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Contents

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<u>Original Paper</u>

Development of the Electronic Social Network Assessment Program Using the Center for eHealth and Wellbeing Research Roadmap

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Abstract

Background: The number of Web-based psychological and behavioral interventions is growing. Beyond their theoretical underpinnings, a key factor to the success of these interventions is how they are designed and developed to ensure usability over a new method of delivery. Our team has adapted ecomapping, a tool for visualizing family caregiver social network resources, for the Web. Here, we describe how we designed and developed the electronic Social Network Assessment Program (eSNAP) Web-based tool using a framework of the Center for eHealth and Wellbeing Research (CeHRes) Roadmap for Web-based intervention development. The CeHRes Roadmap is still new in terms of tool development and we showcase an example of its application.

Objective: The aim of our study was to provide an example of the application of the Web-based intervention development process using the CeHRes Roadmap for other research teams to follow. In doing so, we are also sharing our pilot work to enhance eSNAP's acceptance and usability for users and the feasibility of its implementation.

Methods: We describe the development of the eSNAP app to support family caregivers of neuro-oncology patients. This development is based on the 5 iterative stages of the CeHRes Roadmap: contextual inquiry, value specification, design, operationalization, and summative evaluation. Research activities to support eSNAP development prior to implementation included literature review, focus groups, and iterative rounds of interviews.

Results: Key lessons learned in developing the eSNAP app broadly fell under a theme of translating theoretical needs and ideas to the real world. This included how to prioritize needs to be addressed at one time, how the modality of delivery may change design requirements, and how to develop a tool to fit within the context it will be used.

Conclusions: Using the CeHRes Roadmap to develop Web-based interventions such as eSNAP helps to address potential issues by outlining important intervention development milestones. In addition, by encouraging inclusion of users and other stakeholders in the process, Web-based intervention developers using the Roadmap can identify what will work in the real world and increase feasibility and effectiveness.

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KEYWORDS
intervention development; user-centered design; oncology; caregiver

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Introduction

Web-based health interventions can increase knowledge, adherence to treatment regiments, and patient empowerment [1,2] by addressing access, privacy, and scalability barriers found in traditional, in-person interventions such as education, therapy, or support group sessions. However, not all Web-based interventions are successful; some fail to produce an effect, while others simply fail to become implemented or integrated into practice [3]. While the scientific quality of the intervention is essential to success, ensuring that a Web-based intervention is designed appropriately is also a key factor [4].

Here, we describe steps outlined in the Center for eHealth and Wellbeing Research (CeHRes) Roadmap for Web-based intervention development [5] and how we applied the steps in our work. The CeHRes Roadmap was established based on evaluation of prior frameworks, empirical evidence, and expert input [5]. The roadmap takes an iterative approach through 5 phases of development: contextual inquiry, value specification, design, operationalization, and summative evaluation (Figure 1). As this is a new model of tool development, exemplars of its application are needed.

Our goal was to describe how our interdisciplinary team, consisting of behavioral scientists, designers, and computer programmers, applied the CeHRes Roadmap to partner with social workers and family caregivers and develop the electronic Social Network Assessment Program (eSNAP). eSNAP is a Web-based social network assessment tool grounded in theory, designed to support family caregivers of patients with primary brain tumor. By sharing our pilot work in this process, we hope other research teams will benefit from the example and our lessons learned. All research activities were conducted under institutional review board (IRB) approval.

Figure 1. Stages of the CeHRes Roadmap with research tasks.
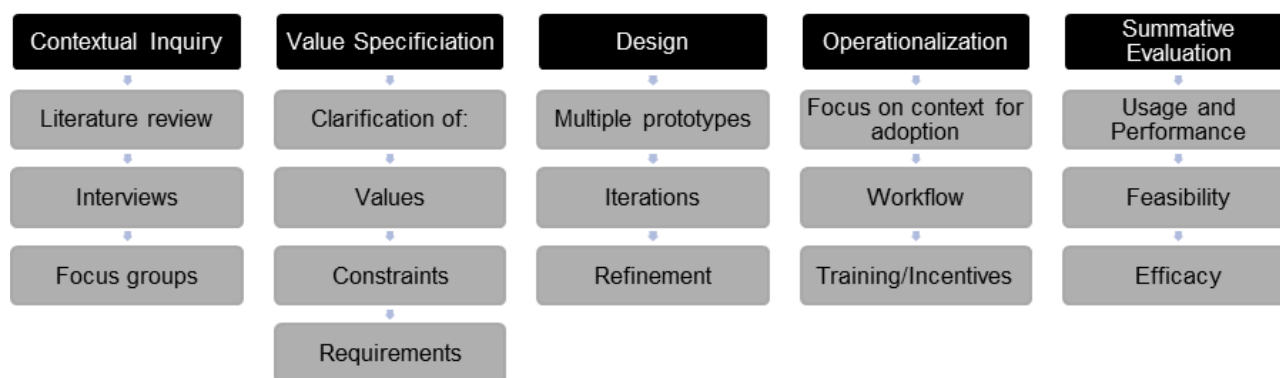
Methods

The CeHRes Roadmap provided the framework for our intervention development. Because the roadmap is iterative and exploratory, we conducted several small studies with various methodologies across the 5 steps. The goal of the first step of the roadmap, contextual inquiry, is to gain an understanding of prospective users, the problem they face, and how one might solve that problem. In order to verify the findings of our literature review, we conducted a focus group with providers and interviews with family caregivers, both of whom we considered important stakeholders. The second step, value specification, is meant to clarify values, constraints, and requirements—what is important to include in the tool and how it should work. To clarify these, we conducted another round of purpose-driven interviews with family caregivers and providers. In later iterations of these interviews, we were also able to identify an information architecture, which helped us moving into the third step, design. Digital prototypes were developed and presented to family caregivers to give feedback on design and flow of the experience. Iterations were tested as new features were added until caregivers were unable to suggest features to improve the tool. At this point, we moved to the fourth step, operationalization, which involves introducing the technology into practice. We are currently conducting a feasibility trial to gather information about implementation of

our tool in the real world and collecting preliminary outcome data, to address the fifth step, summative evaluation.

Results

Contextual Inquiry

Contextual Inquiry involves gaining an understanding of prospective users and their context. This includes defining the problem, gathering input about how to solve the problem, and gaining an understanding of relevant environmental factors. Our team used a variety of approaches to address the goals within this stage, including a review of the literature, interviews, and focus groups.

Literature Review

Family caregivers relieve demands on the formal healthcare system by caring for patients at home. Often, the family member who spends the most time caregiving is a spouse, but can also be an adult child, parent, or other individual. [6] The majority of cancer caregivers are women and on average they are in their mid-50s. [7] While some report benefiting from providing care (eg, learning new skills, strengthening relationships) [8], there is evidence that informal caregiving can be burdensome [9-11] and stress associated with caregiving can adversely affect quality of life, psychological and physical health [12-14], and patient outcomes [15,16]. Caregivers of patients with primary brain tumor are at particular risk for high burden, given the low

survival rate, rapid status changes, and cognitive and emotional impact of the disease [17,18]. In addition, this population often receives little attention in research.

The caregiving stress process model [19] and research evidence [20,21] suggest that a potential solution to reduce caregiver burden is the provision of adequate social support from family caregivers' existing networks of friends, family, and others (eg, information or help problem solving), emotional support (eg, "being there" or validation), and instrumental support (eg, assistance with household tasks). Caregivers who report adequate support have better health and quality of life [22,23]. Thus, the specific problem we chose to address was that, despite the value of support, caregivers—especially caregivers of patients with primary brain tumor—often cut themselves off from their social networks or fail to take advantage of available support to focus on providing care independently [23,24].

To address this issue, healthcare providers have been urged by the Institute of Medicine to assess caregiver social connections [25] and to facilitate use of social resources to reduce burden [26]. Yet, the systematic assessment of caregivers' social resources is not yet integrated into routine clinical practice. A primary barrier is a lack of efficient and user-friendly clinical tools to collect and process this information [11]. Thus, caregivers' social network resources (or lack thereof) are typically invisible to providers [12]. Further, if providers do not engage in discussions with caregivers about social resources, critical information is missed that may impact patient care decisions.

Prior work has outlined several other approaches to increase support. For example, some studies focused on increasing support between patient and caregiver [27]; however, this approach did not seem feasible for a primary brain tumor population since patients may be unable to provide support. Other teams focused on providing Web-based information or support groups, which can provide benefit [28,29] but do not address or leverage the existing social network. Finally, some teams developed tools focused on helping caregivers identify and problem-solve their needs [30]. This seemed like an effective, practical approach for our population; however, a continued barrier is identifying resources within caregivers' existing networks that could provide reliable, valued assistance [31].

Ecomapping is a social work tool for visualizing an existing social network (Figure 2). It organizes and depicts information about that network's size, strength, quality, and function, and can highlight barriers to support, such as social isolation or failure to take advantage of existing support [32]. Visual representation off-loads the cognitive burdens of building and storing mental maps of relationships and allows the perceptual system to quickly search for relationships of interest [33]. Social network visualization can prime or create implicit associations to the availability of these resources.

Specific benefits of using ecomaps have included caregivers identifying unrealized social resources and facilitating provider-caregiver communication and rapport [34-36]. Through visualization, both caregivers and providers can quickly understand caregiver needs and existing resources and providers can be better prepared to help caregivers more effectively and efficiently problem solve the use of existing resources or refer to formal support services. We elected to modify this tool and improve it through automation as a means to solve the problem of caregiver social resource use. Our conceptual model, based on the stress process model [19], is shown in Figure 3. Using our tool to create a visualization of a caregiver's social network is expected to help organize social support resources and facilitate caregiver-provider communication. Through both of these mechanisms, we expect that social support will increase, which will buffer the negative impact of objective stressors and strains on caregiver quality of life and physical health by reducing the appraisal of subjective burden.

To verify this approach and ensure we had considered all the important factors, we conducted pilot interviews and a focus group.

Caregiver Interviews

Four spouse caregivers of neuro-oncology patients undergoing treatment at a National Cancer Institute (NCI) designated Comprehensive Cancer Center were interviewed about social support needs and caregiving. Caregivers were also introduced to the concept of ecomapping and asked their opinions about whether they thought visualization would be helpful in changing how they used their support networks. All participants were female with a mean age of 35.5 years (SD 5.5). The mean length of the relationship between caregivers and spouses was 13 years (SD 2.2).
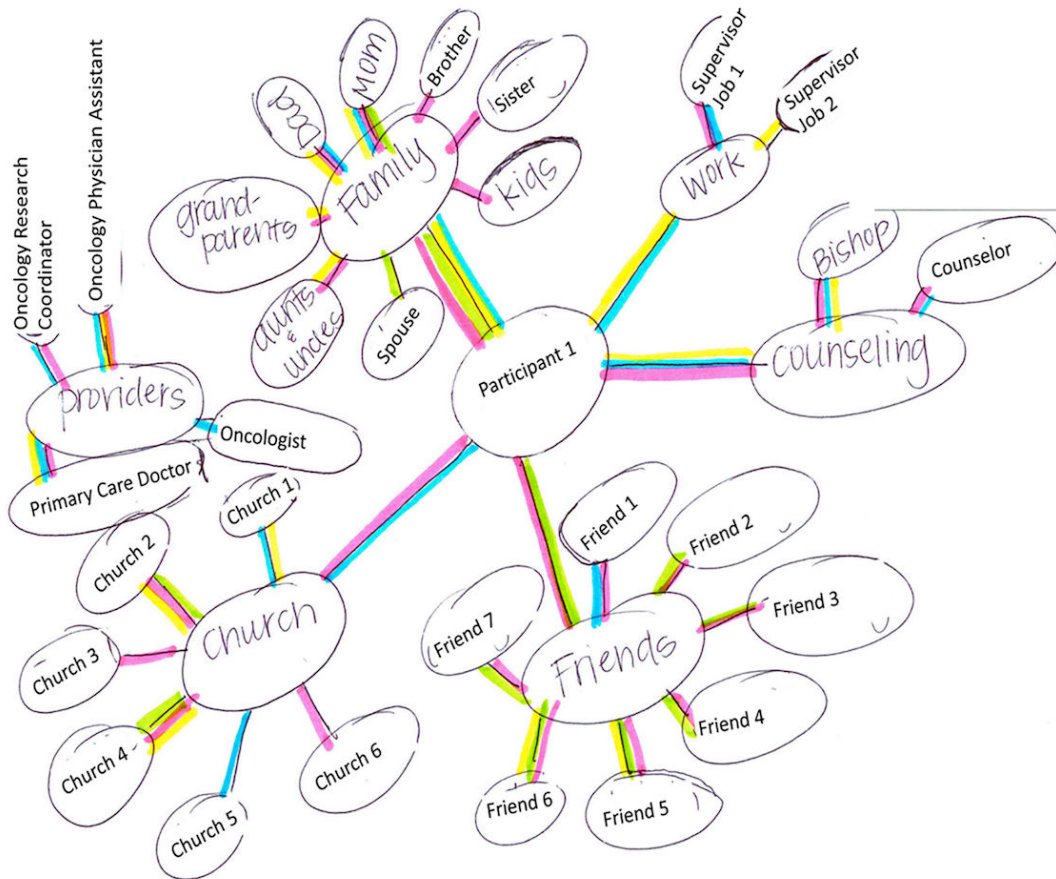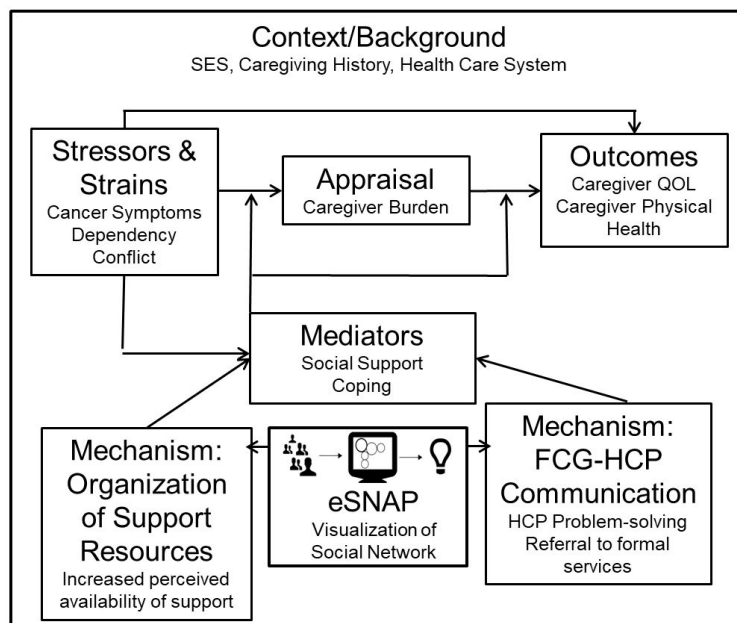
Figure 2. Example ecomap.

Figure 3. Conceptual model.

Table 1. User needs, tool requirements, and feature specifications of eSNAP.

User need	Tool requirement	Feature specifications
Understand the need for support when caregiving	Informative introduction with explanation of purpose	4-page tailored introduction with form, icons, text, and buttons
Understand types of support	List and explain each type of support separately to avoid information overload	Nest data in separate tabbed containers for each category of support
Write down people that can offer support to the user	Provide forms to create lists for each category of support	Include forms within each tabbed container
Evaluate effectiveness of support	Mark the level of helpfulness for each person entered	Add a position slider to rank 1 of 3 levels of effectiveness. Default to "Somewhat Helpful"
Identify the strengths of users' network	Rate each category of support based on number and helpfulness of network members	Include a summary page to rate strength of each support category, based on number of people and helpfulness
Ability for user to take the network with them	Include a printable summary page	Format summary data into printer friendly version
Identify areas of network that can use additional support	Identify the types of support that may benefit from additional resources and provide information	Provide a link to resources for each category that has less than 2 stars on the summary page
Find specific supportive resources	Provide lists of resources for each type of support	Include a backend editable database with caregiver resources
Maintain support network changes and additions	Begin with end in mind by building tool on Web-based technologies ensuring accessibility across various platforms and devices	Design a Web app compatible with Mac and Windows OS, with text and elements sized for various landscape screen sizes.

Caregivers reported discussing support resources with neuro-oncology team members but were hesitant to initiate these discussions. When discussions about support resources occurred, they were viewed as insufficient in terms of time and depth. Consistent with findings in other populations [34,35], caregivers verified that social support was very important but often perceived as lacking. Caregivers felt that it was stressful to identify and organize available resources on their own, but felt that having some kind of visualization of their support network would be helpful. Caregivers also indicated that support changed over time and recommended that an exercise to identify and visualize support be done early on and modified as needed. However, one problem identified by caregivers using traditional ecomaps was that the visualizations tended to be messy; it was difficult to expand the Web to include many resources and there often wasn't a consistent logic to where different resources were placed.

Provider Focus Group

A focus group of neuro-oncology clinic members, including 2 physicians, 1 nurse, 1 medical assistant, and 1 social worker was conducted to discuss social support needs of family caregivers and the utility of social support network visualization. The feasibility of implementing research in the clinic was also discussed.

Providers confirmed that creating a visualization was one way to facilitate in-depth support discussions between caregivers and nurses or social workers; some team members already had familiarity with the concept of ecomapping. All team members mentioned that having this information available, at least to some members of the team, would be helpful and visualizations would save time over gathering narratives. Barriers to ecomap

use included time, the need to maintain clinic workflow, and potential challenges in addressing issues raised by caregivers.

Value Specification

After outlining our problem and identifying and verifying a potential solution, we moved to value specification: identifying the most important stakeholder values to be translated into user requirements. User requirements are detailed descriptions of what has been identified by users as important aspects of the tool. Some initial values were identified within the previous interviews, including the desire to refer back to the visualization and change it over time and the need for the tool to be easy to use both independently and in contexts with available medical professionals, while not interrupting clinic workflow. To follow up on these preliminary interactions with caregivers and healthcare providers, we conducted more detailed and purpose-driven interviews with clinic social workers and family caregivers. These helped to define user needs, tool requirements, and feature specifications (Table 1). These interviews also helped shape the language and scope of the tool.

