ interaction; organization/structure of information; attention-orientation; information hierarchy; iconography; visual composition of information and of interaction elements; naming; navigation; accessibility; input device and interaction; attention-orientation; learnability; interface customization; complexity and density of information; typography/legibility and formatting; media controllers; color and contrast; navigation/task execution; information representation/mental models. [E6, male]</li> <li>• Feedback; visibility; multimodality; help; recognition; mental burden; control; design; real world; language; flexibility; errors; consistency; accessibility; personalization; search history; animation; efficiency; number of steps; shortcuts; hierarchy; legibility; color; cultural context; security; body; discovery; emotion; gamification; predictive; privacy. [E3, female]</li> </ul> <p><i>Feedback; text information; user profile; layout; navigation; content; tasks; errors; consistency; input; ergonomic; emotional; security; gamification.</i> [E2, female]</p> <ul style="list-style-type: none"> <li>• Visual dimension; dimension of information architecture; dimension of social presence; interaction dimension and dimension of user experience. [E1, female]</li> </ul>	7 (78)

Categories	Subcategories	Citations (examples)	Experts, n (%)
	Generic vs specific to technology/ interaction paradigms	<ul style="list-style-type: none"> <li>The recommendations focus on different types of interactive products (feet, audio interaction, robotics, etc). It would make sense in the end, too, to organize and separate the recommendations by product types. [E6, male]</li> <li>I noticed that some recommendations distinguish interaction modalities (with voice, gestures, use of the feet, etc). I selected those that were general and those that were specific for these groups. [E3, female]</li> <li>All recommendations were put in the same bag, regardless of the detail. I think we are using design principles, guidelines, and standards. Standards only make sense when applied to a specific system, and it is very difficult to classify them without having in mind the system being evaluated. Design standards are derived from design principles and guidelines but applied to specific products. What is being done here is very rich and interesting, but it can lead to a “Frankenstein product,” because the recommendations depend on several factors. I think that at this point you should work with principles, point out the guidelines and check the recommendations for the different products. [E1, female]</li> <li>As we are talking about recommendations that cut across different types of interactive products (feet, audio interaction, robotics, etc), it would make sense in the end, too, to organize and separate the recommendations by product types. [E6, male]</li> <li>They are related in the area of interaction, but each one talks about a different interface. [E3, female]</li> </ul> <p>Of the 9 experts, 3 suggested categories for grouping recommendations:</p> <ul style="list-style-type: none"> <li>Voice interaction; feet interaction; robot. [E7, female]</li> <li>Generic; generic/user centered. [E6, male]</li> <li>Voice; feet; real world; robot; touch; click; text; gestures. [E2, female]</li> </ul>	3 (33)

<sup>a</sup>N/A: not applicable.

<sup>b</sup>E: expert.

### Analysis of Experts’ Feedback and Reanalysis of the Recommendations

Based on the external expert’s comments, the recommendations were reanalyzed. Of the 244 recommendations, 61 (25%) were deleted because they were duplicated or redundant, 48 (19.7%) were merged with other complementary recommendations, 62 (25.4%) were rewritten for clarification and language standardization, 14 (5.7%) were split in 2 or more recommendations, and 59 (24.2%) were not changed. This resulted in a preliminary list of 175 recommendations. [Table 2](#) compares the external experts’ recommendations and internal experts’ final decision.

The 175 recommendations were then categorized into 12 mutually exclusive principles (feedback, recognition, flexibility, customization, consistency, errors, help, accessibility, navigation, privacy, visual, and emotional) and within each principle, organized into 2 levels of hierarchy according to the specificity/level of detail.

Of the 175 recommendations, 70 were categorized as level 1 and were generic recommendations applied to all digital solutions, and 105 recommendations were linked to 1 first level recommendation and subdivided by type of digital solution/interaction paradigm. The recommendations of both levels are linked, as level 2 recommendations detail how level 1 recommendations can be implemented. For example, the level 1 recommendation that “the system should be used efficiently and with a minimum of fatigue” is linked to a set of level 2 recommendations targeted at specific interaction paradigms, such as feet interaction and robotics: (1) “In feet interaction, the system should minimize repetitive actions and sustained effort, using reasonable operating forces and allowing the user to maintain a neutral body position,” and (2) “In robotics, the system should have an appropriate weight, allowing the person to move the robot easily (this can be achieved by using back drivable hardware).” [Table 3](#) shows the distribution of the 175 recommendations.

**Table 2.** Comparison of external expert's recommendations and internal experts' decision.

Type of action	External experts' recommendations (N=263) <sup>a</sup> , n (%)	Internal experts' decision (N=244), n (%)
Deleted	44 (16.7)	61 (25)
Merged	108 (41.1)	48 (19.7)
Rewritten	29 (11)	62 (25.4)
Split	4 (1.5)	14 (5.7)
Not changed	78 (29.7)	59 (24.2)

<sup>a</sup>Consensus was not possible for 19 recommendations.

**Table 3.** Distribution of recommendations by level and category.

Category	Level 1, (N=70), n	Level 2, (N=105), n	Technology/interaction paradigm	Total (N=175), n
Feedback	6	5	<ul style="list-style-type: none"> <li>• Feet Interaction: 1</li> <li>• Robotics: 1</li> <li>• Voice Interaction: 2</li> <li>• Web/Mobile: 1</li> </ul>	11
Recognition	5	12	<ul style="list-style-type: none"> <li>• Feet interaction: 1</li> <li>• Robotics: 1</li> <li>• Voice interaction: 5</li> <li>• Web/mobile: 5</li> </ul>	17
Flexibility	6	10	<ul style="list-style-type: none"> <li>• Feet interaction: 1</li> <li>• Robotics: 4</li> <li>• Voice interaction: 2</li> <li>• Web/mobile: 3</li> </ul>	16
Customization	7	6	<ul style="list-style-type: none"> <li>• Feet interaction: 1</li> <li>• Robotics: 1</li> <li>• Voice interaction: 3</li> <li>• Web/mobile: 1</li> </ul>	13
Consistency	2	2	<ul style="list-style-type: none"> <li>• Voice interaction: 2</li> </ul>	4
Errors	5	7	<ul style="list-style-type: none"> <li>• Feet interaction: 3</li> <li>• Robotics: 1</li> <li>• Voice interaction: 3</li> </ul>	12
Help	3	2	<ul style="list-style-type: none"> <li>• Robotics: 1</li> <li>• Web/mobile: 1</li> </ul>	5
Accessibility	8	23	<ul style="list-style-type: none"> <li>• Feet interaction: 8</li> <li>• Robotics: 4</li> <li>• Web/mobile: 11</li> </ul>	31
Navigation	6	6	<ul style="list-style-type: none"> <li>• Feet interaction: 3</li> <li>• Web/mobile: 3</li> </ul>	12
Privacy	3	5	<ul style="list-style-type: none"> <li>• Digital solutions: 5</li> </ul>	8
Visual component	16	22	<ul style="list-style-type: none"> <li>• Feet interaction: 5</li> <li>• Robotics: 2</li> <li>• Web/mobile: 15</li> </ul>	38
Emotional component	3	5	<ul style="list-style-type: none"> <li>• Feet interaction: 1</li> <li>• Robotics: 3</li> <li>• Digital solutions: 1</li> </ul>	8

## Reanalysis of the Shorter List of Recommendations by Experts

A total of 14 experts (8 females and 6 males) with a mean age of 35 (SD 8.8) years old provided feedback on recommendations. Experts were user interface designers (n=6, 43%) and user interface researchers (n=8, 57%) who had a background in design (n=8, 57%) or communication and technology sciences (n=6, 43%). The interviews lasted up to 2 hours each.

All the 175 recommendations reached consensus for the usefulness question. However, for question 2 (Do you consider this recommendation mandatory?), there was consensus that 54 (77%) level 1 recommendations were mandatory. The remaining 16 (23%) level 1 recommendations were considered by 5 (36%) to 9 (64%) experts as not mandatory. For the 105 level 2 recommendations, there was consensus that 91 (87%) were mandatory, and the remaining 14 were not considered mandatory by 5 (36%) to 9 (64%) experts.

Experts' comments were aggregated into 5 main themes: (1) deletion or recategorizing of recommendations, (2) consistency, (3) contradiction, (4) asymmetry, and (5) uncertainty. It was suggested that 1 recommendation be deleted ("The system should be free from errors"), and another moved from the visual component category to the emotional component category. No other suggestions were made regarding the structure of the recommendations. There were comments related to the consistency, particularly regarding the need to use either British or American spelling throughout all recommendations and to consistently refer to "users" instead of "persons" or "individuals." The remaining comments applied mostly to level 2 recommendations, for which experts identified contradictory recommendations (eg, accessibility: "In robotics, the system should meet the person's needs, be slow, safe and reliable, small, easy to use, and have an appearance not too human-like, not patronizing or stigmatizing" vs emotional: "In robotics, the system should indicate aliveness by showing some autonomous behavior, facial expressions, hand/head gestures to motivate engagement, as well as changing vocal patterns and pace to show different emotions"). Experts also commented on the asymmetry across the number of level 2 recommendations linked to level 1 recommendations and on the asymmetry regarding the number of recommendations per type of technology and interaction paradigm. In addition, experts were uncertain about the accuracy of the measures indicated in the recommendations (eg, visual: "In robotics, the system graphical user interface and button elements should be sufficiently big in size, so they can be easily seen and used, about ~20 mm in case of touch screen, buttons" vs visual: "In feet interaction, the system should consider an appropriate interaction radius of 20 cm for tap, 30 cm at the front, and 25 cm at the back for kick").

## Refining and Finalizing the List of Recommendations

Based on the experts' comments and issues raised in the previous step, the term "users" was adopted throughout the recommendations, 1 recommendation was removed, and 1 was moved from the visual component to the emotional component. In addition, all level 1 recommendations for which no consensus was reached on whether they were mandatory were considered

not mandatory (identified by using the word "may" in the recommendation). The internal panel also recognized that level 2 recommendations cannot be used to guide user interface design in their current stage and that further work is needed. Therefore, a final list of 69 generic recommendations is proposed ([Multimedia Appendix 2](#)).

## Discussion

### Principal Findings

To the best of our knowledge, this is the first study that attempted to analyze and synthesize existing recommendations on user interface design. This was a complex task that generated a high number of interdependent recommendations that could be organized into hierarchical levels of interdependency and grouped according to usability principles. Level 1 recommendations are generic and can be used to inform the user interface design of different types of technology and interaction paradigms. Meanwhile, level 2 recommendations are more specific and therefore apply to different types of technology and interaction paradigms. Furthermore, the level of detail and absence of evidence that they had been validated raised doubts about their validity.

The external experts' suggestions formed the basis for the internal experts' (our) analysis. However, there is a discrepancy between the analysis of both panels of experts in terms of the number of recommendations that should be deleted, merged, rewritten, fragmented, or not changed. This was because when analyzing the recommendations, the internal panel verified that there were more recommendations to delete that were repeated or generic beyond those already identified by the external panel. It is likely that these were missed due to the high number of recommendations, which made the analysis a time-consuming and complex task. Furthermore, changing 1 recommendation in line with external experts' suggestions resulted in subsequently having to change other recommendations for coherence and consistency, resulting in a higher number of recommendations that were rewritten. In addition, there was a lack of consensus among external experts, leaving the final decision to the internal experts (us), further contributing to discrepancies.

Regarding the organization of the recommendations, the division into 2 hierarchical levels based on the specificity/level of detail resulted from the external experts' feedback and aimed at making the consultation of the list of recommendations easier. This type of hierarchization in levels of detail was also used in previous studies aimed at synthesizing existing guidelines [23,36].

The recommendations were grouped into 12 categories, which closely relate to existing usability principles (feedback, recognition, flexibility, customization, consistency, errors, help, accessibility, navigation, and privacy [18,37-39]). Usability principles are defined as broad "rules of thumb" or design guidelines that describe features of the systems to guide the design of digital solutions [18,40]. Additionally, they are oriented to improve user interaction [3] and impact the quality of the digital solution interface [41]. Therefore, having the

recommendations organized in a way that maps these principles helps facilitate a practical use of the recommendations proposed herein, as these usability principles are familiar to designers and are well established, well known, and accepted in the literature [23,42].

The results showed an asymmetry in the number of recommendations categorized into each of the 12 usability principles (eg, for level 1, consistency has 2 recommendations while the visual component has 16 recommendations). This discrepancy suggests that some areas of user interface design such as the visual component might be better detailed, more complex, or more valued in the literature, but can also suggest that the initial search might not have been comprehensive enough, as it included a reduced number of databases [32]. Nevertheless, the heterogeneity between categories does not influence its relevance, as it is the set of recommendations as a whole that influences the user design interface of a digital solution.

The number of level 2 recommendations aggregated under each level 1 recommendation is also uneven. Most of the level 2 recommendations that resulted from this study concern web and mobile technologies because their utilization is widespread among the population [43] and therefore more likely to have design recommendations reported in the literature [23,31,44,45]. On the other hand, emerging technologies like robotics and interaction paradigms (eg, gestures, voice, and feet) represent new challenges for researchers, and recommendations are still being formulated, resulting in a lower number of specific recommendations that are published [46-49]. Moreover, the level 2 recommendations raised doubts among experts, namely regarding (1) the lack of consensus on whether they were mandatory or not, (2) apparent contradictions between recommendations, and (3) uncertainty regarding the accuracy of some recommendations, particularly those very specific (eg, the recommendations on the size of the buttons in millimeters). These aspects suggest that level 2 recommendations need further validation in future studies. No data was found on how the authors of the recommendations arrived at this level of detail and how the exact recommendation might vary depending on the target users [50,51], the type of technology [49], interaction paradigm [46], and the context of use [52]. Validation of the level 2 recommendations might be performed by gathering expert's consensus on the adequacy of recommendations by type of technology/interaction paradigm and involving real users to test if the specific user interfaces that fulfill the recommendations improve usability and user experience [50,53].

We believe that level 1 recommendations apply to different users, contexts, and technologies/interaction paradigms and that the necessary level of specificity will be given by level 2 recommendations, which can be further operationalized into more detailed recommendations (eg, creating level 3 recommendations under level 2 recommendations). For example,

recommendation 1 from the recognition category states that “the system should consider the context of use, using phrases, words, and concepts that are familiar to the users and grounded in real conventions, delivering an experience that matches the system and the real world,” which is an example of applicability to different contexts such as health or education. Similarly, recommendation 1 from the flexibility category states that “the system should support both inexperienced and experienced users, be easy to learn, and to remember, even after an inactive period,” also showing adaptability to different types of users. Nevertheless, the level of importance of each level 1 recommendation might vary. For example, recommendation 6 of the flexibility category, which states that “the system may make users feel confident to operate and take appropriate action if something unexpected happens,” was not considered mandatory by the panel of external experts. However, one might argue that it should be considered mandatory in the field of health, where the feeling of being in control and acting immediately if something unexpected happens is of utmost importance. Therefore, both level 1 and level 2 recommendations require further validation across different types of technology and interaction paradigms but also for different target users and contexts of use. Also required are investigations to determine whether their use results in better digital solutions, and particularly for the health care field, increases adhesion to and effectiveness of interventions.

In synthesis, although this study constitutes an attempt toward a more standardized approach in the field of user interface design, the set of recommendations presented herein should not be seen as a final set but rather as guides that should be critically appraised by designers according to the context, type of technology, type of interaction, and the end users for whom the digital solution is intended.

### Strengths and Limitations

The strengths of this proposed set of recommendations are that it was developed based on multiple sources and multiple rounds of experts' feedback. However, although several experts were involved in different steps of the study, it cannot be guaranteed that the views of the included experts are representative of the views of a broader community of user interface design experts. Another limitation of this study is that the initial search for recommendations might not have been comprehensive enough. Nevertheless, external experts were given the possibility of adding recommendations to the list, and none suggested the need to include additional recommendations. The list of level 2 recommendations is a work in progress that should be further discussed and changed considering the technology/paradigm of interaction. Finally, some types of technologies and interaction paradigms are not represented in the recommendations (eg, virtual reality), and it would be important to have specific recommendations for all types of technologies and interaction paradigms in the future.

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## Conflicts of Interest

None declared.

### Multimedia Appendix 1

Mapping of the categories proposed by the experts and the final categories.

[[DOCX File , 16 KB - humanfactors\\_v9i3e37894\\_app1.docx](#) ]

### Multimedia Appendix 2

Final list of 69 generic recommendations proposed.

[[DOCX File , 19 KB - humanfactors\\_v9i3e37894\\_app2.docx](#) ]

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## Abbreviations

**SHAPES:** Smart and Health Ageing through People Engaging in Supportive Systems

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Original Paper

# Consumer Perspectives on the Use of Artificial Intelligence Technology and Automation in Crisis Support Services: Mixed Methods Study

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## Abstract

**Background:** Emerging technologies, such as artificial intelligence (AI), have the potential to enhance service responsiveness and quality, improve reach to underserved groups, and help address the lack of workforce capacity in health and mental health care. However, little research has been conducted on the acceptability of AI, particularly in mental health and crisis support, and how this may inform the development of responsible and responsive innovation in the area.

**Objective:** This study aims to explore the level of support for the use of technology and automation, such as AI, in Lifeline’s crisis support services in Australia; the likelihood of service use if technology and automation were implemented; the impact of demographic characteristics on the level of support and likelihood of service use; and reasons for not using Lifeline’s crisis support services if technology and automation were implemented in the future.

**Methods:** A mixed methods study involving a computer-assisted telephone interview and a web-based survey was undertaken from 2019 to 2020 to explore expectations and anticipated outcomes of Lifeline’s crisis support services in a nationally representative community sample (n=1300) and a Lifeline help-seeker sample (n=553). Participants were aged between 18 and 93 years. Quantitative descriptive analysis, binary logistic regression models, and qualitative thematic analysis were conducted to address the research objectives.

**Results:** One-third of the community and help-seeker participants did not support the collection of information about service users through technology and automation (ie, via AI), and approximately half of the participants reported that they would be less likely to use the service if automation was introduced. Significant demographic differences were observed between the community and help-seeker samples. Of the demographics, only older age predicted being less likely to endorse technology and automation to tailor Lifeline’s crisis support service and use such services (odds ratio 1.48-1.66, 99% CI 1.03-2.38;  $P < .001$  to  $P = .005$ ). The most common reason for reluctance, reported by both samples, was that respondents wanted to speak to a real person, assuming that human counselors would be replaced by automated robots or machine services.

**Conclusions:** Although Lifeline plans to always have a real person providing crisis support, help-seekers automatically fear this will not be the case if new technology and automation such as AI are introduced. Consequently, incorporating innovative use of technology to improve help-seeker outcomes in such services will require careful messaging and assurance that the human connection will continue.

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## KEYWORDS

consumer; community; help-seeker; perspective; technology; artificial intelligence; crisis; support; acceptability

## Introduction

### Background

In 2016, the founder and executive chairman of the World Economic Forum, Klaus Schwab, wrote that “we stand on the brink of a technological revolution that will fundamentally alter the way we live, work, and relate to one another” [1]. Schwab was referring to the advent of the Fourth Industrial Revolution, which will exponentially build upon the simple digitalization seen in the Third Industrial Revolution through innovations that combine the physical, digital, and biological spheres.

One such innovation has been the development of artificial intelligence (AI). AI has been described as the ability of a computer or machine to mimic the capabilities of the human mind, such as learning from examples and experiences, recognizing objects, understanding and responding to language, making decisions, and solving problems [2]. Although AI is widely used in many applications, the awareness of AI’s use and functions is relatively low [3,4]. For example, a survey of 6000 adults across North America, Europe, the Middle East, Africa, and the Asia-Pacific revealed that 84% had recently used at least one AI-powered service or device (eg, email spam filters, predictive search terms, and personal assistants), but only 34% had identified that they had interacted with some sort of AI technology in the recent past [3].

### AI in Health and Mental Health

Importantly, in the fields of health and mental health, AI has been argued to have the potential to enhance existing services by facilitating diagnostics and decision-making, expand the reach and personalization of services to underserved populations and high-risk groups, and ease the human resources crisis in mental health care and support [5-8]. For example, machine learning (ML), a subset of AI that uses advanced statistical and probabilistic techniques to construct systems with the ability to automatically learn from large and varied data sources, is currently being explored to improve the detection and diagnosis of mental health and neurodegenerative conditions such as depression, suicidality, schizophrenia, and Alzheimer disease [9,10].

AI has even been viewed by some academics as representing the future of mental health research methodology because of its superior ability to recognize the complexity of disorders, heterogeneity of clients, and varied mental health contexts compared with traditional statistical approaches that tend to rely on *forecasting* with only a few variables [11,12]. AI can deal with and learn from large and complex data, including the

concurrent analysis of multiple factors rather than traditional additive, interactive, and linear statistical models.

Although the current use of ML techniques for diagnosis in real-world mental health settings is limited because of the lack of clinical validation and readiness of ML applications [6,9,13], AI is already being used to support practitioners and clients in monitoring treatment progress and medication adherence, delivering remote therapeutic sessions, and providing intelligent self-assessments [6]. ML algorithms are also used on social media platforms and virtual assistants, such as Facebook, Google, and Apple, to flag suicidal content posted or voiced by users and direct them to relevant crisis support and emergency services based on the assessments of risk, sometimes with the help of counselors from collaborating crisis support services such as the Crisis Text Line in the United States, Canada, South Africa, Ireland, and the Trevor Project in Australia [14,15]. With increased reliance on mental health and crisis support services observed worldwide in response to the COVID-19 pandemic [16,17], it is clear that crisis support for personal crises, such as suicidality, mental health issues, and situational crises, is an essential part of the mental health and public health systems, where the use of new technologies could substantially enhance the much-needed capacity.

### Lifeline Context

In Australia, the national 24-hour crisis support service for the general community, Lifeline, featured heavily in the Australian Department of Health’s \$10.4 (US \$7.2) million national mental health communications campaign to encourage Australians to reach out for mental health support during COVID-19 [18]. This charitable service has been operating since 1963 and is currently delivered via telephone, SMS text messaging, and web-based chat modalities in 41 centers staffed by 3364 volunteers and paid crisis counselors across Australia [19,20]. In the 2019-2020 financial year, Lifeline serviced 989,192 calls (84.5% call answer rate), 39,680 SMS text messaging contacts, and 53,527 web-based chat conversations, leading to the creation of 43,431 self-harm and suicide prevention plans [19]. Notably, in the context of COVID-19, a 25% increase in service demand (increasing to 90,000 calls per month) was reported compared with that during the same time in the previous year [21]. Half of the calls received in this period were from people reporting difficulties associated with COVID-19, and in 2021, 1 in 5 calls went unanswered [22]. Internationally, COVID-19-related increases in helpline use have resulted in increased call wait time [23], which negatively affects service users’ experience. High call volumes have been cited as a major cause of staff burnout and attrition in this sector [24]. Within Lifeline, telephone crisis supporters’ psychological well-being has been

found to significantly impact counseling ability and service delivery [25]. These statistics highlight that crisis support services, such as Lifeline, need to be familiar with the current and future uses of AI and how it can complement existing practices and enhance capacity, while not replacing vital human aspects of the therapeutic relationship, such as personal connection and trust [5,6,26].

### Consumer Acceptance of New Technologies

Despite the rapid advancement of technological innovations in health care, research on consumers' acceptance of new technologies has been scarce. To the best of our knowledge, there has been no research on consumer perspectives of AI as applied to the fields of mental health and crisis support, representing significant knowledge and practice gaps in this area. A recent systematic review of 117 articles published from 2005 to 2016 on data mining for AI in health care analytics revealed that one-third of the reviewed research did not use expert opinions in any form [27], indicating that a significant proportion of researchers and key stakeholders (ie, patients, service users, carers, and families) may not be consulted in discussions about AI and its application in health care.

In addition, the few studies conducted specifically on consumer perspectives of AI have focused solely on its use in medical health contexts. Nascent research has shown that trust and understanding of AI are important factors in the acceptance of AI in medical applications [28,29]. For example, in a study of 307 adults in the United States, consumer concerns about technology, ethics (perceived privacy concerns, mistrust in AI mechanisms, and social bias), and regulatory processes (ie, unregulated standards and perceived liability issues) were found to contribute to the perceived risks of AI medical devices [28]. Consumers have also been found to be less likely to use medical health care if delivered via an automated computer that uses AI compared with a human provider, even in situations where the performance of AI was explicitly specified to participants as being superior to that of human providers [29]. The researchers attributed this to the psychological driver of *uniqueness neglect*, which they stipulated to occur when consumers believe that AI medical health providers are unable to take into account the uniqueness of their case to the same extent as human providers, suggesting this as a potential target point in consumer education about AI [29].

These concerns have been largely corroborated by reports from surveys of nationally representative and consumer samples. For instance, in a 2020 survey of 2575 Australians, perceptions of the adequacy of current regulations and laws to make AI use safe, the uncertain impact of AI on society and jobs, and reported familiarity and understanding of AI were found to strongly influence AI acceptance more broadly [30]. Interestingly, reports have also shown that consumers have low levels of trust, high levels of fears and concerns, and low levels of awareness or understanding of AI [4,30-35]. In particular, a strong preference for human-centered care and personal contact has been emphasized by participants [31,34,35].

### This Study

To date, research has focused on medical care applications, and the extent to which findings can be translated into AI applications in mental health and crisis support contexts remains unclear. With global investment in AI technology rising from 1.7 billion in 2010 to 14.9 billion in 2014 [36], research into consumers' levels of awareness and support for AI-integrated mental health and crisis support, as well as their concerns and expectations around such support services, is needed to ensure responsible and responsive innovation. This is particularly pertinent for promoting effective communication around the risks and benefits of AI-integrated mental health and crisis support as well as the uptake of initiatives aimed at enhancing capacity and supporting the delivery of existing practices via new technologies such as AI.

A possible avenue for AI-integrated technology to promote increased service capacity and quality is to support the crisis counselor workforce (often volunteer-based) to feel better equipped to support help-seekers, train and support each other, and prevent staff burnout and attrition at an organizational level. Research shows that crisis counselors spend a considerable amount of time taking manual notes and cross-referencing these notes while actively trying to support help-seekers, which adds to their cognitive load [37]. AI-integrated applications could include the development of ML algorithms to automatically detect crisis callers' levels of risk and distress based on validated voice or text features analyzed using speech recognition or natural language processing during contact. Help-seekers' trajectories on highly relevant service-related outcomes (eg, connectedness and suicidality) could then be visually mapped in real time to support crisis support processes and practices. Crisis counselors (and their supervisors) could use this visual reference tool to more quickly identify key presenting crises, check whether the support provided has an appreciable effect on help-seeker outcomes, and tailor support accordingly. Such a tool would be of value to a service such as Lifeline because it receives requests for support from a very broad range of help-seekers and is expected to provide the same quality of care across these diverse groups and types of crises [38]. Recent research has found that not all help-seeker groups experience the same level of positive outcomes from, and satisfaction with, the Lifeline service [39]. AI-integrated technological support may be able to provide supplementary information not captured by current service measures to help services provide highly tailored support at the individual and group levels. Algorithms could even be trained to detect differences in practice and presenting crises across service modalities (eg, telephone, SMS text messaging, and web-based chat), flag features commonly present in repeat or unwelcome contacts to alert crisis supporters (particularly those still training or new) toward appropriate strategies and procedures to prevent burnout, and such AI-derived insights could be incorporated into staff training for quality assurance purposes. However, there are likely to be even greater concerns in the mental health field, as interpersonal communication and the therapeutic relationship between clients and service providers are critical.

This study aimed to address the significant gaps in understanding consumer perspectives of AI in mental health support for crisis

support services by exploring, in the context of Lifeline, Australia's largest crisis support helpline: (1) the level of support for the use of technology and automation, (2) the likelihood of service use if technology and automation were implemented, (3) the impact of demographic characteristics on the level of support and likelihood of service use if technology and automation were implemented, and (4) reasons for not using the services if technology and automation were implemented. These perspectives were explored for the Australian general community and specifically for Lifeline service users (help-seekers). It should be noted that AI can involve the automation of processes, such as self-driving vehicles, but automation does not necessarily include AI. The focus of this research is on AI-integrated technology and automation.

## Methods

### Design

A mixed methods approach using the triangulation design (validating quantitative data model [40]) was undertaken to explore consumer perspectives on the use of technology and automation in Lifeline's crisis support services across 2 different samples of Australians (N=1853). First, a quantitative approach was used to establish the nature and range of participants' levels of support for the collection of user information via AI and the likelihood of service use if technology and automation were implemented, followed by a qualitative exploration of the reasons provided by participants who were identified as not supporting or not likely to use Lifeline's services. Owing to the paucity of precedent studies from which to determine the sample size for this research, the intended and achieved sample sizes were based on obtaining as large a sample as possible within the constraints of available project funding and timelines.

### Participants and Procedure

#### Sample 1—Community Sample

The community sample comprised a nationally representative sample of 1300 community-dwelling adults across Australia [38]. Respondents were aged 18 to 93 (mean 53.43, SD 18.49) years, and 52.8% (687/1300; valid percent) were women.

A computer-assisted telephone interview (CATI) was administered at the Social Research Centre at the Australian National University by trained interviewers. Data collection took place over 5 weeks, from October 28 to November 30, 2019. Contact details were purchased from the commercial sample provider SamplePages and included 16,245 mobile and 11,375 landline telephone numbers across Australia. The landline sample was stratified based on the state and capital city or rest of the state divisions. Geographic-based strata were not put in place for mobile devices, as no a priori geographic information was available. Random digit dialing (RDD) was used to obtain participants from all states or territories of Australia.

The interviews included 910 participants from the mobile RDD sample and 390 from the landline RDD sample. For people contacted on a landline number, any household member aged ≥18 years was eligible to participate. For people contacted on

a mobile number, the survey was conducted with the phone user. Mobile phones were sent a pre-approach SMS text message with an opt-out option before contact by telephone. Interviews were conducted in English only. The average interview length was 14.8 minutes. There were no incentives for participation.

#### Sample 2—Help-Seekers

The help-seeker sample comprised 553 Lifeline help-seekers aged 18 to 77 (mean 39.60, SD 13.92) years, and 313 (74.2%; valid percent) were women.

A self-report survey was made available to Australian residents (aged ≥18 years) who had previously contacted Lifeline. Data collection took place over 6 months, from December 16, 2019, to June 16, 2020, via the web-based survey platform Qualtrics (Copyright 2021 Qualtrics) [41].

Recruitment was conducted through Lifeline Australia's official social media pages (Facebook, Twitter, and LinkedIn) and website; a survey link shared at the end of Lifeline's web-based chat and text message contacts; and snowballing across Lifeline Australia's Lived Experience Advisory Group (LEAG) members and mental health organizations, such as Beyond Blue and SANE Australia. On clicking the survey link, participants were presented with an information sheet detailing the study aims, participant involvement, confidentiality and anonymity, data storage procedures, and investigator and ethics contact information. Informed consent was obtained from all participants through the web. Respondents were able to review and change their answers via a back button if desired.

The survey received 1278 total responses through Qualtrics, but 725 (56.73%) of them were <60% complete or the person had not previously contacted Lifeline. Analyses were compared with these cases excluded and included (using multiple imputation) when complete-case analysis was required. The median completion time was 11.7 minutes. No incentives were provided for participation.

### Measures

#### Overview

The questionnaire measures aimed to determine participants' awareness, expectations, and outcomes of using Lifeline's crisis support services. Demographic questions were asked about age, gender, sexual orientation, country of birth, main language spoken at home, indigenous status, and household composition. These characteristics were chosen because they represent groups of interest to Lifeline that may be at an elevated risk of suicidality and they can be used to assess regional variation. No standardized measures for assessing community or help-seeker expectations of AI as applied to crisis support services have been identified in the literature [42]; therefore, questions were developed by the research team in consultation with Lifeline and their LEAG. There were some minor differences in the questions between the CATI and web-based survey formats owing to the different nature of these data collection methods.

### ***Support for Technology and Automation in Lifeline's Crisis Support Services***

Participants were asked, "When people contact Lifeline there is always a real person on the other end. However, there is the potential in the future for technology and automation to be used to help Lifeline counsellors to provide better services. Using a scale of 1 to 5, where 1 is not at all and 5 is very much, when people contact Lifeline, to what extent would you support Lifeline collecting information about individual users through technology and automation in order to tailor the services provided to the needs of each individual?" The additional prompts of "for example, to identify types of needs callers have and how they are feeling" and "automation refers to things like using artificial intelligence to monitor callers and measure their level of distress" were provided to sample 1 (community). In sample 2 (help-seekers) the following detail was provided: "for example, automation can refer to things like using artificial intelligence to monitor callers and measure their levels of distress."

### ***Likelihood of Service Use if Technology and Automation Were Used***

Participants were asked, "If Lifeline were to use this type of technology and automation, do you think you would be less likely to use Lifeline, more likely to use Lifeline or would it not make a difference to you?" In sample 1 (community), the response options were 1 (less likely to use Lifeline), 2 (more likely to use Lifeline), and 3 (would not make a difference to you). In sample 2 (help-seekers), the response options were 1 (much less likely to use Lifeline), 2 (somewhat less likely to use Lifeline), 3 (neither more nor less likely to use Lifeline), 4 (somewhat more likely to use Lifeline), and 5 (much more likely to use Lifeline). For comparison between the samples, sample 2 scores were rescaled to range from 1 to 3, consistent with sample 1.

### ***Reasons for Not Using the Lifeline Crisis Support Service if Technology and Automation Were Used***

Participants from both samples who indicated that they would be less likely to use Lifeline were asked to elaborate on their response via the following open-ended question: "Why would you be less likely to use Lifeline as a result of Lifeline using this technology and automation?"

### **Analysis**

Quantitative data were analyzed using the statistical package SPSS (version 25.0; IBM Corporation) [43]. Descriptive statistics were computed for each measure and are reported as percentages. Demographics were compared across the 2 sample groups: sample 1 (community members) and sample 2 (help-seekers). To control for demographic differences between the samples, binary logistic regression models were used to determine the effect of sample type, while controlling for and assessing the impact of the demographic characteristics of age, gender, sexual orientation, country of birth, main language spoken at home, indigenous status, and whether living alone.

Categorical data for age were further grouped into regression models to address the issue of small cell counts while broadly categorizing participants into young, middle-aged, and older adult groups for the interpretability of the results.

In the data set, 1.8%-9.7% data were missing at the variable level. Model estimates for each of the regression models were compared when missing data were excluded from the analysis using listwise deletion (the default treatment of missing data for SPSS logistic regression;  $N=1554-1573$ ) and when missing data were included ( $N=1853$ ) using SPSS's multiple imputation of missing values to obtain pooled estimates across 40 imputations ( $m=40$  number of imputations; refer to [Multimedia Appendices 1 and 2](#) for multiple imputation results).

Significance was set at  $P<.01$  to restrict significant effects to those that were more than trivial and provide an adjusted Cronbach  $\alpha$  rate of  $P<.05$  (based on the smallest sample for the help-seekers) [44,45]. Effect sizes were used as an additional criterion, with odds ratios of 1.52, 2.74, and 4.72 considered to be equivalent to Cohen  $d$  values of 0.2 (small), 0.5 (medium), and 0.8 (large), respectively [46].

Open-ended responses to the reasons question were analyzed in NVivo (version 12.0; QSR International [47]) by using thematic analysis, which is a method for identifying, analyzing, and reporting patterns in qualitative data. The coding and analysis of the responses for each sample were initially undertaken separately. In total, 2 coders undertook the coding, with cross-coding and discussion of themes until consensus was achieved. The themes from each sample were then considered together to identify common and unique themes across the samples. An essentialist or realist, inductive, and semantic approach was used to report the experiences, meanings, and reality of participants in ways that were explicitly linked to the data [48,49]. The 15-point Checklist of Criteria for Good Thematic Analysis by Braun and Clarke [50] was used in the transcription, coding, analysis, and written report processes by the authors (JSM and MO). The prevalence of themes was counted as the number of times a theme was evident across the data set. Selected data extracts representative of the main themes in each sample are presented in the Results section.

### **Ethics Approval**

This study was approved by the Human Research Ethics Committee of the University of Canberra (project ID: 2133).

## **Results**

### **Overview**

Descriptive information for the community and help-seeker samples is provided in [Table 1](#). Comparatively, the community sample was significantly older and was more likely to have male and heterosexual participants. The help-seeker sample was younger and more likely to have participants who are female, speak only English at home, come from Australia, and live alone.

**Table 1.** Descriptive statistics for community and help-seeker samples.

	Community sample (n=1300)	Help-seeker sample (n=553)	$\chi^2$ or <i>t</i> (df)	<i>P</i> value	$\eta^{2a}$ or Cramer <i>V</i> / $\Phi^b$
Age (years), mean (SD)	53.43 (18.49)	39.60 (13.92)	17.23 (1279.34)	<.001 <sup>c</sup>	0.14
<b>Gender, n (%)</b>			158.79 (2)	<.001	0.30
Male	606 (46.72)	77 (18.2)			
Female	687 (52.96)	313 (74.2)			
Other	4 (0.30)	32 (7.6)			
<b>Sexual orientation, n (%)</b>			41.25 (1)	<.001	0.15
Heterosexual	1167 (89.76)	302 (76.8)			
Other	133 (10.23)	91 (23.2)			
<b>Country of birth, n (%)</b>			35.00 (2)	<.001	0.14
Australia	961 (73.92)	346 (83.8)			
Another English-speaking country	159 (12.23)	38 (9.2)			
Non-English-speaking country	180 (13.84)	29 (7.0)			
<b>Main language spoken at home, n (%)</b>			7.49 (1)	.006	0.68
English	1105 (85.06)	373 (90.5)			
Other	194 (14.93)	39 (9.5)			
<b>Indigenous status, n (%)</b>			4.05 (1)	.04	0.05
Yes	31 (2.40)	18 (4.5)			
No	1259 (97.59)	382 (95.5)			
<b>Living situation, n (%)</b>			8.07 (1)	.004	-0.07
Lives alone	248 (19.07)	107 (25.7)			
Not alone	1052 (80.92)	309 (74.3)			

<sup>a</sup> $\eta^2$ =eta-squared measure of effect size.

<sup>b</sup> $\Phi$ =phi.

<sup>c</sup>*P* values <.01 are italicized.

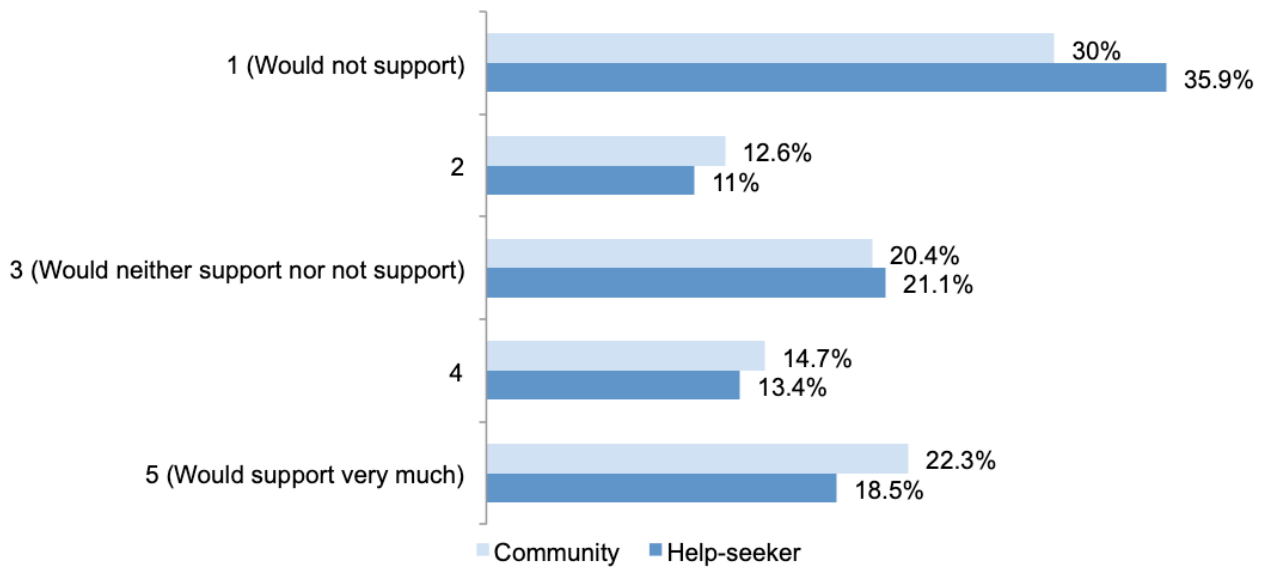
### Support for Technology and Automation in Lifeline's Crisis Support Services

Figure 1 shows the percentage of participant support for the collection of user information to tailor Lifeline's services.

Overall, approximately one-third of the participants would not support the collection of user information, and approximately one-fifth of the participants would support it.



**Figure 1.** Levels of community (n=1268) and help-seeker (n=426) participants' support in the use of technology and automation to tailor Lifeline's crisis support service.



Given the demographic differences between the samples, a direct binary logistic regression was performed on participants' level of support for the collection of user information to tailor Lifeline's services, with sample type and 7 sociodemographic predictors included (age, gender, sexual orientation, country of birth, main language spoken at home, indigenous status, and whether living alone). A test of the full model with all 8 predictors against a constant-only model was statistically significant ( $N=1592$ ,  $\chi^2_{10}=23.4$ ;  $P=.009$ ). The model as a whole explained between 1.5% (Cox and Snell R-squared) and 2.0% (Nagelkerke R-squared) of the variance in support for collecting

user information and correctly classified 57.66% (918/1592) of the cases. As shown in Table 2, only age significantly predicted participants' level of support. Participants aged  $\geq 35$  years had at least 52% greater odds of reporting that they would not support the collection of user information (small effect) compared with those aged 18 to 34 years, controlling for all other factors in the model. Pooled estimates from the  $m=40$  number of imputed data sets ( $N=1853$ ) also found that age was the only significant predictor. Pooled odds for participants aged  $\geq 35$  years were slightly higher (54% vs 52%) but still represented a small effect (Multimedia Appendix 1).

**Table 2.** Logistic regression for support for the collection of user information to tailor Lifeline's services ( $N=1592$ ).

“Would not support” <sup>a</sup>	Odds ratio (99% CI)
Sample type (community)	1.16 (0.82-1.65)
<b>Age<sup>b</sup> (years)</b>	
$\geq 55$	1.55 (1.07-2.24) <sup>c</sup>
35-54	1.52 (1.06-2.19) <sup>d</sup>
Gender (male)	1.11 (0.84-1.47)
Sexual orientation (heterosexual)	0.82 (0.54-1.26)
<b>Country of birth<sup>e</sup></b>	
Australia	1.13 (0.67-1.88)
Another English-speaking country	1.34 (0.72-2.49)
Main language spoken at home (other than English)	1.12 (0.68-1.85)
Indigenous status (Aboriginal or Torres Strait Islander)	0.96 (0.42-2.19)
Living situation (lives alone)	1.22 (0.87-1.72)

<sup>a</sup>“Would support” combined with “Would neither support nor not support” is the reference group for comparison with “Would not support.”

<sup>b</sup>18 to 34 years is the reference group for age. Age groupings broadly reflect young adults (18-34 years), middle-aged adults (35-54 years), and older adults ( $\geq 55$  years).

<sup>c</sup> $P=.002$ .

<sup>d</sup> $P=.003$ .

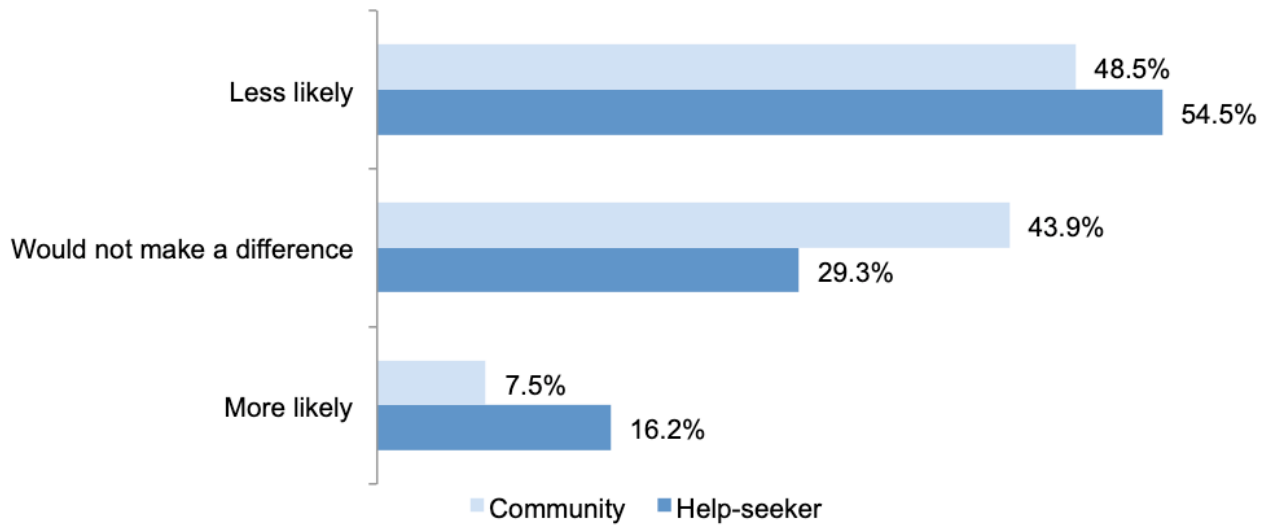
<sup>e</sup>Non-English-speaking country is the reference group for country of birth.

## Likelihood of Service Use if Technology and Automation Were Used

Figure 2 shows that approximately half of both samples stated

that they would be less likely to use Lifeline if technology and automation were implemented, and only a minority would be more likely to use the service.

**Figure 2.** Likelihood of community (n=1247) and help-seeker (n=426) participants using Lifeline if technology and automation were used.



To test the sample effect while controlling for demographic differences, a direct binary logistic regression was performed. A test of the full model with all 8 predictors against a constant-only model was statistically significant ( $N=1572$ ,  $\chi^2_{10}=31.3$ ;  $P=.001$ ). The model as a whole explained between 2.0% (Cox and Snell R-squared) and 2.6% (Nagelkerke R-squared) of the variance in the likelihood of service use if technology and automation were implemented and correctly classified 54.33% (854/1572) of cases. As shown in Table 3,

only age significantly predicted participants' self-reported likelihood of service use. Participants aged  $\geq 35$  years had at least 48% greater odds of reporting that they would be less likely to use the service (small effect) than those aged 18 to 34 years, controlling for all other factors in the model. Pooled estimates from the  $m=40$  imputed data sets ( $N=1853$ ) also found that age was the only significant predictor. However, this effect was only observed at  $P<.01$  for comparisons between participants aged  $\geq 55$  years and those aged 18 to 34 years (odds ratio 1.61, 99% CI 1.00-2.59;  $P=.009$ ; Multimedia Appendix 2).

**Table 3.** Logistic regression for participants' self-reported likelihood of service use if technology and automation were implemented at Lifeline (N=1572).

"Less likely" <sup>a</sup>	Odds ratio (99% CI)
Sample type (community)	1.23 (0.87-1.75)
<b>Age<sup>b</sup> (years)</b>	
≥55	1.66 (1.15-2.38) <sup>c</sup>
35-54	1.48 (1.03-2.12) <sup>d</sup>
Gender (male)	1.27 (0.96-1.67)
Sexual orientation (heterosexual)	0.99 (0.65-1.50)
<b>Country of birth<sup>e</sup></b>	
Australia	1.36 (0.81-2.27)
Another English-speaking country	1.50 (0.80-2.80)
Main language spoken at home (other than English)	0.78 (0.47-1.28)
Indigenous status (Aboriginal or Torres Strait Islander)	2.14 (0.89-5.16)
Living situation (lives alone)	1.25 (0.89-1.75)

<sup>a</sup>"More likely" combined with "Would not make a difference" is the reference group for comparison with "Would not support."

<sup>b</sup>18 to 34 years is the reference group for age. Age groupings broadly reflect young adults (18-34 years), middle-aged adults (35-54 years), and older adults (≥55 years).

<sup>c</sup> $P < .001$ .

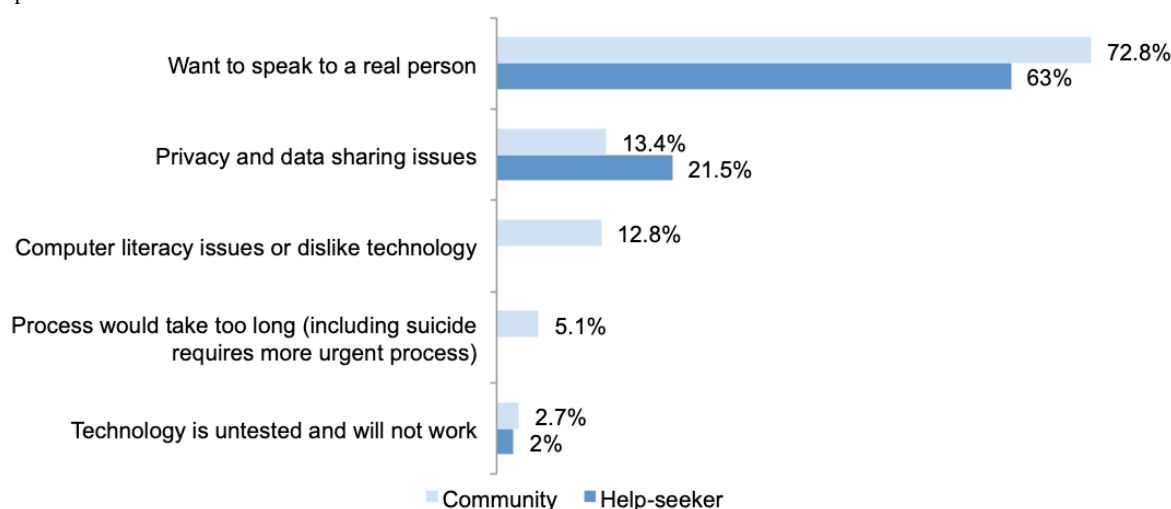
<sup>d</sup> $P = .005$ .

<sup>e</sup>Non-English-speaking country is the reference group for country of birth.

### Reasons for Not Using the Lifeline Crisis Support Service if Technology and Automation Were Used

There were 837 community sample participants and help-seeker participants who indicated that they would be less likely to use Lifeline if technology and automation were used, and 94.9% (795/837) of the participants provided a qualitative response as

to why (Figure 3). Participants could indicate more than one theme in their responses, resulting in a total response rate >100%. "General negative feedback about Lifeline," "Positive feedback about Artificial Intelligence," "Not sure," and "Not applicable" responses make up the remaining percentage to 100% for the help-seeker sample. There were 3 common themes across the samples, and 2 were unique to the community sample.

**Figure 3.** Reasons for community (n=595) and help-seeker (n=200) participants not using the Lifeline crisis support service if technology and automation were used—open-ended.

### Common Themes

#### *Want to Speak to a Real Person*

Respondents overwhelmingly wanted to speak to a real person rather than a *robot* or *machine*. A particular concern was that

human counselors would be replaced with an automated robot or machine services, which were expected to lack *heart*, *thought process*, *compassion*, and *understanding*. For example, a respondent stated the following:

*You are talking to a robot, if I was suicidal, I would rather talk to somebody than [a] computer because the computer may not understand how you feel, but a person you're talking to might have an idea of how to cope.* [Community No 444, Male, 52 years of age]

Another respondent said the following:

*Because automation does not really understand people. Automation is just a script and people don't like talking to machines.* [Community No 235, Male, 45 years of age]

Many emphasized the need for person-to-person contact and viewed this as a strength of the current Lifeline crisis support service:

*Because I think one of the attractions of Lifeline is having a person at the other end, and I'd be concerned that AI [Artificial Intelligence] couldn't pick up what I'm saying.* [Community No 286, Female, 59 years of age]

Another said the following:

*I think Lifeline stands out because it's always got a person there when so many other customer service interfaces are using technology—the reason I/they go to Lifeline is because of the person.* [Community No 293, Male, 27 years of age]

A total of 7 subthemes were identified as specific reasons for respondents wanting to speak to a real person. In the community sample, this included the lack of emotional connection (20/433, 4.6% of main theme), where respondents discussed how they would feel “less important” and “less connected” if technology and automation were used and how they would be left with “a perception that you might be wondering if you are more of a statistic than a person in need of help” (Community No 406, Male, 33 years of age). In the help-seeker sample, this included expectations that the experience would be impersonal (46/126, 36.5% of main theme), that human expertise is greater than what technology and automation could provide (30/126, 23.8%), that the use of technology and automation would be frustrating (9/126, 7.1%), that help-seekers require emotional connection (9/126, 7.1%), that help-seekers would feel devalued if technology and automation were used (6/126, 4.7%), and that only real people can provide comfort (4/126, 3.1%).

In relation to the expectation that the crisis support service would be impersonal, a respondent stated the following:

*The distress and need is immediate. There is so much cold automation out there—sometimes the cause of our issues—the thought of more is depressing and sad. All we want is a human being. Some of us are minutes away from suicide. Don't waste a second on bullshit automation. We need human beings.* [Help-seeker No 205, Female, 49 years of age]

Other respondents questioned how their interactions would differ from interacting with programmed devices:

*Why would I want to talk to a computer instead of a person? I could use Siri or buy a Google home device and talk to it. What is the point of Lifeline if it*

*becomes another computer to talk to?* [Help-seeker No 38, gender not specified, 22 years of age]

Many emphasized the limits of technology and that it could never replace human expertise. For example, a help-seeker stated the following:

*Technology will never improve the human condition more than other humans can.* [Help-seeker No 7, Female, 34 years of age]

Another said the following:

*AI [Artificial Intelligence] cannot sense a person's level of distress and convey empathy the way a human can. When I hear someone say something that sounds automatic and stereotyped (reflections of strengths are a good example of this) I switch off and don't feel able to engage with the person because I don't feel they are listening. An AI service would do that to me—except all the time. There's no one really listening and hearing me so there would be absolutely no point in calling. I'd feel worse after talking to an AI.* [Help-seeker No 195, nonbinary, 48 years of age]

Some respondents raised concerns about whether technologies such as AI could understand the nuances and complexities of help-seekers' crises, particularly when this was already a difficult task for humans. For example, a respondent wrote the following:

*I think there are things robots can do, but in my experience, understanding people is too complex even for humans.* [Help-seeker No 401, gender not specified, 45 years of age]

Help-seekers also noted the following perspectives:

*AI would be based on a more generic format and would not consider the nuances of each particular concern and how the concerns affect people differently on any given day.* [Help-seeker No 138, intersex, age not specified]

Others indicated the following:

*There is nothing more frustrating than being panicked or stressed and having to repeat yourself over and over again to a machine.* [Help-seeker No 45, Female, 27 years of age]

*...when I'm depressed and/or suicidal, the last thing I need to deal with is automated phone “services,” when all I need to do is talk with a human.* [Help-seeker No 65, Male, 54 years of age]

Help-seekers emphasized that automation would only add to existing feelings of stress, particularly for older generations who may not be so familiar with the use of technology, and would result in many hanging up because “nobody wants to feel like they are a number instead of a person and that's even more important when they are distressed” (Help-seeker No 443, Female, 49 years of age).

Finally, a few respondents specifically brought up the notion of comfort, with the perception that automation would take

away the realness of contact. One help-seeker wrote the following:

*Lifeline stands out as a service through which each caller speaks and connects directly to another person. There is intrinsic and immediate comfort in this, and the contact makes a huge difference to my confidence in the service. [Help-seeker No 1, Female, 55 years of age]*

### **Privacy and Data Sharing Issues**

The next most common theme, although much less endorsed, was concerns with privacy and data sharing issues. Respondents were wary of scams, lack of security, and the potential of their data being used against them in the future. For example, a respondent said:

*[I] do not like automation because so many scams rely on voice automation; it would make me stressed. [Community No 30, Female, 66 years of age]*

Another raised the issue of bias, limiting their trust in technology, stating the following:

*Not something that I trust. Also don't think it's great considering these services are used by marginalised people. If the information, no matter how confidential, were leaked, it could be really bad for people who have already been dealt bad hands. The way those technologies are being developed and automated doesn't seem to be going in a good direction. [I] believe that the development of these technologies can include biases, despite people believing that AI and tech is unbiased (built in bias). [Community No 588, Female, 26 years of age]*

Some were also concerned about feeling monitored, the level of control they would have over the information being shared and used, and the protection of their anonymity and confidentiality. A respondent said the following:

*...some people experience paranoia in general and would be less likely to reach out if they felt they were being monitored in any way. [Help-seeker No 71, Female, 56 years of age]*

Another respondent stated the following:

*Without specific details of the types of information to be collected and what would be done with that information, I am erring on the side of caution on this one. As a caller I like to be in control of the information I give out—I personally am quite an open-book anyway, so I generally don't have a problem with sharing, but I think people need to feel trusted, and perhaps won't feel trusted if this is implemented. I would also be concerned that the collection of this information would preference some callers over others somehow. [Help-seeker No 101, Female, 30 years of age]*

A respondent highlighted that this would be a particularly important consideration for vulnerable people:

*...[they] are often abused. Using automation to detect distress could potentially cause an alert, which could put that person at risk of harm, abuse, and further trauma from services (eg, police, ambulance) when all they want is someone to listen. This type of "advancement" would be dangerous. [Help-seeker No 405, Female, 41 years of age]*

### **Technology Is Untested and Will Not Work**

Concerns were also expressed regarding technology being something that was untested and may not work, which would exacerbate help-seekers' levels of stress and anxiety. There were doubts about whether the machines could make judgments and accurately interpret mixed messages. A respondent said that it "can't give instant answers" and involves "lots of hypotheticals" where "lots of things can change and a machine doesn't know" (Community No 162, Male, 62 years of age). Another respondent stated the following:

*I don't believe automation can actually listen to a human being and understand the inflection and tones in the person's voice. People who want to kill themselves don't want to talk to automation. We hate when we speak to automation in other services (eg, banking); not good in this situation. [Community No 794, Female, 57 years of age]*

### **Unique Community Themes**

Community respondents provided 2 additional main themes (computer literacy issues or dislike of technology and the belief that the process would take too long) that were not evident in the help-seeking sample.

#### **Computer Literacy Issues or Dislike of Technology**

Community respondents spoke about how "frustrating" automation could be, particularly for older generations, as well as having a "hatred" or "aversion" to technology and robots. For example, a respondent stated the following:

*Automation could be frustrating particularly if you're not tech-savvy. [No 81, Female, 60 years of age]*

#### **Process Would Take Too Long**

A less common response was the belief that the automation process would take too long. Community respondents highlighted that "people using the service would want someone immediately on the line" and that help-seekers "could have hung up or would be feeling even more distressed by it than they already were" (No 116, Female, 31 years of age). A respondent indicated the following:

*...it's hard enough dealing with your emotions and figure out which number to press to get someone to be able to talk to you. [No 346, Female, 56 years of age]*

Reference was made to how this would be especially problematic for help-seekers who experience suicidality and require immediate support.

## Discussion

The aim of this mixed methods study was to understand the consumer perspectives of AI in mental health support from crisis support services. By surveying both general community members and Lifeline help-seekers, our results show a high level of resistance to and considerable misunderstanding of potential AI technologies in crisis line services.

### Principal Findings

Community and help-seeker participants were broadly consistent in their level of support and likelihood of service use if technology and automation were implemented in Lifeline's crisis support services in Australia. One-third of the participants did not support the collection of information about individual users through technology and automation to tailor Lifeline's services to individual needs, whereas approximately one-fifth of the participants were supportive. Approximately half of the participants reported that they would be less likely to use the Lifeline crisis support service if it implemented technology and automation. These findings reveal that the level of support for the use of technology and automation is not strong, that the likelihood of service use if technology and automation were implemented is not evident for most, that these views are evident across demographic groups, and that the reasons for not using the services if technology and automation were implemented are related to the preference for human contact and distrust of automation.

After controlling for demographic differences across the samples, older people ( $\geq 35$  years) were found to have at least 48% greater odds of reporting that they would be less likely to support the collection of user information to tailor Lifeline's crisis support services or to use these services if technology and automation were implemented compared with younger people. This finding may be attributed to young people, particularly men, who have higher levels of awareness, use, and acceptance of AI [32]. Younger people born after 1995 also belong to what is commonly referred to as the technological generation, with many *digital natives* spending at least nine hours a day interacting in digital environments [51]. As such, the promotion of AI acceptance in crisis support service contexts may be needed more in middle- and older-aged people, many of whom would not have grown up with the same experiences of technology as their younger counterparts. The multiple imputed data analysis corroborated these findings, with the exception of the age effect for being significantly less likely to use the service only applying to people aged  $\geq 55$ . However, it is important to highlight that imputed values may not accurately represent the actual percentage of self-reported likelihood of service use because these values are not obtained from *real* consumers.

Importantly, we found that community and help-seeker participants strongly held assumptions that the use of *technology* and *automation* in crisis support would involve the replacement of human counselors with automated robots or machine services, although the questionnaire clearly stated "however, when people contact Lifeline there is always a real person on the other end." This finding shows that the replacement of people-centered services with robots and machines is a real fear for consumers.

This may be attributed to people obtaining much of their understanding from popular media (ie, films [52]) or past negative experiences with common automated services such as banking (which was a comparison noted by many participants) or the very poorly received Australian debt recovery program, Robodebt [53]. Such preconceptions about automation clearly had a major impact on the reasons community and help-seeker participants provided for not using Lifeline's services if technology enhancements were introduced, which would need to be carefully addressed if AI is to be used effectively to support human decision-making processes in crisis support contexts.

Specifically, "want to speak to a real person" and "privacy and data sharing issues" were the most commonly reported main themes and concerns among both community members and help-seekers. For help-seekers, wanting to speak to a real person was attributed to participants believing that the human element is essential because human expertise is greater than what technology and automation could provide, that the use of technology and automation would be frustrating, that help-seekers require emotional connection and would feel devalued if technology and automation were used, and that only real people can provide comfort. Regarding confidentiality issues, community members were wary of scams, lack of security, and the potential of their data being used against them in the future, which are concerns related to the risks of technology use in general. Help-seekers were more concerned about feeling monitored, the level of control they would have over the information being shared and used, and the protection of their anonymity and confidentiality, particularly for vulnerable people such as those who have experienced abuse.

### Study Implications

These findings show the need for clear communication and education about the potential use and benefits of AI in crisis support services, particularly to assuage fears regarding the replacement of counselors and removal of human-centered care, as well as transparency around confidentiality and how individuals' data are collected, used, and stored so that trust is not eroded [54]. It has been highlighted that even for research in this area, more explicit consideration of the ethical and legal issues in current and future research on algorithmic and data-driven technologies in mental health initiatives is required [55].

Overall, community and help-seeker participants' levels of support for technology and automation largely align with previous research conducted in medical health contexts. The results are consistent with the *uniqueness neglect* psychological driver, as participants strongly felt that only another human could understand the circumstances and nuances of another human, supporting this issue as an important target for consumer education about the role of AI [29]. In particular, strong negative attitudes from prior experiences of automation that were frustratingly unresponsive to human needs (such as banking and government services) will need to be redressed. Attention to involving consumers in AI research and educating them about potential implementation are critical priorities. Such efforts could be used to help train and prepare crisis support

professionals for the inevitable use of new technologies, such as AI, in their services, but also extend to potential consumers, funders, and decision makers to ensure that all stakeholders understand how AI can be used to enhance existing services to continue to support, not replace, human connections and decision-making in ethical ways.

Notably, despite the resistance of about half of the participants to using the service if automation was implemented, the other half said that their decision would be unaffected. Of these, approximately one-tenth reported that they would be more likely to use the service, highlighting the scope for endeavors that aim to promote the acceptability of AI in crisis support services. However, given the paucity of existing research in this area, more quantitative and qualitative studies are needed to better understand why consumers would and would not support the use of AI in their mental health and crisis support services. Research needs to identify the barriers and facilitators to the acceptance of AI and inform the development of AI awareness and promotion education initiatives to modify fear-based or inaccurate assumptions about the role, application, and impact of AI on personal user experiences in mental health support. Our research shows that preconceived notions, such as fears of talking to a *robot*, are pervasive and that the ways in which AI can be implemented to substantially improve the help-seeking experience are not well understood.

### Strengths and Limitations

The strengths of this study include the large nationally representative community sample and large help-seeker sample used to address the study aims and the use of multivariate analyses, which enabled the examination of the extent to which demographic factors impacted consumer perspectives of AI in relation to Lifeline's crisis support service. This study had several limitations. First, with the lack of standardized measures for assessing community help-seeker expectations of AI as applied to crisis support services, support for technology and automation and likelihood of service use were assessed using 2 single-item measures developed in consultation with Lifeline and their LEAG. Although research has shown that single-item measures can perform well relative to their full scales across psychological, health, and marketing research [56,57], it is noted that reliability and validity information for the developed measures is not currently available. Psychometric research is needed to further develop and refine effective measures for assessing consumer expectations in this space.

Second, the depth of the qualitative thematic analysis was restricted to the format of the questions and the inductive approach used, limiting interpretative power beyond the surface descriptions provided by community members and help-seekers. Respondents may have endorsed additional themes if they had been probed specifically about their views and had the opportunity to elaborate. The lack of in-person and group discussions may have also reduced the richness of the qualitative data obtained, although this was mitigated by obtaining data from such large samples. Future research should incorporate in-depth focus groups to explore consumers' reluctance to approve technologically enhanced crisis support services.

Third, the study only focused on why participants would be less likely to use Lifeline's services if technology and automation were used and not on why they would be more likely to do so, which could include faster response times, higher quality interactions, fewer missed calls, and greater capacity to support the community. The explicit form and role of technology and automation in Lifeline's services were also not fully preempted by participants when asking about their reasons for not using Lifeline's services, which may have led to many assuming technology and automation to be relatively extreme and intrusive. We found it difficult to simply and clearly contextualize the relevant questions in a survey format. Explaining the potential uses of AI and debunking myths about automation are difficult without unduly influencing participants' responses, particularly given the complex nature of AI and ML innovations. Nevertheless, future studies would benefit from providing additional framing and specificity around concepts of technology and automation (ie, that human counselors are not being replaced by robots or machines) and incorporating positive reasons for use, which would enable investigation into both the barriers and facilitators of AI-integrated service use in mental health and crisis support contexts.

Fourth, there were significant demographic differences between the 2 samples and different data collection methods were used. For example, men were underrepresented in the help-seeker sample. Although the sample differences were statistically controlled for, other confounding factors may have impacted the results. Finally, this research cannot ascertain causality regarding the link between beliefs and actual help-seeking behavior, and, as such, the integration of technology and automation in services may not result in actual crisis support service use refusal.

### Conclusions

To our knowledge, this is the first mixed methods study to explore consumer perspectives of AI in mental health, specifically regarding its application in crisis support services. As such, this study addresses a significant knowledge and practice gap in relation to consumers' acceptance of new technologies in response to the rapid advancement of technology use in health and mental health care and support. Although some level of consumer support exists for the collection of user information to tailor services via technology, the majority were reluctant to use AI-integrated crisis support services. Greater reluctance was evident among older people. Addressing community and help-seeker concerns about AI in mental health support contexts, including emphasizing how technology will augment rather than replace human connection and decision-making, with the goal of positively and ethically supporting service users' experiences, is of high priority given that these groups are the ultimate consumers of AI. Those most affected, namely, service users and their service providers, need to be fully involved in the development and implementation of innovative technologies to ensure they are appropriately designed and effectively adopted to improve mental health and crisis support services in the near future and beyond. However, the value of the human connection factor should not be lost.

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## Authors' Contributions

JSM performed the comparative quantitative analysis of the computer-assisted telephone interview (CATI) and help-seeker survey data, performed the qualitative analysis of the help-seeker data, performed initial interpretation of results, and drafted the manuscript. MO performed the initial descriptive quantitative analysis of the CATI and help-seeker survey data and qualitative analysis of CATI data. KM oversaw the study design and data collection for the CATI. PJB, SB, KK, NT, and BK contributed to the study design, interpretation of results, and critical revisions to the manuscript. DJR conceived and supervised all aspects of the study, supported the comparative quantitative analysis of the CATI and help-seeker survey data, and contributed to the interpretation of the results and critical revisions to the manuscript. All authors reviewed the results and approved the final version of the manuscript.

## Conflicts of Interest

None declared.

### Multimedia Appendix 1

Logistic regression on multiple imputed data (m=40) for support for the collection of user information to tailor Lifeline's services (N=1853).

[[DOCX File , 79 KB - humanfactors\\_v9i3e34514\\_app1.docx](#) ]

### Multimedia Appendix 2

Logistic regression on multiple imputed data (m=40) for participants' self-reported likelihood of service use if technology and automation were implemented at Lifeline (N=1853).

[[DOCX File , 79 KB - humanfactors\\_v9i3e34514\\_app2.docx](#) ]

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## Abbreviations

- AI:** artificial intelligence
- CATI:** computer-assisted telephone interview
- LEAG:** Lived Experience Advisory Group
- ML:** machine learning
- RDD:** random digit dialing

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Original Paper

# Contrasting the Expectations and Experiences Related to Mobile Health Use for Chronic Pain: Questionnaire Study

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## Abstract

**Background:** Chronic pain is a prolonged condition that deteriorates one's quality of life. Treating chronic pain requires a multicomponent approach, and in many cases, there are no “silver bullet” solutions. Mobile health (mHealth) is a rapidly expanding category of solutions in digital health with proven potential in chronic pain management.

**Objective:** This study aims to contrast the viewpoints of 2 groups of people with chronic pain concerning mHealth: people who have adopted the use of mHealth and those who have not. We highlight the benefits of mHealth solutions for people with chronic pain and the perceived obstacles to their increased adoption. We also provide recommendations to encourage people to try mHealth solutions as part of their self-care.

**Methods:** The Prolific crowdsourcing platform was used to collect crowdsourced data. A prescreening questionnaire was released to determine what type of pain potential participants have and whether they are currently using mHealth solutions for chronic pain. The participants were invited based on their experience using mHealth to manage their pain. Similar questions were presented to mHealth users and nonusers. Qualitative and quantitative analyses were performed to determine the outcomes of this study.

**Results:** In total, 31 responses were collected from people (aged 19-63 years, mean 31.4, SD 12.1) with chronic pain who use mHealth solutions. Two-thirds (n=20, 65%) of the users identified as female and 11 (35%) as male. We matched these mHealth users with an equal number of nonusers: 31 responses from the pool of 361 participants in the prescreening questionnaire. The nonusers' ages ranged from 18 to 58 years (mean 30.8, SD 11.09), with 15 (50%) identifying as female and 15 (50%) as male. Likert-scale questions were analyzed using the Mann-Whitney-Wilcoxon (MWW) test. Results showed that the 2 groups differed significantly on 10 (43%) of 23 questions and shared similar views in the remaining 13 (57%). The most significant differences were related to privacy and interactions with health professionals. Of the 31 mHealth users, 12 (39%) declared that using mHealth solutions has made interacting with health or social care professionals easier (vs n=22, 71%, of nonusers). The majority of the nonusers (n=26, 84%) compared with about half of the users (n=15, 48%) expressed concern about sharing their data with, for example, third parties.

**Conclusions:** This study investigated how mHealth is currently used in the context of chronic pain and what expectations mHealth nonusers have for mHealth as a future chronic pain management tool. Analysis revealed contrasts between mHealth use expectations and actual usage experiences, highlighting privacy concerns toward mHealth solutions. Generally, the results showed that nonusers are more concerned about data privacy and expect mHealth to facilitate interacting with health professionals. The users, in contrast, feel that such connections do not exist.

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**KEYWORDS**

mobile health; mHealth; m-Health; mhealth; m-health; wearable devices; mobile apps; self-management; digital health; chronic pain; pain; wearable; questionnaire; crowdsourcing; crowdsourced; user feedback; usage pattern; patient feedback; perception; attitude; user experience

## Introduction

### Background

Pain is chronic when it lasts more than 12 weeks despite therapy and medication after any initial injuries and when underlying causes have been treated [1]. Various chronic pains are extremely burdensome worldwide and severely detrimental to the quality of life. For instance, roughly 20%-25% of the adult population (between 20 and 59 years old) develops chronic low back pain (CLBP) symptoms at some point in their lives [2]. Treatment of chronic pain is complex and requires a multicomponent approach, which may not always be available [3]. No “silver bullet” solutions to chronic pain exist. Thus, there is always a need to explore potential new ways to alleviate pain symptoms or to improve the quality of life in other ways for people with chronic pain. To this end, and specifically relevant to the human-computer interaction (HCI) community, mobile health (abbreviated as mHealth, mhealth, m-health, or m-Health) is a rapid concept in the field of digital health.

In general, mHealth is defined as medical or public health practice supported by mobile devices [4] and contains a variety of contexts, such as the use of mobile phones to the point of service data collection, care delivery, patient communication, use of alternative wireless devices for real-time medication monitoring, and adherence support [5]. mHealth is not only a solution and tool for personal usage but in many countries has also been adopted in different health care places, such as hospitals and clinics. It is a good solution and tool to collect and provide various types of information about patient health and vital status to medical providers [6]. Most mHealth solutions gather data about a person’s physiology, physical activity, or social behavior and are designed to keep the data for later analysis by providers and caretakers [7]. In other words, mHealth solutions can potentially serve as a complementary tool for collecting, analyzing, and presenting data to users or health professionals to aid their understanding of users’ health and well-being. Smartphones are currently the most popular platform for mHealth delivery [8]. Recent explorations have also started to investigate mHealth for pain management [9]. A preliminary study proposed that mHealth self-management methods, such as mobile apps, could manage chronic pains, such as CLBP, better than only physiotherapy [10], especially since the beginning of 2020 when COVID-19 has globally become prevalent and its impact might last until 2025 [11]. COVID-19 has led to the rapid development of mHealth solutions [12]. Currently, many back pain apps are available in different stores focused on pain management education [13]. App-based solutions are almost available 24/7 and do not have geographical limitations for people from rural or remote areas [14]. Approaches including education, advice, and a major focus on self-management, such as lifestyle change, physical activity, and medications, as required, could be adopted to lift the burden of treatment off the clinicians and help the patients self-manage their pain [15].

In this paper, we set out to understand what people with chronic pain think about mHealth from 2 complementary perspectives. First, we explored how people with chronic pain experience

mHealth solutions. Second, we explored the prevailing expectations toward mHealth by people with chronic pain who do not use mHealth solutions. To this end, we deployed a series of online questionnaires to the crowdsourcing and crowdworking platform *Prolific*. We analyzed responses from 62 participants with chronic pain: 31 (50%) mHealth users and 31 (50%) nonusers. The key contributions in the context of mHealth and chronic pain in our work are as follows:

- We present an overview of user experiences with mHealth, including perceived benefits, obstacles, and practical usability matters.
- We match the overview of user experiences with a corresponding account of expectations toward mHealth from people who have not adopted mHealth devices.
- Finally, based on our results, we highlight implications for mHealth solutions to manage chronic pain.

As a result of the presented data analysis, this study helps understand the future role of mHealth in chronic pain management. This includes an account of the benefits such technology should offer to become more prevalent and an exploration of why people seem to opt out of this potentially beneficial class of advanced health technologies. Put together, our insights have implications for mHealth designers and researchers in the form of topical issues to address and research avenues to explore.

### mHealth

For more than a decade, mHealth has been suggested to improve health care systems and delivery services, although it should be noted that there is no standard and universally accepted definition for mHealth in the research literature. The term “mHealth” was first coined in 2003 and is defined as “mobile computing, medical sensor and communications technologies for health care” [16]. Free et al [17] defined mHealth as “the use of mobile computing and communication technologies in health care and public health.” In another study, mHealth was defined as “a subset of e-health using mobile devices to deliver health services to patients” [18]. The World Health Organization (WHO) Global Observatory for eHealth (GOe) [4] defines mHealth as “medical and public health practice supported by mobile devices.”

Over time, the definition of mHealth has been changing as new technologies have emerged, and recent studies have presented a clearly broader concept for mHealth. More recent studies consider wearable sensors as mHealth solutions [19-21]. At the same time, based on the definition of WHO, other wireless devices could also be interpreted as wearable sensors. These include, for example, smartwatches that connect to wireless networks. It should be noted that the notion of wearable sensors has a tight association with mobile apps. In other words, mobile apps practically always accompany wearable devices, and it is difficult to separate them from smartphones, because of the ambiguous nature of mobile technology. In the same vein, Istepanian et al [16] presented the architecture of mHealth with 3 building blocks: computing and the internet (eg, artificial intelligence [AI], cloud, and big data), communication systems (eg, 5G and internet of things [IoT]), and sensors (eg, body area network [BAN], personal area network [PAN], and tactile).

Later, Istepanian [22] considered medical apps, wearable sensors, and mobile devices as integral parts of mHealth service architecture.

The global adoption of mHealth is growing due to decreasing hardware costs and the increasing amount of, for example, smartphones, tablets, and wearable devices in circulation [23]. The services provided by mHealth solutions also help global adoption of mHealth, such as numerous health applications that encourage healthy lifestyles by assisting users in exercising regularly or monitoring their heart rate, measuring step numbers, etc [24,25]. The factors toward the adoption of mHealth apps among adults are relative advantage, ease of use, and compatibility [26]. Moreover, mHealth apps in developing countries are considered one of the best platforms for ensuring the citizens' safety and health care security [27]. In general, the factors behind adopting mHealth solutions could include performance, effort expectancy, social influence, hedonic motivation, price value, habit, facilitating conditions, privacy, lifestyle, self-efficacy, and trust [28]. The number of connected wearable devices worldwide more than doubled in the space of 3 years, increasing from 325 million in 2016 to 722 million in 2019. The number of such devices was anticipated to grow to more than 1 billion by 2022 [29]. On the software side of things, an estimation 100,000 apps on Google Play Store and Apple Store combined belong to the medical, health, fitness, and wellness categories [30].

mHealth solutions are commonly used in public health care and health services, where they are appreciated for their ease of use, broad reach, and wide acceptance [31]. mHealth has also been shown as beneficial, for example, in rural areas, for the overall development of health care systems [23,32]. As mHealth solutions have become more accessible, their use has been steadily increasing among laypeople as well [33]. Here, purposes include helping people succeed in weight management, stress management, smoking cessation [34]; encouraging and monitoring behavior change, self-diagnosis, and rehabilitation schedule management [35]; and self-monitoring chronic health conditions, medicine adherence reminders, and direct interactions with the health care system [36].

mHealth may also enable meaningful information exchange between consumers and health care professionals. mHealth services can collect and distribute electronic records, patient data, remote monitoring, and electronic prescriptions, or fitness and wellness apps can provide supplementary data to caretakers, for example [37]. Yet, medical experts are still somewhat reluctant to use mHealth solutions as part of their treatment, due to insufficient evidence of their benefits [5]. The key to developing mHealth in a beneficial direction for all stakeholders is cooperation. Indeed, the development of mHealth solutions requires a diverse set of expertise, including software programmers, behavioral scientists, graphical designers, and medical experts, such as doctors and physiotherapists. It also requires end-user feedback about the solutions so that the vendors can match actual users' real-life needs [38,39].

### Chronic Pain Management Using mHealth

mHealth solutions are rated valuable and easy to use by patients living with chronic pain [3,40]. Adherence to medication and

treatment is essential in pain management. mHealth has been shown as applicable to encourage people to continue treatment after being discharged from clinical care [40]. Cheong et al [41] showed an improvement in physical performance, cancer alleviation, and symptoms related to cancer treatment for patients with colorectal cancer undergoing chemotherapy using mHealth and the IoT. Buneviciene et al [42] evaluated mHealth solutions, such as activity/fitness, cognitive behavioral therapy, and mindfulness/stress management interventions, for cancer patients. They showed that mHealth solutions could improve the health-related quality of life of patients with cancer [42]. Hosio et al [43] developed a crowdsourced online system named *Back Pain Workshop*. They collected 2 knowledge bases, 1 from clinical professionals and 1 from nonprofessionals. Professionals found the system beneficial for self-reflection and educating new patients, while nonprofessionals acknowledged the reliable decision support that also respected the nonprofessional opinion [43]. Monitoring hospitalized patients' pain is a crucial problem for clinical caregivers, although collecting pain reports from patients can be challenging and time-consuming for clinicians. Price et al [44] provided a tangible device named *Painpad*, which allows patients to self-log their pain. They found that the self-logged scores might be more faithful than those reported to nurses. They also showed that older adults might prefer tangible interfaces over tablet-based alternatives for reporting their pain [44].

Given how smartphones have grown in recent years, mobile app-based self-management has become prevalent. Studies indicate that app-based therapy can benefit pain reduction, especially when practiced long term [14]. Smartphone app-based self-management programs have been developed to improve the physiotherapy status of patients with CLBP [10]. mHealth-based exercises are a valuable and efficient method to improve back pain [45]. Bailey et al [46] conducted a longitudinal observational study on a large population of patients with CLBP using a mobile app. Participants illustrated a high engagement rate in the study, and the results showed a significant positive relationship between engagement and pain decrease [46]. Hourcade et al [47] presented a zoomable multitouch app to enable children with a chronic headache to draw their symptoms on it during medical appointments. The app gives them the ability to provide more details and context than on paper. They showed that the app helps children better communicate their symptoms, and health care professionals can also better treat them [47]. Adams et al [48] investigated how those living with chronic pain prefer to self-assess their pain levels using smartphones. They developed a novel smartphone-based assessment tool and focused on designing visual interfaces for self-reporting pain intensity on smartphone screens [48]. Nevertheless, despite a perceived high demand from physicians, there are not enough suitable pain apps for clinical usage [49].

Rodríguez et al [50] showed that over two-thirds of people prefer the wearable option when they are given the choice between a wearable device and a mobile app for self-reporting pain. Adams et al [51], motivated by the need to manage chronic pain, reported a new pressure-based tangible user interface (UI) for the self-reporting of pain intensity, named *Keppi*. They also

created wearable versions of Keppi, such as necklaces, bracelets, and keychains [51]. Cuia et al [52] presented a smart baby carrier connected to a digital frame named *CarryLine* to manage postnatal chronic back pain and rehabilitate patients. *CarryLine* encourages physiotherapist-recommended activity in an innovative and engaging way [52].

Chronic pain reveals many different forms and imposes extensive physical restrictions on the patient's body. However, this pain is invisible and incommunicable, and it becomes complicated for the public to understand or even believe the patient, especially the persistent kind of pain. Therefore, the mental and social problems related to chronic pain are often neglected. Jin et al [53] developed a game called *AS IF* to increase nonpatients' empathy for those with chronic pain. In this game, after players connect to their virtual body, they experience a specific level of activity limitation that imitates one of the difficulties due to chronic pain [53]. Shah [54] provided a gameplay tool named *On the Other Side* and made the players aware of the troubled life of a patient with chronic pain.

## Methods

### Study Design

We set out to investigate how mHealth solutions are used and experienced. To this end, we wanted to explore what expectations and assumptions mHealth nonusers have about the technology and how far those assumptions are from the actual experiences of people who have adopted mHealth already. We used the Prolific human subjects pool to collect crowdsourced information, as it combines good recruitment standards with reasonable cost [55]. Prolific is widely used in behavioral research and questionnaire studies and provides data of high validity [56,57]. Prolific manages the privacy and anonymity of its participants through various policies (eg, a privacy policy and legal terms) that both the researchers using the platform and the participants must agree to prior to using the platform. It also meets the high standards of the European data protection law (General Data Protection Regulation [GDPR]) and is commonly used to recruit anonymous participants online. We focused our investigation specifically on a population that experiences chronic pain. Using the Prolific platform allowed us to prescreen the potential participants for those who have reported suffering from chronic pain.

### Ethical Considerations

Our study design followed the ethical procedures required by the host university ethics board (ie, an individual study does not require ethics board reviews as long as the study does not pose a significant risk of harm to the participants). Informed consent from the participants is sufficient for the type of study presented in our work [58].

### Prescreening Questionnaire

Our first step was to design a prescreening questionnaire (Multimedia Appendix 1) to determine what type of pain our potential participants have and whether they are currently using any mHealth solutions for their chronic pain. The prescreening questionnaire contained the following 4 questions:

- What type of chronic pain do you have? (Categorical listing of various types of chronic pain)
- How long have you suffered from it (in years)?
- How do you manage your pain in general? (Text field)
- Do you currently use any mHealth solutions related to your chronic pain (yes/no)?

Using this information, we then later invited participants, especially based on their answer to question 4 (whether they have experience with using mHealth to manage their chronic pain). Participants in this stage were compensated EUR 0.50 (US \$0.58) for their responses, which typically only took a few minutes to complete. The prescreening questionnaire was not piloted before deployment.

We invited 400 participants with chronic pain by using the prescreening options of Prolific. Participants' ages ranged from 18 to 74 years (mean 28.7, SD 10.3), with 234 (58.6%) identifying as female and 164 (41.1%) as male (demographic information of participants was missing). Of the 400 participants, 39 (9.7%) indicated currently using mHealth solutions and 361 (90.3%) revealed that they do not use mHealth. We selected all the 361 mHealth nonuser participants.

### Questionnaire Design

The use of technology is driven by trust and how effectively the technology meets the expectations that its user associates with it. Continued use of potentially useful applications and systems is not always a given, and abandonment of, for example, wearable technologies is a common problem [59]. We designed our investigation based on the expectation disinformation theory (EDT) model [60], with the trust-in-technology concept brought into the model. The EDT model is based on expectations (pre-exposure) and perceived performance (postexposure). Postexposure can *disconfirm* technology expectations, which leads to usage satisfaction and continued use. The theory has been widely used in different contexts, ranging from trust toward digital assistants [61] and unfamiliar online information sources [62], which is something that can often be part of mHealth solutions you are unfamiliar with, and trust toward treatment methods for back pain, for example [63]. Because our questionnaire is not a longitudinal process that incorporates information from a set of users over a period, we relied on generalizing results from 2 subgroups of participants based on our prescreening questionnaire. The mHealth *users* represented the *postexposure* participant pool according to the EDT model, while the mHealth *nonusers* represented the *pre-exposure* participants. However, the same participants for both groups were not used, as it was not optimal in terms of time and facilities to use the same participants for pre-exposure and postexposure groups in this study, although in a nonlongitudinal survey study, the methodology should be valid (comparing 2 groups should be fine).

We investigated related standardized questionnaires to complement the EDT and to ensure appropriate language and framing of each question. Fred [64] designed questions for perceived usefulness, ease of use, and user acceptance of information technology. Lund [65] developed the Usefulness, Satisfaction, and Ease of use (USE) questionnaire to measure the usability of UIs. Kortum and Sorber [66] measured the

usability of mobile apps for phones and tablets using the System Usability Scale (SUS) questionnaire, which has 10 questions that investigate the ease of use and learning and the functionality of the apps. Parmanto et al [67] developed the Telehealth Usability Questionnaire (TUQ) to measure the quality of telehealth interaction and services and the computer-based UI. The TUQ includes 6 categories: usefulness, ease of use, and learnability; interface quality; interaction quality; reliability; satisfaction; and future use [67]. Measuring the acceptability of telehealth users can afford valuable information to services to increase telehealth use. Hirani et al [68] reported developing and validating the Service User Technology Acceptability Questionnaire (SUTAQ). SUTAQ is a tool to measure the acceptability of telehealth, quality of life, well-being, and psychological conditions of the users. SUTAQ scales include increased accessibility, privacy and discomfort, care for personal concerns, telehealth as a substitution, and satisfaction [68]. Reicher et al [69] investigated the adults' attitude toward telemedicine during COVID-19 lockdown using an online questionnaire. They investigated 5 items: the necessity of using telemedicine, satisfaction with it, willingness to use it, change of mind regarding it, and preference to use it rather than going to a clinic [69]. Yen et al [70] developed the Health Information Technology Usability Evaluation Scale (Health-ITUES) questionnaire by asking nurses to rate the usability of a web-based communication system for scheduling nursing staff. The Health-ITUES has 4 categories: quality of work-life, perceived usefulness, perceived ease of use, and user control [70].

Regarding the questionnaire design, we used standardized questionnaires as a basis to seek questionnaire items that are both understandable and domain relevant. We also wanted to explore the topic from multiple viewpoints without overburdening the respondents with too many questionnaires. However, our questionnaires are not intended to be a standardized questionnaire to be used across all of mHealth; they were constructed for the purposes of this study only.

### Finalized Questionnaire Based on Related Research

Incorporating the aforementioned literature, as well as privacy elements, our final adapted and extended EDT-based questionnaire themes were (1) ease of use, (2) functionality, (3) reliability, (4) usefulness, (5) other expectations and impressions, and (6) privacy. The 2 questionnaires used the same themes to contrast expectations (nonusers) and experiences (users). Still, the questions are framed to be either about the participants' expectations *toward* mHealth or the participants' experiences *with* mHealth. The full questionnaires include 22 Likert-type items, 13 open-ended questions, and a single multiple-choice question. The Likert items were articulated using a consistent 1-7-point "not at all" to "extremely" wording scheme, depending on the specific item. The complete questionnaire items can be found in [Multimedia Appendices 2 and 3](#). Additionally, the complete list of topics covered in the questionnaire, along with references from which they were derived, can be seen in [Table 1](#).

**Table 1.** Subthemes and Likert item topics in the 2 questionnaires.

Subtheme	Likert item topics
Ease of use	<ul style="list-style-type: none"> <li>E1: easy to use [64-67,70-73]</li> <li>E2: easy to learn [64-67,70-73]</li> <li>E3: easy to become skillful with it [64,65,67,70]</li> </ul>
Functionality	<ul style="list-style-type: none"> <li>F1: features and functions fulfil expectations [71]</li> </ul>
Reliability	<ul style="list-style-type: none"> <li>R1: reliable [71,72]</li> <li>R2: source credibility concern [71]</li> </ul>
Usefulness	<ul style="list-style-type: none"> <li>U1: useful [64,65,70]</li> <li>U2: data used by doctors in office visit [72]</li> <li>U3: supports routine adherence [72]</li> <li>U4: reduces concern about chronic pain [68]</li> <li>U5: aids chronic pain management [68,72,73]</li> <li>U6: saves time [65,67,68,72,74]</li> <li>U7: control over one's life [64,65,73]</li> <li>U8: supports interaction with medical staff [67,68,72,74]</li> </ul>
Other expectations and impressions (satisfaction)	<ul style="list-style-type: none"> <li>O1: future use [67,74]</li> <li>O2: fun to use [65,75]</li> <li>O3: recommend to others [65,68]</li> </ul>
Privacy	<ul style="list-style-type: none"> <li>P1: invades privacy [73,76]</li> <li>P2: donate data for additional features [77]</li> <li>P3: data access [77]</li> <li>P4: data sharing [30,35,77]</li> </ul>



## Questionnaire Deployment and Participant Overview

We invited the 39 participants who indicated that they used mHealth to complete the follow-up questionnaire and received 26 (67%) responses from the prescreening questionnaire. We conducted a small-scale supplementary data collection using our university mailing lists by adding demographic data questions, which were included by Prolific in the first batch of data. This led to 5 more submissions: in total, we collected 31 responses from people with chronic pain who use mHealth solutions. These participants' ages ranged from 19 to 63 years (mean 31.4, SD 12.1), with 20 (65%) identifying as female and 11 (35%) as male. Of 31 mHealth users, 15 (48%) indicated using a smartwatch, 20 (65%) used mobile apps, 8 (26%) used activity trackers, 1 (3%) used a Holter heart monitor, and 1 (3%) used an oximeter.

Subsequently, to match these mHealth users with an equal number of nonusers, we released the second version of the questionnaire about expectations to obtain 31 (8.6%) responses from our pool of 361 participants who indicated not using mHealth solutions in the prescreening questionnaire. Reaching out to people with chronic pain who used mHealth from a pool of 39 persons was more challenging than reaching out to nonusers from a pool of 361 (of 400 people who had chronic pain, only 39, 9.7%, persons said that they use mHealth and 361, 90.3%, persons answered that they do not use mHealth). Hence, we first had to determine how many users out of 39 we could reach, and then we hired the same number of nonusers to have a fair comparison. Nonusers' ages ranged from 18 to 58 years (mean 30.8, SD 11.9), with 15 (50%) identifying as female and 15 (50%) as male (demographic information of participant was missed in Prolific). In addition, 2 (6%) of the 31 participants had previously used mHealth solutions but did not use one currently.

We compensated the participants with EUR 5.00 (US \$5.91) for their responses.

## Results

### Data Analysis

We presented similar questions to the 2 groups, *mHealth users* and *mHealth nonusers*, with slight modifications. mHealth users were asked to offer their opinions based on their experiences, while nonusers were asked their expectations. Examples of questions that were asked of both groups with slight modifications are as follows:

- “How easy did you find the use of the mHealth solution(s) that you use?” (for users) versus “How easy would you expect the use of the mHealth solution(s) to be?” (for nonusers)
- “How easy did you find learning to use the mHealth solution(s) that you use?” (for users) versus “How easy would you expect learning to use the mHealth solution(s) to be?” (for nonusers)

We analyzed the Likert-type questions using the Mann-Whitney-Wilcoxon (MWW) test, a nonparametric test that checks whether 2 samples are derived from a similar population.

The qualitative data were analyzed following the directed content analysis method [78] based on individual questionnaire items. Our analysis was conducted with specific questions in mind. Due to the COVID-19 pandemic, the authors held multiple online meetings to discuss and resolve any disagreements that emerged. Our results showed that the 2 groups had a significantly differing stance on 10 (43%) of the 23 Likert-type questions (described in detail in the following sections), as seen in Table 2 and Figures 1-5. However, they tended to share similar views in the remaining 13 (57%) questions.

**Table 2.** MWW<sup>a</sup> statistical test results for Likert-type questions (neutral response=4 on a scale of 1-7).

Question	User mean (SD)	Nonuser mean (SD)	P value
<b>Ease of use</b>			
E1: How easy (did you find/would you expect) the use of mHealth <sup>b</sup> solution(s) (that you use/to be)?	5.96 (1.13)	5.32 (1.13)	.01 <sup>c</sup>
E2: How easy (did you find/would you expect) learning to use mHealth solution(s) (that you use/to be)?	5.80 (1.01)	5.38 (1.22)	.20
E3: How easy (was it for you/would you expect) (to become/becoming) skillful at using mHealth solution(s) (that you use/to be)?	5.93 (0.89)	5.48 (1.12)	.10
<b>Reliability</b>			
R1: How reliable (do you find/would you expect) mHealth solution(s) (that you use/to be) in general?	5.51 (1.12)	5.70 (1.07)	.44
R2: How concerned (are you/would you expect to be) about the source credibility of mHealth solutions?	3.51 (1.89)	6.19 (0.90)	<.01 <sup>c</sup>
<b>Usefulness</b>			
U1: How useful (do you find/would you expect) mHealth solutions (/to be) for tracking or managing your chronic pain in general?	5.09 (1.30)	5.74 (1.12)	.02 <sup>c</sup>
U2: How much (does/would you expect) your doctor (/to) use information from your mHealth solution(s) during office visits?	2.93 (2.24)	4.93 (1.56)	<.01 <sup>c</sup>
U3: How much easier (is it/would you expect it to be) to follow medical advice, treatment guidelines, or any potential exercise routine (you are following since starting to use/if you used) mHealth solutions?	5.09 (1.70)	5.29 (1.29)	.97
U4: How helpful (did you find/would you expect) mHealth solutions (/to be) in reducing your overall concern about your chronic pain?	4.09 (1.90)	5.12 (1.47)	.01 <sup>c</sup>
U5: How much (do/would you expect) mHealth solutions (/to) help you in maintaining your chronic pain?	4.19 (2.02)	5.03 (1.40)	.11
U6: How much time, if any, (do you/would you expect to) save because of using mHealth solutions?	4.09 (2.02)	4.70 (1.63)	.23
U7: How much easier (have/would you expect) mHealth solutions (made/to make) it to interact with health or social care professionals?	3.64 (2.15)	5.06 (1.65)	.01 <sup>c</sup>
U8: How much more control (do/would you expect) mHealth solutions (/to) give you over the activities in your life?	5.38 (1.45)	4.90 (1.55)	.21
<b>Other expectations and impressions</b>			
O1: How much (are you planning/would you expect) to use mHealth solutions in the future?	6.03 (1.16)	5.19 (1.66)	.01 <sup>c</sup>
O2: How fun (did you find/would you expect) mHealth solutions (/to be)?	4.93 (1.80)	4.64 (1.68)	.38
O3: How much would you (/expect to) recommend mHealth solutions to other people who are in a similar situation to you (they also have chronic pain)?	5.70 (1.59)	5.38 (1.35)	.11
<b>Privacy</b>			
P1: How much (do you think/would you expect (anticipate)) mHealth solutions (/to) invade your privacy?	3.38 (1.90)	3.61 (1.58)	.57
P2: In your estimate, how safe (are/would you expect) your data collected through your mHealth solutions (treated/to be treated)?	4.87 (1.56)	5.06 (1.54)	.65
P3: How concerned (are you/would you expect to be) about your mHealth solution manufacturer having access to your personal data collected via the mHealth solution?	3.48 (2.14)	4.87 (1.40)	<.01 <sup>c</sup>
P4: How concerned (are you/would you expect to be) about your personal data being shared with, for example, third parties without your permission?	4.00 (1.86)	5.77 (1.25)	<.01 <sup>c</sup>
<b>I (would be/would expect to be) willing to share the following information.</b>			
First name	4.80 (2.21)	4.96 (1.94)	.95
Last name	4.19 (2.38)	4.29 (2.19)	.95
Email address	4.58 (2.09)	4.41 (2.02)	.75

Question	User mean (SD)	Nonuser mean (SD)	P value
Phone number	2.61 (1.89)	2.74 (1.71)	.63
Residential address	1.41 (0.80)	2.09 (1.57)	.06
Iris pattern	1.61 (1.33)	1.90 (1.30)	.13
Fingerprint	1.22 (0.61)	1.38 (0.71)	.32
Birth date and national identification number	1.80 (1.51)	2.58 (1.64)	.03 <sup>c</sup>
Debit or credit card	1.45 (0.99)	1.32 (0.65)	.95
Location data	2.45 (1.82)	2.51 (1.76)	.87

<sup>a</sup>MWW: Mann-Whitney-Wilcoxon.

<sup>b</sup>mHealth: mobile health.

<sup>c</sup>All italicized P values are significant.

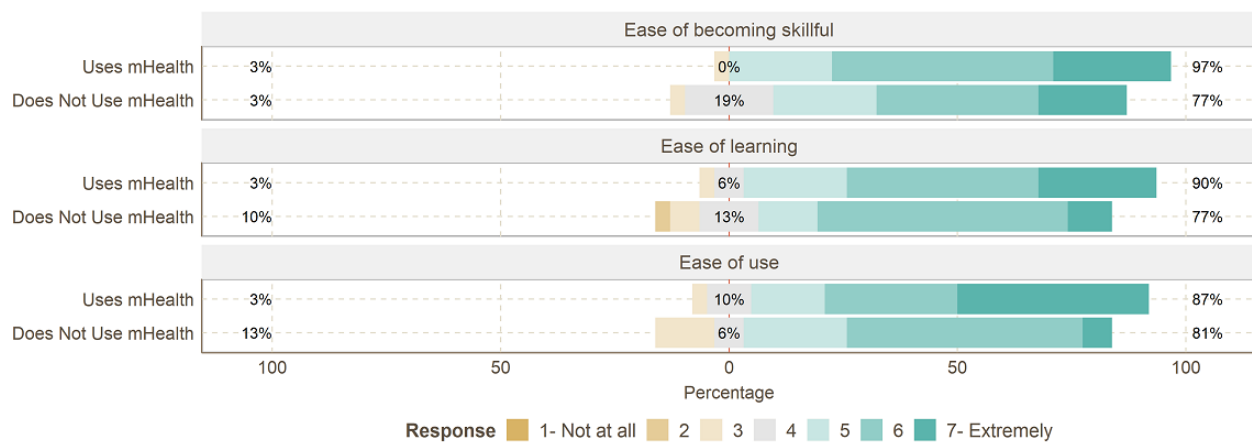
### Ease of Use

We asked participants to share their experiences and expectations regarding the ease of use and learnability of mHealth solutions. mHealth nonusers expected mHealth apps to be easy to use, require less time, be fully automated, and not require looking up documentation. These expectations were matched by the experiences of mHealth users who expressed a positive attitude toward the ease of use of mHealth solutions in general, as summarized by 1 participant:

*[mHealth solutions]...are nicely designed and completely intuitive. [User 18]*

As depicted in Figure 1, the nonusers' expectations and users' experiences did not differ much, as both groups considered *ease of use* an important factor for the adoption and use of mHealth solutions. We also observed a statistically significant difference between mHealth users' experience of *ease of use* and nonusers' expectations (mean 5.96, SD 1.13, vs mean 5.32, SD 1.13;  $P=.01$ ). This is expected as nonusers cannot tell how easy something is to use when they have not used it.

**Figure 1.** Likert item answers to ease of use. mHealth: mobile health.



Despite the reported ease of use of mHealth solutions among mHealth users, setting up of the mHealth solutions was not all smooth for some users, as they reported facing difficulties while getting started. These reported difficulties support a mixture of fear and skepticism expressed by some nonusers about the ease of use of mHealth solutions, with 1 nonuser stating:

*...It won't be a walk in the park. [Nonuser 31]*

However, we believe these fears are realistic, given that the learnability of any software or hardware tool sometimes takes time. To this end, some mHealth users shared some of the difficulties they faced in their early personal experiences with mHealth solutions:

*My wearable tracker was difficult to set up initially, but once it was installed, it was very easy to use. [User 7]*

One participant was, however, quick to point out the availability of documentation to aid in the onboarding process:

*...The instructions are always understandable (discussed step by step). [User 4]*

Concerning previous issues that might have affected the current nonusers' decision to stop using mHealth solutions, the participants mentioned both hardware- and software-related issues, such as Bluetooth pairing between their hardware devices (eg, wearables) and their mobile phones, software bugs after updates, incorrect or poor translations, discomfort with wearing wearable devices, and software crashes. Similar sentiments were expressed by some current mHealth users as well, as 1 participant noted:

*...Auto Bluetooth connectivity to the smartphone is not always great. [User 18]*

Only 1 mHealth user mentioned having had issues with the UI of an mHealth app:

*...Mostly the issues I had were related to the UI not being the most easily understandable (ie, features were hidden in weird places or just hard to find).*  
[User 31]

This was interesting to find as most nonusers were particularly concerned about how mHealth solutions could be “intimidating or overwhelming for inexperienced tech users” (nonuser 18).

**Functionality**

mHealth nonusers outlined various functions they would love mHealth solutions to perform for them. Most mHealth nonusers perceived mHealth solutions as telemonitoring apps that would enable medical staff to monitor them constantly and help patients access help from these health professionals when they feel the need to. One participant believed the use of mHealth apps would help doctors to “...track patient progress at any time” (nonuser 15). Others perceived mHealth apps as a form of a medical emergency solution that will alert health authorities about an emergency by the simple tap of a button. One other highly mentioned feature was *reminders*, a feature that most current mHealth users believe has made their mHealth solutions become their “companions.” Both users and nonusers of mHealth solutions believe the availability of reminders in mHealth solutions plays an enabling role in them taking such actions as taking medication, making medical appointments, and keeping active:

*...My watch tells me to move or stand up if I've been sitting or not moved for an hour.* [User 31]

Other highlighted features include “...quick tips” (nonuser 13), “quick communication with your medical team” (user 20), “...rehabilitation tutorial videos and coaching support” (nonuser 16), “...track diet and physical activity” (user 29), and visualization of reports for “pain levels, medicine intake, heart rate, and stress levels” (nonuser 18).

Concerning met and unmet expectations for mHealth solutions, most users pointed to data accuracy as a significant unmet expectation. They mentioned inaccuracies in measurements, such as blood pressure and daily step count. Others shared their frustrations with being swamped with in-application ads (for monetizing by app developers), software glitches, and subscription-based features. One participant noted that the amount of data required to be entered was daunting:

*...Too many options and things to fill in, it makes me panic.* [User P11]

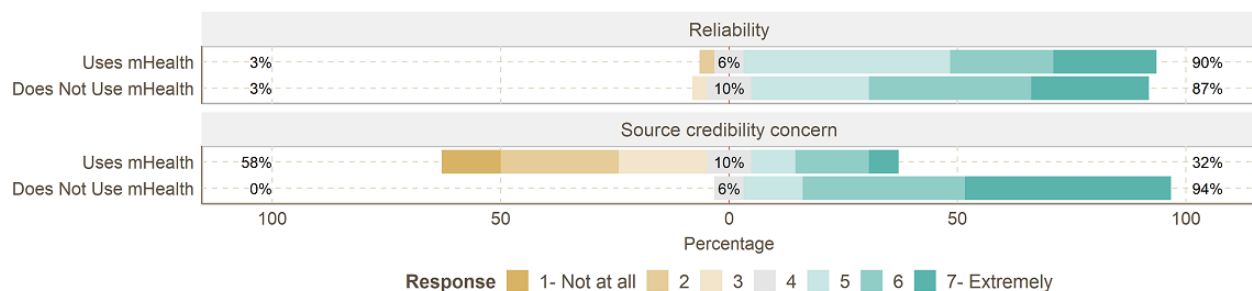
Although mHealth solutions are ubiquitous and allow monitoring one’s health and activities in different ways, it is worth noting that mHealth solutions are aid and, therefore, cannot satisfy all conditions. One such concern was raised by a user about the unsuitability of their mHealth solution for tracking their pain:

*...My chronic pain is on my back, so it's not trackable by my activity tracker.* [User 26]

**Reliability**

We further sought to understand the expectations of mHealth nonusers and the realizations of mHealth users toward the reliability of mHealth solutions. Participants were quizzed about the degree to which the solution will continuously operate properly and the validity of its information sources. Unsurprisingly, a vast majority of concerns about reliability came from nonusers. To this end, nonusers expressed high expectations of mHealth solutions to be reliable. To some, the reliability of mHealth solutions to deliver what is expected of them was crucial for adopting and using mHealth solutions in the first place. As shown in **Figure 2**, mHealth users found their mHealth solutions generally reliable, and nonusers also expected similar reliability. The most significant discrepancy we identified was in source credibility (ie, how well the solutions are backed by science or designed in conjunction with medical experts). Here, 18 (58%) of the mHealth users were not concerned about source credibility, while 29 (94%) nonusers were concerned about it (mean 3.51, SD 1.89, vs mean 6.19, SD 0.90;  $P < .01$ ).

**Figure 2.** Likert item answers to reliability. mHealth: mobile health.



The reliability of mHealth solutions is so important that if they are not reliable, then “...there would be no good in using them” (nonuser 6). Some highlighted that mHealth solutions have human health at stake and that there cannot be room for error. Put bluntly, 1 participant highlighted the need for credibility and reliability of mHealth solutions because “...they are dealing with health which is important and delicate” (nonuser 5) and, as a result, “...there can be no room for mistakes to be made”

(nonuser 15). In this regard, some participants noted the potential negative consequences of mHealth solutions providing unreliable data, a situation that can lead to incorrect diagnosis and pain management routines, a sentiment shared by other participants.

Taking a more realistic approach, 1 nonuser cautioned against having too high expectations of technology, stating, “technology is fallible” (nonuser 17). The inalienable fact of human error

was also mentioned, with a participant noting that human error can contribute to potential reliability issues:

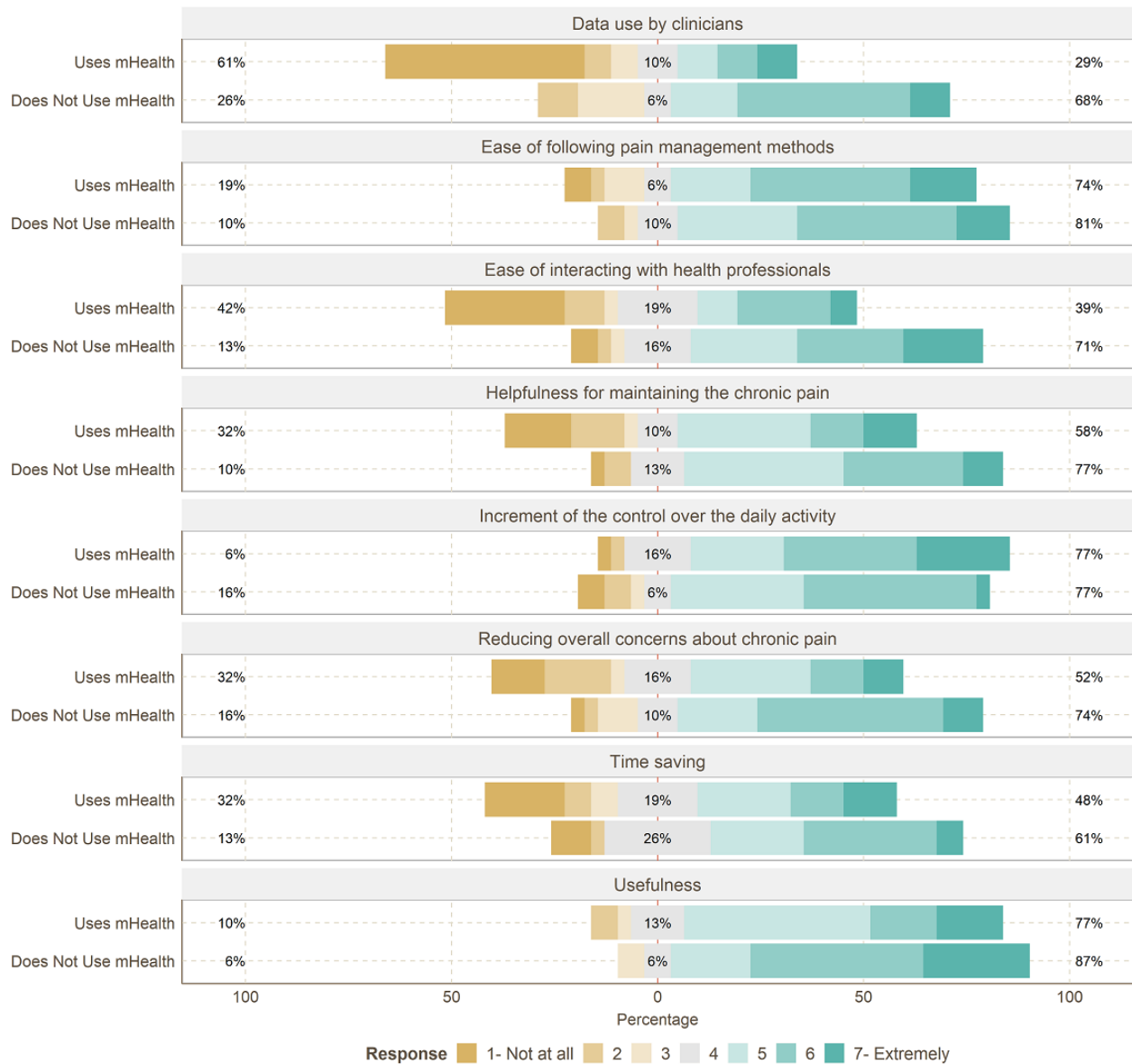
*I don't expect it to be 100% reliable because it will be using information that I give it. I may sometimes make an error or overestimate the amount of pain I am experiencing. [Nonuser 28]*

### Usefulness

Generally, participants expressed a positive complementary role mHealth solutions could play in understanding their pain, accessing and discussing issues with health professionals, and allowing health professionals to monitor data about such pain. To the ordinary user, the ability to visualize their data to gain better clarity to better explain things to health care professionals is of importance to them. Although most participants agreed that mHealth solutions could not replace medical doctors, nor can suggestions in mHealth apps surpass those of medical doctors, they can play a complementary role in assisting users better understand their pain. As such, participants noted that monitoring one's chronic pain would be much easier and more effective for both patients and health care professionals as the mHealth solutions would have vital information for doctors to view and monitor the patient's condition on an ongoing basis, which would allow for more effective treatment over time.

To analyze the answers of participants to each question quantitatively in more detail, as demonstrated in [Figure 3](#), 24 (77%) of the mHealth users (vs n=27, 87%, of nonusers) found mHealth solutions helpful in tracking or managing their chronic pain (mean 5.09, SD 1.30, vs mean 5.74, SD 1.12;  $P=.02$ ). In addition, 15 (48%) of the mHealth users (vs n=19, 61%, of nonusers) declared that mHealth solutions save their time, while 16 (52%) of the mHealth users (vs n=23, 74%, of nonusers) expressed that using mHealth solutions has reduced their overall concern about their chronic pain (mean 4.09, SD 1.90, vs mean 5.12, SD 1.47;  $P=.01$ ). Only 2 (6%) of the mHealth users (vs n=5, 16%, of nonusers) disagreed that using mHealth solutions has increased their control over their daily activity. In addition, 18 (58%) of the mHealth users (vs n=24, 77%, of nonusers) found mHealth solutions helpful to maintain their chronic pain, while 12 (39%) of the mHealth users (vs n=22, 71%, of nonusers) declared that using mHealth solutions has made interacting with health or social care professionals easier (mean 3.64, SD 2.15, vs mean 5.06, SD 1.65;  $P=.01$ ), and 23 (74%) of the mHealth users (vs n=25, 81%, of nonusers) found following medical advice, treatment guidelines, or any potential exercise routine easier than using mHealth solutions. Only 9 (29%) of the mHealth users (vs n=21, 68%, of nonusers) declared that their doctor uses mHealth solutions' data in-office visits (mean 2.93, SD 2.24, vs mean 4.93, SD 1.56;  $P<.01$ ).

Figure 3. Likert item answers to usefulness. mHealth: mobile health.



Users of mHealth solutions shared an overarching sentiment of mHealth solutions, aiding them in following their routines, taking medicines, monitoring weight loss goals, exercising, managing food intake, monitoring pain levels, etc. One user noted:

*It's been useful to track the days I'm feeling worse or better.* [User 15]

The use of mHealth solutions has also enhanced communication between patients and doctors by making data available for medical staff to analyze, a fundamental expectation of the nonusers. As one user put:

*[mHealth solutions have been] useful in presenting data to my practitioner.* [User 18]

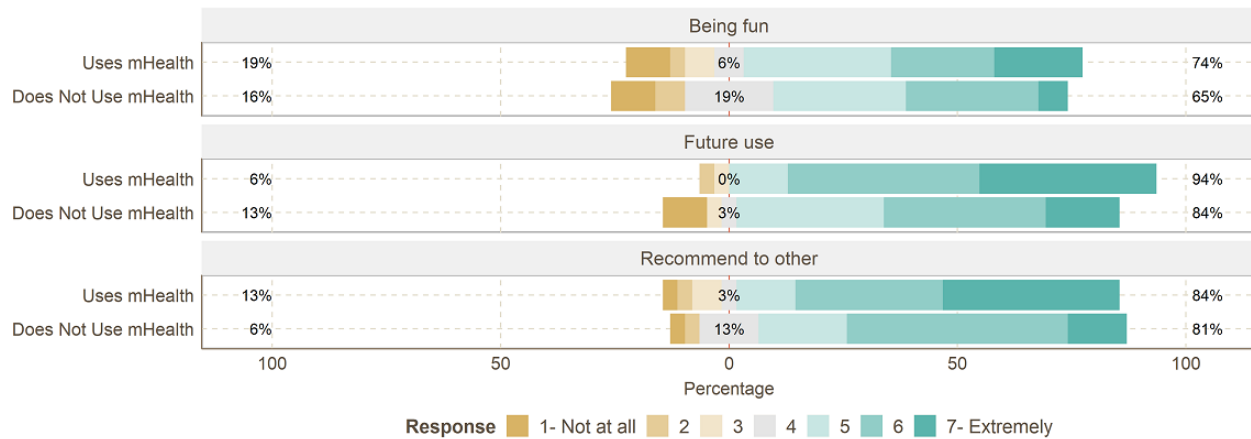
Not all participants had such high expectations for mHealth solutions as mHealth solutions may not suit all conditions. According to 1 participant, using mHealth solutions would not offer any benefit to them:

*In my case, such a service would not be of much use at all.* [Nonuser 3]

### Usage Satisfaction and Other Expectations and Impressions

To investigate the general satisfaction of using mHealth solutions as well as the expected satisfaction of nonusers, participants were quizzed with 3 questions. As depicted in Figure 4, 26 (84%) of the mHealth users (vs n=25, 81%, of nonusers) said they would recommend mHealth solutions to others suffering from chronic pain. In addition, 29 (94%) of the mHealth users said they would continue to use mHealth solutions in the future, while 26 (84%) of the nonusers said they would use mHealth solutions in the future (mean 6.03, SD 1.16, vs mean 5.19, SD 1.66;  $P=.01$ ), and 23 (74%) of the users found mHealth solutions fun, while only 20 (65%) of the nonusers expected mHealth solutions to be fun. On average, 26 (84%) of the mHealth users (vs n=24, 76%, of nonusers) were satisfied with mHealth solutions.

**Figure 4.** Likert item answers to other expectations and impressions. mHealth: mobile health.



**Privacy and Data Management**

Participants were asked about their concerns for privacy and the importance of owning and sharing their data. We noticed that real-world events, such as data breaches, that have occurred worldwide influenced the participants’ position on their willingness to donate their data. One nonuser noted:

*There have been numerous cases where private data were mistreated.* [Nonuser 6]

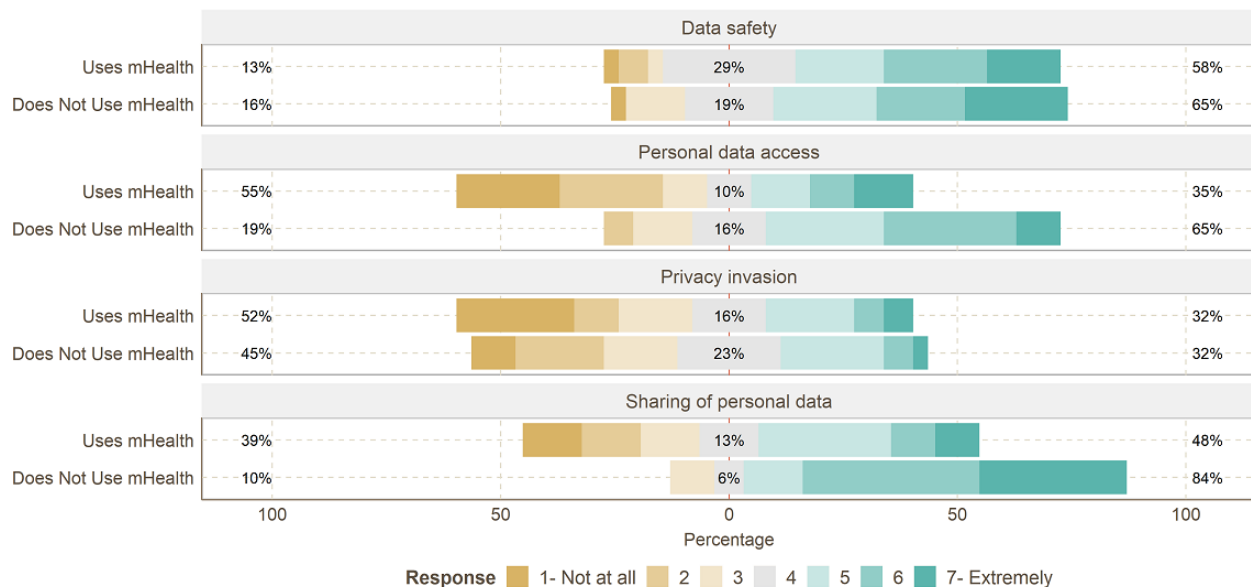
In addition to the fear of data abuse or misuse, participants also expressed concern for the lack of knowledge on how their data

are being protected or even sometimes used for purposes unknown to the data donor:

*I have concerns about my private information being used for other purposes.* [Nonuser 21]

Qualitative and quantitative results showed that mHealth nonusers are more concerned about their privacy compared to users. As shown in Figure 5, 26 (84%) of the nonusers expressed concern about sharing their data with, for example, third parties, while only about half (n=15, 48%) of the mHealth users (mean 4.00, SD 1.86, vs mean 5.77, SD 1.25;  $P < .01$ ) were concerned.

**Figure 5.** Likert item answers to privacy. mHealth: mobile health.



**Willingness to Donate Personal Data**

We went a step further to inquire from participants what types of personal data they would be willing to give to gain additional benefit from the use of their mHealth solutions. Our goal was to understand how willing people are to donate sensitive personal data. Although most did cite privacy concerns for their unwillingness to donate their data, some were not worried about the data they already share on, for example, social media:

*Most data that I would be likely to share is also willingly shared by me on social media.* [Nonuser 10]

Any additional benefits from donating more of their data were generally received negatively. mHealth users, in particular, had serious reservations about their sensitive data, such as fingerprints, mentioning the fear of identity theft as a major concern:

*I don't want to share my fingerprints or national identification because someone can take credit for me or steal my identity.* [User 4]

*Iris, fingerprints and location data seem way too private for a medical app to have.* [User 20]

However, some participants were willing to donate such data if they could be guaranteed anonymity:

*I do not want anyone else having personally identifiable information; they can have anonymized info or info that will not identify me, though.* [User 21]

### Ownership and Control of Personal Data

Most mHealth users believed that they and the mHealth solution provider deserve access to their data. As such, 17 (55%) of them were unconcerned that mHealth solution manufacturers have access to their data. On the contrary, only 6 (19%) of the nonusers (mean 3.48, SD 2.14, vs mean 4.87, SD 1.40;  $P < .01$ ) were unconcerned. mHealth users believed that granting the mHealth solution provider access to their data will enable the provider to “show me better-organized results for example” (user 16). Another participant put it in more precise terms:

*Surely I should have some degree of control as well as the provider for data analysis purposes and data management.* [User 20]

However, concerning control of the data, mHealth users believed they reserve the right to control their data as the data belong to them:

*It's my data so I should be in charge of it.* [User 31]  
*It is my data, so I should have full ownership and control.* [Nonuser 25]

Concerning the potential for misuse of people's data, 1 participant made a plea for the introduction of a third noncommercial party to manage the access and use of personal data to curtail the misuse of such data. The participant noted:

*Data can be misused by commercial enterprises, some level of neutrality (and non-commerciality) might mitigate against this.* [User 18]

Concerning the handling of personal data, 18 (58%) of the mHealth users believed that mHealth solution providers have safely handled their collected data. In comparison, 20 (65%) of the nonusers expected safe handling of their data.

### Future of Personal Data

Lastly, we sought to elicit the participants' opinions on how they envision the future of their data to be in terms of data management. Most nonusers said that they would like to manage their data, but failed to state *how* that could be achieved. However, 1 nonuser was adamant that a neutral third party was the way to go in this light:

*I think that data management should be done by a neutral third party specialized in the field.* [Nonuser 10]

One interesting observation was a call by 1 participant for their data to be linked to an insurance provider:

*I would prefer if my health data was specifically linked to my health insurance provider.* [Nonuser 9]

Although most participants were adamant about a future where they have control over their data, 1 participant made a somewhat

dystopian claim, suggesting an end to personal data ownership and control:

*I imagine soon we won't own any data at all. It will all be taken from us.* [User 18]

### Reasons for Not Using mHealth Solutions in Nonusers' Viewpoint

We sought to understand from mHealth nonusers their reasons for not using mHealth solutions. A lack of knowledge about the existence and potential benefits of using mHealth solutions was a significant sentiment shared by the majority of the participants, with most voicing concern about neither knowing about mHealth solutions at all nor knowing about their potential benefits. One user noted:

*I am not familiar with this product/service and the benefits it can bring to my pain.* [Nonuser 30]

Some participants mentioned that there was simply no need to track their pain. In contrast, others believed they do not use mHealth solutions because it has not been recommended to them by medical health professionals. Those, however, who have known about mHealth solutions but do not use them highlighted financial cost as a major barrier as it “...can be a bit expensive” (nonuser 11) and that most mHealth solutions “...come with costs and ads” (nonuser 21). Some participants, however, were confident they do not need mHealth solutions:

*I don't think I need it. I can manage my pain without it.* [Nonuser 28]

## Discussion

### Principal Findings

As wearable devices, such as Fitbit, Oura Ring (Ōura Health Oy, Finland), and Apple iWatch, are increasingly being highlighted in the media as solutions to improve people's well-being, mHealth represents a class of technologies that are set to proliferate in the near future. Yet, this domain is still a young and unregulated one, and only a fraction of the mHealth apps in the digital app stores online have undergone a rigorous evaluation. Thus, their real impact remains unknown. Our study set out to explore mHealth expectations of mHealth nonusers and experiences of mHealth users for a specific user group, people with chronic pain.

Our sample of mHealth users is naturally self-selecting, as they have chosen to adopt mHealth of their own volition. Thus, it is not easy to comprehensively judge whether, for example, the expectations people have for mHealth would change after they adopt such solutions or whether the people who use mHealth devices have done so due to their earlier expectations. Yet, we argue that the quantitative and qualitative data we present in this paper act as a solid conversation starter to understand the contrast between these 2 groups of people (mHealth users and mHealth nonusers).

### The Future Role of mHealth Devices

The most mentioned feature overall by the 62 participants was *reminders*, which appeals to both users and nonusers as they expressed the need to rely on reminders to “take medicine” or



even “take a break,” much in line with Zhou et al [35] and Siegler et al [36]. Participants expressed a desire for mHealth solutions to become part of their life, as some referred to it as a *companion* [79]. Companion technologies fill the gap between the broad functionality of technical systems and human users’ individual needs. They aim to appear as “companions” to their users. They enable the construction of smart, adaptive, flexible, and cooperative technical systems by applying and combining methods from various research areas. They serve as cooperative agents assisting in specific tasks or even give companionship to humans in a more general sense [80,81]. Variant companions in the HCI field have been developed, such as Artificial Commensal Companions to provide social interactions during food consumption [82], the Prayer Companion that can be used as a resource for the spiritual activity of a group of cloistered nuns [83], and the Flippo that is a social wearable creature prototype and is meant to support people to take breaks away from their desks and move [84]. To this end, as some participants with CLBP expressed that their chronic pain is not trackable with their activity trackers, mHealth solutions could be developed as companion solutions to manage each specific chronic pain, such as CLBP, separately and more professionally. In contrast, most of our participants expressed optimism about mHealth solutions being critical to helping them become independent in managing their pain (in line with Pfeifer et al [14], Yang et al [40], and Amorim et al [85]) by providing interventions just in time, as also discussed by Künzler [86].

Participants further expressed a high expectation of mHealth solutions to be reliable in delivering accurate results and performance. Reliable data present an opportunity for individuals to communicate with their health care providers (eg, doctors and therapists) regarding their pain. By presenting data from these mHealth solutions, participants believed their health care providers would assist them in managing their pain better. At this point, the question is then about finding functional solutions that medical experts would be willing to adopt on a broader scale. One obstacle in using these devices more broadly is data management, with all types of concerns for privacy or misuse, such as sharing with a third party, selling to a third party, and having access of the wrong personnel to mHealth [35,87].

### **It Is Always About the Data: Insights Into the Perceived Privacy of mHealth Solutions**

People expect information to flow in a certain way in a given situation. When it does not, privacy concerns may arise. The benchmark of privacy is contextual integrity (ie, in any condition, a complaint that privacy has been violated is sound if 1 or other types of informational norms have been transgressed [88]). The sensitive nature of personal data that such mHealth apps access poses a problem to data privacy [30].

Studies show that mHealth apps on Google Play Store contain codes that could potentially collect user data and transmit them to their traffic [30] or share the users’ information with a third party [89]. mHealth solutions developers routinely and legally share user data with third parties, often in exchange for services that enhance the user experience or monetize the app [90]. The

participants were also aware of data privacy breaches and expressed their concerns.

However, little transparency exists in third-party data sharing, and mHealth solutions routinely fail to provide any assurances despite collecting and transmitting multiple forms of personal data [91,92].

Participants in our study considered themselves moderately to highly aware of their data privacy rights, and their responses echoed sentiments of not only being aware of but also contributing to their information privacy. Interestingly, although individuals tend to declare their concern about privacy, their actions often belie such claims [77,93]. Individuals passively trade their personal information in exchange for access to use various apps for free (sign up and use for free); they accept terms and conditions without reading them and willingly share sensitive information on social media—a behavior exhibited by our study participants, as well.

We found that our participants, on the one hand, stated that they were concerned about privacy. Yet, on the other hand, they demonstrated diversity in views about the future of management. For example, when it comes to what data to donate, they expressed that they do not trust the platforms with that information. However, in responding to their thoughts on the future management of their health data, we see a contrasting view that they would prefer that their health data were specifically linked to their health insurance provider. In a related paper, Solove [94] stated that people are prone to shouting, “That violates my privacy,” while lacking clarity on what privacy actually means [77,94]. As such, we find that privacy discussions mostly appeal to people’s fears and anxieties, in line with Alorwu et al [87] and Solove [94]. However, we were excited about what types of personal data our respondents were willing to donate in exchange for additional benefits. We are confident that the results demonstrate *healthy carefulness*. Passwords and pins were the main traditional methods that some apps chose to secure themselves. With the increasing vulnerabilities of both passwords and pins due to hacker attacks, biometrics is a good alternative for mobile apps to reduce cyber security threats. In some countries, people need to enter their health care system using their bank account number, and it is worth noting that the banking and finance sector has nearly universally embraced biometric security systems as the primary way to secure access to their apps and services. However, our participants were reluctant to donate their debit or credit card numbers, and their biometrics data included iris patterns and fingerprints. In line with previous research (eg, Presthus and Sørnum [77]), the top 3 personal data participants were willing to donate were their first name, last name, and email address.

### **Managing Chronic Pain With mHealth**

A variety of life events cause chronic pain: injuries, surgery, illnesses, or age. Managing chronic pain is not an easy process, as it is often long term and requires a lot of patience. The degree of pain experienced by people also differs. To this end, mHealth solutions that aim to help people manage their pain should be able to do so without imposing any extra burden and complicating things further. The participants mainly stated their experiences and expectations in health management; the reason

might be the generality of the data that mHealth solutions track and collect. To be more related to managing pain, the mHealth solutions need to have more specific features to measure different items. Hereupon, their development requires a diverse set of expertise, including software programmers, behavioral scientists, graphical designers, and medical experts, such as doctors and physiotherapists. It also requires end-user feedback about the solutions themselves so that the vendors can match actual users' real-life needs [38,39]. However, medical experts are still reluctant to use mHealth solutions as part of their treatment despite the perceived potential, due to insufficient evidence of their benefits [5].

Further, from the medical standpoint, the cost of managing chronic pain can be high, especially for those with a low socioeconomic status to begin with. The cost of higher-end mHealth solutions could be simply too much. Our results also indicate that most mHealth users began using mHealth solutions by their own initiative. Only a handful did so through recommendations from friends, medical doctors, or therapists. As our results show, mHealth users perceive value in their use, so it is fair to speculate that perhaps their wider adoption could be helpful more broadly for others with pain, too. Could doctor-recommended mHealth solutions offer greater benefits to users?

### Implications for the Future of mHealth

Based on our study, we bring forward specific implications. First, we believe there is a potential missed opportunity by mHealth manufacturers by not specifically aiming to make communications with clinicians easier. The nonusers among our participants were expecting the mHealth solutions to facilitate this, yet this was not the case according to the users.

Second, nonusers were more concerned than users about the mHealth solutions having access to personal data and the solution providers sharing those data with third parties. To this end, transparent and ethical data management, and communicating all this to potential new users of mHealth solutions, is critical to driving further mHealth adoption.

Finally, nonusers were significantly more concerned about the source credibility of mHealth solutions. This could be potentially an unfortunate misunderstanding, as the purpose of mHealth is certainly not just to provide accurate medical assistance or even science-backed aid. Many mHealth solutions are simply used to track users' activity or even provide information content based on users' preferences. Again, this offers an excellent way to build credibility for mHealth providers but also a communication opportunity: not all solutions have to be medical grade to fulfill their promise to the consumers.

### Limitations

We admit some limitations of our study. Our sample is not representative of mHealth users as a population. However, we argue it is sufficient for discussing the emerging differences. A larger sample is needed for the increased generalizability of our results. Further, sourcing participants from multiple sources would be a more optimal sampling strategy. To this end, Prolific has been shown to yield valid data for questionnaire studies in HCI and other fields.

We acknowledge that using 2 different samples for *expectations* and *actual experience* is less optimal than, for example, exploring the pre- and postadoption behavior of 1 sample. Our study could potentially be impacted and moderated by social factors, such as demographics, education, income, or marital status. If we had used the same samples in a longitudinal study, the results would potentially differ. However, for our purposes of a questionnaire study, using 2 samples drawn from a reliable human subject pool online, we argue, is adequate.

Our results indicate a trend toward people who do not use mHealth solutions, being more concerned about their privacy than those who use mHealth solutions. However, we cannot know whether people who are less concerned about privacy issues are those who adopt and use mHealth solutions or whether the use of mHealth solutions makes people worry less about their privacy. This presents a promising future research opportunity.

### Future Work

We plan to extend this work by conducting a longitudinal study by letting users elicit their expectations before using an mHealth solution. We will then contrast their felt-experience against their expectations. This will help improve the understanding of how mHealth could be critical to managing chronic pain in the future. Another exciting opportunity is a thorough cross-validation of results obtained through crowdsourced marketplaces (eg, Prolific in our case) and larger-scale questionnaire studies online. Finally, further studies should be conducted with medical professionals to acquire their expert feedback on how mHealth solutions could be helpful to the self-management of conditions such as chronic pain.

### Conclusion

In this paper, we investigated how mHealth is currently used in the context of chronic pain and the expectations of mHealth nonusers for mHealth as a future chronic pain management tool. We conducted 2 studies, an initial study to identify people who use mHealth and a follow-up study to elicit insights into mHealth expectations and experiences between mHealth users and nonusers. Our analysis reveals contrasts between mHealth use expectations and actual usage experiences and highlights privacy concerns regarding mHealth solutions.

### Acknowledgments

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## Conflicts of Interest

None declared.

### Multimedia Appendix 1

Questionnaire for people with chronic pain to investigate how many use mobile health (mHealth).

[[PDF File \(Adobe PDF File\), 157 KB](#) - [humanfactors\\_v9i3e38265\\_app1.pdf](#) ]

### Multimedia Appendix 2

Questionnaire for people with chronic pain who use mobile health (mHealth).

[[PDF File \(Adobe PDF File\), 469 KB](#) - [humanfactors\\_v9i3e38265\\_app2.pdf](#) ]

### Multimedia Appendix 3

Questionnaire for people with chronic pain who do not use mobile health (mHealth).

[[PDF File \(Adobe PDF File\), 469 KB](#) - [humanfactors\\_v9i3e38265\\_app3.pdf](#) ]

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## Abbreviations

**CLBP:** chronic low back pain

**EDT:** expectation disinformation theory

**HCI:** human-computer interaction

**Health-ITUES:** Health Information Technology Usability Evaluation Scale

**IoT:** internet of things

**mHealth:** mobile health

**MWW:** Mann-Whitney-Wilcoxon

**SUTAQ:** Service User Technology Acceptability Questionnaire

**TUQ:** Telehealth Usability Questionnaire

**UI:** user interface

**WHO:** World Health Organization

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Original Paper

# User Experience of the Co-design Research Approach in eHealth: Activity Analysis With the Course-of-Action Framework

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## Abstract

**Background:** The cocreation of eHealth solutions with potential users, or co-design, can help make the solution more acceptable. However, the co-design research approach requires substantial investment, and projects are not always fruitful. Researchers have provided guidelines for the co-design approach, but these are either applicable only in specific situations or not supported by empirical data. Ways to optimize the experience of the co-design process from the point of view of the participants are also missing. Scientific literature in the co-design field generally provides an extrinsic description of the experience of participants in co-design projects.

**Objective:** We addressed this issue by describing a co-design project and focusing on the participants' experiences looking at what was significant from their point of view.

**Methods:** We used a qualitative situated cognitive anthropology approach for this study. Data were collected on a co-design research project that aimed to support the help-seeking process of caregivers of functionally dependent older adults. The methodology was based on the perspective of experience by Dewey and used the course-of-action theoretical and methodological framework. Data collection was conducted in 2 phases: observation of participants and recording of sessions and participant self-confrontation interviews using the session recordings. We interviewed 27% (20/74) of the participants. We analyzed the data through nonexclusive emerging categorization of themes using the constant comparative method.

**Results:** In total, 5 emerging themes were identified. The *perception of extrinsic constraints and the effects of the situation* was central and the most important theme, affecting other themes (*frustrating interactions with others, learning together, destabilization, and getting personal benefits*). Co-occurrences between codes allowed for a visual and narrative understanding of what was significant for the participants during this project. The results highlighted the importance of the role of the research team in preparing and moderating the sessions. They also provided a detailed description of the interactions between participants during the sessions, which is a core aspect of the co-design approach. There were positive and negative aspects of the participants' experiences during this co-design project. Reflecting on our results, we provided potential affordances to shape the experience of participants in co-design.

**Conclusions:** Potential users are an essential component of the co-design research approach. Researchers and designers should seek to offer these users a positive and contributory experience to encourage participation in further co-design initiatives. Future research should explore how the proposed affordances influence the success of the intervention.

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**KEYWORDS**

co-design; caregivers; activity analysis; course-of-action framework; participant experience; intrinsic description; guidelines; affordances

## Introduction

### Background

The scientific community has shown increasing interest in the co-design approach, especially in the field of eHealth, where people work together to design technological solutions to health-related problems [1-4]. Co-design is a human-centered design methodology used in research-action projects to design a product or service [5]. In the co-design approach, end users (or potential users) participate in knowledge creation and idea generation alongside researchers and designers [6]. By engaging users as experts in their experience with a product or service, co-design can foster social innovations in this rapidly changing world [7].

In total, 3 types of benefits to this approach were identified by Steen et al [8]: to the service being designed (ie, improving the creative process), to the users (ie, better fit and higher satisfaction), and to the organization (ie, more successful innovations and better public relations). A systematic review of user involvement revealed that, out of 87 studies using a co-design approach, 52 reported positive contributions to system design, 12 reported negative contributions, and 23 were uncertain [9]. As the authors stated, the relationship between system success (or usability) and user participation “is neither direct nor binary, and there are various confounding factors that play their role.” As participatory research methods can require a great deal of time, effort, and money, why should we take a co-design approach? Moreover, why are some co-design research projects more fruitful than others? Which factors lead to better results?

Some researchers have proposed guidelines for the co-design process. Noorbergen et al [10] proposed 7 guidelines for co-design in mobile health. These guidelines were based on interviews with co-design method experts (n=8) and mobile health system developers (n=8). The participants were not questioned regarding their experience with the co-design approach. Ostrowski et al [11] proposed 10 co-design guidelines for designing social robots. The proposed guidelines are specific to the co-design of social robots and a long-term study design. Cruickshank et al [12] proposed 8 guidelines for a co-design project that aimed to reimagine a large green space in the heart of the city. These guidelines were proposed by the research team to help designers during the co-design study. They were not documented using empirical data.

What is missing is the point of view of participants who engage in a co-design research project; that is, what is significant for them during a co-design session. Participant experience could provide insights into how this research approach can be more contributory [13]. Scientific literature in the co-design domain generally provides an extrinsic description of the experience of participants in co-design projects [5]. It remains unclear what the participants themselves consider significant in their experience during the co-design sessions.

An in-depth understanding of the experience of participants from their own point of view could help researchers understand why some co-design research projects are more effective than others and further help configure or shape the experience for participants. End users are essential in co-design projects and, therefore, researchers should seek to optimize the experience of the co-design process from the point of view of the participant. Here, experience is considered from the perspective of experience by Dewey [14]: “An experience can be distinguished from other experiences when what is experienced ‘runs its course to fulfilment.’”

### Objectives

Our objective was to describe the experience of potential end users acting as co-designers in a co-design eHealth research project. We wanted to describe the intrinsic experience of participants involved in co-design to provide insight into the cognitive aspects underlying their actions during a co-design research project. We wanted to explore whether and how the experience of co-design from the participant’s perspective can inform researchers about which factors result in more fruitful outcomes.

## Methods

### Co-design Project Studied

In this paper, we present the experience of 20 individuals who engaged in a broad co-design research project that aimed to develop an eHealth tool to make the help-seeking process easier for caregivers of functionally impaired older adults. The research project protocol included co-design sessions (n=8) and advisory committee (AC) meetings (n=3) of 3 hours each. The AC guided the prototype’s progression and ensured that it conformed to the decisions made during the co-design sessions. Participants in the co-design sessions and AC meetings included 3 categories of potential users of the tool: caregivers of functionally impaired older adults, health and social service professionals, and community workers from the community health network. Co-design sessions were held in 11 administrative regions of Quebec, Canada, from May 2017 to June 2018. Different participants took part in each co-design session as the sessions took place in different regions of Quebec. The AC participants remained largely consistent as those sessions were held in a single location.

During the co-design project, we considered participants as co-designers and positioned ourselves (the research team) in a similar role from a cocreation perspective, as proposed by Sanders and Stappers [6]. The research team included 4 researchers from 3 background domains: 1 (25%) in design (MT) and 2 (50%) in occupational therapy, one of whom was the project lead (DG), as well as 1 (25%) research assistant in anthropology. We also had strong democratic concerns for our participants, wanting to enhance their ability to take part following the social justice perspective work of Sen [15].

Therefore, members of the research team acted as moderators during the sessions while making some design decisions between sessions.

We followed the elements of experience [16] model to structure the entire co-design process. This model proposes a structured process to work on different aspects of the design (eg, interaction design, navigation design, and information design). Sessions were organized to enable work on the different design dimensions (planes) of the model in a linear yet iterative manner, as proposed by Garrett [16]. The participants then coconstructed knowledge and artifacts based on the work of the previous group. For example, the objective of co-design session 5 was to develop the information architecture of the tool. The participants used the *requirements* ideas that were identified during the previous 2 sessions (co-design sessions 3 and 4). The co-design sessions included a variety of activities such as discussion, brainstorming, personas, paper prototyping, and user testing. Activities were selected according to the objective of each session and the progression of the design [16]. Co-design sessions were carried out in both plenary sessions and subgroup workshops, whereas the AC always met in plenary sessions. If all subgroup workshops had the same objective (as was the case for co-design session 5), they each typically included a representative of each category of participants. The participants were always free to choose their subgroup. When the objectives were different between the subgroups, the participant composition was sometimes homogeneous in terms of category. The eHealth tool designed was a high-fidelity prototype of a website. The website had a user-generated content orientation with 2 main objectives: offering and finding resources.

A complete description of the research project protocol has been published previously [17], and the results are presented in 3 papers: one focusing on user needs [18], the second presenting the identification of requirements based on user needs [19], and a third presenting the overall process [20]. Although the previous papers discussed the process and the results for each part, this paper describes the participants' experience of the process from their point of view.

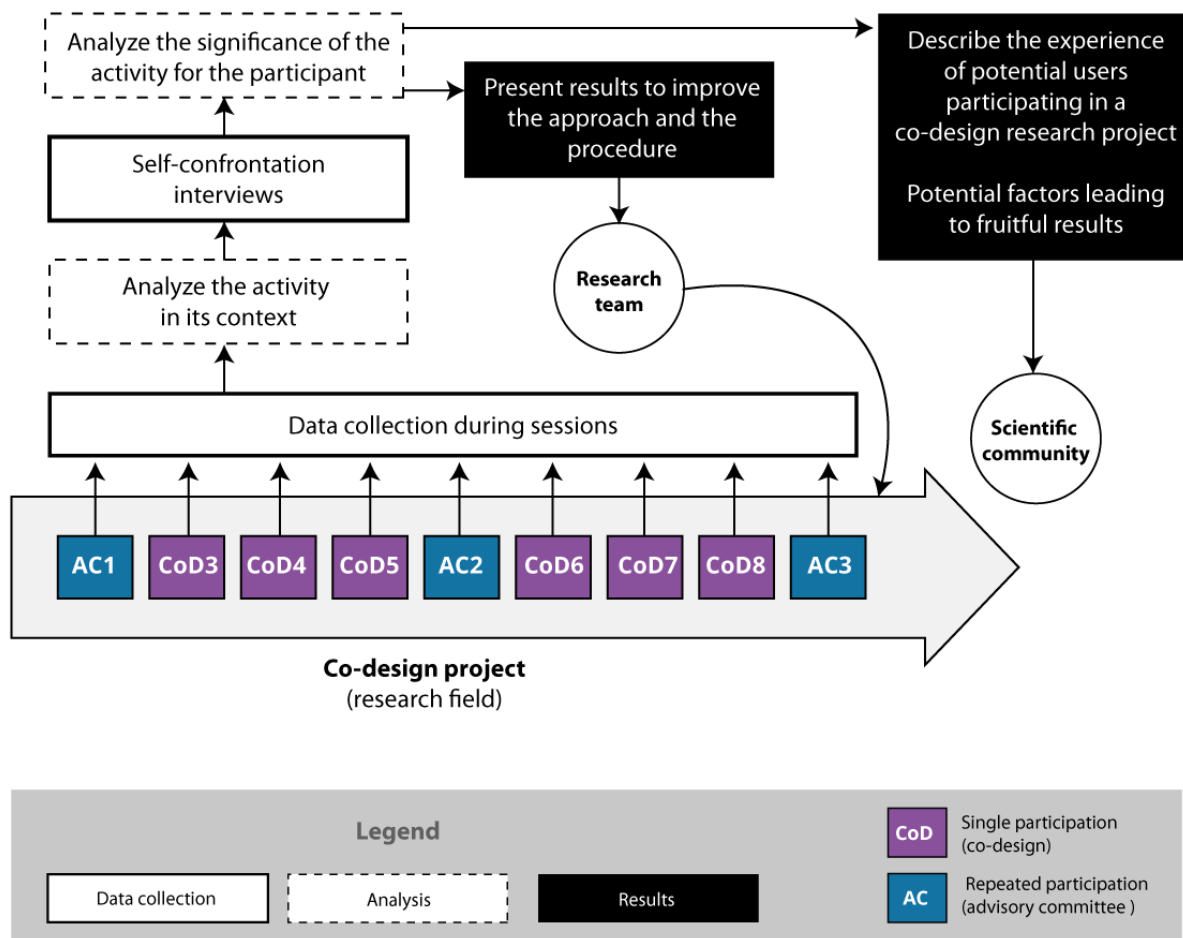
## Study Design

To understand the experience of the co-design research approach, we needed to combine the action with the appropriation of the action or the consequences for the actor. In our study, we used a situated cognitive anthropology research approach informed by the course-of-action framework, focusing on the actions of the participants in real situations [21-23]. The course-of-action framework, developed in French ergonomics [24], considers human activity in terms of how participants interact with the physical and social environment. The focus is on analyzing and describing the activity by prioritizing intrinsic description (from the actor's point of view), although extrinsic description (from the researcher's point of view) is still included. This framework shares epistemological proximity with the co-design approach in that it considers the participants to be the experts in their own experience [25]. This research approach requires phenomena of cognition to be studied in their actual context. This method captures significant parts of the activity from the participant's point of view, in line with the perspective of experience by Dewey, also pointed out by Laudati and Leleu-Merviel [26]. In our case, the activity encompasses everything that the participants (user-co-designers) would go through during their participation in a co-design research project. The focus remains on the significant parts of their experience from their perspective.

We collected data for this study from the first AC meeting to the end of the project. We were not able to collect data during the first 2 co-design sessions as ethical clearance was obtained after these sessions (June 2017). Our study was not initially planned in the co-design protocol. To collect data for our study, we amended the initial ethical clearance of the co-design project (reference 2016-2017-10 MP).

Important aspects of the intrinsic description of the participants' experiences were shared with the research team and AC as needed during the debriefing sessions. All data that could not be observed in the sessions and that could inform design decisions and co-design activity planning were discussed after the session with the research team. Important, unclear, or divisive aspects were then negotiated during AC sessions (Figure 1).

**Figure 1.** Overview of the study methodology. AC: advisory committee; CoD: co-design session. Adapted from Tremblay [5], which is published under Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License (CC BY-NC-SA 4.0) [27]).



**Recruitment**

Study participants were recruited at the same time as the participants for the co-design project. They were informed of the opportunity to take part in an individual interview to share their experience of the activity. During the sessions, they could indicate whether they wished to participate in our study. We used purposeful sampling, which is commonly used in qualitative studies [28]. At the end of each session, 2 of the participants who had accepted to take part were selected based on 2 selection criteria (both inclusionary and exclusionary) and contacted for an interview. The selection criteria were as follows: (1) the participant was a potential user of the tool (excluding researchers) and (2) the study achieved a balanced representation of each category of participants (caregivers, health and social service professionals, and community workers). For example, when possible, we selected a health and social service professional instead of a community worker as we had fewer health and social service professionals recruited.

**The 2-Phase Data Collection Process**

*First Phase: Extrinsic Description by the Researchers*

As stated by Theureau [22], data should be collected in a 2-phase protocol within the course-of-action research program. The objective of the first phase was to document the extrinsic dimension of the co-design research project (observer description). As previously mentioned, the co-design sessions included plenary and subgroup workshops. During the plenary sessions, a camera and an audio recorder were used. For the subgroup workshop sessions, digital tablets (for video) and audio recorders were used for each group. After the sessions, we used the video recordings to create a summary transcript of the session (the partial chronicle), identifying the principal actor or actors and describing the action for each distinct moment of the session (see the example in [Textbox 1](#)).

This partial chronicle was an overview of the session from the researcher’s perspective. It represented all major moments of the session. In this chronicle, we tried to identify what was significant to the participant from our point of view (observer).

**Textbox 1.** Partial chronicle example with the principal actor and description.

- Researcher 2 (timestamp 00:00:00): presentation of the project and explanation of the objective of the session. Presentation of the initial user needs that the tool must address. Participants need to find at least two content or functionality requirements for the user need (*know the services offered*).
- Participant 1 and participant 2 (timestamp 00:36:20): participants are talking about the Zarit Grid, a clinical tool used by professionals to evaluate the burden of caregivers and determine which services they are entitled to.

**Second Phase: Intrinsic Description Provided by the Participants**

The objective of the second phase was to document the intrinsic dimension (participant description). During the second phase, we interviewed the participants to obtain a description of the session from their point of view using the recordings of the session and the partial chronicles. Data were collected using a self-confrontation interview protocol [22,29] enriched with facilitation techniques [30].

The self-confrontation method is a semistructured interview that invites participants to describe the activity from their own point of view. On the basis of the identified moment in the partial chronicle, video excerpts of moments of the session were presented to each participant to help them recall their “observable activity that is prereflexive” [31]. Partial chronicles were also used during the interviews to retrieve a specific moment (*t*) of the session, a significant moment shared by the participant but not previously identified by the researcher.

The interviews were structured to facilitate the emergence of the cognitive components of the participants’ course of action.

These components are described in the *Data Analysis* section. As stated by Theureau [21], participants will have a natural tendency to describe the given moment using these components. During the interviews, the questions focused on unmentioned components, guiding the participants to verbalize what they were doing, thinking, or feeling at a given moment and what preoccupations and expectations they had.

The transcripts of the self-confrontation interviews (descriptions from the participants) were combined with the partial chronicles (descriptions from the researchers) to arrive at a complete description. Segments of the interviews were replaced with the corresponding moments of the session in the partial chronicle to obtain a complete chronicle. Table 1 summarizes the data collection steps, methods, and instruments.

MT performed all the data collection with guidance from the other authors. MT did not identify herself to the participants as a designer and maintained a passive role as much as possible during the sessions to facilitate data collection. Our hypothesis was that the participants might not be open to sharing their experiences with the designer of the project. MT was identified as a member of the research team.

**Table 1.** Data collection and instruments.

Step	Objective	Method	Instruments
1	Collecting traces of the session—collect data on the session	Observation	<ul style="list-style-type: none"> <li>• Audio and video recording devices (camera, digital tablets, and audio recorders)</li> </ul>
2	Partial chronicle—reconstitute the course of events with timestamps	Data condensation of the observation of the session	<ul style="list-style-type: none"> <li>• Audio and video recordings of the session</li> </ul>
3	Verbalization—obtain an intrinsic description of the session as experienced by the participant	Self-confrontation interviews	<ul style="list-style-type: none"> <li>• Audio and video recordings of the session</li> <li>• Audio and video recording devices (computer and cellular phone)</li> <li>• Partial chronicle</li> <li>• Interview template</li> </ul>
4	Complete chronicle—complete the partial chronicle with the participant’s intrinsic description of the session	Interview transcripts	<ul style="list-style-type: none"> <li>• Audio and video recordings of the session</li> <li>• Interview transcript</li> <li>• Partial chronicle</li> </ul>

**Data Analysis**

**What Constitutes a Sign**

The first step in the data analysis within the course-of-action framework is sign reconstitution. On the basis of the theory by Peirce, Theureau [21] proposes the hexadic sign to describe the course-of-action framework, which has 6 components. The hexadic sign demonstrates the cognitive, situated, and dynamic

aspects of the activity. Textbox 2 presents the 6 components [31,32] and their definitions. The given moment (*t*) represents a specific moment of the course-of-action framework. It is a recall in the present moment of a series of past structures. The given moment makes it possible to identify a specific moment of the activity corresponding to a given sign. The sign was identified by the researcher (MT) in the transcript of the participants’ verbalization of the session.

**Textbox 2.** Components of the hexadic sign (interpretation of the studies by Theureau [31] and Ria et al [32]) and their definition.

- Unit (U): fraction of the activity that could be shown, told, or commented on by the participants at a given moment (*t*). Interpretation, action (practical or communication), emotion, or an area of focus.
- Representamen (R): disruptions (perceptive, mnemonic, or proprioceptive) that are significant to the participant at a given moment (*t*).
- Involvement (E): significant preoccupations and concerns of the participants regarding the representamen (R).
- Expectations (A): expectations at a given moment related to the involvement (E).
- Referential (S): knowledge and experience involved at a given moment (*t*) related to the considered element of the situation (R), the involvement (E), and the expectations (A).
- Interpretant (I): learning or appropriation—confirmation or transformation of the triad (A-E-S) at a given moment (*t*).

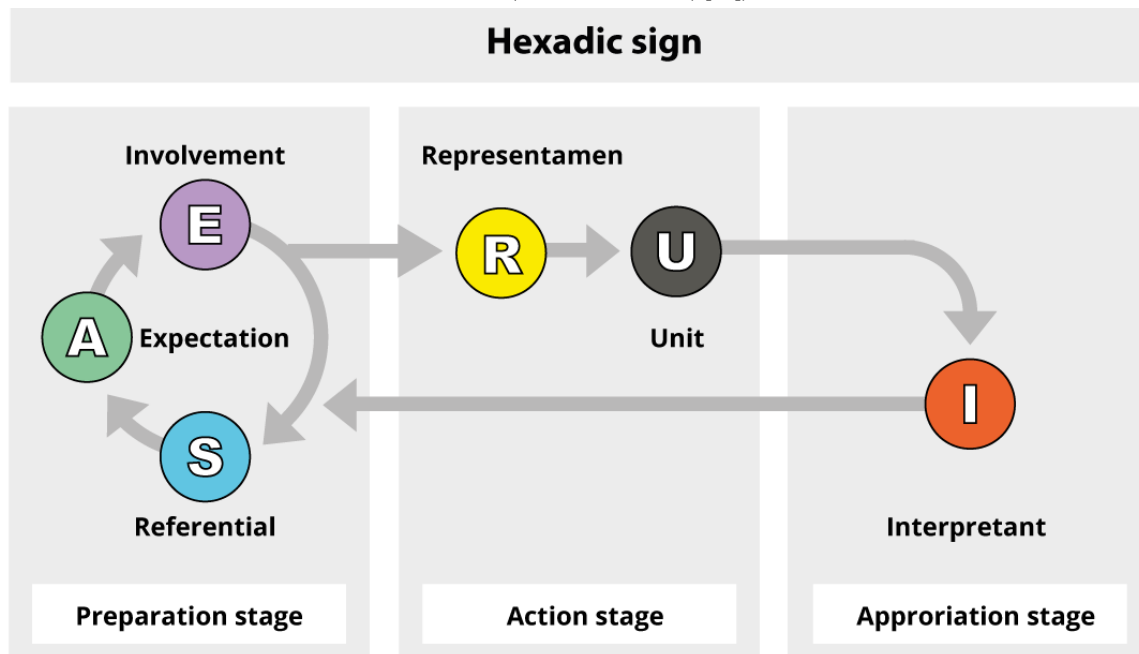
The components of the hexadic sign are presented in a structured order. As stated by Theureau [21], this order is not temporal but structural. Some components (expectations [A], involvement [E], and referential [S]) reflect the preparation stage (Figure 1). Others (representamen [R] and unit [U]) are related to the perception of the action at a given moment (*t*), and the last component (interpretant [I]) reflects the actor’s appropriation of the experience [33], meaning the validation or invalidation of the A-E-S triad, as shown in Figure 2.

Although the course-of-action framework prioritizes the intrinsic dynamic organization, extrinsic considerations are nevertheless important. The course-of-action framework studies the intrinsic dynamic organization of one or multiple actors and the extrinsic constraints and effects.

The reconstitution of signs was carried out by extracting components (U, R, E, A, S, and I) from the discourse, bringing

out the essence of the sign and identifying it. We first identified the unit (U) of the sign from the participants’ comments on what they were doing, thinking, or feeling at a specific moment. To complete the sign, we identified the associated components (R, E, A, S, and I) for that particular unit (U). For example, based on the feeling at this given moment, what were the significant concerns of the participant regarding the element under consideration in the situation (R)? The components were either accompanied by a direct excerpt of the transcript or by a reformulation, attempting to stay as close as possible to what was said by the participant. When we could not directly extract a component from the discourse, we tried to infer it based on the overall experience of the participant. These inferred components were identified (*i*) in the data. This first step of the analysis was performed in table format in Microsoft Word.

**Figure 2.** Structural order of components. Adapted from Tremblay [5], which is published under Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License (CC BY-NC-SA 4.0) [27]).



**Emerging Categorization of Signs**

After sign identification, the second step of the analysis was to answer the specific research questions. As our objective was to describe the experience of participants from the perspective of experience by Dewey [14], we used an emerging categorization

of themes [34] with the constant comparative method [35]. Themes were not mutually exclusive. Signs could be coded with more than one subtheme and, therefore, included in more than one theme. We did not use all the signs in each interview but rather the one or ones that seemed to represent an experience during the session [14]. In total, 2 indicators helped identify

these signs along with MT's own perception of moments that appeared to be an experience for the participants. First, some signs (or moments) were identified during one of the first questions that the participants answered in the self-confrontation interview: *Were there specific moments of the activity that were more important or significant for you?* The participants specified moments of the session, and signs representing those moments were extracted. The second indicator was when several signs were on the same topic. As mentioned by Dewey [14], “[t]here is interest in completing an experience...growing meaning conserved and accumulating toward an end that is felt as accomplishment of a process.” If the participants frequently came back to a specific moment, this moment was more important to them, thereby representing an experience for them. Finally, MT was intensely engaged during all steps of the data collection and analysis process, giving her a deep understanding of the activity of the participants and allowing her to distinguish moments representing an experience for them. Themes emerged from these extracted data.

Intracoder agreement (internal revision) of the themes was performed after 1 month [36]. Subthemes were then identified, helping stabilize the theme categorization. A table of the themes with definitions, subthemes, and 1 example of data for each subtheme was revised by 1 author (CH) to obtain intercoder agreement. The themes and subthemes were negotiated between the researchers and then revised by all the authors, resulting in a slight reformulation to better represent the concept of

experience. The coding was revised a third time by the author (MT).

### Ethics Approval

The study received ethical approval from the Comité d'éthique de la recherche sectoriel santé des populations et première ligne (2016-2017-10 MP). Informed consent was obtained from each participant, who also received a nominal compensation of CAD \$20 (US \$16.45).

## Results

### Participants

From the total number of participants (potential users) in the co-design project (N=74), 20 were recruited for this study. Therefore, we documented the experiences of 27% (20/74) of the participants in the co-design project. We recruited 2 participants for each session except for co-design session 3, where 1 participant withdrew, and co-design session 5, where 6 participants were recruited. Equivalence between the user categories was not completely reached—of the 20 participants, there were 9 (45%) caregivers, 4 (20%) health and social service professionals, and 7 (35%) community workers. A participant in the AC was interviewed twice after the second and third AC sessions. Therefore, the total number of self-confrontation interviews was 21. [Table 2](#) presents the demographic characteristics of the participants included in our study.

**Table 2.** Sociodemographic data of the participants (N=20).

Variable	Caregivers (n=9)	HSSPs <sup>a</sup> (n=4)	CWs <sup>b</sup> (n=7)
<b>Gender, n (%)</b>			
Women	8 (40)	4 (20)	4 (20)
Men	1 (5)	0 (0)	3 (15)
<b>Age range (years), mean (SD)</b>			
25-54	N/A <sup>c</sup>	N/A	43 (9.0)
31-49	N/A	37 (8.3)	N/A
44-82	65 (11.6)	N/A	N/A
<b>Education level, n (%)</b>			
Elementary school	0 (0)	0 (0)	0 (0)
High school	2 (2)	0 (0)	0 (0)
College	0 (0)	1 (5)	1 (5)
University	7 (35)	3 (45)	6 (30)

<sup>a</sup>HSSP: health and social service professional.










<sup>b</sup>CW: community worker.

<sup>c</sup>N/A: not applicable.

### Sessions

[Table 3](#) presents the description of the sessions, objectives, and methods used to reach the objective.

**Table 3.** Session description.

Session	Objectives	Methods	Screen capture of the session
Advisory committee 1—Centre-du-Québec	Validate the design decision made during the first 2 co-design sessions on user needs. Address conflicting results.	Plenary discussion. Face-to-face and videoconference participation.	
Co-design 3—Saguenay	Identification of user needs already met by other tools and identification of functionalities and content of existing tools related to those needs (what co-designers would keep, modify, or change).	Comparison of existing eHealth information and communication technology tools (websites and apps). Small group workshop using a speed dating approach.	
Co-design 4—Bas-Saint-Laurent	Identification of functional or content requirements for the needs not met by existing tools.	Plenary brainstorming and small group workshops.	
Co-design 5—Gatineau, Outaouais	Prioritization of functional requirements and design of information architecture.	Paper prototyping in small group workshops.	
Advisory committee 2—Centre-du-Québec	Decision on conflicting requirements (no consensus reached).	Plenary discussion. A total of 2 documents presenting the results and 3 different clickable PDF prototypes. Face-to-face and videoconference participation.	
Co-design 6—Montréal-Laval	Information design (content creation).	Plenary presentation and small group brainstorming workshops.	
Co-design 7—Trois-Rivières, Mauricie	Information design (content creation).	Plenary presentation and small group brainstorming workshops.	
Co-design 8—Montérégie	Information design (content creation) and interface design.	Small group brainstorming workshops. Usability evaluation with a low-fidelity prototype (version 1). Discussion on interface design of the prototype.	
Advisory committee 3—Centre-du-Québec	Decisions on conflicting results. Obtaining feedback on the latest version of the prototype before website programming.	Medium-high-fidelity prototype (version 2). Plenary discussion. Face-to-face and videoconference participation.	

## Emerging Themes

Looking at the results with codes counting only once per document (course-of-action framework of each participant), a total of 5 emerging themes of experience were identified for the entire project: *perception of extrinsic constraints and effects of the situation* (27/74, 36%), *learning together* (14/74, 19%), *frustrating interactions with others* (6/74, 8%), *destabilization* (18/74, 24%), and *getting personal benefits* (9/74, 12%). [Table 4](#) presents the definitions of the themes and the subthemes related to them.

There were important differences depending on the category of participant (caregivers, health and social service professionals,

and community workers) and type of session (co-design sessions and AC meetings). *Perception of extrinsic constraints and effects of the situation* was strongly mentioned by health and social service professionals (6/19, 32%) and community workers (16/35, 46%) and less by caregivers (5/20, 25%). It was strong during both types of sessions (co-design sessions: 19/55, 35%; AC meetings: 8/19, 42%). The most important theme mentioned by caregivers was *destabilization* (8/20, 40%), which was also stronger during AC meetings (6/19, 32%) than during co-design sessions (12/55, 22%). *Learning together* was another theme that was strong for health and social service professionals (6/19, 32%). The percentage represents the importance of a theme for a category of participants and the type of session in the overall experience for each.

**Table 4.** Themes and subthemes of participant experience.

Theme	Definition	Subthemes
Perception of extrinsic constraints and effects of the situation	On the basis of the extrinsic constraints related to the situation [22]. Perceptions related to effects of the prescribed tasks (or lack thereof) modulating the course of action of the actor. Can apply to either task during sessions or the organization of sessions.	<ul style="list-style-type: none"> <li>• Impression of a lack of guidance or structure from the moderator</li> <li>• Satisfied with useful inputs from the moderator helping them understand</li> <li>• Impression of wasting time on circular discussions</li> <li>• Expecting to work on a more advanced prototype</li> <li>• Perception of insufficient time allowed to reach the objectives</li> <li>• Satisfied with the convenience of small groups</li> <li>• Wishing they had been able to prepare in advance</li> <li>• Satisfied with balanced representation of participant categories (or the opposite)</li> <li>• Feeling they are not really participating or not enough</li> <li>• Wishing for more facilitation from the moderator to provide a democratic space</li> </ul>
Learning together	Inspired by level 3 of the typology of relationships of participation (learning together) by Harder et al [37]. Represents a form of interaction with others where the focus is learning from others' opinions.	<ul style="list-style-type: none"> <li>• Wanting to help caregivers</li> <li>• Wanting to obtain caregivers' opinion</li> <li>• Being able to have access to a diversity of opinions</li> </ul>
Frustrating interaction with others	Feelings related to interactions with other participants. Something that a participant (or more) is doing or saying that is annoying to the person. An irritating experience leading to frustration.	<ul style="list-style-type: none"> <li>• Having strong emotions hearing about a caregiver's situation</li> <li>• Annoyed by the confrontation of perspective</li> </ul>
Destabilization	Uncomfortable, unbalanced, or disruptive feeling not caused by an interaction with other participants.	<ul style="list-style-type: none"> <li>• Disappointment at the lack of joint efforts on the project</li> <li>• Feeling lost, not understanding, or having a lack of knowledge</li> <li>• Unsure about which perspective to adopt</li> <li>• Perceived incapacity to reach the objective of the task</li> <li>• Having trouble with the abstract nature of the task</li> </ul>
Getting personal benefits	Positive contribution to personal interests.	<ul style="list-style-type: none"> <li>• Learning about resources</li> <li>• Feeling valued by their contribution (caregivers)</li> </ul>

### Visual Mapping of Co-occurrences Between Themes and Subthemes

As mentioned in the *Methods* section, the themes were not mutually exclusive. Figure 3 provides a visual representation of the co-occurrences of themes. It also presents a mapping of the experiences of the participants during this co-design research project. The links between themes and subthemes illustrated in this figure indicate the multiple ways in which the experiences of the participants can be understood.

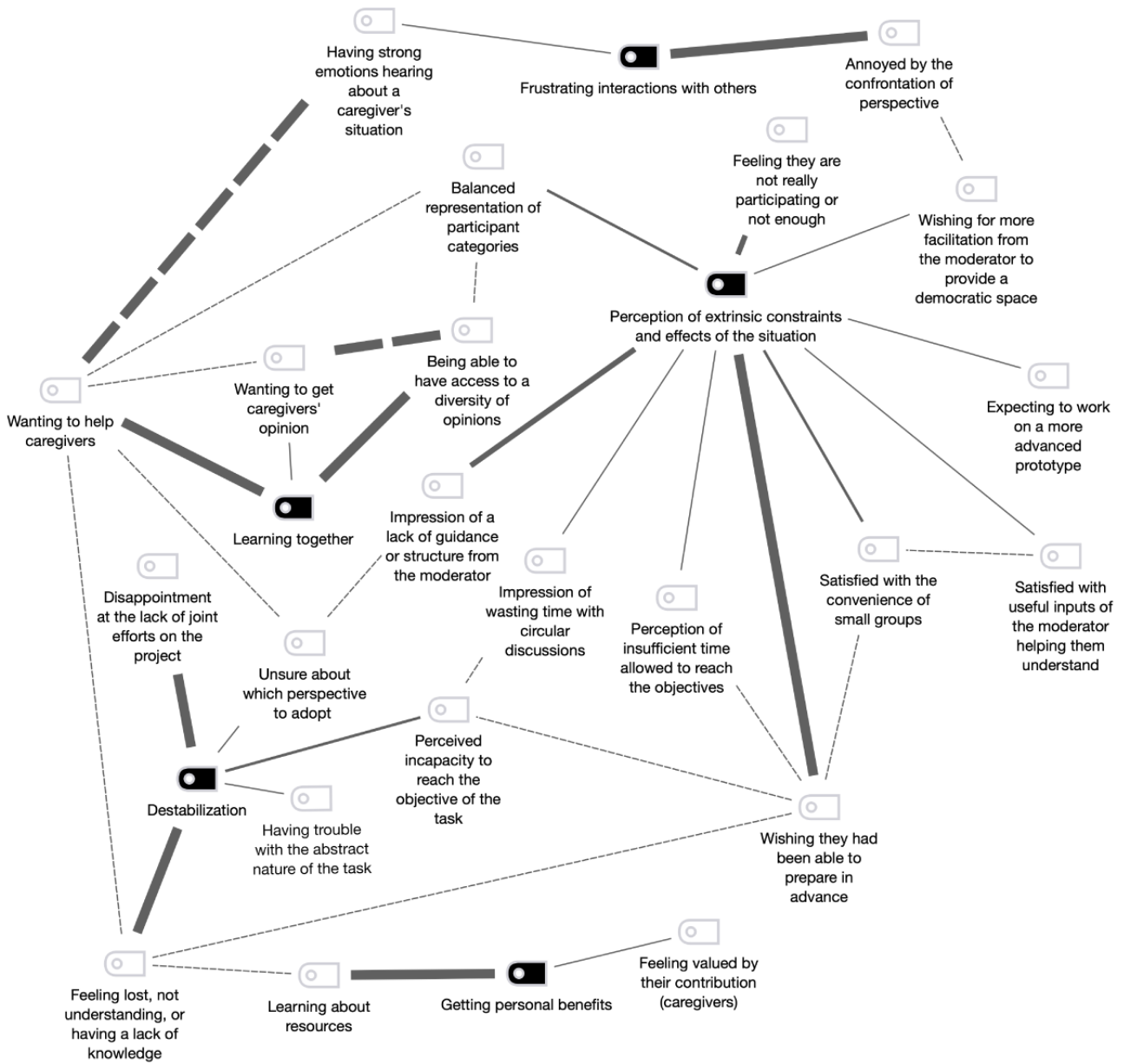
Figure 3 demonstrates the central position of the *perception of extrinsic constraints and effects of the situation* for all sessions, with the prominent star shape and many of its subthemes being linked with other experiences. This theme was strongly mentioned by the participants, and Figure 3 allows us to follow the path of their experience. For example, it shows that *extrinsic constraints* is related to *destabilization* through *impression of a lack of guidance or structure from the moderator*, leading to being *unsure about which perspective to adopt*. The fact that

they were *wishing they had been able to prepare in advance*—leading to *feeling lost, not understanding, or having a lack of knowledge*—also connects *extrinsic constraints* and *destabilization*. We can see that the *extrinsic constraints* of *wishing for more facilitation from the moderator to provide a democratic space* led the participants to be *annoyed by the confrontation of perspective*, which was included in *frustrating interactions with others*. More positive effects can also be seen. For example, *extrinsic constraints* leads to *balanced representation of participant categories*, which is linked with *wanting to help caregivers* and *being able to have access to a diversity of opinions*, leading to *learning together*.

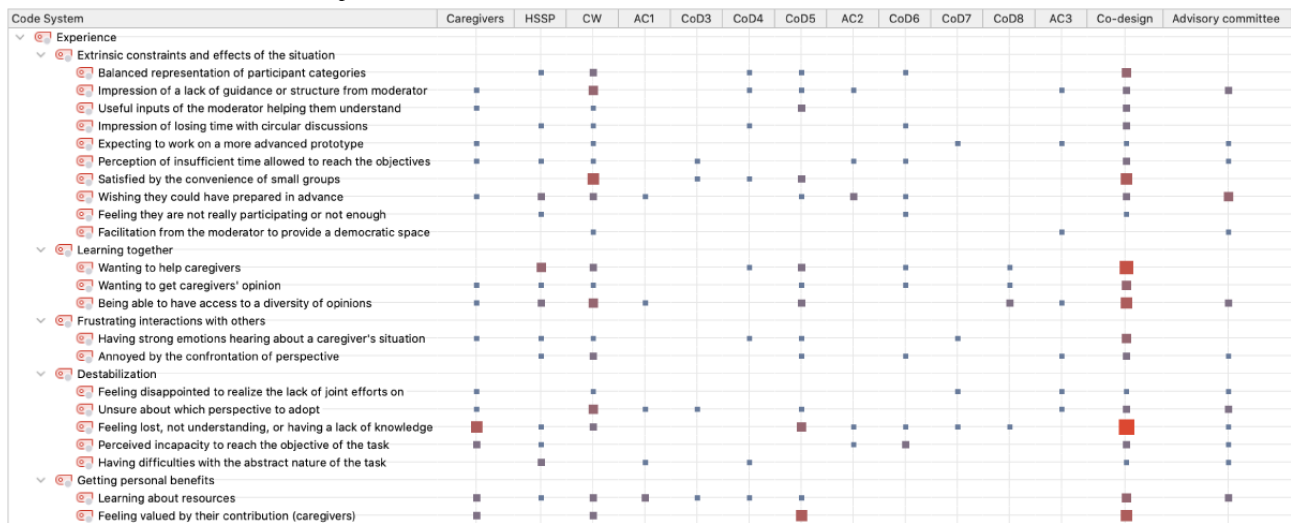
Figure 4 provides context for the themes and subthemes. This figure offers a situated explanation of Figure 3. The first 3 columns divide the experiences among the 3 categories of participants. The next columns indicate the sessions, and the last 2 columns gather the experience for the type of session (co-design and AC).



**Figure 3.** Relationship between mutual themes. This figure was produced using the MAXMap functionality in MAXQDA (VERBI GmbH). Themes are in black, and subthemes are in white connected by solid lines. Dotted lines represent the co-occurrences of codes, and the thickness of the lines represents the importance of the connection (numbers). Adapted from Tremblay [5], which is published under Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License (CC BY-NC-SA 4.0) [27])



**Figure 4.** Themes and subthemes by session and type of participant. This figure was produced using the Code Matrix Browser functionality in MAXQDA (VERBI GmbH). The calculation of the square size refers to all the coded segments. AC: advisory committee; CoD: co-design session; CW: community worker; HSSP: health and social service professional.



## Understanding Experience With the Hexadic Sign

### Overview

The aforementioned figures provide an in-depth understanding of the experience of the participants if we investigate the signs and their components. The course-of-action methodology produces an important quantity of qualitative data (signs and components). The map helped us select qualitative data to present based on what was significant for the participants, visually highlighted in the map. The sign and its components provide a detailed description of the cognitive aspects underlying the action at the junction of each theme and its subthemes.

### Preparation and Moderation of Sessions

The map highlights the importance of the role of the research team in the preparation and moderation of the sessions. For example, the link between *wishing they had been able to prepare in advance* and *perceived incapacity to reach the objective of the task* was mentioned by caregiver 11-11 (AC 2) as she did not have sufficient information to properly understand the research project (component R) and would have liked to obtain all the documents before the session (component I). The link between *feeling lost, not understanding, or having a lack of knowledge* and *wishing they had been able to prepare in advance* was also mentioned by caregiver 11-11 at the end of the session (AC 2):

*I did not familiarise myself with the document, I only got it today. I realise that it is very focused on computers...I don't use computers much (U).*

The link between *impression of wasting time with circular discussions* and *perceived incapacity to reach the objective of the task* was mentioned by health and social service professional 6-6. The first hour of this session (co-design session 6) was dedicated to presenting the progress of the work, explaining the workshops for this session, and providing information on digital health literacy.

*Destabilization* occurred for 10% (2/20) of the participants during the first and second ACs. Health and social service

professional 11-5 was destabilized because she was *having trouble with the abstract nature of the task*. The first AC was held after only 2 co-design sessions, which were mainly focused on user needs. Caregiver 11-11 was destabilized as she did not fully understand her role before engaging in the project. She thought she was just going to share her experience (component A) but realized that the session was putting her back into a work mode (she was a former nurse; component R), which she did not want (component I). She was *feeling lost, not understanding, or having a lack of knowledge* (component S). Although she could have continued to participate as she was part of the AC, she desisted after the session. These 2 reasons were also a source of *destabilization* for other caregivers during co-design sessions (caregiver 5-7, caregiver 6-9, and caregiver 7-7, who was talking about another caregiver participating in the session).

### Interaction Among Participants

The map and sign also provide a detailed description of the interaction between participants during the sessions, which is a core aspect of the co-design approach. The link between *wanting to help caregivers* and *having strong emotions hearing about a caregiver situation* was mentioned by 10% (2/20) of the participants. The first one was health and social service professional 4-4 (co-design session 4). She realized during the session that the caregiver might be upset at hearing that other caregivers were receiving services, whereas she was not (component I). Health and social service professional 4-4 wanted to help this caregiver during the break (component U) to avoid her going back home discouraged by that (component E). The second participant was community worker 5-1, who was alone with caregiver 5-7 (co-design session 5). He was working for her. She was having a difficult time (component R), and community worker 5-1 felt he needed to help her (component U). This participant was dissatisfied with the lack of *balanced representation of participant categories*. He was surprised to be alone with a caregiver (component U) and felt that input from a health and social service professional would have been interesting (component I), explaining the link between this subtheme and *being able to have access to a diversity of opinions*. He mentioned that he would have contributed

differently if he had been placed in another group (component I).

The link between *being able to have access to a diversity of opinions* and *wanting to get caregivers' opinion* was mentioned by 10% (2/20) of the participants. The first one was community worker 5-4 (co-design session 5), who stepped back (component U) as she wanted to let the caregiver talk (component E). She realized that this caregiver was allowing her to obtain another point of view on how caregivers search for resources (component I). The second participant was caregiver 8-9 (co-design session 8), who was with another caregiver in her subgroup workshop. The other caregiver was providing a different opinion from hers, and caregiver 8-9 was interested in seeing how different it was for other caregivers.

The results also show that the caregiving culture was not completely shared by the participants as they were reinterpreting aspects of it. *Frustrating interactions with others* was very strong for health and social service professional 4-4 during co-design session 4. This participant realized during the activity that a caregiver was not receiving the resources she was entitled to (component R). This experience began with a short moment at the beginning of the session (00:37:42). The caregiver said the following:

*I have a social worker, but I think we are not high priority for them because I've been waiting for 3 months now.*

A total of 10 signs from health and social service professional 4-4 were somehow related to this initial situation, with emotions (component U) moving from incomprehension to discouragement and anger. Health and social service professional 4-4 even said during the interview that it was pretty much the end of the session for her:

*I would say, at this point, I was not thinking about the tool [anymore]. It pretty much ended my meeting (I).*

For community workers, 93% (14/15) of the coded signs were from a single participant (community worker 11-6) during the last AC meeting. Community worker 11-6 had a disagreement with another participant about the language that should be used and the posture behind it (patient-centered).

## Discussion

### Principal Findings

Our objective was to explore the potential of the course-of-action framework [21-23] to describe the intrinsic experience—from the perspective of experience by Dewey [14]—of potential users participating in a co-design research project. Our results showed that this framework was particularly well suited for our objective. *Perception of extrinsic constraints and effects of the situation* appeared to be central in this co-design research project, leading to positive and negative experiences for the participants. The course-of-action framework links the intrinsic description with the extrinsic description. However, the extrinsic constraints and effects of the situation should not be confused with the extrinsic description, which is the description by the

researcher performed in the first phase of data collection. The extrinsic constraints and effects of the situation are what the participants identified (their intrinsic description) as elements of the situation that affected their experience. Through their experience, the participants shared the positive and negative effects of the extrinsic constraints of the situation. The results highlight the importance of the role of the research team in preparing and moderating the sessions and provide a detailed description of the interaction between participants during the sessions, which is a core aspect of the co-design approach.

Our results allow us to propose ways to better shape the participant experience [26]. We do not argue that optimizing the experience of the participants will systematically optimize the information obtained by the design. The rationale is that the participation of people is what distinguishes the co-design approach from other design methods. Therefore, they are an essential aspect of data collection. Taking responsibility in the co-design research approach requires reflecting on what designers and researchers can offer participants [38]. This includes offering them a positive and contributory experience to encourage their participation in future co-design projects.

We suggest avenues for shaping the co-design experience as affordances to empower participation [39] reflecting on what was significant in the experience of the participants from their point of view. Affordances, described by Gibson [40], are what the environment provides to the living and, as mentioned by Dewey [14], “[a]t every moment, the living creature is exposed to dangers from its surroundings, and at every moment it must draw upon something in its surroundings to satisfy its needs.” The following affordances are suggestions for co-design researchers to shape the co-design experience for the participants.

### Affordances to Shape the Experience of Co-design

#### ***Provide Clear Information to the Participants About the Co-design Session in Advance***

The participants were *wishing they had been able to prepare in advance*, leading to *feeling lost, not understanding, or having a lack of knowledge*, which in turn affected their participation. Bossen et al [41] noted similar results, identifying project organization as an impediment to user gains. Other negative effects were *feeling they [were] not participating enough* during the long presentation period at the beginning of the session and *expecting to work on a more advanced prototype*, experienced by 10% (2/20) of the participants during the last sessions (co-design sessions 7 and 8). Clear and detailed information provided in advance will allow the participants to know exactly what they will be working on so that they can prepare and have sufficient knowledge to participate and quickly engage in co-design. The participants should be active early in the process, and long, passive presentation periods should be avoided. The information they need could be sent before the session to shorten the introduction part of the process.

#### ***Work in Small Groups With a Moderator and Ensure a Balanced Representation of Categories of Participants***

Among the positive effects, the participants were *satisfied with useful inputs of the moderator helping them understand* and

satisfied with the convenience of small groups. They were also satisfied with the *balanced representation of participant categories*, with an unbalanced representation leading to negative effects on participant experience. This subtheme was linked with *being able to have access to a diversity of opinions*, which is part of *learning together*. Learning together is indeed a constitutive component of the co-design approach [37]. The small groups and the input of the moderator facilitate the *learning together* experience.

### **Optimize Collaboration by Orienting Toward Positive and Constructive Interactions Among Participants**

The participants were *wishing for more facilitation from the moderator to provide a democratic space*, with the lack of facilitation leading some to be *annoyed by the confrontation of perspective*. This is consistent with Tironi [42], who discussed design activities or the process of designing as a space for differences and frictions, reflecting ontological differences among the participants. Dissensus might be a way to innovation [43], but guidance should be provided to avoid transforming dissensus into confrontation, which, in the end, can hinder innovation. We could remind the participants that co-design is a space for dissensus and that all co-designers should adopt a constructive criticism approach. A conflict management protocol could also be helpful.

### **Provide Clear Guidance and Structure**

The *impression of a lack of guidance or structure from the moderator* was sometimes related to the participants being *unsure about which perspective to adopt*. This was the case for community workers not knowing whether they should participate in the role of community worker or put themselves in the caregivers' shoes. This might be specific to this project considering the typical care relationship between service providers and caregivers. Nevertheless, having different categories of participants is inherent to co-design projects. With the goal of adopting empathy in the co-design process [44], it should be clear to the participants which role we want them to adopt for a specific activity.

### **Define Realistic Objectives for the Time Allowed for Each Session**

The participants also had a *perception of insufficient time allowed to reach the objectives* and an *impression of wasting time with circular discussions*, both of which pertain to time constraints, also pointed out by Bowen et al [45], leading to *perceived incapacity to reach the objective of the task* in the theme *destabilization*. This might be difficult to achieve as it is not possible to foresee how the participants will engage in the tasks, and some objectives can take longer to achieve than others. The participants need to feel that their contribution was valuable. They ought to be able to have a satisfying experience. Therefore, it should be made clear to them that their contribution is valuable even if not all of the objectives are reached during a session.