In discussions with oncology social workers and case managers, we found that professionals were concerned with caregiver burnout and wanted this more specifically addressed. Thus, we refined an existing category of "companionship support" to better reflect resources that help promote self-care activities. Similarly, in interviews with caregivers, they mentioned that some of their resources were valued for their ability to share information (eg, sending patient updates) or coordinate others (eg, organizing dinner drop-off). In response, we added a "communication support" category and noticed caregivers were more likely to refer to instrumental support with a more casual

term. The decision we made was to change instrumental support to "hands on" support to better fit with the natural terminology.

Design

Design involves developing prototypes of the technology interface that conform to the user values and specific technical specifications derived from the previous stage. Design can be evaluated at a system level for user-friendliness, content level for tailored, meaningful information, and service level for responsiveness and feasibility for use in the environment.

Our first step was to identify mental models for information architecture or the most logical process to collect and present the information within the tool. We presented caregivers and social workers information processes used in developing the ecomap (grouping people, identifying individuals who can offer support, and identifying types of support) in random order and asked them to order them to reflect their preferred process for data input. We discovered, contrary to how paper-based ecomaps were created, that the most frequent order was to start with the type of support needed, followed by listing individuals who could provide that type of support; few people felt the need to group people.

Based on the previously identified constraints, requirements, and information architecture, the team produced 4 preliminary sketch concepts (Figure 4) that explored options for the design. Each sketch was internally evaluated and 2 moved on to development as digital prototypes for caregiver evaluation sketches (Figure 5). One digital prototype version took visual form as a set of lists for each category of support to appropriately match caregiver's mental models. The other version consisted of a pie chart, which dynamically changed with the input of more information to increase user engagement.

The digital prototypes were presented and tested with caregivers who were asked to give feedback on the design and flow of the experience. The amount of time caregivers tested the prototypes varied by stage. Early on when deciding on an information architecture and general design concept, sessions were relatively short (approximately 10 minutes), but later some participants spent up to 30 minutes with the Web-based prototype. We assessed effectiveness (successful completion of tasks) and efficiency (time to learn and carry out an action) and we collected comments through open-ended questions. The design was iteratively updated based on feedback. Of the 10 caregivers that were interviewed, 9 (90%, 9/10) provided demographic information, 77% were female (7/9), and the mean age was 52.3 (SD 11.8) years. All were non-Hispanic white, half were employed full-time, and 66% (6/9) had at least some college education. Most caregivers were spouses of patients, but 2 (20%, 2/10) were adult children and 1 (10%, 1/10) was a parent of the patient.

Both versions were shared initially with caregivers; however, there was a clear and unanimous preference for the list version after 3 interviews. As a result, we chose to pursue the list version of the design for further development. Users also told us they wanted some element to show when they were finished using the app. In response, we added a summary and evaluation page where we incorporated the wheel element; this version was evaluated much more positively.

Consistent suggestions gathered in the open-ended feedback included adding resources beyond the user's social network. We decided to add a database of supportive resources into the app. Caregivers who tested this feature were able to bookmark contact information for more formal support resources. After testing the new version that included the additional external resources, caregivers were unable to suggest additional features to improve it.

A Web-based app was selected over a native mobile app designed for a particular operating system to allow for flexibility and more accessibility. The design prototype of the app built in InVision was provided to the Web developer. The app was built closely following the specifications provided. This Web-based app was built using Hypertext Markup Language (HTML), Cascading Style Sheets (CSS), and Javascript, and it uses the browser session storage property to store data temporarily, which is removed once the app's browser tab is closed. The app can be used on the most popular browsers; however, it is recommended to be used in the Chrome browser for the best user experience.

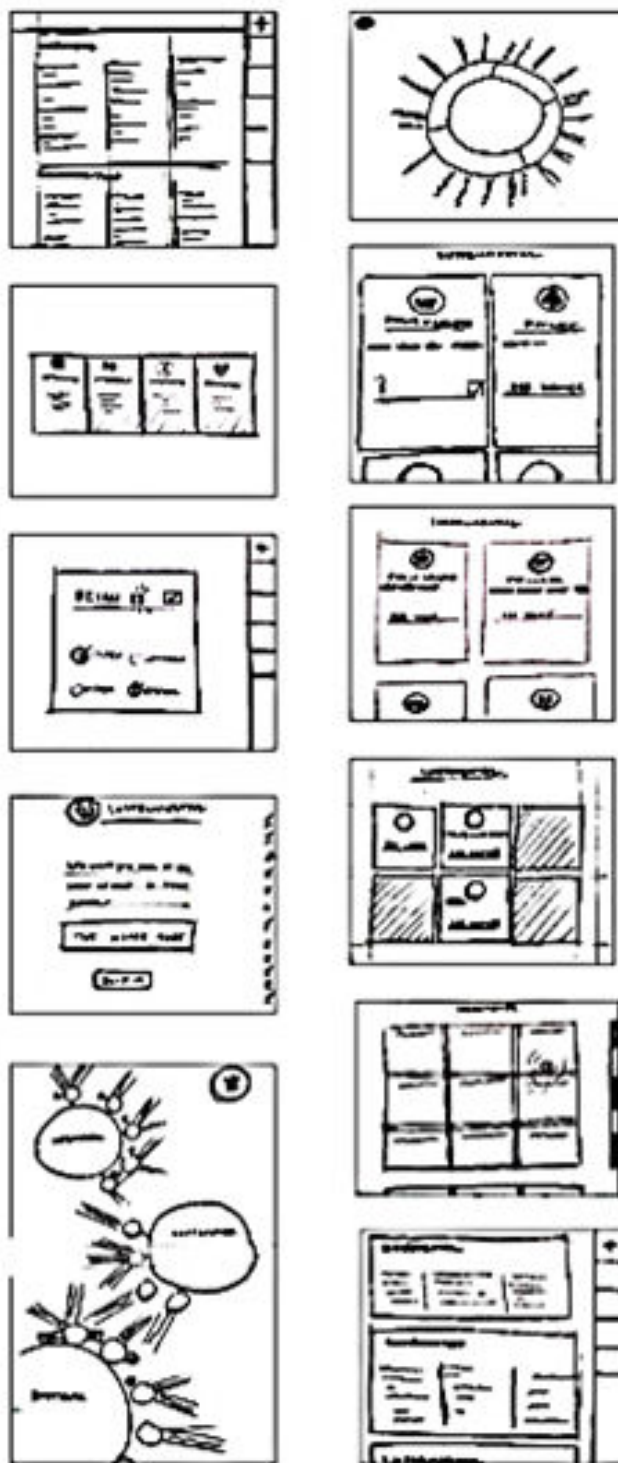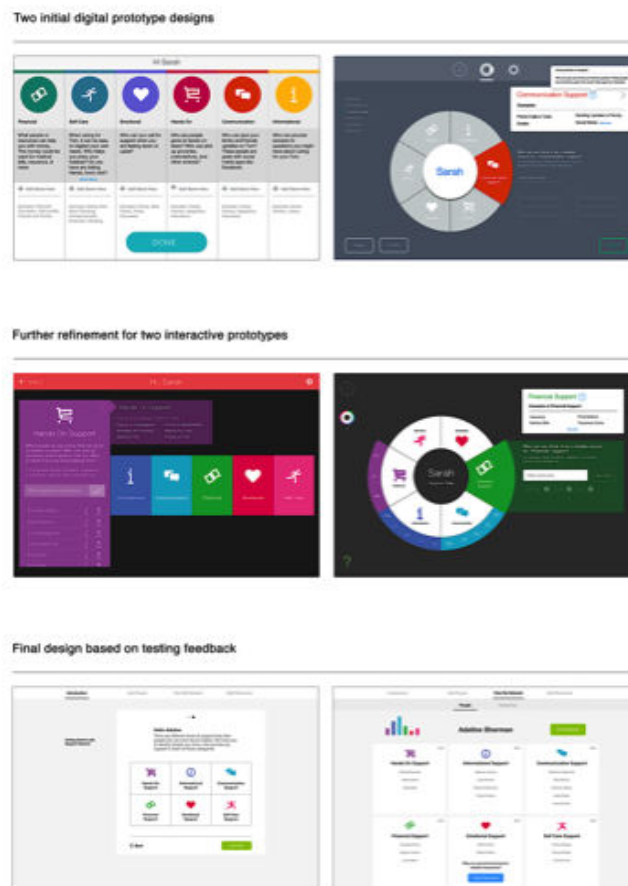**Figure 4.** Preliminary sketch concepts.

Figure 5. Iterations of prototype design.

Operationalization

Operationalization involves the introduction and use of the technology in practice. This includes factors such as training, incentives, and a plan for adoption. While the ultimate goal is for eSNAP to be a standard clinical tool available for use in clinics and connected to the electronic medical record, the current goal is to implement it as a research tool so that we can test its effect on caregiver support, burden, and well-being. To this end, the introduction of eSNAP is somewhat facilitated. Namely, research studies are common in the cancer center environment and clinicians are incentivized to promote participation. Families who receive care at these institutions are also used to being approached to participate in research. As part of the informed consent process, researchers are able to explain the tool being tested, its purpose, and benefits to participation. Moreover, funded research often allows for small participant compensation. Given these incentives, as well as the ability for people to learn about and habituate to the program, electronic health (eHealth) tools that are developed and implemented through research have some advantages, though an eye towards broader implementation and dissemination to the community is also important.

To further encourage use of eSNAP in the cancer center, we engaged clinical stakeholders, including social workers, to ensure buy-in and prevent gatekeeping, and are documenting issues encountered by the research staff in using eSNAP within a clinical setting (ie, problems with connectivity or interruptions that occur as caregivers use the tool). These notes can help determine the appropriate time and place to approach future caregivers without disrupting clinic flow, one of the values of the provider team. This information can also guide the next steps of eSNAP development as we prepare for a larger test of the tool within the clinic and down the road as we broaden our reach. While the tool is currently being developed with a neuro-oncology caregiving population in mind, it may be flexible enough to be adapted for application in other populations.

Summative Evaluation

Summative evaluation includes usage and performance criteria. Not only is it important to ensure that people use the technology, it is also important to know that the technology has the desired effect. The expectation of evaluation is another benefit to rolling out a tool in a research setting. Trained researchers are skilled at selecting appropriate, validated measures and participants expect to complete surveys. Thus, it is more likely that higher quality and more complete evaluative feedback is obtained.

In order to prepare for a summative evaluation and ensure that that the design is optimized we are currently conducting a feasibility trial. This trial will include a sample of 40 caregivers of patients with primary brain tumor. In this study, we will collect preliminary data on what we expect to be key outcomes for eSNAP: caregiver social support, burden, and well-being. We will also obtain information about use of social work or counseling services, which we consider an important mechanism

for how eSNAP may affect caregivers. In a summative evaluation we may expect our tool to change users' support, either through heightened awareness of availability or through recommendations to meet with social workers who have access to caregiver social network visualizations. We hypothesize that more at-risk caregivers will meet with social workers and social workers who have easier access to social network information will be better able to tailor recommendations and problem-solve. Based on our conceptual model (Figure 3), we expect increased support to buffer caregiver stress and potentially provide resources to decrease the appraisal of burden, which in turn will improve caregiver quality of life and physical health. However, our main goal at this stage is to obtain feedback on eSNAP's current design and to determine if a larger trial of the tool is warranted. To do this, we will capture process data, such as how long it takes caregiver participants to use the tool, as well as impressions from clinic staff about the impact of the tool. We will also gather quantitative and qualitative usability and likeability data. Caregiver participants will complete a modified version of a design feedback instrument used in previous research [37-39] and will be asked to provide feedback about what they liked and what they thought could be improved in the tool through open-ended survey questions. This data will be analyzed to inform further refinements of the tool prior to an efficacy trial where we will test the primary psychosocial outcomes identified above.

Discussion

Principal Findings

The promise of the Internet as a dissemination tool has interested many researchers in developing Web-based interventions [40]. In addition to challenges that pertain to all intervention development, such as ensuring theoretical underpinnings and selecting an appropriate methodology [41,42], additional challenges exist for Web-based interventions including design considerations and tailoring content to a broader, more diverse audience [40]. Using the CeHRes Roadmap to develop Web-based interventions such as eSNAP helps to address these issues by outlining important milestones and including users and other stakeholders in the process.

There were several key lessons learned in implementing the CeHRes Roadmap that were critical to the development of eSNAP, largely falling under a broader theme of translating theoretical needs and ideas and applying them to tools that need to be effective in the real world. One key lesson was about user values. Although there is well-established literature on caregiver needs, it often is not clear what needs to be addressed simultaneously. For example, while we were able to gather from the literature that engaging existing social support networks would be an important caregiver need, we also learned that caregivers also valued new ways to identify more formal resources, including services within the cancer center and community that can assist families coping with cancer. Caregivers told us that both informal and formal needs were linked together. This led us to add this element to our tool, which ultimately makes it more engaging and useful for caregivers.

A second key lesson was about how design requirements change depending on the modality. Although there is a lot of support for the use of paper-based ecomapping, which creates a visualization in the form of a "web" of support, we found that applying the same information architecture was not intuitive for caregivers when starting from scratch with only the end goal of visualizing a support network in mind. Rather, they preferred to see the data they entered in a list format. Although these processes seem trivial, making the tool "think" the same way as the user facilitates use by reducing frustration. Beyond our specific tool, this has broader implications for translation of theoretical design concepts to practical use [43].

Finally, we learned that it is important to design eHealth programs that support, rather than interfere with systems currently in existence [44]. One major issue with eHealth research is the failure to account for the context. One early decision we had to make was where caregivers would initially access our tool. Initially, we had hoped to leverage the Web-based tool to allow users to access it from anywhere. However, providers in their focus group worried about caregivers in distress not having a safety net and recommended that the initial use happen with easy clinical access, though because the tool is Web-based, later interactions may happen at home. Thus, we revised our plan to integrate eSNAP with the existing social work system to streamline existing services provided, rather than circumventing or replacing them.

By explicitly calling for evaluation, the CeHRes Roadmap also provides important insight into next steps. Although our current goals for eSNAP are to establish feasibility, our ultimate goal is to create an efficacious tool that can be implemented into clinical practice. To do this, we can create outcome benchmarks to establish success; if those are not met, we can return to different points within the CeHRes process to make adjustments. For example, we can return to caregivers to investigate ways to improve the design and functionality of eSNAP or we can return to providers to investigate better ways to integrate into clinical practice. This also hints at how the tool could be adapted for other populations. Further research could investigate how different types of caregivers use eSNAP and how the tool impacts their experience in obtaining social support.

The primary immediate outcome targeted by eSNAP is caregiver social support, which we believe will buffer objective stressors of caregiving to improve caregiver quality of life and physical health. Successfully improving these outcomes in caregivers can have important implications for how clinical care is delivered and for caregiver health. Within the current healthcare system, shortcomings exist with respect to targeted and tailored referrals and delivery of psychosocial support services.[45] In addition, there is a call for tools to assist oncologists in providing family-centered psychological care services to ensure high quality cancer care [46]. Our work and others' have shown that high support resources for caregivers, especially early in the cancer care trajectory, decreases the burden of care and caregiver stress [20,21,31,47-49]. Lack of support and stress in caregiving has been linked to physical health outcomes including future heart disease and chronic pain, and psychological health outcomes including depression in caregivers [50,51]. Protecting cancer caregivers not only improves the cancer treatment

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experience and allows for better patient care, but has implications for future health years later. Well-developed Web-based interventions, such as eSNAP, can play an important role in providing high quality, family-centered care.

Limitations

In some of our early-stage pilot work, our participant samples were relatively homogeneous and small. However, at these stages our goal was directed more towards verifying the conclusions we had drawn from the scientific literature and getting input and insight about more "real world" issues and values. Similarly, some of the data that we received from users is of a qualitative nature and the instruments used to obtain data are not broadly validated. This limits the generalizability of the results and limits the conclusions that can be drawn. However, because we were only validating design decisions prior to conducting a formal summative evaluation, the data is useful to inform our designs. As we progress through the CeHRes stages and our goals change, our studies include more participants, increase diversity and outcomes are measured more rigorously. Obtaining broader input may impact our sense of the user needs and tool requirements or specifications. However, the CeHRes Roadmap is inherently recursive as Web-based

intervention development needs to be an iterative process. The Roadmap provides a framework for revisiting these stages as new information emerges or evolves.

Conclusion

As more eHealth interventions are introduced, the implications of their design and development for clinical practice become more pronounced. Those tools that are developed in frameworks such as the CeHRes Roadmap, which encourages the involvement of end-users in the development process, will be more suited for use in their intended populations, be better tailored for implementation in the intended environment, and will be better able to show evidence for their efficacy. Well-developed tools will make important contributions to improve patient and family health. If patients, families, and clinicians have good experiences with these tools, they may be more likely to use or recommend eHealth interventions in the future. By addressing how eSNAP is meant to be used effectively in real-world settings and establishing benchmarks for success through the CeHRes Roadmap, we will be in a better position to ensure that it will be effective and remain in use, helping families in the long-term.

Conflicts of Interest

None declared.

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Abbreviations

CeHRes: Center for eHealth and Wellbeing Research
eHealth: electronic health
eSNAP: electronic Social Network Assessment Program

Original Paper

A Technological Innovation to Reduce Prescribing Errors Based on Implementation Intentions: The Acceptability and Feasibility of MyPrescribe

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Abstract

Background: Although prescribing of medication in hospitals is rarely an error-free process, prescribers receive little feedback on their mistakes and ways to change future practices. Audit and feedback interventions may be an effective approach to modifying the clinical practice of health professionals, but these may pose logistical challenges when used in hospitals. Moreover, such interventions are often labor intensive. Consequently, there is a need to develop effective and innovative interventions to overcome these challenges and to improve the delivery of feedback on prescribing. Implementation intentions, which have been shown to be effective in changing behavior, link critical situations with an appropriate response; however, these have rarely been used in the context of improving prescribing practices.