### **Allow Participants to Derive Personal Benefit From Their Participation**

*Learning together* is part of the benefit that participants can derive from their participation. In this co-design project, other potential benefits for the participants were *learning about resources* and *feeling valued for their contribution*. From an ethical perspective of co-design, we should make a commitment to offer benefits to our participants and assume the responsibility for doing so [38].

### **Guide Participants Toward a Cocreative Design Thinking Mode**

Acting as co-designers, the participants are called on to engage in design thinking in terms of designerly ways of knowing [46], which is not necessarily usual for them. In our data, no subthemes or themes were specific to the design of the tools. This appears not to be significant in their experience. Following Manzini [7], we believe that the designers should act as facilitators to help participants understand this mode of thinking and engage in it. It is through this expertise of facilitating design thinking that the designers can offer a meaningful contribution by putting in place the necessary conditions to allow the participants to contribute in their own way.

### **Organize Co-design Projects in Terms of Life Experience and Focus on Empathy Toward the Situation**

Co-design research projects should focus on empathy toward the situation and the participants rather than using a solution-oriented approach [42]. We cannot entirely foresee where the project will lead. In this project, the design of the tool was not identified as a theme in the participants' experience. *Extrinsic constraints and effects of the situation* was the most important theme. More empathy toward the situation might have allowed us to reduce the importance of these constraints, avoid *frustrating interactions with others* by embracing dissensus and orienting co-designers toward constructive interactions, avoid *destabilization* by providing more information in advance, and enhance *learning together*, perhaps being able to reach the last level of participation in the typology by Harder et al [37]: learning as one.

### **Contribution of the Course-of-Action Framework to Describe the Experience**

The course-of-action methodology required a significant appropriation period and a great deal of time for data collection and analysis, but the results were extremely rich. Using the course-of-action methodology, we were able to gain an in-depth understanding of the cognitive aspects underlying the participants' experiences. Moreover, the course-of-action framework did not aim to describe the entire session but rather significant parts of it from the participants' point of view, representing the perspective of experience by Dewey, as pointed out by Laudati and Leleu-Merviel [26]. We believe that the results would not have been as detailed with another methodological approach.

The use of video recording to confront the participants was particularly useful to help them remember the situation and activate their prereflexive consciousness (what they were

thinking at that specific moment). Without this, it might have been difficult for the participants to remember exactly what they were thinking. Moreover, we believe that the reconstitution of the sign and its components significantly strengthened and deepened our understanding of the cognitive aspects underlying the actions of the participants (expectations, involvement, referential, and interpretant). We believe that the extra effort of data collection and data analysis was valuable for our objective.

### Challenges and Limitations

Our study had certain limitations. First, the results presented cannot be considered to account for a saturation of the experience for each moment and each step of the co-design project. We had a defined number of data points, and we performed an in-depth analysis of these following the situated cognitive anthropology of the course-of-action framework. The described experience only applies to the participants included in our data collection.

Second, identifying significant moments for the participants was occasionally a challenge. Moreover, significant moments emerged during the self-confrontation interviews, also described by Perrin [47]. Our study shows that, to address this issue, the researcher must remain highly flexible and allow the participant to *guide* the interview by focusing on the moment they want to talk about. Researchers must sometimes temporarily suspend their own involvement in favor of an approach that is open to the participant's experience [33]. This was especially true as MT had a design background and was sometimes tempted to orient the discussion during interviews to gain more design insights. The partial chronicle helped maintain focus on the session and on the experience of the participant during the interview.

Third, data collection and analysis were influenced by the researchers' course of action. Although we were not able to find any clear mention of this within the course-of-action scientific community, it is consistent with the epistemological perspective of human activity within the course-of-action framework—the activity is cognitive, situated, and dynamic [48]. These considerations of the activity apply to both participants and researchers. As stated by Leblanc [25], the researcher is not in a passive position with regard to the analyzed situation but, rather, is engaged in a collective program with the participants to understand the activity, seeking a compromise between the

scientific community's rigorous expectations and the expectations of the communities under study. From this perspective, it seems utopian to expect a completely objective analysis. As Theureau [21] said, the researcher is an essential instrument for data collection in anthropological research, simultaneously an observer and an interlocutor. The data are coconstructed through the researcher's interaction with the participant, and researchers must acknowledge the effects of this interaction on the situations they are studying.

Finally, the results might have been different if the researcher-designer had been completely engaged in facilitating design thinking with the participants during co-design and AC sessions. The researcher-designer was not identified as a designer for data collection purposes. The anonymity of the role of the designer hindered the possibility of completely engaging in a designer-facilitator role. In that sense, we did not completely follow the co-design approach of Manzini [7]. Participants and members of the research team were all co-designers, but we believe that the role of the designer as designer of the experience for participants in the co-design project and designer-facilitator should not be neglected.

### Conclusions

This paper explored what we can learn from participants' experiences to inform the co-design process. The course-of-action framework strongly contributed to providing a detailed and in-depth description of the experiences of potential users engaging in a co-design research project. We were able to capture what was significant to them from their own perspective. The perception of extrinsic constraints and effects of the situation was the most important theme, leading to positive and negative experiences for the participants. The results highlight the importance of the role of the research team in preparing and moderating the sessions. They also provide a detailed description of the interaction between participants during the sessions. Potential users are essential to the co-design research approach. Researchers and designers should seek to offer them a positive and contributory experience. Reflecting on our results, we proposed affordances to shape the co-design process and, thus, inform researchers and practitioners about potential settings that could lead to a more positive experience for the participants and potentially more fruitful results. Future research should explore how the proposed affordances influence the success of the intervention.

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### Conflicts of Interest

None declared.

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## Abbreviations

**AC:** advisory committee

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Original Paper

# The Influencing Contexts and Potential Mechanisms Behind the Use of Web-Based Self-management Support Interventions: Realistic Evaluation

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## Abstract

**Background:** Self-management can increase self-efficacy and quality of life and improve disease outcomes. Effective self-management may also help reduce the pressure on health care systems. However, patients need support in dealing with their disease and in developing skills to manage the consequences and changes associated with their condition. Web-based self-management support programs have helped patients with cardiovascular disease (CVD) and rheumatoid arthritis (RA), but program use has been low.

**Objective:** This study aimed to identify the patient, disease, and program characteristics that determine whether patients use web-based self-management support programs or not.

**Methods:** A realistic evaluation methodology was used to provide a comprehensive overview of context (patient and disease characteristics), mechanism (program characteristics), and outcome (program use). Secondary data of adult patients with CVD (n=101) and those with RA (n=77) were included in the study. The relationship between context (sex, age, education, employment status, living situation, self-management [measured using Patient Activation Measure-13], quality of life [measured using RAND 36-item health survey], interaction efficacy [measured using the 5-item perceived efficacy in patient-physician interactions], diagnosis, physical comorbidity, and time since diagnosis) and outcome (program use) was analyzed using logistic regression analyses. The relationship between mechanism (program design, implementation strategies, and behavior change techniques [BCTs]) and outcome was analyzed through a qualitative interview study.

**Results:** This study included 68 nonusers and 111 users of web-based self-management support programs, of which 56.4% (101/179) were diagnosed with CVD and 43.6% (78/179) with RA. Younger age and a lower level of education were associated with program use. An interaction effect was found between program use and diagnosis and 4 quality of life subscales (social functioning, physical role limitations, vitality, and bodily pain). Patients with CVD with higher self-management and quality of life scores were less likely to use the program, whereas patients with RA with higher self-management and quality of life scores were more likely to use the program. Interviews with 10 nonusers, 10 low users, and 18 high users were analyzed to provide insight into the relationship between mechanisms and outcome. Program use was encouraged by an easy-to-use, clear, and transparent design and by recommendations from professionals and email reminders. A total of 5 BCTs were identified as potential

mechanisms to promote program use: tailored information, self-reporting behavior, delayed feedback, providing information on peer behavior, and modeling.

**Conclusions:** This realistic evaluation showed that certain patient, disease, and program characteristics (age, education, diagnosis, program design, type of reminder, and BCTs) are associated with the use of web-based self-management support programs. These results represent the first step in improving the tailoring of web-based self-management support programs. Future research on the interaction between patient and program characteristics should be conducted to improve the tailoring of participants to program components.

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## KEYWORDS

self-management; telemedicine; chronic disease; cardiovascular diseases; rheumatoid arthritis; patient dropouts; realistic evaluation; program use

## Introduction

Chronic diseases are a major burden for patients, and the growing number of people with (several) chronic conditions puts a strain on our health care systems. The pressure on health care services may be decreased and the quality of life of people with chronic conditions may be improved if these individuals can self-manage their condition and adapt to their situation [1-3]. Self-management is defined as “the individual’s ability to manage the symptoms, treatment, physical consequences, psychological consequences and lifestyle changes inherent in living with a chronic condition” [4]. This is not easy for patients with chronic conditions because they may not feel confident enough to manage their disease [5,6]. Factors such as disease burden, comorbidities, and competing life circumstances can impair a patient’s capacity to self-manage their condition. These obstacles can be overcome with the help of health care professionals, support staff, peers, or digital support programs.

Self-management support interventions have already been developed for a broad range of long-term medical conditions and have shown improvements in self-management and other health outcomes [7,8]. However, it is challenging to establish self-management support that is feasible for both patients and health care professionals. Web-based self-management support programs may overcome these barriers by providing disease-specific information and personal feedback and by monitoring behavior [9]. Web-based interventions have become more frequent in response to the COVID-19 pandemic, and health care professionals and patients have become more open to digital solutions. Adherence to and uptake of web-based interventions are essential for increasing self-management. However, despite advantages such as easy accessibility and anonymity, studies have shown that the use of and exposure to web-based self-management interventions are unsatisfactory [10,11].

We recently developed 2 comprehensive, multicomponent, and theory-based web-based self-management interventions using the intervention mapping framework [12]: one for patients with cardiovascular disease (CVD) called Vascular View and one for patients with rheumatoid arthritis (RA) called Coping with RA. Both programs were developed in close collaboration with patients and health care professionals to promote their use and meet patients’ needs. These programs have been described in detail elsewhere [13-16]. Unexpectedly, explorative randomized

controlled trials showed no effect of these programs on self-management, possibly because patients were not using them, even though we tried to match them to patients’ needs. Vascular View was used by 62.4% (65/101) of the intervention group and Coping with RA by 63% (50/78) of the intervention group. This phenomenon of participants dropping out of or not using an intervention is called *the law of attrition* and is a major challenge when developing and evaluating eHealth interventions [17].

There are many reasons why participants use or do not use a web-based self-management program. Patient characteristics, such as older age, lower education levels, and lower income, have been associated with lower eHealth use [18-20]. Self-management ability, self-efficacy, and quality of life may also be influencing factors, as they are associated with self-management [21,22]. The use of eHealth interventions demands that patients take control of their chronic diseases; therefore, a basic level of self-management is a prerequisite for the use of web-based interventions. Disease characteristics, such as disease burden, may also influence program use. For example, although some patients with CVD do not experience physical symptoms, they still have to adapt their daily routine by making lifestyle changes and taking medication. Patients with CVD might also experience psychosocial consequences, such as being anxious about a secondary cardiovascular event. RA has a more direct physical impact on patients with symptoms such as pain, stiff joints, and fatigue. RA also has psychosocial consequences on patients, such as changes in social roles and feelings of depression. These differences between CVD and RA may influence the self-management needs and program use of these patients. Finally, program characteristics, such as the type of information or applied implementation strategies, may influence whether a patient uses the program [23,24].

In this study, we identified the patient, disease, and program characteristics that determine whether patients with CVD and patients with RA use the Vascular View and Coping with RA web-based self-management support programs. The findings can be used to tailor web-based self-management support programs to individual patients and thereby increase their use.

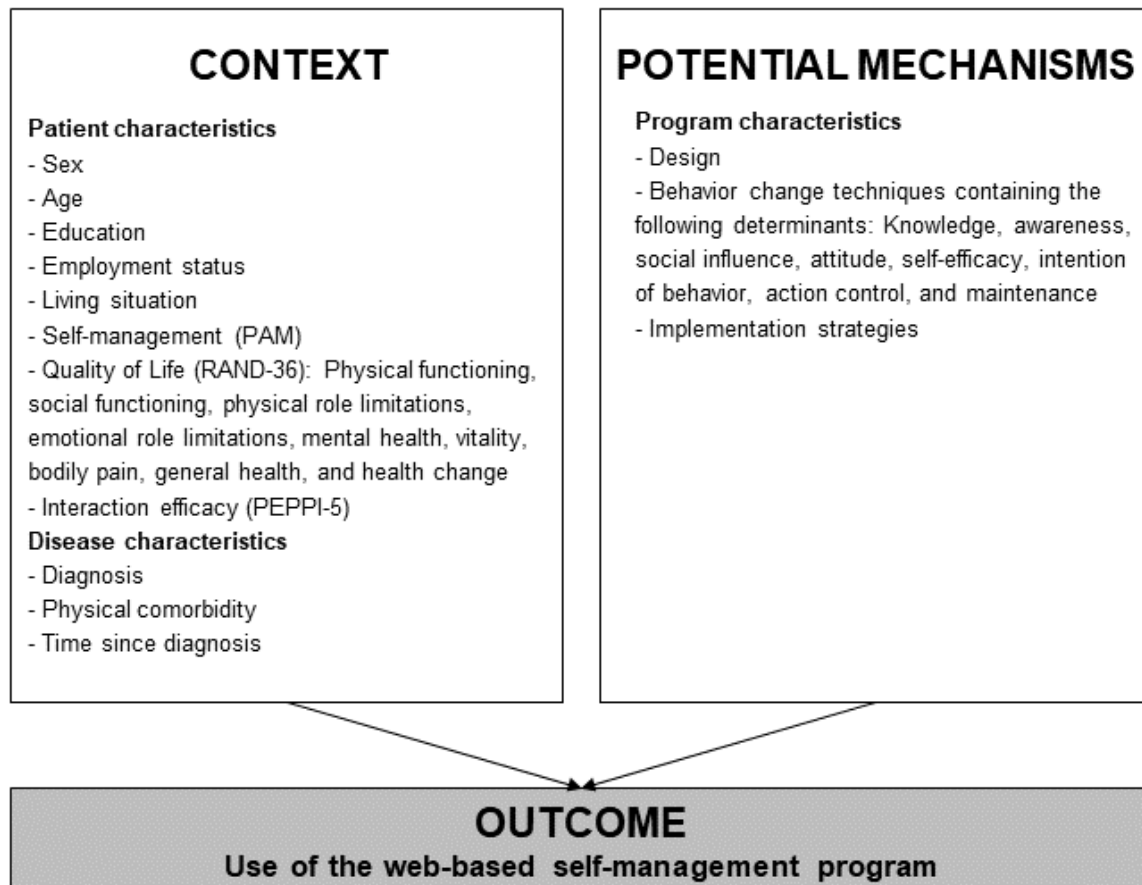
## Methods

### Design

The realist evaluation methodology was used to gain a comprehensive understanding of why patients use or do not use web-based self-management support interventions [25]. We structured the analysis using the context-mechanism-outcome configuration to identify contextual factors (features of the

conditions, eg, patient characteristics, that influence the intervention mechanisms) and potential mechanisms (what and how intervention components are responsible for change) that affect the intervention outcome (Figure 1). The identified mechanisms are described as “potential” as it was beyond the scope of this study to also test their effectiveness. In this study, we used data from 2 previous studies [14,16] that were approved by the medical ethics committee of Arnhem-Nijmegen in the Netherlands (No. 2015-1908 for CVD and 2014-1208 for RA).

**Figure 1.** Realistic evaluation: context, potential mechanisms, and outcome. PAM: Patient Activation Measure; PEPPI-5: 5-item version perceived efficacy in patient-physician interactions; RAND-36: RAND 36-item health survey.



### Context: Patient and Disease Characteristics

#### Overview

This study included data of 2 patient groups with a chronic disease. Patients in the CVD group had experienced a myocardial infarction, cerebrovascular disease, or peripheral artery disease or a combination of these within 2 months to 1 year of the study starting. Patients in the RA group were diagnosed with RA, a chronic autoimmune disease that predominantly affects the joints, before the start of the study. The baseline data were collected at the start of each study. Inclusion criteria were as follows: (1) aged  $\geq 18$  years; (2) ability to read and understand Dutch; (3) access to a computer, internet, and email account; and (4) not receiving psychiatric or psychological treatment.

### Measurements

The included patient and disease characteristics are expected to be associated with self-management and might, therefore, be related to program use. The following patient characteristics were studied to determine whether they were associated with program use: sex (male or female), age (years), education (low: no education, primary education, or lower secondary education; intermediate: secondary vocational education; and high: higher education or university), work participation (yes or no), living situation (alone or together), self-management, quality of life, and communication efficacy. Self-management was measured using the Patient Activation Measure (PAM-13), which includes statements about an individual's knowledge, confidence, and skills for self-management of their behavior in response to their chronic illness and about their level of activation. The PAM-13 scores 13 items on a 5-point scale, with a higher score indicating

a higher level of patient activation [26,27]. Quality of life was measured using the RAND 36-item health survey (RAND-36), which contains 36 items measuring 8 dimensions: physical functioning, social functioning, physical role limitations, emotional role limitations, mental health, vitality, pain, and general health perception [28]. A higher score indicates a better quality of life. Communication efficacy was measured using the 5-item perceived efficacy in patient-physician interactions, which scores 5 items on a 5-point Likert scale that are summed to determine the total score. A higher score reflects greater confidence in interactions with the health care professional [29,30]. A total of 3 disease characteristics were included: diagnosis (CVD or RA), time since diagnosis (years), and physical comorbidity (yes or no).

### ***Mechanism: Program Characteristics***

A total of 2 comprehensive, multicomponent, web-based self-management programs were studied for this realistic evaluation: Vascular View and Coping with RA. [Multimedia Appendix 1](#) describes the characteristics of both the programs. There were similarities between the 2 programs and their execution. First, both the programs used the same web-based platform and program design. Second, health care professionals working in one hospital were asked to invite patients to participate in the study. Third, participants had unlimited access to the programs for 12 months between December 2014 and October 2016 and could use the program modules in any sequence and as often as they wanted. A total of 3 program characteristics were considered as potential mechanisms in this realistic evaluation: design, behavior change techniques (BCTs), and implementation strategies [31].

Vascular View was developed for patients with CVD [13] and contained six modules: (1) coping with CVD and its consequences, (2) setting boundaries in daily life, (3) lifestyle, (4) healthy nutrition, (5) being physically active in a healthy

way, and (6) interaction with health professionals. Relevant BCTs ([Table 1](#)) were translated to practical applications including general written information on the disease, reading quotes and watching videos of other patients with CVD as role models and receiving personalized feedback, and encouraging participants to write in diaries and perform exercises. Patients filled out a questionnaire to read which modules were recommended for them and received feedback after filling out a lifestyle questionnaire. The implementation strategies were applied in 4 ways. First, the patients received a written instruction manual and digital promotion flyer at the start of the program. Second, they received 1 telephone reminder if they had not used the program within 3 months. Third, they received email reminders if they had started modules but left them incomplete. Finally, a newsletter was sent every 2 months to all participants to informally remind them of the program.

Coping with RA was developed for patients with RA [15]. The program contained the following nine modules that dealt with health-related problems: (1) balancing rest and activity, (2) setting boundaries, (3) asking for help and support, (4) using medicines, (5) communicating with health professionals, (6) using assistive devices, (7) performing physical exercises, (8) coping with worries, and (9) coping with RA. BCTs (such as providing general information on the disease, self-monitoring, persuasive communication, modeling, self-persuasion, and tailoring) were translated into practical applications (such as texts, videos, exercises, and a medication intake schedule). The content of each program module was tailored to the specific user based on a questionnaire filled out at the start of the web-based program. A total of 3 implementation strategies were applied. First, health care professionals were asked to inform their patients about the web-based program during the consultation. Second, patients received a written instruction manual at the start of the program. Third, patients received biweekly email reminders to use the program.

**Table 1.** Overview of applied determinants and behavior change techniques per program.

Determinant	Behavior change techniques	Vascular View	Coping with RA <sup>a</sup>
Knowledge	Provide general information about health behavior	✓ <sup>b</sup>	✓
Knowledge	Increase memory and/or understanding of transferred information	✓	✓
Awareness	Risk communication	✓	✓
Awareness	Self-monitoring of behavior	✓	✓
Awareness	Self-report of behavior	N/A <sup>c</sup>	✓
Awareness	Delayed feedback of behavior	✓	N/A
Social influence	Provide information about peer behavior	✓	✓
Social influence	Mobilize social norm	✓	N/A
Attitude	Re-evaluation of outcomes and self-evaluation	✓	N/A
Attitude	Persuasive communication	✓	✓
Attitude	Reward behavioral progress	N/A	✓
Self-efficacy	Modeling	✓	✓
Self-efficacy	Practice and guided practice	✓	✓
Self-efficacy	Plan coping response	N/A	✓
Self-efficacy	Graded tasks and goal setting	✓	N/A
Self-efficacy	Reattribution training and external attribution of failure	✓	N/A
Intention of behavior	General intention formation	✓	N/A
Intention of behavior	Develop medication schedule	N/A	✓
Intention of behavior	Specific goal setting	✓	N/A
Intention of behavior	Review of general and/or specific goals	✓	N/A
Intention of behavior	Use of social support	N/A	✓
Action control	Use of cues	N/A	✓
Action control	Self-persuasion	N/A	✓
Maintenance	Goals for maintenance	✓	N/A

<sup>a</sup>RA: rheumatoid arthritis.

<sup>b</sup>✓: The behavior change technique was included in the program.

<sup>c</sup>N/A: not applicable.

## Outcome: Program Use

Program use was a dichotomous outcome and was divided into nonusers (0 or 1 visit) and users ( $\geq 2$  visits). The cut-off point between users and nonusers was arbitrarily set at 2 visits because this was seen as a reflection of whether a patient would have had the opportunity to benefit from the program.

## Analysis

### *Relation Between Context and Outcome: Quantitative Analysis*

All quantitative data were analyzed using SPSS Statistics (version 25; IBM Corp). Descriptive analyses were used to describe the patient and disease characteristics of nonusers and users. Differences between the characteristics were tested using 2-tailed *t* tests and chi-square tests. A 2-sided *P* value of  $<.05$  was considered statistically significant in all analyses.

Logistic regression analyses were used to determine which characteristics were associated with program use. Program use (nonuser or user) was the dependent factor. Patient and disease characteristics (sex, age, education, employment status, living situation, self-management, quality of life, interaction efficacy, diagnosis, physical comorbidity, and time since diagnosis) were tested as possible factors. The strength of the relations was interpreted using odds ratios with 95% CIs. Factors with a *P* value of  $<.20$  were tested in the final model. The model adequacy in the bivariate logistic regression was confirmed with a backward likelihood ratio test. As this is an explorative analysis, the Bonferroni correction was not applied to counteract the problem of multiple variables.

Sensitivity analysis was performed to compare the characteristics of users and nonusers in the CVD and RA groups. Logistic regression analyses were performed for all characteristics (sex, age, education, employment status, living situation, self-management, quality of life, interaction efficacy, diagnosis, physical comorbidity, and time since diagnosis) and for

diagnosis, characteristic, and diagnosis×characteristic. These analyses determined whether there was an interaction between the diagnosis and characteristic. The strengths of the relationships were interpreted using odds ratios with 95% CI.

**Relation Between Mechanism and Outcome: Qualitative Analysis**

As a sequence of efficacy studies of Vascular View and Coping with RA, interviews were conducted to provide insight into (1) why patients used or did not use the web-based program and (2) the experiences with the web-based program among users. The results of the qualitative study on the Coping with RA program have been described elsewhere [23]. In this study, we focused on a part of the interviews to determine potential program characteristics.

A random selection of Vascular View and Coping with RA users and nonusers were invited for an interview after data on the explorative randomized controlled trials were collected. Purposive sampling was used to select patients regarding the degree to which they used the program. The participants were

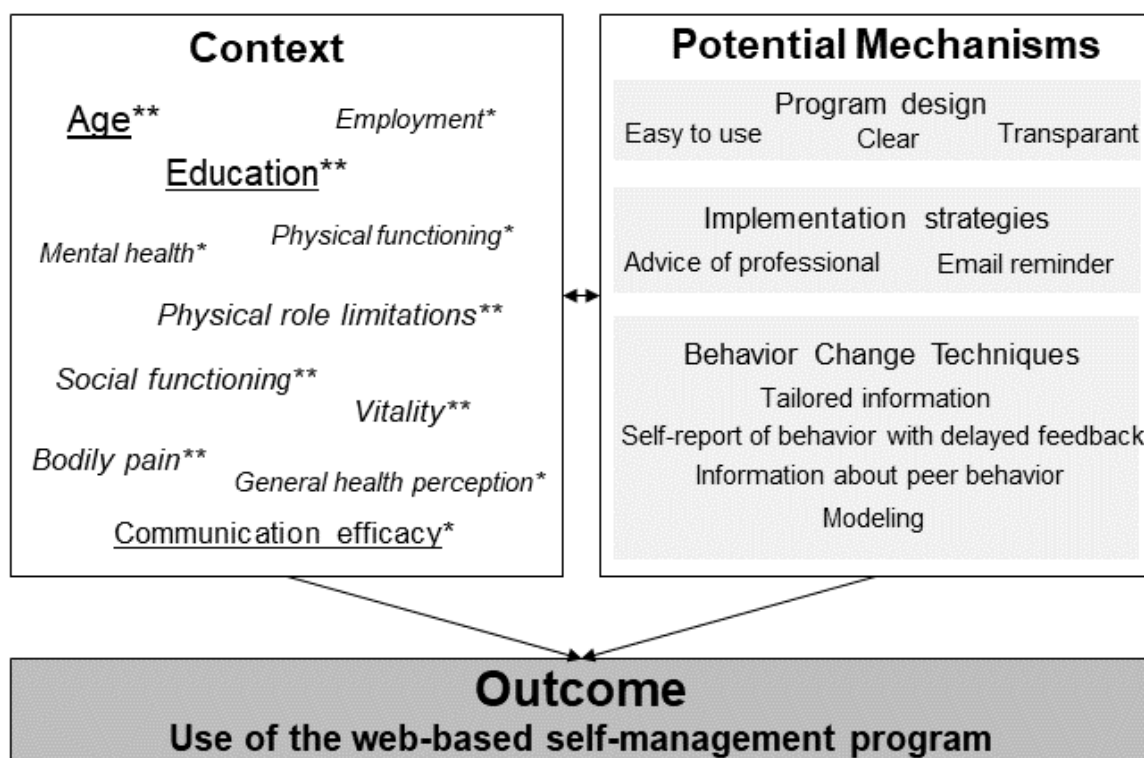
divided into 3 groups: nonusers, low users, and high users. After providing written consent, each patient was interviewed once via telephone. Semistructured interviews, lasting no longer than 30 minutes, were audio-recorded and anonymized. Interviews were transcribed verbatim and transferred to Excel (Microsoft). A total of 3 themes were determined beforehand: Program design, implementation strategies, and BCTs. The first researcher (ME) thematically analyzed the interviews to identify the potential program characteristics that influence use. First, the verbatim text was read and the relevant parts were marked. Next, the researcher determined barriers and facilitating factors for program use, which were divided into the 3 themes.

**Results**

**Overview**

We investigated the relations between context, mechanism, and outcome to determine which factors are associated with the use of a web-based self-management support program. Figure 2 summarizes the patient, disease, and program characteristics that influence program use.

**Figure 2.** Overview of patient and disease characteristics (context) and program characteristics (potential mechanisms) that influence program use (outcome). Underlined variables are factors associated with program use; italicized variables are factors associated with program use in the interaction effect with diagnosis; and the font size reflects the degree of prediction; \* $P < .20$ ; \*\* $P < .05$ .



**Relation Between Context (Patient and Disease Characteristics) and Outcome (Program Use)**

**Descriptive Data**

To analyze the relation between patient and disease characteristics (context) and program use (outcome), 68 patients

were defined as nonusers and 111 were defined as users. More users were diagnosed with CVD (63/111, 56.8%) than with RA (48/111, 43.2%). Patient and disease characteristics of the nonuser and user groups are presented in Table 2.

**Table 2.** Characteristics of the users and nonusers in the total group, cardiovascular disease (CVD) group, and rheumatoid arthritis (RA) group.

Characteristics	Total group	CVD group	RA group
<b>Sex (user), n (%)</b>			
Male	59 (59.6)	42 (58.3)	17 (63.0)
Female	52 (65)	21 (72.4)	31 (60.8)
<b>Level of education (user), n (%)</b>			
Low	21 (77.8)	14 (82.4)	7 (70.0)
Intermediate	40 (51.9)	16 (47.1)	24 (55.8)
High	50 (66.7)	33 (66.0)	17 (68)
<b>Work participation (user), n (%)</b>			
Yes	51 (66.2)	24 (60.0)	27 (73.0)
No	60 (58.8)	39 (63.9)	21 (51.2)
<b>Living situation (user), n (%)</b>			
Alone	19 (61.3)	10 (62.5)	9 (60.0)
Together	92 (62.2)	53 (62.4)	39 (61.9)
<b>Physical comorbidity (user), n (%)</b>			
Yes	50 (61.0)	24 (60.0)	26 (61.9)
No	61 (62.9)	39 (63.9)	22 (61.1)
<b>Age (years), mean (SD)</b>			
Nonusers	64.5 (10.0) <sup>a</sup>	65.1 (9.7) <sup>b</sup>	63.8 (10.5) <sup>c</sup>
Users	60.5 (10.4) <sup>d</sup>	61.5 (9.4) <sup>e</sup>	59.2 (11.6) <sup>f</sup>
<b>Time since diagnosis (years), mean (SD)</b>			
Nonusers	8.7 (10.6) <sup>g</sup>	5.0 (7.9) <sup>h</sup>	13.4 (11.9) <sup>c</sup>
Users	8.1 (10.6) <sup>d</sup>	3.8 (7.7) <sup>e</sup>	13.8 (11.2) <sup>f</sup>
<b>Self-management score, PAM-13<sup>i</sup>, mean (SD)</b>			
Nonusers	40.2 (4.8) <sup>j</sup>	40.7 (4.4) <sup>b</sup>	39.5 (5.4) <sup>k</sup>
Users	40.4 (5.5) <sup>l</sup>	40.4 (5.5) <sup>e</sup>	40.3 (5.6) <sup>m</sup>
<b>Interaction efficacy, PEPPI-5<sup>n</sup>, mean (SD)</b>			
Nonusers	21.4 (3.3) <sup>j</sup>	21.3 (2.8) <sup>b</sup>	21.5 (3.8) <sup>k</sup>
Users	20.5 (3.3) <sup>d</sup>	20.0 (3.6) <sup>e</sup>	21.1 (2.9) <sup>f</sup>
<b>Physical functioning, RAND-36<sup>o</sup>, mean (SD)</b>			
Nonusers	64.0 (27.8) <sup>a</sup>	71.3 (25.3) <sup>b</sup>	54.3 (28.3) <sup>c</sup>
Users	68.8 (25.1) <sup>d</sup>	70.9 (26.0) <sup>p</sup>	66.1 (23.9) <sup>f</sup>
<b>Social functioning, RAND-36, mean (SD)</b>			
Nonusers	71.9 (24.1) <sup>a</sup>	77.6 (22.2) <sup>b</sup>	64.6 (24.8) <sup>k</sup>
Users	74.9 (22.4) <sup>d</sup>	74.4 (26.0) <sup>p</sup>	75.5 (16.7) <sup>f</sup>
<b>Role physical, RAND-36, mean (SD)</b>			
Nonusers	51.1 (43.9) <sup>a</sup>	62.5 (41.0) <sup>b</sup>	36.7 (43.9) <sup>k</sup>
Users	56.8 (41.1) <sup>d</sup>	56.7 (41.2) <sup>e</sup>	56.8 (41.5) <sup>f</sup>
<b>Role emotional, RAND-36, mean (SD)</b>			
Nonusers	75.1 (40.3) <sup>a</sup>	75.4 (40.0) <sup>b</sup>	74.7 (41.5) <sup>c</sup>

Characteristics	Total group	CVD group	RA group
Users	80.8 (34.1) <sup>d</sup>	78.8 (35.1) <sup>e</sup>	83.3 (33.0) <sup>f</sup>
<b>Mental health, RAND-36, mean (SD)</b>			
Nonusers	75.5 (17.0) <sup>a</sup>	78.1 (17.4) <sup>b</sup>	72.1 (16.1) <sup>k</sup>
Users	76.4 (13.9) <sup>d</sup>	75.7 (15.4) <sup>e</sup>	77.4 (11.7) <sup>f</sup>
<b>Vitality, RAND-36, mean (SD)</b>			
Nonusers	58.4 (21.2) <sup>a</sup>	62.5 (19.2) <sup>b</sup>	53.1 (22.9) <sup>k</sup>
Users	57.5 (18.9) <sup>d</sup>	56.1 (20.4) <sup>e</sup>	59.3 (16.9) <sup>f</sup>
<b>Bodily pain, RAND-36, mean (SD)</b>			
Nonusers	70.0 (26.9) <sup>a</sup>	80.2 (23.5) <sup>b</sup>	56.9 (25.5) <sup>k</sup>
Users	72.6 (21.8) <sup>d</sup>	75.4 (23.5) <sup>e</sup>	68.9 (19.0) <sup>f</sup>
<b>General health, RAND-36, mean (SD)</b>			
Nonusers	51.3 (19.1) <sup>a</sup>	55.4 (18.1) <sup>b</sup>	46.0 (19.4) <sup>c</sup>
Users	53.5 (19.0) <sup>d</sup>	53.3 (19.9) <sup>e</sup>	53.8 (17.8) <sup>f</sup>
<b>Health change, RAND-36, mean (SD)</b>			
Nonusers	47.8 (22.3) <sup>a</sup>	51.3 (23.2) <sup>b</sup>	43.3 (20.7) <sup>k</sup>
Users	51.6 (24.8) <sup>d</sup>	52.4 (25.3) <sup>e</sup>	50.5 (24.5) <sup>f</sup>

<sup>a</sup>n=67.<sup>b</sup>n=38.<sup>c</sup>n=29.<sup>d</sup>n=111.<sup>e</sup>n=63.<sup>f</sup>n=48.<sup>g</sup>n=66.<sup>h</sup>n=37.<sup>i</sup>PAM-13: Patient Activation Measure.<sup>j</sup>n=68.<sup>k</sup>n=30.<sup>l</sup>n=110.<sup>m</sup>n=47.<sup>n</sup>PEPPI-5: 5-item perceived efficacy in patient-physician interactions.<sup>o</sup>RAND-36: RAND 36-item health survey.<sup>p</sup>n=63.

### Main Analysis of the Relation Between Context and Outcome

Univariate analyses showed that age, education, and communication efficacy with health care professionals (5-item perceived efficacy in patient-physician interactions) were associated with the use of web-based self-management interventions (Table 3). Table 2 shows that younger patients (mean 60.5, SD 10.4 years) and patients with a lower level of education (21/27, 78% used the intervention) were more likely to use the program than older patients (mean 64.5, SD 10.0

years) and patients with an intermediate level of education (40/77, 52% used the intervention). Furthermore, users scored lower on communication efficacy with health care professionals (mean 20.5, SD 3.3) than nonusers (mean 24.4, SD 3.3). A combination of age and education level provided the best model for predicting the use of the web-based self-management program (Table 4) and correctly predicted whether a person would be a user or nonuser in 69.1% (123/179) of cases. Users were correctly predicted in 91.9% (102/111) of cases and nonusers in 31% (21/68) of cases.



**Table 3.** Results of the univariate logistic regressions for all possible factors for total group.

	OR <sup>a</sup> (95% CI)	P value
Sex	0.79 (0.43-1.46)	.46
Age	0.96 (0.93-0.99)	.02 <sup>b</sup>
Education (reference: low)—intermediate	0.31 (0.11-0.85)	.02 <sup>b</sup>
Education (reference: low)—high	0.57 (0.21-1.60)	.29
Employment status	1.37 (0.74-2.54)	.31
Living situation	1.04 (0.47-2.30)	.93
Diagnosis	0.97 (0.53-1.77)	.97
Physical comorbidity	0.92 (0.50-1.69)	.79
Time since diagnosis	1.00 (0.97-1.02)	.72
Self-management (PAM <sup>c</sup> )	1.01 (0.95-1.07)	.77
Communication efficacy (PEPPI <sup>d</sup> )	0.92 (0.83-1.01)	.08 <sup>e</sup>
Physical functioning (RAND-36 <sup>f</sup> )	1.01 (1.00-1.02)	.23
Social functioning (RAND-36)	1.01 (0.99-1.02)	.40
Role physical (RAND-36)	1.00 (1.00-1.01)	.38
Role emotional (RAND-36)	1.00 (1.00-1.01)	.32
Mental health (RAND-36)	1.00 (0.98-1.02)	.68
Vitality (RAND-36)	1.00 (0.98-1.01)	.78
Bodily pain (RAND-36)	1.01 (0.99-1.02)	.47
General health (RAND-36)	1.01 (0.99-1.02)	.47
Health change (RAND-36)	1.01 (0.99-1.02)	.30

<sup>a</sup>OR: odds ratio.

<sup>b</sup> $P < .05$ .

<sup>c</sup>PAM: Patient Activation Measure.

<sup>d</sup>PEPPI-5: 5-item perceived efficacy in patient-physician interactions.

<sup>e</sup> $P < .20$ .

<sup>f</sup>RAND-36: RAND 36-item health survey.

**Table 4.** Final model of factors associated with the use of web-based self-management programs<sup>a</sup>.

	B	SE	OR <sup>b</sup> (95% CI)	P value
Constant	3.58	1.16	N/A <sup>c</sup>	.002
Age	-0.04	0.017	0.96 (0.93-1.00)	.03
Education (intermediate vs low)	-1.06	0.52	0.35 (0.12-0.96)	.04

<sup>a</sup>Nagelkerke  $R^2 = 0.049$ .

<sup>b</sup>OR: odds ratio.

<sup>c</sup>N/A: not applicable.

### Sensitivity Analysis of the Relation Between Context and Outcome

Sensitivity analysis showed a significant interaction between diagnosis and the RAND-36 subscales social functioning, physical role limitations, vitality, and bodily pain (Table 5). The descriptive data presented in Table 2 show that scores on

self-management (PAM-13) and some quality-of-life subscales (RAND-36) were different between the CVD and RA groups. Patients with CVD with higher scores on self-management and quality of life were less likely to use the program. In contrast, patients with RA with higher scores on self-management and quality of life were more likely to use the program.

**Table 5.** Results of the interaction effects between diagnosis (cardiovascular disease and rheumatoid arthritis) and possible factors.

	OR <sup>a</sup> (95% CI)	P value
Sex	2.06 (0.54-7.89)	.29
Age	1.00 (0.94-1.07)	.95
Education (reference: low)—intermediate	2.84 (0.37-22.06)	.32
Education (reference: low)—high	2.19 (0.27-17.98)	.47
Employment status	3.04 (0.87-10.66)	.08 <sup>b</sup>
Living situation	1.09 (0.22-5.37)	.92
Physical comorbidity	1.22 (0.36-4.18)	.75
Time since diagnosis	1.02 (0.96-1.09)	.50
Self-management (PAM <sup>c</sup> )	1.04 (0.93-1.17)	.52
Communication efficacy (PEPPI <sup>d</sup> )	1.09 (0.90-1.33)	.39
Physical functioning (RAND-36 <sup>e</sup> )	1.02 (0.99-1.04)	.14 <sup>b</sup>
Social functioning (RAND-36)	1.03 (1.00-1.06)	.03 <sup>f</sup>
Role physical (RAND-36)	1.02 (1.00-1.03)	.05 <sup>f</sup>
Role emotional (RAND-36)	1.00 (0.99-1.02)	.64
Mental health (RAND-36)	1.04 (1.00-1.08)	.08 <sup>b</sup>
Vitality (RAND-36)	1.03 (1.00-1.07)	.04 <sup>f</sup>
Bodily pain (RAND-36)	1.04 (1.01-1.06)	.02 <sup>f</sup>
General health (RAND-36)	1.03 (1.00-1.07)	.09 <sup>b</sup>
Health change (RAND-36)	1.01 (0.99-1.04)	.37

<sup>a</sup>OR: odds ratio.

<sup>b</sup> $P < .20$ .

<sup>c</sup>PAM: Patient Activation Measure.

<sup>d</sup>PEPPI: Perceived Efficacy in Patient-Physician Interactions.

<sup>e</sup>RAND-36: RAND 36-item health survey.

<sup>f</sup> $P < .05$ .

### Relation Between Mechanisms (Program Design, Implementation Strategies, and BCTs) and Outcome (Program Use)

A random sample of study participants was interviewed to gain insight into why they did or did not use the web-based self-management program. In the CVD group, 6 nonusers, 6 low users, and 6 high users were interviewed. In the RA group, 4 nonusers, 4 low users, and 13 high users were interviewed. The results were divided into 3 themes: program design, implementation strategies, and BCTs. Table 6 provides quotes that show the barriers and facilitators for program use on the 3 themes: program design, implementation strategies, and BCTs.

Most interviewees were pleased with the program design. However, some experienced difficulties in using the program, and so they did not use it as often. A search function would

make it easier to find relevant information. Several users and nonusers stated that they had overlooked parts of the program; for example, 1 participant only used the diaries because he did not know that training modules were available. Another major reason for not using the program were problems with logging in. These observations indicate that ease of use was an important factor for program use among our respondents.

Explanations given by the respondents as to why they did or did not use the program also revealed factors affecting program use. Several respondents stated that they did not participate for their own benefit but rather to facilitate scientific research. Others used the program following advice from their health care professional or because they were curious and wanted to better understand their disease. The biweekly reminders to fill out the diaries in the Coping with RA program helped many respondents to use the diaries.

**Table 6.** Quotes from the interviews with users and nonusers.

	Barriers	Facilitators
Program design	“Well, I couldn’t log in. Somehow I really couldn’t, or it wasn’t clear to me. Through the internet I find it very difficult to do.” (Coping with RA <sup>a</sup> , participant 5)	<ul style="list-style-type: none"> <li>“Yes I liked the lay-out. The information was orderly, you could easily click on what you wanted to see. So the program was very well organized.” (Coping with RA, participant 21)</li> </ul>
Implementation strategies	Barriers for implementation were not described.	<ul style="list-style-type: none"> <li>“The hospital nurse advised me to use the program.” (Vascular View, participant 1)</li> <li>“If I received an email that said I still had something to do, I always did.” (Coping with RA, participant 8)</li> </ul>
Behavior change techniques	“The program only gives input but I missed feedback options, for example to keep track of my weight.” (Vascular View, participant 16)	<ul style="list-style-type: none"> <li>“I wanted information on how to deal with my recent diagnosis.” (Vascular View, participant 7)</li> </ul>

<sup>a</sup>RA: rheumatoid arthritis.

Comments related to program content were assigned to the relevant BCTs, and some of these BCTs were identified as potential mechanisms affecting program use. The first BCT (providing general information about health behavior) was often mentioned in the interviews. For example, respondents with a long disease history stated that the information was too general. Furthermore, some respondents saw on the overview page that none of the modules contained new or interesting information, and so they did not use the program further. Respondents reported that reliable information was a reason for using the program. The Vascular View program includes a physical activity and nutrition diary (for the self-monitoring of behavior BCT), which was rarely used. One respondent said they had missed a feedback function in the diaries and had already used other, more advanced, mobile apps instead. The pain and fatigue diaries in the Coping with RA program were used more often by respondents (for the self-report of behavior BCT). Patients appreciated the possibility of keeping track of their pain and fatigue and of receiving a graphical overview of their input (the delayed feedback of behavior BCT). Program users also liked the stories and videos of peers (which provided information about peer behavior BCT and modeling BCT). One respondent said that these made her feel recognized and supported and showed her that she was on the right track.

## Discussion

### Principal Findings

In this realistic evaluation of 2 web-based self-management interventions, we searched for patient, disease, and program characteristics that determine whether patients will use the programs. Regarding the relationship between context and outcome, patient and disease characteristics, younger age, and lower level of education were associated with program use. In addition, 4 quality of life subscales (social function, physical role limitations, vitality, and bodily pain) interacted significantly with the diagnosis group to affect program use. Regarding the relationship between Potential Mechanisms (program characteristics) and outcome, participants indicated that an easy-to-use, clear, and transparent design would motivate them to use the program. Email reminders and recommendations from health care professionals were found to be potential

implementation mechanisms for promoting program use. The top five BCT techniques that encouraged interviewees to use the program were (1) tailored information, (2) self-report of behavior, (3) delayed feedback, (4) information about peer behavior, and (5) modeling.

### Tailoring Web-Based Self-management Interventions to Increase Program Use

Our findings show that patient and disease characteristics can be used to tailor web-based self-management interventions and, therefore, increase their use. Younger age increased program use in our study, which is in agreement with the results of previous studies. However, in contrast to our finding that a lower level of education increased program use, earlier studies showed that a higher level of education increased program use [18-20,32,33]. Despite this discrepancy, these results show that age and education both influence program use, possibly because they are both related to eHealth literacy. eHealth literacy is the ability to seek, find, understand, and appraise health information from electronic sources and to use this knowledge to address or solve a health problem [34]. Concerns have been raised about a *digital divide*, which is the gap between patients who are able to use eHealth and those who are not [19]. Our study emphasizes the need to pay attention to these issues, as both age and education are strongly related to eHealth literacy [35], and eHealth literacy is needed to benefit from web-based interventions. Different forms of self-management support should be provided to people with low eHealth literacy.

Disease burden can be both mental and physical and is another possible factor related to the use of web-based self-management support programs. Patients with RA have a lower physical quality of life and experience more pain than those with CVD. Individuals with episodic or deteriorating diseases such as RA have different self-management support needs than those with stable chronic diseases [36,37]. Patients with CVD have reported fewer self-management support needs than those with other chronic diseases because their disease has a smaller impact on their lives [38]. These variations in the perceived burden of disease can affect the motivation to change. A higher perceived disease burden has been associated with a higher perception of the necessity for treatment, which increases adherence to treatment [39]. We have shown this in this study; in the RA

group, users rated their physical quality of life as higher than nonusers, whereas in the CVD group, users rated their physical quality of life as lower than nonusers. This suggests that a certain level of burden is needed to feel urgency and to be motivated to use a web-based self-management support program. However, a web-based intervention might not be sufficient when the disease burden is too high. In such cases, face-to-face support from health care professionals is recommended [23].

### The Influence of Program Characteristics

The study participants provided some recommendations for an effective web-based self-management support program. These recommendations included being easy to use, providing appropriate reminders, tailoring information to the user, allowing patients to self-report their behavior and receive delayed feedback, and providing information about peer behavior and modeling. These results are in line with those of a Delphi study that identified new information and the possibility of monitoring personal progress as important factors promoting the use of an eHealth self-management intervention [40]. In addition, previous research has shown that peer support and email or phone contact increase the use of eHealth interventions [10]. These observations suggest that adding an interactive component to our Vascular View and Coping with RA programs, which allows users to communicate with peers and health care professionals, may promote program use. Counselor support has been found to be important for program use in previous studies [10], and our participants stated that interaction would have stimulated them to use the program. The role of health care professionals should never be underestimated, especially as blended care (a combination of eHealth interventions and face-to-face consultations with a health care professional) increases the use of eHealth interventions, including more program components [41].

### One Size Does Not Fit All

Our results emphasize that one program will not be suitable for every patient. Self-management programs should be tailored to patients' individual needs. It should also be noted that not all patients can use and benefit from web-based interventions. The validated Self-Management Screening (SeMaS) questionnaire can help identify potential barriers to self-management and can help health care professionals determine their patients' support needs [42]. The factors affecting program use identified in this study were in accordance with the components of the SeMaS, including age, education, disease burden (both low and high disease burden can be barriers to self-management), computer skills, and social support. The SeMaS can help health care professionals to choose appropriate interventions and to decide which patients would benefit from a web-based self-management support intervention [43].

### The Use of a Realistic Evaluation

Given the complexity of web-based self-management interventions, realistic evaluations can reveal what makes an intervention work, which a simple cause-and-effect relationship between an intervention and its outcome may not be able to do. This is especially important for eHealth interventions because

dropout and nonuse rates are high [17]. The aim of a realistic evaluation is to determine what works for whom, in what circumstances, and why. We tried to answer these questions by analyzing what patient and disease characteristics influence program use (context) and by describing what program characteristics influence program use (potential mechanisms; Figure 2). Unfortunately, we were not able to analyze the interaction between context and mechanism and how this affects the outcome. This should be addressed in future research to further improve the tailoring and effectiveness of eHealth interventions.

### Limitations

The findings of our realistic evaluation should be considered in the context of several limitations. The principal limitation was that we used retrospective data collected in 2 separate studies. However, both studies were conducted by the same research group and had the same study design. It was already decided in the development phase that the data would be merged for an overarching study; however, we could not include more questions about factors related to program use in the questionnaires. The interviews were conducted to retrieve patients' experiences, not to identify program characteristics that influence program use. Vascular View and Coping with RA were developed based on BCTs, and most of these were unobtrusively included in the program. In addition, Vascular View and Coping with RA applied different implementation strategies that could have influenced program use, making the programs harder to compare. Therefore, the program characteristics identified in this study are *potential* mechanisms and should be tested in future research. Another limitation was that *physical comorbidity* and *time since diagnosis* were measured using a questionnaire. Although this provides insight into patients' experiences, the self-reporting of clinical variables is not always reliable. The last limitation of this study was that we only included participants who had access to the internet and an email address. This may have biased our results by excluding people with a very low level of eHealth literacy. However, the internet is easily accessible in the Netherlands (97% of households have access to the internet [44]), so most people would have been able to participate.

### Conclusions

This realistic evaluation identified contexts and potential mechanisms, in the form of patient, disease, and program characteristics, that are associated with the use of web-based self-management support programs. Our results emphasized the importance of (1) tailoring interventions to patients' needs (depending on age, education, and program characteristics) to increase program use and (2) considering whether all patients can use eHealth interventions (depending on disease burden and eHealth literacy) and providing alternative self-management support when needed. These results are a first step toward improving the tailoring and use of web-based self-management support programs. Future research into the interaction between patient and program characteristics and how this affects program use should be conducted to improve the tailoring of participants to program components.

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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Description of the web-based self-management support programs Vascular View and Coping with Rheumatoid Arthritis. [[DOCX File, 13 KB - humanfactors\\_v9i3e34925\\_app1.docx](#)]

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## Abbreviations

**BCT:** behavior change technique  
**CVD:** cardiovascular disease  
**PAM-13:** Patient Activation Measure  
**RA:** rheumatoid arthritis  
**RAND-36:** RAND 36-item health survey  
**SeMaS:** Self-Management Screening

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Original Paper

# Implementation of Smartphone Systems to Improve Quality of Life for People With Substance Use Disorder: Interim Report on a Randomized Controlled Trial

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## Abstract

**Background:** Researchers have conducted numerous studies seeking to understand how to improve the implementation of changes in health care organizations, but less focus has been given to applying lessons already learned from implementation science. Finding innovative ways to apply these findings efficiently and consistently will improve current research on implementation strategies and allow organizations utilizing these techniques to make changes more effectively.

**Objective:** This research aims to compare a practical implementation approach that uses principles from prior implementation studies to more traditional ways of implementing change.

**Methods:** A total of 43 addiction treatment sites in Iowa were randomly assigned to 2 different implementation strategies in a randomized comparative effectiveness trial studying the implementation of an eHealth substance use disorder treatment technology. One strategy used an adaptation of the Network for the Improvement of Addiction Treatment (NIATx) improvement approach, while the other used a traditional product training model. This paper discusses lessons learned about implementation.

**Results:** This midterm report indicates that use of the NIATx approach appears to be leading to improved outcomes on several measures, including initial and sustained use of new technology by both counselors and patients. Additionally, this research indicates that seamlessly integrating organizational changes into existing workflows and using coaching to overcome hurdles and assess progress are important to improve implementation projects.

**Conclusions:** At this interim point in the study, it appears that the use of the NIATx improvement process leads to better outcomes in implementation of changes within health care organizations. Moreover, some strategies used in this improvement process are particularly useful and should be drawn on more heavily in future implementation efforts.

**Trial Registration:** ClinicalTrials.gov NCT03954184; <https://clinicaltrials.gov/ct2/show/NCT03954184>

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**KEYWORDS**

mobile technology; coaching; substance use disorder (SUD) treatment; technology implementation model; NIATx



## Introduction

This is a midterm report on a randomized trial comparing 2 different strategies for implementing innovations. Implementation and dissemination are ongoing challenges for innovations. While efforts to enhance theories in implementation science theory may help, we need to shift focus more to applying what we already know with efficiency and fidelity. We developed a simple and easily replicable implementation approach and are comparing it to a more traditional approach.

The challenges of implementation have been studied for hundreds (some would say thousands) of years by innovators such as Jethro of Midian [1], Heraclitus [2], Taylor [3], Box [4], Ishikawa [5], Batalden [6], Maslow [7], Phillips [8], Gantt [9], Deming [10], Delbecq [11], Mayo [12], Ohno [13], Maidque [14], Conner [15], Shewhart [16], Utterback [17], Fayol [18], Rogers [19], Van de Ven [20], Barnard [21], Barnett [22], Kanter [23], Gawande [24], Lewin [25], Cooper [26], Berwick [27], Argyris [28], Simon [29], Taguchi [30], Kotter [31], Hage [32], Kilbourne [33], Ackerman [34], and Damschroder [35].

A personal example may help elucidate why we cannot wait for more theory: Tim was 31 years old when he died alone in his room with a half-used syringe on his nightstand. He had fought opioid use disorder for almost half of his life. Ultimately, an act of kindness led to his demise. The last years of his life were among Tim's best. He was in successful recovery. He had been clean and sober for nearly 5 years, reunited with his family, and gotten a job. He was 2 months away from getting his bachelor's degree in brain and behavior studies and was planning to pursue a master's degree. Both Tim's dad (his favorite golfing partner) and his mom (the rock of the family) were hesitantly breathing a sigh of relief. Things were going well. But there was also a warning sign. Tim had stopped using Suboxone (a medication-assisted treatment designed to reduce the desire for opioids) because of side effects (terrible constipation and plummeting libido).

Then a friend of Tim's called him from the hospital—her husband had survived an overdose and would soon be discharged. She knew he had heroin in their apartment. Would Tim search for it and clear the apartment before her husband's return? Tim's kindness drove him; he agreed to help. He sped to the hospital, got their key, returned to their apartment, and removed what he could find. Within hours of having heroin in his possession, for the first time in almost 5 years, Tim relapsed. He died from what was ultimately determined to be a "speedball" (a mixture of heroin and cocaine). Tim's death devastated his family and friends. One of the authors of this

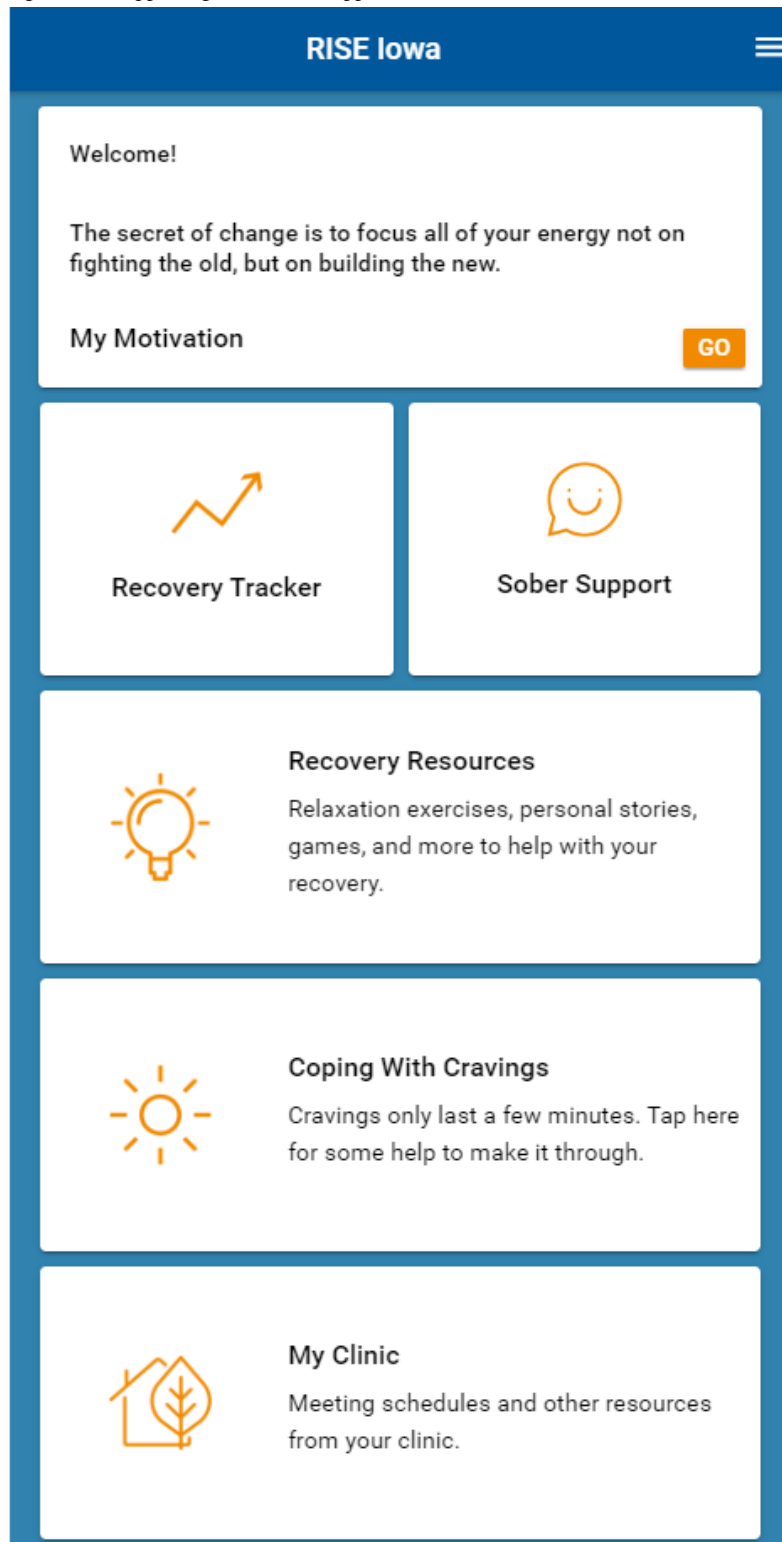
paper attended the funeral. He sat next to a young person who was crying; we all were. The young person said, "Tim was my hope. If he couldn't make it, how can I?" Tim had been trained in evidence-based cognitive behavioral therapy (CBT). One of CBT's key principles relates to "seemingly irrelevant decisions" where one puts themselves in harm's way without realizing it. Tim forgot that principle, and it killed him.

Computer-based technologies that could have helped Tim have been in place since the early 1980s. Examples include the Body Awareness Resources Network (BARN) [36], Computer Based Training for Cognitive Behavioral Therapy (CBT4CBT) [37], Treatment Evaluation Services (TES) [38], and Addiction Comprehensive Health Enhancement Support System (ACHESS) [39]. For instance, ACHESS contains brief reminders of CBT principles that might have called Tim's seemingly irrelevant decision—to help his friend—to his attention. Alternatively, the weekly patient surveys in ACHESS might have called his attention to his increased anxiety and led him to think twice about his decision. However, few people with or without a substance use disorder [40] remember the CBT skills they have learned in treatment or have access to tools that could help them remember in the moments when those skills are most needed.

ACHESS, the original smartphone innovation that we used to compare implementation strategies, was designed to help counselors and patients. It offers a variety of services: communicate anonymously with peer support groups, help assess a patient's relapse risk and link to interventions, use reminders to encourage adherence to therapeutic goals, privately communicate with the patient's counselor, provide addiction-related educational materials and tools, and send alerts if a patient visits a high-risk location such as a favorite bar.

Several studies found that ACHESS reduced heavy drinking [41] and doubled retention in treatment [42]. However, only a few thousand of the millions of people facing substance use disorder (SUD) are using ACHESS or other technologically based systems. Hence, such a system provides an ideal target to compare implementation strategies. For this study, ACHESS was renamed RISE Iowa (Recovering Iowans Supporting Each Other) to make the app more appealing to treatment agencies in Iowa (Figure 1).

This paper seeks to answer the question, "What have we learned so far in this study about how to implement evidence-based practices?" Our ongoing randomized trial compares 2 strategies for widescale implementation, using RISE Iowa as the object of those implementation strategies.

**Figure 1.** RISE Iowa (Recovering Iowans Supporting Each Other) app.

## Methods

### Background

The first strategy is a typical product training approach where a sales representative introduces a product to key personnel in the adopting organization, trains key players on how to use the product, and offers a source for further support, such as training manual and computer accessible responses to frequently asked

questions (FAQs). The second strategy adds a quality improvement (QI) methodology (the NIATx model [43]) that assigns an external coach who calls the agency once a month to monitor, support, and encourage the organization and uses a set of QI tools (eg, a checklist of steps to implement RISE Iowa at their site, flowchart to see how to integrate RISE Iowa into the organization's workflow, and tools to predict and explain an organization's readiness for change or to examine the potential of embedding the innovation). The NIATx model has

been implemented by over 3500 addiction treatment organizations and was tested in a randomized trial involving over 200 addiction treatment agencies [44]. NIATx is designed to add structure and increase fidelity to the implementation process.

In the NIATx model, quality improvement coaches made 1 trip to each agency to get to know and train staff in RISE Iowa and to set implementation goals, followed by monthly Zoom calls

to an organization's change leader and change team. Coaches' calls served as methods to assess progress and roadblocks, train and remind staff, celebrate successes, give feedback on progress, set follow-up goals, and identify and provide answers to questions and concerns. In addition, 4 times during the 18-month implementation period, organizations in the NIATx model were invited to convene via Zoom for more training and to share successes and challenges. Table 1 compares NIATx to the product training approach.

**Table 1.** Comparison of implementation strategies.

NIATx <sup>a</sup>	Product training
Coach and trainer conduct Zoom meeting with leadership of organization to review study and provide overview of RISE <sup>b</sup> Iowa app.	Trainer conducts Zoom meeting with leadership of organization to review study and provide overview of RISE Iowa app.
Staff at organizational sites take survey regarding organization's approach to change.	Staff at organizational sites take survey regarding organization's approach to change.
Coach and trainer conduct Zoom meeting with change leader(s) and teams to review survey results and preview app.	N/A <sup>c</sup>
Trainer provides 2-hour staff training on the RISE Iowa app.	Trainer provides 2-hour staff training on the RISE Iowa app.
Coach provides 2-hour NIATx training.	N/A
Tech support is available via email.	Tech support is available via email.
Coach and trainer hold monthly coaching Zoom meeting with change leaders at study sites, in which coach shares ideas gained from working with other organizations.	N/A
Study staff emails staff and patients with RISE Iowa accounts regarding updates to the app.	Study staff emails staff and patients with RISE Iowa accounts regarding updates to the app.
Study staff send weekly and monthly emails providing data on new RISE Iowa accounts and RISE Iowa usage by staff and patients to change teams.	N/A
Additional resources are added to the app approximately monthly.	Additional resources are added to the app approximately monthly.
One additional cross-agency Zoom meeting is held with executive sponsors as well as 1 with change leaders. Additionally, 2 additional cross-agency training opportunities are offered	N/A

<sup>a</sup>NIATx: Network for the Improvement of Addiction Treatment.

<sup>b</sup>RISE: Recovering Iowans Supporting Each Other.

<sup>c</sup>N/A: Not applicable.

Coaches are individuals with experience in leading NIATx projects in their own organizations and who have received additional NIATx coaching training. Coaches have had at least 10 years of experience leading NIATx quality improvement projects. To assure fidelity and consistency among coaches, the coaches convened monthly with key study team members to review progress with the sites and discuss challenges and potential approaches to those challenges. Due to COVID-19 restrictions, coaches were unable to make in-person visits to 3 of the 11 agencies. Those agencies were trained via Zoom. A resource provided in the NIATx approach is a set of organizational surveys used to predict and explain the likelihood of successful RISE Iowa implementation [45] and assess chances that RISE Iowa will be sustained by the organization in the long run [46]. These analyses are designed to help coaches determine the strengths and challenges they will face in promoting adoption and sustainment at the agency and offer advice on how to overcome the challenges.

This paper presents interim results of our ongoing multicenter randomized trial in Iowa SUD treatment agencies but focuses mostly on lessons learned so far about implementation. No attempt was made to evaluate the RISE Iowa app itself. We are interested in implementation progress with NIATx compared to the product training approach. We expected the NIATx coaching calls alone would be superior, but we also wanted to explore what other aspects of the NIATx approach make a difference.

To compare the 2 implementation strategies, 11 Iowa-based addiction treatment organizations with 43 addiction treatment sites were randomly assigned to receive the product training or the NIATx approach. The sites' progress is being tracked for an 18-month period during which aspects of the 2 implementation strategies are still active (eg, FAQs for product training, monthly coach calls for NIATx), followed by 10 months with no support to examine sustainability. The first cohort began the study intervention in 2019. The final cohort will complete the intervention by mid-2022.

Counselors and peer recovery coaches use RISE Iowa in a variety of ways, including by assigning material within it (eg, reading personal stories of others successfully struggling with SUD), monitoring patient progress by examining the weekly patient surveys, and participating in discussion groups. RISE Iowa automatically collects and stores data on how many patients sign up to use RISE Iowa and the amount of use by both counselors and patients. Counselors can track the data on patient use of RISE Iowa to better understand how well patients are following through on their recovery efforts.

In this report, we compare patient and counselor use of RISE Iowa between sites assigned to the NIATx approach versus product training only. RISE Iowa utilization is summarized as the average number of days logging into RISE Iowa per month and the percentage of patients or counselors who logged in per month.

To better understand the features of the NIATx approach that influenced implementation in this study, 3 coaches and 8 research staff conducted a combination of semistructured interviews and nominal group technique meetings [11,47] to identify and assess factors that played a role in the implementation and ones they would concentrate on if they were to implement RISE Iowa in another setting (or, in other words, what worked). These interviews identified 24 factors that were then evaluated by inviting coaches and research staff to select the 10 factors they considered to be most important in guiding adoption and sustainment. We prioritized these factors by counting the votes (from 11 possible voters) of each of the 24 factors received. We present the 10 factors that received the most votes alongside explanations provided by voters and summarize the number of votes received for the remaining 14 factors. We did not conduct a formal statistical analysis as this is preliminary data.

## Ethics Approval

This study received approval from Advarra Institutional Review Board (# 2018-0997). Interview participants provided oral informed consent.

## Results

### Use of RISE Iowa

Use of the RISE Iowa app was tracked over time for all participants. Here, we present the data collected so far for the first 5 months of each participants' app usage after activating their account. The average number of days per months of app usage was calculated by tallying the number of days per month each participant opened the app and then calculating the mean of all tallies. The percent of active participants per month was calculated by dividing the number of participants who opened the app that month by the number of participants who had access to the app at that time point.

Figure 2 compares counselor retention rates between the implementation approaches. By retention, we mean that counselors continue to log on to RISE Iowa after they are first introduced to it. For example, 24 of 68 (35%) of counselors and peer recovery coaches trained in RISE Iowa with the NIATx approach were still logging in 5 months later versus 2 of 51 (4%) who received product training. Furthermore, those 35% used RISE Iowa an average of about 4 days per week with NIATx versus an average of about 1.5 days per week in the product training arm. For the patient data, an account was removed from the analysis if it had been created on the day the analysis was run. For example, if person A created an account at 10 AM on day X and study staff downloaded the data at 4 PM on Day X, person A would have created an account the day that study staff downloaded the data, so person A would be removed from the analysis.

**Figure 2.** Counselors' average days of use of RISE Iowa (Recovering Iowans Supporting Each Other) app. NIATx: Network for the Improvement of Addiction Treatment.

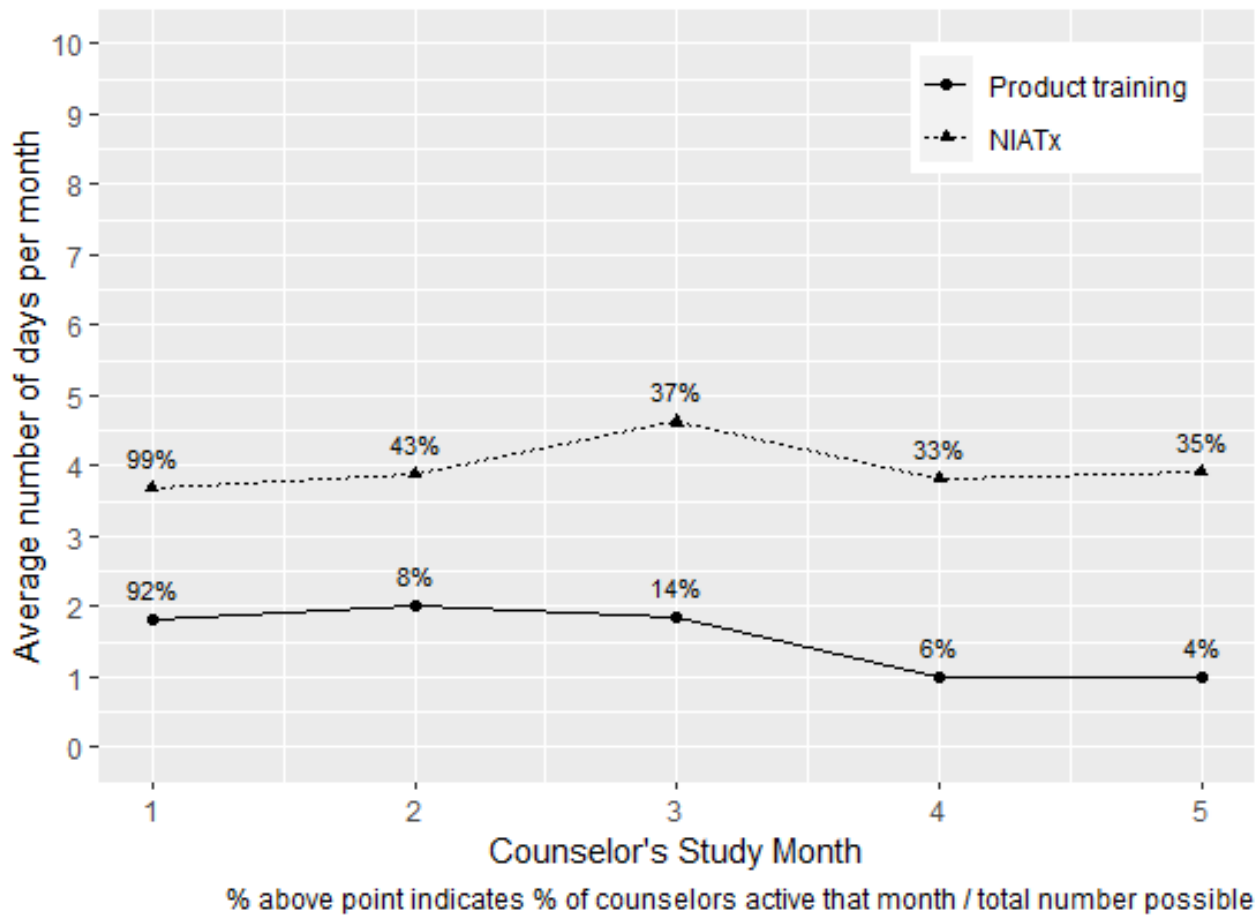
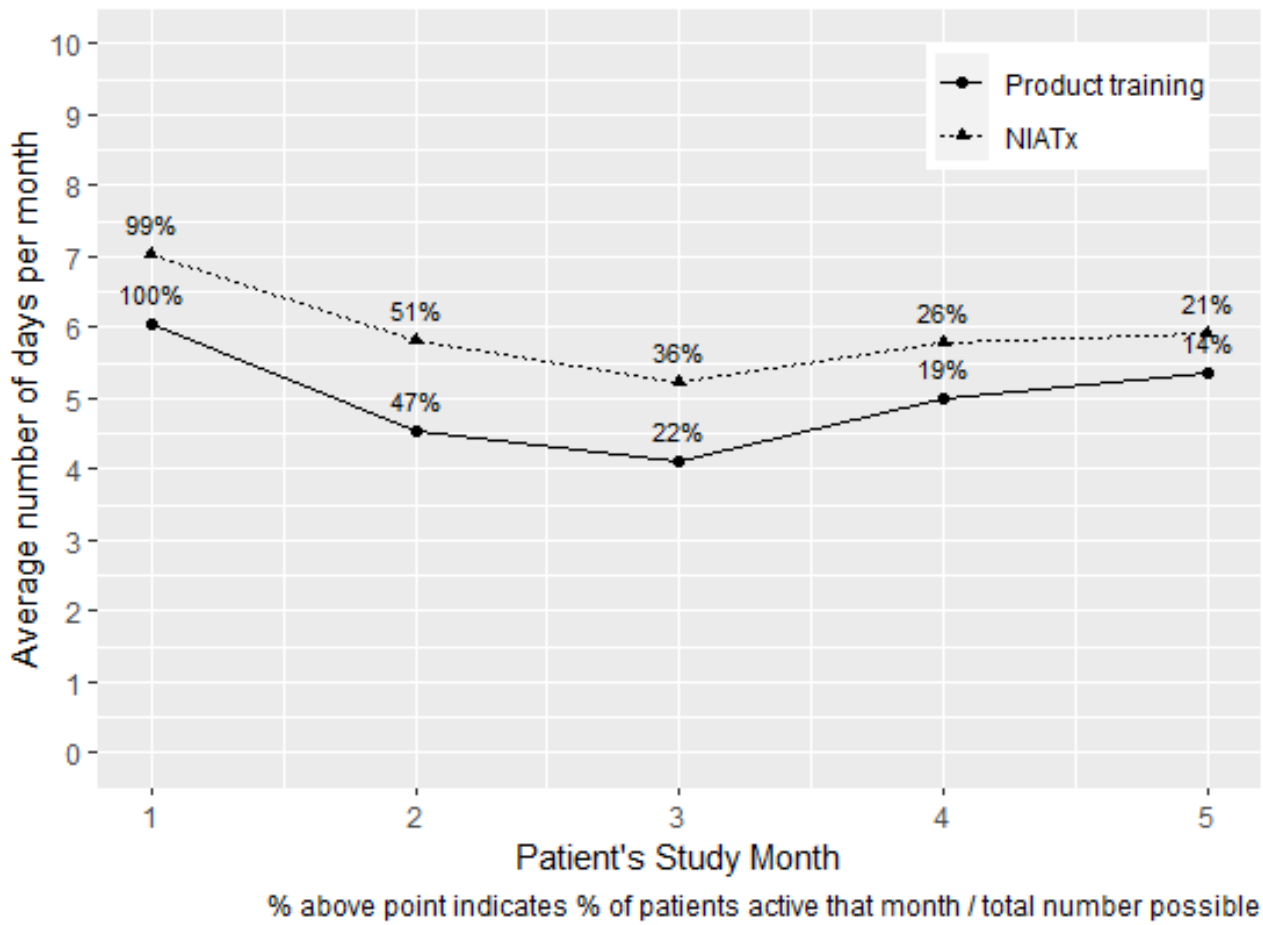


Figure 3 displays differences in patients' use of RISE Iowa between the product training and NIATx approaches. The average days of RISE Iowa use per patient per month was about 6.5 at the NIATx sites versus about 5.5 in product training sites. Further, the number of patients using RISE Iowa is much smaller in the product training approach (11/81,14%) versus in the NIATx approach (150/722, 21%) at 5 months after each patient

first logged on. Finally, it should be noted that the product training sites in this study treat 17% more patients than do the NIATx sites; however, there was a much smaller RISE Iowa enrollment in the product training locations. Table 2 shows the descriptive statistics for use of the RISE Iowa app by participants.

**Figure 3.** Patients' average days of use of RISE Iowa (Recovering Iowans Supporting Each Other) app. NIATx: Network for the Improvement of Addiction Treatment.



**Table 2.** Descriptive statistics for use of the RISE Iowa app by participants.

Type of RISE <sup>a</sup> Iowa user	Arm	Study month	Number of days per month, mean (SD)	People, n	People possible, n	People active, %
Patients	Product training	1	6.05 (5.53)	82	82	100
Patients	Product training	2	4.53 (5.31)	38	81	47
Patients	Product training	3	4.11 (3.61)	18	81	22
Patients	Product training	4	5 (8.27)	15	81	19
Patients	Product training	5	5.36 (8.58)	11	81	14
Patients	NIATx <sup>b</sup>	1	7.02 (6.25)	792	797	99
Patients	NIATx	2	5.83 (6.74)	402	789	51
Patients	NIATx	3	5.24 (6.34)	276	763	36
Patients	NIATx	4	5.79 (7.55)	193	749	26
Patients	NIATx	5	5.92 (7.54)	150	722	21
Counselors	Product training	1	1.81 (1.45)	47	51	92
Counselors	Product training	2	2 (1.41)	4	51	8
Counselors	Product training	3	1.86 (1.46)	7	51	14
Counselors	Product training	4	1 (0)	3	51	6
Counselors	Product training	5	1 (0)	2	51	4
Counselors	NIATx	1	3.67 (2.94)	69	70	99
Counselors	NIATx	2	3.87 (3.42)	30	70	43
Counselors	NIATx	3	4.62 (5.28)	26	70	37
Counselors	NIATx	4	3.83 (5.77)	23	70	33
Counselors	NIATx	5	3.92 (4.80)	24	68	35

<sup>a</sup>RISE: Recovering Iowans Supporting Each Other.

<sup>b</sup>NIATx: Network for the Improvement of Addiction Treatment.

### Factors Influencing Implementation

We explored what it is about the NIATx approach that is thus far leading to better results. Ordered by total number of votes received, the top factors are (including the number of votes each received) are as follows.

First, identify patient and counselor pain points and show how RISE Iowa helps to relieve that pain: 10 votes out of a possible 11. This factor creates a value proposition on why the change should be adopted. As a counselor put it, "From the beginning, I've really tried to make [RISE Iowa] something that will feel useful. I am trying to have our IT [person] put as many relevant things on RISE Iowa as possible [to keep it fresh]." Counselor pain points may include busyness, demands of their job, and having to accomplish several required activities with each patient. Patient pain points include factors that inhibit recovery, such as cravings, triggers, and isolation.

Second, find ways to integrate RISE Iowa into the organization's standard workflow: 9 votes. Another counselor said, "I've been more intentional about going through my case load prior to the monthly coaching calls asking: 'Who are the eligible folks and why aren't they signed up with RISE Iowa yet?'. That's a trigger for me to say, 'Here are the folks that I need to target.'" As

such, the counselor has made RISE Iowa enrollments part of their standard workflow.

Third, use coaches to motivate, help overcome hurdles, assess progress, and share learnings across the sites: 8 votes. A coach said, "Clinicians are asked to manage many competing demands as they assist patients in their recovery. Adding a tool [like RISE Iowa] to their workflow takes mental energy and focus. Coaches trained agency staff in NIATx process improvement and the associated tools. With coaches available, this means that providers do not need to have all the answers as they pilot test improvements in their workflows."

Fourth, get senior executives to encourage agency staff to try RISE Iowa: 8 votes. Another coach said, "Leaders can encourage staff to make RISE Iowa part of their regular client intake and treatment process. Leaders can also free staff time to use RISE Iowa themselves and become familiar with its features."

Fifth, get bugs out of the RISE Iowa app and make it user friendly: 7 votes. A researcher said, "I just know that nothing is more of a deterrent than trying to use something that doesn't work."

Sixth, provide data and administrative support: 6 votes. A coach said, "Administrative staff offer real-time technical support and training to agencies, as well as data on RISE Iowa adoption and

use. It was easier for organizations to justify the allocation of limited resources to support sustainment after staff provided data demonstrating measurable progress.”

Seventh, use testimonials to reinforce the value of RISE Iowa: 5 votes. A coach said, “In my 20 years of facilitating organizational change, stories/testimonials are among the most impactful resources. To hear a story from someone you identify with can provide a path for change and a belief that a change might be worth the effort.”

Eighth, have cross-agency calls to share learnings and concerns: 5 votes. A research staff member noted that “cross agency calls provide a way for counselors and agency staff to learn from each other. Nothing works better than to hear good things from a colleague.”

Ninth, use financial incentives: 5 votes. A researcher noted that “incentives (such as lotteries) can motivate people toward chosen behaviors. Incentives can tip the scales away from competing priorities.”

Tenth, remind and retrain both counselors and patients to use RISE Iowa: 5 votes. One counselor said, “The ‘coping with cravings’ stuff; when I first heard about that, I thought, ‘this is beautiful!’ But that had not been [an] area that I really tapped into. Its presence makes me think of a lot of new things that I could be doing with RISE Iowa.”

Other factors and the number of votes they received (indicated in parenthesis) are listed as follows:

1. Assess organizational readiness for change to learn what areas they need to work on to have the best chance of successful implementation (4).
2. Get many patients on RISE Iowa right away to reach critical mass for discussion groups because there needs to be enough people to have an active discussion (4).
3. Find ways to address the digital divide (4).
4. Give agencies tools they can use to improve quality (4).
5. Protect privacy (3).
6. Celebrate successes (2).
7. Make access to RISE Iowa a privilege. Making people invest to participate makes a system more appealing (1).
8. Do not prejudge who will use RISE Iowa; clinicians may pick and choose which patients are best suited for a recovery app and may misjudge (1).
9. Use lessons from the COVID-19 pandemic. For instance, virtual visits were found to be effective (1).
10. Coaches should make 1 in-person visit if possible (1).
11. Refresh RISE Iowa often to keep it interesting and up to date (1).
12. Make RISE Iowa free of charge (1).
13. Ignore skeptics; however, ignoring skeptics would probably be a mistake because they likely have important insights to offer (0).
14. Do not use inflammatory words, such as “track.” The “recovery tracker” on the app could be seen as an inflammatory term because people do not like to feel like they are being watched (0).

## Discussion

### Interim Findings

This study’s interim results suggest that the NIATx process is especially useful for integrating RISE Iowa within existing workflows and helping clinicians address the challenges they already face at work. It is further notable that in an earlier randomized trial [48] involving 201 addiction treatment agencies across 4 states, we explored whether processes improved more in agencies that received the product training approach versus a full improvement collaborative (ie, periodic face-to-face meetings, coaches, joint calls with all agencies at once) versus joint improvement calls only versus monthly coaching calls with individual agencies, with the latter method used in this study. We found that monthly coaching calls (the NIATx approach) worked at least as well as the full collaborative and better on both cost and effectiveness outcomes than the other arms.

The results of this study point to the importance of identifying and responding to the pain points faced by the implementing organization, along with finding a way to integrate the new technology easily into the organization’s workflow. The more that staff are asked to change their workflow, the less likely the implementation will be to succeed.

Other research finds that the average commercial app loses 77% of its users within the first 3 days after installation. Within 30 days, it has lost 90% of users. Within 90 days, it has lost over 99% [49]. In contrast, in earlier tests of ACHES in Federally Qualified Health Centers, over 60% of actively enrolled people continued using ACHES 4 months after enrolling [44].

Therefore, we were surprised at this study’s retention rate of only 22% at 5 months. Multiple reasons may have influenced this higher-than-expected dropout rate. The first is that in prior studies, we typically delayed offering ACHES (system on which RISE Iowa is based) until the patient demonstrated their commitment to recovery by attending at least 3 clinic visits. In this study, many clinics offered RISE Iowa at the first visit. As it turns out, the dropout rate from treatment after the first visit is high, typically about 30% to 50% in the first month [50,51]. Hence, by the time we offered ACHES in prior studies, only 50% to 70% of the initial patients remained in treatment, and the retention rate among that 50% to 70% of the original population was closer to 28% to 38%. Second, 25% of Iowa residents live in rural areas with no or inadequate access to the internet [52], moving retention rates of potential patients closer to 50% [53]. This study was also conducted during the COVID-19 pandemic, which could have had varied and unpredictable influences on patient retention and on counselors’ ability to introduce patients to the app. Considering these factors, a lower retention rate in this interim analysis is not surprising compared to previous studies of ACHES.

As the voting results demonstrate, we value the use of financial incentives [54] to implement and sustain innovations. However, our counselors and clinic staff felt that incentives would not be their first choice, if given a choice. When we raised with



agencies the option to incentivize counselors and patients with our own grant money, they rejected the option in most cases. Moreover, substantial literature supports the importance of deeply understanding our customers (patients, agencies, and staff) above all [55]. When designing RISE Iowa, we employed critical incident interviews [56] and conducted walk-throughs [57] to understand what it is like to be a patient, a counselor, and an agency administrator. This effort helped us create a value proposition that makes it in the agency's best interest to adopt and use the technology. These efforts resulted in our team simplifying RISE Iowa adoption and ways to use it as much as possible and understanding where RISE Iowa fits in the workflow to make it as easy to adopt as possible. As one counselor said, "I am so busy that if I have to so much as lift a finger to use RISE Iowa, I won't do it."

NIATX coaches provided strategic support to the agencies' implementation efforts. During their monthly phone sessions, coaches attempted to build motivation to use RISE Iowa by stressing how RISE Iowa can help address "pain" points. Coaches encouraged executives to support RISE Iowa, addressed resistance, and removed barriers while stressing the need to build care delivery systems that integrate RISE Iowa into the clinical and administrative workflows. Coaches also made their organizations aware of evidence-based practices, such as contingency management and motivational interviewing, which might facilitate RISE Iowa use. Overall, with just 1 phone call per month, coaches helped organizations over the rough patches and provided persistent motivational support to expand RISE Iowa use.

### Limitations

This report has several limitations. First, these are preliminary findings during the intervention phase of the trial. Therefore, our results do not include the sustainability of postintervention RISE Iowa utilization. However, the primary purpose of the paper is to delve more deeply into reasons why a process like

NIATx would be superior, not a definitive response on the superiority of the intervention. Second, the qualitative results do not include patient perspectives. This study focused on organization implementation [58] aspects of RISE Iowa app use. Accordingly, these results are from clinician, organizational leader, and coach perspectives. Future studies should also include patient perspectives. The people we did include bring an important perspective that needs to be understood. Third, this study was not designed to address the effectiveness of the RISE Iowa app. Past research addressed this issue [44,59]. Fourth, while there were 43 different sites in this study, there were only 11 different organizations. While most of the sites operated independently of their senior leadership, there were times when corporate policy limited independence. In that sense, the number of truly independent units is smaller than might initially appear. Finally, there was a site dropout rate of 7%, and the study design had a planned dropout rate of 20%. We find this to be a reasonable rate due to the impact that personnel changes may have had on needed participation in the research trial. In addition, the organization that dropped out was replaced with an organization with similar characteristics used for randomization.

### Conclusions

As mentioned earlier, this interim report describes what we have found so far. The results imply that the NIATx approach, along with the use of coaching, led to higher adoption by both patients and counselors, but we are awaiting final results, which are approximately 6 months away. After receiving our final results, we will seek to understand more than we do today, particularly about how well RISE Iowa was sustained in this project.

We hope readers will find this interim report valuable. Finally, we want to reinforce our belief that finding easy-to-use tools to reliably implement evidence-based practice is more important today than adding to theory. People need help now.

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### Acknowledgments

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### Data Availability

The data sets generated and analyzed in this study are not publicly available due to the complexity of app use data and personal information embedded in the data set, but they are available from the corresponding author on reasonable request.

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### Authors' Contributions

DG is the main preparer of this manuscript. TM and DG are the principal investigators; they secured funding, developed the initial project framework, and provided input for the project implementation. JH, KF, and OC assisted with data collection and contributed to data analysis. DB, MR, and JR provided coaching to the organizations in this study and helped write the paper. NJ, RG, and TS also helped write paper. All authors reviewed the paper before submission.

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### Conflicts of Interest

DG is a part-owner of CHES Health, which is devoted to marketing information technologies to agencies that deliver addiction treatment. He is also on the board of directors of the nonprofit NIATx Foundation, as well as a small consulting company. These

relationships do not carry any restrictions on publication, and any associated intellectual property will be disclosed and processed according to his institution's policies. TM is a faculty member at CHESS and has a less than .1% ownership with CHESS Health, the organization responsible for making the AChess addiction recovery app commercially available to the public. TM has worked extensively with his institution to manage any conflicts of interest. An external advisory board approved all survey instruments applied, and the individuals who will conduct the data collection and interpretation for this study will have no affiliation with CHESS Health. Additionally, parts of the NIATx organizational change model used in part of this trial were developed by the Center for Health Enhancement System Studies (CHESS) at the University of Wisconsin-Madison, where TM is a faculty member. He is also affiliated with the NIATx Foundation, the organization responsible for making the NIATx organizational change model available to the public. For this scenario, DG and TM have an institutionally approved plan to manage potential conflicts of interest. The individuals who will conduct the data collection and interpretation for this study manuscript will have no affiliation with the NIATx Foundation or CHESS Health.

#### Multimedia Appendix 1

CONSORT-eHEALTH checklist (V 1.6.1).

[[PDF File \(Adobe PDF File\), 346 KB - humanfactors\\_v9i3e35125\\_app1.pdf](#)]

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## Abbreviations

**ACHESS:** Addiction Comprehensive Health Enhancement Support System  
**BARN:** Body Awareness Resources Network  
**CBT:** cognitive behavioral therapy  
**CBT4CBT:** Computer Based Training for Cognitive Behavioral Therapy  
**FAQ:** frequently asked question  
**NIATx:** Network for the Improvement of Addiction Treatment  
**NIDA:** National Institute on Drug Abuse  
**NIH:** National Institutes of Health  
**QI:** quality improvement  
**RISE Iowa:** Recovering Iowans Supporting Each Other  
**SUD:** substance use disorder  
**TES:** Treatment Evaluation Services

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Original Paper

# Digital Graphic Follow-up Tool (Rehabkompassen) for Identifying Rehabilitation Needs Among People After Stroke: Randomized Clinical Feasibility Study

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## Abstract

**Background:** Stroke is a leading cause of disability among adults, with heavy social and economic burden worldwide. A cost-effective solution is urgently needed to facilitate the identification of individual rehabilitation needs and thereby provide tailored rehabilitations to reduce disability among people who have had a stroke. A novel digital graphic follow-up tool Rehabkompassen has recently been developed to facilitate capturing the multidimensional rehabilitation needs of people who have had a stroke.

**Objective:** The aim of this study was to evaluate the feasibility and acceptability of conducting a definitive trial to evaluate Rehabkompassen as a digital follow-up tool among people who have had a stroke in outpatient clinical settings.

**Methods:** This pilot study of Rehabkompassen was a parallel, open-label, 2-arm prospective, proof-of-concept randomized controlled trial (RCT) with an allocation ratio of 1:1 in a single outpatient clinic. Patients who have had a stroke within the 3 previous months, aged  $\geq 18$  years, and living in the community were included. The trial compared usual outpatient visits with Rehabkompassen (intervention group) and without Rehabkompassen (control group) at the 3-month follow-up as well as usual outpatient visit with Rehabkompassen at the 12-month follow-up. Information on the recruitment rate, delivery, and uptake of Rehabkompassen; assessment and outcome measures completion rates; the frequency of withdrawals; the loss of follow-up; and satisfaction scores were obtained. The key outcomes were evaluated in both groups.

**Results:** In total, 28 patients (14 control, 14 Rehabkompassen) participated in this study, with 100 patients screened. The overall recruitment rate was 28% (28/100). Retention in the trial was 86% (24/28) at the 12-month follow-up. All participants used the tool as planned during their follow-ups, which provided a 100% (24/24) task completion rate of using Rehabkompassen and suggested excellent feasibility. Both patient- and physician-participants reported satisfaction with the instrument (19/24, 79% and 2/2, 100%, respectively). In all, 2 (N=2, 100%) physicians and 18 (N=24, 75%) patients were willing to use the tool in the future. Furthermore, modified Rankin Scale as the primary outcome and various stroke impacts as secondary outcomes were both successfully collected and compared in this study.

**Conclusions:** This study demonstrated the high feasibility and adherence of the study protocol as well as the high acceptability of Rehabkompassen among patients who have had a stroke and physicians in an outpatient setting in comparison to the predefined criterion. The information collected in this feasibility study combined with the amendments of the study protocol may improve the future definitive RCT. The results of this trial support the feasibility and acceptability of conducting a large definitive RCT.

**Trial Registration:** ClinicalTrials.gov NCT04915027; <https://clinicaltrials.gov/ct2/show/NCT04915027>

**KEYWORDS**

stroke; rehabilitation; needs assessment; outcome assessment; structured follow-up; follow-up; digital tool; digital health; eHealth; feasibility; randomized controlled trial; RCT; adherence; acceptability; clinical setting; Rankin scale; outpatient

## Introduction

Stroke is the third-leading cause of disability among adults worldwide, with heavy burden for the patients and their families as well as society [1,2]. Recently, a Global Burden of Disease report indicated that there were 143 million disability-adjusted life-years due to stroke globally in 2019 [3]. People who have had a stroke often have heterogenous functional impairments and limitations of various daily and social activities followed by decreased health-related quality of life long after stroke onset. Despite the recommendations by recent Swedish stroke guidelines, structured follow-up to identify patients' rehabilitation needs and provide patient-tailored and precision rehabilitation regimens remains largely lacking in current stroke care [4]. Establishing such care, however, might lead to extra burden for our already time- and resource-constrained health care system. Thus, a cost-effective solution is urgently needed to facilitate identifying individual rehabilitation needs and thereby provide patient-tailored rehabilitation to reduce disability among people who have had a stroke.

To meet these challenges, we developed Rehabkompassen, a novel digital follow-up tool [5], based on well-validated, patient-reported outcome measures (PROMs). The PROMs used as Rehabkompassen questionnaires consisted of the simplified modified Rankin Scale questionnaire (smRSq), Fatigue Assessment Scale (FAS), Eating Assessment Tool (EAT-10), Hospital Anxiety and Depression Scale (HADS), Stroke Impact Scale (SIS) 3.0 plus, and 3 levels EQ-5D (EQ-5D-3L). Rehabkompassen identifies and graphically visualizes the multidimensional rehabilitation needs of patients who have had a stroke at the individual and group levels. The tool can be used as a screening tool for initial triage *before* the visit, as a communication platform *during* the visit, and as a support tool for patient referral *after* the visit. The tool allows serial assessment and may also be used as an evaluation tool *after* the eventual rehabilitation regimens have been delivered or as an illustration of the alterations of rehabilitation needs over time [5]. Both the paper and digital version of the instrument have previously been proven to be feasible, useful, and time-saving tools for the identification of unmet rehabilitation needs among persons who have had a stroke [5,6] or transient ischemic attack [7,8] in clinical practice.

Before starting a large randomized controlled trial (RCT), recruitment and retention rates, the acceptability of the intervention, and adherence to protocol need to be clarified. The aim of this study was to evaluate the feasibility and acceptability of Rehabkompassen as a digital follow-up tool in the outpatient clinic, in comparison to the control group.

## Methods

### Study Design, Setting, and Randomization

A parallel, open-label, 2-arm prospective, proof-of-concept pilot RCT with an allocation ratio of 1:1 was carried out in an outpatient clinical setting at the Department of Neurological Rehabilitation, University Hospital of Umeå, Sweden, from July 2020 to December 2021.

All participants received 2 outpatient visits at 3 and 12 months after stroke onset. At the 3-month follow-up, the participants were randomized into the intervention (an outpatient visit with Rehabkompassen) or control (an outpatient visit without Rehabkompassen) group according to a computer-generated randomization list prior to the study start. At the 12-month follow-up, all participants received an outpatient visit with Rehabkompassen.

This pilot study together with the planned definitive RCT was registered in ClinicalTrials.gov (NCT04915027). The reporting of this feasibility study was based on CONSORT (Consolidated Standards of Reporting Trials) guidelines [9].

### Ethics Approval

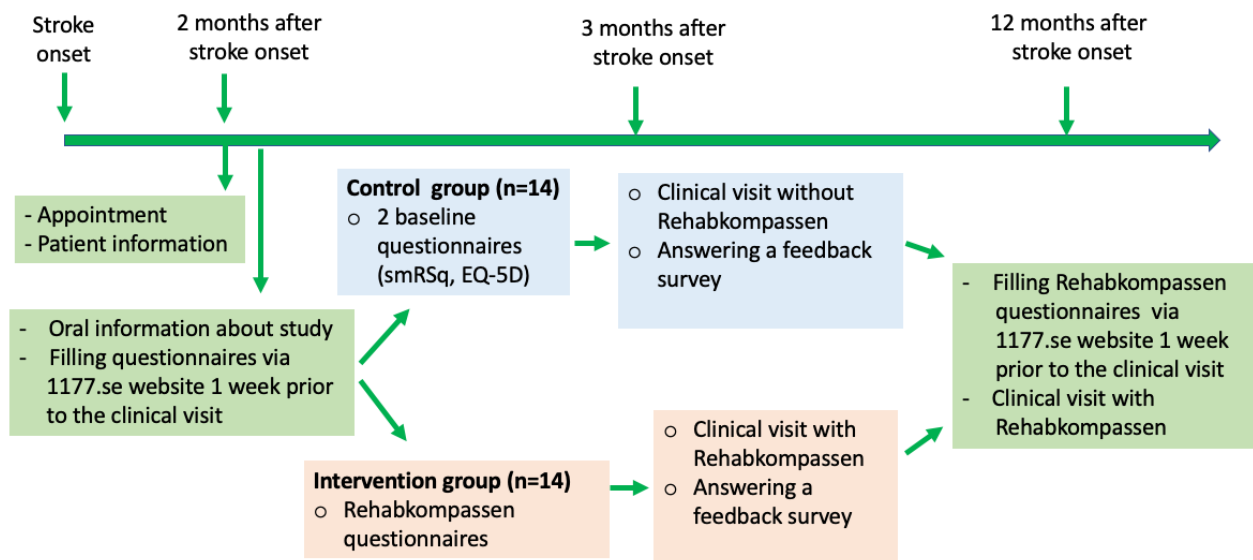
Ethical approvals were obtained from the regional Ethical Review Board in Umeå, Sweden (Dnr 2015/144-31) and completed (Dnr 2019-02830).

### Eligibility Criteria for Participants

All patients with a stroke diagnosis between July 2020 and March 2021 were assessed for study eligibility. Inclusion criteria were (1) aged >18 years, (2) a stroke at least 3 months prior to an outpatient visit, and (3) living in the community. Exclusion criteria were (1) inability to answer the evaluation questions; (2) inability to see the Rehabkompassen graph; and (3) lack of a BankID (a Swedish digital authorization tool), since patients without BankID prior to participating in the study were often digitally naive.

All patients who met the inclusion criteria, together with the appointment for the usual outpatient follow-up, received an invitation to the study around 2 months after stroke onset (Figure 1). The randomization list was created by an independent statistician, who was not involved in outcome assessment or the patients' treatment. Patients who gave their consent were contacted via telephone by a research staff member at the clinic to provide oral information about the study and receive their randomized information. Written consent was obtained from all participants before participation in the study.

**Figure 1.** Process of the patient participants under the study. smRSq: simplified modified Rankin Scale questionnaire.



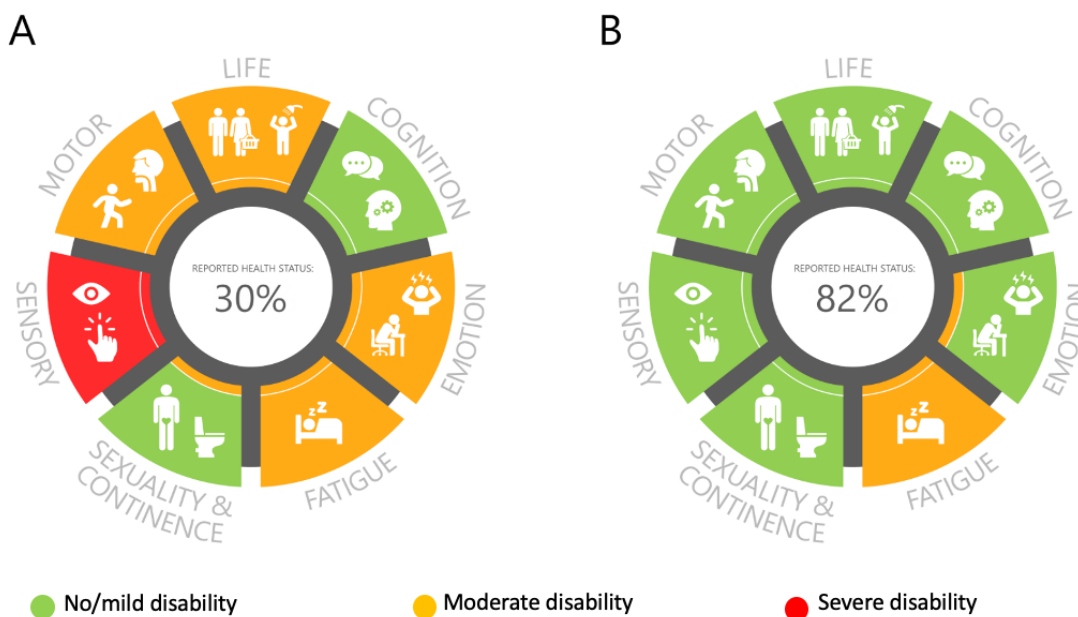
**3-Month Follow-up**

The intervention group consisted of Rehabkompassen and the usual outpatient follow-up that included the patient’s history of disease, examination, and rehabilitation treatment plan. Around 2 months after stroke onset, the patient-participants in the intervention group received the Rehabkompassen questionnaires in their inbox at the 1177.se website, which is a Swedish government-issued digital platform for citizens’ health care as described in the previous study [5]. The patient-participants filled in the Rehabkompassen questionnaires [6] at home by

clicking on the links in their email inbox at the 1177.se website. The Rehabkompassen questionnaires had to be answered no later than 1 week prior to the 3-month follow-up visit (Figure 1).

Prior to the 3-month follow-up, a nurse prioritized the team recourse based on the patient’s Rehabkompassen data. During the follow-up visit, a doctor showed the patient’s personal Rehabkompassen graph (see Figure 2A for an example at the 3-month follow-up) on the computer and used it as an illustration to discuss with patients their health status and rehabilitation needs.

**Figure 2.** Examples of the Rehabkompassen graphs of a patient who has had a stroke showing (A) more rehabilitation needs at the 3-month follow-up and (B) fewer rehabilitation needs at the 12-month follow-up. The Rehabkompassen graphs (A and B) show the self-reported health status of the patient who has had a stroke in a color-coded holistic view with 7 commonly affected areas by stroke: life, cognition, emotion, fatigue, sexuality and continence, sensory function, and motor function. Each area consists of several domains. An extra color-coded field in the inner edge of each area represents the lowest function value in the area.



The control group received the usual follow-up without Rehabkompassen with otherwise identical procedures as the intervention group. To collect the baseline data, the control

group filled in only 2 questionnaires (smRSq and EQ-5D-3L) via the 1177.se website prior to their follow-up appointments (Figure 1).



The length of each visit in both intervention and control groups was the same—approximately 45 minutes. After the visit, all participants in both intervention and control groups received various rehabilitation regimens based on their rehabilitation needs.

### 12-Month Follow-up

All participants from the control and intervention groups filled in the Rehabkompassen questionnaires via the 1177.se website at home 1 week prior to a 12-month follow-up visit (Figure 1). The patients' Rehabkompassen graphs were used in combination with the usual outpatient follow-up as described above for the intervention group. The Rehabkompassen graph at the 3-month follow-up (see Figure 2A for an example for those in the intervention group) could be used as an evaluation tool to compare with the Rehabkompassen graph at the 12-month follow-up (Figure 2B).

### Postvisit Assessments of Satisfaction With the Rehabkompassen Tool

Acceptability was assessed in terms of the patient-participants' satisfaction with Rehabkompassen. After the 3- and 12-month follow-up visits, all patient-participants in both intervention and control groups answered a satisfaction questionnaire through the 1177.se website. The questionnaire addressed their overall experiences of the conversation with the physician and their satisfaction of using the Rehabkompassen graph during the follow-up visit. The satisfaction of Rehabkompassen was rated in terms of how it affected their ability to understand their rehabilitation needs during the consultation throughout the outpatient visit by using a Likert scale from 1 (very easy) to 5 (very difficult). Participants rating either very easy or fairly easy were considered as satisfied with the tool. The patients' satisfaction rate was calculated by the number of patients who were satisfied with the tool divided by the total number of patient-participants.

At the end of the 3-month follow-ups, 2 physicians involved in the study answered a questionnaire with 5 questions regarding the different aspects of utility to provide feedback on the perceived feasibility and satisfaction of the instrument in clinical practice. A Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree) was used, with higher scores indicating better outcomes. Ratings of strongly agree and fairly agree were considered as the physicians being satisfied with the tool. The physicians' satisfaction rate was calculated by the total number of satisfied aspects divided by the total number of aspects.

After analyzing the 3- and 12-month postvisit assessments, we realized that several patient-participants did not fully understand what the Rehabkompassen graph was despite being satisfied with their outpatient visits with Rehabkompassen. Therefore, we amended the questions regarding the graph and added a simple picture of a Rehabkompassen graph to help the participants recall and more easily understand the question. This revised questionnaire will be used in the future definitive RCT.

## Outcomes

### Feasibility Information

To study the feasibility of the study, information on the recruitment rate, adherence, delivery, and uptake of the Rehabkompassen; satisfaction; and possible future use were collected in this study [10,11]. We predefined the following thresholds for specific feasibility and acceptability criteria for deciding whether to progress to the next stage (ie, to carry out the future definitive RCT): (1) the patient recruitment rate would be >20% of the total number of patients who were asked to participate in the study; (2) adherence to the study protocol would be >60% of the total number of the participants with a written consent; (3) the feasibility (delivery and use) of Rehabkompassen would be >60% of the total number of patients using Rehabkompassen as planned; (4) the acceptability of Rehabkompassen (the mean level of satisfaction from both patients and physicians) would be >60% of the total participants; and (5) willingness to use the tool in the future would be >60% of the total participants. However, not reaching the predefined criteria does not necessarily indicate the unfeasibility of the trial but rather underlines that some changes to the protocol would be needed.

### Primary Outcome

The smRSq [12-14] was used to collect the primary outcome of the modified Rankin Scale (mRS) that measures patients' independence or disability level in their daily activities. The smRSq is based on the yes-or-no responses to 5 questions, which is then used to calculate the mRS score ranging from 0 to 5 [12]. A favorable outcome was defined as an mRS score of 0-2 (from no symptoms to independent but with minor disability). A poor outcome was defined as an mRS score of 3-5 (from disability but able to walk to bed-bound and in need of full nursing care) or 6 (death). The completion rates, variances, and 95% CIs for the difference between the intervention arms were analyzed.

### Secondary Outcomes

Secondary outcomes were assessed and collected directly after the patients filled in the Rehabkompassen questionnaires.

Fatigue was measured by FAS [15], a questionnaire used for identifying symptoms of chronic fatigue. It is comprised of 10 questions regarding both physical and mental fatigue answered on a scale from 1 (never) to 5 (always).

Dysphagia was assessed by EAT-10 [16] including 10 questions concerning swallowing difficulties. Each question is to be answered on a scale from 0 (no problem) to 4 (severe problem).

Depression and anxiety were measured by HADS [17], a screening tool for the assessment of anxiety and depression. It comprises 7 questions about anxiety and 7 questions about depression, answered on a scale from 0 (no symptoms) to 3 (severe symptoms). The subscales for anxiety and depression were added and interpreted separately.

Stroke impacts were assessed by SIS [18], a patient-reported, stroke-specific outcome measurement containing 59 questions and a visual analog scale for the estimation of perceived stroke recovery. As secondary outcomes, this study assessed stroke

impacts within 9 domains, namely strength, memory/cognition, feelings/emotions, communication, personal activities of daily living, instrumental activities of daily living, mobility, motor impact, and social participation. In the previous study, we also added items covering continence and sexual function as well as sleep disturbance, which was named SIS-plus [6]. The SIS data are presented in ordinal scores ranging from 0 to 100, with higher scores indicating less impact of stroke [18].

Health-related quality of life and cost-effectiveness were measured by EQ-5D-3L [19,20]. The EQ-5D-3L consists of 2 parts: a visual analog scale and a descriptive system covering 5 dimensions of health (mobility, hygiene, usual activities, pain/discomfort, and anxiety/depression) with 3 response alternatives (ranging from no problems to extreme problems). The latter can be translated to an index value with anchor points 0 (death) and 1 (full health) for eliciting the overall health utility score, corresponding to a quality-adjusted life-years score.

### Data Presentation and Statistics

Descriptive statistics were presented with mean and median values, SDs, quartiles, and proportions. The recruitment rate was calculated by the number of the participants in each group divided by the total number of patients who were assessed for eligibility. The other remaining rate was calculated by the number of the participants in each criterion divided by the number of the patient recruited in its group. In the Rehabkompassen graph, PROMs scale data were converted to

a scale from 0 (worst outcome) to 100 (best outcome) but unchanged in terms of variable properties [6].

Although no statistically significant difference is expected to be found in this feasibility study, the differences on the primary and secondary outcomes on an ordinal scale at the 12-month follow-up between the intervention and control groups were tested using ordinal logistic regression.

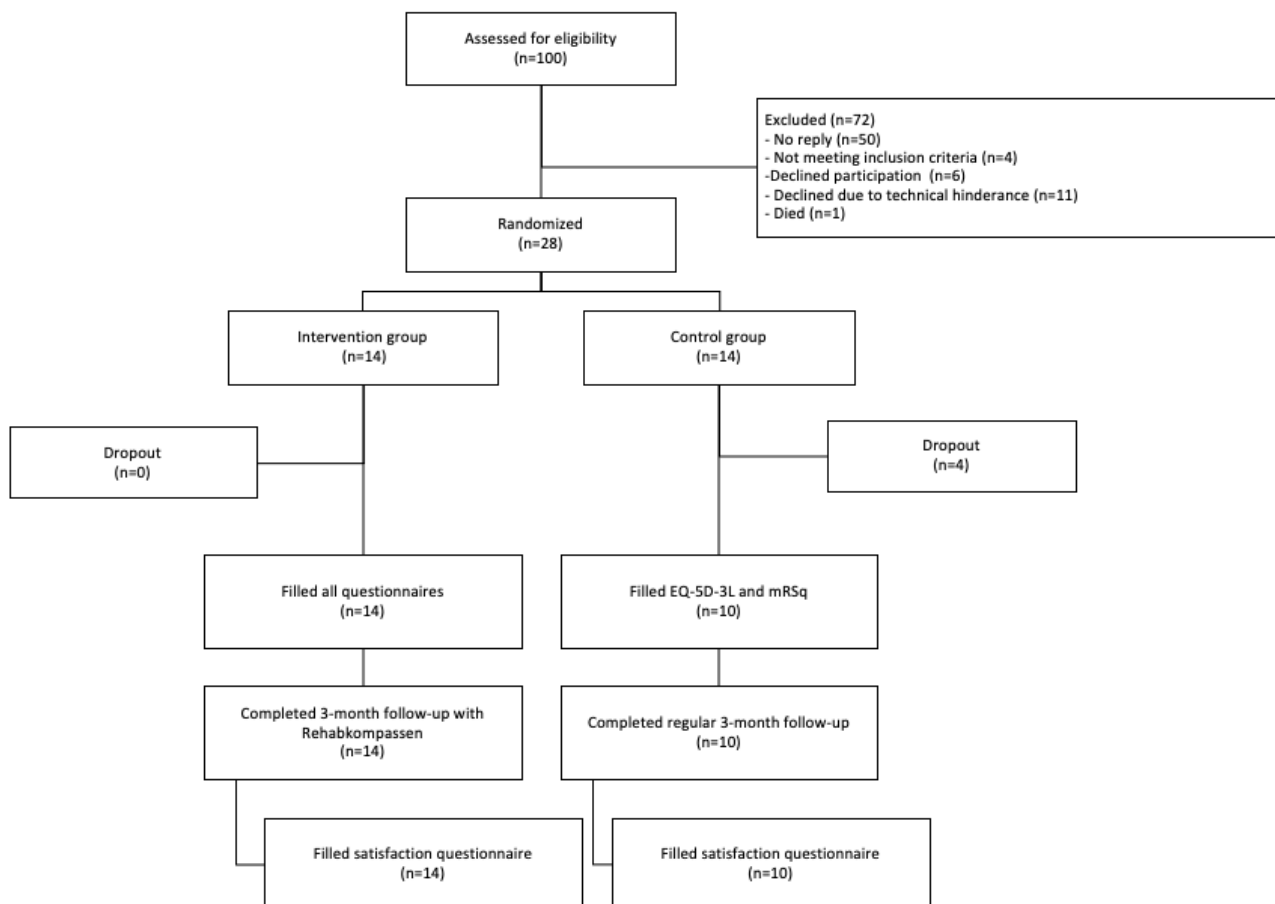
All data were analyzed using SPSS software (version 26.0; IBM Corp). The figures were generated by GraphPad Prism software (version 9; Dotmatics). A 2-tailed  $P$  value of  $<.05$  was considered significant.

## Results

### Patient Recruitment and Feasibility Assessments

In all, 100 patients were assessed for eligibility (Figure 3) from July 2020 to March 2021, to a high extent coinciding with the second wave of COVID-19 in Sweden. Of these 100 patients, 28 participants gave written consent, which equated to a recruitment rate of 28%. Among the 72 patients who did not participate in the study (Figure 3), 50 patients never responded to the study invitation letter; 4 patients did not meet inclusion criteria; 6 patients declined without giving a reason; and 1 patient died. The remaining 11 (N=100, 11%) patients declined participation due to various technical issues, such as no computer at home, no internet, no BankID, or inability to use these technologies.

**Figure 3.** Flowchart of participant recruitment, randomization, and retention. EQ-5D-3L: 3 levels EQ-5D; smRSq: simplified modified Rankin Scale questionnaire.



Of the 14 participants in the control group, 4 dropped out at 3-month follow-up, with no dropout in the intervention group (Figure 3), resulting in a total trial completion rate of 86% (24/28), which was higher than the predefined adherence cutoff (>60%) in the study protocol (Table 1).

All 14 participants in the intervention group at the 3-month follow-up and all 24 participants at the 12-month follow-up

used Rehabkompassen, which resulted in 100% (24/24) on the feasibility of the instrument. This was much better than the predefined feasibility cutoff (>60%; Table 1). Satisfaction with the tool was reported among 79% (19/24) of the patients and 100% (2/2) of the physicians. Moreover, 75% (18/24) of patients and both (2/2, 100%) physicians would prefer to use the tool in the future (Table 1).

**Table 1.** Criteria for the feasibility of Rehabkompassen.

Criterion (predefined cutoff, %)	Intervention group, n (%)	Control group, n (%)	Total, n (%)
Recruitment (total >20%; N=100)	14 (14)	14 (14)	28 (28)
<b>Adherence (total &gt;60%; intervention group: n=14; control group: n=14; total: n=28)</b>			
Dropout at the 3-month follow-up	0 (0)	4 (29)	4 (14)
Dropout at the 12-month follow-up	0 (0)	0 (0)	0 (0)
Adherence of study protocol or retention in the study	14 (100)	10 (71)	24 (86)
<b>Feasibility (total &gt;60%; intervention group: n=14; control group: n=14; total: n=28)</b>			
Delivery of Rehabkompassen at the 3-month follow-up	14 (100)	N/A <sup>a</sup>	14 (100)
Delivery of Rehabkompassen at the 12-month follow-up	14 (100)	10 (100)	24 (100)
<b>Acceptability or uptake (total &gt;60%)</b>			
Patients' satisfaction of Rehabkompassen (n=24)	N/A	N/A	19 (79)
Physicians' satisfaction of Rehabkompassen (n=2)	N/A	N/A	2 (100)
<b>Use in the future (total &gt;60%)</b>			
Patients' willingness to use Rehabkompassen (n=24)	N/A	N/A	18 (75)
Physicians' willingness to use Rehabkompassen (n=2)	N/A	N/A	2 (100)

<sup>a</sup>N/A: not applicable.

## Participant Characteristics

The participants' mean age was 68 years in the intervention group and 66 years in the control group (Table 2). Of the 24 participants, the majority (n=13, 54%) were male. All (n=24, 100%) participants had at least completed primary school, with 50% (n=12) having university degrees, possibly due to the

catchment area being a university city. There were 2 (8%) participants who identified their computer skills as beginner level, whereas the other participants rated their computer skills as average or good. A majority (n=22, 92%) had previous experience with the 1177.se website, whereas 2 (8%) had never logged onto the platform. There were no significant differences in characteristics between the intervention and control groups.

**Table 2.** Baseline characteristic of the patient-participants.

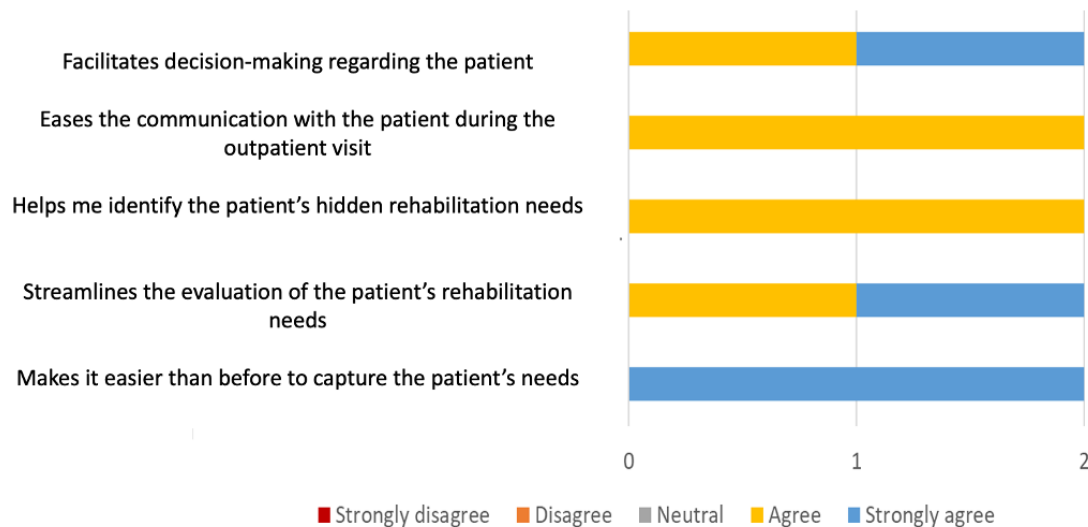
Characteristic, category	Intervention group, (n=14)	Control group, (n=10)
Age (year), mean (SD)	68 (12.0)	66 (11.7)
Sex, female, n (%)	5 (36)	6 (60)
Modified Rankin Scale score, median (IQR)	0 (0-1.25)	1 (0-1)
<b>Highest education, n (%)</b>		
No completed education	0 (0)	0 (0)
Primary school or equivalent	3 (21)	2 (20)
High school or equivalent	3 (21)	4 (40)
University or college	8 (57)	4 (40)
<b>Perceived computer skills, n (%)</b>		
Beginner	2 (14)	0 (0)
Average	6 (43)	6 (60)
Good	6 (43)	4 (40)
Expert	0 (0)	0 (0)

### Assessment of Satisfaction Among Physicians

In total, 2 physicians (one of them is a senior consultant physiatrist) participated in the pilot study to explore the feasibility and satisfaction questions. Both physicians were very positive regarding the potential usefulness of the Rehabkompassen tool (Figure 4). They reported that the tool

facilitated the identification of rehabilitation needs and streamlined evaluation and decision-making regarding the patients' rehabilitation needs. They agreed that the tool made it easier to communicate with their patients and avoid overlooking hidden symptoms. Both (2/2, 100%) physicians would like to use the instrument in the future, which indicated a higher acceptability than the predefined cutoff at 60%.

Figure 4. The 2 physicians' positive feedback on using the Rehabkompassen tool.

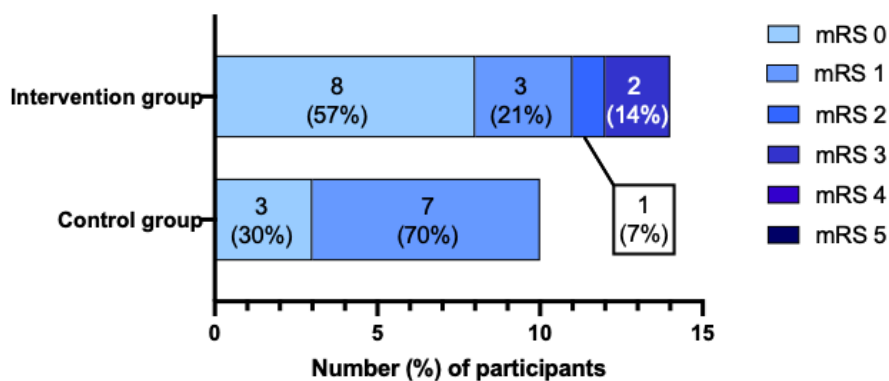


### Primary Outcome

The mRS score at the 12-month follow-up was analyzed in 24 participants, of which 14 patients were allocated to the intervention group with Rehabkompassen and 10 patients were

allocated to the control group without Rehabkompassen at the 3-month follow-up. An ordinal comparison of the distribution of patients across mRS categories at 12 months demonstrated no statistically significant difference between the groups (odds ratio 0.429, 95% CI -1.979 to 1.120;  $P=.59$ ; Figure 5).

Figure 5. Distribution of mRS scores demonstrating no significant difference between the intervention and control groups. mRS: modified Rankin Scale.



### Secondary Outcomes

A panoramic view of various stroke impacts among patients in the intervention and control groups are presented in Table 3. Briefly, the most severe problems reported in median (IQR) by the intervention group were fatigue at 69 (32-89), strength at

72 (50-96), sexual dysfunction at 75 (44-100), and participation at 75 (55-100). In the control group, the most reported problems were strength at 62 (50-100), quality of life at 72 (65-100), pain at 75 (50-100), and daily activity at 80 (80-100). There were no significant differences on each stroke impact between the intervention and control groups (all  $P>.05$ ; see Table 3).

**Table 3.** Extent of rehabilitation needs identified by Rehabkompassen at the 12-month follow-up in both intervention and control groups. The different conditions were assessed by various instruments and grouped into different domains. The extent of rehabilitation needs scores range from 0 (worst outcome or unmet rehabilitation need) to 100 (best outcome or no rehabilitation needs).

Domain, condition (instrument)	Intervention group, median (IQR)	Control group, median (IQR)	<i>P</i> value
<b>Social participation</b>			
Activities of daily living or instrumental activities of daily living (SIS <sup>a</sup> )	94 (82-100)	98 (94-100)	.24
Activity (mRS <sup>b</sup> )	100 (75-100)	80 (80-100)	.59
Participation (SIS)	75 (55-100)	96 (83-100)	.18
Quality of life (EQ-5D)	79 (20-100)	72 (65-100)	.76
Visual analog scale (EQ-5D)	82 (48-92)	75 (61-92)	>.99
<b>Cognition</b>			
Communications (SIS)	96 (86-100)	96 (95-100)	.32
Memory and thinking (SIS)	91 (80-100)	98 (93-100)	.16
<b>Emotion</b>			
Depression (HADS <sup>c</sup> )	91 (70-100)	94 (89-97)	.65
Anxiety (HADS)	85 (70-100)	87 (81-97)	.78
Anxiety (GAD <sup>d</sup> )	90 (75-100)	90 (83-100)	.61
<b>Fatigue</b>			
Fatigue (FAS <sup>e</sup> )	69 (32-89)	81 (62-93)	.25
Sleep (SIS+)	79 (58-94)	88 (75-100)	.39
<b>Continence and sexual function</b>			
Bladder (SIS+)	100 (88-100)	92 (83-100)	.55
Bowel (SIS+)	100 (73-100)	100 (88-100)	.57
Sexual dysfunction (SIS+)	75 (44-100)	88 (56-100)	.66
<b>Sensory function</b>			
Vision (SIS+)	93 (80-100)	93 (79-100)	.80
Smell (SIS)	100 (50-100)	100 (69-100)	.90
Taste (SIS+)	100 (50-100)	100 (69-100)	.56
Hearing (SIS+)	100 (50-100)	100 (94-100)	.29
Sensory (SIS+)	100 (75-100)	100 (88-100)	.95
Pain (SIS+)	88 (25-100)	75 (50-100)	.75
<b>Motor function</b>			
Stiffness (SIS+)	88 (25-100)	88 (50-100)	.99
Strength (SIS)	72 (50-96)	62 (50-100)	.74
Mobility (SIS)	93 (77-100)	100 (89-100)	.14
Hand function (SIS)	98 (64-100)	100 (89-100)	.31
Swallow function (EAT-10 <sup>f</sup> )	100 (66-100)	100 (98-100)	.38

<sup>a</sup>SIS: Stroke Impact Scale.

<sup>b</sup>mRS: modified Rankin Scale.

<sup>c</sup>HADS: Hospital Anxiety and Depression Scale.

<sup>d</sup>GAD: Generalized Anxiety Disorder.

<sup>e</sup>FAS: Fatigue Assessment Scale.

<sup>f</sup>EAT-10: Eating Assessment Tool.

## Discussion

### Principal Findings

This randomized clinical feasibility study investigated the feasibility and acceptability of conducting a definitive trial evaluating Rehabkompassen as a digital follow-up tool among persons who have had a stroke in an outpatient clinic setting. The overall recruitment rate was 28%. Retention in the trial was 86% at the 12-month follow-up, which indicated high adherence to the study protocol. Additionally, a 100% task completion rate of using Rehabkompassen in the study suggested excellent feasibility of the tool. Satisfactions with the instrument reported by both patient- and physician-participants (79% and 100%, respectively) showed the high acceptability of Rehabkompassen and the willingness to use the tool in the future. Furthermore, both mRS as the primary outcome and various stroke impacts as secondary outcomes were successfully collected and compared in this study.

The feasibility of conducting a definitive trial evaluating Rehabkompassen in this study was assessed on recruitment rate, retention rate, and the delivery and uptake of the Rehabkompassen tool. The recruitment rate of 28% was slightly above our predefined cutoff. However, we hope for a better recruitment rate in the future definitive RCT, since this feasibility study was carried out during a heavy COVID-19 pandemic period in Sweden. Compared to the predefined cutoff at 60%, the retention rate of 86% in this study implies that the study protocol was well tolerated by both patients and clinicians. High-quality data may be collected if we achieve a similar retention rate with fewer missing values in the future definitive RCT. Together with a 100% task completion rate of using Rehabkompassen, these excellent feasibility data support our plan of conducting a large definitive RCT.

The acceptability of the tool by both patients (79%) and physicians (100%) could partly explain the higher retention rate in the study compared to the predefined cutoff at 60%. Furthermore, the doctors reported that the tool facilitated communication with their patients and helped identify hidden symptoms, which is partly congruent with feedback from the patients. The satisfaction among the end users is consistent with our previous findings where the usability of the instrument is well demonstrated [5], which is also supported by the high willingness to use the Rehabkompassen tool in the future.

The differences of mRS observed between the treatment arms in this pilot study were not statistically significant, which is consistent with other large RCTs where mRS was chosen as the primary outcome [13,21]. Although no statistically significant difference on mRS as the primary outcome is expected to be found in this feasibility study, the results still raised a critical concern of whether the mRS as a single primary outcome was

sensitive enough to capture the subtle alterations of treatment-effects in the future definitive RCT. Additionally, the background characteristics of the participants demonstrated that most of the target study population had a mild to moderate disability with more limitation on social participation, which is in line with previous Swedish stroke RCTs [13,22]. To catch the minor but important changes on both daily activity and social participation over time, we added Domain 8 in SIS [23] as another primary outcome to use in the future definitive RCT, since mRS covers mainly daily activity [14].

This randomized feasibility study revealed other concerns in addition to the abovementioned amendments, such as the extension of exclusion criteria with BankID and revision on the satisfaction questionnaire. We found that 11% of patients without sufficient computer knowledge were excluded in the study, which provided information on how many patients would need extra help in case such persons would like to participate in the future definitive study. Even with multiple secondary outcomes collected in this study, it was considered less time-consuming for the health care professionals, since these outcomes were based upon PROMs filled out in advance by the patients through Rehabkompassen. Thus, this would not jeopardize the collection of primary outcome data.

Although this feasibility study provides important information and necessary amendments for the future definitive RCT study, there were a couple of limitations. Since this feasibility study was carried out in only 1 outpatient clinic, we cannot generalize the results directly to different participating clinics with various clinical routines in the future multicenter RCT. It remains a challenge to fit the Rehabkompassen tool within various existing clinical routines despite the high rates of feasibility and acceptability demonstrated in this study. Furthermore, this feasibility study was performed by an experienced clinical research team, which is crucial for reaching a high-quality study. Therefore, it is very important that knowledge transfer, timely troubleshooting, and problem-solving by the experienced research team be available during the future definitive RCT. At this stage, the results remain difficult to generalize due to its limited sample size (2 physicians; and 14 patients in the control and intervention groups, respectively) in this pilot study; thus, a further definitive RCT is needed.

### Conclusions

This study demonstrated very high feasibility and adherence to the study protocol as well as the high acceptability of the Rehabkompassen tool among people who have had a stroke and physicians in an outpatient setting in comparison to the predefined criterion. This information may improve the future definitive RCT. The results of this trial support the feasibility and acceptability of conducting a large definitive RCT.

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## Data Availability

The data sets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

CONSORT-eHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 467 KB - [humanfactors\\_v9i3e38704\\_app1.pdf](#) ]

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## Abbreviations

**CONSORT:** Consolidated Standards of Reporting Trials

**EAT-10:** Eating Assessment Tool

**EQ-5D-3L:** 3 levels EQ-5D

**FAS:** Fatigue Assessment Scale

**HADS:** Hospital Anxiety and Depression Scale

**mRS:** modified Rankin Scale

**PROM:** patient-reported outcome measure

**RCT:** randomized controlled trial

**SIS:** Stroke Impact Scale

**smRSq:** simplified modified Rankin Scale questionnaire

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Original Paper

# Alignment Between Heart Rate Variability From Fitness Trackers and Perceived Stress: Perspectives From a Large-Scale In Situ Longitudinal Study of Information Workers

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## Abstract

**Background:** Stress can have adverse effects on health and well-being. Informed by laboratory findings that heart rate variability (HRV) decreases in response to an induced stress response, recent efforts to monitor perceived stress in the wild have focused on HRV measured using wearable devices. However, it is not clear that the well-established association between perceived stress and HRV replicates in naturalistic settings without explicit stress inductions and research-grade sensors.

**Objective:** This study aims to quantify the strength of the associations between HRV and perceived daily stress using wearable devices in real-world settings.

**Methods:** In the main study, 657 participants wore a fitness tracker and completed 14,695 ecological momentary assessments (EMAs) assessing perceived stress, anxiety, positive affect, and negative affect across 8 weeks. In the follow-up study, approximately a year later, 49.8% (327/657) of the same participants wore the same fitness tracker and completed 1373 EMAs assessing perceived stress at the most stressful time of the day over a 1-week period. We used mixed-effects generalized linear models to predict EMA responses from HRV features calculated over varying time windows from 5 minutes to 24 hours.

**Results:** Across all time windows, the models explained an average of 1% (SD 0.5%; marginal  $R^2$ ) of the variance. Models using HRV features computed from an 8 AM to 6 PM time window (namely work hours) outperformed other time windows using HRV features calculated closer to the survey response time but still explained a small amount (2.2%) of the variance. HRV features that were associated with perceived stress were the low frequency to high frequency ratio, very low frequency power, triangular index, and SD of the averages of normal-to-normal intervals. In addition, we found that although HRV was also predictive of other related measures, namely, anxiety, negative affect, and positive affect, it was a significant predictor of stress after controlling for these other constructs. In the follow-up study, calculating HRV when participants reported their most stressful time of the day was less predictive and provided a worse fit ( $R^2=0.022$ ) than the work hours time window ( $R^2=0.032$ ).

**Conclusions:** A significant but small relationship between perceived stress and HRV was found. Thus, although HRV is associated with perceived stress in laboratory settings, the strength of that association diminishes in real-life settings. HRV might be more reflective of perceived stress in the presence of specific and isolated stressors and research-grade sensing. Relying on wearable-derived HRV alone might not be sufficient to detect stress in naturalistic settings and should not be considered a proxy for perceived stress but rather a component of a complex phenomenon.

**KEYWORDS**

stress measurement; heart rate variability; HRV; perceived stress; ecological momentary assessment; EMA; wearables; fitness tracker

## *Introduction*

### **Motivation and Overview**

The World Health Organization classified stress as a 21st-century epidemic [1], as chronic stress can have adverse effects on health and well-being. Stress is the perceived imbalance in demands and resources and is experienced when a situation is appraised as personally significant and taxes or exceeds resources for coping [2]. In the short term, stress is associated with negative feelings, decreased performance and productivity, and muscular problems such as tension and headaches [3,4]. In the long term, stress can lead to significant health problems, including cardiovascular disease, impaired immunity functions, and lower overall quality of life [5,6]. Therefore, the ability to monitor stress through unobtrusive means could help improve health outcomes and well-being.

Stress measurements fall roughly into two broad categories: measuring stress directly through physiological markers such as heart rate (HR) variability (HRV) [7,8], cortisol [9], or electrodermal activity [10] and using physiological data to predict perceived stress using self-reports as ground truth [11-14]. Theories on the role of appraisal on the stress response suggest a positive relationship between perceived stress (through appraising a situation as threatening or demanding) and physiological reactions such as changes in cortisol (ie, the stress hormone), respiration, and HR [2,15-17]. Laboratory studies generally confirm this relationship (see the *Background* section). However, measuring perceived stress in daily life remains an exceedingly challenging task.

Gold standard biological measures of stress such as cortisol (a stress hormone) tend to be time consuming, expensive, and intrusive; they do not allow continuous measurement and may not align with self-reports [18,19]. Researchers have considered other physiological measures associated with the stress response such as HRV, electrodermal activity, and respiration, which can be obtained using less intrusive means such as wearable sensors [20-22]. Wearable sensors are some of the least intrusive methods of measuring physiological stress and yield continuous measures with increased frequency and finer temporal granularity than self-reports or cortisol samples. In recent years, the increased quality and battery life and the low cost of wrist-worn wearables have made it possible for studies to focus on the alignment between physiological (HRV) and self-reported measures in daily life [12,23,24], bringing to light some of the limitations of translating laboratory findings to real-world settings.

Although laboratory studies that induced stress supported an association between HRV and perceived stress (eg, using the Stroop Color-Word Interference Test and mental arithmetic problems [25-28]; also see the study by Kim et al [29] for a review that found differences in HRV in response to stress),

studies in daily life settings with and without wearables have yielded mixed results. For instance, in a study of 223 male white-collar workers, Kageyama et al [30] found that daily job stressors did not correlate with short-term electrocardiogram (ECG)-derived HRV features. In contrast, in a study of 909 participants, Sin et al [31] found that ECG-derived HRV features negatively correlated with longer-term (as opposed to daily) perceived stress measured over a period of 8 days. Similarly, Hynynen et al [32] found that HRV measured in an orthostatic test (sitting up after a period of sleep) but not during night sleep was related to longer-term self-reported (global) stress over the past month. Specifically, HRV features were lower in the group with high stress than in the group with lower stress, whereas HR was higher in the group with high stress. Furthermore, in a study of 20 surgeons monitored continuously over 24 hours, Rieger et al [33] separated surgeons into groups experiencing high and low stress and found significantly higher HR and lower HRV during sleep in the group with high stress.

In real-world settings involving wearables, few studies have used HRV to predict perceived stress and have also found mixed results. Hernandez [23] collected physiological and behavioral data to predict self-reported momentary stress (high vs low) from 15 participants during 5 regular days of work.

Hernandez [23] used a support vector machine model using HRV features, achieving an average accuracy of 56%, slightly better than the 50% at baseline. Similarly, in a 4-month study of 35 participants, Muaremi et al [12] achieved a classification accuracy of 59% in a 3-level prediction task of perceived stress (low, moderate, and high), with 40% at baseline. In a simpler classification task of high versus low stress, Wu et al [24] found that HRV features yielded a classification accuracy of 78% in a study of 8 participants for 2 weeks in a data set with 59% of the samples corresponding to low stress.

These studies demonstrate that HRV associations with perceived stress obtained in situ and with wearables are less consistent than in laboratory studies. The evidence is inconclusive as to whether HRV in real-life settings could reflect *daily* or *momentary* perceived stress, as is often assumed in popular applications [8,34-37]. The greatest success comes from a few small-scale studies with simplified (eg, binarized from ordinal ratings with the removal of the more difficult middle cases) stress classification tasks. Given the recency of incorporating HRV measurement in consumer-grade wearable devices to track stress in daily life and the lack of large-scale studies addressing this issue, we report on a main study, where we collected HRV data from wrist-worn wearables, as well as self-reports for 657 participants across 9 weeks, and a follow-up with 327 (49.8%) of the same participants over 1 week approximately a year later.

We extend previous studies that predicted stress from wearable HRV data in two ways: (1) we collected HRV data in a large-scale longitudinal study in a naturalistic setting (ie, without

control over what stressors occur and when); and (2) we incorporated retrospective stress evaluations, including measures of the timing of stressful periods, to investigate whether contextual knowledge of when stress occurs could help predict perceived stress. Our studies also aimed to shed light on potential factors that could explain why self-reports of stress often do not correlate with physiological measures. Specifically, we aimed to understand the extent to which HRV predicts perceived stress in naturalistic settings. Furthermore, given that HRV is a measure of arousal, we also examined the extent to which HRV is specific to stress beyond other high-arousal affective states, including anxiety, negative affect, and positive affect.

The contributions of this study are as follows:

1. We quantified the degree of association between HRV and perceived stress in a longitudinal large-scale in situ study with information workers.
2. HRV can be calculated in many ways over many time scales (eg, 5 minutes to 24 hours). We identified low frequency (LF)/high frequency (HF) ratio, very LF (VLF), triangular index, and SD of the averages of normal-to-normal intervals (SDANN) calculated between 8 AM to 6 PM as the HRV features most strongly associated with perceived stress. Using these optimal features, we found that HRV is a predictor of perceived stress; however, the relationship is not as strong as in the laboratory, indicating that HRV is limited as a sole indicator of perceived stress, as is often used in modern applications.
3. We found that the same features that indicate stress also predict anxiety, negative affect, and positive affect. However, HRV still uniquely predicts stress after accounting for the shared variance of these related constructs with stress.
4. We describe the limitations of using HRV to measure perceived stress in situ and offer suggestions to improve perceived stress measurement.

## Background

Stress is defined as the physiological response to maintain homeostasis in unexpected situations or when perceiving a threat [38-41]. The stress response is manifested in 2 systems, the autonomic nervous system (ANS)—through the sympathetic nervous system (SNS) and parasympathetic nervous system (PNS)—and the hypothalamic-pituitary-adrenal (HPA) axis [42]. The SNS outputs epinephrine, which promotes rapid and widespread physiological changes such as increased HR [43,44], whereas the PNS generally does the opposite [40,45-47]. The HPA axis outputs cortisol, a stress hormone, which supports the SNS system by increasing available glucose by suppressing other body systems such as immune function and growth [5,48,49]. In general, SNS activity ends when a stressor ends, whereas HPA axis activity may persist for up to 90 minutes after the stressor ends [50-52]. Thus, especially over time and with chronic stressors (eg, caregivers of patients with dementia), there may be a sustained cortisol response in the absence of specific SNS activity [53-55]. Many of the chronic detrimental effects of stress, such as the increased risk of heart disease,

diabetes, and mortality, are associated with increased cortisol [5,56-58].

HRV is a measure of ANS activity and has been associated with health and physical and mental stress [25,29,59-65]. HRV measurement relies on the detection of RR intervals; that is, the time between upward deflections in an ECG. Effective clinical ECG measurements require the assistance of a trained clinician to ensure correct electrode placement. A more user-friendly version for (fitness conscious) consumers is chest straps (eg, Zephyr Bioharness [66,67]) that capture waveforms in the same manner as an ECG and do not require a clinician while still being vulnerable to improper positioning.

At the other end of the spectrum, photoplethysmography sensors approximate the measurement of RR intervals by detecting beat-to-beat intervals (BBI) evidenced by volumetric changes in the microvascular bed of tissue [68,69]. Traditionally used in wearable equipment such as fitness trackers, smartwatches, and armbands, they are easy to fit and have extended battery life, therefore allowing for continuous measurement of BBI and, in consequence, HRV. This has enabled a myriad of applications that use these sensors to measure HRV and provide a measurement of “stress” [8,34-37]. However, although HRV is associated with stress in laboratory studies, as discussed previously, HRV only measures one component of the stress response: ANS activity. Although the short duration and acute stressors may evoke a strong SNS response, chronic stressors that are characterized by increased cortisol in the absence of an SNS response may not be detected by HRV alone but could still influence self-reports of perceived stress.

The differences between SNS and HPA axis activity, their measurement, and the time courses of responses may play a role in when (or whether) a relationship is found between physiological responses and self-reported stress (eg, cortisol assessed via blood shows faster responses than cortisol measured by saliva). For instance, one study [51] induced stress and found that self-reported stress was associated with physiological stress (increased HR and cortisol) only if assessed during the stressor task. Self-reported stress before or after the stressor did not correlate with physiological stress during the same period. Other studies suggest there may be a lag between perceived and physiological stress where subjective stress responses precede cortisol (endocrine) responses [70]. Gaab et al [71] found that anticipatory but not retrospective cognitive appraisal of stress (self-report) is an important determinant of the cortisol stress response, indicating that the timing of the self-report in relation to the stressor affects whether a relationship is found between perceived and physiological stress. In contrast, Oldehinkel et al [72] found that perceived stress *before* a social stressor in the laboratory did not predict physiological responses, although changes in perceived arousal and unpleasantness were associated with changes in HR, respiratory sinus arrhythmia, and cortisol during the stressor. Furthermore, perceived stress measured *after* the stressor was inversely associated with HR during the stressor.

Regarding field studies, in a literature review on the association between salivary cortisol and self-reported stress, Hjortskov et al [18] reported a lack of sufficient evidence of an association

between self-reported mental stress and the cortisol response in field studies. The review suggested that the large diversity in study designs and stress measurements possibly obscured any potential relationship. However, these findings from previous studies on the association between perceived and physiological stress indicate a relationship that may be dependent on the temporal resolution of both measurements.

Taken together, the data suggest that HRV is a reliable measure of perceived stress during stressful tasks in the laboratory. However, reliability can be eroded in naturalistic studies for several reasons. First, ecological momentary assessments (EMAs) for stress may not occur (or be answered) during a stressor, which may reduce the accuracy of physiological signals for predicting self-reported stress. Second, HRV-based measures of stress would require a stressor that evokes an HR or HRV response rather than a chronic stressor that may influence self-reports but not HR (eg, a chronic illness). Third, self-reported stress may be reflecting memory biases or coping responses (eg, see the studies by Redelmeier and Kahneman [73] and Scheier et al [74]). Fourth, there are contradictory results for the best time to measure the physiological response of a self-reported stressor (albeit possibly because of methodological differences), coupled with the lack of precise and complete information on stressors that influence the perceived stress level themselves. Finally, HRV measured from wearable sensors might not be sufficiently reliable and might be too sensitive to noise (eg, motion artifacts), thereby obfuscating any potential relationship [70]. Given these

challenges, this study sought to investigate the relationship between HRV measured through wearable sensors and perceived stress in a large sample across an extended period and in situ.

## Methods

### Data Collection

This data were collected as part of the larger Tesseract Project [75]. Most participants came from 4 distinct organizations (denoted by O1, O2, O3, and O4), and others from various organizations (denoted by U). Participants were enrolled both on site and remotely. The characteristics of the participants, sensing streams, and study details of the Tesseract study are described in the study by Mattingly et al [75].

Participants were enrolled between January and July of 2018 for the main study, where psychological and physiological measurements of 657 participants were collected during the first 56 days of study participation. This data were used to analyze associations between HRV and self-reported perceived stress. On the basis of the results from this study, we conducted a 1-week follow-up study with 49.8% (327/657) of the same participants in April 2019 to ascertain whether the link between HRV and perceived stress could be improved by refining the self-reporting procedure.

### Demographics

Demographics were collected from a survey administered at the onset of participation (Table 1).

**Table 1.** Demographics summary for each study (N=657).

Variable	Main study	Follow-up study (n=327)
<b>Gender, n (%)</b>		
Male	391 (59.5)	211 (65.5)
Female	266 (40.5)	116 (35.5)
<b>Organization, n (%)</b>		
O1 <sup>a</sup>	165 (25.1)	109 (33.3)
O2 <sup>a</sup>	237 (36.1)	78 (23.9)
O3 <sup>a</sup>	85 (12.9)	52 (15.9)
O4 <sup>a</sup>	25 (3.8)	5 (1.5)
U <sup>b</sup>	145 (22.1)	83 (25.4)
<b>Supervisor status, n (%)</b>		
Nonsupervisors	370 (56.3)	206 (63)
Supervisors	285 (43.4)	121 (37)
Unknown	2 (0.3)	0 (0)
<b>Age (years)</b>		
Values, minimum	20	20
Values, maximum	68	68
Values, mean (SD)	35.2 (9.9)	35.9 (10.3)

<sup>a</sup>Distinct organization.

<sup>b</sup>Other organizations.

## Psychological Measures

### Main Study

Stress was measured using the question, “Overall, how would you rate your current level of stress?” on a 5-point Likert scale ranging from 1 (no stress at all) to 5 (a great deal of stress); The responses were distributed as follows: 5303 responses were 1s (no stress at all); 5108 responses were 2s (very little stress); 3593 responses were 3s (some stress), 573 responses were 4s (a lot of stress); and 118 were 5s (a great deal of stress). This item was validated in an unpublished study [76] (available upon request) with 991 Mechanical Turk participants (Table S10 in Multimedia Appendix 1 provides correlations with other measures). Affect was measured using the 10-item Positive and Negative Affect Short inventory [77,78]. The distribution of the responses is available in Figure 1. Anxiety was measured

using a validated single-item omnibus measure of anxiety, “Please select the response that shows how anxious you feel at the moment,” on a 5-point Likert scale ranging from 1 (not at all anxious) to 5 (extremely anxious) [79]. EMAs were administered once a day through Qualtrics Surveys at 8 AM, 12 PM, or 4 PM over 8 weeks. Participants were prompted to answer the EMAs through SMS text messages. The responses were distributed as follows: 7501 responses were 1s (not at all anxious); 5081 responses were 2s (a little anxious); 1659 were 3s (moderately anxious); 354 were 4s (very anxious); and 100 were 5s (extremely anxious).

Given that the variables were measured repeatedly for each participant throughout the study, we used the repeated-measures correlations [80] procedure to correlate the response variables in the main study. The correlations are shown in Table 2.

Figure 1. Distribution of positive and negative affect in the main study.

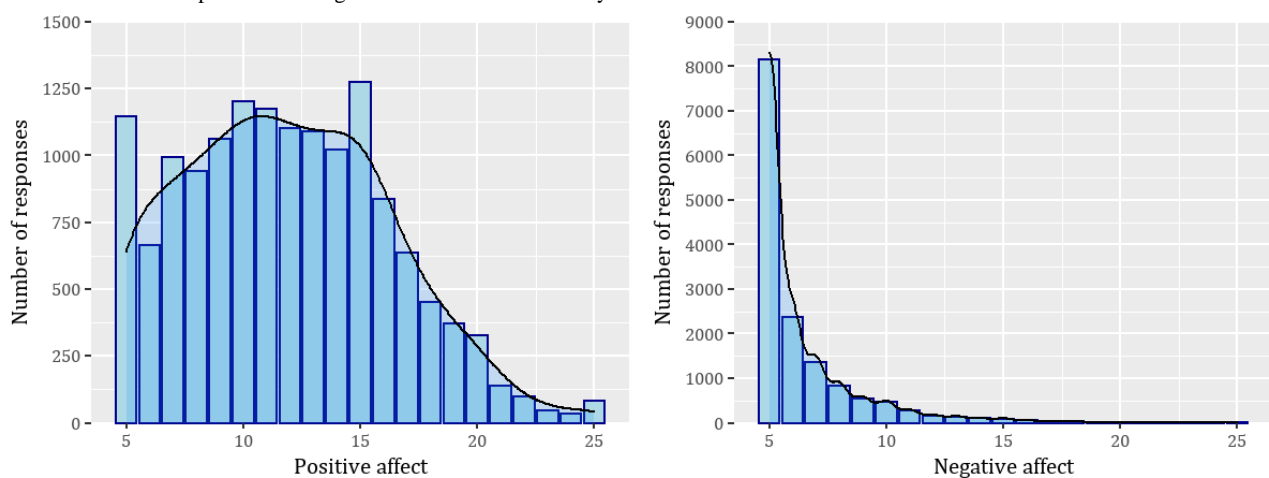


Table 2. Repeated-measures correlation between response measures in the main study and 95% CI.

Variables	Stress, $r_{rm}$ (95% CI)	Anxiety, $r_{rm}$ (95% CI)	Negative affect, $r_{rm}$ (95% CI)	Positive affect, $r_{rm}$ (95% CI)
Stress	1	0.64 (0.63 to 0.65)	0.56 (0.54 to 0.57)	-0.03 (-0.04 to -0.01)
Anxiety	0.64 (0.63 to 0.65)	1	0.62 (0.61 to 0.63)	-0.02 (-0.03 to 0.00)
Negative affect	0.56 (0.54 to 0.57)	0.62 (0.61 to 0.63)	1	-0.05 (-0.07 to -0.03)
Positive affect	-0.03 (-0.04 to -0.01)	-0.02 (-0.03 to 0.00)	-0.05 (-0.07 to -0.03)	1

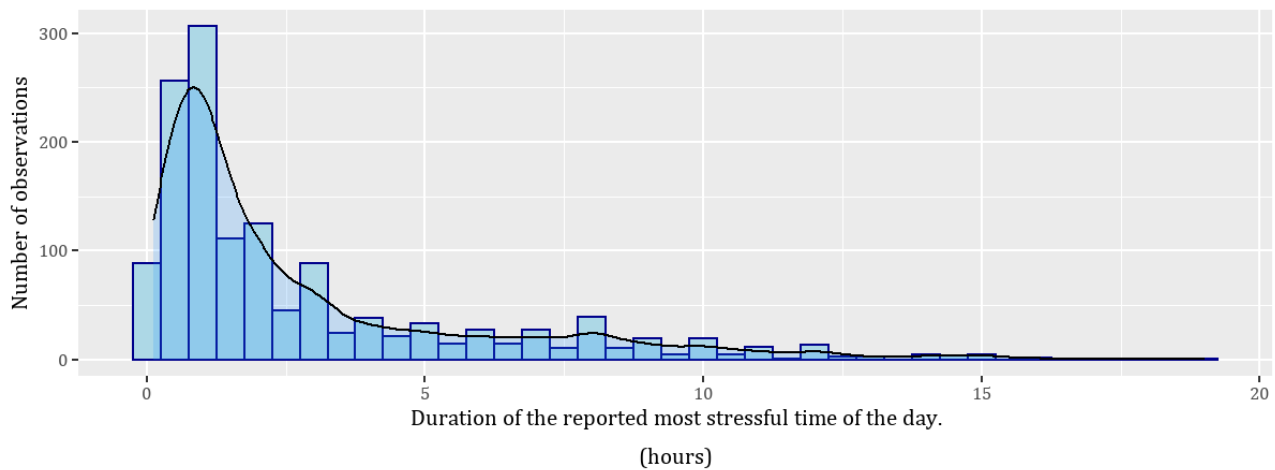
### Follow-up Study

In the follow-up study, EMAs were sent at 4 PM every day over a week (Monday to Sunday). We collected stress by asking the same item as in the main study along with the following questions: “When did the most stressful part of your day start?”—answered by entering hours and minutes in free-form fields; “When did the most stressful part of your day end?”—also answered by entering hours and minutes in free-form fields; and “How stressful was that time?”—answered on a 5-point Likert scale ranging from 1 (no stress at all) to 5 (a great deal of stress). The responses to the stress question as stated in the main study were distributed as follows: 205 responses were 1s (no stress at all); 530 responses were 2s (very little stress); 484 responses were 3s (some stress), 22 responses were 4s (a lot of stress); and 132 were 5s (a great deal of stress).

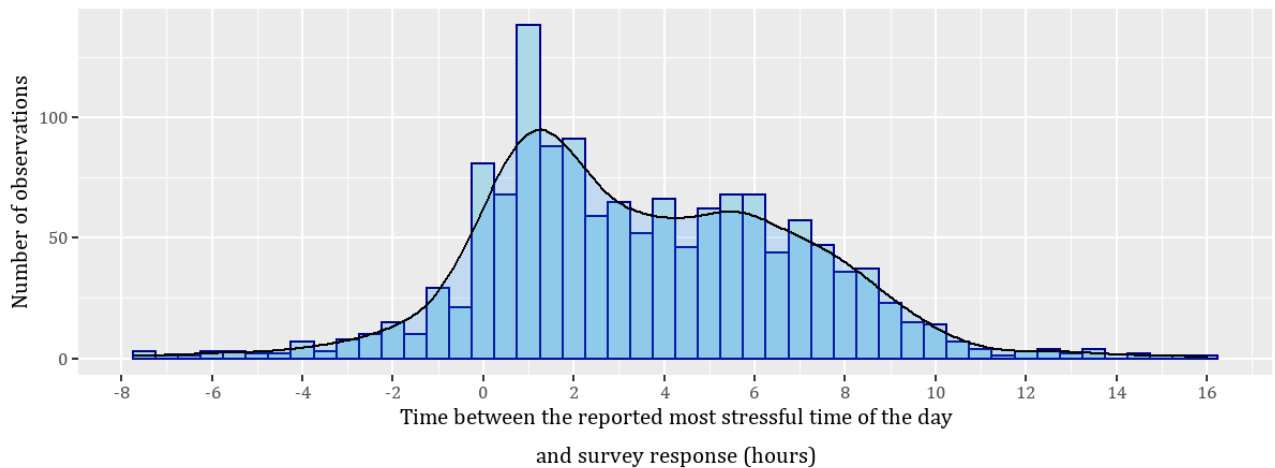
The responses to the question “How stressful was that time?” were distributed as follows: 36 responses were 1s (no stress at all); 254 responses were 2s (very little stress); 732 responses were 3s (some stress), 71 responses were 4s (a lot of stress); and 280 were 5s (a great deal of stress).

From the timings provided by participants, we calculated the duration of the reported most stressful time of the day, as well as the length of time between the end of that moment and when the participant answered the survey. We refer to the stress question asked in the same way as in the main study, as perceived stress at the time of survey response, whereas we refer to the item introduced in the follow-up study as perceived stress at the reported most stressful time of the day. Figures 2 and 3 provide the distribution of responses, and Table 3 shows the correlation of the responses [80].

**Figure 2.** Distribution of the duration of perceived stress at the reported most stressful time of the day. Note that in some cases, this time overlapped with the survey response time.



**Figure 3.** Distribution of the time between the reported most stressful time of the day and the survey response time. Negative values are because of when participants anticipated that the most stressful time of the day would end after the survey response time. Positive times indicate that the most stressful time of the day started and ended before the survey was answered, and negative times indicate the most stressful time of the day at least ended after the survey was answered.



**Table 3.** Repeated-measures correlations of the responses in the follow-up study and 95% CI.

Measures	Perceived stress at the time of survey response, $r_{rm}$ (95% CI)	Perceived stress at the reported most stressful time of the day, $r_{rm}$ (95% CI)	Duration of the most stressful time, $r_{rm}$ (95% CI)
Perceived stress at the time of survey response	1	0.5 (0.45 to 0.54)	0.33 (0.27 to 0.38)
Perceived stress at the reported most stressful time of the day	0.5 (0.45 to 0.54)	1	0.17 (0.11 to 0.22)
Duration of most stressful time	0.33 (0.27 to 0.38)	0.17 (0.11 to 0.22)	1
Time between most stressful time and survey response	-0.29 (-0.34 to -0.23)	-0.12 (-0.18 to -0.06)	-0.43 (-0.48 to -0.38)

**Physiological Measures**

Wearables can accurately detect HR, especially in conditions of rest or mild exercise [81], although they can have missing data [82]. To measure HR and BBI, from which HRV is computed, participants wore the Garmin vivosmart 3 fitness band (24/7) for the duration of their participation. The same sensors were used in the main study and the follow-up.

In both studies, we examined the associations between HRV and the psychological measures in our sample. To do so, we derived a series of HRV features by adopting standards for the measurement, physiological interpretation, and clinical use of HRV from the North American Society of Pacing and Electrophysiology [29]. In total, we computed 16 HRV features across different time windows using the “hranalysis” python library [83], each with a minimum and maximum recording time within the recommended ranges established by Shaffer

and Ginsberg [84]. Of these features, 5 were from time domain analyses, which measure variation in HR over time, or the intervals between HR cycles [29]. Triangular index was the single geometric method used [85]. A total of 7 features were from frequency domain analyses [24] where the power spectral density analysis of the HRV frequency domain provides information about how power in a signal is distributed as a

function of frequency, which allows the autonomic balance to be quantified at a specific time [29]. The remaining 3 features were nonlinear HRV features, which characterize changes in HRV [86-88]. In this study, we focused on features derived from the Poincaré plot (ie, the scatter plot of successive BBIs:  $BBI_n$  vs  $BBI_{n+1}$ ). Table 4 shows the mean and SD of the features across 3 different time windows.

**Table 4.** Mean and SD of heart rate variability features in the main study by window size.

Feature	Type	Description	Values by window size, mean (SD)		
			5-minute	8 AM to 6 PM	24-hour
Mean BBI <sup>a</sup>	TD <sup>b</sup>	The mean BBI for a period	758.1 (130.3)	755 (87.1)	797.8 (90.7)
SDNN <sup>c</sup>	TD	The SD of NN <sup>d</sup> intervals for a period	87.6 (34.2)	135.8 (37.1)	156.0 (45.3)
RMSSD <sup>e</sup>	TD	The square root of the mean of the squares of the successive differences between adjacent NN intervals for a period	68.7 (24.1)	71.7 (18.1)	64.7 (16.1)
PNN50 <sup>f</sup>	TD	The number of interval differences of successive NN intervals >50 milliseconds (NN50) divided by the total number of all NN intervals	33.3 (14.4)	33.3 (10.1)	27.8 (9.2)
SDANN <sup>g</sup>	TD	The SD of the averages of NN intervals in all 5-minute segments of a period	N/A <sup>h</sup>	99.5 (32.0)	130.4 (41.4)
Triangular index	GM <sup>i</sup>	The number of total NN intervals/number of NN intervals in the modal bin	16.1 (5.2)	35.4 (10.4)	41.9 (13.5)
HF <sup>j</sup>	FD <sup>k</sup>	Spectral density power in the HF range	1184.9 (688.1)	1244.3 (500.4)	991.0 (404.0)
LF <sup>l</sup>	FD	Spectral density power in the LF range	1637.3 (1129.7)	1779.9 (799.3)	1628.1 (707.0)
LFnu <sup>m</sup>	FD	LF power in normalized units: $LF / (\text{total power} - VLF^n) \times 100$	56.8 (8.4)	58.4 (3.11)	61.8 (4.0)
HFnu <sup>o</sup>	FD	HF power in normalized units: $HF / (\text{total power} - VLF) \times 100$	43.2 (8.4)	41.6 (3.11)	38.2 (4.0)
LF/HF	FD	Ratio of LF/HF	1.43 (0.7)	1.42 (0.2)	1.65 (0.3)
Total power	FD	The variance of NN intervals over the temporal segment	4224.1 (2859.9)	4517.9 (2026.3)	4035.4 (1730.7)
VLF	FD	Spectral density power in the VLF range	1401.9 (1363.6)	1493.7 (765.4)	1416.4 (670.2)
SD1	NL <sup>p</sup>	The SD of the Poincaré plot perpendicular to the line of identity	48.68 (17.1)	50.7 (12.8)	45.7 (11.4)
SD2	NL	The SD of the Poincaré plot along the line of identity	113.2 (47.1)	185 (51.8)	215.6 (63.8)
SD2/SD1	NL	Ratio of SD2 and SD1	2.39 (0.78)	3.7 (0.8)	4.8 (1.1)

<sup>a</sup>BBI: beat-to-beat intervals.

<sup>b</sup>TD: time domain.

<sup>c</sup>SDNN: SD of normal-to-normal intervals.

<sup>d</sup>NN: normal-to-normal.

<sup>e</sup>RMSSD: root mean square of successive differences.

<sup>f</sup>PNN50: proportion of normal-to-normal intervals that differ by >50 milliseconds.

<sup>g</sup>SDANN: SD of the averages of normal-to-normal intervals

<sup>h</sup>N/A: not applicable.

<sup>i</sup>GM: geometric method.

<sup>j</sup>HF: high frequency.

<sup>k</sup>FD: frequency domain.

<sup>l</sup>LF: low frequency.

<sup>m</sup>LFnu: low frequency in normalized units.

<sup>n</sup>VLF: very low frequency.

<sup>o</sup>HFnu: high frequency in normalized units.

<sup>p</sup>NL: nonlinear.

As HRV features have different applications but are nevertheless correlated among themselves to varying degrees [84,89], we

examined previous studies to select which features to include in our modeling. We started by selecting the three time domain

features and one geometric method feature recommended by the Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology [85]: SD of normal-to-normal intervals (SDNN), root mean square of successive differences (RMSSD), SDANN, and triangular index. As RMSSD and SD1 are identical, as are SDNN and SD2, we only entered RMSSD and SDNN in the models [84]. LF power in normalized units and HF power in normalized units are identical measures that capture the same information as LF/HF; therefore, we only included LF/HF in the models to estimate the ratio between SNS and PNS activity [84,90]. HF is also strongly correlated with PNN50 and RMSSD; therefore,

we did not include it in the models. Despite eliminating SD1, SD2, HF, and LF, we decided to keep the ratios as SD2/SD1 and LF/HF as they could capture additional information compared with the individual measures [84]. The correlations among the final set of features across long-term (24 hours) and short-term (5 minutes) windows are shown in Tables 5 and 6. Finally, as HRV measurements explain different phenomena depending on the time window, we decided to use variance inflation factor (VIF) feature elimination [91] to determine the set of features for each particular model and time window and address concerns with multicollinearity.

**Table 5.** Repeated-measures correlations among the final set of features calculated during the 24 hours of the day when participants answered the surveys and 95% CI (N=14,695 observations from 657 participants).

Measures	Correlations, $r_{rm}$ (95% CI)									
	SDNN <sup>a</sup>	RMSSD <sup>b</sup>	MRRIC <sup>c</sup>	PNN50 <sup>d</sup>	SDANN <sup>e</sup>	Triangular index	LF <sup>f</sup> /HF <sup>g</sup>	Total power	VLF <sup>h</sup>	
SDNN	— <sup>i</sup>	—	—	—	—	—	—	—	—	—
RMSSD	0.2 (0.19 to 0.22)	—	—	—	—	—	—	—	—	—
MRRIC	0.27 (0.25 to 0.28)	0.49 (0.48 to 0.51)	—	—	—	—	—	—	—	—
PNN50	0.21 (0.19 to 0.23)	0.93 (0.93 to 0.93)	0.45 (0.43 to 0.46)	—	—	—	—	—	—	—
SDANN	0.82 (0.81 to 0.82)	0.02 (0 to 0.03)	0.02 (0 to 0.04)	0.04 (0.03 to 0.06)	—	—	—	—	—	—
Triangular index	0.67 (0.66 to 0.68)	0.26 (0.24 to 0.27)	0.29 (0.28 to 0.31)	0.3 (0.29 to 0.32)	0.5 (0.49 to 0.51)	—	—	—	—	—
LF/HF	0.24 (0.23 to 0.26)	-0.33 (-0.34 to -0.31)	0.33 (0.31 to 0.34)	-0.35 (-0.37 to -0.34)	0.17 (0.15 to 0.18)	0.14 (0.12 to 0.16)	—	—	—	—
Total power	0.36 (0.35 to 0.38)	0.84 (0.83 to 0.84)	0.62 (0.61 to 0.63)	0.84 (0.84 to 0.84)	0.13 (0.11 to 0.14)	0.37 (0.36 to 0.38)	0.01 (-0.01 to 0.03)	—	—	—
VLF	0.42 (0.41 to 0.44)	0.69 (0.68 to 0.7)	0.63 (0.62 to 0.64)	0.68 (0.67 to 0.69)	0.18 (0.17 to 0.2)	0.39 (0.37 to 0.4)	0.15 (0.14 to 0.17)	0.94 (0.94 to 0.95)	—	—
SD2/SD1	0.69 (0.68 to 0.7)	-0.5 (-0.52 to -0.49)	-0.14 (-0.16 to -0.13)	-0.48 (-0.5 to -0.47)	0.67 (0.66 to 0.68)	0.37 (0.35 to 0.38)	0.47 (0.46 to 0.48)	-0.29 (-0.3 to -0.27)	-0.14 (-0.16 to -0.13)	—

<sup>a</sup>SDNN: SD of normal-to-normal intervals.

<sup>b</sup>RMSSD: root mean square of successive differences.

<sup>c</sup>MRRIC: mean RR interval.

<sup>d</sup>PNN50: proportion of normal-to-normal intervals that differ by >50 milliseconds.

<sup>e</sup>SDANN: SD of the averages of normal-to-normal intervals.

<sup>f</sup>LF: low frequency.

<sup>g</sup>HF: high frequency.

<sup>h</sup>VLF: very low frequency.

<sup>i</sup>Upper triangle of the correlation matrix was omitted for simplicity and readability.



**Table 6.** Repeated-measures correlations among the final set of features calculated on the 5 minutes centered on the time when participants started answering the surveys and 95% CI (N=14,695 observations from 657 participants)<sup>a</sup>.

Measure	Correlations, $r_{rm}$ (95% CI)						
	SDNN <sup>b</sup>	RMSSD <sup>c</sup>	MRRId	PNN50 <sup>e</sup>	LF <sup>f</sup> /HF <sup>g</sup>	Total power	VLF <sup>h</sup>
SDNN	— <sup>i</sup>	—	—	—	—	—	—
RMSSD	0.63 (0.62 to 0.64)	—	—	—	—	—	—
MRRId	0.27 (0.25 to 0.28)	0.61 (0.6 to 0.62)	—	—	—	—	—
PNN50	0.59 (0.58 to 0.6)	0.95 (0.94 to 0.95)	0.53 (0.52 to 0.54)	—	—	—	—
LF/HF	0.02 (0 to 0.03)	-0.11 (-0.13 to -0.1)	0.22 (0.2 to 0.24)	-0.15 (-0.16 to -0.13)	—	—	—
Total power	0.75 (0.74 to 0.76)	0.81 (0.8 to 0.81)	0.55 (0.54 to 0.57)	0.73 (0.72 to 0.74)	0.13 (0.11 to 0.14)	—	—
VLF	0.73 (0.72 to 0.74)	0.53 (0.52 to 0.54)	0.34 (0.32 to 0.35)	0.46 (0.45 to 0.47)	0.12 (0.1 to 0.13)	0.88 (0.88 to 0.88)	—
SD2/SD1	0.52 (0.51 to 0.53)	-0.27 (-0.29 to -0.26)	-0.28 (-0.3 to -0.27)	-0.28 (-0.29 to -0.26)	0.24 (0.22 to 0.25)	0.05 (0.03 to 0.07)	0.28 (0.27 to 0.3)

<sup>a</sup>SD of the averages of normal-to-normal intervals and triangular index are not included as they should not be calculated in a single 5-minute time window.

<sup>b</sup>SDNN: SD of normal-to-normal intervals.

<sup>c</sup>RMSSD: root mean square of successive differences.

<sup>d</sup>MRRId: mean RR interval.

<sup>e</sup>PNN50: proportion of normal-to-normal intervals that differ by >50 milliseconds.

<sup>f</sup>LF: low frequency.

<sup>g</sup>HF: high frequency.

<sup>h</sup>VLF: very low frequency.

<sup>i</sup>Upper triangle of the correlation matrix was omitted for simplicity and readability.

## Data Exclusion

To account for missing EMA or smartwatch data during both studies (eg, dead battery or device not worn), days were excluded from the sample if any value was missing from the predictors for that day. This resulted in a final data set of 14,695 entries in the main study and 1373 in the follow-up study of matching psychological and physiological measures.

## HRV Analysis

### Main Study

The main purpose of this study was to examine the relationship between HRV and perceived stress as assessed by a daily stress survey. Many of the HRV features calculated are suited for short time frame measurements (eg, 2 minutes), as well as the long term (eg, 24 hours); however, Shaffer and Ginsberg [84] cautioned that these are not to be used interchangeably. Therefore, given the conflicting evidence presented in the related works as to when it is best to measure HRV in relation to a stressful event, we tested a series of models for predicting the daily stress survey response, with HRV features derived (1) 5 minutes before completing the survey, (2) 30 minutes before, (3) 5 minutes after, (4) 30 minutes after, (5) using time windows of varying length (5 minutes, 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, and 24 hours) centered on the moment the survey

was started, (6) during the entire 24 hours on the day a participant answered the survey, and (7) during the “work day” from 8 AM to 6 PM. For sake of brevity, we report all the coefficients only for the model using the time frame with the best fit in the main results, whereas the coefficients of the models across all other time windows are reported in the form of density plots in Figure S5 in [Multimedia Appendix 2](#). Finally, we examined the overall variance explained in the outcome measure of daily perceived stress from the HRV features.

To determine whether HRV specifically predicts stress or simply indicates arousal, which correlates with other psychological measures, we first built models to examine whether our derived HRV features predicted other survey measures that are known to have a relationship with psychological stress or arousal: positive affect, negative affect, and anxiety [92,93]. Then, to understand whether there is specificity in predicting perceived stress, we further built two models: a model predicting stress using anxiety, positive affect, and negative affect as predictors, and a second model incorporating HRV as an additional predictor.

### Follow-up Study

In the analysis conducted in the follow-up study, we leveraged the additional information gained from participants related to their perceived stress duration and evaluated how well the HRV

features can predict perceived stress at the reported most stressful time of the day and again predict perceived stress at the time of survey response (the same question asked in the main study). For predicting perceived stress at the reported most stressful time of the day and perceived stress at the time of survey response, in this study, we computed the HRV features in the same manner as in the main study and used the best performing time window found earlier while also considering HRV features calculated during participants' reported most stressful periods for that day. We proceeded to compare these 2 models in predicting both perceived stress at the reported most stressful time of the day and perceived stress at the time of survey response. In addition, we considered the duration of perceived stress at the reported most stressful time of the day as an outcome measure in itself to better understand whether HRV is related to the saliency (score) of the stress events or the duration.

### Modeling Strategy

As our data comprises repeated observations for each participant, and stress and anxiety are ordinal variables, we used cumulative link mixed-effects models [94] using a random intercept for the participant. We considered using random slopes in our models but decided against it because of model convergence issues in the main study and not having enough observations to support such random effects structure in the follow-up study. In the cases of predicting positive affect and the duration of perceived stress at the reported most stressful time of the day (follow-up study), we used linear mixed-effects models [95,96] as the variables can be considered continuous. In the case of negative affect, we used a negative binomial generalized linear mixed-effects model, given the distribution of the variable (Figure 1). As stated earlier, we used VIF [97] feature elimination to iteratively remove VIFs >3 to address multicollinearity [91,98]. As the predictors were on vastly different scales, all predictor variables were  $z$  score standardized before being entered into the models. Pseudo  $R^2$  values for both marginal (fixed effects alone) and conditional (random and

fixed) effects are reported using the method described by Nakagawa and Schielzeth [99].

### Ethics Approval

The study protocol was approved by the University of Notre Dame Institutional Review Board (17-5-3870).

## Results

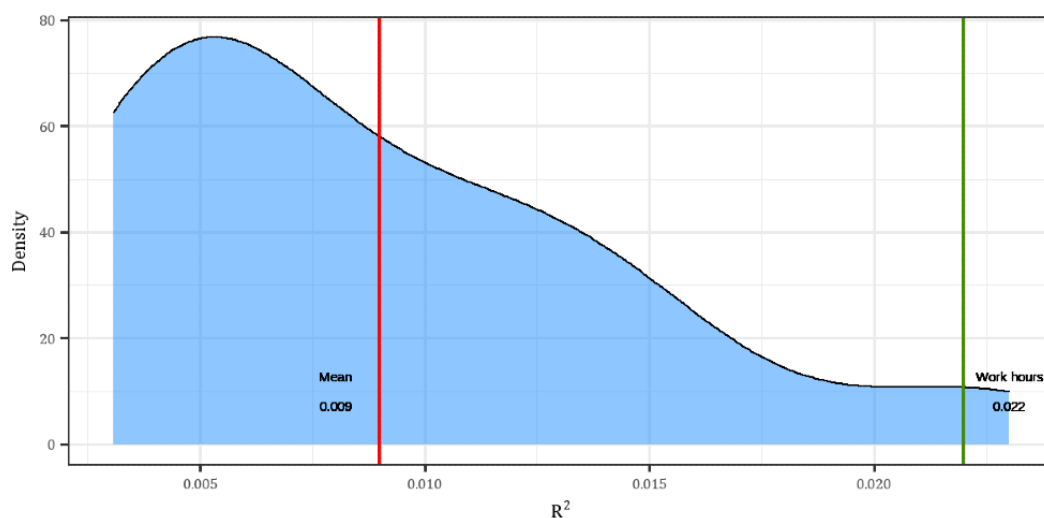
### Main Study

Figure 4 provides a density plot of the variance explained (pseudo  $R^2$ ) by the HRV features across all periods. On average, HRV explained a small portion (approximately 1%) of the variability in perceived stress. We also found that the model with features computed during the hours of 8 AM to 6 PM had the lowest Akaike information criterion (AIC) and explained the highest variance (Figure 4), although this was still modest (2.2%). Coefficients for this model are reported in Table 7, whereas density plots of coefficients across all time windows are included in Figure S5 (Multimedia Appendix 2).

Regarding whether HRV predicts perceived stress specifically or simply predicts arousal, we found that the directionality of most of the associations was the same for stress, anxiety, positive affect, and negative affect (Tables 7 and 8). Mean RR interval was a significant predictor of anxiety and positive affect but was not significant in predicting stress. LF to HF ratio and triangular index were both significant predictors of stress; however, LF to HF ratio was not a significant predictor of negative affect, and triangular index was not a significant predictor of positive affect.

In addition, after controlling for positive affect, negative affect, and anxiety, most HRV features were still significant predictors of perceived stress, and when compared against a model that only considers the measures of affect and anxiety, a model containing HRV provided a better fit (Table 7), as confirmed by likelihood ratio tests and AIC ( $\chi^2_5=157.8$ ;  $P<.001$ ; AIC 23,561 vs 23,709).

**Figure 4.** Density plot of marginal  $R^2$  across time windows from 5 minutes to 24 hours.



**Table 7.** Model for perceived stress with variance inflation factor–reduced HRV<sup>a</sup> features derived from beat-to-beat interval data during normal work hours of 8 AM to 6 PM<sup>b</sup>.

Predictors	Perceived stress at the time of survey response from HRV <sup>c</sup>		Perceived stress at the time of survey response from anxiety, positive affect, and negative affect <sup>d</sup>		Perceived stress at the time of survey response from anxiety, positive affect, negative affect, and HRV <sup>e</sup>	
	OR <sup>f</sup> (95% CI)	<i>P</i> value	OR (95% CI)	<i>P</i> value	OR (95% CI)	<i>P</i> value
MRRI <sup>g</sup>	0.95 (0.89-1.02)	.16	— <sup>h</sup>	—	1.01 (0.94-1.09)	.75
LF <sup>i</sup> /HF <sup>j</sup>	0.86 (0.82-0.91)	<.001 <sup>k</sup>	—	—	0.85 (0.81-0.90)	<.001 <sup>k</sup>
VLF <sup>l</sup>	1.54 (1.42-1.67)	<.001 <sup>k</sup>	—	—	1.31 (1.20-1.43)	<.001 <sup>k</sup>
Triangular index	0.88 (0.83-0.94)	<.001 <sup>k</sup>	—	—	0.94 (0.88-1.01)	.10
SDANN <sup>m</sup>	0.74 (0.69-0.78)	<.001 <sup>k</sup>	—	—	0.81 (0.76-0.86)	<.001 <sup>k</sup>
Anxiety	—	—	5.38 (5.05-5.73)	<.001 <sup>k</sup>	5.30 (4.97-5.64)	<.001 <sup>k</sup>
Positive affect	—	—	0.96 (0.91-1.01)	.11	0.94 (0.89-0.99)	.01
Negative affect	—	—	2.52 (2.37-2.68)	<.001 <sup>k</sup>	2.53 (2.38-2.69)	<.001 <sup>k</sup>

<sup>a</sup>HRV: heart rate variability.

<sup>b</sup>Model fit on 14,695 observations from 657 participants. Cumulative link mixed-effects model thresholds are omitted for brevity. An extended version with threshold values is available in Table S15 in [Multimedia Appendix 5](#).

<sup>c</sup>Random effects:  $\sigma^2=3.29$ ;  $\tau_{00}=2.25$ ; participant intraclass correlation coefficient 0.41; marginal  $R^2$ /conditional  $R^2=0.022/0.420$ ; Akaike information criterion 31,602.

<sup>d</sup>Random effects:  $\sigma^2=3.29$ ;  $\tau_{00}=1.48$ ; participant intraclass correlation coefficient 0.31; marginal  $R^2$ /conditional  $R^2=0.547/0.688$ ; Akaike information criterion 23,709.

<sup>e</sup>Random effects:  $\sigma^2=3.29$ ;  $\tau_{00}=1.52$ ; participant intraclass correlation coefficient 0.32; marginal  $R^2$ /conditional  $R^2=0.548/0.691$ ; Akaike information criterion 23,561.

<sup>f</sup>OR: odds ratio.

<sup>g</sup>MRRI: mean RR interval.

<sup>h</sup>The predictor was not included in this model.

<sup>i</sup>LF: low frequency.

<sup>j</sup>HF: high frequency.

<sup>k</sup>*P* values lower than .05 are highlighted in italics.

<sup>l</sup>VLF: very low frequency.

<sup>m</sup>SDANN: SD of the averages of normal-to-normal intervals.

**Table 8.** Model for anxiety (cumulative link mixed-effects model) and negative affect (linear mixed-effects model) with variance inflation factor–reduced heart rate variability features derived from beat-to-beat interval data during normal work hours of 8 AM to 6 PM<sup>a</sup>.

Predictors	Positive affect <sup>b</sup>			Negative affect <sup>c</sup>			Anxiety <sup>d</sup>	
	Standardized $\beta$	Standardized 95% CI	<i>P</i> value	IRR <sup>e</sup>	95% CI	<i>P</i> value	OR <sup>f</sup> (95% CI)	<i>P</i> value
Intercept	-.01	-0.07 to 0.05	<.001	6.32	6.22 to 6.43	<.001	— <sup>g</sup>	—
MRR1 <sup>h</sup>	-.15	-0.17 to -0.12	<.001	0.99	-0.06 to -0.004	.06	0.90 (0.83 to 0.97)	.004 <sup>i</sup>
LF <sup>j</sup> /HF <sup>k</sup>	-.08	-0.10 to -0.07	<.001	1.00	-0.03 to 0.01	.88	0.92 (0.87 to 0.97)	.002 <sup>i</sup>
VLF <sup>l</sup>	.12	0.09 to 0.15	<.001	1.04	0.06 to 0.12	<.001	1.51 (1.39 to 1.65)	<.001 <sup>i</sup>
Triangular index	.00	-0.02 to 0.02	.91	0.98	-0.08 to -0.03	.001	0.91 (0.85 to 0.97)	.005 <sup>i</sup>
SDANN <sup>m</sup>	-.03	-0.05 to -0.01	.002	0.98	-0.07 to -0.03	<.001	0.76 (0.72 to 0.81)	<.001 <sup>i</sup>

<sup>a</sup>Models fit on 14,695 observations from 657 participants. *P* values <.05 are highlighted in italics. Cumulative link mixed-effects model thresholds are omitted for brevity. An extended version with threshold values is available in Table S16 in [Multimedia Appendix 5](#).

<sup>b</sup>Random effects:  $\sigma^2=9.03$ ;  $\tau_{00}=9.69$ ; participant intraclass correlation coefficient 0.52; marginal  $R^2$ /conditional  $R^2=0.020/0.527$ .

<sup>c</sup>Random effects:  $\sigma^2=0.15$ ;  $\tau_{00}=0.03$ ; participant intraclass correlation coefficient 0.19; marginal  $R^2$ /conditional  $R^2=0.004/0.191$ .

<sup>d</sup>Random effects:  $\sigma^2=3.29$ ;  $\tau_{00}=2.51$ ; participant intraclass correlation coefficient 0.43; marginal  $R^2$ /conditional  $R^2=0.015/0.441$ .

<sup>e</sup>IRR: incidence rate ratio.

<sup>f</sup>OR: odds ratio.

<sup>g</sup>The predictor was not included in this model.

<sup>h</sup>MRR1: mean RR interval.

<sup>i</sup>*P* values lower than .05 are highlighted in italics.

<sup>j</sup>LF: low frequency.

<sup>k</sup>HF: high frequency.

<sup>l</sup>VLF: very low frequency.

<sup>m</sup>SDANN: SD of the averages of normal-to-normal intervals.

## Follow-up Study

We first assessed whether using the context provided by participants to determine an HRV window to calculate the features provided a benefit over the previously found best time window of work hours of the day. Our outcome variables were perceived stress at the time of survey response and perceived stress at the reported most stressful time of the day. In the case of perceived stress at the time of survey response, the model of HRV during work hours (reported in [Table 9](#)) achieved the best fit with an  $R^2$  of 0.032 versus 0.022 and AIC of 3465 versus 3475, therefore favoring the model with HRV features calculated during the workday, as in the main study. It also replicates findings from the main study, which found an  $R^2$  of 0.022. Similar results are obtained when predicting perceived stress at the reported most stressful time of the day ( $R^2$  of 0.023 vs 0.015), with the model based on HRV during work hours reported in [Table 9](#) and a full comparison available in Tables S11 to S12 in [Multimedia Appendix 3](#). Thus, we did not observe

benefits from computing HRV features based on self-reported most stressful time of the day compared with the entire workday. We also found that HRV during work hours was predictive of the duration of perceived stress at the reported most stressful time of the day ([Table 9](#)), although the fit was quite small.

As the duration of perceived stress at the reported most stressful time of the day was correlated with perceived stress at the time of survey response and perceived stress at the reported most stressful time of the day scores ([Table 3](#)), we conducted a post hoc analysis to investigate whether HRV could predict the saliency of the perceived stress while controlling for the effects of the duration of the event and elapsed time since it occurred—contextual features provided through self-report. Including HRV features along with contextual features provided a better fit ( $R^2$  of 0.064 vs 0.050) over simply using the contextual features. This was further confirmed by likelihood ratio tests and AIC ( $\chi^2_5=22.9$ ;  $P<.001$ ; AIC 3242 vs 3255; see [Tables S13 and S14 in Multimedia Appendix 4](#) for the full models).

**Table 9.** Prediction of perceived stress at the time of survey response, perceived stress at the reported most stressful time of the day, and duration of perceived stress at the reported most stressful time of the day with the same predictors—heart rate variability during work hours—as in the best model in the main study<sup>a</sup>.

Predictors	Perceived stress at the time of survey response <sup>b</sup>		Perceived stress at the reported most stressful time of the day <sup>c</sup>		Duration of perceived stress at the reported most stressful time of the day <sup>d</sup>		
	OR <sup>e</sup>	<i>P</i> value	OR	<i>P</i> value	$\beta$	95% CI	<i>P</i> value
Intercept	— <sup>f</sup>	—	—	—	.02	−0.06 to 0.10	.64
MRRIG <sup>g</sup>	0.98 (0.79 to 1.23)	.89	0.86 (0.70 to 1.07)	.18	−.03	−0.12 to 0.07	.59
LF <sup>h</sup> /HF <sup>i</sup>	0.84 (0.73 to 0.98)	.03 <sup>j</sup>	0.85 (0.73 to 0.99)	.04	−.02	−0.09 to 0.05	.57
VLF <sup>k</sup>	1.56 (1.22 to 1.99)	<.001 <sup>j</sup>	1.54 (1.21 to 1.97)	<.001	.15	0.05 to 0.25	.005
Triangular index	0.79 (0.63 to 0.99)	.04 <sup>j</sup>	0.98 (0.79 to 1.24)	.93	−.11	−0.19 to −0.03	.03
SDANN <sup>l</sup>	0.75 (0.61 to 0.91)	.003 <sup>j</sup>	0.73 (0.60 to 0.89)	.002	−.10	−0.20 to −0.01	.008

<sup>a</sup>The models were fit with 1373 observations from 327 participants. Cumulative link mixed-effects models threshold values are omitted for brevity. An extended version with threshold values is available in Table S17 in [Multimedia Appendix 5](#).