Objective: Semistructured qualitative interviews were conducted to evaluate the acceptability and feasibility of providing feedback on prescribing errors via MyPrescribe, a mobile-compatible website informed by implementation intentions.

Methods: Data relating to 200 prescribing errors made by 52 junior doctors were collected by 11 hospital pharmacists. These errors were populated into MyPrescribe, where prescribers were able to construct their own personalized action plans. Qualitative interviews with a subsample of 15 junior doctors were used to explore issues regarding feasibility and acceptability of MyPrescribe and their experiences of using implementation intentions to construct prescribing action plans. Framework analysis was used to identify prominent themes, with findings mapped to the behavioral components of the COM-B model (capability, opportunity, motivation, and behavior) to inform the development of future interventions.

Results: MyPrescribe was perceived to be effective in providing opportunities for critical reflection on prescribing errors and to complement existing training (such as junior doctors' e-portfolio). The participants were able to provide examples of how they would use "If-Then" plans for patient management. Technology, as opposed to other methods of learning (eg, traditional "paper based" learning), was seen as a positive advancement for continued learning.

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Conclusions: MyPrescribe was perceived as an acceptable and feasible learning tool for changing prescribing practices, with participants suggesting that it would make an important addition to medical prescribers' training in reflective practice. MyPrescribe is a novel theory-based technological innovation that provides the platform for doctors to create personalized implementation intentions. Applying the COM-B model allows for a more detailed understanding of the perceived mechanisms behind prescribing practices and the ways in which interventions aimed at changing professional practice can be implemented.

Introduction

Despite being one of the most common interventions that patients receive when admitted to a hospital, prescribing is rarely an error-free process [1,2]. Prescribing errors place a substantial burden on the health system and can result in preventable adverse drug events, prolonged hospital stay, and an increased risk of death. The cost to the National Health Service (NHS) in England is in excess of £750 million annually [3].

The causes of prescribing errors are complex. Contributing factors include individual lack of knowledge and experience, lack of professional support focused on prescribing practices, and limitations in the work environment [2,4,5]. Consequently, there is a need to develop effective and innovative ways of improving prescribing practices. Foundation doctors are a particularly important professional group to target, as they order approximately 70% of hospital prescriptions and are twice as likely to make errors than the consultants [1].

Prescribers receive little feedback on their mistakes and ways to change future practice. In addition, the feedback that is provided is often irregular and insufficient [6]. A number of recent systematic reviews suggest that audit and feedback interventions may be an effective way of changing the behavior of health professionals [7-9] through improving performance and professional standards. A recent study examining the effectiveness of a pharmacist-led audit and feedback intervention found that it increased appropriate antimicrobial prescribing [10], suggesting that this may be an appropriate strategy for improving prescribing in general.

Once they receive feedback on their prescribing practices, the prescribers have to decide what to do differently in the future to change their behavior. Providing feedback alone has been shown to be less effective than feedback that includes both explicit targets and an action plan [7]. Implementation intentions or "If-Then" plans have been shown to be effective in changing behavior in general [11]. Our preliminary work has shown that workshops based on these psychological theories may be helpful in improving prescribing safety [10].

However, audit and feedback interventions on prescribing are rarely used in hospitals because of logistical difficulties such as problems identifying the prescriber from a signature alone [12]. In addition, it is important to identify ways in which we can deliver audit and feedback interventions in a busy clinical environment. Running workshops for patient-facing health professionals in hospitals is particularly difficult because of

shift work [10]. More research is therefore needed to examine novel delivery methods specifically focused on applying audit and feedback to prescribing within hospitals. Technology-based interventions are particularly appealing as a delivery method, as they are perceived as helpful in numerous areas of clinical practice such as providing tailored information to patients [13], providing timely access to information to support practice [14,15], and emphasizing responsibility and competence relating to areas of clinical practice [15].

Implementation Intentions

Theoretical approaches to behavior change in the context of prescribing behaviors creates an opportunity to develop interventions based on increasing awareness of mistakes and encouraging critical reflection [16]. Implementation intentions are "If-Then" plans that link a critical situation ("if") with an appropriate response ("then") [17]. They are a commonly used technique to address health behavior change and have been shown to have sustained effects on behavior change [18,19]. This method has been used successfully in a wide range of health contexts [18,20-22]. There have also been a number of successful applications of this approach in areas of health professional practice, including delivery of mental health services [23], improving clinical nursing practices [24], enhancing vaccination rates [25], as well as helping nurses and midwives incorporate healthy lifestyle behaviors in their own lives [26]. However, it remains unclear whether this approach can be used in the context of improving the prescribing practices of health professionals. An implementation-intentions−based intervention can be delivered via a technological platform without the need for debriefs with expert input. One of the aims of our study was to examine whether implementation intentions are perceived as an acceptable and feasible intervention delivery component for interventions aimed at improving prescribing practices.

The COM-B System of Behavior

The COM-B system [27] presented in Figure 1 [28] has been developed as a part of the behavior change wheel, designed to specifically inform intervention design [27,29]. The COM-B (capability, opportunity, motivation, and behavior) system proposes that engagement in behavior change occurs when one or more conditions are met. Individuals must have the capability to engage in the behavior, the opportunity to carry out a behavior, and the motivation to engage in the behavior rather than any other competing behaviors at the time. The model recognizes that behavior change is determined by an interacting

system involving these different components [27]. The *capability* component includes both psychological and physical ability to carry out the behavior, *motivation* includes both reflective and automatic processes involved in initiation of the behavior, and *opportunity* includes the physical and social environment that facilitates the behavior change [27]. The COM-B model has been applied to health professional practice such as behavior change relating to test ordering behavior [30], identifying target behaviors associated with adult hearing aid fitting consultations [31], and examining the barriers and enablers to delivering health assessments [32] and writing discharge prescriptions [33].

Using the COM-B model allows theoretical insights to be used to formulate specific recommendations for intervention design [27]. The model also includes consideration of specific barriers and facilitators involved in the uptake of interventions and the subsequent behavior change. This study aims to examine the acceptability and feasibility of a novel technological innovation aimed at health professional behavior change, which is lowering the incidence of prescribing errors. As such, the COM-B model provides important insights into the barriers and facilitators to delivering interventions aimed at changing prescribing behavior as well as to inform the design of interventions.

Figure 1. The COM-B (capability, opportunity, motivation, and behavior) model based on Michie et al.
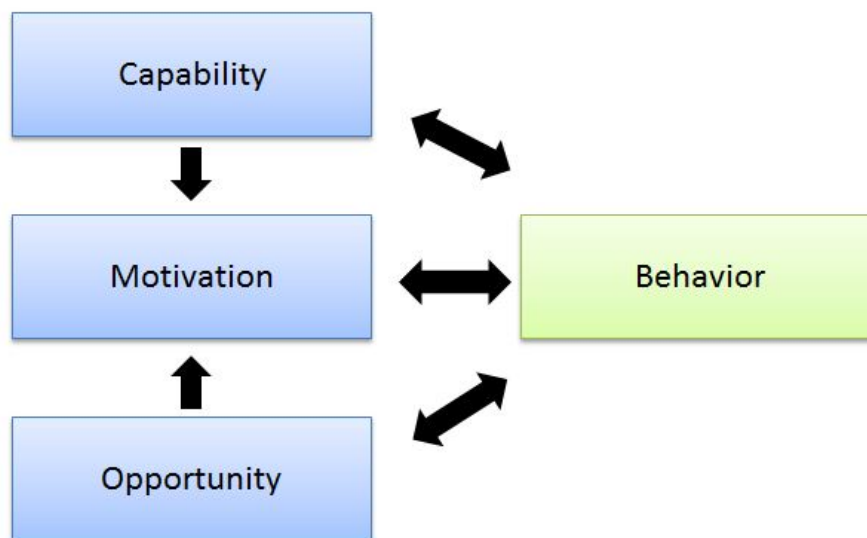
Aims

Through qualitative semistructured interviews with foundation doctors, this study addressed three specific aims: (1) to evaluate the acceptability and feasibility of providing prescribing error feedback via a technological innovation (MyPrescribe, a mobile-compatible website informed by implementation intentions), (2) to analyze and discuss the findings in the context of an established behavior change theory, the COM-B model, and (3) to outline a series of practical implications and recommendations for using MyPrescribe to change the prescribing behavior of health professionals involved in prescribing.

Methods

Development of MyPrescribe

MyPrescribe is a mobile-compatible website that delivers feedback on prescribing errors in an appropriate manner to both medical and nonmedical prescribers and enables implementation

intentions [17] (ie, what to do differently in future occasions) to be used without the need for debriefs with expert input. Throughout the development of MyPrescribe, a series of workshops with pharmacists and junior doctors were conducted to ensure that the most appropriate technological solution was developed for prescribers working in acute care trusts. Regular meetings were conducted with clinical pharmacists working on wards to ensure that data collection integrated with their existing workflow. Prescribing error data were collected by clinical pharmacists at the study sites using a previously developed data collection tool, $Form^2$[34], for use on an Apple iPad. This allowed ease of data collection and transfer of information to MyPrescribe. A unique identifier was used to send the information from $Form^2$ to MyPrescribe. Doctors could log in and work through a series of screens, where they were presented with details of their prescribing error and asked to construct a personalized implementation intention as to how they planned to prevent such an error from occurring in the future. Relevant screenshots from MyPrescribe are presented in Figure 2.

Figure 2. Screenshots of MyPrescribe user interface.
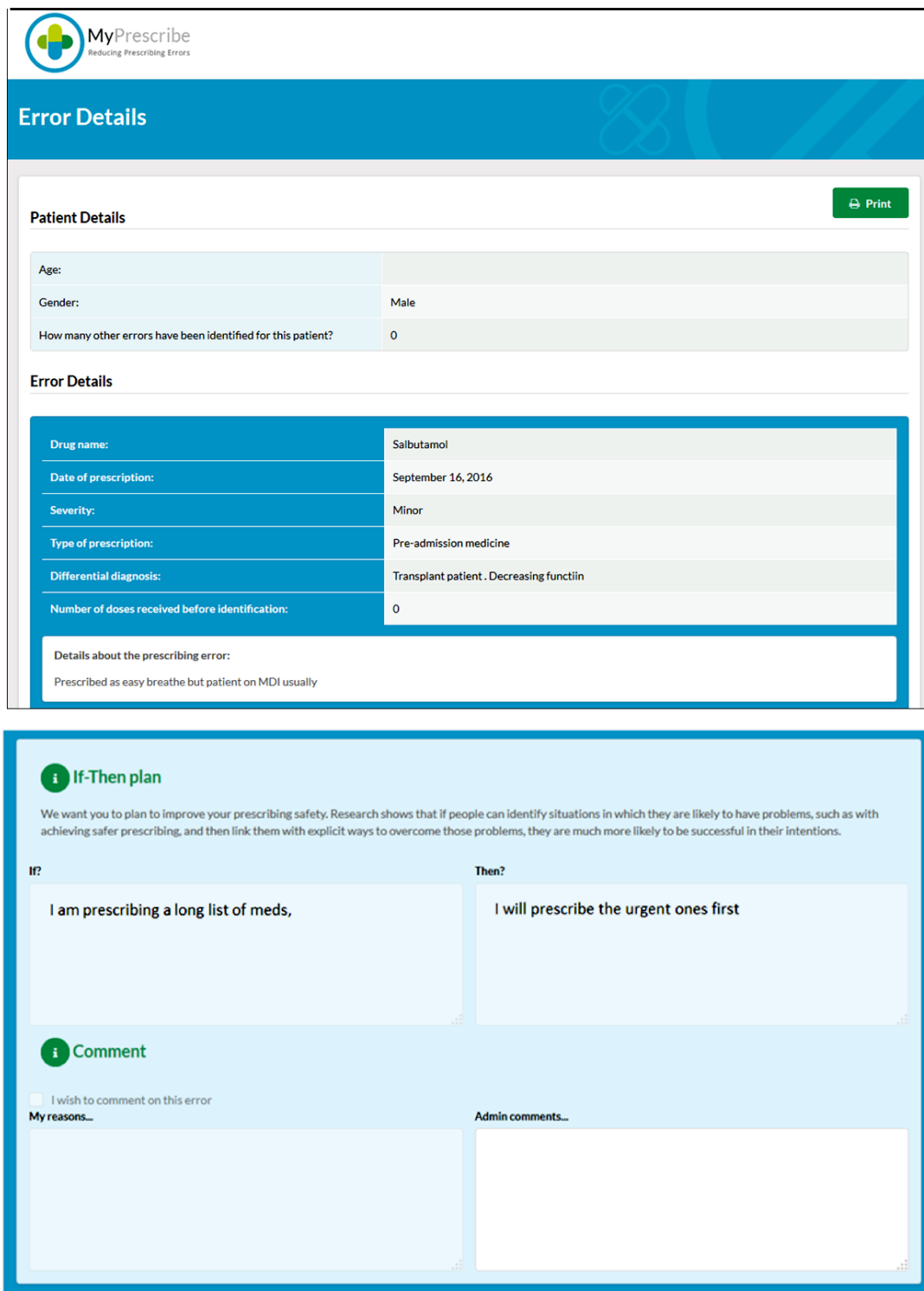
Platform and Browser Compatibility

Since October 2004, all websites must meet the World Wide Web Consortium (W3C) specification for accessibility to comply with the UK Government Disability Discrimination Act 1995. The website was developed to conform to the W3C standard of HTML5, where possible, as well as CSS 3.0. The website was developed to meet the W3C's Web Accessibility Initiative level A specification and therefore was fully functional in browsers that comply with W3C standards, including Internet Explorer, Firefox, Chrome, Safari, and Edge. As a standard, the website designers HMA (Health Marketing Agency) checked browser compatibility on Internet Explorer 10+ as well as the last 2 versions of Firefox, Chrome, and Safari. The website was fully functional on previous versions of these browsers as well as those not listed. However, some styling may vary for these browser types.

The website was developed to conform to NHS software requirements and security systems. Data security during the transfer between the device and the server was achieved by using Transport Layer Security/Secure Sockets Layer for all communication. This is a cryptographic protocol that is designed to protect against eavesdropping, tampering, and message forgery, which is also used for Web-based banking transactions. Data are stored on the Amazon Web Service (AWS), which has the strictest and most evolved IT compliance standards globally. The website uses the AWS servers in Ireland, which comply with European regulations on data protection.

Participants and Methods

Pharmacists and junior doctors (foundation year 1 [FY1] and foundation year 2 [FY2]) were recruited from two large NHS Foundation Trust hospitals in Greater Manchester. To obtain a sufficient amount of data, pharmacists (n=11) were invited to collect prescribing error data for junior doctors (n=52) over a 4-month period. The two trusts provided two different environments (electronic and paper-based prescribing) to maximize the potential for the website to be rolled out more broadly to other hospitals at a later stage.

A subsample of foundation doctors recruited though convenience sampling was asked to trial the website using data collected by clinical pharmacists with whom they usually worked. The participants were asked to log into the website, view a series of errors, and asked to interact with the website, thereby engaging with all the components. The same group of participants was then invited to take part in semistructured interviews exploring the perceptions of the acceptability and feasibility of MyPrescribe as a training tool aimed at improving prescribing practices. The interview was conducted immediately after the participants had used the intervention (within a 24-hour period) to aid recall of the specific errors identified and the specific perceptions of using the system. Participants were aware of both aspects of the study beforehand. The topic guide was developed to address each component of the COM-B model to gain insights into the key issues associated with the prescribing practices and the implementation of MyPrescribe. The topic guide explored three key areas, including (1) the extent to which this intervention could be integrated into daily practice, (2) the acceptability of how a psychological theory (implementation intentions) had been used to inform MyPrescribe, and (3) the perceptions of whether this intervention could reduce prescribing errors generally.

The potential participants were identified by the members of the pharmacy team at each study site and sent an invitation to be a part of the study. The doctors who were interested were provided with a participant information sheet outlining the purpose of the study, and their written consent was obtained. The recruitment strategy used a purposive sample to ensure maximum variation in terms of the grade of the doctor (FY1 and FY2), hospital site, and clinical specialty. The study received governance approvals from a local R&D approval office (ref 191058) and a university research ethics committee (ref 15541).

Data Analysis: Mapping Findings to the COM-B System

Interviews were transcribed verbatim, and NVivo was used to code and categorize the data. Analysis was informed by the principles of framework analysis [35], with findings mapped to the components of the COM-B model. This approach was chosen, as it enabled both predetermined and emergent issues to be explored in depth while using the COM-B model as an explanatory framework. It is particularly useful for research in applied health service settings. Initial coding was carried out by one of the authors (CK) and themes were discussed and agreed upon with a second study author (MPT), whereas the emerging theoretical concepts and issues were agreed upon by all study authors. After an agreement was reached, the themes and code names were matched to the relevant domains of the COM-B model, which included capability, opportunity, and motivation. This involved rereading the data relating to each code and mapping them to the appropriate domain within the model.

To maximize trustworthiness of the data analysis, researcher triangulation was used, which employed a range of perspectives from within the research team to discuss and interpret the data [36]. The emerging themes were discussed with the team members, each from a different background, including pharmacy practice, health psychology, and health services research. This process reduced bias and ensured that the findings were verified and the appropriate interpretation given.

Results

Across the two hospitals, pharmacists (n=11) collected data relating to 200 prescribing errors for 52 FY1 and FY2 doctors (mean=3.9 errors per doctor; range=1-11 errors). A total of 15 FY1 and FY2 doctors (FY1: n=9; FY2: n=6) were recruited from the study sites to take part in a face-to-face semistructured interview (males: n=4; females: n=11). The participants were from a range of specialties/wards, including Heart Care (n=5), Renal transplant/renal (n=6), Gastroenterology (n=3), and mixed specialties (n=1). We limited our demographic information to maintain confidentiality. Interviews ranged from 20 min to 38 min, with a mean length of 27 min. The findings are presented according to the four major themes identified, which have been mapped onto the three components of the COM-B model [27], as illustrated in Figure 3. Illustrative quotes are presented verbatim, with unique participant IDs (allocated in order of the interview) presented alongside.