<sup>b</sup>Random effects:  $\sigma^2=3.29$ ;  $\tau_{00}=1.21$ ; participant intraclass correlation coefficient 0.27; marginal  $R^2$ /conditional  $R^2=0.032/0.292$ .

<sup>c</sup>Random effects:  $\sigma^2=3.29$ ;  $\tau_{00}=0.97$ ; participant intraclass correlation coefficient 0.23; marginal  $R^2$ /conditional  $R^2=0.023/0.245$ .

<sup>d</sup>Random effects:  $\sigma^2=0.60$ ;  $\tau_{00}=0.40$ ; participant intraclass correlation coefficient 0.40; marginal  $R^2$ /conditional  $R^2=0.019/0.414$ .

<sup>e</sup>OR: odds ratio.

<sup>f</sup>Cumulative Link Mixed Models have multiple thresholds rather than one intercept. Therefore, no value for an intercept is included in this table.

<sup>g</sup>MRRIG: mean RR interval.

<sup>h</sup>LF: low frequency.

<sup>i</sup>HF: high frequency.

<sup>j</sup>*P* values lower than .05 are highlighted in italics.

<sup>k</sup>VLF: very low frequency.

<sup>l</sup>SDANN: SD of the averages of normal-to-normal intervals.

## Discussion

### Principal Findings

Stress is associated with many negative outcomes [3-6], thereby making accurate measurement and management of it an important aspect of improving both physical and mental health outcomes. To this end, the ubiquitous computing and mobile health communities have turned to wearables and, more specifically, identified wearable-sensed HRV as an attractive method for passively sensing stress [12,23,24,29]. However, does the evidence support associating HRV—as measured with wearables in the wild—with stress, as perceived by the user?

We found that the best model yielded a marginal  $R^2$  of 2.2%, which approximately corresponds to a correlation of 0.15 and a Cohen  $d$  of 0.30, which lies between a small (Cohen  $d=0.20$ ) to medium (Cohen  $d=0.50$ ) effect [100,101]. Thus, HRV was weakly, although significantly, associated with perceived stress when measured using a wearable in naturalistic settings. The size of this effect is, to some degree, expected, given that HRV only measures ANS activity and not HPA activity, thus being an incomplete assessment of stress, even in ideal conditions. That said, we would have expected a stronger relationship between perceived stress and HRV a priori, given its popular use in assessing stress [8,34-37]. Nevertheless, despite the small magnitude of the effect, we also found some evidence for incremental prediction in that HRV uniquely predicted perceived

stress above and beyond self-reported positive affect, negative affect, and anxiety (Table 7).

We do not believe the small effect size is because of how perceived stress was assessed, as using validated assessments of related constructs, such as negative affect and anxiety, yielded similar results (Table 8) and was highly correlated with stress (Table 2). Our findings suggest that the signal provided by wearable-measured HRV is of limited use in predicting perceived stress in the wild in the absence of clear and isolated stressors (such as those provided in laboratory studies).

Regarding the optimal temporal association between HRV and perceived stress, we found that HRV features measured around the time of the survey response—when participants were assessing their current stress level—yielded a lower fit than a generic time window covering the workday (ie, between 8 AM to 6 PM). This is different from the results in laboratory settings, which suggest the optimal time window to be shorter and closer to the assessment of stress, given the quick SNS response to induced stress. Although the length of the time window in which HRV is measured can affect what contributes to the changes in the HRV features (eg, circadian rhythms might be captured with longer-term HRV but not short term [84]), the estimates found within the “workday” time window of 8 AM to 6 PM were generally consistent in directionality with previous literature for changes in HRV because of stress.

Specifically, triangular index and SDANN were both negatively associated with perceived stress. Both of these match the expectation that lower HRV would indicate higher stress [29]. VLF was positively associated with perceived stress, which is to be expected as SNS activity because of stress (among other reasons) modulates the amplitude and frequency of HRV measured in this band [84,102]. Finally, the ratio of LF to HF was negatively associated with perceived stress in the work hours time window, which might be considered counterintuitive. In controlled conditions, LF/HF can be used as a measure of autonomic balance; that is, it is assumed that PNS and SNS activity contributes to LF, and PNS largely contributes to HF [84]. Therefore, one could have expected a higher LF/HF ratio to equate to higher perceived stress, as it would indicate more SNS than PNS activity. Nevertheless, as highlighted in the study by Shaffer and Ginsberg [84], because of the complex relationship between SNS and PNS activity, LF/HF ratio will not always index autonomic balance. Thus, it is possible that in the conditions of this study, either a higher LF/HF was an indicator of higher PNS activity over SNS activity, or a higher PNS activity was a better marker for the saliency of a previous stressful event from which the participant was recovering at the time of the survey response.

In the follow-up study, our modified stress survey aimed to identify and compute HRV based on participants' most stressful time of the day. Although this is impractical for a real-world use case, it does allow measurement of HRV closer to the stressor, as in many laboratory studies. Nevertheless, measuring HRV during the most stressful time of the day yielded a lower model fit than using the generic 8 AM to 6 PM time window (Multimedia Appendix 3). Therefore, we believe the small effect of HRV as a predictor of stress ostensibly resides in the conditions of measurement themselves. Specifically, in laboratory-based studies, the measurements of changes in HRV because of stress occur in the presence of clear and isolated stressors (eg, stress being induced by the study conditions, causing an increase in SNS activity), which, in turn, implies that HRV changes because stress, and these changes can often cease with the end of a stressor [51]. Discrete and isolated stressors in controlled laboratory studies may not be as common in naturalistic settings, making results from these studies under controlled conditions not fully applicable to daily life settings.

In naturalistic settings, identifying perceived stress at the precise moment of a clear and isolated stressor would be difficult to achieve from HRV alone for several reasons. First, physiological stress is different from perceived stress. For instance, physical exertion or exercise is generally classified as a physiological stressor (and would exhibit increases in HR, decreased HRV, and increases in cortisol); however, it is well known that exercise can reduce perceived stress [103] and generally would not be reported as *stressful* by participants. Second, self-reports are subject to emotional perception and expression biases [104-107], as well as memory biases and/or coping responses [73,74]. Finally, EMAs are designed to measure stress at either random or specific times, although participants may not respond at the designated time (eg, at the end of a stressor as opposed to the middle of a stressor).

In summary, our main conclusion is that the reported association between HRV and perceived stress may depend on laboratory conditions. In naturalistic studies, there are no clear and direct links between isolated stressors and SNS responses. Although there is still an observable association between wearables and perceived stress, it is weak, and it suggests that HRV alone should not be considered a valid proxy measure of perceived stress in naturalistic studies.

### Implications of This Study

Although HRV has been shown to be a useful biomarker of perceived stress in laboratory studies, we have shown that in the wild, perceived stress does not always align strongly with physiological stress. This is of special importance as an increasing number of studies and commercial applications in the ubiquitous computing community use wearables to measure stress using HRV, sometimes under the assumption that there is a very strong alignment between the two, when, in fact, the alignment is more tenuous. Although it is beneficial to have wearables capable of providing continuous measurement of HRV unobtrusively, we caution against the use of HRV features as sole or main indicators of "stress" in user-facing applications, as the results may not align with perceived stress. This level of inaccuracy risks an increase of distrust in health and well-being applications at a minimum. It can have more profound negative effects as well, and based on the present findings, labeling HRV as "stress" without proper validity data would be highly suspect. Therefore, we would encourage future work in the scientific community to investigate complementary sensing streams that could serve as markers of stress and use those in conjunction with HRV.

To realize the goal of monitoring the health of individuals, such sensing streams should be rigorously vetted through longitudinal studies to appropriately measure their predictive power for capturing intraindividual differences over time. Nevertheless, it is unlikely that any single physiological sensing stream would be able to perfectly align with perceived stress. Therefore, rather than looking at a single biomarker of the ANS, as is HRV, a more complete view of the ANS response could perhaps delineate a viable strategy for health monitoring unobtrusively in the wild. More broadly, approaches based on multimodality are more likely to yield successful outcomes in health monitoring, as recent studies show in other fields such as sleep monitoring [108], job performance monitoring [109,110], and personality prediction [111].

### Limitations

It is important to note that this study has limitations. First, our sample comprised information workers who might be less likely to have movement artifacts that could affect the wearable measurements of HRV. Second, our sample was fairly homogenous, with participants whose income and education levels were above the US average (low-income and lower education populations were underrepresented). Third, we are unable to determine the accuracy of self-reported stress durations and timing of stress. Similarly, the duration of the most stressful time of the day was correlated with the perceived stress at that time, and it is possible that participants' response to one question influenced the answer to the other (ie, judging stressors that last

longer as more intense). Finally, the items introduced in the follow-up study were not validated in this or other studies. Addressing these limitations is a goal for future work.

### Conclusions

We examined the alignment of physiological stress (HRV), as measured with a consumer-grade wearable device, and perceived stress in an 8-week study with information workers from multiple organizations across the United States. We found a

weak but significant association between HRV and perceived stress, which was replicated in a week-long follow-up study a year later. Computing HRV across the workday outperformed other time windows, including self-reported stressful events. Overall, our findings suggest that wearable-based HRV should not be used as a sole biomarker for perceived stress in naturalistic settings. Instead, it might best be used in conjunction with other measures to measure this complex phenomenon in the wild.

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### Conflicts of Interest

None declared.

#### Multimedia Appendix 1

Correlation of the stress item with other validated measures.

[[DOCX File, 59 KB](#) - [humanfactors\\_v9i3e33754\\_app1.docx](#) ]

#### Multimedia Appendix 2

Summary of odds ratios of predictors across different time windows.

[[DOCX File, 120 KB](#) - [humanfactors\\_v9i3e33754\\_app2.docx](#) ]

#### Multimedia Appendix 3

Comparison between models, including heart rate variability calculated during the workday and during the reported most stressful time of the day.

[[DOCX File, 18 KB](#) - [humanfactors\\_v9i3e33754\\_app3.docx](#) ]

#### Multimedia Appendix 4

Additive value of heart rate variability features over considering only the participants' subjective assessment.

[[DOCX File, 18 KB](#) - [humanfactors\\_v9i3e33754\\_app4.docx](#) ]

#### Multimedia Appendix 5

Expanded versions of the tables included in the main paper, including the threshold values for the ordinal models.

[[DOCX File, 23 KB](#) - [humanfactors\\_v9i3e33754\\_app5.docx](#) ]

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## Abbreviations

- AIC:** Akaike information criterion
- ANS:** autonomic nervous system
- BBI:** beat-to-beat intervals
- ECG:** electrocardiogram
- EMA:** ecological momentary assessment
- HF:** high frequency
- HPA:** hypothalamic-pituitary-adrenal
- HR:** heart rate
- HRV:** heart rate variability
- LF:** low frequency
- PNS:** parasympathetic nervous system
- RMSSD:** root mean square of successive differences
- SDANN:** SD of the averages of normal-to-normal intervals
- SDNN:** SD of normal-to-normal intervals
- SNS:** sympathetic nervous system
- VIF:** variance inflation factor
- VLF:** very low frequency

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Original Paper

# Patient Perspectives on Using a Smartphone App to Support Home-Based Exercise During Physical Therapy Treatment: Qualitative Study

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## Abstract

**Background:** Home-based exercise is an important part of physical therapy treatment for patients with low back pain. However, treatment effectiveness depends heavily on patient adherence to home-based exercise recommendations. Smartphone apps designed to support home-based exercise have the potential to support adherence to exercise recommendations and possibly improve treatment effects. A better understanding of patient perspectives regarding the use of smartphone apps to support home-based exercise during physical therapy treatment can assist physical therapists with optimal use and implementation of these apps in clinical practice.

**Objective:** The aim of this study was to investigate patient perspectives on the acceptability, satisfaction, and performance of a smartphone app to support home-based exercise following recommendations from a physical therapist.

**Methods:** Using an interpretivist phenomenology approach, 9 patients (4 males and 5 females; aged 20-71 years) with nonspecific low back pain recruited from 2 primary care physical therapy practices were interviewed within 2 weeks after treatment ended. An interview guide was used for the interviews to ensure that different aspects of the patients' perspectives were discussed. The Physitrack smartphone app was used to support home-based exercise as part of treatment for all patients. Data were analyzed using the "Framework Method" to assist with interpretation of the data.

**Results:** Data analysis revealed 11 categories distributed among the 3 themes "acceptability," "satisfaction," and "performance." Patients were willing to accept the app as part of treatment when it was easy to use, when it benefited the patient, and when the physical therapist instructed the patient in its use. Satisfaction with the app was determined by users' perceived support from the app when exercising at home and the perceived increase in adherence. The video and text instructions, reminder functions, and self-monitor functions were considered the most important aspects for performance during treatment. The patients did not view the Physitrack app as a replacement for the physical therapist and relied on their therapist for instructions and support when needed.

**Conclusions:** Patients who use an app to support home-based exercise as part of treatment are accepting of the app when it is easy to use, when it benefits the patient, and when the therapist instructs the patient in its use. Physical therapists using an app

to support home-based exercise can use the findings from this study to effectively support their patients when exercising at home during treatment.

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## KEYWORDS

patient perspectives; mobile health; mHealth; home-based exercise; adherence; low back pain; physical therapy

## Introduction

The effectiveness of exercise therapy in the treatment of musculoskeletal disorders has been studied extensively, and exercise therapy remains an important part of treatment in clinical practice [1]. However, treatment is not limited to supervised exercise. Home-based exercise (HBE) programs allow patients to exercise at home between visits to the clinic. Unfortunately, the effectiveness of HBE relies heavily on patient adherence, which has been shown to be low [2-5].

Different factors contribute to patient adherence to HBE, including several factors that can be easily influenced by a physical therapist [6,7]. For example, a physical therapist can not only provide support and positive feedback, but also follow up on exercise recommendations during future visits to reinforce patient adherence. Additionally, practitioners can increase patient adherence to HBE by recommending a feasible maximum of 2-4 exercises, supporting and improving self-efficacy, and supporting patients to incorporate exercise into their daily life [6]. These strategies aim to improve or reinforce patient adherence to the frequency, intensity, and quality of their performance of exercise recommendations. However, increasing adherence to HBE remains challenging even when employing different strategies.

Smartphone apps have the potential to provide new solutions to support adherence to exercise recommendations. Exercise apps using personalized exercise programs, video instructions, and reminders to exercise can increase adherence by providing performance guidance and remote support, and improving physical therapist-patient interactions regarding HBE [8,9]. Furthermore, apps supporting health behaviors provide health benefits and additional support in the patient's own home environment [10,11]. Research has shown that patients with nonspecific low back pain (LBP) are mainly worried that despite the benefits of new technologies (eg, reminders and remote support), their use leads to less personalized care [12]. However, patients also expect these technologies to support HBE by increasing performance and adherence to exercise recommendations [12]. To our knowledge, and based on our review of the literature, no qualitative studies are available on patients who used an app to support HBE alongside physical therapy, highlighting an important gap in the literature.

With the increasing availability of apps to support physical therapy treatment, a better understanding of patient perspectives on using these apps during physical therapy can assist physical therapists to effectively tailor the use of these apps for their patients and consequently improve treatment efficacy. Therefore, the aim of this study was to investigate patient perspectives on the acceptability, satisfaction, and performance of an app to

support HBE following recommendations from a physical therapist.

## Methods

### Design

This study was performed using qualitative methods associated with phenomenology and an interpretivist approach. Data were collected by interviewing a sample of patients with LBP who used Physitrack (Physitrack Limited) during treatment in a primary care physical therapy practice.

### Ethics Approval

The Medical Research Ethics Committee of the University Medical Center Utrecht ruled that the Medical Research Involving Human Subjects Act does not apply to this study (protocol number 17-034/C). This study complies with the Declaration of Helsinki, and the standards for reporting qualitative research were followed in reporting this work [13].

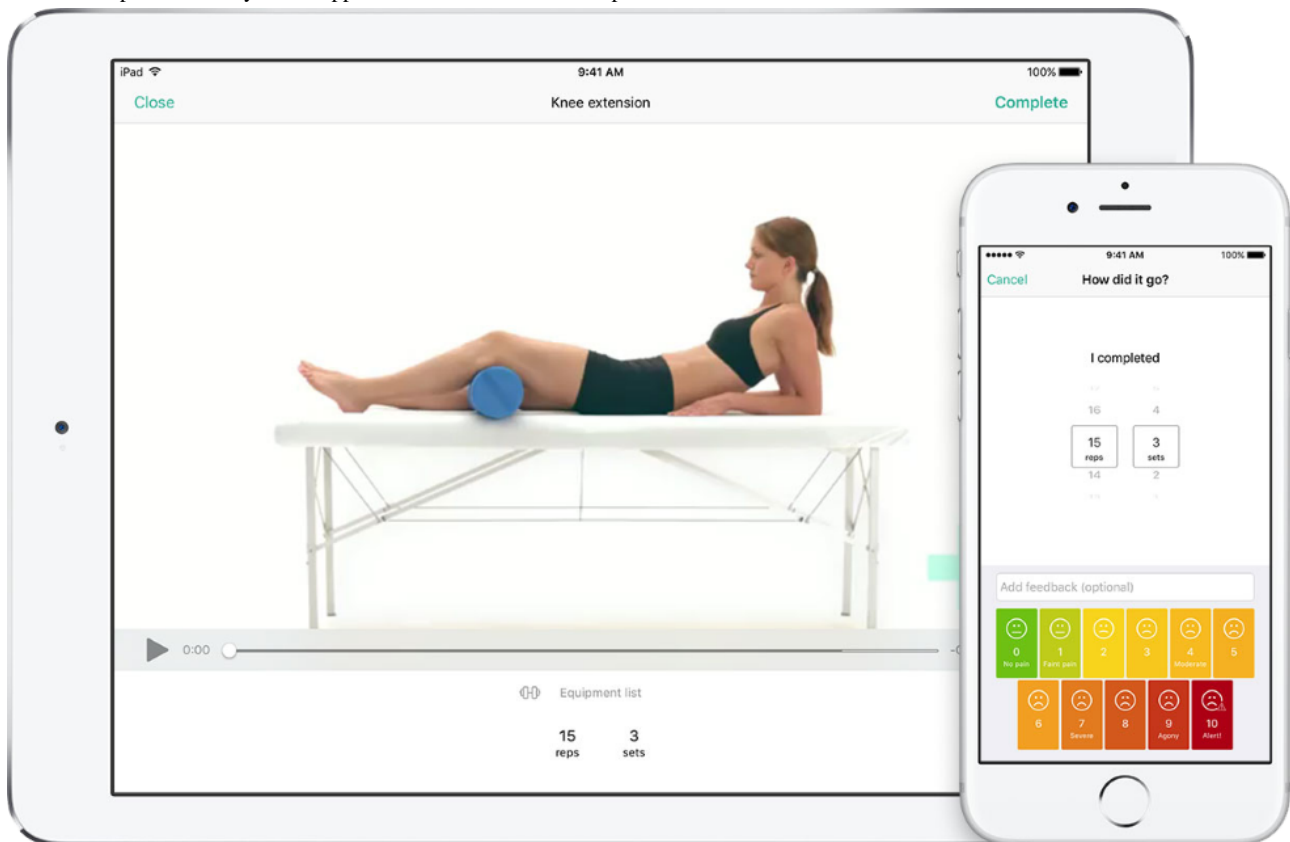
### Study Procedures and Recruitment

All patients were recruited from January to April 2018 from 2 participating primary care physical therapy practices in the Netherlands. For each participating practice, a physical therapist specializing in the treatment of spinal pain volunteered to recruit patients. Both physical therapists had 2 years of experience working with Physitrack. Physitrack allows physical therapists to create and share personalized exercise programs with patients through the Physitrack app, email, or paper handouts (see [Figures 1](#) and [2](#) for examples). The app allows patients to set reminders to perform their exercises, track their adherence, rate pain scores during the exercises, and send direct messages to their physical therapists. To be eligible for participation, a patient had to have been treated by one of the participating physical therapists, their treatment had to have ended less than 2 weeks prior to participation in the study, and the physical therapist had to have sent the patient HBE recommendations using the Physitrack app during treatment. Patients were excluded if they had insufficient command of the Dutch language for casual conversation. Patients interested in the study were contacted by a researcher (RA) and were provided with information about the study and procedures. An appointment for the interview was made with interested patients, and written informed consent was obtained prior to the interview. A purposive sampling method was chosen to include a heterogeneous sample based on age and gender. Additionally, the participants were asked to complete the Systems Usability Scale (SUS) to provide an objective measure of usability for Physitrack [14]. The SUS consists of 10 items rated on a 5-point scale ranging from strongly agree to strongly disagree. The SUS score ranges from 0 to 100, and usability of the app is acceptable

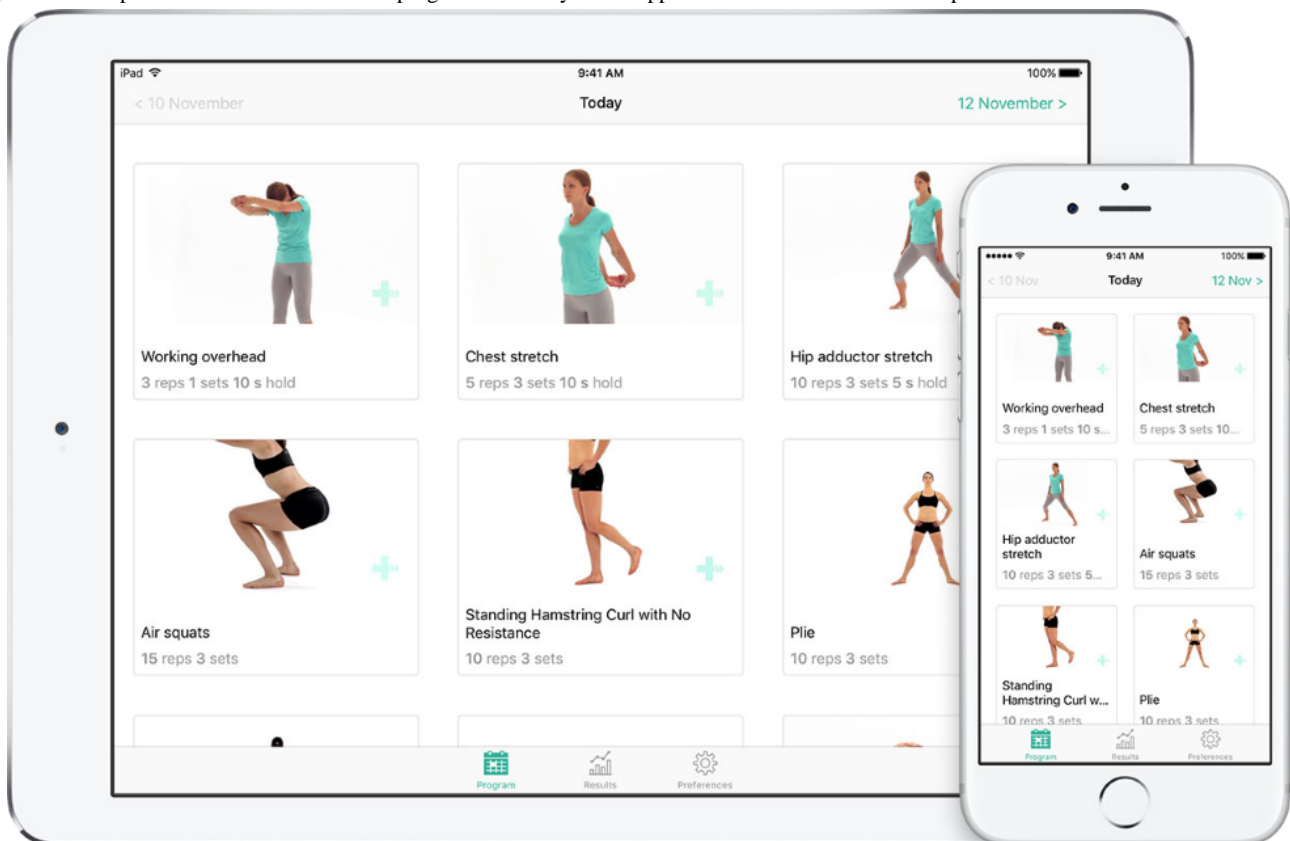
for ratings of 70 or higher [15]. The goal was to recruit similar numbers of males and females with a high variation in age until saturation of the data was achieved. Data saturation was reached

when new data repeated previous data without adding new information, and saturation was checked during data analysis in an iterative process [16].

**Figure 1.** Examples of the Physitrack app used on a tablet and a smartphone.



**Figure 2.** Examples of a home-based exercise program in the Physitrack app viewed on a tablet and a smartphone.





To guide the interviews, an interview guide based on the conceptual framework for testing electronic adherence monitoring devices was used [17]. The conceptual framework contains an objective dimension and a subjective dimension. Because the focus of this study was on patients' perceptions, only the subjective dimension and the components performance, satisfaction, and acceptability were used [17]. A first draft of the interview guide was created and refined using feedback from an expert meeting consisting of 15 researchers from the Physiotherapy Science research group at Utrecht University. Additionally, 5 physical therapists from the Leidsche Rijn Julius Healthcare centers were consulted to further refine and improve the interview guide. All researchers and physical therapists involved in this stage had experience working with mobile health (mHealth) apps in clinical practice, developing mHealth apps for other patient groups (eg, patients after stroke, patients with osteoarthritis, and those with musculoskeletal complaints), or both.

### Interviewer

All interviews were performed by a trained research assistant with a background in physical therapy and prior experience conducting interviews. The interviewer received an additional 2-hour training in qualitative interviewing techniques, and 2 pilot interviews were performed, recorded, and discussed with a researcher (RA) to ensure the thoroughness of the interviews. During data collection, the interviewer discussed each completed interview with the same researcher to ensure consistency between interviews.

### Interviews

The interviews were conducted in a private room in the practice where the participant had received treatment. The research assistant audio recorded and transcribed each interview verbatim. A researcher (RA) checked the transcription for accuracy using the interview recording, after which a written summary of the interview was sent to the participant for a member check. The participant was asked to read the summary and provide additional information or corrections when the summary did not properly reflect their perspectives. None of the participants requested changes to their interview during the member check.

### Data Analysis

The transcripts were anonymized and subsequently analyzed using the "Framework Method" [18]. This approach consists of 7 stages, namely transcription, familiarization with the interviews, coding, development of a working analytical framework, application of the analytical framework, charting

of data into the framework matrix, and interpretation of the data. The goal was to describe the common experiences and perspectives of the participants. Stages 1 and 2 were completed during data collection.

An "inductive coding" approach was chosen for stage 3, the coding stage, and Microsoft Excel 2016 was used to aid with the analysis. Coding was performed by extracting meaningful quotes from the transcripts to an Excel datasheet, adding a short descriptive code to the quote, grouping related or similar quotes, and repeating the process until the entire transcript was coded. The first 3 interviews were independently coded by 2 researchers (RA and CK) [19]. After an interview was coded, the researchers compared results and discussed differences in coding until they reached a consensus, and they labeled the codes with a short descriptive name. If the researchers could not reach a consensus, a third researcher (MP) was consulted. The remaining interviews were coded by 2 researchers (RA and CK) working together. During the coding process, the researchers continuously refined and adjusted the codes to best fit the data.

In stage 4, paper prints of the codes and their associated quotes from the first 3 interviews were used to allow a hands-on approach for the creation of categories and an initial analytical framework. Categories were formed by grouping codes that appeared to be related until all codes were assigned to a category. The categories were then grouped under themes based on the topics from the interview guide. To reduce bias introduced by the personal perspectives of a single researcher, the researchers (RA and CK) worked together to construct the framework and discussed each new category and its place within the framework until they reached a consensus. The analytical framework was continuously developed in an iterative process. Categories were merged, split, or relabeled, and codes were assigned to different categories in an attempt to best fit the data until all interviews were analyzed. After each iteration, the members of the research team (RA, CK, MP, TK, RO, and CV) discussed the new framework matrix and used the input from the discussion for the next iteration. The final framework matrix contained all categories with the summarized data from each interview and was used to interpret the data, completing stages 6 and 7 of the analysis.

## Results

### Participant Characteristics

Once data saturation was reached after 9 interviews, recruitment ended. The characteristics of the patients included in the study can be found in [Table 1](#).

**Table 1.** Participant characteristics.

Participant number	Gender	Age (years)	SUS <sup>a</sup> score (0-100)
1	Male	42	70
2	Female	29	82.5
3	Male	39	90
4	Female	33	90
5	Female	38	92.5
6	Female	45	97.5
7	Female	52	77.5
8	Male	71	85
9	Male	20	92.5

<sup>a</sup>SUS: System Usability Scale.

Data analysis revealed 11 categories distributed among the 3 themes “acceptability,” “satisfaction,” and “performance.” “Acceptability” describes what was required for participants to accept the app as part of their treatment. The categories grouped under “satisfaction” describe the perceived benefits of using the app during treatment. The theme “performance” contains a single category with the same name and describes the most important app functions according to the participants, as well as suggestions to improve the performance of the app.

### Acceptability

#### Usability

The app was easy to use, according to the participants. The app was simple in design, which made it very accessible.

*I think it just has to be simple, without too many bells and whistles, and for me, it worked like that.*

[Participant #3]

#### Availability

The availability of the exercises on the patients’ smartphones was perceived as an advantage because using a smartphone was already integrated into their daily lives. None of the participants experienced the requirement to own a smartphone in order to use Physitrack as a problem.

*It’s just very easy. You carry your phone with you every day anyway, so when you forget something, you can just open the app and find it; very easy.*

[Participant #7]

#### Willingness to Use the App

Participants were unaware that Physitrack existed before starting treatment, but all were willing to try the app to see if it would be useful for them. The perceived benefit from using the app during treatment determined its continued use for the participants.

*I didn’t have any expectations, and I went pretty open-minded into it. I thought that if it adds anything, it’s great, but if it doesn’t, I can just remove it from my phone.* [Participant #2]

Although patients were open-minded, perceived privacy issues were a concern for participant #1.

*After reinstalling the app on my phone, I had to look through my old e-mails to find the login code, and it’s, of course, strange that if anyone else gets his hands on that e-mail, they can see all my exercises and my private information.* [Participant #1]

#### Importance of Instructions

Participants found it essential to be taught how to use the app and told which functions of the app are important for them. The interviewees saw the physical therapist as the person responsible for properly instructing patients in the use of the app.

*I only used the videos because the physical therapist showed me, but I didn’t look for any other options. I think that if you want to use all the functions of the app, the physical therapist has to explain them or provide a manual or something.* [Participant #4]

Patients rarely mentioned experiencing problems when using the app, suggesting that instructions by the physical therapist were sufficient to use the app in daily life. The only issues mentioned were setting the reminder for the exercises and not receiving the reminders.

*After checking, I found that reminders were turned off, which is odd since I turned the reminders on and then didn’t get any.* [Participant #1]

#### Satisfaction

##### Being Reminded

The reminder messages for the app’s exercises helped almost all participants to exercise more often or more regularly than they expected to without using the app.

*In my busy life, the reminders motivated me to take some time to get it done.* [Participant #4]

Only participant #6 found the reminders useless, as they would come at inconvenient moments, even though the participant chose the time for the reminders.

*Nine out of ten times when I set a reminder, I don't get to doing it anyway, so I just turned them off after a while. [Participant #6]*

### Feeling Supported

Being able to review the exercise recommendations at home and having something to fall back on were positive experiences and gave the patients the feeling that the app was supporting them.

*After listening to the therapist, I would come home and still have questions or forgot what the therapist said. Then, I had something to fall back on, and that was very pleasant. [Participant #8]*

### Satisfaction With Own Adherence

Participants were delighted with their adherence to the exercise recommendations and felt that the app helped them exercise as often as recommended and correct their performance.

*The app helped with exercising. Not because I forgot them, ... but I could check which exercises I had to do and how often. [Participant #5]*

*Thanks to the app, I could see what exactly it was I was supposed to do ... That definitely increased how often I exercised. [Participant #9]*

Although the app supported the patients with exercising, usage of the app generally declined quickly when exercises remained the same or when complaints were resolved.

*The first time, I watched all the videos and memorized them. After that, I think I read the instructions for the exercises once or twice, but mostly used the app for the reminders. [Participant #5]*

*I used the app only when new exercises were added because I already knew the others. [Participant #6]*

### Supporting Treatment

Patients considered the use of the app to record problems, adherence, or pain scores or the use of the chat function to ask a quick question as contributing to the quality of the treatment. The physical therapist had access to information recorded by the patient between therapy sessions and could use it to personalize treatment for the patient. Participants saw the app as something to combine with the expertise of the physical therapist rather than a replacement. The physical therapist used the face-to-face treatments to adjust and personalize the HBE program, and the participants used the app to bring the support from their physical therapist into their own homes.

*First, we practiced the exercises together, then I received the app, and the next week the therapist asked me how it went. If I had any problems, I could discuss them with him so he could change the exercise program for me. [Participant #7]*

*The app is good progress, but it's not yet a replacement of the physical therapist. [Participant #8]*

### Quality of Exercise Performance

Patients felt that the app helped to improve their performance of the recommended exercises and perceived the app as a tool to maintain the quality of performance expected from them by the physical therapist. The visual examples of the app's exercises appeared to increase self-efficacy and might have increased adherence.

*There was one exercise I had trouble doing right, so if I didn't have the video, I probably wouldn't have remembered how to do it and probably wouldn't have done it at all. [Participant #3]*

*I wouldn't say it improves how you do it if you already did it well. But it does make sure you don't do it worse. It helps to keep the quality high. [Participant #9]*

### Self-monitoring

Not all patients mentioned recording pain or adherence to exercises in Physitrack. However, patients who did record these metrics used the information to monitor their progress or demonstrate to the physical therapist that they had followed the exercise recommendations.

*I felt that my back was very painful this week, but actually my pain score after doing the exercises is decreasing. That is, for me, a reminder I'm going in the right direction, and I find that very reassuring. [Participant #2]*

### Performance

According to the patients, the most appreciated or essential functions of Physitrack were the video and text instructions and the reminder function. Recording and monitoring their own progress and the chat function were mentioned less often but were still considered important by several patients.

*Something that should stay in the app is this overview with all the videos and the names of the exercises and how often I'm supposed to do them. Together with the reminder, I think those are important. [Participant #5]*

The patients also suggested several improvements for the app, including connecting the app with the calendar on users' mobile phones, such that follow-up visits could be automatically entered into the calendar. Other suggestions included repeated reminders when exercise performance was not recorded in the app, the option to connect the exercise videos to the television, and a loop or timer in the videos so that the patient could exercise along with the video.

## Discussion

### Principal Findings

The aim of this study was to investigate patient perspectives regarding an app to support HBE recommended by a primary care physical therapist. Qualitative data analysis revealed 11 categories describing the 3 themes of "acceptability," "satisfaction," and "performance."

The “acceptability” theme contains the subthemes of usability, availability, willingness to use the app, and importance of instruction, and it describes what the patients perceived as essential to accept the app as part of treatment. Participants commented on how easy or difficult it was to use the app in their daily lives. Patients’ acceptance and continued use of the app as part of treatment appear to be based mainly on the perceived benefit. When a patient did not perceive or no longer saw any benefit from using the app, use declined quickly. The participants unanimously agreed that Physitrack was easily integrated into their daily routine. Although none of the participants had previously used Physitrack or a similar app during physical therapy, the app was accepted by all participants. Unfortunately, the quick and easy acceptance of a new mHealth app is not always reliable and depends on several different factors such as “perceived usefulness,” “social influence,” and “attitude” [20,21].

The acceptance of Physitrack in this study was possibly realized by the combination of the physical therapist introducing the app as part of treatment and the ease of use of the app. Even when a participant no longer found the app useful, it was very easy for them to stop using the app. As a result, there was no downside for the participant to try the app, as they could decide on its usefulness and continued use later on.

The participants felt that more instructions from their physical therapist were needed for optimal use of the app. The participants viewed the app as part of treatment and therefore relied on the physical therapist to provide guidance and support. Similarly, when participants experienced a problem using the app, they relied on the physical therapist for assistance. This finding underlines the importance of instructions, personal contact, and support from a physical therapist during treatment when using apps such as Physitrack [22]. It appears that part of the success of the integration of Physitrack into treatment relies on patient-therapist interaction. This is further supported by previous findings that the diagnosis of the patient does not seem to significantly impact the acceptance of mHealth apps during treatment [20].

“Satisfaction” describes the perceived benefit of using the app during treatment and how the app supports treatment and adherence. Having easy access to the exercise recommendations from the physical therapist through their own smartphone made it easy for patients to not only exercise as often as recommended, but also maintain proper form during the exercises. The push messages sent by the app as a reminder to perform the exercises, the option to set the reminder at a preferred time, and the video instructions of the exercises all contributed to patients’ confidence when exercising at home.

In a previous study, participants had no experience with digital technologies to support exercise adherence but were asked about their expectations regarding new technologies [12]. The patients were not very enthusiastic about the idea of reminder messages on their smartphones and expected them to be too intrusive. It is possible that in practice, it is important for a patient to use a new technology as part of treatment for some time before deciding on its added value. The participants in this study mentioned using this strategy to determine the usefulness of the

app for themselves. Therefore, physical therapists should support patients with the shift toward the use of mHealth apps during treatment to allow patients to experience the benefits these new developments bring.

The last theme, “performance,” describes which functions of the app are most important according to the patients and how the performance of the app could be improved in the future. The video and text instructions, the reminders, and the option to self-monitor adherence were considered to be the most important functions of the app. Suggestions for future improvements were mainly aimed at making it even easier to use the app at home.

The findings of this study are similar to the results from studies on other mHealth or eHealth apps [23,24]. For instance, Svendsen et al reviewed the qualitative literature on digital interventions for the self-management of LBP [23]. After analyzing the included studies, 4 major themes were found: information technology (IT) usability and accessibility, quality and amount of content, tailoring and personalization, and motivation and support. A different review found that health status, usability, convenience and accessibility, perceived utility, and motivation were the main themes describing the barriers to and facilitators of engagement with remote measurement technology for health management [24].

Although the terminology describing the themes differs between studies, the content of the themes is broadly similar. For instance, “reminders and notifications,” “accessible at all hours and locations,” “easily accessible with low effort,” and “high user friendliness” were found to be facilitators for IT usability and accessibility in the study by Svendsen et al, whereas the themes “usability” and “convenience and accessibility” from the study by Simblett et al have similar facilitators [23,24]. In this study, the use of reminders, easy integration in daily life, and the high usability of the app contributed to its acceptability, corresponding with the findings from the previous studies. The high agreement between previous studies and this study, despite the different types of apps used by patients with different health problems, suggests that these findings can most likely be generalized between apps and health problems. This study adds to the findings that patients view the interaction between patients and physical therapists as vital when using an app as part of treatment. This suggests that Physitrack is well suited to support treatment but not to replace a physical therapist.

### Limitations and Trustworthiness

To put these results into perspective, several issues must be discussed. First, none of the included participants scored the usability of Physitrack lower than 70 (ie, acceptable) on the SUS. A possible explanation is that the physical therapists treating potential participants for the study only used Physitrack with patients they expected to benefit from the app. Patients who might have found the app unusable or who would not be able to use the app effectively might not have been offered the app as part of treatment.

A second limitation of the study was that the participants were relatively young, with just one exception. Older patients might not be able to use an app as effectively as younger participants.

Similar to the first limitation, the physical therapists might not have offered the app to patients they expected would have no or little benefit from it. In addition to age, a patient might not have been suitable for treatment using an app for other reasons. Using an instrument, such as the “Dutch Blended Physiotherapy Checklist,” can assist physical therapists with deciding when to and when not to use an app such as Physitrack [25].

The last limitation is that the generalizability of the results in this study might be limited because of the specific app used and the inclusion of only patients with LBP in the study. However, the advantages of Physitrack mentioned by the patients relate mainly to features of the app and the patient-therapist interaction. Patients did not mention the cause of their complaints as having an impact on their acceptance of the app or how they used the app. Combined with the previously mentioned findings that barriers and facilitators related to the acceptance of mHealth apps do not seem to be impacted by a specific diagnosis, the results of this study can most likely be safely generalized to patients with other musculoskeletal disorders [20,23,24].

To increase the trustworthiness of data collection, prior to interviewing participants, the interviewer practiced the interviews and use of the interview guide with volunteers not participating in the study. The feedback from the volunteers helped to improve the thoroughness and consistency of the interviews. During data collection, a member check was performed by providing participants with a written summary of the interview and the opportunity to request changes or additions to their interviews to ensure its completeness. Furthermore, the use of the “Framework Method” methodology provided a transparent and rigorous method for data analysis [18].

## Implications

Physitrack appears to be a useful tool to complement physical therapists’ face-to-face treatment of patients with LBP. Although other mHealth solutions have displayed beneficial effects for patients with LBP and other musculoskeletal complaints, further research is required to investigate whether adherence to HBE interventions improves when using these apps during treatment [26-28]. Knowledge of the added value from Physitrack and similar apps to support HBE and the results of this study can support the implementation of these apps in clinical practice. The apparent importance of the physical therapist–patient interaction found in this study should be investigated further. Additional information on physical therapists’ perspectives regarding working with mHealth apps to support HBE and the effects of the physical therapist–patient relation on treatment results might lead to more effective treatments in the future. Although explorative research regarding the usability and acceptability of an app to support HBE by physical therapists is available, research involving physical therapists, patients, and their interactions when using smartphone apps to support HBE is still lacking and should be further investigated [29].

## Conclusion

Patients who used Physitrack accepted the app as part of treatment when it was easy for them to use, when it benefited their needs, and when the therapist instructed them in its use. Satisfaction is determined by the perceived support from the app when exercising at home and the perceived increase in adherence. Patients considered the video and text instructions, reminder functions, and self-monitor functions to be the most important aspects for the performance of the app during treatment. Physical therapists using Physitrack and similar apps to support HBE can use the findings from this study to effectively support their patients when exercising at home during treatment.

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## Conflicts of Interest

None declared.

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## Abbreviations

**HBE:** home-based exercise

**IT:** information technology

**LBP:** low back pain

**mHealth:** mobile health

**SUS:** System Usability Scale

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## Short Paper

# Role of Trusted Sources and Behavioral Beliefs in Promoting Mitigation Behaviors During the COVID-19 Pandemic: Survey Study

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## Abstract

**Background:** During the ongoing COVID-19 pandemic and in preparation for future public health crises, it is important to understand the relationship between individuals' health beliefs, including their trust in various sources of health information, and their engagement in mitigation behaviors.

**Objective:** We sought to identify relationships between trust in various sources of health information and the behavioral beliefs related to vaccination and mask wearing as well as to understand how behavioral beliefs related to vaccination differ by willingness to be vaccinated.

**Methods:** We conducted an online survey of 1034 adults in the United States and assessed their trust in federal, local, and media sources of health information; their beliefs about vaccination; and their masking intention and vaccination willingness.

**Results:** Using regression, masking intention was predicted by trust in the World Health Organization ( $P < .05$ ) and participants' state public health offices ( $P < .05$ ), while vaccine willingness was predicted by trust in participants' own health care providers ( $P < .05$ ) and pharmaceutical companies ( $P < .001$ ). Compared to individuals with low willingness to be vaccinated, individuals with high willingness indicated greater endorsement of beliefs that vaccines would support a return to normalcy, are safe, and are a social responsibility ( $P < .001$  for all).

**Conclusions:** Results can be used to inform ongoing public health messaging campaigns to manage the COVID-19 pandemic and increase readiness for the next pandemic. Additionally, results support the need to bolster the public's trust in health care agencies as well as to enhance trust and respect in health care providers to increase people's adoption of mitigation behaviors.

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## KEYWORDS

behavioral beliefs; health literacy; vaccination; trusted sources; social media; vaccine hesitancy; health information; masking; healthcare; public health; health beliefs

## Introduction

COVID-19, the illness caused by the novel SARS-CoV-2 virus, has caused a global health crisis. As of early 2022, more than 78 million cases and 930,000 COVID-19 deaths have been reported in the United States [1]. Individual engagement in mitigation behaviors like mask wearing and vaccination is critical for decreasing transmission of the virus. However, despite clear evidence of the effectiveness of both masking and

vaccines and the widespread availability of both, participation in these mitigation behaviors is inconsistent in the United States [1,2].

In many models and explanatory theories of health behavior, especially planned behaviors like mask wearing and vaccination, beliefs are predictors of behaviors [3]. During the COVID-19 pandemic, beliefs have been affected by limited and changing information due to the novelty of the virus as well as



misinformation spread both deliberately and unintentionally [4-6].

The spread of misinformation has compounded an already eroding trust in government agencies, including public health agencies and organizations [7,8]. Despite diminished trust in public health and polarized attitudes toward health care workers during the pandemic [9], most Americans report sustained trust in health care systems and their health care providers [10]. Availability of information from trusted sources is crucial for establishing beliefs and promoting people's acceptance of and engagement in mitigation strategies.

The goal of this research was to identify relationships between trust in various sources of health information and the behavioral beliefs related to vaccination and mask wearing as well as to understand how behavioral beliefs related to vaccination differ by individuals' willingness to be vaccinated. Understanding these relationships between beliefs and health behaviors that mitigate the risk and spread of COVID-19 (specifically mask wearing and vaccination) is critical for promoting uptake of mitigation behaviors among individuals who are resistant and for managing this and future pandemics. Findings can also be used to inform important lessons that can be applied to other current public health issues and better prepare health care workers, public health officials, and others to respond to future crises.

## Methods

### Survey

We administered an online survey in October 2020 to a convenience sample of adults in the United States using a Qualtrics purchased panel (Qualtrics International Inc) [11,12]. We developed the survey based on the reasoned action approach to health behaviors [3] and informed by two small pilot tests (total n=210). The final survey included a variety of questions to assess beliefs, attitudes, and behaviors related to COVID-19. Of interest in this paper are questions about behavioral intention and willingness, trust in sources of information, beliefs associated with vaccination, and demographics. See [Multimedia Appendix 1](#) for a copy of study items from the survey.

Mask wearing intention and vaccine willingness were each assessed with a single question. Participants' trust in various sources of information was assessed by asking "How much do you trust information from the following sources about COVID-19?" and participants rated each source separately. Participants' beliefs associated with vaccination were assessed through 7 items exploring safety, concern about side effects, perception of social responsibility, and similar beliefs. All survey questions used 7-point scales; higher scores indicated greater behavioral intention/willingness, trustworthiness, and agreement.

Demographic information included sex, age, race, income, geography (urban, suburban, rural), and state of residence.

### Data Analysis

Data analyses were multiple regressions and multiple analysis of variance (MANOVA), which were conducted in SPSS

(version 27; IBM Corp), with  $\alpha$  set at .05. Missing data were minimal (<2% for each item), missing at random, and excluded from analyses with pairwise deletion.

### Ethical Considerations

The study was reviewed and determined exempt by the Montana State University Institutional Review Board (FWA: 00000165; protocol #KF100720). Participants provided informed consent before completing the survey.

## Results

The sample consisted of 1034 adults residing in the United States. A description of the sample is provided in [Multimedia Appendix 2](#). Descriptive statistics of the study variables are shown in [Table 1](#).

To understand the relationship between trusted sources and COVID-19 mitigation behaviors, we conducted two multiple linear regression models that predicted (1) intention to wear a mask and (2) willingness to be vaccinated (as the dependent variables) based on reported trust. These regressions included the 10 variables assessing trust in various sources of information about the COVID-19 pandemic and demographic variables of age, sex (0=male, 1=female), education, income, and geography (1=rural, 2=suburban, 3=urban) as predictors using the enter method. Regarding potential multicollinearity, we noted that while some predictor variables were correlated (with the highest correlation between trust in the Centers for Disease Control and Prevention and trust in the World Health Organization,  $r=.79$ ), the variance inflation factor did not exceed 3.5 for any predictor in either model. Therefore, we retained all predictor variables in both models [13]. Both regression models were significant overall and significant predictors differed between the models ([Table 2](#)).

The model for participants' intention to wear a mask was significant ( $F_{15,923}=13.32$ ;  $P<.001$ ;  $R^2=.18$ ;  $f^2=.22$ ). Three trusted sources were significant predictors. Trust in the World Health Organization and trust in the state's public health office were both positively associated with intention to wear a mask, while trust in the White House/President was negatively associated and was the strongest predictor. Demographic variables of age and sex were significant predictors, with increasing age associated with greater intention to mask and women (more than men) intending to mask.

The model for willingness to be vaccinated was also significant ( $F_{15,916}=18.73$ ;  $P<.001$ ;  $R^2=.23$ ;  $f^2=.30$ ). In this model, participants' trust in their local health care provider and trust in pharmaceutical/drug companies were significant predictors and both positively associated with willingness to be vaccinated. The only demographic variable that predicted vaccination willingness was geography, with willingness to be vaccinated increasing as geographic density increased (ie, urban participants were more willing to be vaccinated than rural or suburban participants).

To better understand differences in beliefs between those willing to be vaccinated and those unwilling to be vaccinated, we grouped participants based on their willingness response into

low (responses of 1 or 2;  $n=299$ ) and high (responses of 6 or 7;  $n=356$ ) and conducted a MANOVA with the 7 beliefs about vaccination as the dependent variables. The overall MANOVA was significant ( $F_{7,647}=70.42$ ;  $P<.001$ ; partial  $\eta^2=.43$ ). Applying a Bonferroni correction for multiple comparisons adjusted the  $\alpha$  for follow-up analysis of variance (ANOVA) to .007. The ANOVA revealed significant differences between groups for 3

of the 7 beliefs. Compared to those with low willingness to be vaccinated, participants with high willingness agreed significantly more that vaccination will get things back to normal ( $F_{1,653}=306.38$ ;  $P<.001$ ; partial  $\eta^2=.32$ ), is safe ( $F_{1,653}=364.55$ ;  $P<.001$ ; partial  $\eta^2=.36$ ), and is a social responsibility ( $F_{1,653}=338.56$ ;  $P<.001$ ; partial  $\eta^2=.34$ ) (Figure 1).

**Table 1.** Study variable descriptives.

	Participant answers, n	Mean (SD)
<b>Behavioral intention/willingness</b>		
Intent to wear a mask	1026	5.69 (1.94)
Willingness to be vaccinated	1020	4.18 (2.24)
<b>Trusted sources</b>		
Trust World Health Organization	1030	4.64 (2.07)
Trust Centers for Disease Control and Prevention	1027	4.92 (1.85)
Trust White House/President	1029	3.70 (2.28)
Trust state's public health office	1025	4.76 (1.84)
Trust local public health office	1026	4.82 (1.77)
Trust health care provider	1027	5.25 (1.75)
Trust pharmaceutical/drug companies	1027	4.53 (1.84)
Trust television news stations	1022	4.15 (1.92)
Trust social media	1023	3.64 (2.05)
Trust work colleagues/classmates	1024	4.22 (1.84)
<b>Beliefs related to vaccination</b>		
"Getting an FDA-approved <sup>a</sup> vaccination to prevent COVID-19 will get things 'back to normal.'"	1023	4.46 (1.86)
"Getting an FDA-approved vaccination to prevent COVID-19 is safe."	1020	4.51 (1.76)
"I would be concerned with the side effects of an FDA-approved vaccination to prevent COVID-19."	1018	4.86 (1.74)
"I would be concerned about the effectiveness of an FDA-approved vaccination to prevent COVID-19."	1017	4.83 (1.73)
"Getting an FDA-approved vaccination to prevent COVID-19 when it becomes available is a social responsibility that I have."	1020	4.72 (1.86)
"I don't need to get an FDA-approved vaccination to prevent COVID-19 because other people will get a vaccination."	1018	3.59 (2.00)
"There will be harmful chemicals in an FDA-approved vaccination to prevent COVID-19."	1019	4.30 (1.83)

<sup>a</sup>FDA: Food and Drug Administration.

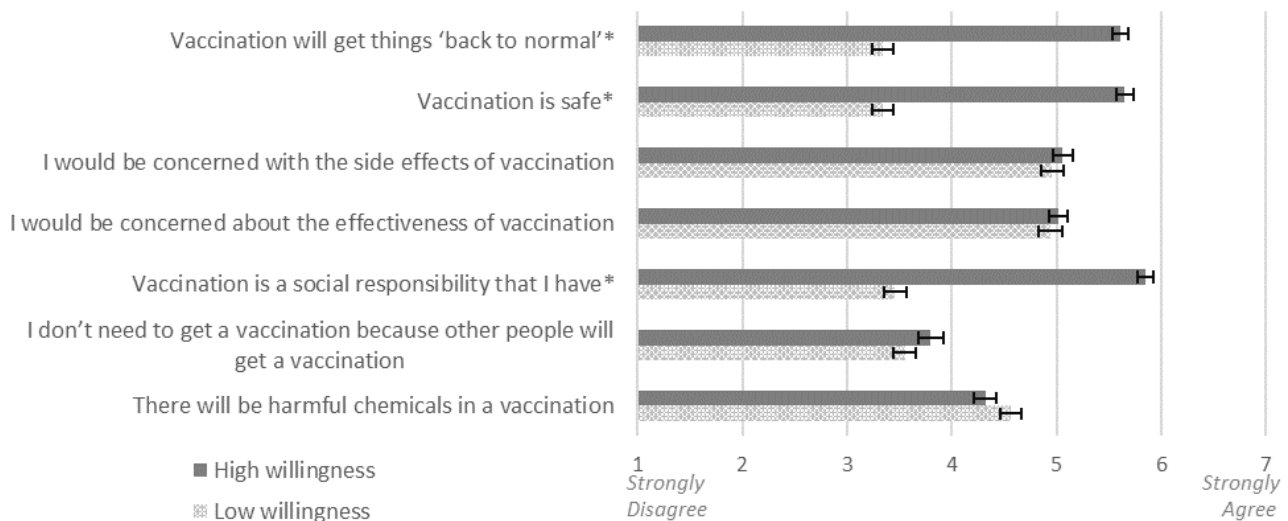
**Table 2.** Regression models to predict mask wearing intention and vaccine willingness.

Predictor	Intent to mask		Willingness to be vaccinated	
	B (95% CI)	β	B (95% CI)	β
Trust World Health Organization	.13 (.03 to .22)	.13 <sup>a</sup>	.06 (-.05 to .17)	.06
Trust Centers for Disease Control and Prevention	.10 (-.02 to .21)	.09	.08 (-.05 to .21)	.06
Trust White House/President	-.15 (-.21 to -.09)	-.18 <sup>b</sup>	.06 (-.01 to .13)	.06
Trust state’s public health office	.12 (.01 to .23)	.11 <sup>a</sup>	.03 (-.09 to .16)	.03
Trust local public health office	-.03 (-.15 to .09)	-.03	.06 (-.07 to .19)	.05
Trust health care provider	.09 (-.01 to .19)	.08	.14 (.03 to .25)	.11 <sup>a</sup>
Trust pharmaceutical/drug companies	.03 (-.07 to .12)	.02	.19 (.09 to .30)	.16 <sup>b</sup>
Trust television news stations	.01 (-.09 to .10)	.01	.02 (-.08 to .13)	.02
Trust social media	-.03 (-.12 to .06)	-.03	.01 (-.09 to .12)	.01
Trust work colleagues/classmates	-.04 (-.13 to .06)	-.04	.03 (-.07 to .14)	.03
Age	.01 (.01 to .02)	.11 <sup>a</sup>	.00 (-.01 to .01)	.00
Sex	.53 (.28 to .79)	.14 <sup>b</sup>	-.19 (-.48 to .01)	-.04
Education	-.01 (-.09 to .07)	-.01	.06 (-.03 to .15)	.05
Income	.06 (-.03 to .14)	.05	.01 (-.09 to .10)	.01
Geography	-.05 (-.21 to .12)	-.02	.27 (.08 to .45)	.09 <sup>a</sup>

<sup>a</sup>P<.05.

<sup>b</sup>P<.001.

**Figure 1.** Vaccine-related beliefs by willingness to be vaccinated. Error bars represent standard errors. Table 1 provides the complete wording of each item. \*P<.001.



## Discussion

This study identified the relationship between trusted sources of information regarding COVID-19 and individuals’ intention to wear a mask and willingness to get vaccinated and provides useful information for promoting public health during the current COVID-19 pandemic as well as for increasing capacity to respond efficiently and effectively in the future.

The spread of health misinformation has risen to the level of an “urgent threat,” according to the US Surgeon General, and combating misinformation is a priority focus of his office [14]. Identifying trusted sources is a critical first step in spreading accurate messaging to the public and communicating public health science to combat misinformation [15]. In our study, trust in the World Health Organization and state public health offices was positively associated with intention to wear a mask, suggesting that information from these sources should be amplified and that bolstering the public’s trust in these offices

could support individuals' masking behaviors. Trust in the White House was negatively associated with masking intention, which is unsurprising given our survey was conducted in October 2020, and the Trump administration did not consistently promote or encourage masking [16].

Different predictors were associated with participants' willingness to be vaccinated. Trust in their personal health care provider and the pharmaceutical industry predicted willingness to be vaccinated. Ensuring trust in health care providers and promoting them as health information sources are necessary for the public to seek and obtain accurate health information [17]. Additionally, low trust in pharmaceutical companies could be hampering vaccination [18-21].

Since the survey was conducted before vaccines were approved in the United States, we lack data on actual vaccine behavior, which is an important limitation. Nonetheless, willingness is an important predictor of behavior and, given the lagging uptake of vaccination, promoting trusted sources continues to be important. For all mitigation behaviors, including masking and vaccination, understanding who the intended audience considers to be a trusted source for health information is an important consideration in efforts to provide public health information. Effective health interventions should be tailored to the intended audience, including using trusted sources to deliver the information [22].

Further, our research found that, compared to those with low willingness to be vaccinated, participants with high willingness indicated greater endorsement of beliefs that vaccination will get things back to normal, is safe, and is a social responsibility. This represents an important opportunity to frame communication about vaccination in ways that promote these

protective beliefs, such as fostering a sense of social responsibility through communication that seeks to cultivate a sense of community and intentionally promotes a shared vision. Efforts may also seek to promote health literacy, as health literacy includes understanding the importance of protecting ourselves as well as others [23].

Interestingly, while beliefs about social responsibility did differ based on willingness, belief that others getting vaccinated negates one's own need for vaccination did not differ. Beliefs about vaccine effectiveness, side effects, or chemicals also did not differ based on willingness, suggesting that messaging around these topics may be less effective in promoting vaccination behaviors.

The data were gathered from a convenience sample of adult participants and therefore may not generalize to all people or communities in the United States. Additionally, behavioral intention and willingness were measured with single survey items, thereby preventing reliability estimates. Future research might explore behavioral beliefs related to mitigation behaviors as well as the mitigation behaviors directly with additional samples and using alternative instruments.

Despite limitations, the results have actionable implications. Taken together, findings from this study can be used to inform communication efforts that empower people to find accurate information regarding their health decisions, including engagement in mitigation efforts during the COVID-19 pandemic. Lessons can also be applied to the development of relevant messages targeting specific beliefs and encouraging behaviors that promote public health more quickly and effectively during the next pandemic or another public health crisis.

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## Conflicts of Interest

None declared.

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### Multimedia Appendix 1

Survey items.

[DOCX File, 29 KB - [humanfactors\\_v9i3e37454\\_app1.docx](#) ]

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### Multimedia Appendix 2

Sample description.

[DOCX File, 23 KB - [humanfactors\\_v9i3e37454\\_app2.docx](#) ]

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## Abbreviations

**ANOVA:** analysis of variance

**MANOVA:** multiple analysis of variance

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Original Paper

# Modeling Adoption, Security, and Privacy of COVID-19 Apps: Findings and Recommendations From an Empirical Study Using the Unified Theory of Acceptance and Use of Technology

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## Abstract

**Background:** The global health crisis caused by COVID-19 has drastically changed human society in a relatively short time. However, this crisis has offered insights into the different roles that such a worldwide virus plays in the lives of people and how those have been affected, as well as eventually proposing new solutions. From the beginning of the pandemic, technology solutions have featured prominently in virus control and in the frame of reference for international travel, especially contact tracing and passenger locator applications.

**Objective:** The objective of this paper is to study specific areas of technology acceptance and adoption following a unified theory of acceptance and use of technology (UTAUT) research model.

**Methods:** We presented a research model based on UTAUT constructs to study the determinants for adoption of COVID-19-related apps using a questionnaire. We tested the model via confirmatory factor analysis (CFA) and structural equation modeling (SEM) using travelers' data from an insular tourist region.

**Results:** Our model explained 90.3% of the intention to use (N=9555) and showed an increased understanding of the vital role of safety, security, privacy, and trust in the usage intention of safety apps. Results also showed how the impact of COVID-19 is not a strong predictor of adoption, while age, education level, and social capital are essential moderators of behavioral intention.

**Conclusions:** In terms of scientific impact, the results described here provide important insights and contributions not only for researchers but also for policy and decision makers by explaining the reasons behind the adoption and usage of apps designed for COVID-19.

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**KEYWORDS**

COVID-19; SARS-CoV-2; UTAUT; empirical study; structural equation modeling; confirmatory factor analysis; security; privacy; global health; technology solution; research model; technology acceptance; digital health; mobile health

## Introduction

### Background

There have been many papers addressing COVID-19–related impacts; more than 23,000 papers have been published between January and May 2020, and hence, it has proved difficult to remain up to date with all the released studies [1]. However, it is evident to all of us that the global health crisis caused by COVID-19 [2] has drastically changed human society in a relatively short time.

The pandemic's socioeconomic impacts [3] are unprecedented (eg, in the education sector, more than a billion students were affected due to schools' closure [3,4]). This situation created stress, especially for low-income families [3]. The COVID-19 pandemic has severely challenged the health care sector, especially medical workers severely exposed to physical and psychological repercussions [5]. In addition, people of color and other minorities have experienced more severe COVID-19 impacts than others due to socioeconomic conditions, health care disparities, and a lack of privileges [6,7]. In summary, the ongoing pandemic has disclosed to the world and exacerbated problems and inequalities based on gender, age group, ethnicity, socioeconomic situation, and nationality [8]. Supporting communities to promote well-being, social cohesion, and safe behaviors, especially for vulnerable groups, are welcome suggestions. However, governments and health institutions play an essential role in supporting well-being and providing economic, social, and health services and fostering trust [9].

The pandemic has challenged our progress and growth-based society and its capitalistic nature, and tourism, as a growth-based phenomenon, has suffered from these challenges [10]. However, the COVID-19 situation that has been ongoing for more than 2.5 years has provided an impetus to imagine and shape futures [11] by addressing existing problems, exploring new solutions to local and global challenges, and understanding the role of COVID-19 in affecting and changing people's lives. Although much effort was made to develop and deploy several COVID-19 contact-tracing mobile apps [12,13], these technologies have raised several ethical challenges (eg, privacy, security, surveillance) [14-16] and their adoption has not been as expected [17], as the privacy policies have negative impacts on users' privacy worries and the elements influencing personal benefits are greater than the community interests and outcomes when adopting an app. In addition, although technologies for citizen engagement have been considered helpful to manage crises [18], there is still a lack in this research area concerning COVID-19.

The general aim of this paper is to examine users' perceptions and attitudes toward a COVID-19–based app through a case study on a European island, which deployed a successful safety system to mitigate the impact of the pandemic, while preserving mobility after lockdown and isolation. More specifically, the research aims of this work are (1) to investigate the effects of the COVID-19 pandemic on technology adoption and especially safety, security, privacy, and trust; (2) to increase our understanding of differences in the determinants of safety in technology use; and (3) to improve the predictive accuracy and explanatory power of a parsimonious questionnaire based on a

known unified theory of acceptance and use of technology (UTAUT) [19] model for broader application in human-computer interaction (HCI) research.

A vital component of this research's successful execution was the evaluation's contained and isolated nature (ie, small European island with an extensive tourism economy [20]), which enabled rapid mobilization of research in tandem with the deployment of COVID-19 security measures. By designing and performing this research, we got an opportunity to analyze the near future in which safety tech apps will be 1 of the best attempts to deal with this "new normal," and we collected data from an international audience recovering from the pandemic's first wave.

However, the urgency to study COVID-19 phenomena could increase errors in the research and then decrease both rigor and validity. To avoid making such mistakes, we designed and distributed a questionnaire based on the UTAUT model [19] and collected data from 9555 participants from different nationalities. We applied exploratory and confirmatory factor analysis (CFA) and structural equation modeling (SEM) to analyze the data. The results of this study contain several implications for HCI research and COVID-19 tech design. The empirical findings demonstrate the validity of parsimonious assessment in evaluating a UTAUT-based model to understand the adoption and usage of the deployed safety app. Safety concerns and willingness to follow precaution measures are strong predictors of the intention to use, which also affects security. Privacy is a central concern that needs to inform the design of safety apps. Our results are valid across the moderating roles of demographics, such as gender, age, and social capital.

The rest of this paper is organized as follows: We start by providing an overview of the current literature pertinent to this study. Next, we describe the research questions, hypotheses, and methods adopted for this study and the results. The work outcomes are analyzed and discussed, and the limitations of the research are presented, also considering the particular context of the research, the COVID-19 pandemic. At the end of the paper, we present the conclusion and future works.

### Literature Review

This section presents the background and literature review related to the main topics of this paper. The first subsection provides an overview on the transformations of the tourism sector and research caused by COVID-19; the second subsection deals with the technological measures and their ethical challenges involved with the COVID-19 pandemic; the third subsection touches on citizen engagement and social capital studies also in the context of COVID-19; and finally, the last subsection surveys the technology adoption scales and methodology that we used and extended in our study.

### Tourism Transformations in Times of COVID-19

One of the sectors most scarred by the COVID-19 pandemic crisis is tourism [3,21]. According to a United Nations World Tourism Organization's (UNWTO) report from May 2020 [22], the health crisis was associated with the 22% less international arrivals in tourist destinations during the first quarter of 2020 and threatened many tourism jobs. This led to substantial policy



measures [23] to support Europe's tourism, which is an essential source of income for many countries.

As described by Sigala [10], the COVID-19 pandemic has challenged the capitalistic society in which often tourism is embedded. Nevertheless, COVID-19 can also be seen as an occasion for "slowing down" [24] to criticize the current state of affairs [25] and explore transformations by reimagining and redesigning tourism [10] toward more sustainable alternatives [26], community-oriented initiatives, and "socialized" tourism [27,28]. Zenker and Kock [29] suggested some possible directions for the tourism research agenda involving COVID-19: (1) to address the complexity of the current pandemic and trace relationships among different impacted areas and involved variables; (2) to consider the possible drifts in the "destinations' images" based on the pandemic history of the destination itself; (3) to examine behavioral changes in the visitors (eg, changes in travel choices), (4) locals (eg, in-group and out-group dynamics between locals and visitors), and (5) the tourism sector (eg, increase collaborations among different sectors); and finally (6) to predict and assess the long-term and secondary consequences of COVID-19 in tourism, such as observing the change in priorities in the sector.

The redesigning in the tourism sector could also benefit from the use of COVID-19 technologies. An invitation for a change in the domain of e-tourism research has been made [30] to reinvent the field from an ontological and epistemological perspective. As mentioned by Gretzel et al [30], although technology solutions are powerful catalysts for transformations and have been already used in the tourism research and sector, e-tourism research should reflect on COVID-19, look at the future, and be reshaped following the principles of historicity, reflexivity, transparency, plurality, creativity, and, finally, social equity and diversity. All of them require different points of view and research fields to develop theories and interventions.

### **COVID-19, Technological Interventions, and Ethical Challenges**

COVID-19 has also changed our relationship with technology [31]. Thanks to digital tools, we are able to monitor the evolution of the pandemic day by day (see, eg, [32-34]); to perform predictions based on models [35]; to participate in digital meetings, conferences, and classes; and to remain in contact with our loved ones [31].

Several tools have been developed and proposed to mitigate the risks associated with the COVID-19 and the spread of the disease and to perform diagnosis. Kumar et al [36] discussed different technologies (eg, artificial intelligence [AI]) used for several COVID-19 apps by dividing them into the following groups: (1) diagnosis using radiology images, (2) disease tracking, (3) health condition prediction, (4) computational biology, (5) protein structure prediction, (6) drug discovery, and (7) social awareness, web, and tech control. Whitelaw et al [37] provided a framework for describing the digital apps in response to COVID-19 (eg, planning, management, tracking, testing, and quarantine) by explaining their functionalities, the technology used, the countries that adopted these digital tools, and their respective advantages and disadvantages. Ting et al [38] reviewed the impact of several technologies (eg, AI, big

data, internet of things [IoT]) in the service of health interventions for COVID-19 (eg, monitoring, surveillance, prevention, and diagnosis). Finally, Golinelli et al [39] provided a literature review that tackles the digital measures embraced by the health care system to manage COVID-19. One result of the study [39] outlines that diagnostic tools form the majority, followed by surveillance and prevention technologies.

Many surveys have been performed to classify and discuss contact-tracing apps [12,39,40]. Contact-tracing technology has been promptly identified as a powerful tool to control and mitigate the spread of the pandemic, and several frameworks exist, such as centralized, decentralized, and hybrid architectures, and various data management concerns populate the literature [12,39-41]. To deal with some of the differences and find common ground, in April 2020, the European eHealth Network developed a toolbox for the European states to follow, called *Mobile Applications to Support Contact Tracing in the EU Fight Against COVID-19 Common EU Toolbox for Member States* [42]. According to this document, the European Union (EU) apps should be compliant with some sociotechnical requirements: epidemiological (eg, inform the persons who have been at risk of contracting the virus), technical (eg, use of proximity technology), interoperability (eg, epidemiological alignment among member states), cybersecurity (eg, adoption of encryption), and safeguards (eg, voluntary-based app). The EU toolbox for contact tracing addresses further ethical challenges (eg, the importance of accessibility and inclusivity as fundamental rights to be preserved and protected in the development and deployment of such apps).

Due to the ethical issues involving COVID-19 digital tools, many authors have examined this dimension [14-16,43]. Tang [15] described and discussed concrete privacy-aware digital interventions for contact tracing, while Morley et al [43] proposed some ethical guidelines for the development and the deployment of tracking and tracing applications. The authors identified some general and universal principles (ie, necessity, proportionality, scientific soundness, and time-boundedness) and enabling conditions that influence the execution of the tools (eg, voluntariness, consent, anonymity, right to be forgotten, accessibility). In addition, Dubov and Shoptawb [14] considered the ethical challenges of contact-tracing technology; for example, the number of tests necessary for a practical contact-tracing app; deciding how to collect data; and issues on privacy, voluntariness and consent, transparency, and inclusion. The research reported by Gasser et al [16] was more general since they discussed the ethical and legal challenges of COVID-19 digital health tools (eg, symptom checkers, quarantine compliance), not just tracking and contact-tracing apps. Examples of these challenges are the validity and necessity of the research, privacy requirements, the autonomy of the users, possible discrimination risks, and the risk of repurposing retrieved data for other aims.

The users' perception and acceptance of COVID-19 contact-tracing approaches were investigated by Lu et al [44] and Utz et al [45]. The former focused on participants' perception of contact-tracing strategies (ie, digital apps and human contact tracing), with results that include aspects, for instance, of privacy, security, and accessibility and suggest both

hybrid approaches for contact tracing that combines technological and human supports to strengthen values such as trust and transparency. The latter provided a study on users' acceptance of COVID-19–tracing apps across countries (ie, Germany, the United States, and China), reporting that different places show different acceptances, preferences, and requirements. All these issues are closely connected with several ethical principles, such as autonomy, privacy, solidarity, and justice, that are fundamental to recommendations for COVID-19 digital tools.

### ***Technologies, Citizen Engagement, and Social Capital***

Despite the plethora of digital tools proposed for COVID-19 (see, eg, [12]), many are still debated due to ethical challenges and criticalities regarding user perceptions and preferences [46]. The development and importance of apps based on *citizen engagement* and *participation* in times of COVID-19 have been proposed as an alternative [47,48] since engagement and communication are critical factors for managing a crisis, as also identified by Chen et al [18] during this latest pandemic emergency, in which they studied the effect of the national health authority's social media accounts on citizen engagement.

Public and citizen engagement is based on communication and building relationships between authorities and citizens, for instance, through dialogue and participation [18,49]. Today, digital platforms and near-universal access to mobile technologies have the power to support citizen engagement with governance and municipalities (see, eg, [50]), regarding pretty much any issue that relates to the citizens' lives. Digital technologies can truncate citizen feedback loops with the government and enhance the implementation of public policy and improve citizen-municipality relationships [51]. For this reason, many self-service apps are being deployed, as many important cities have promoted mobile technologies [52]. Yet, self-service apps can be expensive and hard to deploy for smaller communities dealing with public funding [51]. Recently, the health care industry has focused on wearables devices [53,54], in which technology is seen as an enabler for self-prevention programs. However, the adoption, trust, and sustained use of these systems is challenging and involves critical and complex design considerations [53].

Digital technology for citizen engagement can also facilitate the development of *social capital* [55]. "Social capital" is a term that is commonly used but often poorly defined and conceptualized [56], yet it can be generally defined as the values of social relationships and networks that a person *has* in terms of membership [56,57]. As described by Mandarano et al [55], relationships, trust, and norms are the 3 elements that constitute social capital and can be increased with participation, collective actions, and decisions. Social capital and health are also connected, such as in the mortality rate and heart disease, especially when associated with one's level of income [58,59]. Focusing specifically on COVID-19, the study of Borgonovi and Andrieu al [59] showed that communities with high social capital could be more prepared for COVID-19 also in terms of change in behaviors and isolation to protect other members. Another study [60] confirmed that social distancing measures alone are inadequate to mitigate COVID-19 spreading; instead,

increasing a sense of community and consequently social capital is more effective in preventing the effects of the pandemic.

### ***Technology Adoption, Its Privacy-Based Extensions and Applications***

Models are widely used to study people's intentions to adopt technology. The Technology Acceptance Model (TAM) [61] and UTAUT [19] were designed and tested to measure people's tendency toward technology. TAM is derived from another popular theoretical framework called the theory of reasoned action (TRA) [62] that itself explains human behavior. TAM applies the TRA to explain users' behavior and acceptance in reference to computer systems on the basis of the users' attitudes/intentions, perceived usefulness and ease of use, and other variables. Although TAM is a useful theory, it has some flaws. Indeed, it does not include some important factors, such as the social and organizational contexts in which the technology is encountered [63]. To solve some of these issues [64,65], UTAUT was proposed by bringing together several user acceptance models, including TAM and the TRA. According to UTAUT [19], the following indicators are connected with the use of information technology: (1) performance expectancy (usefulness), (2) effort expectancy (ease of use), (3) social influence, and (4) facilitating conditions, which influence behavioral intention and use behavior, constituting the main predictors of behavioral intention.

As reviewed by Venkatesh et al [66], there are several applications, integrations, and extensions of the UTAUT paradigm. For instance, Khalilzadeh et al [67] and Shin [68] investigated security elements in the field of ecommerce and mobile payments by adopting UTAUT and extending it with security constructs, such as perceived security, perceived risk, and trust. Based on some of the definitions given by Khalilzadeh et al [67], Shin [68], and Mandrik and Bao [69] and adapting them for information systems, (1) perceived security is the user's belief that an information system will be secure [67,68], (2) trust is defined as the user's belief that the information system provider will satisfy the user's needs and expectations [67,68], and (3) perceived risk is related to the sense of doubt or anxiety related to the (possible negative) final result of an action, behavior, or situation [67,69] associated with an information system.

The literature shows that users perceive as risky several of the so-called new products, so perceived risk has been often included in UTAUT [65,67,70]. For instance, Thakur and Srivastava [71] measured perceived risk, and their results confirmed their hypothesis stating that risk negatively influences the adoption intention of users. Focusing on trust, it has been shown that this aspect has an effect on performance and effort expectancy [72]. Trust also involves the users' expectation concerning the compliance promise of the service provider; this aspect of trust is particularly important, especially in some domains in which the users are more vulnerable and then exposed to risks (eg, electronic financial transactions and medical care) [73,74]. As shown by Wilkowska and Ziefle [75], in the eHealth domain, privacy and security are central topics that influence the use and acceptance of technology. In a study conducted by Schnall et al [76], in the context of mobile health

technologies, similar findings revealed that privacy (eg, access to information), security, and trust concerns do exist among users of such apps.

The UTAUT model, including its extensions, was also used in 2020 in the context of COVID-19 technologies. For instance, Békés and Aafjes-van Doorn [77] examined psychotherapists' attitudes regarding web-based psychotherapy, also considering the new exigencies of the pandemic. Tiwari [78] focused their study on the adoption of university online classes. Finally, the research carried out by Chayomchai et al [79] centered on the use of technology by Thai people during the quarantine. We built on these efforts to extend the UTAUT scale to measure users' attitudes in COVID-19 times.

### Research Questions and Hypotheses

This work was motivated by a unique set of circumstances to deploy safety measures at scale in a European island with a significant tourism industry in order to better understand the factors affecting the adoption and use of dedicated COVID-19 apps. We were particularly interested in investigating the role of safety, security, privacy, and trust in the context of the adoption of a voluntary COVID-19 app that supports air and sea access to an insular region. We also wanted to understand the effect of moderator variables (gender, age, education, and social capital) in the adoption of COVID-19 safety systems.

The *Madeira Safe to Discover* app was part of the COVID-19 safety mechanism designed by the local Health Authorities of Madeira Islands in order to achieve 2 main goals: to support travelers coming into the region by guiding them through the health requirements and to empower the health authorities with an information system that facilitates the monitoring and managing of the potential COVID-19 effects on the region. After the lockdown, the region opened borders, implementing a mandatory COVID-19 polymerase chain reaction (PCR) screening test. Travelers coming to the islands needed to present a valid COVID-19 test 72 hours before entry or be subject to testing upon entry. Registration of personal and travel details on the regional health system was mandatory, either manually through a form or by using the *Madeira Safe to Discover* system. Note that the use of the *Madeira Safe to Discover* app was neither a necessary requisite nor easier compared to the alternative (ie, the physical document); in fact, the travelers could choose either solution. After entering the region, travelers would undergo a voluntary 14-day vigilance period to submit

an electronic daily health inquiry. The health authorities deployed a web-based *Madeira Safe to Discover* app to stimulate compliance with the safety procedures, since screening and monitoring procedures were constitutionally optional.

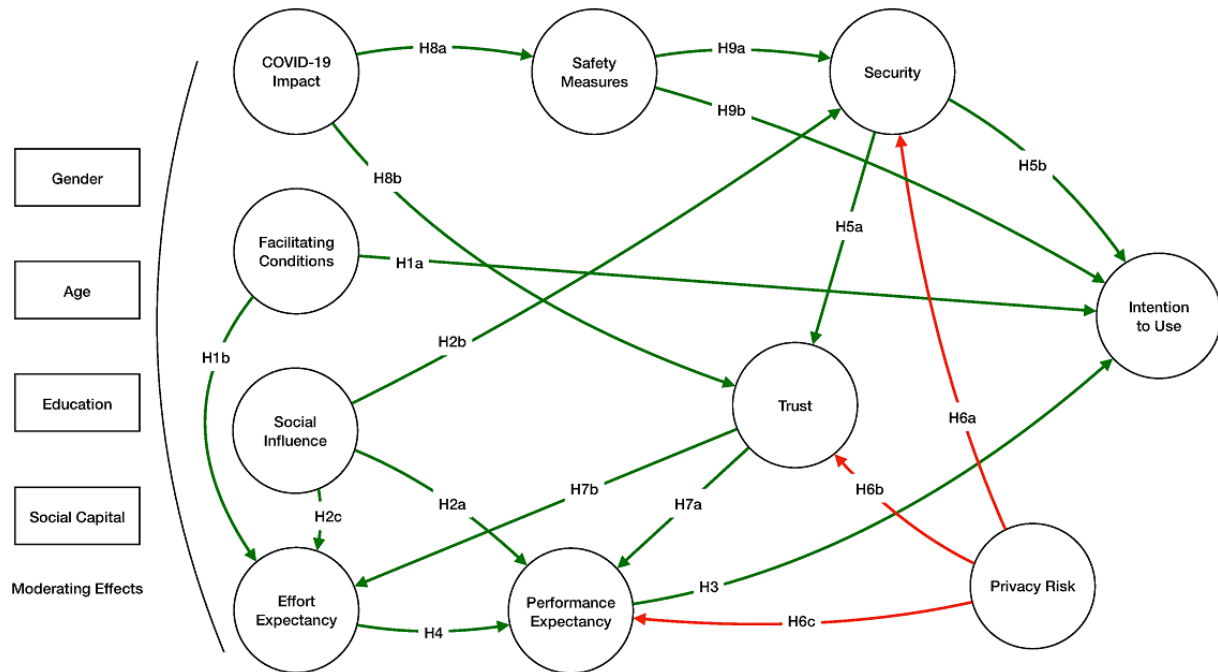
During their vigilance period, travelers received reminders for submitting their health inquiries via the Short Message Service (SMS). Those using the *Madeira Safe to Discover* app could receive their test results and submit their daily health inquiry electronically. In addition, they could decide to share their location while using the app voluntarily, but the system could not implement any automated contact-tracing mechanism. In summary, the *Madeira Safe to Discover* app is an optional digital tool that would improve COVID-19 safety measures for health authorities, while providing some practical benefits for travelers at their data expense.

The researchers involved in this study were asked to assist with the system's design and advise on data protection and privacy issues, while producing an independent adoption and usage report. This set the stage to investigate at scale the effects of safety, privacy, and trust in the adoption of mobile apps and safety-monitoring systems.

More specifically, the research purposes of this work were (1) to investigate the effects of the COVID-19 pandemic on technology adoption, especially safety, security, privacy, and trust; (2) to increase our understanding of differences in the determinants of safety in technology use; and (3) to increase the analytical potential and predictive precision of a parsimonious questionnaire based on a known UTAUT model for broader application in HCI research.

This study proposes a questionnaire adapted from a UTAUT model that incorporates variables such as safety, trust, perceived security, perceived usefulness (performance expectancy), and ease of use (effort expectancy). [Figure 1](#) presents the *Madeira Safe to Discover* acceptance/use model proposed for this study.

For testing the hypothesis, the questionnaire comprised 27 questions (items) for responses on a Likert-type scale: 1 for strongly disagree, 2 for disagree, 3 for undecided, 4 for agree, and 5 for strongly agree. Concerning the questionnaire's validity, the questions (items) were both adapted from the existent literature and reformulated considering the COVID-19 *Madeira Safe to Discover* app, which can be generalized for safety-monitoring systems.

**Figure 1.** Proposed research model. H: hypothesis.

### Items Based on UTAUT Constructs

For the purpose of this research, several hypotheses were developed on the basis of the original UTAUT constructs; we will lay them out in detail here.

*Facilitating conditions* are directly and positively related to user behavior but have no effect on behavioral intentions [19]. Our study followed the work of Khalilzadeh et al [67] in using behavioral intention as a surrogate for user behavior, although in the original UTAUT model, they are separate constructs. Therefore, we hypothesized that:

- Hypothesis 1a (H1a): The facilitating conditions (eg, owning a smartphone) for using the COVID-19 Madeira Safe to Discover app positively influences users' intentions to use it.
- H1b: The facilitating conditions (eg, knowledge to use the app) for using the COVID-19 Madeira Safe to Discover app positively impacts effort expectancy.

*Social influence* directly and positively impacts behavioral intention. This means that people often discuss new technology with their friends, family members, and other people who are influential for them. These kinds of discussions could potentially produce changes in the opinions of the people concerning the new technologies. Following the argument founded by Khalilzadeh et al [67], focusing on the relationship between perceived security in the financial sector, we consider that perceived security is also central in health aspects; therefore, we assumed that perceived security should be relevant for the model. We thus hypothesized that:

- H2a: The social influence (eg, recommendation from significant others) for using the COVID-19 Madeira Safe to Discover app positively predicts effort expectancy.
- H2b: The social influence (eg, recommendation from significant others) for using the COVID-19 Madeira Safe

to Discover app directly and positively influences perceived security.

- H2c: The social influence (eg, recommendation from health authorities) for using the COVID-19 Madeira Safe to Discover app directly and positively influences performance expectancy.

*Performance expectancy* is the most influential predictor of behavior intention [19]. As reported by Khalilzadeh et al [67], Yang [80] identified 2 kinds of performance expectancy, utilitarian performance expectancy and hedonic performance expectancy. Yet, according to Rodríguez and Trujillo [81], there is only a small effect of hedonic motivation. One of the characteristics of the Madeira Safe to Discover app is the ability to let travelers enter their own data and avoid queues and paper forms during an already stressful airport transit in pandemics' context. For these reasons, since the app offers utilitarian benefits that could influence adoption, we hypothesized that:

- H3: Performance expectancy (ie, usefulness) positively affects behavioral intention to use the COVID-19 Madeira Safe to Discover app.

*Effort expectancy* is 1 of the most influential predictors of the intention to use mobile apps [82-84]. Others have also found effort expectancy to significantly impact behavioral intention [85,86]. Although in the original UTAUT model, effort expectancy affects the intention to use, the studies on which this research is based (eg [67,80]) in a departure from the original model posit that effort expectancy predicts performance expectancy.

As the Madeira Safe to Discover app provides a new way to secure travel, we expect that the perceived ease to use such an app will influence the behavioral intention of the users. Following the previous analyses and UTAUT's hypotheses, we formulated that:

- H4: Effort expectancy (ie, ease of use) positively affects performance expectancy (ie, usefulness) to use the COVID-19 Madeira Safe to Discover app.

### **Items Based on UTAUT Extensions for Security and Privacy**

Security, trust, and risk have become critical additional constructs in studies on technology adoption [65,67], especially in the case of sharing medical information.

*Perceived security* is supposed to directly affect behavioral intention [67]. Because the COVID-19 Madeira Safe to Discover app involves sensitive health information, we anticipated that perceived security would be influential in our model [67]. As stated by Khalilzadeh et al [67], perceived security is also an aggregate construct that changes over time and according to public opinion and social influence. Therefore, we hypothesized that:

- H5a: The perceived security of the COVID-19 Madeira Safe to Discover app positively and directly predicts perceived trust.
- H5b: The perceived security of the COVID-19 Madeira Safe to Discover app positively and directly predicts the behavioral intention to use the COVID-19 Madeira Safe to Discover app.

*Privacy risk* is usually associated with perceived security; the more a user senses privacy risks, the less secure they are likely to feel, leading to a negative relationship between risk and security [67,87]. Based on the findings retrieved from the literature (see the Literature Review section), which state that perceived risk has a negative impact on perceived security, trust, and performance expectancy, the following hypothesis were formulated:

- H6a: The privacy risk of using the COVID-19 Madeira Safe to Discover app directly and negatively impacts perceived security.
- H6b: The privacy risk of using the COVID-19 Madeira Safe to Discover app directly and negatively impacts perceived trust.
- H6c: The privacy risk of using the COVID-19 Madeira Safe to Discover app directly and negatively impacts performance expectancy.

*Trust*, together with perceived security, usually affects positively behavioral intentions [67,68]. Yet, considering only trust, its effect on behavioral intention has been considered significant [68,88]. As digital technologies become ubiquitous, trust supersedes more traditional technology adoption factors. Akin to Chandra et al [88], this study included trust as a singular construct. Hence, following Khalilzadeh et al [67] and Yang [80], we hypothesized that trust positively affects the effort expectancy and we formulated that:

- H7a: Trust positively impacts the performance expectancy (ie, usefulness) to use the COVID-19 Madeira Safe to Discover app.
- H7b: Trust positively affects the effort expectancy (ie, ease of use) to use the COVID-19 Madeira Safe to Discover app.

### **Items Related to the COVID-19 Impact and Safety Measures**

The COVID-19 pandemic had a significant social, economic, and personal behavioral impact on citizens worldwide. Most countries in Europe were on complete lockdown for several weeks and months, and many closed airports and borders to prevent the spread of the pandemic. After COVID-19 lockdown, measures were enforced in public spaces (eg, use of masks, temperature screening, hand hygiene) to mitigate the risk of contagion. As introduced in the Literature Review section, technology adoption models are inspired by the TRA; according to this, subjective norms and the attitude toward an action impact the behavioral intention to use, so these 2 influence how individuals perform an action [62]. Adapted from the TRA and TAM, the UTAUT definition of attitude toward a behavior is “an individual’s positive or negative feeling about performing the target behavior” [19], while subjective norm refers to a “person’s perception that most people who are important to them think they should or should not perform the behavior in question” [19]. Therefore, we developed the following hypotheses:

- H8a: The extent to which someone is impacted by COVID-19 positively affects the intention to follow safety measures.
- H8b: The willingness to follow COVID-19 safety measures positively affects the intention to use the COVID-19 Madeira Safe to Discover app.

Furthermore, it is noteworthy that the attitude of a person concerning a particular behavior is dependent upon their beliefs as well as evaluations, and different works have stressed the relationship between security, safety, and behavioral intentions [65,67]. Despite the importance of trust and privacy risk in influencing the behavioral intention to use digital technologies, the current literature has not invested in understanding the role of perceived risk (eg, [73]). As travelers are likely to perceive the COVID-19 safety measures as risky, we expect that trust will play a significant secondary role in behavioral intention than privacy risk. However, trust might be more important in minimizing the risk perception. Hence, given the wide applicability of UTAUT, we can anticipate that:

- H9a: The willingness to follow COVID-19 safety measures positively and directly influences perceived security.
- H9b: The extent to which someone is impacted by COVID-19 positively and directly predicts perceived trust.

## **Methods**

### **Study Design**

This study followed the recommendation for a 2-stage analytical procedure [89]. To test the measurement model’s validity and reliability, we applied CFA, followed by SEM, to perform multiple regression analysis. CFA and SEM allow simultaneous analysis of both observed and latent variables, while providing overall fit statistics [90,91]. CFA was conducted using R v 4.0.2 (R Foundation for Statistical Computing) using maximum likelihood estimation. Path analysis of the structural relationships were also conducted using R with SEM libraries

(lavaan v. 0.6-7 [92] and semTools v. 0.5-3 [93]). Moderation analysis [94] was also undertaken in R.

### Participants and Procedures

The questionnaire was sent via email to 58,954 participants who were registered in the system and who gave prior permission to be contacted via email. The questionnaire was sent at the end of August 2020 to travelers who had already finalized their trips or had stayed after the 14-day monitoring period (July and August 2020). The email was sent in all the 5 different languages supported by the app and contained a general explanation of the study, the details of the privacy policy and data treatment, and a link to a Google Forms survey. The questionnaire was translated into 5 languages corresponding to the supported idioms of the app according to the following breakdown: 36,930 (62.6%) in Portuguese (PT), 10,178 (17.3%) in English (EN), 6575 (11.2%) in German (DE), 3735 (6.3%) in French (FR), and 1536 (2.6%) in Spanish (ES). In total, we collected data from 9555 participants; corresponding to the overall participation of 16.2%, the participation was higher in DE (18.6%) and PT (17.7%) and lower in FR (12.2%), EN (11.6%), and ES (11.4%).

In terms of the general demographics (N=9555, summary in [Table 1](#)), the sample comprised a slightly higher proportion of women (n=5019, 52.5%) than men (n=4493, 47.0%), with 43 (0.5%) classifying themselves differently. There were a majority of Portuguese respondents (n=5847, 61.2%), followed by the major traditional tourism markets of Madeira Islands (n=1310,

13.7%, German; n=532, 5.6%, United Kingdom; n=516, 5.4%, French; n=328, 3.4%, Spanish; n=125, 1.3%, Italian), a few other EU (n=603, 6.3%) and other non-EU (n=125, 1.3%) markets, and a minority of 169 (1.8%) from non-European nationalities. In terms of age groups, young (<18 years old, n=142, 1.5%) and older (>65 years old, n=484, 5.1%) people were a minority compared to segments of the adult population (18-25 years old, n=3122, 32.7%; 18-25 years old, n=3203, 33.5%; 36-49 years old, n=2581, 27.0%). Finally, the sample was characterized with high education levels, with 70.4% holding a higher degree, 2307 (24.1%) having secondary education, and only 277 (2.9%) with basic education. The questionnaire also gathered some data on the frequency of travel, which is harder to characterize because of the different possible combinations between tourists, locals, and visitors. Nevertheless, surprisingly, 3726 (39.0%) respondents said it was their first time in Madeira, almost half of the respondents came regularly (n=4711, 49.3%), and 1080 (11.3%) said they were local residents. Note that the sample does not reflect the official tourism statistics, which changed drastically with the COVID19 pandemic. Indeed, the annual official statistics for 2019 report that 87% of visitors were foreign (13% nationals), and of these, the majority were German (24%) and UK (23%) nationals.