Figure 3. The acceptability and feasibility of MyPrescribe mapped to the components of the COM-B (capability, opportunity, motivation, and behavior) model.
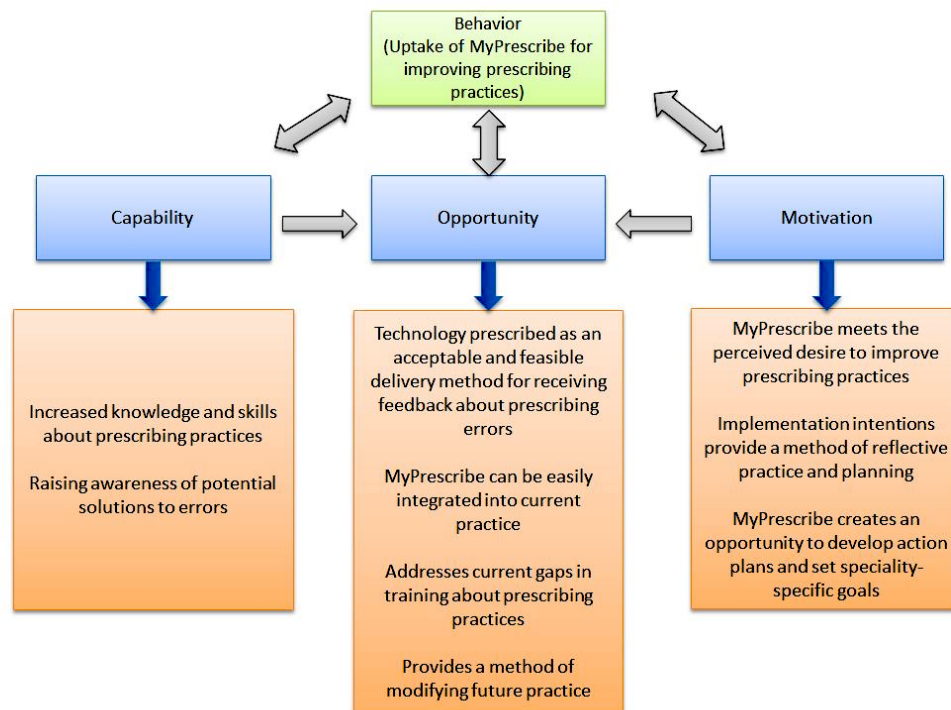
Domain 1: Capability

Current Feedback Insufficient to Change Prescribing Practices

Doctors reported a desire to improve their prescribing practices as a part of their continued professional development. Developing their knowledge and skills relating to prescribing practice was perceived as important, both in terms of raising awareness of past mistakes and taking steps to improve future practice by keeping errors to a minimum. One of the participants notes:

> I think it's really important to be able to think about why you're doing...'cause everybody makes some kind of error...mistake, at one point, but it's if you think about it, then you can minimize the chances of it happening again. [P7; FY1]

Barriers to improving their professional practice relating to prescribing behaviors were also highlighted. Participants reported that opportunities to develop more advanced prescribing skills were hampered by the inadequacies of current feedback on prescribing errors as a part of routine practice. Doctors were not always informed by the clinical pharmacist about the errors they had made. Errors were often corrected by a colleague on another shift with little or no explanation of the error. Consequently, there were limited opportunities to increase their knowledge and skills about appropriate prescribing practices. The participants noted:

> A lot of the time with F1 [FY1] s, especially if you're seeing people who you don't see on a regular basis, you'd be writing Kardexes [in-patient prescription charts] or prescribing things like anti-emetics or sleeping tablets or whatever and actually you never see that patient again. So if you have made an error there's no way you're ever going to know unless someone tells you. I mean there's definitely situations where I've probably made errors and don't know about it and I've seen errors made by colleagues that will never know about it because they never went back to that patient. [P10; FY1]

Attitudes Toward and Approaches to Prescribing

MyPrescribe was perceived as a useful tool for changing the ways doctors approach prescribing. This was both in terms of identifying unhelpful patterns in current practice, as well as enabling doctors to think in a more structured way about future practice. An important potential consequence of using MyPrescribe was equipping doctors with the knowledge and skills to identify the possible solutions to challenges they faced in prescribing practices through the application of "If-Then" plans to situations where an error had been made. One of the participants stated:

> Yeah, I think if it comes up and especially if you tend to make certain errors more common than others, you can pick up on patterns and what you think, like what our common mistakes are, and then when I think about situation like oh yeah, I always do this when I try and be on the phone and do this at the same time. You tend to realize that the behavior that you might not pick up on. [P13; FY1]

Participants were aware of the impact prescribing errors had on patient care. MyPrescribe was perceived as a way of increasing

awareness of the implications of making errors and the importance of being informed of any errors made. Consequently, MyPrescribe was a way of changing attitudes toward prescribing practices. Another participant noted:

> *But personally, I think it would change my attitude to prescribing. I'd probably be a bit more wary on the things that I've made a mistake on before, and things like that. Because even now, I probably have made mistakes, and sometimes [the clinical pharmacist] just corrects them, or someone else corrects them without telling me, and I won't know, and I'll probably make that mistake in the future. So if I'd got this system, I'd know all the mistakes that I've...potentially. So that would be good.* [P11; FY1]

MyPrescribe was perceived as a way of ensuring safer prescribing/patient safety through a more transparent error feedback process. This also created more efficient working practices such as saving time for both the pharmacists and the doctors, as well identifying opportunities to minimize errors made by less experienced doctors:

> *It'll make you think more and probably mean that I'd make less mistakes in the future because I'll be thinking and it's safer. It will save the pharmacist time, save me time, all the patients get treated faster I guess.* [P10; FY1]

> *So, it's nice to have something like this where you can, hopefully, very quickly, get some data. Get some feedback about how you've been prescribing, and hopefully there's nothing too serious, but certainly, things that will stop you from doing something that serious.* [P2; FY1]

Domain 2: Opportunity

Technology Perceived as a Way of Delivering Timely and Effective Feedback to Health Professionals

Participants described how technology supported their practice generally, reporting how technology allowed them to recognize errors and reflect on past mistakes in their own time in a nonthreatening way. Timing was highlighted as an important issue, not only in terms of receiving timely feedback on their own practice but also at a critical point during their foundation year training period. The participants noted:

> *I'd probably do it from home once a week and set aside one evening when I was going to log in and do it, just so that then I know that I'm not going to be disturbed, I've got no-one looking over my shoulder and then I can do the work that I need to do related to, if I've made any errors and where they were made.* [P1; FY2]

> *I think mostly F1s [FY1s], F2s [FY2s] now, would like that. Especially in their first couple of years when you are getting used to like what's right and patients I think.* [P14; FY1]

MyPrescribe was perceived as an important learning resource that strengthened junior doctors' current e-learning strategies. This was seen as a way of complementing existing learning

tools that focused on critical reflection and satisfying the requirements of their e-portfolio (a tool for recording career progression, professional development, and evidence illustration training competencies). One of the participants said:

> *Yeah, I think when people have to do their portfolio thing, they more likely look into this, because you can...I think also it's very useful if this can connect to our e-portfolio somehow...it would be great, because then we could use it as evidence in certain situations that, you know, when you're seeing this patient has errors and acted on it.* [P13; FY1]

More generally, technology was a feasible and acceptable delivery method for techniques to improve prescribing practices by modifying future behavior. MyPrescribe was perceived as a positive addition to a range of apps currently used by junior doctors, allowing it to be easily integrated into their routine practice. Consequently, participants reported that this would lead to improvements in working practices:

> *I think it's easier than paper, especially if you're busy and you just have it to hand, I think it's rather nice and then you can access it, you know, anytime and you don't have to be on the ward or...you know. Yeah I think the app in itself is a good idea. We use apps all the time already.* [P7; FY1]

Domain 3: Motivation

Impact of Implementation Intentions

Participants suggested that MyPrescribe was a way of identifying areas of their clinical practice that could be improved, particularly in relation to specialty-specific prescribing. A key factor for successful implementation as reported by the participants was that the intervention addressed knowledge gaps in their training about prescribing practices. This allowed doctors to think more critically as well as consciously about their prescribing:

> *Well, if I'm making errors related to, I don't know, a certain subset of medications related to a certain specialty, say I'd been finding it difficult with prescribing cardiac drugs, you know, it's going to make you look further, not only into the pharmacology in that area but then the conditions you're treating with those medicines. So actually it's going to help you with a whole range of things.* [P1; FY11]

Implementation intentions were perceived as an effective method for encouraging more reflective practice. This was particularly important in the context of a busy clinical environment that maximizes the chances of errors being made and limits the time for critical reflection because of an increased workload and a high turnover of patients. One of the participants stated:

> *It would encourage me to reflect and think about it more when the pharmacist tells me, oh you've done this, nothing...just something minor. I'm like, okay I'll change it and I couldn't even tell you...I couldn't tell you one now. Nothing sticks out in my mind that I've done minor because you fix it and you forget about it. So maybe logging it, anything conceived and*

repeated the same sort of things, and it probably would change. [P14; FY1]

Participants described specific ways in which "If-Then" plans could be used for modifying future practice. This involved knowing how the identification of specific errors creates opportunities to learn from previous mistakes. Having a system of documenting previous mistakes in place, especially minor errors that were not routinely remembered, and possible solutions, was seen as particularly important for enabling more structured ways of reflecting on practice. The participants were able to provide examples of how "If-Then" plans could be used in specific areas of clinical practice. This was seen as a way of ensuring repeated mistakes were minimized and also as a prompt for future situations where prescribing is a challenge:

Participants described the reflective processes they were able to engage in as a result of using MyPrescribe. Action planning and goal setting were highlighted as two important decision-making processes they were able to engage in for prescribing behavior. This allowed them to think about their past prescribing behavior and practice more generally. It was perceived that MyPrescribe, and the implementation intentions in general, could integrate into (and complement) existing training. A participant noted:

> *So if I make a mistake…all right, if I'm in a situation where I could potentially make a mistake, these are the things I need to do to avoid those errors. I like it because it's simple to fill in, but it's also, you're creating an action plan at the same time. So you're reflecting and action planning at the same time. So, again, it's about efficiency.* [P2; FY1]

Domain 4: Behavior

Creating a More Structured, Reflective Approach to Health Professional Practice

Feedback about current practice was perceived as important for highlighting areas of junior doctors' day-to-day practice that could be improved. Some participants were driven to change their own behavior by the desire to keep prescribing errors to a minimum:

> *Well, personally, I want to not make mistakes, which I think anything that improves your prescribing practice is only a good thing.* [P9; FY1]

> *I think people who have got portfolio things to do…prescribing's a big thing in the new curriculum, for the foundation so, I think anything that can ensure that you're thinking more about prescribing and changing what you're doing is going to be popular.* [P8; FY1]

Participants described specific ways that MyPrescribe translated into behavior change in terms of changing specific prescribing behaviors. Doctors reported that implementation intentions provided a way of transforming critical reflection into practice change by highlighting solutions to a problem (action planning) and how this could be implemented in day-to-day practice (action):

> *It's useful to think about a solution to the problem, so if this…if I'm in the situation then this is how I'm going to tackle it and then put it into action.* [P1; FY2]

> *So I've prescribed something then…it's been wrong, maybe too high a dose or something. And then it's been flagged up to me that it was wrong, and then obviously I'd go back to this and I'll know not to do that in the future.* [P5; FY2]

One of the major perceived barriers to practice change was the heavy workload faced by junior doctors. This was particularly important for working in different specialties or settings that pose different challenges in terms of prescribing practices. MyPrescribe was perceived to facilitate professional behavior change by providing the platform to a more structured, reflective approach to prescribing:

> *I think it's a good approach to take, especially for prescribing. It makes you think about the different situations that you're prescribing in and the different external things that impact on your prescribing, which is easy to overlook when you're busy..* [P1; FY2]

> *You are kind of enabled to think about your prescribing more, I think people should become more comfortable with prescribing the more they use it. If it's helping improve their practice...I think it will probably help people to see prescribing as a much more structured activity and to think about it actively more from this.* [P7; FY1]

Discussion

Principal Findings

This paper describes the development of a novel theory-based technological innovation aimed at reducing prescribing errors by foundation doctors. To our knowledge, this is the first study to examine this type of intervention specifically for prescribing behaviors, using a recognized theoretical framework such as implementation intentions [16]. MyPrescribe was perceived as a highly acceptable and feasible delivery method of providing doctors with information about prescribing errors, as well as providing opportunities to construct personalized implementation intentions aiming at modifying future practice.

The COM-B model, which focused specifically on understanding the key elements of intervention design and explaining target behaviors [27,28] identified the barriers and enablers to the uptake of MyPrescribe and the specific mechanisms through which the intervention operates (see Figure 3). First, MyPrescribe was perceived as a way of increasing knowledge and skills about prescribing practices by identifying prescribing errors, and more importantly, raising awareness of potential solutions (*capability*). Second, technology was perceived as a feasible and acceptable vehicle for both delivering and receiving feedback about prescribing errors. This was seen as being critical in terms of ongoing professional development, addressing gaps in current training about prescribing practices, and modifying future clinical practice (*opportunity*). Third, implementation intentions provided a method of conscious, reflective planning, which was particularly important in the

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context of changing prescribing behaviors. Participants were able to think more critically about their practice and create action plans to modify future practice. Consequently, participants were motivated to improve their prescribing practices (*motivation*).

Although it is primarily the foundation doctors who undertake the majority of prescribing in hospitals, they are rarely given feedback on their prescribing errors [12]. Current feedback methods for prescribing range from formal audit and feedback interventions [7] to the more informal routine feedback as part of day-to-day clinical practice [12], or "ad hoc" feedback as errors are identified [5,12]. Doctors often use pharmacists as a prescribing "safety net" [5,16,37], which consequently limits opportunities for professional development and can cause avoidable stress in the early stages of clinical practice [38]. Common features of previous feedback interventions include limited opportunities for personal reflection about one's mistakes and the platform to create personal action plans for professional development. MyPrescribe demonstrates a feasible and acceptable way of delivering feedback on prescribing errors aimed at improving future practice by addressing these known barriers. The participants in this study expressed concerns about gaps in prescribing teaching as has been seen elsewhere [5], which MyPrescribe was perceived to address. Additionally, the challenges in evaluating eHealth applications, particularly around engagement with interventions, have been well documented [39]. MyPrescribe was perceived to overcome such barriers because the participants reported that the intervention was a way of complementing current training tools. Technology-specific barriers to using Web-based interventions to facilitate professional practice such as time and organizational constraints [40] were also perceived to be addressed.

By including implementation intentions as a specific evidence-based theoretical framework [41], we have provided recommendations to inform the design and delivery of future interventions that would help improve prescribing practices. Implementation intentions have been widely used for a range of patient/public behavior change strategies with a high degree of success [19]. Our study demonstrates that this strategy is acceptable and feasible in the context of prescribing practices as a part of health professional behavior change, a growing area in the context of evidence-based behavior change interventions. Our findings suggested that the participants were able to develop specific skills that could be mapped to an existing framework of behavior change techniques (BCTs), which included goal setting (BCT 1.1) and action planning (BCT 1.4) [27,28]. The precise mechanisms through which implementation intentions work in the context of health professional behavior change have been suggested, which helps to explain how this can be applied to prescribing practices. When forming action plans, health professionals are able to create a conscious mental link between a contextual cue (ie, a prescribing situation) and goal-directed behaviors (ie, appropriate prescribing). Health professionals may be more likely to perform the behavior as an automatic response [42,43]. Using the COM-B model has identified the behavioral determinants of prescribing behavior change and implementation of MyPrescribe. Interventions that aim to target prescribing practices must build on this work by clearly specifying intervention functions most relevant to this area of clinical practice.

Strengths and Limitations

This is the first study to develop a theory-based technological intervention aimed at improving the prescribing practices of foundation doctors. The involvement of key health professionals (pharmacists and foundation doctors) at all stages of the development process ensured the creation of an intervention that could easily be integrated into their busy day-to-day practice. By including implementation intentions as the key theoretical framework for the intervention and explaining the perceived mechanisms behind the intervention using the COM-B model, this allowed for a more detailed understanding of how the intervention works in practice, thereby satisfying the first phase of developing interventions according to a recognized and widely used framework [44].

However, there are limitations that must be considered in light of our findings. The intervention has not yet been tested to investigate whether the perceived impact translates into actual impact on prescribing errors. This study is at the development stage of evaluating complex interventions, where the Medical Research Council guidance has suggested that it is essential to initially "develop the intervention to the point where it can reasonably be expected to have a worthwhile effect" [44]. Qualitative investigations have teased out the ways in which the intervention *could* work. Future research will continue the evaluation process, with feasibility studies leading to evaluation studies of effectiveness and cost-effectiveness, a necessary component needed to draw firm conclusions about the effect of MyPrescribe on reducing prescribing errors.

Conclusions

This paper described the development of MyPrescribe, a novel technological intervention aimed at improving the prescribing practices of foundation doctors. In summary, implementation intentions provide the theoretical foundations on which information about prescribing errors should be delivered and present opportunities for prescribers to formulate solutions to past and future errors. MyPrescribe could make a valuable addition to medical prescribers' training in reflective practice.

Conflicts of Interest

None declared.

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Abbreviations

AWS: Amazon Web Service
BCTs: behavior change techniques
COM-B: capability, opportunity, motivation, and behavior
FY: foundation year
NHS: National Health Service
W3C: World Wide Web Consortium

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Original Paper

Usability Assessment of the Missouri Cancer Registry's Published Interactive Mapping Reports: Round One

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Abstract

Background: Many users of spatial data have difficulty interpreting information in health-related spatial reports. The Missouri Cancer Registry and Research Center (MCR-ARC) has produced interactive reports for several years. These reports have never been tested for usability.