The study took place within the scope of the Science4Covid Research project funded by the Portuguese National Science Foundation in collaboration with regional and national health authorities.

**Table 1.** Characteristics of respondents (N=9555).

Demographic and group	Frequency, n (%)
<b>Gender</b>	
Woman	5019 (52.5)
Man	4493 (47.0)
Other	43 (0.5)
<b>Age (years)</b>	
<18	142 (1.5)
18-35	3122 (32.7)
36-49	3203 (33.5)
50-65	2581 (27.0)
>65	484 (5.1)
N/A <sup>a</sup>	23 (0.2)
<b>Nationality</b>	
Portuguese	5847 (61.2)
German	1310 (13.7)
United Kingdom	532 (5.6)
France	516 (5.4)
Spain	328 (3.4)
Italian	125 (1.3)
Other EU <sup>b</sup>	603 (6.3)
Other non-EU	125 (1.3)
Other (non-European)	169 (1.8)
<b>Education</b>	
Basic	277 (2.9)
Secondary	2307 (24.1)
Graduation	3686 (38.6)
Postgraduation	3035 (31.8)
N/A	250 (2.6)

<sup>a</sup>N/A: not applicable.

<sup>b</sup>EU: European Union.

## Ethical Considerations

Given that the study did not involve sensitive or health-related information, did not involve risks or benefits, and was completely voluntary, it was not necessary to obtain an ethics board review. Nevertheless, the study complied with the provisions of the General Data Protection Regulation—Regulation (EU) 2016/279 of the European Parliament and of the Council of April 27, 2016—and follows the recommendations of the Declaration of Helsinki for research.

## Participants' Motivations and Sources of Influence for Travel

Two questions addressed the main motivations and sources of influence for travel. Among the motivations for the trip, 1940 (20.3%) participants reported the sun, 1891 (19.8%) rest, 1749 (18.3%) nature, and 1491 (15.6%) family, followed by 1414

(14.8%) for COVID-19. Culture, work, and wellness were ranked much lower in terms of preference (n=612, 6.4%; n=325, 3.4%; n=134, 1.4%, respectively). In terms of nationality breakdown, family ranked higher for Portuguese nationals, while COVID-19 was higher for German and Spanish nationals. In terms of travel frequency, COVID-19 was almost equally higher for local residents and first-time visitors, which suggests that some people choose to travel to a destination because of COVID-19. This was confirmed by analysis of the sources of influence where safety had 3019 (31.6%) responses ranked first, followed by personal (n=2933, 30.7%) and family (n=2169, 22.7%) responses and a much lower influence on media, tour/agencies, and social media (n=812, 8.5%; n=401, 4.2%; and n=201, 2.1%, respectively). In terms of age, motivations were not significantly different, although COVID-19 consistently rose from 1041 (10.9%) for lower-age groups (<18

years) to 1815 (19.0%) for higher-age groups (>65). The same trend was not observed for safety in the sources of influence.

### Measurement Model

Inspired by the methodology described by Khalilzadeh et al [67], we examined the SEM assumptions by visually inspecting the variables shown in the diagrams, which ultimately appeared to have a normal distribution. In addition, the residuals manifested a normal distribution and no relationship was identified between predictors and residuals [75]. Focusing on the model itself (provided in [Multimedia Appendix 1](#)), its fits were good, reaching goodness-of-fit indices (GFIs) higher than the recommended thresholds of 0.8 for the adjusted goodness-of-fit index (AGFI) and 0.9 for other indexes [75,95-97].

Specifically, the GFI was 0.959, the AGFI was 0.928, the comparative fit index (CFI) was 0.959, the normative fit index (NFI) was 0.958, and the Tucker-Lewis index (TLI) was 0.950. Similarly, there was no misfit evidence, with satisfactory levels of 0.053 for the root-mean-square error of approximation (RMSEA) and 0.063 for the standardized root-mean-square residual (SRMR), which compared favorably to the benchmarks reported by Wilkowska and Ziefle [75], Fornell and Larcker [95], Bagozzi and Yi [96], and Etezadi-Amoli and Farhoomand [97], suggesting that values of 0.06 or less reflect a close fit. The SRMR was also good, at 0.063, below the overall fit threshold (<0.06). Due to the big sample size (N=9555), the model  $X^2$  was significant. After verifying the measurement fits of the data against the known thresholds, we built the initial

measurement model to refine the questions and check the validity and reliability of the measurement items. All the loadings were significant at an  $\alpha$  level of .001, with most factor loadings higher than 0.7 and 2 factors (impact and safety) slightly below the threshold at 0.470, indicating good convergent validity [95].

[Table 2](#) shows the results of CFA. All items loaded significantly to the underlying constructs ( $P<.001$ ), pointing to adequate convergent validity and reliability in all cases. We examined the convergent validity of the model by measuring the average variance extracted (AVE) and the reliability of each measure and each construct (provided in [Multimedia Appendices 2 and 3](#) [98]). We compared the shared variance among constructs with the AVE from the individual construct to check discriminant validity (provided in [Multimedia Appendices 2 and 3](#)). Discriminant validity was checked by confirming that the heterotrait-monotrait ratio of correlations (HTMT) was below the 0.85 threshold [99]. Finally, the model was checked for composite reliability as an indicator of a latent construct of the shared variance among the observed variables. The composite reliability was 0.97, which indicated high measurement reliability of our measurement model [100].

In this model, we analyzed the moderating effect of the model factors and their effect on variables. In this sense, we can expect that the model will show unexpected moderating relationships [67]. In summary, we concluded that the measurement model exhibits good reliability and good convergent and discriminant validity.



**Table 2.** The measurement model.

Construct and item	$\alpha$	SE	Z value	P value
<b>Impact of COVID-19 (Impact), <math>\alpha=.74</math></b>				
Impact_1	.75	N/A <sup>a</sup>	N/A	N/A
Impact_2	.76	0.015	58.294	.001
Impact_3	.55	0.016	46.660	.001
<b>Facilitating conditions (FacCon), <math>\alpha=.92</math></b>				
FacCon_1	.90	N/A	N/A	N/A
FacCon_2	.94	0.009	117.527	.001
<b>Privacy risk (Privacy), <math>\alpha=.91</math></b>				
Privacy_1	.92	N/A	N/A	N/A
Privacy_2	.90	0.014	69.501	.001
<b>Social influence (SocInf), <math>\alpha=.60</math></b>				
SocInfl_1	.65	N/A	N/A	N/A
SocInfl_2	.61	0.024	44.3131	.001
<b>COVID-19 safety measures (Safety), <math>\alpha=.73</math>, <math>R^2=0.446</math></b>				
Safety_1	.74	N/A	N/A	N/A
Safety_2	.62	0.021	50.066	.001
Safety_3	.72	0.021	55.529	.001
<b>Effort expectancy (EffExp), <math>\alpha=.92</math>, <math>R^2=0.628</math></b>				
EffExp_1	.90	N/A	N/A	N/A
EffExp_2	.93	0.007	136.111	.001
<b>Performance expectancy (PerfExp), <math>\alpha=.85</math>, <math>R^2=0.757</math></b>				
PerfExp_1	.89	N/A	N/A	N/A
PerfExp_2	.85	0.010	105.849	.001
<b>Security, <math>\alpha=.91</math>, <math>R^2=0.521</math></b>				
Security_1	.84	N/A	N/A	N/A
Security_2	.84	0.010	108.731	.001
Security_3	.92	0.008	126.270	.001
<b>Trust, <math>\alpha=.85</math>, <math>R^2=0.510</math></b>				
Trust_1	.79	N/A	N/A	N/A
Trust_2	.94	0.014	79.631	.001
<b>Behavioral intention (IntUse), <math>\alpha=.70</math>, <math>R^2=0.903</math></b>				
IntUse_1	.65	N/A	N/A	N/A
IntUse_2	.82	0.015	66.639	.001

<sup>a</sup>N/A: not applicable.

## Structural Model

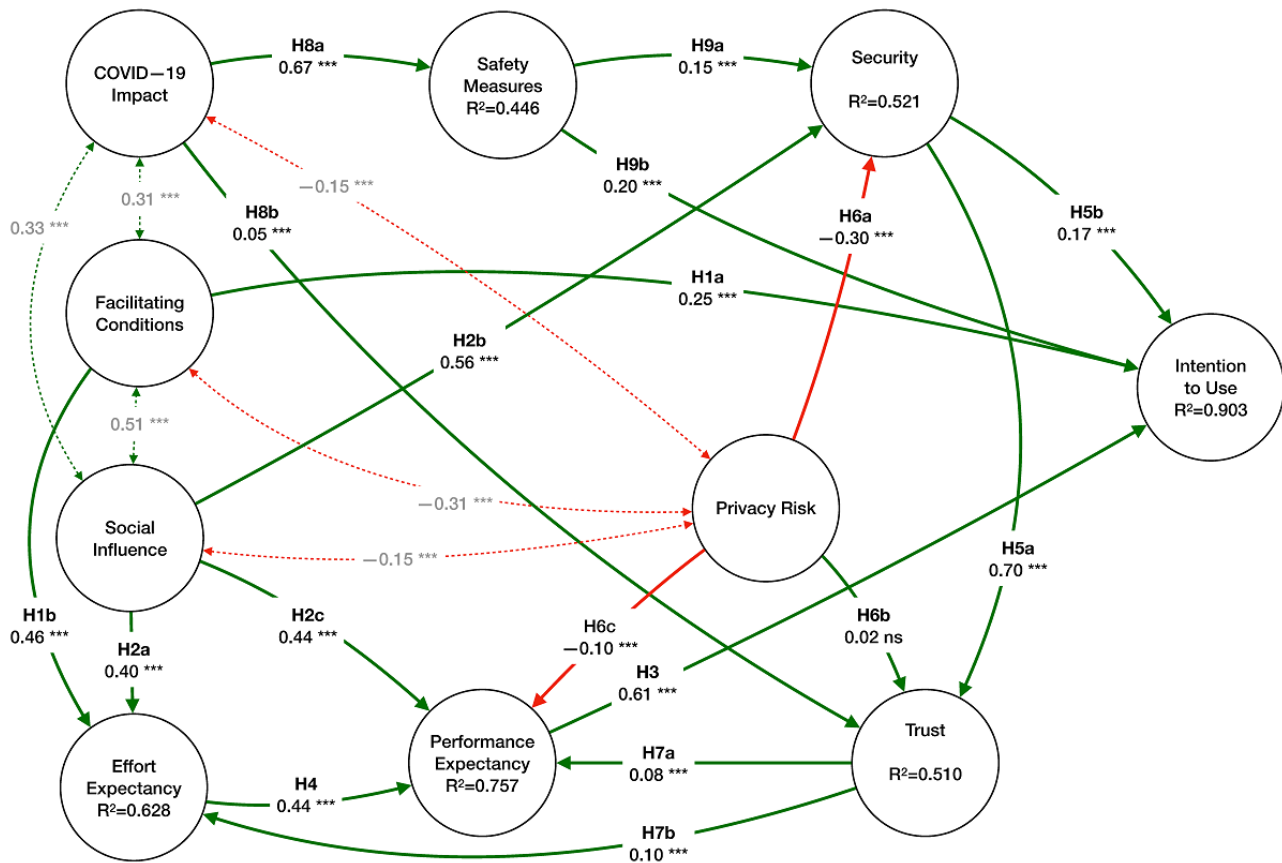
In the absence of measurement misfit, we applied SEM to perform multiple regression analysis of the data. This kind of technique is adopted to evaluate the fitting of the data upon the theoretical measurement model [68]. Here, we extended the proposed research model to include COVID-19-related constructs (COVID-19 impact and safety measures) and new

interactions between these constructs and security, trust, and behavioral intention. The structural relationships were tested by estimating the causal paths defined by the hypotheses (see [Figure 2](#) and [Multimedia Appendix 4](#)). All hypothesized causal paths, except H6b, were supported at  $P<.001$ . For all the constructs of the model, we calculated the squared multiple correlations (SMCs) represented as  $R^2$  in [Table 2](#). This coefficient indicates the predictive accuracy and explanatory

power of a model [75]. The SMC represents the share of the variance of the endogenous variable explained by the exogenous variables. The  $R^2$  value of the behavioral intention was the highest at 0.903, showing that the research model explains a large amount of the dependent variable variance. The lowest amount of  $R^2$  represented in the model was related to COVID-19

safety measures ( $R^2=0.446$ ), followed by trust ( $R^2=0.510$ ) and security ( $R^2=0.521$ ), due to the nature of the constructs (rooted in subject beliefs) and also their proximity to independent variables. The coefficient for performance and effort expectancy was also high at  $R^2=0.757$  and  $R^2=0.628$ , respectively, consistent with previous results [67].

Figure 2. Results of the research model. H: hypothesis.



**Moderator Effects**

To investigate demographic moderator effects, we followed the work of Shin [68], in which the split sample approach was adopted [101,102]. As described by Shin [68], the split sample approach is based on some moderators that are selected from the data and that cannot be changed. Some examples are a person’s nationality, gender, or age, which naturally form different moderator levels. We tested the moderator effects of gender (woman/man), age (divided into 2 groups, <36 and >36 years), education (basic/secondary education and higher education), and a proxy of social capital [56,57], which was

calculated from a combination of nationality, residence, and regularity of travel. We classified local residents as high social capital, regular travelers or first-time national visitors as medium social capital, and first-time international visitors as low social capital.

We compared different groups to test the moderating effects of these variables after testing for measurement invariance using  $X^2$  difference tests and the fit indexes (provided in Multimedia Appendix 5). Invariance was also tested for factor structure, loadings, residuals, and means. The model supported good evidence of measurement invariance at  $P<.001$  significance. The results of this analysis are presented in Table 3.

**Table 3.** Results of moderator effects.

Hypothesis	Gender		Age (years)		Education		Social capital		
	Woman	Man	<36	≥36	Basic/secondary	Higher education	Low	Medium	High
H1a	0.25 <sup>a</sup>	0.23 <sup>a</sup>	0.26 <sup>a</sup>	0.25 <sup>a</sup>	0.27 <sup>a</sup>	0.25 <sup>a</sup>	0.24 <sup>a</sup>	0.24 <sup>a</sup>	0.40 <sup>a,b</sup>
H1b	0.43 <sup>a</sup>	0.49 <sup>a</sup>	0.45 <sup>a</sup>	0.47 <sup>a</sup>	0.51 <sup>a,c</sup>	0.45 <sup>a</sup>	0.49 <sup>a</sup>	0.43 <sup>a</sup>	0.52 <sup>a,c</sup>
H2a	0.42 <sup>a</sup>	0.37 <sup>a</sup>	0.38 <sup>a</sup>	0.41 <sup>a</sup>	0.36 <sup>a</sup>	0.40 <sup>a</sup>	0.36 <sup>a</sup>	0.41 <sup>a</sup>	0.40 <sup>a</sup>
H2b	0.60 <sup>a</sup>	0.50 <sup>a,d</sup>	0.51 <sup>a</sup>	0.60 <sup>a</sup>	0.62 <sup>a,c</sup>	0.53 <sup>a</sup>	0.52 <sup>a</sup>	0.57 <sup>a</sup>	0.57 <sup>a</sup>
H2c	0.44 <sup>a</sup>	0.48 <sup>a</sup>	0.41 <sup>a</sup>	0.47 <sup>a</sup>	0.43 <sup>a</sup>	0.45 <sup>a</sup>	0.39 <sup>a,d</sup>	0.43 <sup>a</sup>	0.60 <sup>a,b</sup>
H3	0.61 <sup>a</sup>	0.62 <sup>a</sup>	0.61 <sup>a</sup>	0.61 <sup>a</sup>	0.59 <sup>a</sup>	0.61 <sup>a</sup>	0.63 <sup>a</sup>	0.63 <sup>a</sup>	0.42 <sup>a,d</sup>
H4	0.43 <sup>a</sup>	0.43 <sup>a</sup>	0.46 <sup>a</sup>	0.41 <sup>a</sup>	0.48 <sup>a</sup>	0.42 <sup>a</sup>	0.48 <sup>a</sup>	0.45 <sup>a</sup>	0.24 <sup>a,d</sup>
H5a	0.68 <sup>a</sup>	0.74 <sup>a</sup>	0.71 <sup>a</sup>	0.70 <sup>a</sup>	0.71 <sup>a</sup>	0.70 <sup>a</sup>	0.67 <sup>a</sup>	0.72 <sup>a</sup>	0.71 <sup>a</sup>
H5b	0.16 <sup>a</sup>	0.19 <sup>a,c</sup>	0.18 <sup>a</sup>	0.16 <sup>a</sup>	0.18 <sup>a</sup>	0.17 <sup>a</sup>	0.20 <sup>a,c</sup>	0.13 <sup>a,d</sup>	0.24 <sup>a,b</sup>
H6a	-0.29 <sup>a</sup>	-0.32 <sup>a</sup>	-0.34 <sup>a,c</sup>	-0.27 <sup>a,d</sup>	-0.22 <sup>a,d</sup>	-0.33 <sup>a</sup>	-0.29 <sup>a</sup>	-0.32 <sup>a</sup>	-0.26 <sup>a,d</sup>
H6b	0.02 (ns <sup>e</sup> )	0.01 <sup>a,d,e</sup>	0 <sup>d,e</sup>	0.03 <sup>b,e</sup>	0.01 <sup>d,e</sup>	0.02 <sup>e</sup>	-0.02 <sup>d,e</sup>	0.04 <sup>b,f</sup>	0.02 <sup>b,e</sup>
H6c	-0.11 <sup>a,c</sup>	-0.07 <sup>a,d</sup>	-0.09 <sup>a</sup>	-0.11 <sup>a,c</sup>	-0.08 <sup>a,d</sup>	-0.10 <sup>a</sup>	-0.10 <sup>a</sup>	-0.10 <sup>a</sup>	-0.08 <sup>a,g</sup>
H7a	0.09 <sup>a,c</sup>	0.05 <sup>d,g</sup>	0.07 <sup>a</sup>	0.08 <sup>a</sup>	0.05 <sup>d,g</sup>	0.09 <sup>a,c</sup>	0.09 <sup>a,c</sup>	0.07 <sup>a,d</sup>	0.07 <sup>f</sup>
H7b	0.10 <sup>a</sup>	0.10 <sup>a</sup>	0.12 <sup>a,c</sup>	0.08 <sup>a,d</sup>	0.09 <sup>a,d</sup>	0.10 <sup>a</sup>	0.10 <sup>a</sup>	0.13 <sup>a,b</sup>	0.01 <sup>d,e</sup>
H8a	0.66 <sup>a</sup>	0.67 <sup>a</sup>	0.63 <sup>a</sup>	0.70 <sup>a</sup>	0.65 <sup>a</sup>	0.68 <sup>a</sup>	0.63 <sup>a</sup>	0.65 <sup>a</sup>	0.78 <sup>a,c</sup>
H8b	0.06 <sup>a,b</sup>	0.02 <sup>d,e</sup>	0.03 <sup>d,e</sup>	0.06 <sup>a,b</sup>	0.05 <sup>f</sup>	0.05 <sup>a</sup>	0.04 <sup>d,f</sup>	0.05 <sup>a,c</sup>	0.04 <sup>d,e</sup>
H9a	0.14 <sup>a</sup>	0.15 <sup>a</sup>	0.18 <sup>a,c</sup>	0.11 <sup>a,d</sup>	0.14 <sup>a</sup>	0.15 <sup>a</sup>	0.18 <sup>a,c</sup>	0.12 <sup>a,d</sup>	0.17 <sup>a,c</sup>
H9b	0.15 <sup>a</sup>	0.18 <sup>a,c</sup>	0.14 <sup>a,d</sup>	0.17 <sup>a</sup>	0.16 <sup>a</sup>	0.17 <sup>a</sup>	0.17 <sup>a</sup>	0.16 <sup>a</sup>	0.08 <sup>d,g</sup>

<sup>a</sup>Significant at  $P < .001$ .

<sup>b</sup>Highly significant increase in the Z value.

<sup>c</sup>Significant increase in the Z value.

<sup>d</sup>Significant decrease in the Z value.

<sup>e</sup>ns: not significant.

<sup>f</sup>Significant at  $P < .05$ .

<sup>g</sup>Significant at  $P < .01$ .

## Results

### Research Model Analysis

Results from the study demonstrated that our research model explains 90.3% of the intention to use the Madeira Safe to Discover app compared to previous research [67,103,104], which explained between 70% and 87% of the variance. Our model has stronger explanatory and predictive power, including new constructs related to the safety and personal impact of COVID-19, hence shaping a more complex network of interrelated causal relationships, which are not present in the original UTAUT and UTAUT2 models. This idea, borrowed from Khalilzadeh et al [67], which extends the UTAUT and UTAUT2 models with the inclusion of other influential constructs, increases the explicability of the model, while keeping parsimony. In line with some authors (eg, [100,105]), we reduced the number of items in some constructs, while

preserving reliability, thus condensing the scale even further than previous research [67]. According to the recommendations of Worthington and Whittaker [67], we were able to retain factors with only 2 items, retaining validity, reliability, and correlation. The inclusion of the COVID-19 impact construct enabled us to understand whether there was a significant but weak impact on trust (H8b), especially when considering the moderation effects. Our results showed that for some groups (men, young people, and participants with some social capital on the premises), the COVID-19 impact on the user's personal context is not significantly correlated to trust in the technology. The same weak link between the influence of trust on effort expectancy was illuminated for the group that had social capital on the premises, according to H7b. On the contrary, the role of COVID-19 safety measures in security (H9a) and behavioral intention (H9b) retained significance regardless of moderator variables. The effect of COVID-19 safety on security (H9a) decreased for old people and varied between groups that retained

different social capital values at the arrival destination. Conversely, the role of COVID-19 safety in the intention to use (H9b) decreased for young people and people with higher social capital. In addition, results showed several significant relationships between the COVID-19 impact and several other constructs, which we did not hypothesize. These relationships showed stronger ties than our initial hypothesis on the COVID-19 impact and trust (Figure 2). Overall, the results demonstrate that the COVID-19 impact could be affected by facilitating conditions and social influence and it could influence privacy risk. Further research could highlight these effects. Interesting also was a negative influence of the COVID-19 impact on privacy, which we did not hypothesize.

Contrary to other empirical studies on mobile payments [67], our results showed a higher role of social influence in security and performance expectancy and a lower impact of privacy risk on performance expectancy and trust. Although for mobile payments, 67% of the variance in the security construct is explained by social influence (H2b) and risk perception (H6a), in our study, the variance explained was lower (52%) but social influence contributed more than privacy (H6a) and safety (H9a). Like Khalilzadeh et al [67], our results confirmed that users have severe concerns about their privacy and system performance. However, the impact of privacy was substantially reduced, which could be related to users' compliance and acceptance of safety measures in general.

In terms of privacy and trust, our results differed significantly from previous studies [67,68]. The negative influence of risk on performance expectancy (H6c) was lower (from  $-0.25$  to  $-0.10$ ), and we could not confirm the hypothesis that privacy negatively impacts trust (H6b). We also observed negative correlations between perceived privacy and other constructs, which we did not hypothesize (COVID-19 impact, facilitating conditions, and social influence). Although some of these effects are reported in other studies on security and privacy [67-69], the COVID-19 impact on privacy should be further researched. In addition, the direct impact of social influence on security (H2b) was significant and robust and much higher than previous empirical research.

In addition to the COVID-19 impact, which is a new construct introduced here, security and privacy had a reduced impact on trust as well. Our results suggested that the impact of COVID-19 potentially affects privacy more than it does trust (1 of the unexpected results). Therefore, working on users' privacy concerns is crucial for other similar COVID-19 systems since privacy influences perceived security and affects users' trust toward these apps. Privacy also emerged as a more interrelated construct influencing performance expectancy and security but also showing significant relationships with the COVID-19 impact, facilitating conditions, and social influence. This clearly indicates that privacy needs to be addressed carefully while designing these apps and that its impact is not mitigated by the COVID-19 impact or the users' willingness to follow safety measures.

Overall, the results indicated that performance expectancy (usefulness) is the biggest predictor of behavior intention to use (H3), which suggests that usability and ease of use are still

crucial in designing COVID-19 systems. Effort expectancy was followed by facilitating conditions, COVID-19 safety measures, and, finally, security. Our results suggest that the willingness to follow COVID-19 safety measures (H9b) is a stronger predictor of usage behavior than security (H5b). This influence of H9a (Table 3) is stronger in young people and varies with different levels of social capital. These results suggest that special care should be taken to personalize apps for these groups when designing apps specific for COVID-19.

Finally, from all the moderator effects analyzed, clearly our indirect measure of social capital was the one showing more differences across the hypotheses. The predictors of the intention to use were significantly stronger for this group than any other group (Table 3), which suggests that designing an app targeting the local context will predict significantly higher adoption. Another relevant trend in the moderation of our hypothesis was the education level of the users, with lower education leading to fewer concerns about privacy (H2b) and security (H6a) but also less importance given to trust on performance (H7a) and effort (H7b) expectancy (also facilitating conditions).

## Discussion

### Principal Findings

The COVID-19 pandemic should be a stimulus to re-examine how we approach existing challenges (eg, social inequalities, sustainable tourism) and study some aspects of human behavior, such as our relationship with technology and its role during emergencies, for instance, in tourist destinations.

Against the backdrop of the COVID-19 pandemic, this paper provided the first detailed research on adopting mobile safety apps designed to mitigate the pandemic's consequences. Although we expect that some of our findings will not be generalized beyond the context of the COVID-19 Madeira Safe to Discover app, others can provide early insight into the increasingly important role of safety, security, privacy, and trust in mobile app adoption and usage.

This research aimed at improving the predictive and explanatory power of technology use and adoption research models in the COVID-19 context. In addition, we investigated the variations in the determinants of COVID-19 systems' acceptance in a reasonably diverse European demographic context.

The results from this work make apparent how privacy is a fundamental aspect when dealing with users' perceptions of COVID-19-related systems. Indeed, privacy influences essential aspects, such as security and performance expectancy. Moreover, privacy concerns still stand, even when the impact of COVID-19 on the personal context of the user increases, showing the importance of privacy even in an emergency context. More generally, the impact of COVID-19 on people positively influences the adoption of safety measures (eg, use of masks, temperature screening, hand hygiene). Moreover, users who are more willing to follow COVID-19 safety measures are also more prone to using the COVID-19 Madeira Safe to Discover app. Several steps can be taken to further improve the usefulness of the app and ensure user trust and security, as was achieved with COVID-19 contact-tracing apps [106,107],

although early receptibility proved to be low in some countries [108]. In Japan, the contact-tracing app COCOA [109] prioritized the protection of users' privacy from a variety of parties, while enhancing the capacity to balance the current load of excessive pressure on health care systems, concluding in simulations that the participation rate in Japan needed to be close 90% to effectively control the spread of COVID-19. The COVID-19 Madeira Safe to Discover app proved to be well accepted by both citizens and visitors by not only recommending safe locations but also providing daily symptom inquiries and keeping that data available for the health authorities in following the design principle of electronic health records [110], being designed by considering the usability engineering [111] of the app and trustworthiness that was conveyed to the users, although this could be further improved by being even more transparent about how the data are processed, anonymized, and transmitted to the health authorities, showing the process in a data pipeline diagram.

Finally, this work's fundamental contribution is an increased understanding of the essential role of privacy, security, and trust in the intention to use safety apps. Although security has a strong, direct and indirect effect on the model's fundamental construct, it emerges to be as equally important as safety concerns. Furthermore, our research shows an increased role of social influence in security, of security in trust, and of trust in performance expectancy compared to previous research that inspired our model. Conversely, we observed a reduced negative impact of privacy on security and a rejection of the hypothesis of the positive role of privacy on trust compared to previous research. Together with a more complex influence of privacy on the overall model, these are significant results for future research implications.

### Limitations

Despite the contributions described previously, this research had some limitations, which also provide useful avenues for additional research discussed in the next section. Here, we reported on 1 of the first empirical studies to examine the technology acceptance of the COVID-19 Madeira Safe to Discover app by applying multidisciplinary constructs to the best of our knowledge. Still, several limitations affected the range of our results. Although we had a significant sample of several European nationalities and cultures, there was still a bias toward a specific nationality. To understand this bias's effect, we analyzed the moderator effects of nationality in our model, which showed the same evidence of invariance measurement compared to other moderators (gender, age, etc). However, we did not record cultural and nationality differences in our sample. Previous work shows a significant impact of cultural diversity on social influence, usefulness, and behavior intention [112,113].

Another significant limitation of our study is that it involved people who traveled during the pandemic period. Given the

mobility restrictions in place, the drastic reductions in travel, and the pandemic's economic consequences, our sample could be biased. The sample accessed in this study could express different perceptions toward the COVID-19 Madeira Safe to Discover app compared to the general public. This potential bias effect limits the generalizability of this research, although the design method reduces the impact of the common method bias (CMB), which we encountered in this research, particularly for the new COVID-19 constructs. In addition, objectively measuring outcome variables separately (eg, frequency of use) will lead to results less likely to produce biases related to the measurement and methods used.

Despite the aforementioned limitations, we believe that this study advances the understanding of the intention to use mobile apps and those associated with safety concerns, such as COVID-19, and will provide a useful set of design guidelines and recommendations for the provision of mobile services with safety, security, and trust concerns to different user groups.

### Conclusion

In this research, recognizing the moderating role of demographics is especially significant. The intention to use the COVID-19 Madeira Safe to Discover app differs among demographic groups. Notably, the impact of social influence varies with gender, age, education, and social capital. We also observed a significant change in the role of the COVID-19 impact over demographics. Finally, high indicators of users' social capital have a tremendous effect on the intention to use COVID-19 safety systems, which suggests that localized versions of these apps are likely to be more successful than general ones.

Anticipating user behavior is notoriously tricky, especially under unprecedented circumstances. An obvious direction for future work would be to apply our measurement model to a longitudinal approach on a more comprehensive technology, such as digital contact tracing. Such a study will sample a more extensive and more culturally diverse user base. This could be accomplished using quota sampling or stratified sampling to guarantee a specific demographic distribution. Longitudinal research could observe changes in the importance of constructs over time. However, a more thorough validation of the generalized application of our research model would imply a widespread data collection process. Nevertheless, this would enable examining the significant effects of safety, privacy, and trust on behavioral intention over time. Future research could also consider supplementing other precursors of behavioral intention. The results of this study could open new avenues for future research. For instance, this research model could be applied to other contexts where safety plays an important role, such as health care, and where privacy is a major concern, such as surveillance and social networking. In addition, understanding how to study the UTAUT model through more parsimonious items can reduce the overload of the questionnaires.

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## Conflicts of Interest

None declared.

### Multimedia Appendix 1

Goodness-of-fit indices.

[[DOCX File , 14 KB - humanfactors\\_v9i3e35434\\_app1.docx](#) ]

### Multimedia Appendix 2

Discriminant validity through the heterotrait-monotrait ratio.

[[DOCX File , 17 KB - humanfactors\\_v9i3e35434\\_app2.docx](#) ]

### Multimedia Appendix 3

Validity measures.

[[DOCX File , 15 KB - humanfactors\\_v9i3e35434\\_app3.docx](#) ]

### Multimedia Appendix 4

Summary of hypothesis tests.

[[DOCX File , 16 KB - humanfactors\\_v9i3e35434\\_app4.docx](#) ]

### Multimedia Appendix 5

Fit indices for invariance checks of moderator effects.

[[DOCX File , 18 KB - humanfactors\\_v9i3e35434\\_app5.docx](#) ]

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## Abbreviations

- AI:** artificial intelligence
- AGFI:** adjusted goodness-of-fit index
- AVE:** average variance extracted
- CFA:** confirmatory factor analysis
- EU:** European Union
- HCI:** human-computer interaction
- HTMT:** heterotrait-monotrait ratio of correlations
- SEM:** structural equation modelling
- SMC:** squared multiple correlation
- SRMR:** standardized root-mean-square residual
- TAM:** models of technology adoption
- TRA:** theory of reasoned action
- UTAUT:** unified theory of acceptance and use of technology

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Viewpoint

# COVID-19's Impact on Digital Health Adoption: The Growing Gap Between a Technological and a Cultural Transformation

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## Abstract

Health care in the 21st century has started undergoing major changes due to the rising number of patients with chronic conditions; increased access to new technologies, medical information, and peer support via the internet; and the ivory tower of medicine breaking down. This marks the beginning of a cultural transformation called digital health. This has also led to a shift in the roles of patients and medical professionals, resulting in a new, equal partnership. When COVID-19 hit, the adoption of digital health technologies skyrocketed. The technological revolution we had been aiming for in health care took place in just months due to the pandemic, but the cultural transition is lagging. This creates a dangerous gap between what is possible technologically through remote care, at-home lab tests, or health sensors and what patients and physicians are actually longing for. If we do it well enough now, we can spare a decade of technological transformations and bring that long-term vision of patients becoming the point of care to the practical reality of today. This is a historic opportunity we might not want to waste.

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## KEYWORDS

COVID-19; digital health; future; cultural transformation; medical information; technology adoption; health care; physician burnout; burnout

## Introduction

Health care in the 21st century has been going through major changes due to the rising number of patients with chronic conditions; increased access to new technologies, medical information, and peer support via the internet; and the disintegration of the ivory tower of medicine [1]. A cultural transformation called digital health has begun [1].

This has also led to a shift in the roles of patients and medical professionals. The role of the passive patient who only turns to physicians after a symptom arises, has been changing into a proactive, empowered role with a desire to be involved in their care. These “empowered patients” (e-patients) are equipped with technologies and information, they are experts in their health or disease management, and they use electronic devices to measure data [2]. Similarly, the role of a burnt-out physician spending half of their time with administrative tasks has been changing into an “empowered physician” (e-physician) role where they are guides for their patients in the jungle of digital

information instead of being the keyholders to the ivory tower of medicine [3].

The new roles have started breaking down the status quo too, that is, the hierarchical relationship between patients and medical professionals. In its place is a new, equal partnership. To put it simply, patients have become the newest members of the medical team [4].

However, the biggest shift in this transformation is about digital health technologies making patients the point of care, receiving diagnosis or treatment wherever they are. Health sensors and portable diagnostic devices measuring fitness activities, sleep quality, electrocardiography, or blood pressure have allowed patients to become further involved in their care by providing them with data that were previously only accessible within the ivory tower [5].

It seems that technologies are becoming available at an unprecedented rate and that the cultural transformation is the component that will take time. Learning to deal with equal partnership takes more time than learning to use a sensor or

smartwatch. Regardless, if the technological and cultural transformations can take place almost simultaneously, there is a big chance that the core elements of care such as empathy, compassion, and relationships based on trust will remain intact.

## ***COVID-19's Impact on Digital Health***

When COVID-19 hit, the adoption of digital health technologies skyrocketed. It was a necessity, not a choice. Still, telemedical applications and services, health sensors, 3D printed protective equipment, and at-home laboratory tests have become part of everyday care in just weeks in March and April 2020.

In Catalonia, Spain, telemedicine took the place of face-to-face primary care visits in less than a month. While around 18,000 telemedical and 150,000 face-to-face visits were conducted in early March 2020, the number of telemedical visits rose to over 100,000 and the number of face-to-face visits decreased to 21,000 just 4 weeks later [6]. In the United States, appointments on telemedicine services such as PlushCare and Amwell increased by 70% and 158%, respectively.

After remote care, remote testing was the next major disruptor. Waiting in lines to take a biological sample meant a risk of exposure to infection. Wherever it was possible, at-home lab tests were prioritized. COVID-19 antigen and antibody tests appeared on the market in addition to companies offering direct-to-consumer blood test sampling and analysis. The sample collection for many tests from food allergy to genetic analyses started taking place in patients' homes.

The pandemic has had a lasting toll on mental health. The meditation smartphone app Headspace has seen a greater than 500% increase in inbound interest from companies seeking mental health help for their employees [7]. The number of users starting its "stressed meditation" offering increased by 6 folds.

Disinfectant robots started roaming hospital floors, reducing people's risk of infection. Do-it-yourself groups around the world started producing 3D printed materials such as medical tools, protective equipment, and practically anything else needed when traditional production or supply was scarce and health institutions were overwhelmed.

Artificial intelligence (AI) has taken the central stage too [8]. The first report about a potential outbreak in Wuhan, China, came from a Canadian start-up called BlueDot. It used a machine learning algorithm to sift through news reports, airline ticketing data, and reports of animal disease outbreaks to detect public health trends and dangers. AI has also been used to organize supply chains; sort out ventilators in a country; find new drug combinations that could treat sick patients through network science; analyze, monitor, screen, and triage patients with COVID-19 to support hospitals with resource allocation; or facilitate drug discovery and vaccine development. Researchers at the Massachusetts Institute of Technology even developed an AI-based voice analyzer to identify asymptomatic patients with COVID-19 from cough recordings on their smartphones.

Even before the pandemic, digital health investments were steadily increasing year by year; however, 2020 was a record-breaking year. Venture funding for the sector shot up

66% over 2019, with a record \$14.8 billion raised globally, according to Mercom Capital Group [9]. Telemedicine, of course, was the leading investment target, receiving \$4.3 billion in venture capital funding in 2020 [9].

Needless to say, digital health has seen an unprecedented rate of adoption. However, clinical reality does not reflect this optimism. Health care is overwhelmed worldwide, physicians rapidly burn out under immense pressure, patients with chronic conditions lack access to care, treatments get delayed, and medical professionals do their best to maintain the system. There are not many resources left to innovate.

## ***The Lagging Cultural Transformation***

Many examples have shown that the use of technologies does not automatically lead to better care [10]. Family members have to use a telemedical robot equipped with a tablet device to communicate with their loved ones in the hospital. Even some end-of-life discussions had to take place through telemedical robots [11]. Without proper guidance, such use of an advanced technology can lead to mental health issues for families later on.

Recent papers (eg, Ritchey et al [12]) concluded that although technology does not replace face-to-face encounters, it can offer meaningful connection; such an experience requires redefining the traditional palliative care model. Caregivers and family members have to learn to live with the constant fear that technology might fail and have to give themselves permission to make mistakes while they learn a new care model [12].

Another challenge that was amplified due to the rise of technologies and access to information was the fight against misinformation about COVID-19 and vaccination. Antivaccination groups make it harder to vaccinate enough people to leave the pandemic behind [13]. It has also indicated how important a trustful and strong medical and scientific leadership is.

## ***Discussion***

The technological revolution we had been aiming for in health care took place in just months due to the pandemic, but the cultural transition is lagging. This creates a dangerous gap between what is possible technologically through remote care, at-home lab tests, or health sensors and what patients and physicians are really longing for. Based on our previous studies [2,3], it is empathy, attention, and time, not AI or more health sensors.

The idealistic vision of digital health is to allow patients to have meaningful conversations with medical professionals while being surrounded and supported by advanced, seamless, and almost invisible technologies.

It usually takes a few months to adopt a new habit. We will have been living with masks, social distancing, and remote care for so long by the time the pandemic ends that we might never go back to the old "norm" [14]. Additionally, once most patients realize they have a choice between getting the required information virtually in minutes or in person by traveling and

waiting for hours, all the while increasing their risk of exposure to infections, they might never want to go back.

This new kind of e-patient and e-physician, who are reimbursed for virtual visits, could stay with us indefinitely [15]. Therefore, we, patients and health care professionals alike, have to find a way to live up to this new norm emotionally, mentally, and culturally.

Certain efforts have been demonstrated to help ease this process: health information campaigns launched by governments [16],

medical associations providing guidance on using digital health technologies [17], medical curriculums designed to prepare students for working with e-patients [18], and policies that support remote care services and consider them the new norm [19].

If we do it well enough now, we can spare a decade of technological transformations and bring that long-term vision of patients becoming the point of care to the practical reality of today. This is a historic opportunity we might not want to waste.

## Conflicts of Interest

None declared.

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## Abbreviations

**AI:** artificial intelligence

**e-patient:** empowered patient

**e-physician:** empowered physician

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Original Paper

# Barriers to and Facilitators of the Use of Digital Tools in Primary Care to Deliver Physical Activity Advice: Semistructured Interviews and Thematic Analysis

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## Abstract

**Background:** Physical inactivity is a leading risk factor for many health conditions, including cardiovascular disease, diabetes, and cancer; therefore, increasing physical activity (PA) is a public health priority. Health care professionals (HCPs) in primary care are pivotal in addressing physical inactivity; however, few HCPs provide PA advice to patients. There can be obstacles to delivering PA advice, including lack of time, confidence, or knowledge. Digital technology has the potential to overcome obstacles and facilitate delivering PA advice. However, it is unknown if and how digital tools are used to deliver PA advice in primary care consultations and what factors influence their use.

**Objective:** We aimed to understand the use of digital tools to support primary care consultations and to identify the barriers to and facilitators of using these systems.

**Methods:** Overall, 25 semistructured interviews were conducted with primary care HCPs. Professionals were sampled based on profession (general practitioners, practice nurses, and health care assistants), prevalence of long-term conditions within their practice area, and rural-urban classification. The data were analyzed thematically to identify the influences on the use of digital tools. Themes were categorized using the COM-B (capability, opportunity, and motivation—behavior) model and the Theoretical Domains Framework to identify the barriers to and facilitators of using digital tools to support the delivery of PA advice in primary care consultations.

**Results:** The identified themes fell within 8 domains of the Theoretical Domains Framework. The most prominent influence (barrier or facilitator) within psychological capability was *having the skills to use digital tools*. *Training in the use of digital tools* was also mentioned several times. The most notable influences within physical opportunity were *limited digital tools to prompt/support the provision of PA advice*, *time constraints*, *efficiency of digital tools*, *simplicity and ease of use of digital tools*, and *integration with existing systems*. Other physical opportunity influences included *lack of access to digital tools* and *technical support in the use of digital tools*. Within social opportunity, a notable barrier was that *digital tools reduce interpersonal communication with patients*. *Patient preference* was also identified. Several important influences were within reflective motivation, including *confidence to use digital tools*, *beliefs about the usefulness of digital tools*, *the belief that digital tools “are the way forward,”* *beliefs related to data privacy and security concerns*, and *perceptions about patient capabilities*. About automatic motivation, influences included *familiarity and availability* regarding digital tools and the fact that digital tools *prompt behavior*.

**Conclusions:** A variety of influences were identified on the use of digital tools to support primary care consultations. These findings provide a foundation for designing a digital tool addressing barriers and leverages the facilitators to support PA advice provision within primary care to elicit patient behavior change and increase PA.



**KEYWORDS**

physical activity; capability, opportunity, and motivation—behavior; COM-B; Theoretical Domains Framework; TDF; primary care professionals; health care professionals; physical activity advice

## Introduction

### Background

Physical inactivity is a leading cause of death and noncommunicable disease worldwide [1]. Being physically active can reduce the risk of all-cause mortality and help prevent and manage a wide range of long-term conditions, including cardiovascular disease (CVD), some cancers, and neurodegenerative diseases [2,3]. Moving from a state of inactivity to meeting the UK government physical activity (PA) recommendations of 150 minutes per week of moderate to vigorous PA can reduce the risk of CVD incidence by 17%, CVD mortality by 23%, and type 2 diabetes incidence by 26%, even after adjusting for body weight [4]. Furthermore, PA has positive impacts on mental health and well-being [2,3].

Therefore, identifying effective methods to increase PA in the population is of great importance. One approach is to provide PA advice to patients in primary care. As a trusted source of health-related information that frequently interacts with large proportions of the population, health care professionals (HCPs) within primary care have pivotal roles in encouraging greater PA [5,6]. As many as 1 in 4 people say they would be more active if they were advised by a general practitioner (GP) or a nurse.

Delivering brief PA advice in primary care has been shown to be cost-effective [7,8], with positive impacts on PA and health outcomes [9,10]. As such, the National Institute for Health and Care Excellence recommends that brief PA advice be provided in primary care [11]. However, delivery of brief PA advice in primary care is not routine and remains to be fully established. Only one-third of all patients report receiving such advice [5,12]. Despite knowledge among HCPs that increasing PA is beneficial for their patients [13], a number of reviews and studies have identified key obstacles that limit the delivery of PA advice in primary care. Important obstacles include a lack of knowledge (of national PA guidelines, of how to deliver advice, of what advice to give, and of how to communicate effectively) [6,9,13-15], a lack of tools or resources [6], an inability to follow-up on patients [6,13], the perceived readiness and motivation of the patient to change [6,16], and lack of confidence and time constraints [6,13,17].

Establishing the routine delivery of PA advice in primary care requires overcoming such obstacles. A promising avenue is the use of digital tools, which may provide opportunities to facilitate the delivery of PA advice in primary care. These can include electronic tools that are integrated within clinical information technology systems in primary care or stand-alone technology that can help facilitate and signpost patients to various resources. The World Health Organization has highlighted the importance of using innovative digital technologies to promote PA and

reduce sedentary behavior in its Global Action Plan on Physical Activity [18].

Digital tools have previously been used to deliver PA advice in primary care [19-21] either by supporting [22] or replacing [23] face-to-face delivery of PA advice. Digital tools appear to have potential utility in increasing PA by supporting the delivery of PA advice [19,24,25]. However, primary care HCPs have mixed views on the usability of digital tools, with barriers to their use including technical issues and complexity, disruption to service workflow, and increasing workload [19,26-28].

### Objective

To determine the value of digital tools to support the delivery of PA advice and how to optimize their development and integration, it is important to fully understand the existing challenges of delivering PA advice, the influence on using digital tools, the required characteristics of digital tools, and the opportunities to incorporate digital tools into existing practice. However, there is a paucity of evidence surrounding the obstacles facing the use of digital tools to deliver PA advice. Studies rarely use a behavioral framework to systematically identify barriers and facilitators or instead focus on patient perspectives [19]. Studies have considered only specific digital tools, such as eHealth or mobile health (mHealth) interventions, and not all potential digital tools.

Systematic approaches to investigating the factors that influence health-related behaviors and professional practices can be facilitated using behavioral science tools. The capability, opportunity, and motivation—behavior (COM-B) system is a model of behavior change that helps to understand the influences on performance of a behavior [29]. A related model is the Theoretical Domains Framework (TDF), which can be mapped onto COM-B to further categorize influences into the facilitators that increase, and the barriers that hinder, the behavior [30]. COM-B and TDF have been widely used in previous studies to synthesize findings on barriers and facilitators for a range of behaviors, including a review of physician-reported barriers to using evidence-based recommendations for low back pain [31], a review of the factors influencing the implementation of screening and brief interventions for alcohol in primary care [32], and specifically for promoting PA by HCPs [16]. In this study, we used COM-B and TDF to systematically map the barriers to and facilitators of using digital tools to deliver PA advice in primary care.

We aimed to understand the use of digital tools to support primary care consultations and to identify the barriers to and facilitators of using these systems to deliver PA advice.

The specific objectives were (1) to gain insights into the use of digital tools within primary care settings to understand the influences on their use to deliver PA advice and (2) to systematically map the influences of using COM-B and TDF

to understand the barriers to and facilitators of using digital tools within primary care to deliver PA advice.

## Methods

### Study Design

This was an exploratory qualitative study drawing on interviews with HCPs in primary care.

### Sample

A sample of HCPs was recruited purposively (by a third-party recruiter) based on profession (GPs, practice nurses, and health care assistants [HCAs]), prevalence of long-term conditions within the area (in particular, obesity, depression, hypertension, coronary heart disease, and diabetes), and rural-urban classification. During recruitment, HCPs were also screened to ensure a range of experience levels (based on the length of time working in primary care, self-reported levels of delivering PA advice, and self-reported digital skills). Data collection ceased once saturation of themes was reached, resulting in a total of 25 interviews being completed, transcribed, and coded.

### Inclusion Criteria

To be included, study participants had to be a GP, nurse, or HCA; must have worked in general practice; must have worked in the United Kingdom health care system for a minimum of 1 year; must be an English speaker; and must be aged  $18 \geq$  years.

### Data Collection

Semistructured interviews lasting 60 to 90 minutes were conducted via telephone in March and April 2020. This time frame coincided with the introduction of the first COVID-19 pandemic protocols in the United Kingdom, including the national lockdown on March 23, 2020. Hence, all study interviews were conducted via telephone. In line with ethical guidelines, written informed consent was obtained from the participants before commencing the interview. A topic guide based on COM-B [33] was used by the interviewers to support discussions.

During interviews, HCPs were asked a series of open-ended questions about their routines and working days; the systems and resources they use routinely to identify patients and to deliver and record advice; their capability, opportunity, and motivation to use these systems and resources effectively; any barriers to using these tools and resources; and suggested solutions and improvements to overcome them.

The topic guide included various prompts and follow-up questions to help elicit data relevant to the research question.

### Data Management and Analysis

The interviews with the 25 HCPs were recorded on password-protected and encrypted machines to ensure data privacy and security. The recordings were uploaded to the encrypted, password protected Citrix platform to be transcribed verbatim by a third-party provider, and the original recordings were then deleted from the study team's systems. The third-party provider removed any identifying information during the

transcription and returned anonymized transcripts to the study team for data analysis.

The anonymized transcripts were imported into Microsoft Excel for analysis. Participant responses were broken down into constituent parts to analyze distinct thoughts and ideas independently. Content analysis, informed by the COM-B model, was used to analyze the data. One researcher (VM) read each of the 25 transcripts, extracted data relevant to the use of digital tools, and inputted the data into an Excel spreadsheet. In this study, we defined a "digital tool" as any use of information and communications technology to support HCPs in primary care to deliver PA advice. This definition was adopted from the World Health Organization's definition of digital health [34].

In total, 165 comments from the participants relating to the use of digital tools were recorded. Another member of the research team inductively coded the data line by line using constant comparison techniques within and between codes to ensure that they accurately reflected the material. Codes were then examined for similarities and grouped inductively into themes regarding barriers to and facilitators of using digital tools to identify patients and to deliver and record PA advice. The themes that emerged from this process, that is, the ones that were identified as being important, were either articulated by multiple respondents (high frequency) or were articulated particularly clearly and forcefully (elaboration) or both. Once the data were coded as a barrier, facilitator, or both; they were deductively classified under the COM-B model [29] and TDF [35] to systematically understand these behaviors and needs. When multiple COM-B components and themes could be used to code data, further data segmentation was considered if it was deemed that the existing data segment contained discrete thoughts. Further data segmentation was reported during coding by putting a forward slash (/) between the COM-B components and the themes.

Classifying data into COM-B components followed expert guidelines [33]. One researcher (AG) was tasked with classifying all the extracts, and a second researcher (SSJ) coded 20% of the extracts to highlight and resolve any discrepancies in the coding. A random number generator was used to provide a random sequence of Excel cell numbers containing data segments that would be coded by SSJ. After independently completing one round of coding, AG and SSJ met via video calls to discuss codes. Any disagreements over codes were discussed until consensus was reached, and the data set was updated accordingly. Similarly, the decision to split the data segments was discussed between researchers until an agreement was reached.

### Ethics Approval

Ethical approval for this study was provided by the Public Health England Research Ethics and Governance Group (#NR0181). Participants provided written informed consent before taking part.

## Results

### Participant Summary

Participant characteristics are presented in [Table 1](#). Participants tended to be practice nurses or HCAs, older, and working in an urban setting, with a range of primary care experience.

The barriers to and facilitators of using digital tools to deliver PA advice in primary care are presented in [Table 2](#). Additional participant responses are presented in [Multimedia Appendix 1](#). Important themes were identified within psychological capability, physical and social opportunities, and reflective and automatic motivation.

**Table 1.** Summary characteristics of participants recruited for interviews (n=25; 23 respondents for age and 24 respondents for location).

Characteristic	Participants
<b>Profession, n (%)</b>	
General practitioner	6 (24)
Practice nurse	10 (40)
Health care assistant	9 (36)
<b>Age (years; n=23, 92%), n (%)</b>	
18-30	3 (13)
31-50	7 (30)
50+	13 (57)
<b>Primary care experience, n (%)</b>	
1-10 years	7 (28)
11-20 years	9 (36)
20+ years	9 (36)
<b>Location (n=24, 96%), n (%)</b>	
Rural	7 (29)
Suburban	1 (4)
Urban	16 (67)

**Table 2.** Important themes identified by participants during interviews on the barriers to and facilitators of using digital tools to deliver physical activity advice in primary care.

COM-B <sup>a</sup> and Theoretical Domains Framework	Themes
<b>Capability</b>	
<b>Psychological</b>	
Knowledge skills	<ul style="list-style-type: none"> <li>• Having the skills to use digital tools</li> <li>• Training in the use of digital tools</li> </ul>
<b>Physical capability</b>	
Physical skills	<ul style="list-style-type: none"> <li>• Not reported as an influence</li> </ul>
<b>Opportunity</b>	
<b>Physical</b>	
Environmental context and resources	<ul style="list-style-type: none"> <li>• Availability</li> <li>• Efficiency of digital tools</li> <li>• Integration with existing systems</li> <li>• Lack of access to digital tools</li> <li>• Limited digital tools to prompt or support the provision of physical activity advice</li> <li>• Simplicity and ease of use</li> <li>• Technical support in the use of digital tools</li> <li>• Time constraints</li> </ul>
<b>Social</b>	
Social influences	<ul style="list-style-type: none"> <li>• Digital tools reduce interpersonal communication</li> <li>• Patient preferences</li> </ul>
<b>Motivation</b>	
<b>Reflective</b>	
Beliefs about capabilities	<ul style="list-style-type: none"> <li>• Confidence to use digital tools</li> <li>• Perceptions about patient capabilities</li> </ul>
Beliefs about consequences	<ul style="list-style-type: none"> <li>• Beliefs about the usefulness of digital tools</li> <li>• Beliefs related to data privacy and security</li> <li>• Belief that digital tools are “the way forward”</li> </ul>
<b>Automatic</b>	
Reinforcement emotions	<ul style="list-style-type: none"> <li>• Familiarity</li> <li>• Prompt behavior</li> </ul>

<sup>a</sup>COM-B: capability, opportunity, and motivation—behavior [29,35].

### Psychological Capability

*Having the skills to use digital tools* was reported by numerous respondents as an important factor influencing the use of digital tools in primary care to deliver PA advice, being described as both a barrier and a facilitator. Although some respondents reported feeling confident in their digital skills and ability to use digital tools, a number of HCPs discussed how not having the skills and/or confidence to use digital tools may act as a barrier to their use. Although providing appropriate training may facilitate the use of digital tools within primary care, HCPs overwhelmingly discussed the lack of adequate training to provide them with the skills and confidence to use digital tools (barriers). Hence, *training in the use of digital tools* was identified as another notable theme. Because of the lack of formal training, some staff members discussed having to rely on other members of staff within the practice with more

experience using digital tools to teach them how to use the systems. Therefore, HCPs may benefit from some form of training on how to use digital tools:

*I'm pretty good but EMIS is one of those things that there is always something more to learn really. You can learn the basics in quite a short period of time but I am still finding things that I think, God, if I'd have known that a few years ago, that would have saved me an awful lot of time. [Nurse, 31-50 years]*

*There is no formal training by and large, other than you may get sent a document of how to do something. So we have relied upon one of our staff members who, for want of a better word, is like an IT manager who will take overall charge of these things and oversee their introduction and development, and disseminate that information as a practice and ensure that we're all up to speed. So you need to have one person who*

*has that as their responsibility and role within the practice.* [General practitioner, ≥50 years]

### Physical Opportunity

Physical opportunity was the most frequently coded COM-B component (Table 1). A substantial barrier to the use of digital tools in the provision of PA advice in primary care was the lack of digital options to prompt or support the delivery of PA advice; this was coded under the theme *limited digital tools to prompt/support the provision of PA advice*. Some interviewees cited existing templates that initiate discussion of PA, whereas several others said that they were not aware of any digital tools that prompt or support the provision of PA advice. Specifically, diabetes-related templates and National Health Service Health Check templates prompt PA questions or advice (and may lead patients to a program that increases their PA):

*I think it'd be quite useful really because with EMIS you can see people's BMI and results and things like that, so it would be quite useful to have a prompt in the corner to say "encourage physical activity" or blah blah blah. It's something that would be nice to have.* [Nurse, ≥50 years]

*It's not on the diabetic template to ask about physical activity but it is on the NHS [Health Check] to check their physical activity.* [Nurse, ≥50 years]

*We use templates [in our consultations]... If there is a patient with pre-diabetes, we... ask them: "would you like to go for the diabetes prevention programme?"... There's no other template for us to use... On the system for the diabetes... we need to tell them... [to do] exercise—either walking or... going to the gym or any sort of exercise at home.* [Nurse, ≥50 years]

Another important barrier is *time constraints*. It was clear that HCPs often experienced time pressures and did not always have time to consider other ways of working (ie, they will often default to what they are used to). On the flip side, there was a feeling that digital tools could save time by increasing efficiency; hence, the theme of *efficiency of digital tools*. Digital tools have been reported to make more efficient use of the limited time available for consultations, allowing data to be more easily captured and stored in comparison with manual data recording (facilitators):

*When you're so busy and flat out, you don't have sometimes that time to just sit back and reflect and think, well, is there another way I could be doing this more efficiently?* [General practitioner, ≥50 years]

*You have your clinics. You have your QOFs to do. You want to follow the NICE guidelines on every patient with a long-term condition. We have all of those responsibilities as well as the urgent on the day requests. Jiggling time is always a factor.* [Nurse, ≥50 years]

Relating to the themes of *efficiency of digital tools* and *time constraints*, was the theme of *simplicity and ease of use*, which may act as either a barrier or facilitator, depending on the design and subsequent functionality of the digital tool. For example,

templates need to be as simple as possible, quick to use, and easy to navigate and must also facilitate the collection of all mandated or important data. Another way in which digital tools can be made easier to use is if they allow for *integration with existing systems*. This was also highlighted by the respondents as both a barrier and facilitator. This was categorized as a separate theme, as it was deemed to be a specific requirement. Another physical opportunity barrier to the use of digital tools is the *lack of access to digital tools* in some areas. Another physical opportunity consideration was the presence of *technical support in the use of digital tools*. Respondents reported that having technical support to hand facilitated the use of digital tools:

*It's much easier. Much easier than sitting there writing things out. You can click. It gives you more time to do other things. It gives you more time with the patient. You're not spending lots of time writing things out. You are more for the patient than you are writing things down.* [HCA, 31-50]

*I think sometimes in general practice the issue is we don't have much time... So I think any way in which we can reduce the number of clicks, to put it simply, the better, and if this system was generated automatically, it flags it up, then that would be better than having to deal with all those issues and then think about doing something else on top as well. I think the easier to use, the quicker to use, the less steps involved the better really.* [General practitioner, 31-50 years]

*It would have to be something that would be compatible with the system that we're using, and unfortunately I'm trying to get an ECG machine to be compatible with EMIS. So it's all about compatibility and whether one talks to the other.* [HCA, ≥50 years]

The final physical opportunity factor was *availability*, which has been mentioned several times. One respondent, for example, said that they used specific digital tools because it was what was available to them and was what they had always used:

*I suppose it's what we've always used, we've never been told there's anything else that can be used.* [Nurse, 18-30 years]

### Social Opportunity

Barriers and facilitators related to social opportunities were less frequently discussed by the HCPs. However, there was an indication that some HCPs felt that *digital tools reduce interpersonal communications* with patients (a barrier). One respondent also stated that their propensity to use digital tools may be influenced by *patient preferences* (barriers or facilitators):

*Part of me doesn't mind but other times I think, Oh gosh I feel I'm looking at a computer screen rather than looking at a patient. I wasn't trained to do that; I'm very old school as well because I trained back in the eighties so I don't mind using it, I appreciate we have to move on with the times, but I don't like it too*

*much because I find that I'm watching the screen and making sure I've got everything that I need to fill on there without actually looking at the patient and just talking to them properly.* [Nurse, ≥50 years]

### Reflective Motivation

One of the clearest themes under reflective motivation to emerge from the data was that of *confidence to use digital tools*. All respondents who mentioned confidence discussed it as a facilitator, expressing that they had the confidence required to use such systems. However, it is implicit in the notion of confidence that one could just as easily have it as not have it; a lack of confidence would, of course, be a barrier to the use of digital tools. It should be highlighted that *confidence to use digital tools* often goes hand in hand with *having the digital skills to use digital tools*, as having the skills to do something tends to breed confidence, while not being confident may indicate a skill deficit. Despite this overlap, skills and confidence are different influences and are coded differently within COM-B, which explains why some quotes in [Multimedia Appendix 1](#) could seemingly fit into either:

*I mean I'm of the generation which is fairly IT savvy, so I feel quite confident.* [General practitioner, 31-50 years]

Another theme that could be both a barrier and a facilitator for the use of digital tools was *beliefs about the usefulness of digital tools*. If someone believes that a system has utility, they will be more inclined to use it (facilitator), whereas if they believe the system is not useful or is indeed a hindrance, they may be disinclined to use it (barrier). Most respondents who mentioned the usefulness of digital tools within their practice felt that such systems *were* useful, but this was not unanimous. A common belief discussed by HCPs with positive views toward the usefulness of digital tools is that these systems save time and increase efficiency by, among other things, facilitating the sharing of data with secondary health care providers. It was also mentioned that digital tools present unique opportunities to provide varied care to patients digitally when there is limited opportunity to provide physical care to patients face to face. However, others said that templates do not provide useful options and may be too time consuming to use during consultations and that patients might also benefit from having a physical copy of advice:

*We can even do things like video consultations now which I think we've had to embrace because of the current situation with COVID. I think it will change the way we practise ongoing because we can see the efficiencies of these. I think the model of general practice personally is going to change hugely after this because we can see we can do things safely and differently and more efficiently.* [General practitioner, ≥50 years]

*I don't find the template is particularly useful... I don't think it's very useful in the information that it's asking for. Then the options it gives you, do you want to refer them to the health trainer? Nearly everybody will say no to that because it's too involved. It's too time consuming.* [HCA, ≥50 years]

A related theme to *beliefs about the usefulness of digital tools* was the *belief that digital tools "are the way forward."* Sometimes, this theme overlapped with *beliefs about the usefulness of digital tools*; respondents said that digital tools were the way forward and then went on to support this with reasons based on usefulness, but sometimes it appeared to be offered as a reason in its own right. The *belief that digital tools "are the way forward"* was a facilitator of the use of digital tools:

*The opportunities are there aren't they, we're moving forward and everything's IT and it's the way forward, for patients as well, apps and doing everything online and using phones.* [Nurse, ≥50 years]

*Beliefs related to data privacy and security was another theme under reflective motivation that emerged from the data. This theme was both a barrier to and a facilitator of the use of digital tools, depending on the particular beliefs of each respondent. Some felt that digital tools improved security around patient data by reducing mistakes, whereas others said that the safety features required to ensure patient safety within digital tools could act as a barrier to their use:*

*They're just safer, and they protect patient confidentiality, and they're safer to use, things we can audit, trails, process it all, and obviously check if anything goes wrong, if there was a fax it may reject or get sent somewhere else if the number was wrong.* [HCA, 18-30 years]

The final theme under reflective motivation was HCPs' *perceptions about patient capabilities*, and again, this was both a barrier and facilitator. Several respondents suggested that their inclination to use digital tools during a consultation would depend on the technical capabilities of the patient in question:

*My dad, he needs everything explained manually and wouldn't go near a computer; for him, I'd need to spend more time with him, to discuss a questionnaire I'd need to print it out and go through it with him, even phones.* [Nurse, ≥50 years]

### Automatic Motivation

A common facilitator of the use of digital tools in primary care within automatic motivation was that digital tools, specifically templates, *prompt behavior*. For instance, templates were described as useful as they provided guidelines and tick boxes to prompt HCPs to ask relevant questions and ensure that nothing was missed during consultations. Another theme under automatic motivation, which was mentioned by a few respondents, was *familiarity*. For example, one respondent highlighted that newly introduced digital tools can be a bit daunting, but that this feeling subsides over time as they become familiar:

*They're optional, yes... I choose to use them, yes... It's easier and I feel like it's more thorough, and when it's a busy day especially, it's nice to just have that as a prompt.* [HCA, 18-30 years]

*I mean, sometimes when you first learn them, it is a bit daunting. You think, "oh," and you're looking through them, but once you've done it a few times, you get a rhythm... As I said, if you go through every box, you can't go wrong. [HCA, 31-50 years]*

## Discussion

### Principal Findings

This study aimed to investigate the use of digital tools to deliver PA advice. However, we found that digital tools for delivering PA advice were limited. Some templates include PA prompts, but no template focuses specifically on facilitating PA advice. Hence, we considered the use of digital tools in primary care; with the identification of themes based on high frequency, elaboration, or both. This study has implications for the development of digital interventions to facilitate the delivery of PA advice in primary care.

Barriers and facilitators to using digital tools to deliver PA advice identified in this study included *skills and training to use digital tools; efficiency of digital tools, including their integration with existing systems and simplicity and ease of use; patient preferences; confidence to use digital tools; beliefs about the usefulness of digital tools; perceptions about patient capabilities; and beliefs relating to data privacy and security. Limited digital tools to prompt/support the provision of PA advice, time constraints, and the fact that digital tools reduce interpersonal communication* were barriers; and the use of digital tools to *prompt behavior, the belief that digital tools are "the way forward," and having technical support in the use of digital tools* were facilitators.

This qualitative study expands on previous findings on the barriers and facilitators to delivering PA advice in primary care [6,16], using a behavioral framework to systematically identify the barriers to and facilitators of using digital tools to deliver PA advice in primary care. The findings from this study indicate that important influences related to knowledge, time, and confidence in delivering PA advice are also important for using digital tools. However, other themes, including the efficiency and integration of digital tools and data privacy and security concerns are important influences, specifically for using digital tools in this context. As for delivering PA advice, there was variability across HCPs as to whether themes were barriers, facilitators, or both to using digital tools.

The mixed views regarding the usability and utility of digital tools emerging from this study build on previous findings for eHealth interventions to deliver PA advice. Similarly, some HCPs find eHealth interventions useful and easy to use, but others perceive eHealth interventions to be time consuming or ineffective, with technical issues, inexperienced staff, and the complexity of programs as barriers to their use [6,19,20,28].

As with delivering PA advice [6,36], time was a barrier to using digital tools, which is closely related to their efficiency and ease of use. Cumbersome digital tools that are poorly integrated slow down work and disrupt workflow, creating a barrier to their use to support the delivery of PA advice [26,37,38]. A digital tool needs to be simple, easy, and time efficient to fit within short

consultations [37,38] but also versatile, given that time constraints are likely to vary depending on consultation length, which may differ between countries. In agreement with the results of this study, integrating an eHealth tool into existing medical programs and workflows is important to facilitate its use [37-39]. The ability of a digital tool to facilitate (or hinder) the delivery of PA advice depends on how simple, effective, and well integrated the system is.

Many participants agreed that digitization was the way forward, providing an efficient, simple, and easy-to-use solution. However, interviews were conducted during the COVID-19 pandemic, when face-to-face consultations were canceled. Before the COVID-19 pandemic, the use of digital tools instead of face-to-face PA advice was previously identified as a barrier in terms of interpersonal communication, with HCPs preferring face-to-face communication [26]. In this study, some participants highlighted that video consultations facilitated giving PA advice to those who were unable to attend in person. In contrast, participants indicated that in-person digital tools could be a barrier if the system excessively detracted from interacting with the patient. Digital tools can facilitate PA advice when they improve communication, which could be achieved by providing templates with recommendations and set phrases or prompts. Digital tools can be used to generate personalized recommendations in an appropriate language to facilitate the delivery of PA advice [37,40], which can be time efficient by using tools before the consultation [37,38,41-43]. mHealth tools can perform important tasks, such as diagnosis, helping to reduce the workload [20]. For example, digital tablets in the waiting room can save time by automating the collection of routine data and performing health screening [39], which is flexible enough to accommodate discussions across varying durations of consultations [19] and support discussions with patients with limited health literacy [44].

### Commentary on the Findings

Previous studies have shown that knowledge, training, or access to educational resources are common barriers and facilitators to delivering PA advice [6,9,45]. This study builds on these findings by indicating that knowledge and training are also barriers and facilitators to using the digital tool itself. The participants pointed out a current lack of technical support for the use of digital tools. There can be educational barriers and technical difficulties in using digital tools such as tablets or apps [38]. Delivering PA advice increases the workload of HCPs [16], and digital tools have the potential to facilitate the delivery of PA advice through improvements in efficiency and ease of use. However, the benefit of a digital tool in reducing workload is likely dependent on the quality of training provided to use digital tools and the resources within it. Digital eLearning systems are already used to provide PA education [46] and training to increase knowledge, confidence, and skills to deliver PA advice, such as the Moving Healthcare Professionals Programme [21]. A systematic review indicated that mobile tools may facilitate PA promotion by addressing knowledge and resource barriers [16] and providing a centralized, integrated tool for easy access to PA resources [47]. However, these systems do not provide training for digital tools. Provision of

education and training in digital tools should also be considered if they are being used to support the delivery of PA advice.

Previous studies have identified patient-related factors as an important theme affecting the motivation of HCPs to give PA advice, with patient abilities to use digital tools, preferences, and readiness to change as barriers and facilitators [37]. In this study, patient motivation to change was not an important theme in using digital tools, but HCPs' perceptions of patient motivation to use a digital tool were a barrier to or facilitator of their use, depending on whether patients preferred physical prints or had the technical capability to use a digital tool. The lack of print materials has also been cited as a barrier to delivering brief PA interventions [36,48]. Importantly, HCPs use their subjective perception of patient capability and motivation to change to determine whether to deliver PA advice [6]. Discussions could be facilitated using digital tools before consultation to assess patient readiness and suitability using a standardized approach [16].

In this study, computer-based interventions were previously proposed to facilitate the delivery of advice by acting as a prompt [39]. The lack of a consistent contextual cue has been a barrier to discussing PA in different contexts [49], whereby structured protocols or templates facilitate the delivery of brief PA advice [36]. Digital tools need to be well integrated, fit in with, and aid the current workflow to be effective prompts [26,40,49]. These are also important themes in this study. PA advice also needs to be delivered in the right context to increase patient receptivity [6]. The ability to adjust the template to suit the consultation and provide a contextual prompt also facilitated the use of a digital tool in this study. Therefore, the use of a digital tool as a prompt requires physical opportunity barriers to be addressed.

In this study, the ability to track and share patient data was considered to be a facilitator to using digital tools. Indeed, the inability to monitor follow-up is a barrier to delivering brief PA advice [6], which could be overcome by using a digital tool to provide a platform to track and monitor patient PA over time at follow-up [37].

One theme in this study, largely unmentioned previously, was that digital tools may prevent mistakes and ensure patient safety by addressing the information gaps in HCPs. In addition, the participants highlighted that the time efficiency of a digital tool may depend on the extent of the safety measures used to ensure patient confidentiality, which may differ across health care systems in different countries.

### **Implications for the Development of Digital Tools to Facilitate the Delivery of PA Advice in Primary Care**

The results of this study provide several recommendations for the design of a digital tool to support the delivery of PA advice by addressing barriers and leveraging facilitators. First, there appears to be a lack of digital tools that facilitate the delivery of PA advice. We argue that there is an opportunity to develop a digital tool to prompt and guide HCPs to discuss PA with patients. Second, the digital tool should be integrated into the existing workflow of primary care HCPs to reduce any friction and, most importantly, not to produce additional workload for

HCPs. Therefore, we recommend developing a relevant contextual prompt at critical points within the consultation to discuss PA. Third, digital tools should facilitate conversations between HCPs and patients. It should be universally applicable to different patients, yet it should give HCPs the freedom to tailor the conversation to the patient. Fourth, the ease, simplicity, and efficiency of digital tools can address some barriers to the delivery of PA advice. However, this requires barriers to using the digital tool itself to also be addressed, such as sufficient education and training in digital tools, confidence in using digital tools, or access to in-house support for using the digital tool. For example, digital tools can be used to generate personalized, printable guides from computer-based assessments of readiness to change and PA levels, as has been recently implemented in the Portuguese National Health Service [42]. The provision of digital templates and eLearning within existing platforms could facilitate HCPs lacking in communication skills or knowledge of PA, with a monitoring system to provide follow-up. Finally, further work should include interdisciplinary collaborations to ensure that the digital tool is usable and efficient and that HCPs engage with it to support the delivery of PA advice in primary care. Hence, the next step should bring together developers who design digital tools in primary care, service users (HCPs) of digital tools to consider the user journey and needs, and behavioral scientists to translate design recommendations into tangible prototypes to be tested.

### **Strengths and Limitations**

A strength of this study is the use of a behavioral framework for interviewing and analysis to systematically identify the barriers to and facilitators of using digital tools to deliver brief PA advice. The study also asked participants to consider any digital tool where many previous studies have focused on certain aspects of digital tools, such as eHealth or mHealth interventions.

The limitations include the range of HCP specialisms in this study, which included GPs, nurses, and HCAs and therefore did not consider the views of other HCPs within primary care. Furthermore, this study was conducted during the initial months of the COVID-19 pandemic, which may have influenced perceptions of using digital tools. Finally, barriers and facilitators to using digital tools to support the delivery of PA advice in primary care may differ across health care systems in different countries. Hence, the results from this UK study might not be applicable to other national health care systems. However, digital health care tools are becoming increasingly common worldwide, and similar issues have been identified across health care systems.

### **Conclusions**

Using a behavioral framework and qualitative approach, this study systematically identified important barriers and facilitators to using digital tools to support the delivery of PA advice in primary care. Important themes were found within 8 theoretical domains, most often within physical opportunity. These barriers can be addressed by designing efficient and flexible digital support tools to facilitate HCPs in delivering PA advice in primary care. To do so, future work should combine designers,



service users, and behavioral scientists to design and develop testable prototypes.

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## Authors' Contributions

PB contributed to coding of the data; data analysis; and writing, reviewing, and editing the manuscript. SJD wrote, reviewed, and edited the paper and contributed to visualization. SSJ contributed to data extraction, coding, data analysis, writing the manuscript, and reviewing draft manuscript. VM contributed to study design, data collection, data extraction, coding, and reviewing draft manuscript. CS contributed to technical oversight, study design, and review draft manuscript. All authors have reviewed and contributed to the final manuscript.

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## Conflicts of Interest

None declared.

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## Multimedia Appendix 1

Summary of the barriers and facilitators on the use of digital systems to deliver physical activity advice in primary care. [DOCX File, 31 KB - [humanfactors\\_v9i3e35070\\_app1.docx](#) ]

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## Abbreviations

- COM-B:** capability, opportunity, and motivation—behavior
- CVD:** cardiovascular disease
- GP:** general practitioner
- HCA:** health care assistant
- HCP:** health care professional
- mHealth:** mobile health
- PA:** physical activity
- TDF:** Theoretical Domains Framework

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Corrigenda and Addenda

# Metadata Correction: Identifying Contextual Factors and Strategies for Practice Facilitation in Primary Care Quality Improvement Using an Informatics-Driven Model: Framework Development and Mixed Methods Case Study

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In “Identifying Contextual Factors and Strategies for Practice Facilitation in Primary Care Quality Improvement Using an Informatics-Driven Model: Framework Development and Mixed Methods Case Study” (*JMIR Hum Factors* 2022;9(2):e32174) the authors noted one error.

In the originally published manuscript, a footnote was erroneously displayed in the authorship list noting equal contribution only for author Jiancheng Ye.

This footnote has been removed from the corrected manuscript, as no equal contribution should be noted in the authorship list.

The correction will appear in the online version of the paper on the JMIR Publications website on July 8, 2022, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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Original Paper

# Apprentices' Attitudes Toward Using a Mental Health Mobile App to Support Healthy Coping: Mixed Methods Study

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## Abstract

**Background:** Apprenticeships are a common pathway for young people transitioning into the workforce. Apprentices often face many employment-related challenges and have high levels of psychological distress, drug and alcohol use, and suicidal ideation. Little is known about the attitudes of apprentices toward using smartphone apps to support their mental health and the content that would engage them.

**Objective:** This study explored (1) apprentices' interest in using an app to support their mental health and (2) the healthy coping strategies used to manage their mental well-being in the face of workplace challenges, in order to inform future app content.

**Methods:** A mixed methods study was conducted with 54 apprentices (50/54 male, 93%) with a mean age of 22.7 (SD 5.7) years. Participants completed a survey on preferred ways of using an app to support mental health. Across 8 focus groups, participants were asked to describe healthy strategies they used to cope with occupational stressors.

**Results:** Only 11% (6/54) of participants currently used a well-being app, but there was high interest in using an app to support their friends (47/54 participants, 87%) and develop self-help strategies to manage or prevent mental health issues (42/54 participants, 78%). Four major types of coping behaviors were identified: (1) social connection for disclosure, advice, and socializing; (2) pleasurable activities, such as engaging in hobbies, time-outs, and developing work-life separation; (3) cognitive approaches, including defusing from thoughts and cognitive reframing; and (4) self-care approaches, including exercise, a healthy diet, and getting adequate sleep.

**Conclusions:** There is interest among apprentices to use an app with a positive well-being focus that helps them to develop self-management skills and support their friends. Apprentices utilized a range of healthy behaviors to cope with workplace stressors that can be incorporated into mental health apps to improve uptake and engagement. However, many of the preferred coping strategies identified are not those focused on by currently available apps, indicating the need for more targeted digital interventions for this group.

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**KEYWORDS**

apprentice; coping strategies; mental health; app; wellbeing; focus group; coping behaviour

## *Introduction*

Young people aged 16 to 24 have the highest prevalence of mental disorders but are the least likely to use mental health services [1]. Apprenticeships are a common pathway for young people making the transition from adolescence to adulthood and the working life. In Australia, there were approximately 400,000 individuals commencing apprenticeships or in apprenticeship training in 2020, with about 70% aged under 25 [2]. Men are more likely to enter into apprenticeships than women, with the construction, electrical, and metals and vehicle industries being the largest trade apprenticeship areas [3]. Workers employed in these male-dominated industries or occupations (eg, construction, transport and utilities, mining, and manufacturing) are at higher risk than the general population for psychological distress [4], depression [5], alcohol- and drug-related harms [6], and suicide [7]. Young apprentices face the additional challenges of unrealistic expectations, long work hours, job insecurity, workplace hierarchies, and bullying, which can impact their mental health and well-being [8]. Apprentices have higher levels of psychological distress and drug and alcohol use than national population norms [9,10]. Almost a third of construction apprentices experienced suicidal ideation in the previous year, which is significantly higher than the national norms for young people aged 16 to 25 years [11].

The small body of Australian research mainly focuses on apprentices in the commercial cookery and construction industries and suggests that apprentices tend to manage their work-related stress through maladaptive coping strategies. Two-thirds of apprentices consumed alcohol at harmful levels [12], and a quarter of apprentices reported they had used cannabis in the previous month [9]. A recent study found that apprentices used a range of stress management strategies, such as hobbies and exercise, alcohol and drug use, and taking stress home to their partners and families [13]. Their employment-related stress also contributes to apprentices not completing their training, with about half of trade apprentices in Australia dropping out, and many doing so within the first year of training [14]. While there is a lack of research on help-seeking by apprentices, it is known that those employed in male-dominated occupations are less likely to seek help from professional sources than those in other occupations [15]. They are more likely to adhere to traditional masculine norms [15], in which help-seeking is seen as a sign of weakness, loss of control, and incompetence; stoicism and self-reliance are preferred [16,17].

Smartphone apps may be more acceptable to apprentices as an accessible tool to self-manage their work stress and mental health. Apart from general advantages, such as privacy and anonymity, ease of access, and immediacy, digital mental health interventions are more acceptable to young people who prefer self-reliance and have concerns about stigma [18]. Young people in Australia aged 18 to 34 most commonly use mobile phones to access the internet (97%), many going online multiple times a day; they are quick to adopt different platforms and apps [19].

There is promising evidence that smartphone apps can improve depression and stress among young adults [20]. Recent studies suggest that about 25% of college students [21] and young people during the pandemic [22] were interested in using mental health apps. While many college students perceive mental health apps to be beneficial, some feel they would not personally use them or do not see a use for them [23]. Little is known about the attitudes of apprentices toward using smartphone mental health apps or the content that would engage them.

Taking into account user preferences is important in improving the uptake and engagement of smartphone mental health apps [24]. A review of young people's preferred features in digital mental health interventions recommended that apps build on the existing interests of young people in nonconfronting ways, have relatable content and aesthetics, and provide opportunities to learn psychological skills to improve well-being without too much educational or patronizing content [25]. These suggestions are similar to those reported by workers in male-dominated industries, who preferred mental health apps that provided quick, solution-focused strategies for fixing problems and avoided using the stigmatized term "mental health" [26]. Young men have also expressed a preference for online programs that are relevant to their everyday lives and interests and focus on action-based strategies [27]. They are more attracted to digital interventions that focus on positive aspects of mental well-being, such as "happiness," "strength," and "mental fitness" [28]. This suggests the possibility that a smartphone app focusing on self-help strategies and healthy coping may be more acceptable to apprentices, especially those working in male-dominated industries.

In order to inform the development of a smartphone mental health app that is acceptable and relevant to apprentices, the current study aimed to (1) explore their interest in using an app to support their mental health and (2) explore the healthy coping strategies used by this group to manage their mental well-being in the face of workplace challenges to inform future app content.

## *Methods*

### **Participants and Recruitment**

Registered group training organizations in Sydney and Newcastle, Australia, promoted the study to apprentices through their communication channels, which included emails, flyers, newsletters, and intranet notices. The promotional material invited apprentices to take part in a study exploring how to support apprentice mental well-being. Interested participants registered with an onsite training group coordinator. Participants had to be enrolled in an apprenticeship program, be fluent in the English language, and be a resident of Australia.

### **Procedure**

A mixed methods study was conducted with 54 apprentices from September to November 2017. This study was part of a larger qualitative study exploring the mental health challenges of apprentices in the workplace [8], their healthy coping



strategies, and their attitudes toward using an app to support their mental health (the focus of this paper); the larger study also included focus testing of the Headgear smartphone app (a behavioral activation and mindfulness app that was initially designed to improve the mental health of workers in male-dominated industries) [29]. All participants were reimbursed with an Aus \$40 (US \$27.97) Visa gift card for their time.

### Survey

Participants completed a brief, anonymous, paper-based survey at the beginning of the focus group, which included demographic items and questions about current app use for well-being. They were asked to nominate their 2 most significant psychosocial stressors at work. They were also asked to rate how interested they were in the following mental health app content: education about mental health, ways to seek help, self-help strategies, and ways to support a mate. Finally, they were asked how interested they were in using an app focusing on the following areas: managing or preventing depression, anxiety, stress, sleep problems, and substance use; finding out about their risk of developing a mental health problem; and improving physical health, with items scored on a 5-point Likert scale from “not at all interested” to “extremely interested,” based on previous work [30].

### Focus Groups

Eight activity-based focus groups (with between 3 and 11 participants in each session) were conducted by mental health researchers with experience working with young people. Participants provided written consent. Each focus group was conducted by 2 researchers and lasted approximately 90 minutes. A semistructured discussion guide was used to explore the workplace mental health challenges faced by apprentices (as reported by Einboden et al. [8]) and the types of healthy coping strategies they used to manage these challenges, which is the focus of the current paper. Sticky notes were used to capture individual responses to questions related to mental health challenges prior to sharing as a group. Activity-based approaches are useful for accessing views and opinions on sensitive topics

and give variety to the discussion, which is especially useful for young people [31].

### Analysis

Consistent with methods for the analysis of generative participatory data [32], the transcripts of audio recordings were collated with the participant-generated artifacts and coded using an inductive approach to thematic analysis [33-35]. The coding was conducted independently by 2 researchers, manually (KP) and using Quirkos software (RE). The researchers compared codes and discussed their findings, reaching consensus on coding structures and common concepts. Themes were generated and refined through discussion over a series of meetings, and then reviewed by the research team [34]. Following this, MD reviewed the recordings and artifacts to provide additional input. Psychosocial stressors reported in the survey were classified into 8 distinct thematic categories. These categories were not established a priori, but instead were guided by the responses provided.

Survey data were analyzed using Statistical Package for the Social Sciences (SPSS) for Windows (version 23.0.0, IBM). Only descriptive data are reported.

### Ethics Approval

This research was approved by the Human Research Ethics Committee at the University of Sydney (2017/648).

## Results

### Participant Characteristics

Participants were predominantly male (93%), with a mean age of 22.7 (SD 5.7) years (range 16 to 42 years). Most were completing their apprenticeship in the Sydney metropolitan area (76%), were in the first or second year of their apprenticeship (83%), and were undertaking the apprenticeship full-time (83%). The groups included apprentices with 7 different specializations, with the majority undertaking an electrical-related, commercial cookery or hospitality, or construction apprenticeship (Table 1).

**Table 1.** Sample characteristics (N=54).

Characteristics	Values
Age (years) mean (SD)	22.7 (5.7)
<b>Gender, n (%)</b>	
Male	50 (93)
Female	4 (7)
<b>Type of smartphone owned, n (%)</b>	
Android	23 (43)
iPhone	28 (52)
Other (Google, Windows)	3 (6)
<b>Regular use of well-being or health apps, n (%)</b>	
No	48 (89)
Yes	6 (11)
<b>Length of time in apprenticeship, n (%)</b>	
Less than 1 year	15 (28)
1 to 2 years	30 (56)
3 to 4 years	8 (15)
Not reported	1 (2)
<b>Type of apprenticeship, n (%)</b>	
Full-time	45 (83)
Part-time	7 (13)
School-based	2 (4)
<b>Area of study, n (%)</b>	
Electrical-related	26 (48)
Commercial cookery or hospitality	14 (26)
Construction (electrician, plumber, or bricklayer)	10 (19)
Not reported or other	4 (7)
<b>Location of apprenticeship, n (%)</b>	
Metropolitan area (Sydney)	41 (76)
Regional areas (Hunter and Central Coast)	11 (20)
Not reported	2 (4)

## Survey Findings

### *Attitudes Toward Using an App for Mental Health*

Only 6 of the 54 participants (11%) reported regular use of a well-being app. One female participant mentioned Headspace (a commercial mental health app focused on mindfulness meditation) [36], while 5 male participants reported using fitness monitoring apps, such as Apple iOS Health or Garmin. However, apprentices expressed considerable interest in using a smartphone app for managing mental health and as a source of information about mental health issues. The greatest level of interest among apprentices was in finding ways to support a friend, with 87% (47/54) of respondents “moderately, very, or extremely interested” in using their smartphone to discover strategies for this issue. Self-help strategies to manage or prevent mental health issues were also associated with high levels of

interest, with 78% (42/54) reporting moderate or greater interest. Education about mental health and ways to seek mental health if needed were the least popular elements, but still saw 69% (37/54) and 72% (39/54) scoring at least moderate interest, respectively.

Respondents were most interested in an app that focused on improving their physical health; 78% (42/54) reported moderate or greater interest. There was moderate interest in an app that offered strategies to reduce anxiety, with 67% (36/54) reporting moderate or greater interest; stress, with 67% (36/54) reporting moderate or greater interest; and depression, with 65% (35/54) reporting moderate or greater interest. There were lower rates of interest in an app to improve substance use, with 57% (31/54) reporting moderate or greater interest, and sleep, with 57% (31/54) reporting moderate or greater interest. Most respondents (38/54, 70%) were moderately, very, or extremely interested in

an app that helped identify their risk of future mental health problems.

### **Psychosocial Stressors**

A total of 90 individual work-related stressors were reported among the participants. The most commonly reported workplace stressors related to issues around workplace pressures and expectations (38/90, 42%), followed by personal time factors (work-life balance and long hours) (14/90, 16%), workplace bullying and hostility (11/90; 12%), and interpersonal problems with other employees or the public (11/90, 12%). The remaining reported stressors related to study issues (5/90; 6%); anxiety, boredom, and uncertainty (5/90; 6%); a lack of guidance (3/90, 3%); and financial issues (3/90, 3%).

### **Focus Group Findings**

Overall, 10 key strategies emerged as a means of coping with work stress. These strategies were categorized into four types of healthy coping behaviors: (1) social connection, (2) pleasurable activities, (3) cognitive approaches, and (4) self-care. In addition, active learning, starting to save or make a budget, and substance use were coping strategies that were mentioned infrequently.

#### **Social Connection**

Social connection was discussed by participants in all focus groups. Social connection was characterized into 2 distinct, but related, forms. First, it was used as a social strategy (disclosure and advice) for coping, particularly for obtaining advice. In this form, “talking” was viewed as an action, that is, a specific avenue to overcome problems and receive reassurance. Second, it was used as a way of spending time and being together (ie, socializing), which places a greater emphasis on the intangible functions of “social” connections (eg, friendship). There was a feedback relationship between these 2 themes that directly impacted the effectiveness of each element (eg, the more trust within a social connection that was built in the latter, the greater the use of that connection in the former).

Within the strategy of disclosure and advice there was significant use of active verbs (eg, “ask,” “talk,” and “discuss”) to off-load and share stress and a tendency toward seeking information from others; representative quotes are shown in parentheses (eg, “Find someone to talk to like family or partner”). Commonly reported sources of support were friends, family, romantic partners, bosses, and coworkers. Trust played a crucial role in the process (eg, “Talk to family, friends, trustworthy co-workers,” “Rant to another chef you know well enough,” “Pull my head chef or other close work colleagues aside”). Overall, this strategy provided 3 main functions: advice-seeking (eg, “Talking to people that can help come up with strategies with expenses, balance, stresses”), learning skills and practical support (eg, “Ask other apprentices for assistance with difficult studies,” “Ask colleagues for help and tips”), and coping with stress or work issues (eg, “Confronting the issue of pay and co-workers,” “Talk about stuff I am struggling with to parents and friends”).

The most common topic was simply the act of “talking,” while other topics included work issues, skills or study, and

“off-loading about work.” Participants were reticent to mention mental health or employment-related stress specifically, preferring instead to use vague terms such as “my problems” or “hard stuff” when talking to others.

The socializing theme emphasized aspects of sharing with, being with, and spending time with friends and family, with primary use of passive verbs (eg, “being with,” “see friends,” “hang out with,” “spend time with”). Reiterating the frequent mention of friends in the “time-out” theme (discussed below), friends and romantic partners were the most commonly mentioned connection. The direct role that socializing played in coping was rarely expressed; instead, it seemed that the act of maintaining these connections satisfied an innate need for support and belonging that was essential to coping. There were also clear links to other themes and strategies, particularly disclosure and advice, work-life separation, and hobbies.

#### **Pleasurable Activities**

Hobbies were discussed as a prominent means of coping. Common hobbies reported were related to music, movies, television, videos, and outdoor activities.

One participant described hobbies as a way to escape negative feelings: “Have a hobby, find something you like and [you] have an escape.” The use of hobbies for escapism was a means of cognitive distraction: “watch movies and videos to get it off your mind.” Related to the idea of distraction was personal enjoyment, in that hobbies, as one participant put it, equated to “Me time,” that is, “Have a hobby—do things away from work that are healthy, and you enjoy.” The ability to devote time freely to one’s own pursuits rather than feeling the external pressure and constraint experienced at work was viewed as an important component in the use and benefits of hobbies. This was discussed specifically in the context of bullying, workplace constraints and authoritarian workplace structures, and the demands of study.

The second strategy (time-out) was related to the idea of escapism but focused on physical or mental distance without the need for a hobby to fill this space. This was achieved in different contexts and places, both at work (eg, “smoko” [Australian slang for a cigarette break or a rest from work], “being on-break”) and away from work in usual surroundings (eg, “Enjoy weekend off work,” “Speak to work and take a day off”) or on holidays (eg, “Go down the coast somewhere or away,” “Just drive”), as well as mental time-outs (eg, “Zoning out at lunch and smoko breaks”).

The third strategy involved work-life separation and described a higher-level goal of this domain: addressing challenges related to working hours and high pressure. This was particularly pronounced within the context of apprenticeships, which require juggling study, long working hours, overtime, and commuting. These all contributed to increasing stress and the demands of work on respondents’ time and thus required a very deliberate and premeditated “separation” in order to switch off: “When I leave work of an evening I turn all notifications (email) off and forget about work-related issues.”

Both hobbies and time-outs functioned as facilitators to work-life balance, but the role of strict “planning” was central

to this strategy. There were also links to other domains, such as scheduling in time for friends and family, exercise, and adequate sleep (“Plan out your week so you have a balance of work/social life/and any sports etc.”).

### **Cognitive Approaches**

There were 2 strategies discussed that utilized a cognitive approach to coping. The first was widely discussed and focused on cognitive strategies to defuse from thoughts. The second used elements of cognitive reframing that allowed respondents to motivate and challenge themselves, often fostering a “big picture” focus on their aims and goals to provide motivation to support them through day-to-day challenges. Overall, these approaches provided a source of internal support and strengthened self-belief and resilience.

Defusion strategies varied, but included using distraction (eg, “Try not to think about work,” “Distract yourself from work issues when at home”), relaxation and breathing techniques (eg, “Take some deep breaths and refocus myself on the job at hand”) and “worry time” (eg, “Set aside X amount of time a day for worries then move on”).

Reframing strategies sought to refocus thoughts and take perspective. Means to achieve this included focusing on a positive (eg, “Think about the money,” “Knowing and remembering that it is something that I want to do and I love to do”), or an end goal (eg, “Knowing that I have only a few months left to complete,” “[just] finish the apprenticeship”), using humor as stress relief (eg, “Have a joke,” “Find a funny side...”) and practicing acceptance (eg, “More stressing will not change an outcome”).

### **Self-Care Approaches**

Exercise and physical fitness were the most frequently discussed self-care strategies. In all groups, there was a consistent theme of pursuing an ideal of masculine strength: “Train[ing] hard to release the beast.” However, the indirect benefits of exercise (enjoyment, tension release, getting outside, and mental fitness) were also discussed. Furthermore, physical fitness was discussed in the context of being “able to perform necessary functions at work,” especially if the respondents were in a physically demanding industry. The most commonly reported forms of physical activity were walking, going to the gym to work out and train, going to the beach or surfing, and sports generally.

Two other strategies that were less commonly discussed were eating a healthy diet and getting adequate sleep. Healthy diet was generally described as “attempting to have a healthy diet,” while often experiencing lapses into unhealthy food consumption (eg, “[you have to] Try to meal prep so you do not eat shit”). The idea of prepreparation and taking meals to work was specifically related to the challenges associated with time management.

The strategy of getting adequate sleep was raised as a mitigating factor against common challenges related to fatigue, early starts, and long hours (eg, “Get enough rest the night before work”). It was mentioned as both an exercise in self-discipline (eg, “Go to bed early enough so I get enough sleep for the next day”) and a reward (eg, “sleeping in [whenever you're able]”).

### **Other Approaches**

The following approaches were less frequently mentioned in the focus groups. Active learning was one technique used in order to address the challenges of study and work expectations. Some participants mentioned using proactive approaches to reinforce concepts and knowledge (eg, “[I] practice electronics outside of work,” “[I focus on] getting my assignments correct and passing...and learning more at work”). Similarly, this practical approach to problem solving was also mentioned in the context of financial challenges, collectively termed savings and budgets (eg, “Saving for a certain thing rather than blowing money,” “Make a budget for the week”). Despite being asked specifically to describe “healthy coping strategies” in the interviews, substance use (eg, “Having a drink,” “Drugs,” “Smoking”) was mentioned by one group as a usual activity they engaged in during time-outs.

## **Discussion**

### **Principal Findings**

This study aimed to explore the attitudes of apprentices toward using an app to support their mental health and to explore their use of healthy coping strategies to manage their mental well-being in the face of workplace challenges, in order to inform relatable and nonconfronting app content. All participants owned a smartphone, but few had ever used a mental health or well-being app. Most of the male apprentices who had used a well-being app had used a fitness-monitoring app, but none had used an app specifically for their mental health. There was a high level of interest among apprentices in using an app to support their friends or to learn self-help strategies to manage or prevent mental health issues. Consistent with previous research on preferences for mental health app features among young people [25], apprentices were least interested in using the app for education about mental health.

### **Apprentice Mental Health App Design Considerations**

#### ***Focus on Positive Aspects of Well-Being***

Supporting the idea that apprentices may be more attracted to positive aspects of well-being, and perhaps reflecting a generally healthy sample, there was high interest in an app focusing on physical health and identifying future risk for mental health problems. These findings suggest an app meeting these needs may be more acceptable (and perhaps less threatening and stigmatizing) than one focused on mental illness. Digital intervention developers and researchers looking to engage apprentices may be best served using approaches that are less direct and improve mental health outcomes circuitously, by encouraging positive coping strategies that enhance well-being in general and outcomes such as physical health, work satisfaction, and “supporting a mate.”

Understanding the healthy coping strategies used by apprentices can inform the design of digital interventions with a nonclinical focus to improve uptake and engagement among this group. The apprentices in this study reported using a range of healthy coping strategies to manage occupational stress, including social connection, pleasurable activities, cognitive approaches, and self-care.

### ***Social Connectedness and Seeking Advice***

Social connection was a key coping strategy mentioned by all focus groups. While the apprentices reported that socializing and sharing activities with friends were a central part of social connection, they also emphasized the importance of talking and seeking emotional support through disclosure of challenging work situations and seeking advice. However, there was a general reluctance to discuss their internal emotional experiences, and they instead focused on the external forces at play. This is consistent with literature indicating that, when experiencing psychological distress, men are more likely to focus on external circumstances than the emotional experience itself [37]. These results suggest the focus in apps for apprentices should be on encouraging social support and seeking advice, rather than emotional disclosure. Further, apps that build in elements of social support may also facilitate engagement [38], especially among this group.

### ***Behavioral Strategies and Self-Care***

Many current digital mental health interventions have a cognitive therapy base, whereas the participants in this study have indicated that behavioral strategies (social connection, pleasurable activities, and self-care) form a large part of their healthy coping behaviors. Being able to switch off from work, whether through engaging in a hobby, exercise, time-out activities, or practical strategies such as turning off emails, was a key part of managing their stress at work. This suggests the need for more targeted, action-oriented approaches to engage this group. Mental health apps developed for male-dominated industries and young men with a focus on behavioral activation [39] and positive psychology and social connection [40] have shown promising results. Healthy diet and regular sleep were less commonly discussed, and their importance, with strategies to improve physical health, could be further emphasized in apps for this group.

### ***Practical Psychological Skills***

Notwithstanding the results described above, the use of cognitive strategies among participants suggests that many cognitive behavioral therapy and mindfulness approaches may still play an important role among apprentices. Defusion strategies were commonly mentioned, which suggests a use and preference for more practical and action-based strategies (eg, calm breathing and worry time) among this group. Participants also reported some use of reframing strategies, such as focusing on positives or end goals. This suggests there is room to introduce value-driven goal setting as part of behavioral activation to reconnect apprentices to an environment of positive reinforcement and improve well-being.

### ***Short, Action-Based App Activities***

Our sample of apprentices reported that time pressure, workload, and long hours were key workplace stressors. While apps are generally well-placed to support those who are short on time, activities offered in apps also need to be of appropriate length, easily integrated into the daily lives of apprentices, offered in different modalities, and customizable to facilitate engagement [38]. For example, an appropriate activity might be a 2-minute

breathing exercise or a value-driven activity planning exercise that apprentices can practice during breaks or after work.

### **Limitations**

There are several limitations to this study that should be considered. There was a high representation of male apprentices in this sample, the apprentices were recruited from a limited number of male-dominated industries, and they were completing their apprenticeships primarily in the Sydney metropolitan area. The issues faced by and coping strategies used by this cohort may not be representative of all apprentices, especially those working in other trades, industries, or geographic areas, or by female apprentices. Most of the participants were in their late teens or early twenties, though there were a very small number of apprentices who were over 30 years old, so the findings may be less relevant to mature-age apprentices. Participants knew that this study was focused on mental health and well-being, so it is likely there was a bias toward those who were more comfortable discussing these issues. The study did not examine the mental health status of participants, so it is unclear whether their personal experiences of mental health affected their choice of coping strategies or their attitudes to an app to support mental health. While apprentices were asked about their smartphone and well-being app use, we did not explore other aspects of digital literacy in this study. Finally, expectations of a mental health app and preferred features were not directly explored during the focus groups, but were instead explored during the user-testing phase of the Headgear app [29].

### **Conclusions**

Although many evidence-based smartphone mental health apps exist, most focus on mental health problems, such as depression, anxiety, or distress [20,41]. They do not cater to the user preferences and needs of apprentices, as evidenced by our finding that only one apprentice reporting having used a mental health app. Given that apprentices have shown a preference for apps with a positive well-being focus that helps them to develop self-management skills, our team has adapted a behavioral activation and mindfulness-based smartphone app (Headgear) for apprentices. Headgear provides a risk-profiling tool and a tailored 30-day mental health challenge that includes psychoeducational videos; mindfulness exercises; value-driven activity planning, goal setting and review; and coping skill development (problem solving, sleep, grounding, alcohol use, assertiveness, and training in adaptive forms of coping). In a large-scale randomized controlled trial, the app was found to reduce depression symptoms and prevent incident depression caseness [39]. Adaptations for apprentices included minor modifications to personalization of the risk-profiling tool, altered wording to increase accessibility, the addition of an orientation video, improved navigation, specific apprentice support service guidance, the ability to skip through certain challenges, and elements to enhance gamification (including badges for achievements). A pilot trial of the app showed promising uptake, good engagement, and good acceptability among apprentices, though a full-scale efficacy trial is still needed [29].

The current findings indicate that there is interest among apprentices in male-dominated industries in using an app to support their mental health. Further, there is scope to develop

smartphone apps for apprentices with a well-being focus by incorporating healthy coping strategies, including social connection, behavioral strategies and self-care, and practical psychological skills, which may be seen as more relevant and acceptable ways to support mental health among this population.

A mental well-being app targeting the needs of apprentices, such as by helping them learn how to support friends or use short, action-based self-management activities, may be a way to engage apprentices in developing these healthy coping skills and improve their well-being.

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## Conflicts of Interest

None declared.

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Original Paper

# Development of an Assistive Technology for Cognition to Support Meal Preparation in Severe Traumatic Brain Injury: User-Centered Design Study

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## Abstract

**Background:** Although assistive technology for cognition (ATC) has enormous potential to help individuals who have sustained a severe traumatic brain injury (TBI) prepare meals safely, no ATC has yet been developed to assist in this activity for this specific population.

**Objective:** This study aims to conduct a needs analysis as a first step in the design of an ATC to support safe and independent meal preparation for persons with severe TBI. This included identifying cooking-related risks to depict future users' profiles and establishing the clinical requirements of the ATC.

**Methods:** In a user-centered design study, the needs of 3 future users were evaluated in their real-world environments (supported-living residence) using an ecological assessment of everyday activities, a review of their medical files, a complete neuropsychological test battery, individual interviews, observational field notes, and log journals with the residents, their families, and other stakeholders from the residence (eg, staff and health professionals). The needs analysis was guided by the Disability Creation Process framework.

**Results:** The results showed that many issues had to be considered for the development of the ATC for the 3 residents and other eventual users, including cognitive issues such as distractibility and difficulty remembering information over a short period of time and important safety issues, such as potential food poisoning and risk of fire. This led to the identification of 2 main clinical requirements for the ATC: providing cognitive support based on evidence-based cognitive rehabilitation to facilitate meal preparation and ensuring safety at each step of the meal preparation task.

**Conclusions:** This needs analysis identified the main requirements for an ATC designed to support meal preparation for persons with severe TBI. Future research will focus on implementing the ATC in the residence and evaluating its usability.

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**KEYWORDS**

user-centered design; needs assessment; assistive technology; brain injury; activities of daily living; cognitive rehabilitation; meal preparation; mobile phone

## Introduction

### Background

Assistive technology for cognition (ATC), which are devices and software designed to meet the specific needs of persons with cognitive deficits, hold great promise [1-10]. However, few have been designed based on an exhaustive understanding of the complex and unique needs of individuals who have sustained a severe traumatic brain injury (TBI). TBI is defined as an alteration in brain function caused by an external force, such as a car accident, causing cognitive, physical, behavioral, and emotional disabilities [11]. These disabilities have an important impact on engagement in Activities of Daily Living (ADL) [12], and as most TBI survivors are young adults, they will live for an average of 50 years with the resulting difficulties [11]. When considering the extremely high lifetime care costs associated with severe TBI [13], providing safe and adapted environments, including ATC that enable the functioning of TBI survivors, should be deemed a societal priority.

ATC can help individuals with TBI realize their domestic and community activities [14,15]. In a recent meta-analysis, Nam and Kim [16] concluded that assistive devices may be an effective intervention for people with brain injuries. In addition, individuals living with moderate to severe TBI and their caregivers have expressed an interest in and willingness to use ATC [1,17]. Although a wide range of potentially supportive ATC exists, few have been developed with the active participation of persons with TBI and their families. Hence, their design may not capture the complexity of the cognitive needs associated with brain injury or the factors contributing to their acceptance and adoption in real-life settings. In addition, the design of most over-the-counter technological devices does not target the specific needs of persons with TBI, making it generally challenging for this population to use these devices independently.

To meet the needs of people with TBI and create useful and effective ATCs, our team developed a partnership with a supported-living residence for TBI in the province of Quebec, Canada. All stakeholders, including residents with TBI, actively participated in setting up a living laboratory to implement innovative technologies. The residence accommodated 10 people with severe cognitive deficits but negligible physical impairments, requiring 24/7 staff supervision. Of these 10 people, 6 (60%) lived in small apartments with cooking facilities, and 4 (40%) lived in basic rooms. All residents had access to common areas, including a central cafeteria where staff served daily meals. The residence was associated with a regional rehabilitation center.

In 2013, we completed the first study, with 7 residents, 4 caregivers, and 5 health care providers working at the residence. The goal was to identify and rank daily needs that they would like future ATCs, that would be developed by our team, to address in the context of a living laboratory project designed to

support the specific needs of all stakeholders from this particular residence [18]. Meal preparation was identified as a priority [18]. At the time, no resident had permission to cook with a stove because of the high level of risk involved (eg, fires and burns). Residents were only allowed to prepare light meals, such as breakfast. In addition, to the best of our knowledge, no ATC was commercially available at that time to support meal preparation by persons with TBI. Although descriptions of 3 prototypes had been published in peer-reviewed journals [19-22], they could not be used in the context of this project, as they had not been researched, designed, or adapted to the needs of individuals with TBI. For instance, the first technology used a robot and did not provide assistance adapted to the needs of persons with TBI [19]. The second was a cooking support system that used kitchen sensors and displayed cooking instruction videos. Although this system provided assistance adapted to the user's progress [21], it was not designed for the specific needs of people living with TBI. The third [22] was an application called Smart Kitchen for Ambient Assisted Living, tested for older adults. This application showed good usability and cognitive accessibility, but it was neither specific to TBI nor designed considering evidence-based cognitive rehabilitation practices. More recently, Wang et al [21] published a feasibility study of an automatic, context-aware, prompting system designed to support persons with TBI with multitasking specific to cooking. This study provided a starting point for the potential of ATC for people with TBI during meal preparation. However, although helpful, the ATC's design is limited to guiding the person step by step through task performance. Though this type of compensatory approach is well supported for persons living with TBI, it fails to grasp the full potential of ATC, as it does not consider the breadth of other possible rehabilitation approaches such as metacognitive strategies considered as evidence-based rehabilitation strategies in TBI [23].

In the context of this study, which was conducted using a living laboratory approach [24], we aimed to co-develop with, and for, the residents with TBI, an ATC that would support their needs to prepare meals safely but also tap into their rehabilitation potential by implementing evidence-based cognitive rehabilitation interventions to optimize their independence in meal preparation. To do so, we used a user-centered design (UCD) method involving the following steps: (1) needs analysis, (2) design and prototyping, (3) experimentation, and (4) iterative follow-up [25-27]. Research on ATC development has shown the importance of considering the user, including persons with TBI, at all stages of the UCD process [28-31]. The continuous involvement of future users leads to the development of safer, more effective, and efficient products and enables faster postdesign deployment [29], smoother transfer into the environment [31,32], contributing to product acceptance and overall future success [29,33]. Residents with TBI were thus considered as equal members of the design team throughout the design process.

## Objectives

The general goal of this project was to conduct a needs analysis of the residents and develop an ATC for meal preparation as requested by them. More specifically, the study aimed to (1) depict future users' profiles, including their difficulties in meal preparation; and (2) establish the clinical requirements for designing an ATC that would support meal preparation accordingly. The subsequent steps of the project were to design the ATC, implement it in the residence, and explore its usability. These steps have been previously published elsewhere [34]. The ATC was ultimately named the *Cognitive Orthosis for Cooking (COOK)*.

## Methods

### Overview

As mentioned earlier, we used a UCD method to collect data pertaining to the needs analysis step of an ATC design. To do so, this study was separated into two parts based on two specific objectives: (1) methods used to depict the future users' profiles and (2) methods used to determine the clinical requirements for the ATC. The needs analysis was conducted over a 24-month period between July 2014 and August 2016.

### Conceptual Framework Supporting the Study

We opted to use the Disability Creation Process [35] as a conceptual framework. This framework is used in all rehabilitation centers in Quebec, including the supported residence where this study took place. It allowed for a shared vocabulary among stakeholders, which is very important in a living laboratory involving multiple stakeholders, and was a facilitator both for collaboration [36] and for the conceptualization of the ATC's requirements.

According to the Disability Creation Process, a person with TBI experiences a disabling situation, which has the potential to be modified to facilitate more complete social participation. Full social participation refers to *the total accomplishment of life habits, resulting from the interaction between personal factors (impairments, disabilities, and other personal characteristics) and environmental factors (physical or social; facilitators and obstacles)*. Life habits are defined as regular activities (eg, eating meals, communicating with others, and moving around) and social roles (such as holding a job) that ensure a person's survival and well-being in society [35]. When a person can achieve full social participation, they are considered independent [37]. On the other end of the spectrum of social participation, there is a disabling situation, which is defined as "the reduced accomplishment of life habits, resulting from the interaction between personal factors and environmental factors." In a disabling situation, a person is considered dependent on others to complete a given task.

In this study, the framework was used to help determine how the ATC could support the independence of a person with TBI in terms of features and services; or, more precisely, what were the *clinical requirements* that had to be addressed by the ATC. Identifying these requirements is a prerequisite for the design of any ATC [38]. In accordance with the framework, they should address all components leading to disability in meal preparation:

(1) addressing the identified impairments (eg, rehabilitation of executive functions), (2) providing environmental compensation for the person's deficits in the event of a dangerous situation (eg, cutting the stove's power supply), and (3) simplifying the activity (eg, guidance for the preparation of a simple meal using a step-by-step format that is easy to follow).

### Participants

Out of the 10 resident members of our living laboratory, 6 (60%) could participate in the development of the ATC, as they lived in small apartments with cooking facilities. The other 40% (4/10) lived in basic rooms. The selection criteria to participate in this study were as follows: (1) to be motivated to participate in the study, (2) to present a stable life situation (eg, not currently experiencing a period of heavy alcohol consumption or major life stressors), and (3) to demonstrate potential to resume meal preparation as evaluated by the rehabilitation team working at the residence. The exclusion criteria consisted of a diagnosis of depression or any other significant medical condition that could impede participation in the study. Of the 6 participants, 3 (50%) met the inclusion criteria and are identified in the text as resident 1, resident 2, and resident 3. Although the ultimate objective of our team was to develop an ATC that would be useful for diverse profiles of persons who have sustained a TBI, we had to start with the specific needs of these 3 residents, with the intention of progressively increasing the number of functionalities in the future. The other stakeholders (2 caregivers, 3 residence staff, 3 health care professionals, and the 2 administrators of the residence) also agreed to participate in the project.

### Ethics Approval

This study was approved by the Ethical Review Board of the Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal (reference CRIR-19-11-2013) and the Ethical Review Board of the Centre Intégré Universitaire en Santé et Services Sociaux De L'Estrie-Centre Hospitalier Universitaire De Sherbrooke (reference 2017-715-IUGS). Procedures followed by the ethical review boards were in accordance with the ethical standards of committees responsible for human experimentation in Canada and in the province of Quebec. All participants and their legal guardians, when required for residents with severe TBI, gave their written informed consent.

### Part 1: Depict Future Users' Profiles—Data Collection for Objective 1

Table 1 presents the data collection tools that were used to determine the users' profiles. A detailed portrait of the challenges specific to the 3 future users was prepared based on the Disability Creation Process [35], including an evaluation of personal factors, life habits (regarding meal preparation), and the environment. The process was led by 2 occupational therapists (SP and CL). To document personal factors, residents' medical files were reviewed (including medical reports and physiotherapy and occupational therapy reports), and each was administered a complete neuropsychological test battery. This battery comprised the following tests: Trail Making Test A and B [39], Wechsler Adult Intelligence Scale 4th Edition (Digit Span Forward, Letter-Number Sequencing, Digit Span

Backward, Block Design Visuospatial and Motor Skills, and Visual Logic Reasoning [40]), Rey Auditory Verbal Learning Test (word list) [41], Brief Visuospatial Memory Test-Revised [42], Delis–Kaplan Executive Function System Color Word Interference Test (Stroop) [43], and the Tower of London Mental Flexibility-Drexel University [44].

Residents were also interviewed regarding their perception of using technology to support meal preparation, their expectations

of the future ATC, and their personal objectives and expectations related to resuming meal preparation activities.

To document life habits, a team of occupational therapists (SP, CB, and NB) led the process of documenting each resident's profile. Four data sets were collected: independence in everyday activities before the TBI, current level of independence in meal preparation at the residence, number of light meals prepared per week without using a stove, and level of independence and satisfaction with all life habits.

**Table 1.** Data collection to depict future users' profiles.

Categories and data sets	Tools
<b>Personal factors</b>	
Medical files	Hand search
Neuropsychological assessment of the 3 residents	Complete neuropsychological test battery
Perception of technology	Individual interviews with the participants
<b>Life habits</b>	
Independence in everyday activities before the TBI <sup>a</sup>	ADL <sup>b</sup> Profile [45,46]: individual interviews with the participants and their family members
Independence in meal preparation at the residence	IADL <sup>c</sup> Profile [47-50]: performance-based assessment; ADL Profile questionnaire [45,46] with the participants and their family members
Number of meals prepared per week	Observation log journal kept by the residence staff to document the number of meals prepared
<b>Environment</b>	
Obstacles or facilitators to meal preparation	Field interviews and observations in situ

<sup>a</sup>TBI: traumatic brain injury.

<sup>b</sup>ADL: Activities of Daily Living.

<sup>c</sup>IADL: Instrumental Activities of Daily Living.

To assess the level of functioning of participants before their TBI and at present, we conducted a review of their medical records, individual interviews (based on the ADL Profile) [45,46], and interviews with a family member. Current level of independence in meal preparation was assessed with the Instrumental Activities of Daily Living (IADL) Profile [47], a performance-based measure of independence in IADL viewed through the lens of executive functions. This assessment used a nondirective approach and was administered in the person's home and community environment. The IADL Profile consists of 3 scenarios (inviting someone for dinner, obtaining information, and making an annual budget) that the person is invited to think through and carry out in their home and community environment. Considering the focus of the research project, we only completed the first scenario, which included six interrelated tasks: (1) putting on outdoor clothes, (2) going to the grocery store, (3) shopping for groceries, (4) preparing a hot meal, (5) having a meal with a guest, and (6) cleaning up after the meal. The tool has excellent psychometric qualities and has been extensively validated with individuals who have sustained a moderate or severe TBI [48-50]. For 2 residents, the meal preparation was videotaped to enable a more detailed analysis of their performance and identification of any at-risk behaviors. For the third resident, extensive notes were taken during the evaluation.

The IADL Profile was administered to each participant 3 times, in part or in full, depending on their level of collaboration. Slight variations were made to the tool's standard instructions when administering the tool for the second and third times. These variations were used to allow for an observation of different potential contexts of use of the technology and the associated performance of future users. Three meals were prepared by resident 1 (simple spaghetti, hot sandwiches and cookies, and meat loaf) and resident 3 (minestrone soup, roast beef and vegetable rice, and sauerkraut and sausage), and only 2 by resident 2 (meat macaroni and a chicken Caesar salad) because of his limited cooperation.

The number of meals prepared by the participants each week was documented in an observation log. The log was completed using a short daily interview (conducted by CL) with the residence staff. It consisted of a chart created to document tasks completed over 5 consecutive days, collecting the number of meals prepared by each participant and including whether it was a cold or hot meal. The log also allowed us to record each participant's failures and successes in unsupervised meal preparation.

Each resident's social and physical environments were also documented with field observations by residence staff as well as by formal and informal discussions between members of the research team and all stakeholders. The stakeholders included the rehabilitation team (ie, social workers, specialized education

technicians, and nursing staff), residence staff, and managers. Information was collected using written memos during informal interviews and formal meetings about the project.

### Data Analysis for Part 1

A deductive qualitative analysis [51] based on the Disability Creation Process was used to organize the data collected from multiple sources and yielded the level of social participation in meal preparation for each participant. The data were analyzed by SP, and the content was validated by CL, CB, and NB. Discordance was discussed among all evaluators, and a consensus was reached for all information classified in the Disability Creation Process. Results of each IADL assessment were validated by SP, CL, and one of the authors of the IADL Profile assessment (CB) to increase the validity of the results.

### Part 2: Establish the Clinical Requirements for the Assistive Technology

The most relevant interventions that could be offered to address the needs of future users were identified, and the recommended clinical interventions were translated into requirements to guide the ATC design. The following steps were used to translate user needs into clinical requirements for the ATC: (1) identify evidence-based practices known to improve independence in persons with TBI, (2) from among these practices select those that are appropriate to the needs of each future user and are most likely to improve their independence (individualized intervention plan), and (3) identify the clinical requirements for the future ATC for meal preparation to guide design and technological development.

To identify evidence-based practices known to improve independence in persons with TBI, a rapid review was conducted by clinical specialists on the design team. This team of clinical specialists included 4 occupational therapists: a doctoral student in rehabilitation sciences (SP), 2 academics and clinical scientists (CB and NB), and a research coordinator (CL). Cognitive rehabilitation can be defined as systematic therapeutic activities that aim to improve injury-related deficits to maximize safety, daily functioning, independence, and quality of life [23]. Although numerous evidence-based clinical recommendations for the cognitive rehabilitation of persons with TBI have been published [23,52-54], it is those of Haskins et al [23] and Bayley et al [53] that were adopted in this study. For Haskins et al [23], this choice was based, in part, on the support from the American Congress of Rehabilitation Medicine and the accompanying practice guidelines that assist in their application. Regarding the Guidelines for Cognitive Rehabilitation following TBI proposed by Bayley et al [53], the choice was made because of its rigorous development process, including an extensive literature review.

Each resident's intervention plan was developed according to (1) an analysis of the interaction of the resident with his occupation and living environment, combined with his individual needs to promote engagement; and (2) evidence-based cognitive rehabilitation interventions found in the rapid review.

Finally, to identify the clinical requirements for the future ATC, the research team *translated* each intervention plan into usable terms for the computer science team (eg, the ATC should be automatically shut down if a burner is left open on the stove for an extended period of time). To this end, team members listed the difficulties observed during meal preparation for each of the 3 participants and added complementary information obtained from the stakeholders. Subsequently, a list of possible functionalities of the ATC was defined (eg, to support meal preparation with or without recipes, to support grocery list preparation, and to support budget management related to shopping for meal preparation). A classification of the level of importance for each functionality was established by the design team according to whether the functionality was considered necessary, ideal, or optional for each participant.

## Results

### Future Users' Profiles

Participants' social participation in meal preparation was analyzed according to the Disability Creation Process. The entire process included up to 6 in-person meetings with each of the future users, 2 meetings with resident 1's mother, 1 meeting with resident 2's mother, and up to 6 meetings per resident with the residence's staff, health care professionals, and administrators.

### Personal Factors

The complete profile of each participant is presented in [Table 2](#). All 3 participants were single, middle-aged men with physical and cognitive disabilities. They could stand up and walk with (resident 1) or without (resident 2 and resident 3) an orthosis and could use both hands to at least stabilize objects (resident 1). Resident 1 had a left hemiparesis. Resident 3 presented with anosmia, deafness, and severe food allergies. Cognitive impairments in residents 1, 2, and 3 could interfere with meal preparation tasks and have an impact on safety. These included deficits in working memory and executive function (residents 1, 2, and 3), episodic memory (resident 1), and abstraction and reading difficulties (resident 1 and resident 2). All participants were able to name some of their cognitive impairments but not their impact on their performance in a meal preparation task.

**Table 2.** Residents' profile and personal factors.

Personal factors			
Participant	Medical file	Neuropsychology analysis	Perceptions and expectations about the ATC <sup>a</sup>
Resident 1	<ul style="list-style-type: none"> <li>Male, aged 48 years</li> <li>Severe TBI<sup>b</sup>, 19 years since TBI</li> <li>11 years of education</li> <li>Hemiparesis to his left hemi-body</li> </ul>	<ul style="list-style-type: none"> <li>Mild difficulties related to short-term memory and working memory</li> <li>Mild difficulties in reasoning and difficulties in problem-solving (planning)</li> <li>Anxiety, impulsivity, and behavioral outbursts</li> </ul>	<ul style="list-style-type: none"> <li>Perceptions: open to using technology but anxious about his ability to learn to use technology</li> <li>Frequently uses his computer for social networking and to surf on the internet</li> <li>Expectations <ul style="list-style-type: none"> <li>To cook his own sauces with alcohol as before</li> <li>To cook a spaghetti sauce</li> <li>To prepare all his meals</li> </ul> </li> <li>Motivated and collaborative</li> </ul>
Resident 2	<ul style="list-style-type: none"> <li>Male, aged 37 years</li> <li>Severe TBI, 32 years since TBI</li> <li>9 years of education</li> <li>Chronic pain in the feet and back and chronic headaches</li> </ul>	<ul style="list-style-type: none"> <li>Mild deficits in working memory</li> <li>Difficulty alternating between 2 concepts; mild difficulties in reasoning</li> <li>Difficulty following verbal commands, reading, and calculating quantities</li> </ul>	<ul style="list-style-type: none"> <li>Perceptions: open to using the ATC but anxious. Says that he will need help</li> <li>Frequently uses his own computer for social networking</li> <li>Expectations <ul style="list-style-type: none"> <li>To eat what he wants when he wants</li> <li>To prepare a recipe for bœuf bourguignon de la France</li> <li>To manage his budget and grocery list with assistance</li> </ul> </li> <li>Agreed to participate in the project but said that he does not need help to cook</li> </ul>
Resident 3	<ul style="list-style-type: none"> <li>Male, aged 55 years</li> <li>Severe TBI, 10 years since TBI</li> <li>15 years of education</li> <li>Several food allergies</li> <li>Deafness, lack of dexterity with his right hand, and balance problems</li> </ul>	<ul style="list-style-type: none"> <li>Very slow processing visual information</li> <li>Difficulty alternating between 2 concepts but able to plan and solve problems in some contexts</li> <li>Difficulty with episodic memory with no improvement when the material is repeated and loss of the information after a delay</li> </ul>	<ul style="list-style-type: none"> <li>Perception: open to using the ATC and not anxious because he had used technology in his work before his TBI</li> <li>Frequently uses his computer to search for information on the internet</li> <li>Expectations <ul style="list-style-type: none"> <li>To have the possibility of eating alone in his apartment</li> <li>To cook simple meals (soup) for his evening snacks</li> <li>To be able to prepare pasta</li> </ul> </li> <li>Generally collaborative, but this varied over time</li> </ul>

<sup>a</sup>ATC: assistive technology for cognition.

<sup>b</sup>TBI: traumatic brain injury.

## Life Habits

### Overview

Before their TBIs, resident 1 and resident 3 were completely independent in managing their life habits and social roles, including cooking. Resident 1 used to be a chef. Resident 2 had his TBI at the age of 5 years. Independence in meal preparation after his TBI at the residence is presented in the following sections.

Overall, the 3 residents were dependent on others for carrying out at least one life habit and were under a trusteeship to manage their finances. All 3 required 24-hour supervision owing to the high level of verbal assistance needed to facilitate their functioning and to ensure their safety. All of them relied on cafeteria services for their meals. None had permission to use a stove, and all were dissatisfied with their functioning in meal

preparation. The detailed profile of each resident is presented in the following section.

### *Resident 1—Independence in Meal Preparation at the Residence*

Before his TBI, resident 1 worked as a cook in restaurants and was, therefore, able to prepare complex meals. He enjoyed creating new healthy recipes for himself. At the onset of the project, resident 1 generally ate a simple breakfast (eg, a muffin) in his apartment and all other meals at the cafeteria. Hence, for the last 20 years, resident 1 had not cooked any meals, except for the few times when his cooking ability was assessed in rehabilitation or to help a friend during a visit.

In general, based on the IADL Profile, resident 1 was able to independently formulate a goal, plan, and carry out a well-known simple meal preparation using the stove, without

a recipe, and verify the attainment of the goal. However, he needed verbal assistance to carry out a new recipe that was given to him. For example, he had to reread certain parts of the recipe 4 to 5 times to remember the cooking time and temperature required for baking cookies; he still made mistakes with both. Potential risks were identified, such as forgetting something on the burner while consulting social media, eating raw beef, handling a hot plate in a dangerous manner, using the stove as a place to store plates but forgetting to remove them when turning on the stove, and carrying boiling water in an unsafe manner. In addition, he was exhausted at the end of the evaluation. The major issues for him were, therefore, distractibility, energy management, and difficulty in remembering information over a short period of time (ie, remembering the cooking time until he programmed the timer). His level of fatigue also had an impact on his level of anxiety, an observation that was confirmed by the evaluation as well as by the staff and resident 1's mother.

An important element was reported by the mother. She told the evaluator that the evaluations seemed to have had a very positive impact on his self-awareness and on his functioning in general. She told the evaluator, "I don't know what you did with him, but please continue. He has never been so aware of his difficulties in the last 20 years" (note from memos). Resident 1 also demonstrated a capacity to learn. After the first IADL Profile assessment, he received feedback on safety issues; he then modified all his behaviors accordingly during the second evaluation.

Resident 1 prepared an average of 7 simple meals per week in his apartment, preparing only breakfast (eg, toast or muffin with coffee) with no stove access.

### ***Resident 2—Independence in Meal Preparation at the Residence***

Resident 2 had sporadically worked for a few hours per week as an assistant cook in different restaurants. He mentioned difficulties when preparing meals, such as forgetting to turn off the tap or burner if he was distracted at work. Before being involved in the study, resident 2 ate most of his meals at the residence's cafeteria but frequently ordered fast food from the restaurant, although he was struggling financially. He frequently ate the same type of food. He cooked easy meals that did not require him to follow recipes (eg, macaroni) in a microwave oven or on an electric cooking plate (discreetly and illegally) in his apartment.

The IADL Profile was very difficult to administer to this participant, and the evaluator had to make major modifications to the presentation of the evaluation because of resident 2's behavioral problems. He cooperated during the first evaluation, although he needed assistance in choosing the recipe and did not want to be videotaped. However, he was able to prepare the meal (ie, macaroni with meat and vegetables) without difficulty or any safety issues. The second evaluation was more difficult to administer, because he refused to use the oven to cook and made a Caesar salad with baked chicken, for which the evaluator (SP) had to provide a considerable amount of assistance in formulating the goal and planning. He was able to carry out the task and verify the attainment of the goal by himself. He refused

to undergo a third evaluation. To complete the assessment, the evaluator had to change the evaluation approach toward a more collaborative one by suggesting that they *make a meal together*. During this meal preparation involving the use of a recipe, he had difficulty reading and understanding the information as well as calculating the quantities. Therefore, he needed a considerable amount of verbal assistance to carry out the meal. During the evaluation, the evaluator noted a lack of hygiene: he did not wash his hands after manipulating the cat litter while he was cooking and was not motivated to clean up after meal preparation; upon the evaluator's insistence, he asked for help in cleaning and said that he did not care about cleanliness. During all 3 meal preparations, the main safety issues noted for resident 2 were the risk of food poisoning because of hygiene issues that did not appear to bother him (eg, not cleaning before and after cooking, manipulating food and cat litter at the same time, and not cleaning up dead flies and dirty dishes), the risk of falling because of the presence of a cat, the risk of fire owing to forgetting something on the stove while stepping outside to smoke, and the poor organization of his apartment (paper and objects lying around, and on the stove).

The staff and rehabilitation professionals also noted issues related to perseveration and hygiene. According to the observations made by his health professionals, resident 2 had difficulty diversifying his menu over a 1-week period and tended to repeatedly eat the same foods (eg, he ate Caesar salad every day for a whole month). They also reported that he had difficulty cleaning his apartment, more precisely in initiating the activity and required prompts to do so. The staff also identified safety issues related to cooking, because resident 2 was cooking food with a propane camping stove in his apartment (it was removed from the apartment when the staff became aware of it).

### ***Resident 3—Independence in Meal Preparation at the Residence***

Resident 3 mentioned being a good cook before his TBI through following recipes. He avoided restaurants because of his severe food allergies. Since his TBI, he has never had the occasion to cook again.

During the first IADL Profile evaluation, he formulated the goal of preparing a meal independently and decided to prepare a simple minestrone soup following a recipe in a cookbook. During subsequent evaluations, we observed that he functioned better with a recipe than without, because he did not have to improvise. He prepared his shopping list independently, based on the ingredients in the cookbook. He also used his list adequately when at the grocery store. However, he was dependent on the evaluator to verify whether the ingredients were safe for him to eat, considering his allergies. In fact, he twice bought ingredients that were dangerous for him, and planned to eat them anyway, despite extensive cautionary verbal guidance from the evaluator. He was unable to adequately self-evaluate the goal attainment for preparing a meal, despite extensive verbal assistance. Moreover, he consistently said that he had adequately attained his goal even if the final meal was not of good quality and did not meet the initial task instructions (ie, inviting a guest for a meal). He served only broth to his guest and went to the cafeteria to eat instead of eating the meal

he had prepared for himself and his guest. Other safety issues were noted regarding improper use of the stove (difficulty using the controls properly) and lack of hand hygiene before and during cooking. He also mentioned his concern about not being able to smell burning food because of anosmia. Resident 3 did not cook at all in his apartment.

Residence and rehabilitation staff were worried about his inability to manage his allergies. An incident of mismanagement of his allergies once sent him to the emergency room, despite very attentive and cautious cafeteria services. Therefore, he was considered dependent on another person to buy food that contained none of his allergens.

### Environments

All 3 residents lived alone in a 3 and a half apartment at the supported-living residence. Each apartment had an open-concept floor plan for the kitchen and living room, a bedroom, and a private bathroom. Possession and use of standard stoves were prohibited for safety reasons. Each apartment was equipped with 3 emergency call bells, and cafeteria services (3 meals per day) were available in the building. The social environment of these 3 participants included (1) caregivers (resident 1: mother, resident 2: mother, and resident 3: none); (2) residence staff who were on site 24/7 to provide supervision and support; (3) health professionals employed by the rehabilitation center affiliated with the residence, who carried out intervention plans; (4) residence manager, who managed staff and the logistics of the residence; and (5) coordinator of the research projects' clinical team, who was trained in occupational therapy.

### Clinical Requirements for Designing the ATC

From evidence-based practice guidelines in TBI [23,53], the team identified six types of approaches for cognitive interventions: (1) compensating for the cognitive deficits with external aids (eg, using a calendar or smartphone to manage a

schedule), (2) modifying environmental factors (eg, turning the television off when engaging in a complex task such as cooking), (3) incorporating strategies to promote generalizations by increasing the metacognition of the person with regard to his difficulties and ability to find solutions and providing education, (4) task-specific training to engage the person in meaningful activity in their own environment, (5) metacognitive strategy training (eg, Cognitive Orientation to Occupational Performance [55] or multicontext approaches [56,57]), and (6) restorative treatment such as training to address specific cognitive deficits (eg, training attentional capacities).

For the ATC design, the team selected three of these evidence-based intervention approaches based on the difficulties identified in the 3 participants [23]: (1) task-specific training to facilitate the learning of new routines in meal preparation, (2) compensation interventions or external strategies to compensate for cognitive impairments, and (3) metacognitive strategy training (specific to meal preparation or otherwise). These approaches were in line with the team's intention to develop an ATC with both restorative and compensatory functions. Table 3 presents the interventions selected to address and provide support for the residents' difficulties.

Clinical requirements for promoting safety and limiting the impact of cognitive impairments are presented in Tables 4 and 5. The goals chosen for the ATC were to support independence, functioning, and safety during a meal preparation task. Supporting *independence* means that the ATC must allow residents to cook in their residences independently, safely, and without human assistance. Supporting *functioning* means that the ATC must support the person during the actual meal preparation. Supporting *safety* means that the ATC must ensure not only the safety of the participants within their individual apartments but also that of the residence where several other people with cognitive impairments also live.



**Table 3.** Cognitive intervention plan for each participant.

Participant and main challenges interfering with meal preparation	Approaches	Specific interventions
<b>Resident 1</b>		
<ul style="list-style-type: none"> <li>• Impaired awareness</li> <li>• Fatigability and anxiety</li> <li>• Distractibility</li> <li>• Working memory deficits</li> <li>• Forgetting to plan side dish</li> <li>• Difficulty following recipes</li> <li>• Unsafe behavior</li> </ul>	<ul style="list-style-type: none"> <li>• Increasing awareness</li> <li>• Metacognition</li> </ul>	<ul style="list-style-type: none"> <li>• Video feedback [58]: identifying the behaviors that need to be modified</li> <li>• COOP<sup>a</sup> global strategy [55]</li> <li>• Energy management: identifying more demanding activities</li> <li>• Schedule management: avoiding planning to do 2 tasks at the same time to facilitate energy management</li> <li>• Time pressure management [59]</li> <li>• Pacing [60]</li> </ul>
	<ul style="list-style-type: none"> <li>• Education</li> </ul>	<ul style="list-style-type: none"> <li>• Training on safety issues surrounding cooking: increasing level of knowledge about safety to help change behavior</li> </ul>
	<ul style="list-style-type: none"> <li>• Task-specific compensation</li> </ul>	<ul style="list-style-type: none"> <li>• Logbook [60]: writing down any ideas or concerns not related to the cooking task to avoid internal distractors</li> <li>• Stop and think [23]: a stop sign as a reminder to concentrate on the cooking task</li> <li>• Reminders to modify behavior before and during the task: (eg, do not eat raw meat and check oven before cooking)</li> <li>• Checklist to integrate better habits; for example, check before cooking that your Facebook and phone are turned off and the sign on the door is in place (do not disturb)</li> <li>• Adaptation (recipe presented on a single page, highlight vital information, etc) and repetition of recipes (spaghetti sauce recipe)</li> <li>• Human assistance for grocery shopping and budget management</li> </ul>
<b>Resident 2</b>		
<ul style="list-style-type: none"> <li>• Abstraction and attention difficulties</li> <li>• Safety behavior</li> <li>• Difficulty following recipes</li> <li>• Apartment-cleaning issues</li> <li>• Difficulty preparing a balanced meal plan for the week that includes healthy choices and not eating the same thing every day</li> </ul>	<ul style="list-style-type: none"> <li>• Task-specific compensation</li> </ul>	<ul style="list-style-type: none"> <li>• Integration of a routine to clean before and after the task with checklist, reminders, and human assistance</li> <li>• Support in developing a weekly meal plan: schedule, list of healthy meals selected with him, and human assistance to plan</li> <li>• Positive behavior reinforcement regarding cleaning</li> <li>• Adaptation of the recipe and repetition of recipes important for him</li> <li>• Human assistance for grocery and budget management</li> </ul>
	<ul style="list-style-type: none"> <li>• Education</li> </ul>	<ul style="list-style-type: none"> <li>• Training on safety issues related to cooking: increasing level of knowledge about safety to modify his behavior</li> </ul>
<b>Resident 3</b>		
<ul style="list-style-type: none"> <li>• Allergy management</li> <li>• Difficulty with his selective attention</li> </ul>	<ul style="list-style-type: none"> <li>• Task-specific compensation</li> </ul>	<ul style="list-style-type: none"> <li>• Reminders and human assistance when purchasing ingredients at the grocery store and follow-up home verification of potential allergens before cooking</li> <li>• Adaptation of recipes to facilitate meal preparation</li> </ul>
	<ul style="list-style-type: none"> <li>• Education</li> </ul>	<ul style="list-style-type: none"> <li>• Training on safety issues related to cooking: increasing level of knowledge about safety to modify his behavior</li> </ul>

<sup>a</sup>COOP: Cognitive Orientation to Occupational Performance.

**Table 4.** Translation of security needs into clinical requirements.

Safety needs and clinical requirements <sup>a</sup>	Prioritization <sup>b</sup>
<b>Decrease risk of fire or injury if stove left unattended during cooking</b>	
1 and 2— <i>Verbal and visual assistance</i> (prompting): ask user to watch what is on the stove when needed ( <i>at the right moment; context-aware</i> )	2
3— <i>Compensation</i> : the ATC <sup>c</sup> must shut down the stove if the user steps away and does not return to watch what is on the burners	1
<b>Decrease risk of fire or injury if burner left turned on and forgotten</b>	
1 and 2— <i>Verbal and visual assistance</i> (prompting): ask the user to turn off the burner	2
3— <i>Compensation</i> : turn off the stove if the user does not turn off the burner	1
<b>Decrease risk of injury if oven door left open and forgotten</b>	
1 and 2— <i>Verbal and visual assistance</i> (prompting): ask user to close the oven door	2
<b>Support routine about hygiene and cleanliness management</b>	
2— <i>Verbal and visual assistance</i> (prompting): remind user about good hygiene habits (eg, wash hands before cooking)	2
<b>Support routine checking of expired food to prevent food poisoning</b>	
2— <i>Verbal and visual assistance</i> (prompting): provide relevant information on expiry dates of prepared foods	3
<b>Decrease risks related to severe allergies</b>	
3— <i>Compensation</i> : prevent user from cooking before ingredients are verified by an employee	1
2— <i>Verbal and visual assistance</i> (prompting): remind user to check if he has his EpiPen (allergy emergency medication) before cooking	2
3— <i>Compensation</i> (supervision): only allow the employee to reactivate the stove after the safety lock has been activated	1

<sup>a</sup>1: detect the problem, 2: warn or assist the person, and 3: compensate for the problem.

<sup>b</sup>1: essential, 2: ideal, and 3: optional.

<sup>c</sup>ATC: assistive technology for cognition.

**Table 5.** Translation of cognitive needs into clinical requirements.

Cognitive needs	Clinical requirements <sup>a</sup>	Prioritization <sup>b</sup>
Support planning (eg, choose recipe and diversify menu)	2— <i>verbal and visual assistance</i> : support planning process by asking directed (or orientated) questions	2
Support difficulties in carrying out the recipes (eg, errors)	3— <i>task and environment adaptation</i> : types of recipes and the way in which recipes are presented must be adapted. Adaptations such as, for example, different colored measuring cups must be available to support these difficulties	2
Reduce internal distractions	2— <i>provide logbook</i> : provide a logbook that the user can use to discard his “distracting” thoughts and ideas before and during the task	2
Reduce external distractions	2— <i>provide reminders</i> and contribute to <i>increased awareness</i> : remind user to reduce distractors before starting the task	1
Manage fatigability	2— <i>pacing</i> : support the user’s planning of required breaks during the task	2
Manage fatigability	3— <i>reminder</i> : remind and request that the user take a break at the right time during the task	3

<sup>a</sup>1: detect the problem, 2: warn or assist the person, and 3: compensate for the problem.

<sup>b</sup>1: essential, 2: ideal, and 3: optional.

For independence, it was determined that the ATC should increase the number of meals prepared over a 1-week period. For functioning, it was determined that the ATC had to reduce performance errors. For safety, it was necessary to reduce errors leading more specifically to safety issues. If errors could not be avoided with the support of the ATC, human intervention would be planned in advance and, in certain instances, given as a

preventive measure to ensure safety (eg, checking for potential food allergies in the grocery bag).

The research team translated each safety and cognitive need into design specifications. For example, to decrease the risks of fire, the clinical requirements were that the ATC had to (1) detect when the stove was left unattended (the problem), (2) warn the person about the problem, and (3) compensate by turning off the stove if the person did not react to the warning.

The team determined that assistance would be provided both verbally and visually. Once all requested functionalities had been listed, they were prioritized by the team so that the ATC would support an *Agile* development method [61] and, more specifically, use a feature-driven development method [62] that would address each future user's needs one at a time, progressively adding specific features as needed. This iterative and incremental approach was used to guide the development of a series of functional prototypes.

## Discussion

### Principal Findings

This study presented a needs analysis as the first phase of designing an ATC, named COOK, to support independence and safety in meal preparation for individuals with severe TBI and living in a supported-living residence. Using a UCD method, the needs analysis included two steps: (1) identifying the future users' profiles, including their difficulties with meal preparation and (2) identifying the clinical requirements for the design of an ATC to support meal preparation based on the risks and future users' profiles. The results showed that many issues had to be considered for the development of COOK for the 3 residents, including cognitive issues such as distractibility and difficulty remembering information over a short period of time and important safety issues, such as potential food poisoning and risk of fire on the stove. These issues led to two main clinical requirements to be developed by the team: (1) providing cognitive support based on evidence-based cognitive rehabilitation to facilitate meal preparation and (2) ensuring safety at each step of the meal preparation task. Our results also showed that using multiple sources of data, including the perspectives of the multiple stakeholders involved, led to an in-depth needs analysis that considered all the difficulties faced by the 3 residents.

The cognitive profiles that were documented in this study were consistent with the most frequent ones following severe TBI, including distractibility, problem-solving difficulties, difficulty remembering information, fatigue, and behavior problems [63,64]. Hence, this first prototype of COOK is based on 3 cognitive profiles but nonetheless responds to the most frequently documented difficulties of the population with chronic severe TBI. The addition of more functionalities to make it useful for individuals with a broader range of cognitive difficulties was planned as a subsequent step to this study in the ongoing iterative and UCD of the ATC. Other recent work on COOK has expanded its validation by testing its suitability for use by other persons having sustained a TBI or living with neurodegenerative diseases. Results from these other studies have shown that COOK's main functionalities are well suited for a broader group of individuals with TBI [65-68] as well as in the continuum from normal aging to early Alzheimer disease [69].

Evidence-based cognitive interventions included in COOK comprise 3 recognized rehabilitation approaches: task-specific training, compensation interventions, and metacognitive strategies [23]. Although other approaches exist, these are the most recommended in the field of cognitive rehabilitation for

TBI [23,53], making COOK a technology that can provide cognitive support to a large number of persons with TBI. Integrating evidence-based interventions for a TBI clientele in the design of an ATC is an emergent design strategy that will improve future efficacy. In the specific context studied here, the ATC will be a new intervention option to facilitate resumption of meal preparation, so it is essential to explore evidence-based practice guidelines in designing it [2,23,53]. In this study, we addressed the limitations of other existing prototypes to support meal preparation, which only integrated a step-by-step approach into the ATC [21]. In the future, adding other metacognitive strategies and educational approaches to the design of this ATC will provide greater flexibility to clinical specialists who will then be able to adjust the technology to various and complex needs.

As for the elements related to safety, to our knowledge, this study is the first to document, with specific details, the safety elements related to meal preparation in TBI. The main safety issues were the risks of stove fire and food poisoning. Exploring the risks related to meal preparation in this study showed that this is a complex activity with many safety issues, and these risks are exacerbated by cognitive impairments [70]. Indeed, being safe at home requires a person to be able to identify potential risks and hazards when cooking, develop and implement problem-solving strategies when they occur [71], and then evaluate the results of the strategy put in place [72]. However, persons who have sustained a severe TBI have difficulty recognizing situations of risk and solving problems, which in turn compromises their safety at home [73]. For these reasons, high-risk situations specific to meal preparation identified in this study (eg, serious food allergies) may not be fully addressed by technology and may still require human assistance to ensure safe meal preparation. This study also showed that meal preparation includes related tasks (eg, grocery shopping and budget management), which require the implementation of complementary interventions to the ATC to facilitate greater social participation. To our knowledge, this is the first time that an ATC was developed considering not only the support for one particular activity but also for a wide range of other elements, including other closely related activities. This study illustrates the importance of considering the complex interactions between personal factors, environments, and life habits, when developing and using an ATC, especially when the activity is complex and poses a high risk for a person's safety.

### Strengths and Limitations

This study has several strengths. First, multiple sources of data and stakeholder perspectives were used to identify needs related to meal preparation, which increases the validity and generalizability of the results [29]. In this needs analysis process, the IADL Profile evaluation was found to add valuable information about the participants. Its nondirective approach provided a thorough understanding of the degree of independence that participants were able to sustain during a complex activity. The IADL Profile evaluation also helped to identify whether participants were able to find solutions and correct their errors related to meal preparation and safety issues, as well as what kind of assistance they needed. This evaluation

is also congruent with the proposal by De Vito Dabbs et al [29] of completing a contextualized evaluation where the goal is simply to learn how users perform their tasks. De Vito Dabbs et al [29] proposed that the evaluator is the apprentice of sorts, and the user is the expert, which is in line with the underlying nondirective approach inherent to the administration of the IADL Profile. To our knowledge, our study is the first to detail the specific needs of persons with TBI in the context of a UCD study with such an evaluation.

Second, in this study, clinical professionals with an occupational therapy background led the needs analysis, and the design team perceived this to be an important strength, because it allowed for a detailed specification of the clinical requirements. Although completing a detailed and exhaustive evaluation of individuals with such severe injuries is time consuming, as it requires direct observation of performance, it is essential for the development of new technology for a proper understanding of the end user's competence and needs.

Third, the use of an intervention plan as a means of facilitating communication between the clinical and technological teams facilitated the integrative synthesis essential to interdisciplinary work and clearly supported the exchanges between the supported-residence stakeholders and clinical and computer scientists collaborating on this project.

This study has some limitations that are important to consider. First, a limited number of housing resource residents participated in the design process. However, as noted earlier, the main cognitive profiles and cognitive rehabilitation approaches implemented in COOK are representative of the needs and clinical strategies that are most frequent in the TBI population. It is to be expected that the completion of more studies on

COOK, with more persons with cognitive impairments, will improve the generalizability of the interventions provided by the ATC to different cognitive profiles. Second, the study was conducted in the specific context of a residence with supervised assistance provided 24/7. Thus, the results are only applicable in this specific context, as expected in a living laboratory project based on the needs of a specific group of stakeholders such as in our study. Future studies on COOK will need to determine whether these results can be applied to other living contexts such as persons with TBI living alone in their homes in the community or in other supported residences. Preliminary results indicate that COOK is also promising in these other contexts [65-68], although some modifications may be necessary to tackle their specificities such as the absence of 24/7 supervision.

## Conclusions

This study aimed to determine the design requirements for a new ATC, named COOK, to support meal preparation for persons with severe TBI. Here, we have reported the first steps of the development process. Results of the needs analysis showed that safety and cognitive support were the 2 main categories of needs that required an ATC. Evidence-based interventions were identified to guide the design of an ATC that can support these needs, using an empirically based foundation. This paper also proposed interesting tools to support interdisciplinary work to design an ATC, such as the use of a common framework and a detailed functional evaluation based on observation methods. The next step involved developing COOK and implementing it in the residence to evaluate and improve its usability [34] as well as validating its use with other persons with a wide variety of cognitive deficits and in different living contexts.

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## Authors' Contributions

SP contributed to the protocol development, data collection and analysis, and manuscript writing. CB, MC, and NB contributed to the protocol development, analysis of the results, and writing and revision of the manuscript. CL contributed to data collection and analysis as well as revision of the manuscript. HP, SG, and MO contributed to the protocol development and collaborated to translate the needs into clinical requirements for facilitating the design. They also contributed to the revision of the manuscript. AA contributed to the writing and revision of the manuscript. All coauthors have approved the manuscript.

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## Conflicts of Interest

None declared.

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## Abbreviations

**ADL:** Activities of Daily Living  
**ATC:** assistive technology for cognition  
**COOK:** Cognitive Orthosis for Cooking  
**IADL:** Instrumental Activities of Daily Living  
**TBI:** traumatic brain injury  
**UCD:** user-centered design

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Original Paper

# The Redesign and Validation of Multimodal Motion-Assisted Memory Desensitization and Reconsolidation Hardware and Software: Mixed Methods, Modified Delphi–Based Validation Study

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## Abstract

**Background:** In recent years, the delivery of evidence-based therapies targeting posttraumatic stress disorder (PTSD) has been the focus of the Departments of Defense in countries such as Canada, the Netherlands, and the United States. More than 66% of military members continue to experience symptoms of PTSD that significantly impact their daily functioning and quality of life after completing evidence-based treatments. Innovative, engaging, and effective treatments for PTSD are needed. Multimodal motion-assisted memory desensitization and reconsolidation (3MDR) is an exposure-based, virtual reality–supported therapy used to treat military members and veterans with treatment-resistant PTSD. Given the demonstrated efficacy of 3MDR in recently published randomized control trials, there is both an interest in and a need to adapt the intervention to other populations affected by trauma and to improve accessibility to the treatment.

**Objective:** We aimed to further innovate, develop, and validate new and existing hardware and software components of 3MDR to enhance its mobility, accessibility, feasibility, and applicability to other populations affected by trauma, including public safety personnel (PSP), via international collaboration.

**Methods:** This study used a modified Delphi expert consultation method and mixed methods quasi-experimental validation with the purpose of software validation among PSP (first responders, health care providers) participants (N=35). A team of international experts from the Netherlands, the United States, and Canada met on the web on a weekly basis since September 2020 to discuss the adoption of 3MDR in real-world contexts, hardware and software development, and software validation. The evolution of 3MDR hardware and software was undertaken followed by a mixed methods software validation study with triangulation of results to inform the further development of 3MDR.

**Results:** This study resulted in the identification, description, and evolution of hardware and software components and the development of new 3MDR software. Within the software validation, PSP participants widely acknowledged that the newly developed 3MDR software would be applicable and feasible for PSP affected by trauma within their professions. The key themes that emerged from the thematic analysis among the PSP included the desire for occupationally tailored environments, individually tailored immersion, and the applicability of 3MDR beyond military populations.

**Conclusions:** Within the modified Delphi consultation and software validation study, support for 3MDR as an intervention was communicated. PSP participants perceived that 3MDR was relevant for populations affected by trauma beyond military members and veterans. The resulting hardware and software evolution addressed the recommendations and themes that arose from PSP participants. 3MDR is a novel, structured, exposure-based, virtual reality-supported therapy that is currently used to treat military members and veterans with PTSD. Going forward, it is necessary to innovate and adapt 3MDR, as well as other trauma interventions, to increase effectiveness, accessibility, cost-effectiveness, and efficacy among other populations affected by trauma.

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## KEYWORDS

multimodal motion-assisted memory desensitization and reconsolidation; multimodal motion-assisted memory desensitization and reconsolidation; 3MDR; participants; therapists; patients; military; virtual reality; mobile phone

## Introduction

### Background

Military service commonly involves engagement in high-risk activities, whether during physical training, daily trade-related tasks, overseas deployment, or in response to natural disasters. Such activities place military members, individually and collectively, at a heightened risk of physical and psychosocial injury. They are also more likely to have increased exposure to highly traumatic and stressful events [1] and exhibit higher rates of injuries and illnesses, such as posttraumatic stress disorder (PTSD), depression, anxiety, sleep disorders, and mild traumatic brain injury compared with civilians [2,3]. In Canada, approximately 11% of military members and 16% of veterans experience PTSD [4]. In the United States, the prevalence of combat-related PTSD ranges from 1.09% to 38.84% [5]. The rate of probable PTSD among UK military personnel has been reported to be 6.2%, and among veterans who had been deployed in combat roles, it was 17.1% [6,7]. In Australia, approximately 8.3% of Defense Force members will have experienced PTSD [8]. Among currently serving and retired military personnel in New Zealand, 30% had symptoms of posttraumatic stress, and 10% had clinically relevant posttraumatic stress [9].

Hypervigilance, impaired cognition, comorbid mood and anxiety disorders, and significant functional and relational sequelae are associated with PTSD [1]. Military members and veterans are also more prone to developing moral injury than civilians, which is the persistent distress that can evolve from exposure to potentially morally injurious events, including perpetrating, witnessing, or failing to prevent an act that transgresses core beliefs [10-13]. Up to 67% of military members are exposed to potentially morally injurious events during deployment, the sequelae of which have not yet been fully explored, although it has been suggested that moral injuries might contribute to treatment-resistant PTSD (TR-PTSD) [14,15].

### Trauma-Focused Therapies and TR-PTSD

The delivery of evidence-based therapies specifically targeting posttraumatic stress throughout the military health care system has been the focus of the Departments of Defense in numerous

countries, including Canada, the Netherlands, and the United States. Greater than 66% of military members who complete first-line treatments for PTSD continue to experience symptoms that significantly affect their daily functioning and quality of life [16]. Even in those responsive to treatment, PTSD symptoms often persist at or above the diagnostic thresholds for PTSD, with approximately 60% of patients retaining the diagnosis [17,18]. The effectiveness of these first-line psychotherapies is hypothesized to be limited because of cognitive avoidance and premature treatment dropout [19,20]. The reasons for higher dropout rates among this population vary but may include geographical proximity to services, perceived stigma from self and others, challenges managing operational demands of a military career with therapy attendance, barriers to establishing patient-therapist rapport, and the aforementioned issues with treatment effectiveness [19,20].

The classification of TR-PTSD has been adopted for military members and veterans who do not experience a clinically significant reduction in symptoms following the receipt of at least two evidence-based treatments [21,22]. As knowledge of TR-PTSD is limited, general recommendations for TR-PTSD have been suggested. However, specific protocols or evidence-based TR-PTSD therapies are lacking, complicating clinical attempts to address or manage this condition. Consequently, more innovative and effective treatments are needed to assist military members, veterans, and other populations affected by trauma in rehabilitation and recovery from PTSD and occupational stress injury.

### Multimodal Motion-Assisted Memory Desensitization and Reconsolidation

Multimodal motion-assisted memory desensitization and reconsolidation (3MDR) is a personalized, exposure-based, virtual reality (VR)-supported intervention developed in the Netherlands and is being used with military members and veterans with PTSD in the Netherlands, the United Kingdom, the United States, Israel, and Canada [23]. 3MDR enhances visual and auditory immersion by incorporating patient-selected images and music into the therapy and helps patients access traumatic memories as they walk toward images that remind

them of those experiences [24]. The treatment shows promise for breaking through persistent avoidance and optimizing engagement in military members and veterans with TR-PTSD [25,26]. Two recently published randomized controlled trials conducted with veterans with TR-PTSD have contributed to the evidence base regarding the effectiveness of 3MDR [27,28]. Further studies are also underway.

For 3MDR, treadmill walking on a flat surface was chosen as the method of moving forward (literally and metaphorically) versus using other devices, such as a stair climber, which involves other movement patterns and requires more engagement of energy systems and cardiorespiratory abilities. As walking is a basic form of human movement that engages multiple processes and areas of the brain, it has been hypothesized that the act of moving forward through ambulation is integral to 3MDR and may increase divergent thinking abilities, thereby allowing previously held negative cognitions related to trauma to be challenged. In addition, a harness can be easily attached and added to a treadmill setup, making it a safer option than using other movement devices or virtual boundaries (ie, VR or augmented reality [AR] headset systems such as Oculus, Google Glass, or Microsoft's HoloLens).

The 3MDR application was originally designed to be used on a large-scale, immersive VR-based system called the Motek Computer Assisted Rehabilitation Environment (CAREN; Figure

1) and the Gait Realtime Analysis Interactive Lab (GRAIL; Motek Medical BV) [29]. These were designed as dedicated solutions for gait analysis and training under challenging conditions to improve gait patterns. CAREN is a room-sized dynamic system that includes a motion platform that can translate and rotate in all directions. The platform contains an embedded, centrally located treadmill that moves in synchronization with the virtual environments projected onto a large curved screen. The package contains real-time feedback and user-friendly assessments and applications. The GRAIL originally used an instrumented dual-belt treadmill with optional pitch and sway, a motion capture system, video cameras, and synchronized VR environments (VREs). The treadmill's ability to measure forces and the independent control of left and right treadmill belt speeds has allowed a split-belt walking protocol and advanced gait research applications that can mimic tripping or slipping. The 3MDR application has progressively evolved to include other hardware options (ie, CAREN Lite) since the initial proof of concept was piloted in 2011 [23]. These versions of 3MDR hardware allowed for preliminary research to assure participant safety with clear, tangible boundaries as opposed to virtual ones, as experienced within the VR or AR headset systems. This was especially important at the time of the intervention's developmental process when there were still many unknowns about the participant's experience of 3MDR and the responses it may elicit.

**Figure 1.** Multimodal motion-assisted memory desensitization and reconsolidation therapists and a participant in the Computer Assisted Rehabilitation Environment system.



The 3MDR intervention comprises 10 sessions, including selecting images and music, trauma processing and reconsolidation, and six 90-minute therapy sessions in the VRE, including a 30-minute debriefing. The 3MDR sessions include a *preplatform session* (session 1), during which the patient selects and orders images and music. Symbolic representations in the form of images (ie, photographs and sketches) related to their traumatic experiences are selected and ordered from least to

most distressing. Music that reminds the patient of the past time of trauma and facilitates the emotional memory network is also identified, which supports a return to the present (ie, a second contemporary piece that is soothing, compassionate, and joyful). Sessions 2 to 7 are *platform sessions* that involve 3 phases. In the *preplatform phase* of the session, the therapist and patient confirm the order of images and music for the session. During the *platform phase*, the patient dons a safety harness and is

accompanied by a 3MDR therapist while walking continuously on a treadmill at a self-selected pace. The patient first warms up by walking on the treadmill while listening to self-selected music, which connects them to their traumatic experiences, and then, during each of seven 3 to 5 minutes cycles, walks down a virtual *hallway* toward a self-selected trauma-related image. The patient describes the image, physical sensations, and feelings to the therapist. The therapist then assists the patient with generating descriptive words and phrases that are then projected in front of the image on the screen. The patient is then instructed to read the words and phrases out loud. For a duration of 30 seconds, the patient then reads aloud numbers as they appear on a ball oscillating horizontally in the foreground of the image and words. The patient cools down after the seventh cycle by walking while listening to self-selected music, which facilitates a reconnection to the present. Each session concludes with a *postplatform phase*, which includes discussion, reconsolidation, a mental wellness check, and a self-care plan. *Postplatform sessions* 8 to 10 focus on reconsolidation and contribute to meaning making of the acquired gains and emotional release. More in-depth descriptions of 3MDR have been published elsewhere [25,30].

### Challenges With the Current Iteration of 3MDR

Recently, published randomized controlled trials have demonstrated the efficacy of 3MDR therapy among military and veteran populations who experience combat-related TR-PTSD and indicate that 3MDR is ready for trials with various populations affected by trauma in real-world contexts [27,28]. However, access to the CAREN VREs used to deliver 3MDR in earlier studies is limited because of the cost and infrastructure required by these large systems and the reality that only limited international partners in the Netherlands, Tel Aviv, the United States, the United Kingdom, and Canada have access to equipment currently used to deliver the intervention. 3MDR systems that are mobile, customizable, accessible, cost-effective, and adaptable to other populations affected by trauma are needed to increase accessibility to treatment. There is a sense of urgency in the 3MDR international consortium to develop further systems, particularly in light of their need within military and veteran populations, as well as among other populations affected by trauma. The COVID-19 pandemic has acted as a reminder that emergency medical professionals and first responders, among others, also require access to innovative and effective evidence-based treatments.

Despite the urgent need for accessible interventions for PTSD, a barrier to the expanded access to 3MDR in community-based health service contexts is the use of equipment and technologies approved by the United States Food and Drug Agency and Health Canada. Although these approvals are imperative to protect the health and safety of patrons of health care systems, the approval process requires the determination of appropriate hardware (eg, treadmills, projection systems, and AR equipment)

and the development of software that is adaptable for various populations. Provision of research and evidence demonstrating equipment validity, safety, efficacy, and effectiveness specific to the target demographic is the first step toward improving access to novel interventions with technological applications. Now that research has demonstrated that 3MDR holds promise, new research may involve the exploration of adaptations including the delivery of 3MDR via more mobile, affordable, and immersive mechanisms, such as AR headsets, and to additional populations affected by trauma.

### Purpose

The purpose of this mixed methods study was to further innovate, develop, and validate new and existing hardware and software components of 3MDR to enhance the mobility, accessibility, feasibility, and applicability of 3MDR for other populations affected by trauma, including public safety personnel (PSP), via international collaboration.

## Methods

### Project Design and Scope

This mixed methods study used a (1) modified Delphi expert consultation method and, (2) a mixed methods quasi-experimental software validation study [31].

### Modified Delphi Expert Consultation

#### Overview

The team of international experts from the Netherlands, United States, United Kingdom, and Canada comprised health care professionals (psychiatrists, psychologists, and occupational therapists), biomedical and electrical engineers, computing science experts, and graphic designers with prior experience in working with populations affected by trauma and the 3MDR system. The team met virtually on the web on a weekly since September 2020 to discuss the current and future development of 3MDR. Discussions revolved around hardware design, software design and validation, adoption of 3MDR in real-world contexts, the use of 3MDR with nonmilitary and veteran populations affected by trauma, and 3MDR therapist training. This involved consideration of the various systems that have been used for 3MDR, as well as salient features, emerging technologies, and potential future states. This manuscript focuses solely on the hardware design and software development and validation, which are described in the following section, whereas the implementation of 3MDR in community-based service contexts and training of 3MDR therapists will be included in future publications and an upcoming 3MDR training manual.

### Considerations for Hardware Design

The 3MDR system requires the components described in [Textbox 1](#). The 3MDR system must have the characteristics described in [Textbox 2](#).

**Textbox 1.** Multimodal motion-assisted memory desensitization and reconsolidation system components.

**Treadmill**

- The treadmill must be a medical-grade, clinical treadmill designed for heavy use over long periods and with patients of varying body types and compositions. The belt moves to the rear, requiring the user to walk at a speed matching the belt. The rate at which the belt moves is equal to the rate of walking. The speed of walking needs to be controlled and measured.

**Safety harness**

- A safety harness is required to prevent potential injuries due to falls. An option is to support it using a connector hanging from the ceiling. Other support options include a frame setup around the treadmill or a gantry built into the treadmill.

**Visual display**

- The visual display must be a sufficiently large screen that allows the display of images in a way that maximizes immersion. The display can be a series of mounted computer monitor screens or projection screens combined with short-throw projectors. Typically, to allow immersion, the screens must surround the person to enable the feeling of walking in the virtual reality environment. An augmented reality (AR) system provides another alternative to monitor- or projector-based display systems. Unlike a virtual reality headset, an AR headset (eg, Microsoft HoloLens 2 and Magic Leap) is neither fully opaque nor fully immersive [32]. The AR headset superimposes a digital display over the participant's regular visual field, providing a blend of virtual and real visual stimuli. AR allows patients to walk confidently as they can still see real-world anchors. The patient and therapist can also see each other, which is important for rapport during therapy and to allow the therapist to read the patient's facial cues.

**Computer**

- The computer must have graphics processing capability to drive the display system without noticeable frame dropping, which would create distracting "jerkiness" in the display.

**Treadmill or computer interface**

- There must be a means of synchronization between the treadmill's motion and the motion of the patient in the virtual environment. Options include direct control of the treadmill by a computer to match the movement in the virtual environment or sensing of the treadmill's motion by a speed sensor, which is then used to control the movement in the virtual environment.

**Eye-tracking capability**

- The ability to capture eye movement and visual avoidance or focus using eye-tracking equipment was considered.

**Textbox 2.** Multimodal motion-assisted memory desensitization and reconsolidation (3MDR) system characteristics.

<p><b>Access</b></p> <ul style="list-style-type: none"> <li>It is desirable that the system accommodates being located in community-based contexts and standard clinical settings, possibly with space limitations and noise considerations.</li> </ul> <p><b>Physical footprint</b></p> <ul style="list-style-type: none"> <li>The system must have a relatively small physical footprint such that it can be situated in standard rooms in clinical settings without extensive renovations.</li> </ul> <p><b>Portability</b></p> <ul style="list-style-type: none"> <li>Portability may be desirable for certain clinical applications (eg, mobile 3MDR operations).</li> </ul> <p><b>Therapist positioning</b></p> <ul style="list-style-type: none"> <li>The final system must allow the therapist to stand beside the patient. Discussions with patients in previous studies have indicated that this positioning is important, with patients expressing distaste for the therapist being behind or in front of them.</li> </ul> <p><b>Operation of the system</b></p> <ul style="list-style-type: none"> <li>The final system would best be managed by the therapist, without the need for a dedicated 3MDR operator, so as to enhance therapist control over the session and reduce personnel costs.</li> </ul> <p><b>Cost</b></p> <ul style="list-style-type: none"> <li>Affordability is a concern as we work toward the deployment of 3MDR systems more widely in clinical settings outside of research environments. We are currently exploring the use of off-the-shelf components to reduce costs.</li> </ul> <p><b>Acceptability or ease of use</b></p> <ul style="list-style-type: none"> <li>The system should be easy for therapists to set up, use, and adapt. It should also be able to record data and enable note-taking while therapists deliver the intervention. Visualization of changes over time is also essential to facilitate treatment planning.</li> </ul>
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## Software Design

The original 3MDR software was developed by a team in the Netherlands using the D-Flow software [29] in combination with Lua scripting. Our team of clinical and technical experts identified salient features of the original 3MDR software, as well as aspects that would benefit from redesign or further development. The new 3MDR software development was completed in the Warfighter Performance Department, Naval Health Research Center, San Diego, California, United States. As all components of the 3MDR intervention were already included in the D-Flow version, these essential components were maintained for consistency, although optimized. These included a user interface (UI) and 2 distinct visual scenes. The UI contained application settings, image selection options, and a drop-down menu to record subjective units of distress scores, which were measured as part of the 3MDR therapy. Examples

of application settings include the frequency of eye movement desensitization and reprocessing (EMDR) stimuli, which are incorporated within 3MDR therapy, and treadmill speed. The 2 visual scenes included the following:

- Warm-up or cool down scene: bright lighting and white ground with blue honeycomb overlay; open, flat, and endless
- Corridor scene: darker lighting and dark ground with red honeycomb overlay; starts with doors at a distance, which opens to the first of 2 enclosed hallways with another set of doors at a distance, which open to a second hallway at the end of which the image related to a traumatic event is visible

## Considerations for Software Design

The new 3MDR software required the components described in [Textbox 3](#).

**Textbox 3.** New multimodal motion-assisted memory desensitization and reconsolidation system components.

#### Ease of adaptation to new technologies

- The new system needs to be built on a cross-platform game engine that allows easy adaptation to new technologies and that can be ported to different devices, displaying the same visuals on different types of screens or through head-mounted displays.

#### User interface

- The new user interface should be therapist centered and user-friendly so that both operators and therapists feel confident using the application. The primary therapist interface, which mirrors the participant view, should allow the application to be configured and launched. The interface should allow session information to be input (eg, identification number, protocol number, and therapist initials), image and data folders to be selected, and site-specific settings to be chosen. Once the application is launched, secondary application-specific interfaces should appear on the operator or therapist display to control different aspects of the virtual environment. Other critical considerations include enhancing the therapist's ability to dynamically select and modify the order of the images and music; adjust the motion and speed of the oscillating ball for eye movement desensitization and reprocessing; capture and record the emotional, cognitive, and narrative associations; and record subjective units of distress scores as well as therapist notes.

#### Music selection

- Audio features must be built into the software to support the integration of patients' self-selected music within the multimodal motion-assisted memory desensitization and reconsolidation protocol.

#### Data capture and reports

- The system must provide clinical output sheet summaries generated on a per-session basis, as these are vital for treatment planning, case review, and research purposes.

### *Mixed Methods Quasi-Experimental Software Validation Study*

After the adaptation and redesign of the software and hardware, a validation study was implemented with the goal of ensuring the face validity of the new version of the 3MDR software for health care professionals and first responders. We used a mixed methods, concurrent, parallel approach following a data transformation model [31].

#### Participants

Potential participants were recruited through snowball sampling and advertising via email, social media (Facebook and Twitter), hardcopy posters in targeted work environments, and word of mouth. Potential participants were asked to positively enroll via emailing or texting the research team. Eligible participants had to be health care professionals or first responders, including police officers, firefighters, border patrol officers, nurses, physicians, physical therapists, occupational therapists, crisis management workers, corrections officers, emergency medical personnel, dispatchers, respiratory therapists, psychologists, psychiatrists, and other professionals or managers associated with these professionals within a health care setting. Participants had to be able to communicate in English; live in Canada; and have access to a digital device such as a computer, tablet, or smartphone where videoconferencing was possible.

#### Data Collection

Questionnaire data were collected and managed using the secure REDCap (Research Electronic Data Capture; Vanderbilt University) system [33,34]. The demographics questionnaire gathered information on participants' gender, age, and profession. The validation questionnaire included Likert scale questions and open-ended questions regarding various aspects of the software displayed in the demo video (ie, overall appearance, beginning scene, transition through the clouds, the

scene around the first door, ground grid, hallway, image size, ball and movement, picture fade, transition to second door and hallway, timing, visual field, and flow), the impact of 3MDR on medical condition, ease, clarity, understanding of interaction with the 3MDR system, and ease of use of the system. The validation questionnaire was developed via discussion and collaboration among 3MDR international consortium researchers in Canada, the Netherlands, and the United States.

Focus group interviews were used to collect qualitative data for the validation study. Zoom videoconferencing was used. Members of the research team received training on how to execute the focus group for fidelity and consistency. A semistandardized script ([Multimedia Appendix 1](#)) was developed to further improve the reliability. Eligible participants were scheduled for 1 of the 25 researcher-led videoconferencing focus groups in July 2021. Each focus group lasted approximately 20 minutes and had attendance ranging from 1 to 12 attendees. The researcher leading the focus group proceeded as follows: (1) provided an introduction to 3MDR via 2 videos developed by the 3MDR team in the United Kingdom, (2) provided a weblink to the web-based informed consent form through the REDCap system, (3) displayed a 5-minute demo video of the adapted 3MDR software that participants were evaluating, and (4) provided a weblink to the demographics and validation questionnaire presented in REDCap. After completing the forms, the participants left the videoconference.

#### Data Analysis

Descriptive statistics were computed for demographic characteristics and Likert scale questions regarding various aspects of the software demonstration. For a given question, the number and percentage of different answer choices selected across the participants (N=35) were computed.

The open-ended questions in the validation questionnaire were thematically analyzed by the research team using the deductive

and inductive methodology outlined by Braun and Clarke [35] in 2006. Thematic analysis involves examining the text in detail to identify recurring patterns (open coding) that are refined into themes through inductive and deductive analysis. Although deductive coding was guided by the preconceived research questions in the validation questionnaire, inductive coding was used to examine the participants' views while limiting researchers' preconceived biases and expectations. A total of 3 members of the research team read all open-ended responses and developed preliminary open codes and axial codes. To ensure trustworthiness, rigor, and reliability, a larger research team was involved in verifying the preliminary themes. Participant quotes illustrating each subtheme were selected based on their representativeness and the incidence of divergent opinions.

A concurrent parallel approach following a data transformation model was used for data triangulation [31]. Converging data allowed the research team to compare and contrast quantitative and qualitative data and support the subsequent study design, data collection, and analysis.

### Ethics Approval

This study was approved by the University of Alberta Research Ethics Board (Pro00084466) as part of a Canadian 3MDR study [30].

## Results

### Hardware Specification

Hardware design based on expert consultation produced designs for two 3MDR systems: one using an external display (3MDR

compact system) and the other using an AR headset (3MDR AR system). Both systems are described in the following sections.

### 3MDR Compact System

The 3MDR compact system (Figures 2 and 3) was designed to have a smaller physical footprint than the large COSMED system used in earlier 3MDR studies. We identified the COSMED T150 clinical treadmill as a viable option around which to build the 3MDR compact system [36]. The COSMED T150 is a heavy, robust treadmill designed for clinical use in physical rehabilitation, with a maximum load rating of 250 kg (551 lbs) and variable speed options up to 18 km per hour (11.2 miles per hour). It has a built-in safety harness and gantry to support the harness. This makes installation easier and avoids the need for other solutions, such as a separate frame around the treadmill to support a harness or a harness support system installed on the ceiling of the room. The COSMED T150 has a serial port interface capability that allows a computer to control it programmatically, which enables synchronizing treadmill motion with movement in the virtual environment. The treadmill, with medical certification (C0123, Medical Device Directive risk class IIb) available for clinical applications, has a durable belt (including a reverse option) and an alternating current motor designed to not interfere with other medical equipment and can be interfaced with a PC, electrocardiogram, ergospirometer, blood pressure, or printer. A wide range of options and accessories are available for the heavy-duty-built treadmills in the series, including oversized treadmills for cycling or skiing applications and wheelchairs. The units also reportedly require low maintenance.

**Figure 2.** Compact system of the multimodal motion-assisted memory desensitization and reconsolidation.

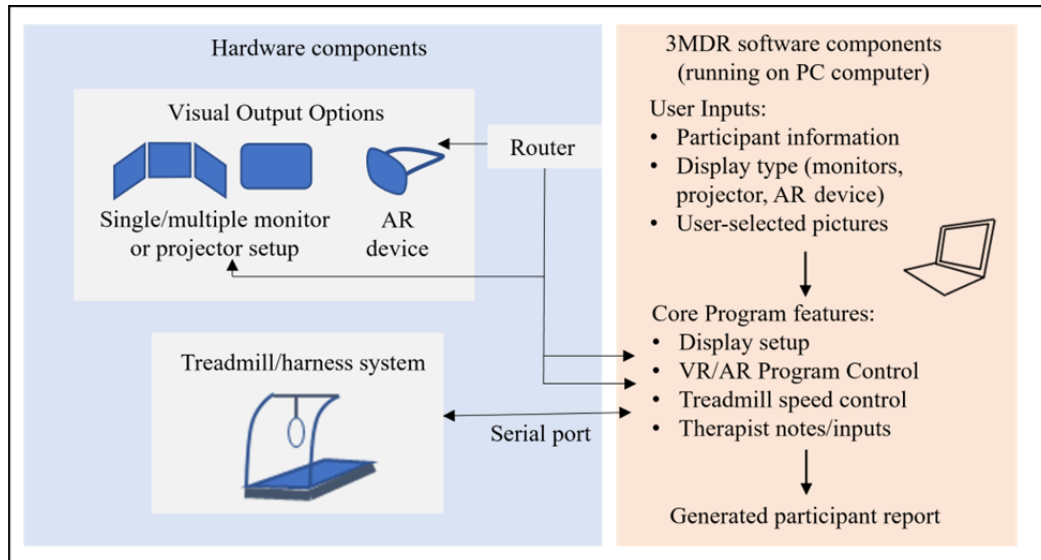




For the control computer, the research team in San Diego used computers built around the Nvidia Quadro P5000 graphics card [37], with 3 Canon WUX500\_WUX450ST projector setups to project a blended image using Scalable Display Technologies' Warp and Blend system [38,39]. The research team in

Edmonton, Alberta, Canada, is currently looking into a similar approach using computers built around the Nvidia Quadro RTX 6000 graphics card and short-throw light-emitting diode projectors [40].

**Figure 3.** Schematic diagram of the hardware and software components of the compact system and future integration of an AR system. 3MDR: multimodal motion-assisted memory desensitization and reconsolidation; AR: augmented reality; VR: virtual reality.



### 3MDR AR System

The team determined that the AR system would use a HoloLens 2 system (Figure 4) for the visual display in place of large computer monitor screens or projection systems [32]. The 3MDR AR system includes a laptop, router, treadmill, and HoloLens 2 headset. There are 3 reasons why HoloLens 2 was chosen over the other devices: safety, rapport, and eye-tracking capability.

Walking in HoloLens 2 versus other more immersive and isolating VR headsets posed less risk for our participants. Walking was required throughout the duration of each session, and the AR head-mounted display (HMD) was less of a safety risk as users could actively look down and see their feet on the treadmill. In addition, many VR HMDs are tethered devices that require cables connecting the HMD to a computer. These cables can be viewed as tripping hazards and restrict movement to a limited area, which would be prohibitive for 3MDR where walking is a key component. Although VR headsets might have

provided greater immersion in the virtual environment, walking is an essential component of the 3MDR therapy.

In other 3MDR publications [41], it has been noted that the connection between the therapist and client is an important aspect of 3MDR. It is beneficial for the participant to be able to see the therapist alongside them for guidance and reassurance. The AR HMD does not restrict users from seeing their therapist during 3MDR. Rapport is key for this approach, and an AR HMD allows us to provide digital content in front of the user (and we can lock the content at that location). Therefore, when they turn to their side, they turn away from the 3MDR environment and can see their therapist unobstructed through the device, akin to looking through sunglasses. In a VR HMD, turning one's head would only show users a different view of the virtual environment. On the basis of participant feedback, it was decided that an avatar (digital representation in the virtual world) of the therapist would not suffice as a stand-in, especially when AR allows users to see the real person and digital content.

**Figure 4.** HoloLens 2 augmented reality system.

## Software Redesign

### Overview

The new software for 3MDR was developed by a research team in the Warfighter Performance Department, Naval Health Research Center, San Diego, United States. To allow for use across different hardware platforms, the Unity development platform was chosen to develop a new controlled version of 3MDR for both PC and HoloLens 2 systems (Figure 4) [42]. The new version of 3MDR was redesigned in Unity 3D, a cross-platform game engine that allows easy adaptation to new technologies. Unity 3D is an open-source C#-based game development platform or program commonly used for game and simulator development, which allows for deployment to multiple platforms. Unity 3D allows for enhanced graphics and physics, as well as programmatic flexibility so that applications can be modified and can evolve over time. The visual scenes were modified to achieve higher resolution and provide greater realism based on therapist feedback on the earlier D-Flow version of the 3MDR software. The Unity 3D platform is very extensible and handles deployments to a large number of software bundles, including PC stand-alone, Universal Windows Platform, and the Apple standard iOS [43]. Similarly, it allows flexibility in integrating heart rate monitors, eye trackers, and other wearable devices for future use. The design of this program emphasizes *modularity* to integrate and subtract devices for research and therapeutic purposes and *polymorphism* to deploy to a variety of current and future devices. The 3MDR application can be ported to different devices, displaying the same visuals on different types of screens or through HMDs.

### Two Views: Therapist and Patient

This application has 3 scenes: introduction, corridor, and conclusion. Each has a different configuration for the patient and therapist. The introduction and conclusion are in the same

environment, in which a blue sky celestial environment is used to transition the participant into and out of the therapeutic environment using self-selected music discussed with the therapist. The corridor scene contains a self-selected series of images previously selected during the discussion with the therapist. Visual flow from the simulation is synchronized directly to the treadmill motion to immerse the patient in therapy. The therapist's view (Figure 5) overlays the control and data entry UI atop the mirrored visual flow. The following are all entered and automatically saved during the application process: walking speed; patient disposition notes and subjective units of distress scores; and emotional, cognitive, and narrative associations. Data are saved in a text file for postsession review. After establishing high involvement with the traumatic memories being worked through, a disengaging working memory task analogous to EMDR is displayed. An oscillating red ball is presented for a duration of 30 seconds, moving from left to right in the foreground of the screen. The patient reads aloud the superimposed number on the red ball. The purpose is to enable the patient to learn to disengage from traumatic memories by tapping into another brain circuit in a similar way to EMDR. After 30 seconds, the picture fades, and the scene transitions to a new cycle. Between cycles, the patient can take time to decompress through battle breathing exercises, drinking water, and reorienting to the new upcoming cycle. Therapists can manipulate the presentation and timing of these tasks and visuals to adapt to the patient's response to therapy.

This final interface design was created through active consultation with therapists practicing 3MDR using the previous Motek design. Input was sought through bimonthly demonstrations of both the VRE and UI. Modifications were made to minimize UI complexity; mirror the view of the participant to the control system; and create summaries of each session, which can be readily reviewed by therapists following sessions for clinical notation.

**Figure 5.** Therapist view on a PC.



### Display Options

The current application supports deployment to either three-screen or HoloLens 2 for patient display. The 3-screen setup supports either a Scalable Display Technologies warp and blend for projected screens or independent television screens. The HoloLens setup uses the Photon Networking system (Exit Games) to pass information between the therapist controller and the patient viewport [43]. The visual flow is updated based on the walking speed and dynamically compensates for the ping rate by the Photon engine. Data are saved locally on the therapist control computer for both the 3-screen and HoloLens 2 displays.

### Adaptation to Specific Patient Groups

Although it was originally thought that specific changes and adaptations would need to be made for various populations affected by trauma, it was determined that self-selected images and music rather than changes to the foundational elements of the 3MDR environment were required for tailored immersion.

### Software Validation

The quantitative and qualitative study findings in the subsequent sections reflect participant feedback (N=35) regarding the new 3MDR software.

### Demographics

Table 1 shows the demographics for participants (N=35) recruited in Edmonton in July 2021.

**Table 1.** Demographics of the participants (N=35).

Demographics	Values, n (%)
<b>Gender</b>	
Woman	22 (63)
Man	12 (34)
Rather not say	1 (3)
<b>Age (years)</b>	
20-29	4 (11)
30-39	13 (37)
40-49	13 (37)
50-59	3 (9)
≥60	1 (3)
Unknown	1 (3)
<b>Role or designation</b>	
Police	5 (14)
Firefighter	2 (6)
Correctional worker	2 (6)
Registered nurse	4 (11)
Support worker	3 (9)
Respiratory therapist	4 (11)
Psychologist	4 (11)
Medical physician	1 (3)
Manager	1 (3)
Social worker	4 (11)
Clinical social worker	2 (6)
Exercise specialist	1 (3)
Care provider for older adults	1 (3)
Other	1 (3)
<b>Supported COVID-19?<sup>a</sup></b>	
No	2 (6)
Yes	31 (89)
Unknown	2 (6)

<sup>a</sup>Indicates the number of participants who provided support and services during the COVID-19 pandemic.

### **Quantitative Results**

Table 2 shows histogram results for Likert scale questions asking participants about various aspects of the 3MDR video. Most participants liked most aspects.

**Table 2.** Distribution of responses to Likert-style questions on various aspects of the demonstrated software from participants (N=35).

Question	Strongly disagree, n (%) <sup>a</sup>	Disagree, n (%) <sup>a</sup>	Slightly disagree, n (%) <sup>a</sup>	Neither, n (%) <sup>a</sup>	Slightly like, n (%) <sup>a</sup>	Like, n (%) <sup>a</sup>	Strongly like, n (%) <sup>a</sup>	Unknown, n (%) <sup>b</sup>
Overall appearance	0 (0)	0 (0)	0 (0)	2 (6)	4 (12)	20 (59)	8 (24)	— <sup>c</sup>
Blue beginning scene	0 (0)	0 (0)	0 (0)	1 (3)	2 (6)	20 (57)	11 (31)	1 (3)
Transition through the clouds	0 (0)	0 (0)	0 (0)	2 (6)	2 (6)	20 (59)	9 (26)	1 (3)
Scene around the first door	0 (0)	0 (0)	0 (0)	2 (7)	9 (30)	14 (47)	5 (17)	—
Ground grid	0 (0)	0 (0)	0 (0)	5 (17)	6 (21)	13 (45)	5 (17)	—
Hallway	0 (0)	0 (0)	0 (0)	4 (14)	4 (14)	15 (54)	5 (18)	—
Image size	0 (0)	0 (0)	0 (0)	3 (9)	8 (24)	17 (50)	6 (18)	—
Ball and movement	0 (0)	0 (0)	0 (0)	4 (12)	4 (12)	16 (47)	10 (29)	—
Picture fade	0 (0)	0 (0)	0 (0)	5 (14)	6 (17)	14 (40)	10 (29)	—
Transition to second door and hallway	0 (0)	0 (0)	0 (0)	6 (18)	4 (12)	16 (48)	7 (21)	—
Timing	0 (0)	0 (0)	0 (0)	2 (6)	1 (3)	24 (69)	8 (23)	—
Visual field	0 (0)	0 (0)	0 (0)	2 (6)	2 (6)	18 (53)	12 (35)	—
Flow	0 (0)	0 (0)	0 (0)	2 (6)	2 (6)	18 (51)	13 (37)	—

<sup>a</sup>Results for different response options.