Objective: The aims of this study were to: (1) conduct a multi-approach usability testing study to understand ease of use (user friendliness) and user satisfaction; and (2) evaluate the usability of MCR-ARC's published InstantAtlas reports.

Methods: An institutional review board (IRB) approved mixed methodology usability testing study using a convenience sample of health professionals. A recruiting email was sent to faculty in the Master of Public Health program and to faculty and staff in the Department of Health Management and Informatics at the University of Missouri-Columbia. The study included 7 participants. The test included a pretest questionnaire, a multi-task usability test, and the System Usability Scale (SUS). Also, the researchers collected participants' comments about the tested maps immediately after every trial. Software was used to record the computer screen during the trial and the participants' spoken comments. Several performance and usability metrics were measured to evaluate the usability of MCR-ARC's published mapping reports.

Results: Of the 10 assigned tasks, 6 reached a 100% completion success rate, and this outcome was relative to the complexity of the tasks. The simple tasks were handled more efficiently than the complicated tasks. The SUS score ranged between 20-100 points, with an average of 62.7 points and a median of 50.5 points. The tested maps' effectiveness outcomes were better than the efficiency and satisfaction outcomes. There was a statistically significant relationship between the subjects' performance on the study test and the users' previous experience with geographic information system (GIS) tools ($P=.03$). There were no statistically significant relationships between users' performance and satisfaction and their education level, work type, or previous experience in health care ($P>.05$). There were strong positive correlations between the three measured usability elements.

Conclusions: The tested maps should undergo an extensive refining and updating to overcome all the discovered usability issues and meet the perspectives and needs of the tested maps' potential users. The study results might convey the perspectives of academic health professionals toward GIS health data. We need to conduct a second-round usability study with public health practitioners and cancer professionals who use GIS tools on a routine basis. Usability testing should be conducted before and after releasing MCR-ARC's maps in the future.

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Introduction

Geographic information system (GIS) tools should be planned to achieve the desires and perceptions of the tools' targeted users. The development of GIS tools does not seem to be an issue; the problem seems to be their effective and efficient use [1,2].

Health care and public health fields have started using sophisticated technology to analyze and visualize health-related databases. Advanced visualization technology is becoming essential and important nationally and internationally to help control many health-related problems. This technology has positively impacted health-related research and policy development. Therefore, these databases need to be held wisely, investigated sufficiently to produce consistent results, not mislead the audiences, and produce the expected impact [3].

As the previous literature has pointed out, high percentages of any new digital technology's potential users find difficulties in interpreting and understanding the associated complicated and combined information [4-6]. For the GIS tools where statistical and spatial information are combined, users have faced similar difficulties. Several reasons have been identified: inadequate experience and training on how to use the technology; lack of awareness among potential users; refusal to use the technology; and the technology being vague, complicated, and not user friendly [7].

Static and interactive health-related mapping reports could generate knowledge, yield proof, and enhance policies [8]. Each interactive mapping report should convey an unambiguous purpose and transmit a flawless meaning to the addressees [9]. Pursuing the health scientists and decision makers, the health-related maps should embrace references of the used data resources and the approach that was used to get the mapped results. The usability of the health-related mapping reports must be accordingly scrutinized and assessed using a representative sample of the potential users before and after releasing the maps [3].

The current scientific literature supports the importance of cooperation between public health scientists and health professionals in integrating health information from diverse sources via portals and applications. These systems can guide public health professionals in designing and developing useful public health policies and interventions [10]. Over the last two decades, the mapping reports have transformed from being static to being dynamic [11]. GIS users prefer interactive reports over static and animated ones [3]. The same literature encourages map developers to consider the practical and social issues of users during development, evaluations, and updates of GIS tools [12].

A number of cancer registries have started interactively mapping their databases' results, but few of them are assessing the usability and functionality of this technology [13-17]. We are seeking to fill this gap and give an exemplary model to help other registries conduct usability testing studies to tailor their visualized and mapped material according to their potential users' perceptions and preferences.

This study was the first usability study to assess the quantitative and qualitative metrics data from the sampled health professionals while they are interacting with the published Missouri Cancer Registry and Research Center (MCR-ARC) InstantAtlas mapping reports. Investigators conducted a multiple methodology usability testing study of the published interactive mapping reports of the MCR-ARC. The goals were to understand the ease of use (user friendliness) and user satisfaction with the maps and to measure their effectiveness and efficiency using a convenience sample of health professionals. These maps had been implemented with InstantAtlas (GeoWise Ltd., Scotland); see Multimedia Appendices 1 and 2 [18,19]. The study aims to refine the registry's published reports to increase the satisfaction of their professional end users. The investigators also wanted to assess whether, and to what extent, the users' performance would be affected by their demographics, experience, education level, and type of work.

Methods

Study Design

The investigators chose a mixed methodology approach. The tested reports had been published on the MCR-ARC website [20]. The researchers conducted a pretest questionnaire, a multi-task usability test, and the System Usability Scale (SUS) for every participant [21].

The Pretest Questionnaire

The questionnaire included questions on every participant's work type, personal information, total experience in the public health field, experience in use of GIS tools, years of practicing public health, and the participant's education level (see Multimedia Appendix 3). This step was followed by the multi-task test.

Multi-Task Usability Test

The multi-task usability test was composed of ten individual tasks that were applied on the tested mapping reports. These tasks were performed by the participants to diagnose the usability of the tested reports. Based on the published mapping reports functionality, the multi-task usability test was constructed by the study investigators to measure the efficiency and effectiveness of the tested reports. The tasks were in the same order for all participants (see Multimedia Appendix 4). The 10 assigned tasks covered most of the maps' functionality. By conducting all these tasks effectively and efficiently, the users could reach the designer's expected benefits of our visualized data.

The System Usability Scale (SUS)

The System Usability Scale (SUS) is an industrialized and simple 10-item scale to measure the participants' subjective evaluation of the tested mapping reports' usability. The SUS was conducted immediately after the completion of the multi-task usability test. The SUS scores range between 0 and 100. Scores above 68 points were counted as acceptable according to usability literature, and higher scores represent the optimal to best score [21].

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Participants

The study's proposal was approved by the Health Sciences Institutional Review Board (IRB) of the University of Missouri-Columbia. Recruiting emails were sent to faculty in the Master of Public Health (MPH) program and faculty and staff in the School of Medicine's Department of Health Management and Informatics (HMI) at the University of Missouri-Columbia. Using a convenience sample, investigators ran the study's trial on the first 7 potential respondents who agreed to participate. The minimum number of participants needed to conduct a successful usability study is 5; a 5-participant study will be able to demonstrate between 55-100% of the usability problems of tested material [22,23]. In this study, we increased the number to 7 subjects to catch more usability issues of our tested reports [24].

Study Procedure

Every participant tried ten tasks in a safe and private space for an average of 30 minutes per participant. The researchers used a computer laptop to conduct the trial. Windows Media Player software (Microsoft, Washington USA) was installed to record the screen and spoken comments of the participants as they took part in the trial. Task completion time and task completion success were analyzed manually based on the recordings.

The following outcomes were measured:

Performance metrics: A few metrics were utilized to assess the effectiveness and the efficiency of the tested mapping reports and to uncover usability problems. Some of these metrics are defined in terms of critical errors—an error that resulted in an incorrect or incomplete task. If a participant sought help from the test observer to finish a task, it was considered a critical error [25]. The investigators measured the following metrics:

a. Effectiveness: Task completion rate (TCR). TCR is a measure of tasks that were completed without critical errors, and the outputs of the task were correct [24,25]. TCR represented the mapping reports' usability effectiveness and was analyzed in two distinct ways: by participant and by task.

TCR per participant: The percentage of tasks that were successfully completed by a participant [25].

TCR per task: The percentage of participants who successfully completed a given task [25].

b. Efficiency: The resources expended in relation to the "accuracy and completeness with which users achieve goals" [26]. Using the video records, the time per task was measured from the beginning of the task until the time the participant started the next task.

The investigators calculated the efficiency and the productivity of the tested mapping reports using the following metrics:

Time-based efficiency (TBE) per task. This is a task-specific version of an overall TBE as shown in Figure 1 [25].

Overall relative efficiency (ORE) per task. This is a task-specific version of an overall TBE as defined in [25] and shown in Figure 2.

User satisfaction: Overall satisfaction per study subject was measured by the SUS survey. See the details under study design section.

Before conducting the study, study researchers expected that there would be some factors that might impact the participants' performance and their satisfaction with the tested maps, and we assessed the influence of these elements on the participants' performance. These factors were the participants' education level, work type, experience in health care field, and previous experience with mapping reports and GIS tools [27]. The investigators used a variety of statistical methods, as needed, to explore these relationships (Wilcoxon-Mann-Whitney test, Pearson correlation, and simple linear regression). The Wilcoxon-Mann-Whitney test was conducted using the Web implementation of the method described in the study by Marx et al [28], and the remaining analyses were conducted using Excel (Microsoft). The intended sample size of this study was small since we primarily wished to uncover major usability problems; post-hoc power calculations for simple linear regression with the observed sample data indicate that the power for testing the relationships between the participants' factors and the TCR or SUS ranged between 3-24% [29]. We used a type I error rate (alpha) of .05 for the hypothesis tests conducted in this project.

Figure 1. Time-based efficiency (TBE) calculating formula.

$$\bar{P}_{t,j} = \frac{1}{N} \sum_{i=1}^{N} \frac{n_{ij}}{t_{ij}}$$

where

N = Total number of tasks

n_{ij} = Result of task i by user j

$$= \begin{cases} 1 & \text{if the user successfully completes the task} \\ 0 & \text{otherwise} \end{cases}$$

t_{ij} = The time spent by user j on task i.

Figure 2. Overall relative efficiency (ORE) per task calculating formula.

$$\bar{P}_j = \frac{\sum_{i=1}^{N} n_{ij} t_{ij}}{\sum_{i=1}^{N} t_{ij}} \cdot 100$$

Results

Participant Demographics

A total of 7 health professionals were interviewed: 1 white male and 6 white females; their ages ranged from the early 30s to late 60s (mean=49.57 years, median=49.17 years). Of the 7 participants, 3 were from the MPH program and 4 were from the HMI department. Four held a doctoral degree in a health care-related field, and 3 had master's degree in public health, health administration, or health informatics. Furthermore, 5 of the 7 participants were working as research or teaching faculty. Two participants were both staff members and doctoral students in the health informatics program, working in public health research; both had experience in working with mapping reports for at least one year. All 7 participants had experience in the health care field, ranging from 3-38 years (mean=17.8 years, median=13 years). The participants' total experience in using mapping interactive reports at work ranged between a few months to 15 years (mean=5.6 years, median=2 years). Our participants' work types can be classified, according to their daily work roles, into two broad categories: Faculty and analysts (n=5) and directors and staff (n=2).

Reports' Effectiveness and Efficiency

The Mapping Reports' Effectiveness

Effectiveness per Participant

A PhD-holding participant, who had 13 years of experience in the public health field and in GIS use, could not accomplish two of the assigned tasks because she "had no idea how to navigate them" as she commented. Three of the remaining 6 participants—a PhD-holding faculty member and two staff members—were not able to follow expected pathways to finish the assigned tasks and got false results for some tasks; these participants thought that they completed the tasks successfully and did not ask for help or clarification. All 3 participants had 1-6 years' experience using GIS tools. Of the remaining 3 participants, all completed the tasks effectively and efficiently, including one who had the least amount of experience with mapping reports and tools of the 7 participants.

The effectiveness was defined as: "The accuracy and completeness with which users achieve specified goals" [26]. The results in our study ranged from 70-100%, with only 1 participant finishing the trial with a TCR <78% (Figure 3), 78% is the minimum TCR score accepted by some scholars [25]. Four of the 7 subjects attained a TCR of 90% or more.

Effectiveness per Task

The investigators used the task completion formula to measure the TCR by task. The results are shown in Figure 4. Six of the ten assigned tasks reached a TCR of 100%, and two of the ten tasks had a TCR of 90%, whereas one task had a TCR of 80%, and the remaining task had a TCR of 70%.

Figure 3. Task completion rate (TCR) per participant. Dark gold indicates participants who finished the trial with >78% TCR; red indicates participants who finished the trial with <78% TCR.
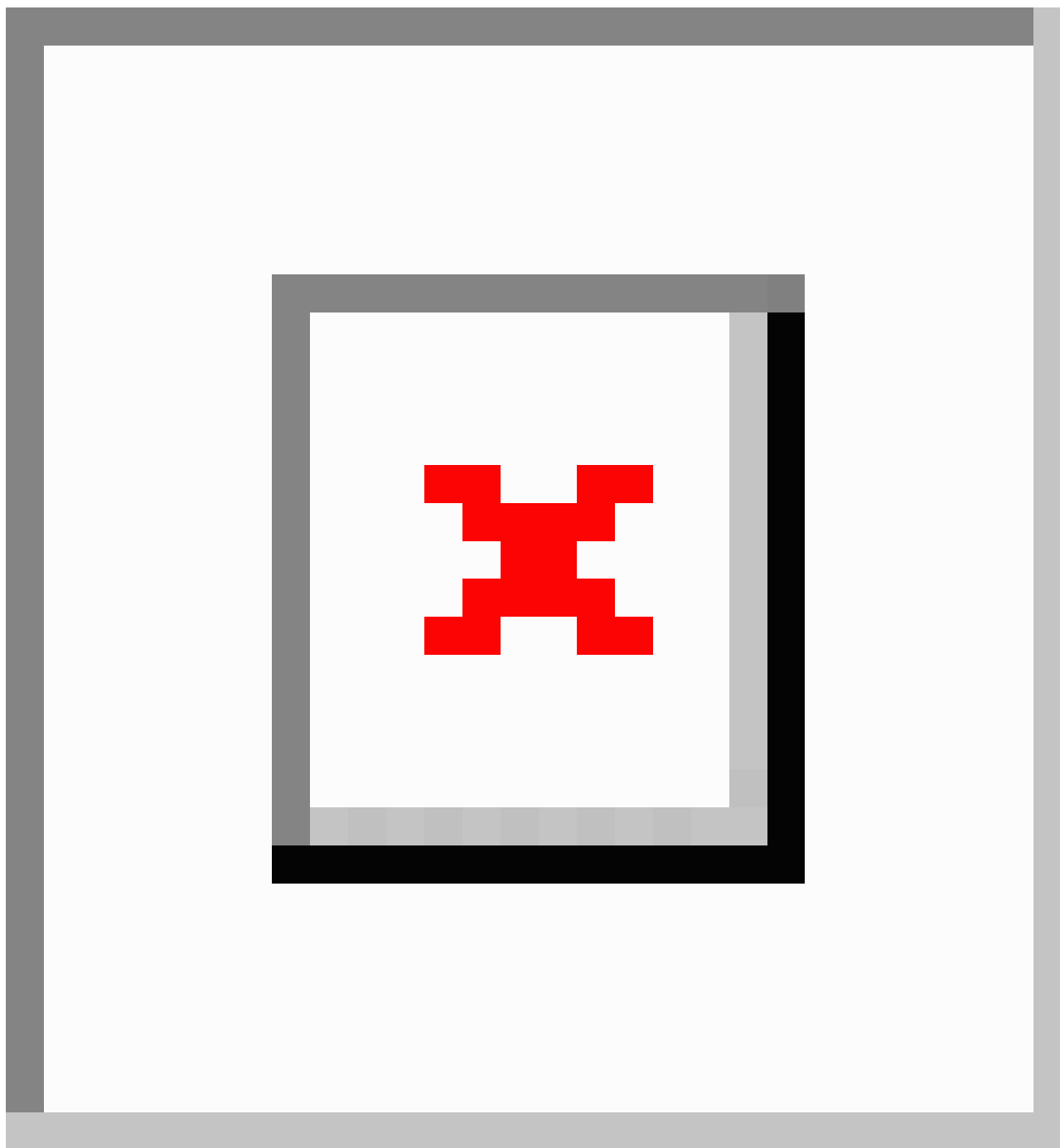
Task numbers 1, 2, 7, 9, and 10 were very simple, such as open or close a functional button on the reporting map. All had a TCR of 100%.

Task numbers 3, 4, 5, and 8 got lower TCRs than the previously mentioned tasks, with scores ranging between 70-90%. Before conducting this study, the study investigators ranked task numbers 3, 4, 5, and 8 along with task number 6 as complicated tasks that need specific skills and knowledge to be completed successfully. One complicated task, number 6, was completed effectively by all subjects.

Figure 4. Task completion rate (TCR) per task. Blue indicates tasks involving the area health profile (Tasks 1-6); red indicates tasks involving the double map (Tasks 7-10). Light blue indicates tasks that had >78% TCR; dark blue indicates the task (Task 5) with <78% TCR.
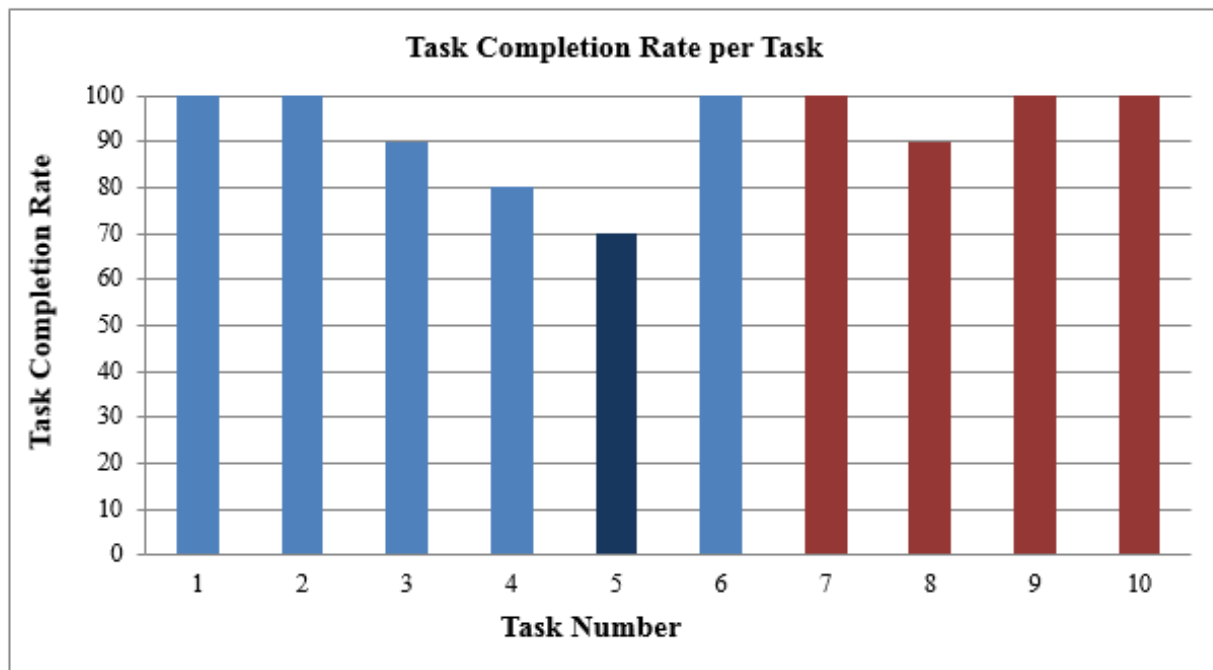
Mapping Reports' Efficiency and Productivity

The time per tasks ranges from the minimum 2 seconds for task number 10 to the maximum 297 seconds for task number 8, which included three subtasks. As seen in Table 1, even among the tasks with a 100% completion rate, there was variation in the time spent by the participants. The median time on task number 6 was the highest, followed by task numbers 8, 5, 4, and 3, respectively; this was relatively related to the complexity of the tasks.

Table 1. Time on study tasks.

Task #	Task time range (seconds)	Task time mean (seconds)	Task time median (seconds)
1	3-62	19.4	12
2	10-51	23	16
3	13-64	34.8	33
4	20-87	57	53
5	11-268	95.8	75
6	46-215	136	145
7	2-20	11	11
8	90-297	165.1	141
9	3-16	41.5	21
10	2-38	3.2	3

Time-Based Efficiency (TBE) and Overall Relative Efficiency (ORE)

Figures 5 and 6 show the time-based effeciency (TBE) and the overall relative effeciency (ORE) for each of the tasks.

From Figure 5, we can see that the TBE per task varied for the ten tasks. Task number 10 had the highest TBE (19.2 goals/min); this result conforms to the simplicity of the task (close the map). It is followed by task numbers 7, 9, and 1, which are also simple tasks (proceed to the "double map" link on the desktop, open the "area profile," map link in the desktop, and check the sources of our mapping report data, respectively). Task numbers 2, 3, and 4, all complicated tasks, had very low TBE rates. Task numbers 5, 6, and 8 were the most complicated tasks; they had the lowest TBE levels.

Figure 6 shows that the highest ORE rates were for task numbers 1, 2, 9, and 10; they were all simple tasks. Task number 6 had about 97% ORE rate despite it being ranked as one of the

complicated tasks. Task numbers 3, 4, 5, and 8 had the lowest ORE per task.

Users' Satisfaction

SUS is a standard 10-question questionnaire given to every participant after the tasks to measure user satisfaction with the tested maps [20]. As Figure 7 shows, the SUS score range for all the participants was 20-100 points with an average of 62.86 points and a median of 50.50 points. The SUS scores for 3 of the 7 study participants were above the target of 68 points, and they were satisfied with the maps they tested. The remaining 4 of our participants' scores were below 68 points. The interpretation of the SUS scores for the study subjects ranged between worst imaginable to best imaginable, and according to the school grade scale, the scores were between A and F with an average of D.

Factors Affecting the Participants' Performance

As discussed in the methods section, we expected that there are some factors that could impact the participants' performance and their satisfaction with the tested interactive mapping reports.

Education Level and Work Type Factors

We assessed whether the education level of the participants impacted the distribution of either their TCR or SUS score using the Wilcoxon-Mann-Whitney test [27]. We classified the participants as PhD or master degree holder subjects, and we tested these two groups' TCR. We did not find any statistically significant difference in the distribution of the TCR by education level (P=.91). Also, there was no statistically significant difference in the distribution of the SUS score by education level (P=.82).

The Wilcoxon-Mann-Whitney test was used also to assess whether the participants' distribution of TCR differs by their work type. We categorized the participants into two groups: a faculty and analysts group and a staff and directors group. The difference in the distribution of TCR between the two groups was statistically insignificant (P=.75).

Figure 5. Time-based efficiency (TBE) per task.

Figure 6. Overall relative efficiency (ORE) per task. Purple indicates tasks with 100% ORE per task, dark tan indicates tasks with less than 100% ORE per task.

Figure 7. System Usability Scale (SUS) scores of the study's participants. Brown color indicates SUS score of >68 points, and blue color indicates SUS score of <68 points.

Table 2. Demographic and previous expertise factors of the study participants versus the trial's task completion rate (TCR) and the participants' System Usability Scale (SUS) scores.

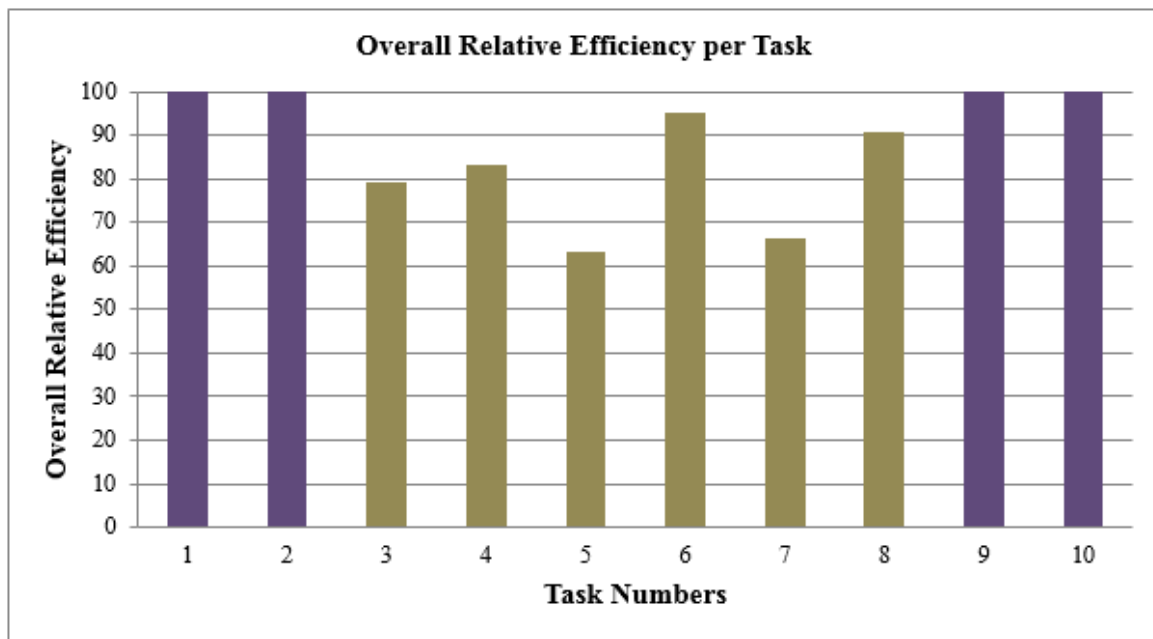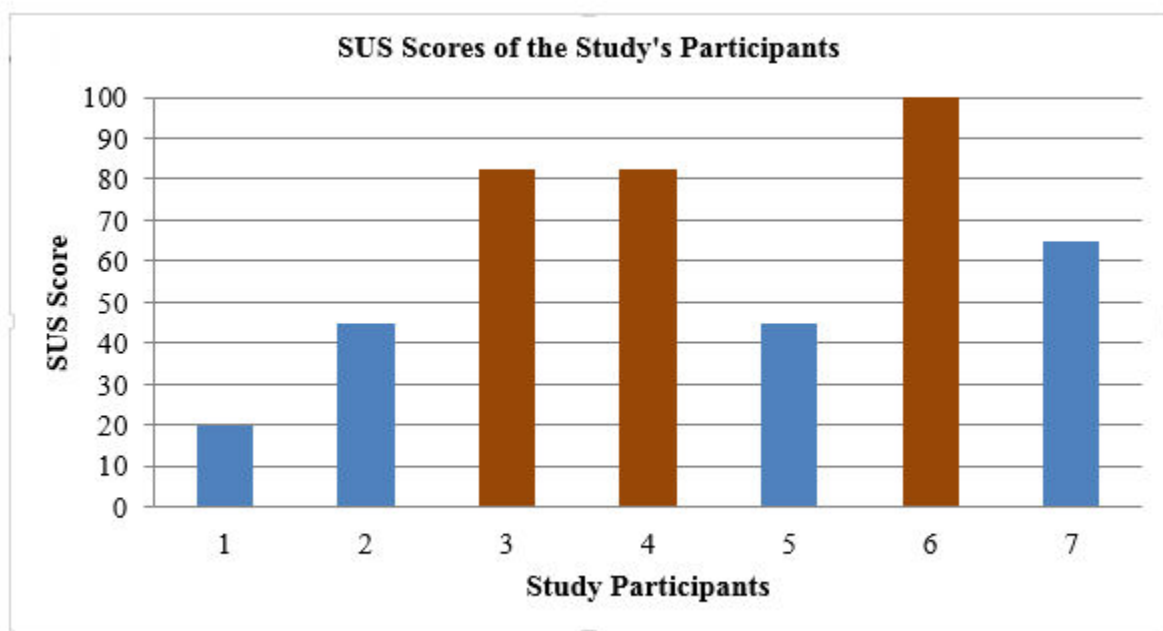| The studied factors	P value
Education level versus TCR[a]	.91
Education level versus SUS[b] score	.82
Work type versus TCR	.75
Previous experience in health care field versus TCR	.70
Previous experience in GIS[c] use versus TCR	.03
Previous experience in health care field versus SUS score	.82
Previous experience in GIS use versus SUS score	.17

[a]TCR: task completion rate.

[b]SUS: system usability scale.

[c]GIS: geographic information system.

Table 3. Correlation between the studied usability elements (effectiveness, efficiency, and satisfaction).

The studied factors	Correlation coefficient	P value
TCR[a] per participant versus SUS[b] score	.70	.08
TCR per task versus TBE[c]	.50	.25
TCR per task versus ORE[d]	.92	P>.0.01
Efficiency per participant[e] versus SUS score	.70	.07

[a]TCR: task completion rate.

[b]SUS: System Usability Scale.

[c]TBE: tine-based efficiency.

[d]ORE: overall relative efficiency.

[e]The total time in seconds of the whole trial per participant.

Experience in the Health Care Field and Experience With Mapping Reports and Geographic Information Systems (GIS) Tools

We conducted simple linear regressions to explore the relationship between the TCR of the study subjects on the usability test and between both experience in the health care field and previous experience with mapping reports and other GIS tools. The relationship between the TCR and experience in the health care field was insignificant (P=.70). There was a statistically significant relationship between the subjects' TCRs and experience using GIS tools (P=.03). There was no statistically significant relationship between the SUS levels and previous experience in the health care field or with GIS tools for the study participants. The P values for these results were (P=.82) and (P=.17), respectively.

Table 2 has the results from studying the demographics and experience in the health care field and experience with GIS tools versus their TCR and SUS scores of the trials they performed in this study.

Correlation Between the Studied Usability Elements (Effectiveness, Efficiency, and Satisfaction)

As Table 3 shows, we studied the relationship between the TCRs and the SUS scores, and this revealed a positive, but statistically insignificant, correlation between the two studied factors (r=.70, P=.08). The relation between the TCR and both the TBE and the ORE factors were explored. The results revealed that there were positive correlations between the effectiveness (TCR) and both the efficiency in terms of TBE (albeit statistically insignificantly) and ORE (statistically significant) for the studied maps (r=.50, P=.25 and r=.92, P P>.0.01, respectively). There was a positive, but statistically insignificant, correlation between the time spent by the participants for all tasks and the SUS scores they gave after they finished the test. The correlation was positively strong (r=.70, P=.07).

Discussion

Main Findings

This study concluded that the tested maps should undergo extensive refining using a user-centered approach to overcome the discovered usability issues. This approach could enable map designers to facilitate good user-software interaction and usability. This will let the designers meet their maps' potential users' expectations [30]. Usability testing studies should be conducted before and after releasing the maps to their potential users.

Effectiveness and Efficiency

Effectiveness per Participant

In any usability study, the investigators should always aim for a 100% TCR per participant; however, some usability scholars consider a TCR of ≥78% per participant acceptable [25]. Six of the 7 participants exceeded the target TCR per participant of 78%, and just 1 participant out of the 7 got a rate less than 78% (Figure 3). These results reveal that the trial was carried out effectively by 6 of the total 7 participants. Surprisingly, a PhD-holder participant with years of experience in the public health field and in GIS use could not accomplish two of the assigned tasks, whereas other participants with lower education and null experience handled the trial effectively.

Three participants incorrectly thought that they had effectively completed some tasks because there were no alerts or pop-ups to make them aware that they made mistakes. Some tasks were not dependent on each other, so the participants were not interrupted if the task was wrongly handled. Also, some of these tasks need to be answered by writing on paper and needed specific cognition and knowledge to be answered.

Effectiveness per Task

Our results support the scientific evidence from a study conducted in 2006 that concluded that technology effectiveness is affected by task complexity factor [31]. Task numbers 1, 2, 7, 9, and 10 were very simple, such as open or close a functional button on the reporting map. These tasks did not require that participants find or interpret complicated epidemiologic or statistical results so all the participants were able to complete these tasks successfully.

All the subjects accomplished task number 6 effectively, although it is categorized among the trial's complicated tasks. This could be due to the study subjects' previous experience in public health and health care; also, all the subjects were epidemiologists or researchers familiar with biostatistics and epidemiology. Additionally, it may be because the task is very connected to the preceding tasks and it was very easy to accomplish when they solved the previous tasks.

Not surprisingly, the remaining complicated tasks, numbers 3, 4, 5, and 8, received the lowest TCR scores. Participants who lacked specific skills and knowledge were unable to complete these tasks successfully.

According to the study subjects' comments and by reviewing the recorded trial videos, additional usability issues with the published maps were revealed. These usability problems explained why these tasks were hard to be accomplished even with expert participants in public health, in the health care field, and in GIS tool use. The maps' designer has refined the maps according to comments made by the participants and rereleased them.

Efficiency

From Table 1, we determined that even for the tasks that were ranked easy and uncomplicated, some study subjects took more time and effort to get the tasks successfully conducted than others. This might need usability adjustment by the tested maps'

designer in the future so these tasks could be completed by all users within comparable times.

From the TBE results (Figure 5), we expected that in addition to the cognition and knowledge needed to accomplish these tasks, usability issues we discovered in this study might make these tasks even more complicated than the investigators thought. The ORE results supported previous literature's findings that the efficiency is relatively associated with the complexity of these tasks [31].

After reviewing the recorded videos, the primary investigator concluded that task number 6 was easy to handle by the study subjects because it was closely related to its preceding three tasks. The study's audio-video recordings revealed that repeating and retrying the foregoing tasks allowed task number 6 to be accomplishment by all the participants.

Participants' Satisfaction

Based on the SUS scores, we demonstrated that we need to consider participants' comments and refine our tested maps in order to make potential users more satisfied and pleased.

We were surprised that many of the SUS scores were very low; this reinforces the need to test systems on potential users rather than assuming they will find the system usable. To improve user satisfaction, we are willing to consider all the participants' comments to refine the tested maps. User surveys already were available on the reports to assess the users' satisfaction and collect their feedback on using the mapping reports. The study investigators have made modifications according to this study's participants' comments, but this remodeling has not yet resulted in much feedback. The mentioned modifications could improve the evaluated reports and might make published reports more understandable and usable and could increase the users' satisfaction [32].

Factors Affecting the Participants' Performance

As the study researchers expected, there was a statistically significant relationship between the subjects' TCRs and their experience in using GIS tools. So, there is dependency of the TCRs on the participants' previous experience with GIS technology. This finding supports the findings of 2 previous studies revealing that the performance of users on a specific technology are related to previous exposure to that technology [27,33]. Also, these results supported previous findings of several studies concluding that experience and knowledge affects the task success rates of the tested technology [34,35].

The investigators did not find any statistically significant relationship between education level in terms of the graduate degree the participant holds and participants' TCRs. There was no statistically significant relationship between participants' education level and their SUS scores. The relationship between participants' TCRs on the test and their work type was statistically insignificant. The relation between participants' TCRs and between their experiences in the health care field was statistically insignificant. The study failed to discover any statistically significant relationship between SUS levels and both TCRs and previous experience with GIS tools for the study participants.

Correlation Between the Studied Usability Elements (Effectiveness, Efficiency, and Satisfaction)

The results revealed strong correlation between the three usability elements. The results support our assumption that the user will be satisfied if they can conduct the trial effectively and efficiently.

Strengths and Limitations of the Study

This is the first usability study to assess published MCR-ARC InstantAtlas reports. This is a good first step; these results might be generalized to assess the usability of all MCR-ARC's mapping reports as well as GIS reports published elsewhere.

The 7 participants were all health professionals from academic departments. The small sample size coupled with the use of a nonprobability convenience sample of academic health professionals limits the generalizability of these results.

The video records were reviewed manually by one of the investigators. This study could not capture all the performance and behavior of the participants while they were interacting with the tested maps. A better way to capture participants' awareness and cognitive processes would be to make use of an eye tracking system. The investigators are thinking of using advanced usability software to track user behavior in the future.