<sup>b</sup>Participants who did not provide a response.

<sup>c</sup>Not applicable.

## Qualitative Results

Thematic analysis of the open-text survey questions resulted in 3 discovered themes: occupationally tailored virtual environments, individually tailored immersion, and applicability beyond military populations.

### Occupationally Tailored Virtual Environments

A predominant theme for participants was the need for the 3MDR environment to be occupationally tailored to accurately reflect their specific occupations, needs, and traumatic events. For example, one of the participants noted the following:

*...the hallway itself is slightly triggering, hospitals have long hallways with doors that automatically open similarly. So for me I found I was stressed about what I would find behind the doors. [P7]*

Another participant shared similar concerns for health care providers:

*One of my very first impressions is that the maroon color of the flooring in the approach leading up to the hallway immediately reminded me of blood/bodily fluids on the floor such as you might find in response to a patient bleeding or in other trauma situations. This may put people on edge before they even start walking down the hallway toward the actual images, which I am not sure is the desired effect of the study... [P31]*

Specific professions reported differences in work cultures and commonly encountered traumatic scenarios, expressing the view that 3MDR would need to be adapted to their contexts. For example, a firefighter participant noted the following:

*...most Firefighter Stressors are interactions with patients and the death and dying experience rather than Firefighting Operations. Medical Aid events are similar to paramedics and the patient care and the onus of that patient in death and dying. [P36]*

Similarly, a police participant shared the following:

*If there is a way to help members reconcile moral injuries which is prevalent in the policing profession, that would be great.*

Another participant noted the following:

*...traumatic events in my field often occur when standing still rather than moving or walking, not sure if that would affect the therapy. [P4]*

Some participants also shared that the “opening scenery, before entering the hallway presents as ominous and foreboding,” which “if deliberate, this is spot on. If not the intent, then something to consider [P19].”

### Individually Tailored Immersion

The theme of personalization highlighted the need for the 3MDR environment to be both specific and flexible enough that, in addition to being culturally tailored (ie, for individual professions), it could also be adaptable at the personal level. Some of the suggested personal adaptability elements included the possibility of the virtual environment being completely neutral and unrelated to any occupational environment, “Cultural or location centered imagery ie. various hospital settings [ICU, ER, general wards unit] or out of hospital settings [inner city vs. in patient's home, etc]” or “a choice between a nature scene or tunnel” (P2). Equally, it was noted that some participants

may struggle with the visual and auditory stimulation of the environment, which would need to be addressed:

*I found the hallway movement in the video almost brought me to dissociation [between the movement and the "lights"] [P35]*

Another participant noted the following:

*...while red stands out and sets a certain tone [floor grid, moving EMDR ball], it is also the most common color to have vision challenges with. The white text in the red balls may be exceptionally challenging for people with some vision impairments. This should be considered as part of the build [P20]*

This also applied to the use of the harness:

*For some people I have worked with, having a harness on could take some getting used to from a sensory perspective. Many members feel constriction in their chest when activated. So there just might be an adaptation period to prepare for [P21]*

Another participant shared the following:

*...any inclusion of various spiritual or faith-based options would be nice [P27]*

### Applicability Beyond Military Populations

The final theme identified was large-scale support for 3MDR. Participants reported enthusiasm that 3MDR could have great relevance for populations affected by trauma beyond military members and veterans. For example, one of the participants shared the following:

*I am excited to see if this intervention can be researched and disseminated to other communities with trauma, in addition to veterans/safety personnel. For example, folks with a history of sexual trauma or intergenerational trauma from other sources [P16]*

Participants identified that potentially meaningful populations could include "refugees from war zone, youth from abusive homes, sexual assault victims, youth who had gang involvement" (P12). However, equally, participants noted that frontline PSP and health care providers may be especially vulnerable because of the nature of their work:

*Needs to be available to populations beyond the military. Health care and corrections greatly need support like this [P23]*

*For military and first responders, this system is a must have...3MDR could possibly solve issues before they start. I believe with some adjustments to some of the timing issues this could be a viable treatment [P32]*

Thus, the potential viability of 3MDR in broad populations affected by trauma needs to be explored.

## Discussion

### Principal Findings

Over the past decade, 3MDR has evolved from an intervention requiring physically large and costly infrastructure to more

mobile options. The CAREN and GRAIL systems offered an opportunity to trial 3MDR with military members with TR-PTSD using a VRE originally developed for physical rehabilitation. Technologies have since become more mobile, accessible, and cost-effective. Through the research and innovation of this 3MDR international collaboration, the existing hardware and software components of 3MDR were adapted, followed by new components being incorporated, modified, and further validated to enhance the mobility, accessibility, feasibility, and applicability of 3MDR for use with trauma-affected populations. This mixed methods approach, which included a modified Delphi approach, hardware and software development, validation, descriptive statistical analysis, qualitative thematic analysis, and triangulation of the data, allowed the research team to conceptualize, build, and evolve a new 3MDR system. Doing so has positioned 3MDR to be ready for the next wave of populations affected by trauma, which will require novel trauma interventions, including PSP affected by the COVID-19 pandemic.

New hardware and software will benefit from continued studies on feasibility, acceptability, usability, and validity. Although it is expected that the new 3MDR setup will provide similar results to those from previous studies that used the GRAIL, CAREN, and CAREN Lite, new and unpredicted variables could potentially change the experience and outcomes of 3MDR. For example, it remains unknown how patients may react to HoloLens 2 and other wearable metrics and whether this may disrupt the connection between them and their therapist. That said, 3MDR is a protocolized psychotherapeutic intervention. Despite the adaptations and changes in hardware and software, it is not anticipated that deviations from the protocol will result.

### Moving Forward: Hardware

The salient hardware components of the 3MDR compact system were identified through expert consultation. These included the treadmill, safety harness, computer system, treadmill or computer interface, graphics card, visual display, and eye-tracking capability. The characteristics considered included access, physical footprint, portability, therapist positioning, system operation, cost, acceptability, and ease of use. The results yielded a more modular, cost-effective 3MDR compact system and a 3MDR AR system, both of which increased the potential for customized and tailored immersions for populations affected by trauma. The 3MDR compact system comprised a COSMED T150 clinical treadmill, together with a computer built around the Nvidia Quadro P5000 graphics card and short-throw light-emitting diode projectors with display screens [36,37]. Regarding the 3MDR AR system, a blend of virtual and real visual stimuli was determined to be essential, as was the ability of the patient and therapist to effectively see each other and read facial cues. The HoloLens 2 system, together with a laptop, router, and treadmill, were selected [32].

### Moving Forward: Software

Through the modified Delphi consultation process, specific needs were identified that the new 3MDR software would have to meet to reach the goals of enhanced mobility, accessibility, feasibility, and applicability. The team identified (1) ease of adaptation to new technologies, (2) a user-friendly interface,

(3) the ability to integrate audio and visual playback components, and (4) data capture and reporting capabilities as priorities for the software. The first was addressed via the integration of Unity 3D to allow for easy adaptation because of its flexibility, modularity, and polymorphism, enabling applications to maintain their relevance with evolving technical innovation. It also offers flexible integration of heart rate monitors, eye trackers, and other wearable devices for future use and can be ported to different devices and displayed using variable means. This would also address the key theme of individualized-tailored immersion, which was recognized by the PSP as a priority in software validation. The UI was designed to be easy for therapists to use, with higher resolution images and rendering. The music selection was integrated into the software. Furthermore, walking speed, notes, and biomarkers can be entered, automatically saved, and easily reviewed. Although many of the aspects incorporated into the software coincided with the results of the software validation study, not all assumptions of the team were matched to the data from the PSP (N=35). Although the research team opted to have a standard VRE display within the software with the music and images being customizable, the PSP expressed a desire to customize the environment to their professions and individual circumstances. The team and the PSP were similar in that they were passionate about 3MDR being adapted and used for other populations affected by trauma. The perceived strengths, weaknesses, and recommendations of the PSP participants will inform further modification and improvement of future 3MDR software.

### Limitations

There were several barriers and limitations that were faced throughout this initiative. The software validation study used a relatively small sample size, and the COVID-19 pandemic necessitated that focus groups be web-based opposed to in person. This meant that some potential participants could not engage because of reduced access to devices; bandwidth; and wired or wireless internet that would allow them to view videos, complete the web-based forms, and engage in focus groups. In addition, pandemic restrictions provided barriers to physically accessing research facilities, which precluded the validation of hardware. In the future, further validation of the hardware and software will be addressed through ongoing consultation with patients, clinicians, and policy makers as further development of 3MDR is pursued.

### Future Directions

Future research and evolution of 3MDR will continue to enhance accessibility and cost-effectiveness while ensuring the effectiveness of 3MDR and patient safety, thereby positioning 3MDR for continued development as technologies emerge. Further study and development will involve populations beyond the military and PSP to include other civilians who have experienced gender-based violence, adverse childhood experiences, natural disasters, global conflicts, intergenerational trauma, and other complex traumas that require novel approaches to rehabilitation and recovery. In addition, 3MDR has traditionally been used in adult populations aged 18 to 65 years. Further studies will involve the efficacy of this

intervention for other periods of the life span. Increased mobility and portability will also increase the ability of populations in geographical areas with limited information technology infrastructures, such as remote rural areas and combat zones, to potentially use 3MDR. This may include VR or AR headsets, which are becoming more accessible and common to general consumers. Future studies may also address levels of immersion among different populations affected by trauma with the evolving 3MDR hardware and software to determine whether these modifications influence the efficacy of the intervention.

Future opportunities for 3MDR evolution and research may involve the use of eye tracking and other wearable biosensor systems with the aim of providing therapists with real-time information regarding neurobehavioral indicators and trends. For example, eye-tracking information could provide the therapist with information on the visuoperceptual processing of the patient, including whether they are avoiding certain aspects of the image or neglecting part of the screen and facing challenges tracking the EMDR ball. The use of electroencephalography could potentially measure changes in brain activity to better assess the components of 3MDR that affect neurobehavioral changes. Furthermore, neuroimaging captured before and after the intervention may detect changes resulting from 3MDR.

In addition, increasing the use of narrative approaches, which may include videos, could be implemented to facilitate the impact of the patient's story. Through tailored immersion, other sensory systems could be integrated into the new 3MDR system to include smells, tactile feedback, environmental sounds, and integration of vestibular and other senses, in addition to visual stimuli. In addition, studies examining the effectiveness of combined treatments to improve the rehabilitation process and timelines should be explored. The consideration of individual and group 3MDR sessions is also worthy of exploration.

### Conclusions

Although military members and veterans continue to exhibit higher rates of PTSD because of their increased exposure to combat and other traumatic scenarios, the effects of PTSD, moral injury, and other occupational stress injuries that continue to disrupt the health, well-being, and quality of life of populations affected by trauma require immediate attention. As an exposure-based, VR-supported therapy, 3MDR is currently being used to treat military members and veterans with TR-PTSD. As this paper has demonstrated, there is both an interest in and a need to adapt the intervention for other populations affected by trauma and improve accessibility to treatment. The aim of this initiative was to enhance the mobility, accessibility, feasibility, and applicability of 3MDR for use with other populations affected by trauma. The resulting hardware and software innovation from this initiative was demonstrated to have some level of construct and face validity and will now be used in further clinical trials of 3MDR with PSP who have been affected by trauma related to the COVID-19 pandemic.

As novel interventions for trauma involving VR and AR may change the traditional therapeutic constellation in the near future, it is of utmost importance to investigate their potential to reduce the symptoms of PTSD and increase the quality of life, daily

functioning, and safety of populations affected by trauma, as well as that of their families, wider organizations, and communities. As 3MDR continues to emerge in the literature and shows promise, international efforts are positioning 3MDR for more widespread adoption as a potential first-line treatment for PTSD to add to evidence-based trauma treatments. This has involved the current initiative, which focused on hardware development, software optimization, and validation, as well as

facilitation of the adoption of 3MDR in mental health clinics, 3MDR therapist training and certification, and new research directions.

Efforts to evolve and advance 3MDR by further improving mobility, accessibility, feasibility, and applicability will continue to be explored with the goal of continuing to adapt to changing technology, as well as the needs of stakeholders, especially populations affected by trauma.

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## Conflicts of Interest

EV created multimodal motion-assisted memory desensitization and reconsolidation but would not stand to benefit financially were it to be adopted into routine clinical practice. JVD, VPO, AAG, SK, MJR, and PS are military service members and employees in the U.S. government. This work was prepared as part of their official duties. Title 17, U.S.C. §105 provides that copyright protection under this title is not available for any work of the U.S. Government. Title 17, U.S.C. §101 defines a U.S. Government work as work prepared by a military service member or employee of the U.S. Government as part of that person's official duties.

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## Multimedia Appendix 1

Focus group instructions and semistructured scripts for the multimodal motion-assisted memory desensitization and reconsolidation software validation study.

[\[DOCX File, 15 KB - humanfactors\\_v9i3e33682\\_app1.docx\]](#)

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## Abbreviations

- 3MDR:** multimodal motion-assisted memory desensitization and reconsolidation
  - AR:** augmented reality
  - CAREN:** Computer Assisted Rehabilitation Environment
  - EMDR:** eye movement desensitization and reprocessing
  - GRAIL:** Gait Realtime Analysis Interactive Lab
  - HMD:** head-mounted display
  - PSP:** public safety personnel
  - PTSD:** posttraumatic stress disorder
  - REDCap:** Research Electronic Data Capture
  - TR-PTSD:** treatment-resistant posttraumatic stress disorder
  - VR:** virtual reality
  - VRE:** virtual reality environment
  - UI:** user interface
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Original Paper

# Remotely Conducted App-Based Intervention for Cardiovascular Disease and Diabetes Risk Awareness and Prevention: Single-Group Feasibility Trial

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## Abstract

**Background:** Cardiovascular disease and type 2 diabetes mellitus are two of the most prevalent chronic conditions worldwide. An unhealthy lifestyle greatly contributes to someone's risk of developing these conditions. Mobile health is an emerging technology that can help deliver health promotion interventions to the population, for example, in the form of health apps.

**Objective:** The aim of this study was to test the feasibility of an app-based intervention for cardiovascular and diabetes risk awareness and prevention by measuring nonusage, dropout, adherence to app use, and usability of the app over 3 months.

**Methods:** Participants were eligible if they were aged 45 years or older, resided in Australia, were free of cardiovascular disease and diabetes, were fluent in English, and owned a smartphone. In the beginning, participants received an email with instructions on how to install the app and a user guide. After 3 months, they received an email with an invitation to an end-of-study survey. The survey included questions about general smartphone use and the user version of the Mobile Application Rating Scale. We analyzed app-generated and survey data by using descriptive and inferential statistics as well as thematic analysis for open-text comments.

**Results:** Recruitment took place between September and October 2021. Of the 46 participants who consented to the study, 20 (44%) never used the app and 15 (33%) dropped out. The median age of the app users at baseline was 62 (IQR 56-67) years. Adherence to app use, that is, using the app at least once a week over 3 months, was 17% (8/46) of the total sample and 31% (8/26) of all app users. The mean app quality rating on the user version of the Mobile Application Rating Scale was 3.5 (SD 0.6) of 5 points. The app scored the highest for the information section and the lowest for the engagement section of the scale.

**Conclusions:** Nonusage and dropouts were too high, and the adherence was too low to consider the intervention in its current form feasible. Potential barriers that we identified include the research team not actively engaging with participants early in the study to verify that all participants could install the app, the intervention did not involve direct contact with health care professionals, and the app did not have enough interactive features.

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**KEYWORDS**

mobile health; feasibility studies; primary prevention; cardiovascular disease; diabetes mellitus, type 2; mHealth; cardiology; heart disease; diabetes; smartphone; participate engagement; app-based intervention

## Introduction

Cardiovascular disease (CVD) and type 2 diabetes mellitus (T2DM) have a high prevalence worldwide, although both diseases could often be prevented through a healthier lifestyle [1,2]. From a behavioral perspective, tobacco smoking, excessive alcohol consumption, poor diet, and physical inactivity contribute greatly to the development of these conditions [2]. Technology-based behavior change interventions have the potential to promote health and prevent chronic diseases such as CVD and T2DM [3]. Commercial app stores such as Google Play Store and App Store offer a wide range of health-related apps [4]. Safavi et al [5] showed that most commercial products were not assessed for their clinical effectiveness and none were assessed for improving costs or access to clinical care. If digital health companies evaluated their products, they usually enrolled a healthy population but never assessed disease prevention as an outcome [5]. To overcome the shortcomings of the currently available health-related apps, we have developed an evidence-based and theory-based app to help people understand the risks of developing CVD and T2DM and to monitor their health behaviors. The app consists of 4 modules: a calculator for 5-year CVD and T2DM risk; goal setting and tracking functions for diet, physical activity, smoking, and alcohol intake; and an education section. A detailed description of the app can be found elsewhere [6]. We conducted usability testing on the prototype and improved the app design based on participants' feedback. Our goal was to create an easy-to-use app without too much functionality so that it was suitable for less tech-savvy people and did not require users to own anything besides a smartphone.

Kumar et al [7] emphasized that mature intervention testing for mobile health interventions, such as larger randomized trials, should only be conducted after feasibility, usability, and preliminary efficacy have been demonstrated. In this study, we wanted to evaluate the feasibility of a remotely conducted app-based intervention. A particular problem with mobile health studies, as Eysenbach [8] pointed out, is high rates of dropout and discontinuance. Therefore, these were among the outcomes we intended to measure in the study. Furthermore, a systematic review by Donkin et al [9] showed that adherence to web-based interventions was positively associated with physical health outcomes such as physical activity, fruit and vegetable intake, and smoking. Perski et al [10] also noted that digital behavior change interventions require a certain level of user engagement to be effective. Therefore, another outcome measure for the feasibility study was adherence to app use. Perski et al [10] defined engagement with digital behavior change interventions as "(1) the extent (e.g. amount, frequency, duration, depth) of usage, and (2) a subjective experience characterised by attention, interest and affect." This underlines that different measures might be required to determine engagement. Therefore, we collected objective data on app adherence as well as subjective data related to app usability. Overall, the objectives of this study were to evaluate the feasibility of the intervention by measuring nonusage, dropout, adherence to app use, and usability of the app over 3 months. As studies from the United States, United Kingdom, Canada, and Australia showed that mobile health

users tended to be younger and female ([11-14] and Buss et al, unpublished data, 2022), a subquestion of the study was to assess whether there were any sex or age differences among the participants in terms of app usage.

## Methods

### Ethical Considerations and Informed Consent

We received ethics approval from the University of New South Wales Australia Human Research Ethics Advisory Panel G: Health, Medical, Community and Social (approval HC210520) and reciprocal approval from the Commonwealth Scientific and Industrial Research Organisation Health and Medical Human Research Ethics Committee (approval 2021\_071\_RR). All participants provided consent to participate in this study.

### Sample Size

Our predefined sample size was 40 participants. The number was based on a sample size calculation according to Hooper [15] and previous studies. The sample size was sufficient to determine a dropout rate of 30% to within a 95% CI of SD 7% and an adherence rate of 50% to within a 95% CI of SD 8%. We based dropout and adherence rates on data from other studies [16,17]. Other researchers recommended 24-50 participants for feasibility studies [18,19]. We used quota sampling to represent different groups within the target population. We aimed at roughly 10 participants per group (female and 45-64 years, female and  $\geq 65$  years, nonfemale and 45-64 years, nonfemale and  $\geq 65$  years). To be inclusive of nonbinary identities, we defined the sex groups as female and nonfemale assuming that about 50% of the Australian population identifies as female. We used a random number generator in Excel to select equal numbers of potential participants from each group to be invited to the study.

### Participants

People were eligible to take part in the study if they were aged 45 years and older, resided in Australia, were fluent in written and spoken English, owned a smartphone (Android or iPhone) with internet access, and had an email address. We set the start age to 45 years according to the guidelines of the Royal Australian College of General Practitioners. These state that general practitioners should screen for chronic diseases in the low-risk population and potentially initiate preventive measures starting from that age [20]. Since the intervention was for primary prevention, we excluded people who had already been diagnosed with CVD or diabetes (type 1 or 2). Participants were reimbursed for their participation with a A\$30 (US \$21) gift voucher.

### Intervention

We recruited participants with the help of a recruitment agency that identified and contacted potential participants from panelists. Panelist members received a link to an eligibility survey. If people fulfilled the inclusion/exclusion criteria and indicated interest in participating, we contacted them via email. After providing consent via a web-based survey, participants received another email from us that included the study instructions, the user guide, and a unique identifier. Participants

were asked to download the app from the app store on their phones and then use it for 3 months (approximately 90 days). It was up to the participants how often they used the app. We only said that we encouraged regular use. For questions or technical issues, participants could get in touch with us via email. After 3 months, participants received an invitation to an end-of-study survey. The app contained 4 core modules. The first module comprised risk scores for the 5-year risk of CVD and T2DM. These were the Framingham risk score for CVD and the Australian Type 2 Diabetes Risk tool for T2DM [21,22]. The algorithms calculated the risk with information that users provided during the registration. The registration process included 21 questions. Five of these required users to enter numerical values, while the remaining questions had answer options provided. During the usability study, app testers needed less than 5 minutes to complete the process [6]. Participants could update their risk at any time. The second module was a goal-setting function. The goals were about smoking, physical activity, fruit and vegetable intake, consumption of sugary drinks, and alcohol intake. In the third module, participants could track their behavior related to these goals. They received messages to acknowledge when they achieved their self-set goals. The fourth module was for educational purposes. It included links to external websites, educational videos, and the user guide. We published a detailed description of the app elsewhere [6].

### Data Collection

We collected 2 types of data: app-generated and survey data. The outcomes we measured were nonusage rate (defined as the proportion of participants who never used the app), dropout rate (defined as the proportion of participants who completely stopped using the app at least 14 days before they received the end-of-study survey invitation), adherence rate (defined as the proportion of participants who used the app each week at least once during the 3 months), and usability of the app. For the usability assessment, we used the user version of the Mobile Application Rating Scale (uMARS), a validated instrument to measure the quality of mobile health apps [23]. The quality rating of uMARS measures the engagement, functionality, aesthetics, and information of the app. The survey contained

further questions about general smartphone use. These questions were derived from a survey of the Australian Office of the eSafety Commissioner [24]. Other outcomes of interest were related to the information entered in the app and the frequency with which they were entered. Only participants who had not withdrawn from the study were asked to fill out the end-of-study survey. They received 2 reminders via email before they were considered lost to follow-up. Every participant received a unique identifier. This allowed us to control who had access to the app because even though the app was free to download from the app store, registration was only possible after entering one of the unique identifiers. We also asked participants to provide their unique identifiers at the beginning of the end-of-study survey, which allowed us to link the app data with the survey responses.

### Data Analysis

After the data collection was completed, we conducted the data analyses in RStudio using the programming language R. We used the following functions from the R Stats package. For differences between means, if data were normally distributed, we used the unpaired 2-sample *t* test (alternative hypothesis: true difference in means is not equal to 0) [25], and if data were not normally distributed, the nonparametric 2-sample Wilcoxon rank test (alternative hypothesis: true location shift is not equal to 0) [26]. For differences between categorical variables, we used Pearson chi-squared test with Yates correction for continuity [27]. We tested for correlations between variables by using Pearson product-moment correlation (alternative hypothesis: true correlation is not equal to 0) [28]. We tested for outliers by using Tukey's rule (below:  $Q1 - 1.5 * IQR$  or above:  $Q3 + 1.5 * IQR$ ) [29]. We assessed if there were differences in the outcome variables between men and women and between midaged (45-64 years) and older participants (65 years and older). We preset the significance level for all tests to .05. We gave every survey respondent a score based on their smartphone use to see whether there were differences in general smartphone use between those who used the app and those who did not (maximum score 10 points, Table 1). We thematically analyzed the free comments at the end of the survey by using a deductive approach [30].

**Table 1.** Score items for smartphone use.

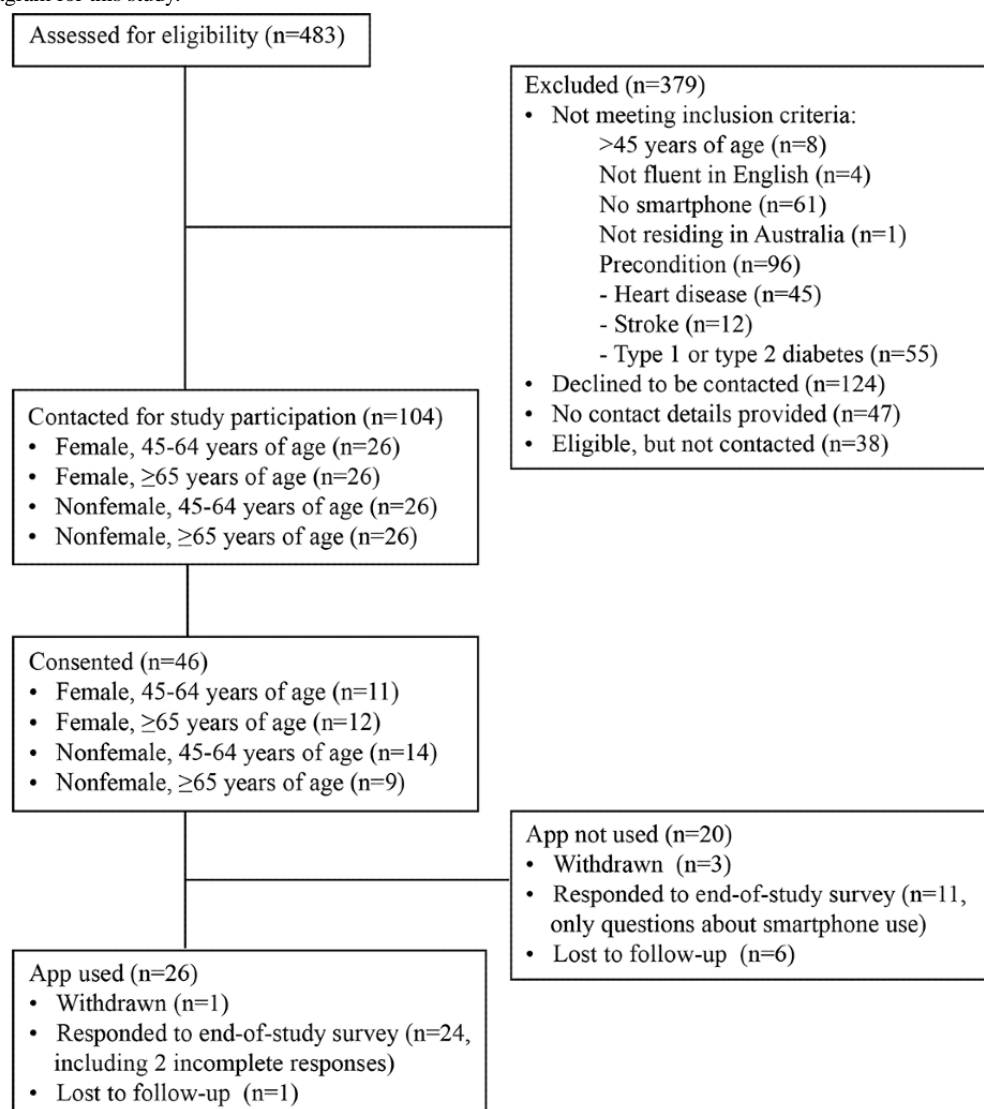
Scoring items	Points
Use smartphone multiple times a day	1
Access the internet multiple times a day	1
Have mobile data on the smartphone	1
Type on the smartphone's touchscreen without assistance	1
Use a search engine on the smartphone without assistance	1
Send an email with the smartphone without assistance	1
Take and send a picture with the smartphone without assistance	1
Install and update an app with the smartphone without assistance	1
Message or chat using internet-based apps with the smartphone without assistance	1
Make video calls with the smartphone without assistance	1

## Results

### Participants

This study took place between September 2021 and January 2022. We assessed 483 persons for eligibility, of which 142 persons were eligible (Figure 1). We randomly selected 26 participants for each group since this was the number of eligible individuals in the smallest group (women aged 65 years and older). Then, we invited these individuals to take part in this study, and 46 participants provided their consent. Enrolment took place between September 22, 2021 and October 14, 2021. Depending on the participants' enrolment date, we sent out the end-of-study survey invitations on December 14, 2021 or January 5, 2022, with up to 2 reminders. Of the 46 participants, 24% (11/46) individuals were females aged 45-64 years, 26% (12/46) were females aged 65 years and older, 30% (14/46) were males aged 45-64 years, and 20% (9/46) were males aged 65 years and older. There were no statistically significant differences between the groups ( $\chi^2_1=0.4$ ;  $P=.55$ ); none of the participants identified as nonbinary.

**Figure 1.** Flow diagram for this study.



We received 35 end-of-study survey responses from the 46 participants at baseline regarding their general smartphone use. These consisted of 24 responses from participants who had used the app and 11 responses from participants who had not used the app (Figure 1). The 4 participants who had withdrawn from the study did not receive an invitation to the end-of-study survey. The remaining 7 participants were lost to follow-up. Most respondents (33/35, 94%) accessed the internet and used their smartphones multiple times a day and 2 respondents (6%) once a day. They stated that they connected their smartphones to the internet using a home internet connection (30/35, 86%), mobile data (31/35, 89%), public Wi-Fi (8/35, 23%), and a work internet connection (3/35, 9%). Most respondents were able to do various tasks with their smartphones without requiring assistance (Table 2). We ranked people based on their general smartphone use. The median score was 10 out of 10 points, and the minimum score for any user was 3 points. There was no statistically significant difference in the score for general smartphone use between those who used the app and those who did not ( $W=140$ ;  $P=.75$ ).

**Table 2.** Tasks that participants (n=35) stated that they could do with a smartphone.

Tasks	Without assistance, n (%)	Require assistance, n (%)	Never tried before, n (%)
Type on the touchscreen	32 (91)	1 (3)	2 (6)
Use a search engine	34 (97)	1 (3)	0 (0)
Send an email	33 (94)	2 (6)	0 (0)
Take and send a picture	33 (94)	2 (6)	0 (0)
Install and update an app	32 (91)	2 (6)	1 (3)
Message or chat using internet-based apps	30 (86)	1 (3)	4 (11)
Make video calls	28 (80)	0 (0)	7 (20)

### Nonusage, Dropout, and Adherence to App Use

The nonusage rate was 44% (20/46). Of the 26 participants who used the app, 16 participants were 45-64 years old and 10 were 65 years or older. There was no statistically significant difference between app use and age groups ( $\chi^2_1=0.7$ ;  $P=.41$ ), but there was a statistically significant difference between sex and app use ( $\chi^2_1=7.2$ ;  $P=.007$ ), with more men (18/26) using the app than women (8/26). The median age of app users at baseline was 62 (IQR 56-67) years. The oldest app user was 73 years old, and the youngest was 47 years old. Table 3 shows further characteristics of the app users at baseline and the

duration of app use. The dropout rate was 33% (15/46). Eight participants used the app at least once a week. That represents an adherence rate of 17% (8/46) of the total sample and 31% (8/26) of all app users. The median time between the first and last app use was 54 (IQR 4-83) days. Owing to small differences between enrolment and survey completion dates, the maximum potential time for a participant to be included in the study varied slightly. There were no statistically significant correlations between age and duration of app use ( $t_{24}=-0.84$ ;  $P=.41$ ;  $r=-0.168$ ; 95% CI  $-0.522$  to  $0.234$ ). Neither was there a statistically significant difference between sex and duration of app use ( $W=65$ ;  $P=.72$ ).

**Table 3.** Baseline characteristics of app users (n=26) and their duration of app use.

Characteristics of app users	Values, n (%)
<b>Demographics</b>	
Female	8 (31)
Age $\geq 65$ years	10 (39)
Born in Australia	17 (65)
<b>Cardiovascular risk</b>	
Low	16 (64)
Moderate	4 (16)
High	5 (20)
<b>Diabetes risk</b>	
Low	0 (0)
Moderate	7 (27)
High	19 (73)
Regular smoker	7 (27)
<b>Healthy lifestyle</b>	
Physical activity, 2.5 hours per week	18 (69)
Daily fruit and vegetable intake	19 (73)
<b>Duration of app use</b>	
1 day	5 (19)
2-7 days	2 (8)
8-30 days	3 (12)
31-60 days	3 (12)
61-90 days	13 (50)



App users calculated their CVD and T2DM risk in a median twice (IQR 1-4), with a maximum of 14 times. For some app users, the risk changed over time, but only on 4 occasions this led to a different risk category displayed in the app. After the registration, app users were automatically directed to the goal-setting module. They set goals of a median of once (IQR 1-3) and a maximum of 11 times, which was an outlier. Six app users never set a goal, and 3 never tracked health-related behaviors. The median number of times app users tracked health-related behaviors was 14 (IQR 1-57), with a maximum of 137 times. This value was not an outlier. Among those (15/26, 58%) who tracked their health behaviors on at least 7 days, 12 persons (80%) tracked them on a median every day, 2 persons (13%) on a median every second day, and 1 person (7%) on a median every third day. Among those who regularly tracked health-related behaviors, 4 people (33%) never reached their goals for all health-related behaviors in 1 day. The maximum was reached by 1 person who achieved their goals in 8 days. This corresponded to 13% (8/61) of the days that the person recorded health-related behaviors. The health-related behavior that app users achieved the least was minutes of physical activity per week.

### Usability of the App

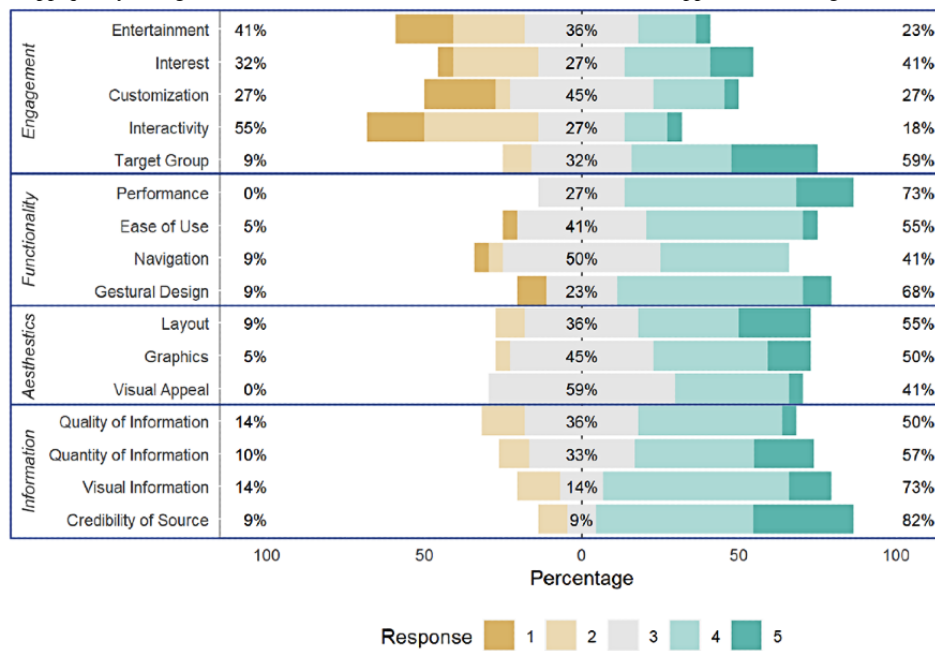
The results from the uMARS are based on 22 participants who had used the app and had completed the end-of-study survey in its entirety. The overall app quality rating on the uMARS was 3.5 (SD 0.6) points out of a maximum of 5 points. Figure 2 shows the responses of the uMARS app quality rating on a 5-point Likert scale for each item. The highest score was for information with a mean of 3.70 (SD 0.67) points, followed by aesthetics (3.58 [SD 0.65]), functionality (3.57 [SD 0.56]), and engagement (2.99 [SD 0.86]).

Regarding the subjective quality of the app, of the 22 users, 2 (9%) app users stated that they would recommend the app to everyone, 3 (14%) would recommend it to many people, 3 (14%) would recommend it to several people, 9 (41%) would recommend it to very few people, and 5 (23%) would not recommend it to anyone. Of those 8 app users who would recommend the app to everyone, many people, or several people, 6 (75%) were 45-64 years old, 2 (25%) were 65 years or older, 6 (75%) were males, and 2 (25%) were females. They rated the app quality with a mean score of 4.07 (SD 0.41). Among the 14 app users who would recommend the app to only very few or none, 8 (57%) were 45-64 years old, 6 (43%) were 65 years and older, 12 (86%) were males, and 2 (14%) were females. They provided a mean app quality score of 3.11 (SD 0.32). The difference in the mean scores was the greatest for engagement (3.78 [SD 0.65] vs 2.54 [SD 0.61]), followed by aesthetics (4.17 [SD 0.59] vs 3.24 [SD 0.40]), information (4.25 [SD 0.42] vs 3.38 [SD 0.32]), and functionality (4.09 [SD 0.40] vs 3.27 [SD 0.39]). When asked how often they think they would use the app in the next 12 months, 10 (46%) app users answered never,

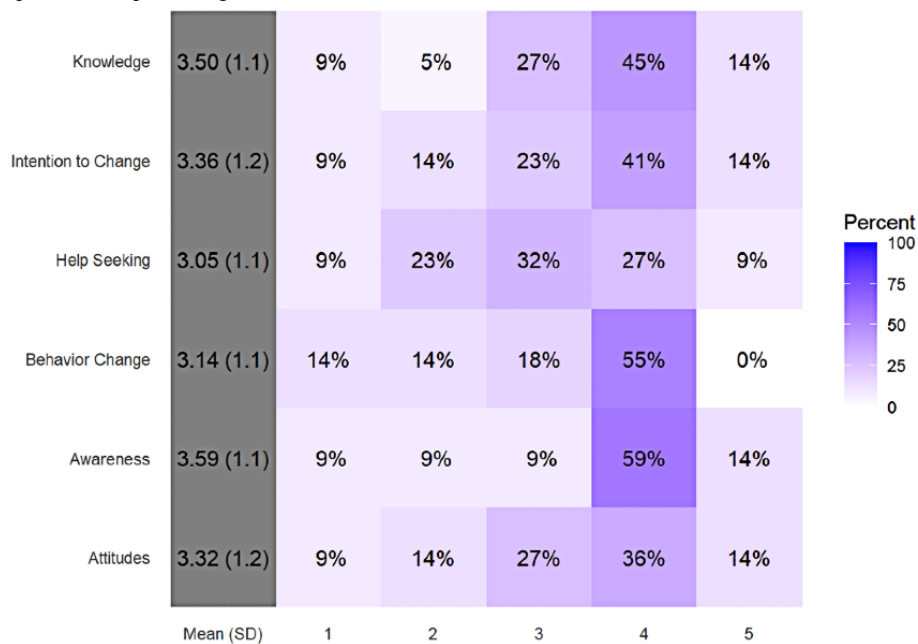
1 (5%) answered once or twice, 3 (14%) answered 3-10 times, 6 (27%) answered 10-50 times, and 2 (9%) answered more than 50 times. When asked about payment, 14 (64%) app users responded that they would definitely not pay for the app, 4 (18%) responded probably not, 3 (14%) responded they might or might not, and 1 (5%) responded probably yes. The last set of uMARS questions was about the perceived impact on the users' knowledge, attitudes, and intentions related to the target health behavior. Responses were based on the 5-point Likert scale (Figure 3). All mean values were between 3.0 and 4.0. The highest score was for awareness (mean 3.6 [SD 1.1]), with 73% (16/22) of the app users somewhat or strongly agreeing that the app had increased their awareness of the importance of addressing the health behaviors. The lowest score was for help-seeking (mean 3.1 [SD 1.1]), which asked whether participants agreed that the app would encourage them to seek further help to address the health behavior (if needed).

Among the app users, 15 people left comments about the app at the end of the survey. We identified 6 themes (issues with self-monitoring, lack of interaction, credibility, user-friendliness, interaction with health care professionals, and privacy). One of the main themes we identified was issues with self-monitoring of health-related behavior. Some app users could not see the health-related behavior trends shown over time. One described initial confusion over the difference between daily and weekly goals when entering the number of alcoholic drinks consumed. Others mentioned that it took them too long to enter the values manually. One said it would have been nice to link the app to a step counter app on the phone. Some participants would have liked reminders for self-monitoring. This also relates to the theme of lack of interaction between users and the app. One specifically stated that the app lacked features that incentivize app use. A further theme was the credibility of the information. One person found the app inaccurate because it only considered waist circumference but not BMI. However, others mentioned that they liked the health information provided and found it credible. Regarding the user-friendliness of the app, some found the app clunky, while others specifically said that they felt it was easy to use. Concerning interaction with health care professionals, one person explained that using the app encouraged the person to get blood glucose levels checked and make an appointment with a cardiologist. Another person outlined that they were already working with their general practitioner on the health behaviors targeted with the app due to increased disease risk and reported using a diet-tracking app. One person raised privacy concerns and suggested that to protect their privacy, a password should be included to safeguard their information from other people who might be using their smartphones. One person who did not use the app said they could not access it. Other participants (10/46, 22%) had reached out to us via email at the beginning of the study to receive help downloading the app and registering.

**Figure 2.** Results of the app quality rating on the Likert scale in the user version of the Mobile Application Rating Scale (n=22).



**Figure 3.** Results of the perceived impact rating on the Likert scale.



## Discussion

### Principal Results

Our objectives were to evaluate nonusage, dropout, adherence to app use, and usability of the app-based intervention for cardiovascular and diabetes risk awareness and prevention over 3 months. The nonusage and dropout rates were high, and the adherence rate was low. The overall quality rating on the uMARS was satisfactory. However, scores for interactivity and entertainment, which are part of the engagement section, were particularly low. We noticed differences between those who would recommend the app to everyone, many, or several people and those who would recommend it to only very few people or no one. Interestingly, the difference in the mean scores was the

smallest for app functionality. Since our sample size of app users was quite small, one must interpret these differences cautiously.

Our results showed issues with the adoption of and engagement with the app-based intervention. We have different hypotheses about what might have contributed to these issues. Possible explanations for nonadoption are (1) problems installing the app, as stated by a participant in the survey; (2) the use of other health apps that better suit their needs and preferences, as mentioned by 2 participants in the survey; and (3) other pressures such as those caused by the COVID-19 pandemic with people potentially being more concerned with them or a family member contracting COVID-19 than developing CVD or T2DM. A likely explanation for the low engagement is that

the app lacked interactive features. Although the app included 2 types of push notifications when users achieved their goals, the data analysis showed that participants barely met the required conditions to see these messages. That means participants received little to no notifications through the app. Although the registration process required app users to answer a total of 21 questions, we saw no indication that this affected adherence. Since each participant had to enter a unique identifier at the beginning of the registration process before proceeding to the questions, we could determine that all app users completed the registration. The non-app users never saw the questions. Participants did not indicate that they perceived the risk scores as disempowering or that they were overwhelmed by 2 conditions being integrated into the app. Even though the Framingham CVD risk score does not directly rely on data about physical activity and diet [21], the app did not show users exactly how the risk was calculated unless they used the link to the external source.

### Limitations

We estimated that a sample size of 40 participants would be sufficient to detect a 30% dropout and 50% adherence rate. We did not factor in nonusage when calculating the sample size because we did not anticipate nonusage to be an issue. When analyzing the data, we decided to differentiate between nonusage and discontinuation of use, that is, dropout. In retrospect, a larger sample size could have been beneficial. However, the sample size was sufficient to answer our research question. This study showed that asking people aged 45 years and older to download the app and expect them to use it over 3 months without additional interaction was not feasible. In addition to the small sample size, another limitation of this study was that we recruited participants through a recruitment agency. We noticed that some participants had completed the end-of-study questionnaire in full, including the question from the uMARS, even though they did not use the app. Those answers were excluded from the analysis. A further limitation of this study was that we did not collect data about the participants' educational level or socioeconomic status. Another factor that may have influenced the study is that it took place during the COVID-19 pandemic, and some participants might have been in a government-regulated lockdown. It might partly explain the high nonuse and dropout as well as the low level of engagement, as participants may have had other health priorities on their minds. However, others such as Wright et al [31] have pointed out that the COVID-19 pandemic had led to decreased screening and prevention service rates for chronic diseases, which underscores the value of this app-based intervention.

### Comparison With Prior Work

In comparison to the findings in our study, Krishnamurthi et al [32] reported that recruitment for their app-based study for stroke risk assessment was feasible and that the app had reasonable acceptance. However, more participants in the app intervention group dropped out (7/26) than those in the control group (1/24) [32]. Krishnamurthi et al [32] also found that owning a smartphone did not automatically mean that the owner could download and use the study app. In a preventive CVD intervention in collaboration with the patients' general

practitioners and including a web application, Coorey et al [33] reported that participants logged in, on average, 18 times within 12 months, most frequently to check the goal tracking/progress module and least frequently to use the chat function. In this study, too, participants rarely used the web application [33]. In contrast to the app in our study, participants had the option to receive heart health advice, motivational messages, and reminders via email or text message to support the computer-user interaction [33]. About half of those who signed up found the messages helpful [33]. As opposed to our study findings, Lavikainen et al [34] found in their app-based study for T2DM prevention that older people were more likely to engage with the app [34]. The authors reported that only those who intensely interacted with the app achieved noteworthy changes in lifestyle-related risk factors. These active users were more likely to have already had a better diet, higher levels of physical activity, and lower stress levels at baseline [34]. Leung et al [35], in their study of an app-based intervention for T2DM risk, showed that app users who received a high risk of developing T2DM significantly improved their daily vegetable intake and physical activity over 2 years but not their smoking behavior or alcohol consumption. In our study, participants ranked the credibility of sources particularly high on the uMARS. We included links to the sources for the risk scores because, during usability testing, we noticed that users wanted to know more about the scores used in the app. In contrast, Fijacko et al [36] found in their systematic review of 3 major app stores that only 9 out of 31 apps intended for T2DM risk calculation disclosed the name of the risk score they had implemented in the app.

Several studies focusing on weight loss reported differences in self-monitoring of diet, physical activity, and body weight by using apps. For example, Carpenter et al [37] found that consistency with an app-based intervention over 6 months was higher for self-monitoring physical activity. At the same time, disengagement was higher for self-monitoring of weight and diet intake. Participants who additionally received a face-to-face interventional component had better outcomes for consistency and disengagement for self-monitoring of dietary intake. Interestingly, greater consistency and longer time to disengagement for self-monitoring of diet and weight led to greater weight loss, but this was not the case for self-monitoring of physical activity [37]. Turner-McGrievy et al [38] stated that participants who had to enter dietary intake manually were more likely to form the habit of self-monitoring than those who used lower burden options (wearable bite-counter device or photo-based app). Further, Butryn et al [39] detected better adherence to self-monitoring over time for physical activity, which was tracked via sensors instead of diet and weight, which were tracked via a food diary in the app and a wireless body weight scale. Although these findings are not specifically associated with CVD or T2DM risk, we think they still have a relevant implication for our study: adherence to self-monitoring does not necessarily mean that users would achieve behavioral goals.

Carpenter et al [37] also argued that even though automated tracking is more convenient for app users, it might not achieve the anticipated behavior change. Some app users suggested

automated tracking of physical activity to increase engagement with our app. We believe that it is likely to increase the frequency of tracking but not necessarily the achievement of physical activity goals or even disease risk reduction. We did not include automatic physical activity tracking in the app because of privacy and equity issues. As mentioned by a participant, it would be possible to collect daily step counts by linking the app to another app such as Samsung Health, Google Fit, or Apple's Health app. However, that would require data-sharing permissions with third-party providers. However, we decided against implementing wrist-worn devices in the intervention because we did not want to disadvantage people who cannot afford wearable devices. Montgomery et al [40] showed that these are legitimate concerns. However, we could provide users with the option to link the app to another app, a physical activity tracker, or a smartwatch, ensuring that they were aware of the data-sharing permissions and keeping the option to enter data manually.

### Implications and Future Work

This study demonstrated that it would not be feasible to implement the app-based intervention in the current form because we would not expect sufficient engagement with the app to achieve significant behavior change in participants. There are different options on how we could adjust the intervention to hopefully achieve fewer nonusage and dropouts as well as higher adherence. One option would be to check in with participants at the beginning of the study to ensure that they could download the app. Potentially, that could significantly reduce the number of people who never used the app. Another option is to increase the number of interactive features in the app so that app users feel more motivated to use the app regularly. We could also enable voice input options to facilitate data entry. However, that would require access to the phone's audio input, which may risk the user's privacy. Additionally, it would increase app-specific storage. Further, we could include interactions with health care professionals in the intervention to improve adherence. We considered this when developing the intervention. However, the evidence for its superiority was inconclusive, for example, as reported by Cucciniello et al [41]

in their systematic review of mobile apps for chronic disease management. We saw a potential advantage for primary prevention by directly approaching health consumers because preventative measures traditionally leave out certain population groups because they do not visit a general practitioner. Feng et al [42] found that Australians with multiple lifestyle-related risk factors are among the least likely to see their general practitioner. Hence, they argued that preventative interventions should also be offered outside the traditional health care setting.

Byambasuren et al [43] reported that people found a recommendation by their general practitioner to be a facilitator for the uptake of mobile health apps. Similarly, Nguyen et al [44] explained that general practitioners could be involved in mobile health interventions through app promotion and regular review of patient-centered app data. They explained that general practitioners could review the data during the medical consultation or remotely via a web-based portal [44]. Nguyen et al [44] pointed out that an issue with this approach is that general practitioners in Australia are typically time-poor. It would not be easy to fit the data review into their schedule. The same was confirmed by general practitioners in the study by Coorey et al [33]. Therefore, Nguyen et al [44] proposed involving allied health professionals such as nurse practitioners or community pharmacists. In the next step, we could implement the discussed options and test them in another feasibility study before considering an implementation study to assess the intervention's effectiveness.

### Conclusions

The app-based intervention proved to be unfeasible in its current form because too many study participants never used the app or dropped out and too few used the app weekly. We identified potential barriers such as no active query from the research team at the start of the study as to whether participants were able to install the app, insufficient interactive app features, as well as no direct interaction with health care professionals. We believe it was important to conduct this feasibility study before evaluating the intervention's effectiveness in a larger trial. It saved resources for a study that likely would not have shown intervention effectiveness owing to low user engagement.

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### Conflicts of Interest

None declared.

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## Abbreviations

**CVD:** cardiovascular disease

**T2DM:** type 2 diabetes mellitus

**uMARS:** user version of the Mobile Application Rating Scale

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Original Paper

# Bridging the Digital Divide in Psychological Therapies: Observational Study of Engagement With the SlowMo Mobile App for Paranoia in Psychosis

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## Abstract

**Background:** Marginalized groups are more likely to experience problems with technology-related access, motivation, and skills. This is known as the “digital divide.” Technology-related exclusion is a potential barrier to the equitable implementation of digital health. SlowMo therapy was developed with an inclusive, human-centered design to optimize accessibility and bridge the “digital divide.” SlowMo is an effective, blended digital psychological therapy for paranoia in psychosis.

**Objective:** This study explores the “digital divide” and mobile app engagement in the SlowMo randomized controlled trial.

**Methods:** Digital literacy was assessed at baseline, and a multidimensional assessment of engagement (ie, adherence [via system analytics and self-report] and self-reported user experience) was conducted at 12 weeks after therapy. Engagement was investigated in relation to demographics (ie, gender, age, ethnicity, and paranoia severity).

**Results:** Digital literacy data demonstrated that technology use and confidence were lower in Black people and older people (n=168). The engagement findings indicated that 80.7% (96/119) of therapy completers met the a priori analytics adherence criteria. However, analytics adherence did not differ by demographics. High rates of user experience were reported overall (overall score: mean 75%, SD 17.1%; n=82). No differences in user experience were found for ethnicity, age, or paranoia severity, although self-reported app use, enjoyment, and usefulness were higher in women than in men.

**Conclusions:** This study identified technology-related inequalities related to age and ethnicity, which did not influence engagement with SlowMo, suggesting that the therapy design bridged the “digital divide.” Intervention design may moderate the influence of individual differences on engagement. We recommend the adoption of inclusive, human-centered design to reduce the impact of the “digital divide” on therapy outcomes.

**Trial Registration:** ISRCTN Registry ISRCTN32448671; <https://www.isrctn.com/ISRCTN32448671>

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**KEYWORDS**

paranoia; psychosis; digital health; apps; human-centered design; user experience; adherence; engagement; therapy

**Introduction**

Digital therapeutics have the potential to overcome barriers to the implementation of evidence-based health care, supported by the rapid growth in technology use. In the United Kingdom, approximately 79% of the population now own an internet-enabled mobile phone [1]. However, there is a well-documented “digital divide” whereby marginalized social, cultural, and demographic groups experience technology-related inequalities through the lack of access, confidence, and skills [2]. Given that engagement with digital therapeutics is a necessary condition for delivering benefit, reducing the impact of technology-related exclusion in minoritized groups is essential for equitable implementation [3,4]. This study therefore explored the “digital divide” and engagement in relation to SlowMo therapy, a blended digital therapy for paranoia in psychosis. SlowMo helps people learn to *slow down for a moment* to find ways of feeling safer. The technology consists of an intuitive web app to augment face-to-face individual cognitive behavioral therapy (CBT) sessions, which is synchronized with a native mobile app for use in daily life. In a recently completed randomized controlled trial (N=362), SlowMo demonstrated improved paranoia, self-concept, and well-being outcomes over 6 months compared with treatment as usual (TAU), with small to moderate effects [5]. This adjunct study investigated whether demographics commonly found to be associated with the “digital divide” were related to engagement in the SlowMo trial.

We propose that mental health is a highly relevant area in researching technology exclusion and health care engagement, as people in contact with mental health services have been found to be disproportionately affected by the “digital divide.” This is particularly marked in psychosis, with Robotham et al [6] reporting that approximately one-fifth of their sample was digitally excluded compared with only 3% of those with depression, although this rate had reduced from 30% in an earlier study [7]. Of note, excluded participants (ie, those with reduced technology access, confidence, and use) were significantly older—a finding that was replicated in a study examining factors associated with uptake of remote therapy in psychosis [8]. In a previous study by Robotham et al [7], Black people also had higher rates of exclusion, although this finding was not replicated in the follow-up study. A recent review found that White people and women with psychosis engage more with digital interventions than men and minoritized ethnic groups [9,10]. Given that the nature of technology use is complex and varies over time, there is a need for further research to investigate the “digital divide” in psychosis, especially as previous studies have tended to rely on small samples or purposive recruitment.

Perski et al [3] propose an evidence-based framework to account for how the “digital divide” may influence engagement, outlining that engagement is moderated by both the context (population and setting) and intervention (content and delivery). The emerging evidence indicates older, female, White, digitally skilled, and confident people without mental health problems

appear more likely to engage, although further research is needed. The multidimensional assessment of engagement is also recommended, incorporating self-report and objective metrics [3]. This study used both experiential and behavioral assessments of engagement. A review of studies evaluating the usage of digital therapies in mental health found that more frequent and prolonged use was assumed to be desirable [11,12]. However, this assumption risks conflating engagement with adherence and not recognizing that disengagement may reflect the e-attainment of personal goals if skills acquisition has been sufficiently supported. It is therefore suggested that optimal usage should be defined a priori, based on the intervention’s theoretical principles and mechanisms of change.

The identified relationships between engagement, population characteristics, and intervention content and delivery underscore the need for digital interventions to be designed so that the widest range of people are willing and able to use them. Human-centered design is increasingly employed in health care innovation to enhance user experience, thereby promoting engagement [13-17]. SlowMo therapy is an exemplar of an inclusive, human-centered design approach and therefore aims to overcome barriers to implementation across diverse groups [18,19]. Our multidisciplinary team of experts by experience, clinicians, researchers, industrial designers, and software developers integrated best practice principles of design thinking and participatory design to co-design the therapy. A risk inherent in participatory design is that the most willing, able, and vocal users are more likely to be involved, neglecting the needs of minoritized groups. To address this, we purposively sampled people from a wide range of backgrounds (ie, gender, age, ethnicity, cognitive abilities, use of technology, and attitudes to therapy) [20,21]. Adopting design thinking methodology meant we were able to address the problem of digital solutions often being skeuomorphic, replicating analogue versions of therapy artefacts (eg, a pen-and-paper form for monitoring and evaluating thoughts) and therefore failing to address barriers to use [22,23]. Our design research identified the importance of SlowMo therapy being usable, trustworthy, enjoyable, personalized, and normalizing and of it offering flexible interpersonal support [19].

In summary, this study examined digital literacy and engagement in the SlowMo therapy trial sample [5] to investigate if there was evidence of a “digital divide” and if demographics were associated with engagement. The therapy sample was first characterized in relation to their digital literacy at baseline, followed by a description of the SlowMo mobile app adherence based on self-report and system analytics data, and user experience evaluated using a self-report questionnaire. Associations between demographic factors, digital literacy, and engagement were also investigated. The research questions were as follows:

1. What is the digital literacy of the therapy sample and is this associated with demographic factors (ie, gender, age,

- ethnicity, and paranoia severity), suggesting a “digital divide”?
- Does the SlowMo mobile app demonstrate acceptable rates of self-reported and system analytics adherence, and is adherence associated with demographic factors (ie, age, gender, ethnicity, and paranoia severity)?
  - What are the self-reported rates of usefulness, enjoyment, and usability for the SlowMo mobile app, and is user experience associated with demographic factors (ie, age, gender, ethnicity, and paranoia severity)?

## Methods

### Design

This was a planned adjunct study to the SlowMo trial, a parallel-group randomized controlled trial that tested the efficacy of SlowMo therapy in reducing paranoia severity when added to TAU, compared with TAU, with 1:1 allocation and blinded assessors. Recruitment was from community mental health services with identical procedures across 3 main sites in England: South London and Maudsley National Health Service (NHS) Foundation Trust, Sussex Partnership NHS Foundation Trust, and Oxford Health NHS Foundation Trust. Additional patient identification centers, NHS trusts near each of the 3 main recruitment sites, were also used.

### Ethics Approval

The trial received a favorable ethical opinion (Camberwell St. Giles Research Ethics Committee: 16/LO/1862; IRAS: 206680).

### Participants

Inclusion criteria were an age of  $\geq 18$  years; persistent ( $\geq 3$  months) distressing paranoia (assessed using the Schedules for Clinical Assessment in Neuropsychiatry [24]); a score of  $> 29$  on the Green Paranoid Thoughts Scale (GPTS), part B, persecutory subscale [25]; a diagnosis of schizophrenia-spectrum psychosis (F20-29, ICD-1025); capacity to provide informed consent; or a sufficient grasp of English to participate in trial processes. Exclusion criteria were profound visual or hearing impairment; the inability to engage in assessments; currently in receipt of psychological therapy for paranoia; or a primary diagnosis of substance abuse disorder, personality disorder, organic syndrome, or learning disability. All participants gave written informed consent. The primary outcome was self-reported paranoia severity measured by the GPTS over 24 weeks. From May 1, 2017, until May 14, 2019, we assessed 604 people for eligibility and, of these, recruited 362 participants: 181 were allocated to the SlowMo group, and 181 were allocated to the control group. Of the 181 participants in the SlowMo group, 168 (92.8%) engaged with at least 1 SlowMo therapy session, and 145 (145/181, 80.1%) completed all 8 sessions. The sample attending at least 1 session ( $n=168$ ) were predominantly male (122/168, 72.6%), with a mean age of 42.77 (SD 11.99) years, and were mainly White British (111/168, 66.1%; followed by Black African: 13/168, 7.7%; Black Other: 13/168, 7.7%; Black Caribbean: 8/168, 4.8%; Asian: 6/168, 3.6%; mixed heritage not specified: 6/168, 3.6%; Arab: 5/168, 3.0%; Chinese: 4/168, 2.4%; Hispanic: 2/168, 1.2%). A schizophrenia diagnosis was most common (105/168, 62.5%;

schizoaffective disorder: 23/168, 13.7%; other schizophrenia-spectrum diagnoses: 40/168, 23.8%).

Digital literacy was assessed at the beginning of therapy, with 91.1% (153/168) of participants providing data. System analytics adherence data incurred some data loss at the beginning of the trial due to a bug in the code. Once rectified, analytics data were stored when the participant had the version of the mobile app with the analytics code installed; for individuals in therapy when the analytics issue was resolved, the app could be updated to this version at any stage of therapy. Participants were defined as having missing analytics (28/168, 16.7%) when there were insufficient data points to determine mobile app adherence according to our a priori criteria of at least 1 home screen view for at least three sessions. Analytics adherence data were available for 83.3% (140/168) of those attending at least 1 session. Self-reported adherence and user experience surveys (UESs) were assessed at the end of therapy, so data were only available for participants who completed every therapy session. Further, this assessment was not offered to the first 45 therapy cases, and a further 3 participants were not eligible to complete the UES, as they declined any engagement with the SlowMo mobile app. User experience data were obtained for 83 participants (83/168, 49% of therapy attenders; 83/97, 85% completion rate once UES collection commenced).

### Intervention Structure, Content, and Technology

SlowMo consisted of 8 individual, face-to-face sessions, each module addressing a specific topic, typically lasting 60 minutes to 90 minutes, within a 12-week time frame. The intervention followed a clinical trial manual that was consistent across the trial. The software includes an intuitive web app to augment face-to-face individual therapy sessions, which is synchronized with a native mobile app for use in daily life. Therapy sessions were delivered at locations of the participants' choosing, including clinic settings or at home, and behavioral work was carried out in the participants' locality. Therapy was delivered by 11 trained doctoral-level psychologists (10 clinical and 1 counseling) experienced in CBT for psychosis, with weekly group supervision, using recorded sessions.

The SlowMo web app is delivered via a touch screen laptop with interactive features including information, animated vignettes, games, and personalized content. In sessions, people learn that fast thinking is part of human nature. However, fast thinking can fuel worries, and thinking slowly is helpful in dealing with fears about other people. This key principle frames the sessions in which people are supported to try out ways to slow down (eg, by considering the impact of mood and past experiences and looking for safer alternative explanations). SlowMo therapy is presented as a journey that supports people to notice the large, fast spinning, and grey worry bubbles that fuel distress and make use of slow spinning and colored bubbles to shrink fears and feel safer. The use of personalization, ambient information, and particularly the use of visual rather than verbal metaphors targeted a step change in therapy delivery by enhancing appeal and reducing cognitive demands.

The SlowMo native mobile app was installed on a standard Android smartphone provided to participants. It assists people to notice their fears and thinking habits as they occur in daily

life and to access SlowMo strategies or personalized safer alternative thought bubbles. It consisted of a redesigned CBT thought record for managing paranoia, which is a commonly used tool for identifying and modifying distressing cognitions. Thought records are often digitally reproduced with the same interface as in paper versions, usually text prompts and response boxes presented as a form. These skeuomorphic designs do not address obstacles to the use of thought records, such as being cognitively demanding and having an unappealing, impractical interface. The mobile app interface therefore attempted to overcome the limitations of paper and skeuomorphic digital thought records. This incorporated an attractive visual representation of thoughts and their attributes (eg, conviction, distress, and thinking style); simple touch screen interactions to support monitoring and modifying thoughts; easy access to previously identified helpful suggestions and thoughts; positive reinforcement for engaging in slowing down; and a flexible interface that afforded several ways of slowing down fast thinking, depending on a person's needs and preferences (eg, quick access to safer thoughts on the home screen or sequentially slowing down a thought over multiple screens). Concerns about privacy were addressed by developing a native app with opt-in data transfer. The mobile app also relied on user-initiated interaction and optional push notifications to accommodate those who might find notifications intrusive [26,27].

### Research Question 1: Digital Divide—Digital Literacy

This was assessed in relation to (1) the self-reported ownership of smartphones or access to a computer, (2) the frequency of use of smartphones (excluding phone calls) and computers, and (3) confidence in using smartphones and computers. The frequency of use and confidence were assessed on scales from 0 to 100, with the anchors of “never” to “all the time” and “not at all” to “totally,” respectively.

### Research Question 2: Engagement—System Analytics and Self-reported Adherence

System analytics adherence was operationalized as at least 1 out-of-session interaction for a minimum of 3 out of 7 possible therapy sessions (session 8 data could not be included, as mobile app data syncing did not occur following the end of therapy). The adherence criterion was based on the assumption that engagement with the mobile app would be indicative of its usefulness, usability, and appeal, with app use also potentially reducing as the skill of slowing down is internalized, reflecting e-attainment [11,28]. Home screen views were selected as the target interaction, given the multiple routes to slowing down can be accessed via the home screen. Self-reported adherence was assessed by asking participants how much they were using the mobile app and if they intended to use it in the future (rated from “0 – never” to “100 – all the time”).

### Research Question 3: Engagement—UES

A 12-item self-report measure of user experience with the mobile app was developed (see [Multimedia Appendix 1](#)), adapted from a 26-item self-report measure employed by [10]. The UES consisted of 4 items assessing usefulness, 4 items assessing usability, and 4 items assessing enjoyment. Each item was rated on a scale from 0 to 100, with anchors of “totally

disagree” to “totally agree.” Items were summed (with 4 items reverse scored; range from 0 to 400 for each category), and a percentage score was calculated.

### Statistical Analysis

Summary statistics were calculated for all variables for the SlowMo therapy arm and split by site. The analysis investigated the associations between demographics and digital literacy (to evaluate the “digital divide,” research question 1) and demographics and engagement (assessed by behavioral [adherence] and experiential [self-reported user experience] metrics, research questions 2 and 3). Independent group *t* tests (gender and GPTS paranoia severity) or one-way ANOVAs (ethnicity and age) were performed for the continuous dependent variables of digital literacy, self-reported app adherence, and the UES, and chi-square tests were performed for smartphone ownership, computer access, and system analytics app adherence (rated adherent or nonadherent). Independent group *t* tests were also conducted to examine the association between system analytics adherence and pretherapy smartphone literacy. Categories for the participant demographics were gender (male, female), age (<35, 35-50, and ≥50 years), ethnicity (White ethnicity, Black ethnicity, and other minoritized ethnic groups), and paranoia severity (low and high, dichotomized by a median split of <61 and ≥62 on the GPTS). All statistical tests were 2-tailed

## Results

### Research Question 1: Digital Literacy and the Digital Divide

The SlowMo therapy group's rates of smartphone ownership, computer access, technology use, and digital confidence are displayed in [Table 1](#), by site and overall. This indicates that just over three-quarters of the sample owned a smartphone, which was consistent across all sites. The pattern of results suggests that computer and smartphone access, frequency of use, and confidence were generally lower in the inner-city site (London) compared with the other 2 sites, which were more rural (Oxford and Sussex). The impact of gender, age, ethnicity, and paranoia severity on smartphone and computer ownership, use, and confidence are shown in [Figures 1](#) and [2](#), respectively, with inferential statistics presented in [Table S1](#) in [Multimedia Appendix 2](#). Ownership is a binary outcome and is represented using bar charts. Use and confidence are continuous variables and shown with violin plots, as these indicate the data distribution. In support of previous findings indicating a “digital divide” in relation to age, there were significant age differences in smartphone literacy, with older people being less likely to report ownership and confidence in using them. Older people were also significantly less confident in using computers, with a comparable, nonsignificant pattern for frequency of phone and computer use. Similarly, in line with research identifying digital exclusion in relation to ethnicity, Black people reported significantly less computer access and smartphone and computer confidence compared with the White and other minoritized ethnic groups. However, paranoia severity did not have a significant impact on digital literacy, albeit the high paranoia group skewed toward lower ratings for all variables apart from

smartphone confidence. Women were less confident in using computers, and although not reaching significance, computer use and smartphone confidence were also relatively lower for women compared with men.

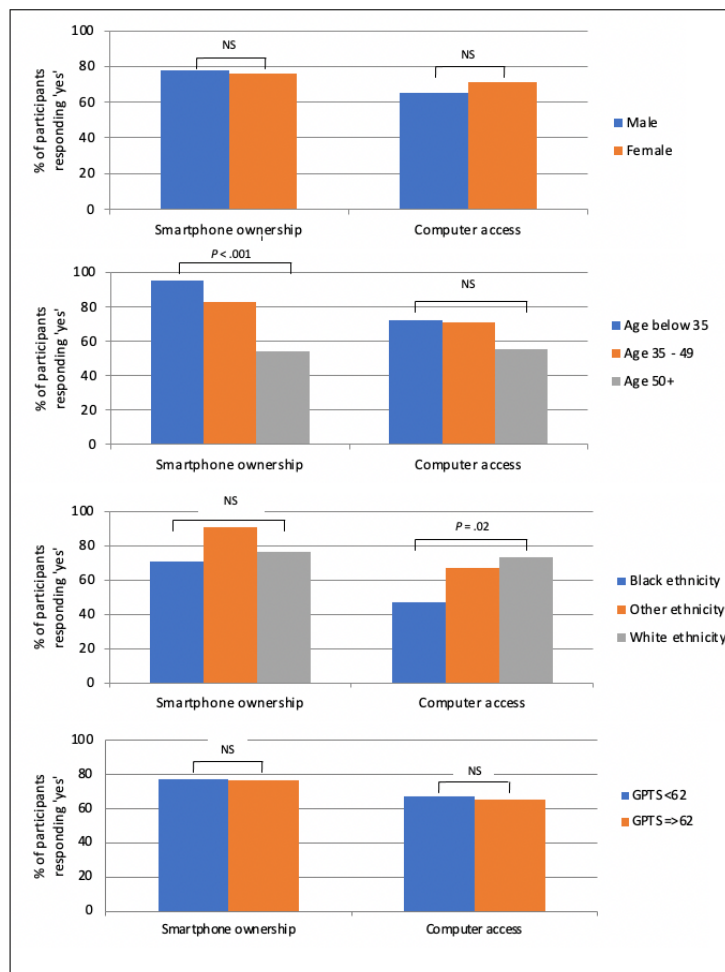
**Table 1.** Smartphone and computer access, use, and confidence in the SlowMo therapy group (n=168).

Variable	Location			Total
	Sussex (n=57)	Oxford (n=48)	London (n=63)	
Smartphone ownership reported <sup>a</sup> , n (%)	44 (77.2)	30 (76.9)	48 (77.4)	122 (77.2)
Computer access reported <sup>b</sup> , n (%)	42 (77.8)	26 (66.7)	34 (56.7)	102 (66.7)
Smartphone use, mean (SD)	63 (37)	61 (38)	57 (35)	60 (36)
Smartphone confidence, mean (SD)	65 (32)	62 (31)	55 (36)	60 (33)
Computer use, mean (SD)	51 (38)	46 (34)	43 (33)	47 (35)
Computer confidence, mean (SD)	63 (32)	57 (26)	50 (32)	56 (31)

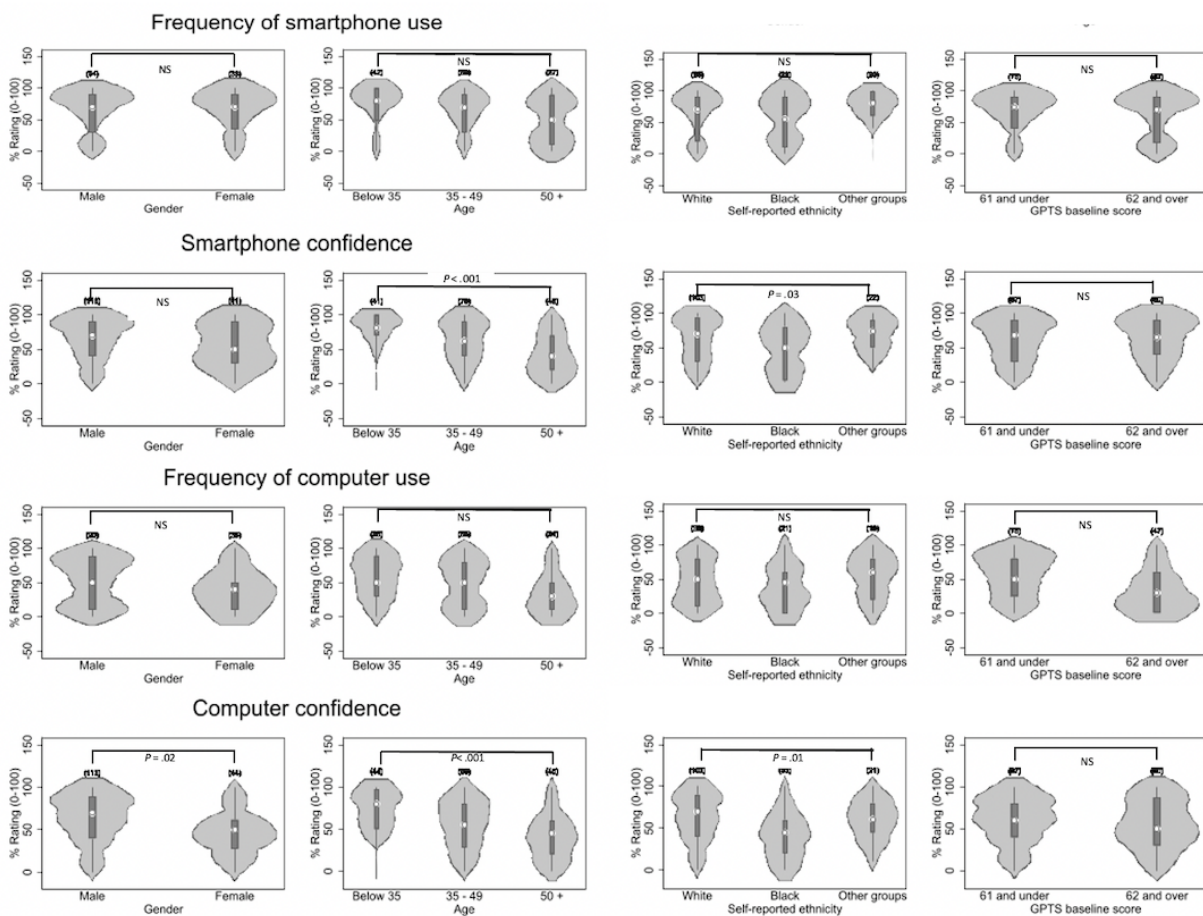
<sup>a</sup>n=158, 93% completion.

<sup>b</sup>n=153, 91% completion.

**Figure 1.** Smartphone and computer ownership by gender, age, ethnicity, and paranoia severity in people attending at least 1 therapy session (n=168). GPTS: Green Paranoid Thoughts Scale; NS: nonsignificant.



**Figure 2.** Frequency of smartphone use, smartphone confidence, frequency of computer use, and computer confidence by gender, age, ethnicity, and paranoia severity in people attending at least 1 therapy session (n=168). GPTS: Green Paranoid Thoughts Scale; NS: nonsignificant.



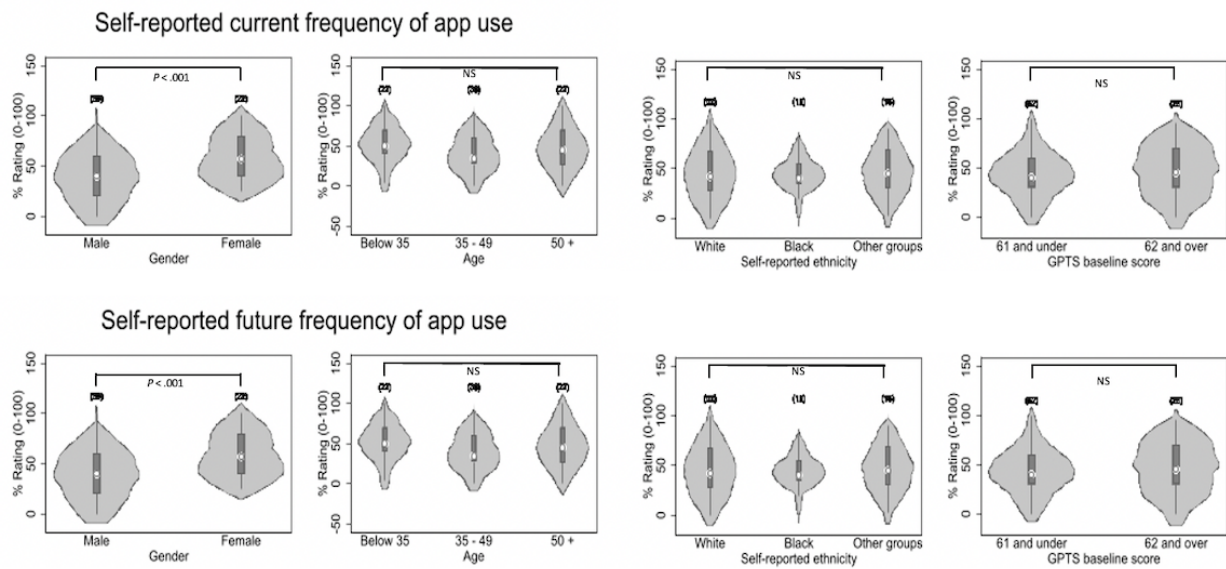
**Research Question 2: Engagement—Self-reported and System Analytics Adherence to the SlowMo Mobile App**

Self-reported current and intended future use of the mobile app are reported in Table S2 in Multimedia Appendix 2. The data indicate that rates of current use varied from “never” to “all of the time,” with participants on average reporting using the app just under half of the time (mean 44.77, SD 25.69). All participants reported at least some intention to use the app again in the future, and average frequency of intended use was also higher than current use, at just over half of the time (mean 62.19, SD 23.00). Self-reported adherence was compared by participant characteristics of age, gender, ethnicity, and paranoia severity, as shown in Figure 3 and Table S3 in Multimedia Appendix 2. Women reported significantly more current and future intended use of the app than men. There were no significant differences

in current and intended use for age, ethnicity, or paranoia severity.

For system analytics adherence, 65.4% (100/153) of participants in the therapy group met the mobile app criterion. This increased to 71.4% (100/140) for participants who attended at least 1 session (and were therefore provided with a mobile phone with the mobile app installed). In the subgroup who attended all 8 sessions, this increased further to 80.7% (96/119), suggesting a high rate of adherence. One-fifth of participants (26/119, 21.8%) used the mobile app outside of every recorded session. System analytics adherence was compared for demographic factors and pretherapy smartphone use and confidence, as shown in Table 2. There were no significant differences in analytics adherence to the mobile app for age, gender, ethnicity, or paranoia severity. However, adherence in people who attended all 8 sessions was associated with using smartphones more frequently and being more confident in their use prior to therapy.

**Figure 3.** Self-reported current frequency of app use and self-reported future frequency of app use as measures of adherence for participants who completed SlowMo therapy and a user experience assessment (n=82). GPTS: Green Paranoid Thoughts Scale; NS: nonsignificant.



**Table 2.** System analytics of adherence to the mobile app compared by age, gender, ethnicity, paranoia severity, and smartphone digital literacy (n=140).

Participant variable	Attended at least 1 session			Attended all 8 sessions		
	Test value	P value	MD <sup>a</sup> CI	Test value	P value	MD CI
Age	$\chi^2_2=4.65$	.10	N/A <sup>b</sup>	$\chi^2_2=2.32$	.31	N/A
Gender	$\chi^2_1=1.01$	.32	N/A	$\chi^2_1=0.65$	.42	N/A
Ethnicity	$\chi^2_2=0.19$	.55	N/A	$\chi^2_2=0.96$	.86	N/A
Paranoia severity	$\chi^2_1=0.37$	.54	N/A	$\chi^2_1=0.01$	.95	N/A
Smartphone use—frequency	$t_{101}=-1.17$	.24	-27.49 to 7.07	$t_{90}=-2.48$	.02	-46.33 to -5.13
Smartphone use—confidence	$t_{124}=-1.58$	.12	-23.19 to 2.55	$t_{108}=-2.17$	.03	-32.16 to -1.45

<sup>a</sup>MD: mean difference.

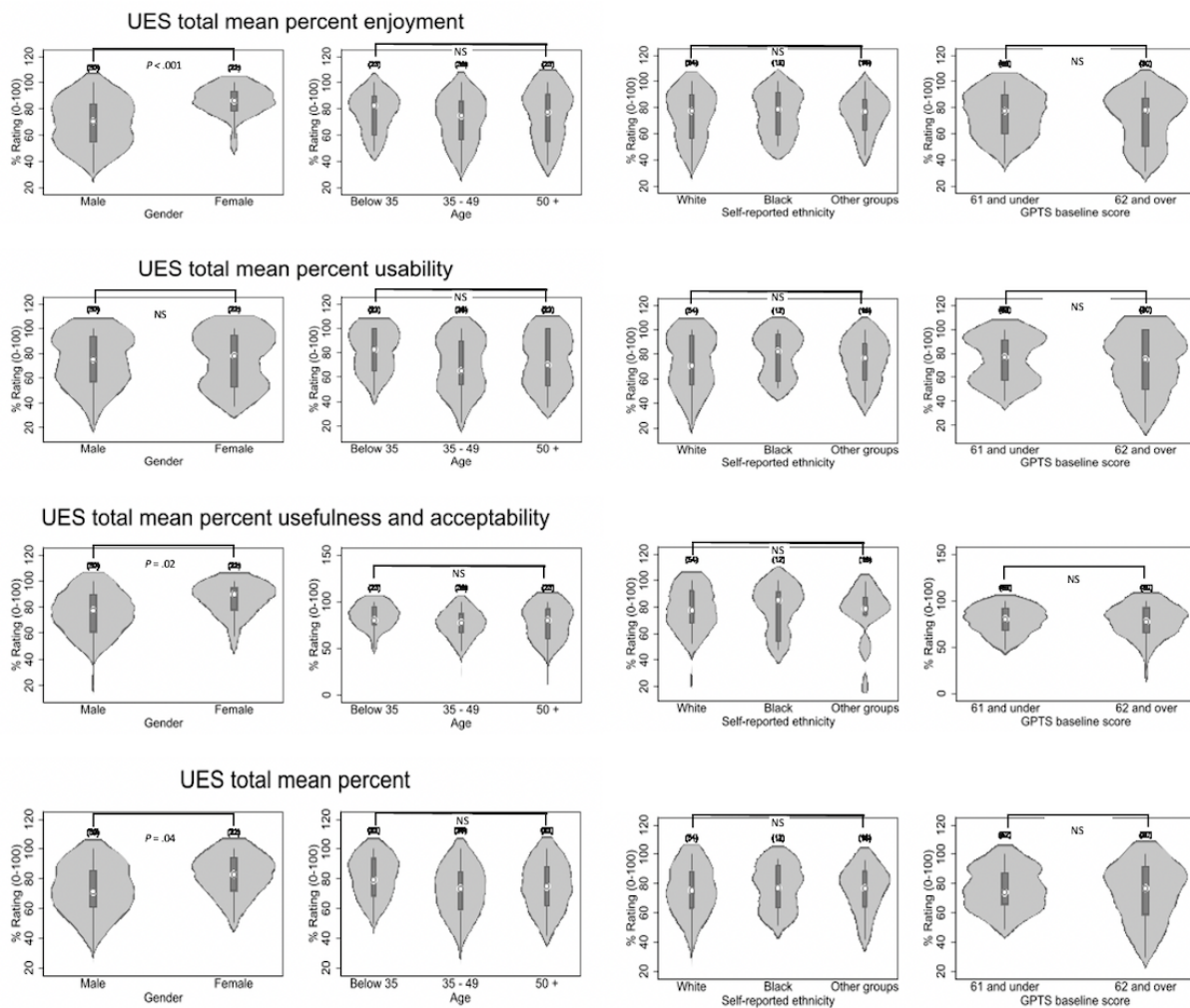
<sup>b</sup>N/A: not applicable.

### Research Question 3: Engagement—UES for the SlowMo Mobile App

The UES findings for each subscale and the total score are presented in Table S4 in Multimedia Appendix 2. UES ratings were comparable across all subscales, with the majority of people providing positive ratings for enjoyment, usability, and usefulness (overall score: mean 75%, SD 17.06%). However, there was a large range of scores, suggesting that the mobile app was positively received by most, but not all, participants.

The UES ratings were compared by demographics (see Figure 4 and Table S5 in Multimedia Appendix 2). There were significant differences for gender, with women reporting higher rates of enjoyment and usefulness, although rates of usability were similar for men and women. Significant differences in digital literacy prior to therapy did not appear to generalize to self-reported user experience, as there were no significant differences for age and ethnicity. There were also no differences in UES ratings in relation to paranoia severity.

**Figure 4.** Mean scores on the user experience survey (UES) subscales of enjoyment, usability, usefulness, and acceptability as well as total scores by gender, age, ethnicity, and paranoia severity in participants who completed SlowMo therapy and a user experience assessment (n=82). GPTS: Green Paranoid Thoughts Scale; NS: nonsignificant.



## Discussion

### Principal Findings

In this study, the presence of the “digital divide” was replicated in relation to age and ethnicity, with older people and Black people reporting reduced phone or computer access and less confidence in using both types of technology. This is consistent with previous studies of psychosis [6] and the general population [2], indicating higher rates of digital exclusion in relation to age and ethnicity. Women were also found to be less confident in using computers compared with men. Previous evidence is equivocal in relation to gender, with indications of female exclusion in the general population and an absence of gender effects or male exclusion being more common in mental health samples [2,29]. Although we did not find an association between paranoia severity and digital literacy, in contrast to previous findings indicating higher rates of exclusion in mental illness, this may be due to sample characteristics, as a schizophrenia-spectrum diagnosis was an inclusion criterion for the SlowMo trial. Alongside the between-group effects, it is notable that the digital literacy variables often had multimodal distributions, suggesting marked variability in technological

competencies. This underscores the need for an individual assessment of digital literacy, regardless of a person’s demographic background, to identify needs and support engagement.

The results further indicated high rates of engagement with the SlowMo therapy mobile app, based on a multimodal assessment incorporating behavioral and experiential measures. The a priori criterion for mobile app adherence was met by 81% of participants who completed all 8 sessions. This is of note, given that prompts were not provided as mandatory nor was use incentivized as part of the trial design, in contrast to other research investigating mobile apps for psychosis [30-32]. We have also previously reported high rates of engagement with therapy sessions (80%) and the SlowMo web app session content (95%) [5,33]. Killikelly et al [34] reviewed adherence in 20 studies of digital therapeutics for psychosis and found that adherence ranged from 28% to 100%, with a mean of 83%, suggesting that adherence to the SlowMo mobile app and web app was consistent with previous research. This is notable, as our sample (n=140) was markedly larger than the included studies (70% sampled, n<40, range=9-104). Further, the experiential assessment of engagement strengthened the

conclusions from the behavioral measurement, as the self-report user experience ratings suggest that most people perceived the mobile app as easy to use, enjoyable, and useful.

Importantly, age, ethnicity, and paranoia severity were not associated with any behavioral or experiential engagement measures, in line with our previous findings that these variables also did not moderate therapy outcomes [5]. This suggests that the SlowMo therapy design was effective at bridging the “digital divide,” as demographic differences in digital literacy at baseline did not generalize to differences in engagement during therapy. Unsurprisingly, people who reported being more confident, frequent users of smartphones prior to starting therapy were more likely to be adherent to the mobile app. As mentioned previously, this insight reinforces the importance of digital literacy assessments so that individualized technical support can be provided as needed. We also found that women were significantly more likely than men to report current and future adherence to the mobile app and higher rates of usefulness and enjoyment, although usability ratings and adherence assessed by analytics were comparable. This is consistent with previous findings that women in the general population and those with psychosis are more likely to engage in digital therapeutics than men [35,36]. We tentatively suggest that a key obstacle to men’s engagement with the mobile app may have been due to the home screen displaying users’ worries, which is inconsistent with design research insights that, on average, men prefer solution-orientated approaches [36]. Accordingly, we plan to modify the interface to focus primarily on safer thoughts and strategies, with additional interactions required to access upsetting thoughts, and will test if this does optimize the user experience for a diverse range of men.

Overall, the study results suggest that the SlowMo therapy design did enhance the user experience as intended for a diverse range of people and therefore shows promise in overcoming well-documented challenges to engagement. Our previous inclusive, human-centered design research highlighted the need for psychosis digital therapeutics to be usable, trustworthy, enjoyable, personalized, and normalizing and to offer flexible interpersonal support [19]. This shaped the SlowMo therapy design, such as the use of personalized bubbles as a simple visual metaphor to represent thoughts and coding a native app to support privacy. We therefore recommend adopting an inclusive, human-centered design approach in the development of digital therapeutics. This includes applying design thinking methodology and critically, ensuring purposive sampling from a wide range of people, to support co-design that is representative of the target population.

The findings are also in line with the framework by Perski et al [3] for factors influencing engagement with digital therapeutics, which, as mentioned previously, demonstrates how an individual’s sociocultural context may influence digital therapeutic engagement. In support of this framework, we found demographic differences in digital literacy, which appeared to be attenuated by the SlowMo therapy design, as these differences did not generalize to behavioral or experiential engagement. Consistent with findings of lower digital literacy in women [2,29], we found men were more confident in using technology at baseline. Conversely, women reported more use

and satisfaction with the mobile app, in line with findings indicating that women engage better with health apps [35]. Our findings build on the framework by Perski et al [3] by highlighting how therapeutic design interacts with population characteristics to determine engagement, although this hypothesis requires more rigorous research with experimental manipulation of intervention designs in different demographic groups. A limitation of the work is that at least some mobile app analytics were lost for 28 people in the therapy sample due to a bug in the code, although we do not consider that these analytics data likely differed from the rest of the sample. Future work will allow us to validate our findings with larger samples.

### Clinical Implications

Digital therapeutics need value propositions of delivering clinically meaningful outcomes for a wide range of people, given that most health technologies fail to be adopted, scaled up, spread, and sustained, even where they are efficacious in randomized controlled trials [37]. The tailoring of the SlowMo design to its specific target problem, a range of intended users, and the delivery context, as evidenced by the bridging of the “digital divide,” supports initial adoption. We are currently refining an implementation strategy for SlowMo, incorporating the learning from this study. Given the impact of SlowMo on a range of outcomes including well-being, we plan to build on this by incorporating other therapeutic targets and techniques, using principles of agile science and responsive technology [38,39]. This study suggests that inclusive, human-centered design should be incorporated in the design of digital therapeutics, to increase the likelihood they are fit for purpose “in the wild.”

### Conclusion

In conclusion, the findings suggest that the SlowMo therapy trial sample experienced a “digital divide” with a lack of technology access, confidence, or use associated with age, ethnicity, and gender that was consistent with previous research indicating digital exclusion in those who are older, are female, or are from a minoritized ethnic group [2,3]. Experiential and behavioral measures of engagement however found that these differences did not generalize to the user experience of the SlowMo mobile app for age and ethnicity. Self-reported user experience was higher in women, consistent with findings of women engaging more with health apps [35]. The study validates our previous design research [19], as it suggests the SlowMo design optimized the user experience of the intervention as intended and resulted in high rates of adherence for a diverse range of people. This study is in line with a recent co-produced call for digital therapeutic research to focus on how we can enhance existing interventions, the impact of psychosis on engagement, and whether digital therapies can improve reach and access for minoritized groups [40]. Together with the clinical efficacy and moderation results from the SlowMo trial, the findings support the further development of SlowMo therapy and testing in routine services. Our approach underscores the need to focus on user experience as a means of optimizing effectiveness when developing therapeutics, and we strongly advocate the adoption of this strategy to improve outcomes in mental health care.



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## Conflicts of Interest

DF reported receiving personal fees from Oxford VR outside the submitted work. No other disclosures were reported.

### Multimedia Appendix 1

User experience survey (UES).

[[DOCX File , 15 KB - humanfactors\\_v9i3e29725\\_app1.docx](#) ]

### Multimedia Appendix 2

Supplementary tables.

[[DOCX File , 26 KB - humanfactors\\_v9i3e29725\\_app2.docx](#) ]

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## Abbreviations

**CBT:** cognitive behavioral therapy  
**GPTS:** Green Paranoid Thoughts Scale  
**NHS:** National Health Service  
**NIHR:** National Institute for Health Research  
**TAU:** treatment as usual  
**UES:** user experience survey

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