Ongoing Work and Recommendations

The investigators conducted a second round of the usability study using professionals who are working directly in day-to-day cancer research and policy after a revision to published maps due to this first round. The researchers assumed that second round professionals might have more valuable perspectives and insights toward the tested GIS reports. The investigators conducted the second-round study after considering the first round participants' responses and suggestions. All the future MCR-ARC mapping reports' usability should be assessed during the designing process and after publishing the maps. The

investigators should use advanced usability tools to test the published maps.

Conclusions

The three main elements of the tested mapping reports' usability were measured and assessed by this study in terms of effectiveness, efficiency, and user satisfaction. The tested maps' effectiveness outcomes were better than the efficiency and satisfaction outcomes. The trial was conducted effectively by 6 of the total 7 participants. The study discovered that effectiveness and efficiency metrics were related to the given tasks' complexity; easier tasks were accomplished more effectively and efficiently than complicated tasks. Although most of the study subjects accomplished most of the tasks effectively and efficiently, the users' satisfaction was surprisingly poor.

This study revealed that there was a statistically significant relationship between the subjects' performance on the study test and their experience using GIS tools.

The study researchers discovered that the pretest questionnaire and the multi-task usability test were not enough to discover all the usability issues of the tested maps. Seeking users' text comments and analyzing the video recordings are very valuable in exploring more usability concerns and in revealing potential users' preferences and perspectives toward GIS tools and maps. The study revealed that to facilitate good map-user interaction and usability, designers need to conduct usability trials on the maps, including the maps' potential users before and after publishing them.

This study's results might be generalized to other mapping reports and might be used to refine the usability and functionality of these reports as well as other GIS reports and tools of the MCR-ARC. The study findings might point the importance of including GIS tools' end users in the basic stages of designing and developing GIS tools.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Cancer, demographics, and behavioral risks—area health profile report.

[PNG File, 494KB - humanfactors_v4i3e19_app1.PNG]

Multimedia Appendix 2

Cancer, demographics, and behavioral risks—double map report.

[PNG File, 646KB - humanfactors_v4i3e19_app2.PNG]

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Multimedia Appendix 3

Pretrial questionnaire.

[PNG File, 17KB - humanfactors_v4i3e19_app3.PNG]

Multimedia Appendix 4

Multi-task usability testing.

[PNG File, 35KB - humanfactors_v4i3e19_app4.PNG]

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Abbreviations

GIS: geographic information system
HMI: Health Management and Informatics
IRB: institutional review board
MCR-ARC: Missouri Cancer Registry and Research Center
MPH: Master of Public Health
ORE: overall relative efficiency
SUS: System Usability Scale
TBE: time-based efficiency
TCR: task completion rate

Original Paper

Exploring User Learnability and Learning Performance in an App for Depression: Usability Study

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Abstract

Background: Mental health apps tend to be narrow in their functioning, with their focus mostly being on tracking, management, or psychoeducation. It is unclear what capability such apps have to facilitate a change in users, particularly in terms of learning key constructs relating to behavioral interventions. Thought Challenger (CBITs, Chicago) is a skill-building app that engages users in cognitive restructuring, a core component of cognitive therapy (CT) for depression.

Objective: The purpose of this study was to evaluate the learnability and learning performance of users following initial use of Thought Challenger.

Methods: Twenty adults completed in-lab usability testing of Thought Challenger, which comprised two interactions with the app. Learnability was measured via completion times, error rates, and psychologist ratings of user entries in the app; learning performance was measured via a test of CT knowledge and skills. Nonparametric tests were conducted to evaluate the difference between individuals with no or mild depression to those with moderate to severe depression, as well as differences in completion times and pre- and posttests.

Results: Across the two interactions, the majority of completion times were found to be acceptable (5 min or less), with minimal errors (1.2%, 10/840) and successful completion of CT thought records. Furthermore, CT knowledge and skills significantly improved after the initial use of Thought Challenger (P=.009).

Conclusions: The learning objectives for Thought Challenger during initial uses were successfully met in an evaluation with likely end users. The findings therefore suggest that apps are capable of providing users with opportunities for learning of intervention skills.

Introduction

Mental Health Apps

Commercially available mental health apps have been rapidly emerging over recent years, and demand for them is high [1,2].

Roughly two-thirds of Americans own smartphones, and nearly 20% of all Americans rely on this technology as their only method for Internet access [3]. Additionally, 80% of Americans use the Internet for some form of digital health purposes, including searching for health information or tracking

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health-related factors [4]. This tremendous growth in smartphone ownership and the use of the Internet for health purposes has made it an attractive avenue for the delivery of behavioral health interventions via apps. Apps are accessible for independent download on app stores or may be used in conjunction with ongoing psychotherapy or with the support of a professional or paraprofessional [5-7].

Most apps with a focus on mental health are designed with a narrow functionality, focusing primarily on providing information to users as a way to enhance learning about their mental health symptoms or their management [5,8]. One categorization of their functionality used the following groupings: informing, instructing, recording, displaying, guiding, alerting, or communicating with users. Most apps fell into the grouping of informing (through the dissemination of psychoeducation), with a growing number of apps falling under the grouping of instructing [8]. Apps intended for instruction are skills-based, such that they enable the practice of specific intervention skills in a user's own daily environment (ie, practicing a skill on a mobile device during daily life).

One such skills-based app is Thought Challenger, an app currently available through the Google Play Store [9]. Thought Challenger is one app in the IntelliCare suite, a collection of apps in which each app focuses on one behavioral strategy commonly used in the treatment of depression or anxiety [10,11]. Thought Challenger instructs users in the process of cognitive restructuring, the core strategy in cognitive therapy (CT) that involves identifying and appraising maladaptive thoughts and creating adaptive counter thoughts [12]. Thus, Thought Challenger is intended to teach users this specific CT skill and to help build mastery in this skill through repeated practice. Users are expected to use Thought Challenger on an as-needed basis and are prompted to return to the app through notifications. However, the interactions with Thought Challenger remain constant over time. It is therefore important to explore how effective Thought Challenger is, and how other instructive apps might be, at teaching this core skill.

Learning in Cognitive Therapy as a Framework for Learning in Thought Challenger

The focus of CT is on educating patients about the impact of their thoughts on their mood while demonstrating how identifying, appraising, and modifying thoughts can lead to ultimate symptom reduction [12]. Patient learning and application of skills are noted to be among the possible mechanisms supporting symptom change in cognitive interventions [13,14]. Thought Challenger was designed to promote the learning and application of skills associated with symptom change in CT. However, the effectiveness of Thought Challenger in achieving this design aim is unknown.

The effectiveness of behavioral health intervention apps to achieve proximal goals purported to lead to ultimate symptom change is rarely evaluated. Apps are most often evaluated using randomized controlled trials; many researchers, however, have noted the limitations of these trials in the evaluation of mobile app technologies [15-17]. As such, it makes sense to leverage evaluation methodologies that are better suited for mobile technologies. One example would be usability testing, which

is a method of evaluation that involves testing users' interactions with a product and system to improve design. This process is intended to ensure that a technology is intuitive and easy to use. Usability testing requires systematic observation of a planned task or scenario carried out by an actual or potential user [18]. The International Organization for Standardization provides standards for usability testing, which define how to identify the information necessary for a designer to consider when specifying or evaluating usability of an evaluated product [19]. These techniques are used in engineering and computer science to evaluate and refine products, and are being used with increasing frequency in the context of behavioral health interventions delivered via technologies [20-22]. Indeed, usability testing is an ideal methodology to systematically examine users' learning of CT skills because of interactions with a mobile behavioral health intervention, such as Thought Challenger.

It is also important to evaluate how well a user will learn a depression intervention skill through the use of an app, without first reviewing any instructions. The evaluation of learning without instruction is important, given that most users are unlikely to engage with instructions or help materials before use, despite the likely benefits of doing so [23]. This behavior is referred to as the Paradox of the Active User and has been found to extend to the use of apps [24]; it helps to explain why users may be quick to reject apps that are initially perceived as not meeting their needs, even when detailed "Help" or "FAQ" sections exist. Therefore, apps should be able to achieve their aims through intuitive design [25]. Thus, evaluating the first-time user experience of an app such as Thought Challenger is critical, as this initial experience shapes subsequent use (or nonuse).

Purpose

Despite the growth in skills-based apps for mental health, the efficacy of such apps in promoting skills-based learning through their use is unknown. Furthermore, it has recently been documented that mental health providers may have concerns about the credibility and risk associated with treatment provided via mobile phone apps [6,26] and may be skeptical about the capabilities of such apps. The purpose of this study is to understand CT skill learning in the context of an app for depression, Thought Challenger, via usability testing methodologies. This study tested three learning objectives to evaluate the efficacy of the app, which included: (1) how well a user initially interacts with the Thought Challenger app without instruction; (2) the user's ability to learn the skill of cognitive restructuring from the app; and (3) the effect of using Thought Challenger on knowledge of CT elements.

Methods

We will first describe Thought Challenger, following the framework for the evaluation of the app, and the specific procedures of the usability testing.

Thought Challenger

Thought Challenger, currently available through the Google Play Store, was informed by CT. It was specifically designed to aid users in engaging in the CT-based technique of thought

restructuring. This process involves identifying thought distortions, which are unhelpful or erroneous thoughts that occur automatically but cause distress or mood changes in a person. Following the identification of such thought distortions, thought restructuring involves asking oneself questions to help challenge this distorted thought and to come up with a more helpful alternative thought [12].

Thought Challenger has two functions: challenge and review. The challenge feature is a tool designed to help restructure each thought through 5 steps: (1) "Catch It": enter a recent maladaptive thought; (2) "Check It": reflective questions are posed regarding the thought; (3) "Choose a Distortion": identify in which type of cognitive distortion the thought likely falls; (4) Consider reflective questions tailored to the chosen type of distortion; and (5) "Change It": enter a more adaptive thought.

Within steps 1 and 5, Thought Challenger provides examples of possible maladaptive and adaptive thoughts, which users may select and use in their interaction with the thought restructuring tool. Thought Challenger also provides a review function so that users can see their past entries of all thoughts, listed by automatic thought, rational response, distortion, and date and time of interaction.

Framework

Attributes are usability features that measure different usability qualities of technology products [27]. Table 1 displays the usability attributes, learnability, and learning performance used to measure the learning of users with Thought Challenger. The tasks, measurement, and objectives used in this evaluation are detailed below.

Table 1. Usability attributes and their application to learning evaluation.

Qualifier	Learnability	Learning performance
Description	Level of ease through which a user gains proficiency	Actual impact on performance of a task/acquisition of knowledge
Tasks for testing	Complete two attempts at using the Thought Challenger tool	Complete a pre-and posttest of cognitive therapy and skills
Measurement via	Time to complete interactions Error rate Rating of completed thought record	Scores on pre-and posttest
Learning objectives	Identify how user interacts without instruction or didactic material Examine whether user learns to use the app within an acceptable time limit, with a low error rate	Measure change in knowledge of cognitive therapy skills and concepts following initial use

Learnability

Learnability is defined as the level of ease through which a user gains proficiency with an app [28]. Learnability of the Thought Challenger tool was ascertained through multiple methods. First, *time to completion* for unguided interactions with the tool was measured across two separate attempts. As users report spending about 5 min or less to learn how to use an app [29], successful time to completion was defined as an interaction completion time of 5 min or less. Second, learnability was measured by *error rate*. Errors were categorized as slips (ie, an unintended action with the correct goal, such as a typo), mistakes (ie, a behavior with an incorrect goal, such as typing in today's date rather than a date of birth), or fatal errors (ie, an error that prevents the user from completing the task even with provided instruction/guidance) [30,31]. Error rates were obtained by dividing the total number of errors made by the number of error opportunities. Error opportunities are the total number of actions a user must complete to finish an interaction without errors [32]. For the purposes of the structured interaction with Thought Challenger, the number of error opportunities was 21. To the best of our knowledge, the literature does not define an ideal error rate for initial app use. Therefore, error rate was established for this app, along with the identification of any violated usability heuristics (ie, general principles of design). Third, learnability will also be measured via the *number of accurately completed thoughtrecords* using the Thought Challenger app. Thought restructuring can be a difficult skill for patients to grasp

on initial attempts [12,33,34]. A successful rate for this measure of learnability will be that licensed psychologists experienced in administering thought records in the course of CT will rate 63% or more of entries into the app as accurately completed for the skill of thought restructuring. This rate is based upon the findings of patient abilities to accurately complete thought records on their own during face-to-face delivery of cognitive interventions [33].

Learning Performance

Learning performance is an attribute of usability relating to the actual impact of a technology on the performance of a task or acquisition of knowledge, such as the ability of a technology to aid in increasing capabilities to complete assignments in a classroom [35]. As the testing of this study occurred during single in-lab sessions, learning performance was measured via *scores on a pre/posttest* of CT knowledge and skills. Successful learning performance was defined in this study as a significant increase in the score of a questionnaire evaluating CT knowledge and skills in a pre/posttest administration. Learning performance was measured in this testing as a means of evaluating objective 3, that is, measure change in the knowledge of CT intervention elements following initial use of Thought Challenger.

Recruitment

Recruitment of participants occurred from July to August 2015 from Web-based postings in the Chicago area of the United States, resulting in the participation of 20 adults. Inclusion

criteria required that participants were at least 18 years of age, able to attend an in-lab testing session, and able to speak and read in English. As depression is a condition that is frequently chronic, characterized by patterns of remissions and relapses [36-38], equal numbers of participants currently above and below the criteria for a referral for psychotherapy were recruited [39]. This sampling ensured that learning objectives were being measured with likely end users, ranging from those with no or mild depressive symptoms (subthreshold for a referral to psychotherapy as measured by a Patient Health Questionnaire-9 [PHQ-9] score of less than 10) to those with moderate or severe depressive symptoms (threshold for a referral to psychotherapy as measured by a PHQ-9 score greater than or equal to 10) [40]. Participants who completed in-lab usability sessions were compensated US $20 in petty cash for their time and participation. In compliance with the University's institutional review board (IRB), participants completed a Web-based screening consent before the collection of any data and were consented in person for the usability testing session.

Procedure

Participants were invited to a laboratory room located within Northwestern University's Feinberg School of Medicine and were accompanied by a moderator, who provided guidance and noted participants' actions throughout the testing session. Before the testing of Thought Challenger, participants engaged in a card-sorting task to identify the barriers to the use of apps for depression [41]. Following this, participants were provided a description of the app, which is also listed in the Google Play Store site when one would download the app: "Thought Challenger helps you gain control of how you feel and what you do by teaching you to notice and challenge negative and unhelpful thoughts. Thought Challenger is built on cognitive therapy - a structure that has been found in clinical studies to be useful in examining negative thoughts and reframing them to help you feel better and do the things you want to do" [9]. Users were then instructed to pick up the Android phone used for testing (lying on table directly in front of user), open the Thought Challenger app, challenge a recent negative thought, and inform the testing moderator when the user believed the task was completed. The interaction was timed and recorded, and the moderator wrote down any observed errors and alternative paths made in completing the first interaction. Users were then queried about any alternative paths taken to complete the interaction, whether they were able to find the log of the tool interaction they just completed, and whether they were able to find more information about the app (ie, Frequently Asked Questions or Help sections). These interactions were also recorded and timed and allowed for a delay between the two challenge tool interactions measured. Once completed, the users were prompted: "Now, please log another recent negative or unhelpful thought you have had." This interaction was also timed and observed, and all entries into the tool were recorded for later review. Participants therefore had two complete interactions with the Thought Challenger tool during the evaluation. Following a brief interview of the user impressions of Thought Challenger, users completed questionnaires on a lab computer.

Data Collection Approaches

Traditional data collection methodologies, which have been successfully used in other evaluations of apps [21,28,42], were chosen for the testing of Thought Challenger. Specifically, data collection included the following: (1) video/audio recording of the interactions; (2) standardized interview questions with the option to prompt regarding specific behaviors or observations; (3) questionnaires (see Measures section); (4) timing of all interactions via stop watch; and (5) recording of all user actions into the app's thought restructuring tool (ie, entry of thought and assignment of type of thought distortion).

Measures

Study data were collected and managed using REDCap (Research Electronic Data Capture) tools hosted at Northwestern University [43]. REDCap is a secure, Web-based application designed to support data capture for research studies, providing the following: (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources.

At screening, the participants were asked to provide demographic information (ie, gender, race/ethnicity, age, education, and employment status). Thereafter, they completed the PHQ-9 and CT Tool Knowledge and Skill Pretest at screening [40,44]. Following the completion of the interactions with Thought Challenger in the usability testing session, participants completed the CT Tool Knowledge and Skill Posttest, which is identical to the Pretest.

The PHQ-9 is a 9-item self-report instrument measuring depressive symptomology with scores ranging from 0 to 27 [40]. The CT Tool Knowledge and Skill Pre/Posttest is a measure adapted from the Cognitive Therapy Awareness Scale (CTAS) [44]. The CTAS is a measure evaluating understanding of CT constructs and skills. The language in the CTAS was modified to reflect only language and concepts presented in the Thought Challenger app. The range of possible scores is 0 to 40. The CT Tool Knowledge and Skill Pre/Posttest were administered at screening (pre) and after interacting with the app during the testing session (post). These time points allowed for about 1 week's delay between the pre- and posttest administration, with the intent of negating possible priming effects associated with pre/posttests.

Data Analysis

The thought record entries in Thought Challenger were collected to measure success of users in Thought Challenger tool use, that is, identifying how accurately users engaged in thought restructuring on the app. Following the completion of all testing sessions, doctoral-level clinical psychologists blindly rated participants' entries of maladaptive thoughts, assignment of type of cognitive distortion, and entries of alternative thoughts across their two interactions with the tool (such that each complete entry was rated by 2 separate psychologists). The psychologists were instructed to evaluate the entries as if they were thought records, a tool typically administered via paper, handed out in face-to-face CT to enable the practice of thought

restructuring [12]. The ratings were binary, such that the psychologists rated each entry section as either accurately or inaccurately completed. When there was conflict in the psychologist ratings (each entry was rated by 2 psychologists), a third clinician was invited to provide consensus on the entry.

Given the small sample size and anticipated non-normal distribution (ie, participants ranging from no depressive symptoms to severe), nonparametric tests were conducted to analyze quantitative usability testing data. Wilcoxon signed-rank tests were used to analyze comparison of time to completion of the tool interaction on the first and second attempt, as well as comparison of scores before and after the interaction with Thought Challenger. To ensure that there were no significant differences between the participants recruited with PHQ-9 scores above and below 10, Mann-Whitney U-tests were performed to compare the participants on times to completion, total scores on completed measures, and demographic variables. Chi-square

tests were completed to compare categorical demographic variables. All analyses were run in Statistical Package for the Social Sciences version 23 (IBM Corp), at the nominal 0.05 type I error rate.

Results

Participants

Table 2 displays the sample characteristics for the evaluation of Thought Challenger. One extra participant was recruited to the PHQ-9< 10 group, making the groups roughly equal. There was no significant difference between participants above and below the criteria for a referral for psychotherapy for age, gender, or race. Those meeting the criteria for a referral to psychotherapy had significantly higher depressive symptom severity (14.4 vs 3.8, $P<.001$) and a significantly higher prevalence of past depressive episodes (77.8% vs 18.2%, $P=.008$).

Table 2. Usability testing sample characteristics.

Demographic	PHQ-9[a]<10 (n=11)	PHQ-9≥10 (n=9)	Total (n=20)
Female, n (%)	7 (63.6)	8 (88.9)	15 (75)
Age in years, mean (standard deviation)	34.5 (10.3)	40.6 (14.0)	37.2 (12.2)
African American, n (%)	4 (36.4)	1 (16.7)	5 (25)
Asian, n (%)	2 (18.1)	0 (0)	2 (10)
Hispanic white, n (%)	1 (9.1)	0 (0)	1 (5)
Non-Hispanic white, n (%)	5 (45.5)	8 (88.9)	13 (65)
PHQ-9, mean (standard deviation)	3.8 (3.2)	14.4 (5.8)	8.6 (7.0)
History of depression, n (%)	2 (18.2)	7 (77.8)	9 (45)
History of anxiety, n (%)	2 (18.2)	5 (55.6)	7 (35)

[a]PHQ-9: Patient Health Questionnaire-9.

Learnability

Completion Time

Table 3 displays the completion times for the Thought Challenger tool interactions. For all participants, the median time to complete an initial, unguided interaction with the Thought Challenger tool was 4:05 min. Sixty-five percent of

the sample met the criterion requiring about 5 min or less for the first interaction [29]. Median time to complete the task on second attempt was significantly faster (4:05 vs 2:34, $P=.001$). Of note, the median times to complete the task across time points were identical for the PHQ-9≥10 group. However, the interquartile range (IQR) was smaller (7:30 vs 3:40), indicating that there was less variance in times on the second attempt for this group.

Table 3. Tool interaction completion times, median (interquartile range).

Time point	PHQ-9[a]<10	PHQ-9≥10	Total
Time 1	4:13 (4:01)	3:57 (7:30)	4:05 (4:04)
Time 2	2:08 (1:11)	3:57 (3:40)	2:34 (2:00)

[a]PHQ-9: Patient Health Questionnaire-9.

Error Rate

Ten errors occurred across the two interactions for each participant with the Thought Challenger tool. On the first attempt at the Thought Challenger challenge interaction, 9 mistakes were made, relating to attempts to interact with the

Thought Challenger word cloud on the home screen (ie, clicking on the word cloud rather than a button), selecting "Review" rather than "Challenge" to begin to challenge a thought, and persistence in the remaining challenge interactions after first entering a maladaptive thought (eg, "I entered my thought in

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like it said, now what?"). No slips or fatal errors occurred for any participants across the first interaction.

On the second interaction with the Thought Challenger challenge tool, one fatal error occurred, preventing the user from completing the task even with provided instruction and guidance because of frustration saturation (ie, "I don't want to start all over again and re-enter everything."). This fatal error occurred by the user clicking "cancel" while entering data into the challenge tool. Thought Challenger brought the user back to the Thought Challenger home screen without saving the entered data and without prompting the user that data would be lost. This is an example of violating the usability heuristic of error prevention, which guides designers to reduce or eliminate conditions that are likely to lead to errors in interactions [27]. Of note, no slips occurred during the second interactions. Although participants had in-the-moment slips, such as typos, these were not maintained in the system because of the Android operating system's algorithm to correct slips such as auto-populating words when a suspected typo occurs during text entry.

The total error rate for all initial interactions with the Thought Challenger tool was therefore defined by 10 (errors)/(21 [error opportunities] x 2 [number of interactions] x 20 [participants])=.012. Therefore, the error rate on initial interactions with Thought Challenger's tool was 1.2%.

Successful Completion of Tool Records

The majority of tool entries were rated as appropriate by doctoral level psychologists, with 75% (30/40) success in entries of a maladaptive thought, 51% (20/39) success in choice of type of thought distortion, and 74% (29/39) success in the entry of an adaptive thought. Consistent with face-to-face findings, the rate of success was determined to be 63% or greater [33]. The ratings provided by doctoral-level clinical psychologists indicate learnability consistent with testing aims via the Thought Challenger tool.

Learning Performance

Acquisition of Skills and Knowledge

To identify learning performance of users following use of Thought Challenger, all participants completed a pre- and posttest of CT skills and knowledge. Table 4 displays the medians and IQRs of pre- and posttest scores. A Wilcoxon signed-rank test indicated significant improvement in median scores for the entire sample, following the use of Thought Challenger (28.5 vs 31.0, P=.009). Successful learning performance was achieved for Thought Challenger, as there was a significant increase in performance on a CT knowledge and skills questionnaire following interactions with the app.

Table 4. Cognitive therapy pre-and posttest scores, median (interquartile range).

Time point	PHQ-9[a]<10	PHQ-9≥10	Total
Pretest	26.0 (11.0)	29.0 (5.5)	28.5 (11.3)
Posttest	29.0 (6.0)	32.0 (10.0)	31.0 (6.8)

[a]PHQ-9: Patient Health Questionnaire-9.

Consistent Performance Across Symptom Severity

No significant differences in completion times or in the performance on the pre- and posttest of CT skills and knowledge before or after interactions with Thought Challenger were identified between the two groups above and below the threshold for a referral to psychotherapy (PS>.13).

Discussion

This study aimed to evaluate CT learning during initial interactions with a publicly deployed, skills-based app for depression [10,11]. Thought Challenger presents a challenge tool for thought restructuring without separate didactic material; it is learnable within an acceptable time frame for initial use of an app [29] and produces a low error rate. Results also indicate that the Thought Challenger tool promotes effective execution of thought restructuring and that CT knowledge and skills improve significantly after initial use. Ultimately, users are able to meet the learning objectives for Thought Challenger during initial use, indicating that skills-based apps can teach an intervention skill for depression through very brief interactions.

Thought Challenger Performance

Thought Challenger met the evaluated learning objectives, creating entries in the tool that met the standard of accurately reflecting CT thought records at a rate of about 75%. This exceeded the benchmark of 63% of patients who were able to accurately complete the records as between-session homework throughout treatment [33]. One possible reason for the comparable performance of participants without the guidance of a therapist was that Thought Challenger provides the option of viewing example maladaptive and adaptive thoughts. However, in the 40 tool interactions in this testing, only 7 interactions (approximately 17%) employed example thoughts in the entries. Although not used frequently, the example thoughts may have provided a scaffold for participants to appropriately select and enter their own maladaptive and adaptive thoughts. Initial Thought Challenger entries are comparable in accuracy to thought records completed in the course of face-to-face interventions.

Thought Challenger was able to impact learning without requiring users to read or engage with didactic content. This is in contrast to most currently available mental health apps, which focus on providing information about symptoms and/or their management (ie, inform) [8]. Furthermore, when psychoeducation is presented in depression apps, a static

interface is predominantly used (ie, similar to reading an e-book) [5]. Thought Challenger differs from this design by training users in a skill via interactive engagement with its tool. With continued use of the tool, users practice the skill of thought restructuring. Thought Challenger produced CT skills, demonstrated both through the ability to produce accurate thought records and by the significant improvement in user knowledge of the intended construct. This finding supports the idea that people can learn psychological constructs and skills solely through skills training apps, without psychoeducation.

Opportunities for Improvement

Although Thought Challenger met the criteria for learnability and learning performance established for this study, the evaluation indicated opportunities for improvement of the app. First, a fatal error occurred (ie, an error that prevented the user from completing the task even with provided instruction/guidance) [30,31] in one user's interaction with the app. This error violated the usability heuristic of error prevention [27], as this error could have been prevented through the use of a warning notification with the following options: (1) to warn the user that his/her data would not be saved if s/he continues with the action; or (2) offering the option to save the data for a later interaction before exiting to the home screen. Second, mistakes that occurred could likely be minimized through the usability heuristic of help and documentation [27]. In providing more guidance to users who might be confused by the options (ie, word cloud on home screen, whether to select "Review" or "Challenge" buttons), the likelihood of mistakes could be reduced. Evaluations of apps through RCTs are likely to miss such fatal errors, focusing instead on exploring whether the app generally leads to a clinical benefit for participants. The possibility for such errors within an app may be one reason that behavioral health apps show low rates of retention when deployed in public marketplaces [45]. As such, it is critical to explore the use of these resources through methodologies such as usability testing in addition to evaluating their efficacy through other methodologies.

Limitations

There are several limitations and caveats that should be considered in interpreting these results. First, this was an evaluation of learnability and learning performance of Thought Challenger following initial use. It is unclear how these results would apply to long-term use, knowledge, skill application, or symptom reduction. Furthermore, as an evaluation of learning, there was no opportunity for comparison to other apps that promote learning (eg, different skills and psychoeducation only). Second, this study examined Thought Challenger in the context of users with symptom severity ranging from absent to severe depression, with the majority in the mild depressive range. It is unclear how these findings extend to users with other psychiatric or medical comorbidities. Third, while in-lab sessions were chosen over field-testing for multiple reasons, it is possible that the presence of a session moderator impacted user confidence or performance in a way that might have differed from field use. Finally, because of geographical limitations, the sample comprised urban and primarily younger users; it is unclear how well these findings extend to users in differing geographical locations and demographic groups.

Future Direction

This study employed usability methodology [27], borrowed from the field of engineering, to provide insight into user learning from initial interactions with an app targeting users with depression. This was ultimately to promote the design and dissemination of treatment apps that can be both trusted by providers, and useful and usable for patients. There is a need for future research evaluating how skills-based learning and practice through apps impacts long-term symptom management. This work should also extend to other chronic conditions beyond depression, as currently available apps may not be consistently usable for diverse and vulnerable populations [46].

Conclusions

To the best of our knowledge, this is the first use of usability testing methods to evaluate learning in an app intended to help users to learn and practice an intervention skill. Future research is needed to explore the role of learning in such apps and how to continue to improve skills-based learning, particularly in users with depression. This will promote improved design and dissemination of such apps. There has been some noted skepticism of clinicians on the efficacy of mental health apps. However, the findings from this study suggest that users can learn to complete a therapeutic intervention skill effectively through the use of a mobile tool alone, without engaging in didactic content.

Conflicts of Interest

None declared.

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Abbreviations

CBITs: Center for Behavioral Intervention Technologies
CT: cognitive therapy
CTAS: Cognitive Therapy Awareness Scale
IQR: interquartile range
IRB: institutional review board
PHQ-9: Patient Health Questionnaire-9
REDCap: Research Electronic Data Capture

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<u>Original Paper</u>

Usability of a Culturally Informed mHealth Intervention for Symptoms of Anxiety and Depression: Feedback From Young Sexual Minority Men

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Abstract

Background: To date, we are aware of no interventions for anxiety and depression developed as mobile phone apps and tailored to young sexual minority men, a group especially at risk of anxiety and depression. We developed TODAY!, a culturally informed mobile phone intervention for young men who are attracted to men and who have clinically significant symptoms of anxiety or depression. The core of the intervention consists of daily psychoeducation informed by transdiagnostic cognitive behavioral therapy (CBT) and a set of tools to facilitate putting these concepts into action, with regular mood ratings that result in tailored feedback (eg, tips for current distress and visualizations of mood by context).

Objective: The aim of this study was to conduct usability testing to understand how young sexual minority men interact with the app, to inform later stages of intervention development.

Methods: Participants (n=9) were young sexual minority men aged 18-20 years (Mean=19.00, standard deviation [SD]=0.71; 44% black, 44% white, and 11.1% Latino), who endorsed at least mild depression and anxiety symptoms. Participants were recruited via flyers, emails to college lesbian, gay, bisexual, and transgender (LGBT) organizations, Web-based advertisements, another researcher's database of sexual minority youth interested in research participation, and word of mouth. During recorded interviews, participants were asked to think out loud while interacting with the TODAY! app on a mobile phone or with paper prototypes. Feedback identified from these recordings and from associated field notes were subjected to thematic analysis using a general inductive approach. To aid interpretation of results, methods and results are reported according to the consolidated criteria for reporting qualitative research (COREQ).

Results: Thematic analysis of usability feedback revealed a theme of general positive feedback, as well as six recurring themes that informed continued development: (1) functionality (eg, highlight new material when available), (2) personalization (eg, more tailored feedback), (3) presentation (eg, keep content brief), (4) aesthetics (eg, use brighter colors), (5) LGBT or youth content (eg, add content about coming out), and (6) barriers to use (eg, perceiving psychoeducation as homework).

Conclusions: Feedback from usability testing was vital to understanding what young sexual minority men desire from a mobile phone intervention for symptoms of anxiety and depression and was used to inform the ongoing development of such an intervention.

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Introduction

Mental Health and Sexual Minority Youth

Individuals identifying as lesbian, gay, or bisexual experience mental health disparities relative to the general population [1]. Gay men, specifically, experience mood and anxiety disorders at 2-3 times the rate of heterosexual men [2]. Similarly, young sexual minority men are at greater risk for anxiety and depressive symptoms than their heterosexual peers [3], and male sexual minority youth experience more associated symptoms than adult sexual minority men [4]. Additionally, anxiety and depression have been linked with human immunodeficiency virus (HIV) risk behavior (eg, condomless anal sex) among young sexual minority men (eg, [5-7]); this is especially salient given that rates of new HIV infections are particularly high in young sexual minority men aged 13-24 years, accounting for 24% of new HIV diagnoses among all sexual minority men and 91% of new HIV diagnoses in all men their age [8].

Adolescence and young adulthood may be a particularly challenging phase of development for sexual minority people. In the normal developmental process of identity formation and integration [9], these individuals also come to understand that their sexual orientation places them in a stigmatized minority. Developing an identity to incorporate that status, attempting to extricate one's self concept from the societal stigma attached to it, and integrating this new identity into the whole self is a unique source of stress in this population [10]. Unfortunately, the extent to which existing psychotherapy protocols for anxiety or depression are efficacious among these young men is unknown. There is evidence, however, that psychological treatments culturally tailored for use with sexual minority men can produce results more quickly than standard cognitive behavioral therapy (CBT) (eg, by producing more rapid decreases in methamphetamine use among methamphetamine-dependent gay and bisexual men) [11]. There has been only limited research devoted to the development of psychological interventions for anxiety or depression that are specifically tailored for sexual minority youth and the factors that may drive their higher rates of distress.

Interventions for This Population

To date, we are aware of only two such interventions in the research literature. One, a face-to-face intervention for young gay and bisexual men, was developed using an approach and guiding principles [12,13] similar to those we describe here. A small randomized controlled trial demonstrated some promising outcomes compared with a wait-list control [14]. However, the intervention was delivered to sexual minority men between the ages of 18-35 years, and thus, was not specific to youth. The other intervention, Rainbow SPARX, is a computer-based intervention for depression that conveys concepts from CBT to adolescents in the form of a game [15]. This intervention was adapted for sexual minority youth from an existing intervention designed for a general adolescent population (SPARX) [16]. An open pilot study demonstrated promising outcomes and indicated that Rainbow SPARX is acceptable to and feasible with sexual minority youth [17].

Technology may be a relatively inexpensive way to disseminate a culturally tailored evidence-based intervention to sexual minority men. Despite acknowledgment that population-specific clinical competencies are vital to providing care to these individuals, there is a shortage of psychologists adequately trained in these competencies [18-20]. Other barriers to care for this community include cost, privacy concerns, and stigma concerning mental health issues and sexual orientation [21]. An anxiety or depression intervention provided on a mobile phone platform would be privately and inexpensively accessible wherever and whenever its user might feel distressed and could help compensate for the lack of culturally competent clinicians. Among youth in particular, mobile technology may be especially promising given the pervasive use of mobile phones among this age group [22]. However, to our knowledge, there have been no studies examining the use of a mobile intervention for symptoms of anxiety and depression designed for young sexual minority men.

The TODAY! App

To address this need, we developed TODAY!, a mobile phone app that offers young sexual minority men concrete steps they can use to more effectively manage anxiety and depressive symptoms. The frequent comorbidity of these symptoms and the cooccurring psychosocial problems sexual minority men frequently experience suggested that a transdiagnostic approach might be the most appropriate [12,23]. We therefore used concepts from transdiagnostic CBT [23] to inform the creation of the didactic modules and tools that comprise the core of TODAY! Many tools were designed to be presented to the user immediately after he reports a negative mood. The inclusion and development of these tools were heavily influenced by the concept of just-in-time interventions [24] and maximizing our ability to deliver tailored assistance to an individual at the moment he is experiencing distress.

Tailoring CBT concepts to this population required a working theory that accounted for the disparities in psychological distress experienced by these youth. These disparities are best understood in light of the minority stress theory that is well supported by the research literature. This theory posits that stress resulting from the extra burden of societal stigma is responsible for disparate rates of mental health concerns among sexual minority individuals [25,26]. This societal stigma includes discrimination, bullying, physical violence, and anti-gay public rhetoric, as well as the accumulation of microaggressions [27]. This stigma, when internalized by sexual minorities against themselves, is known as internalized homonegativity and becomes a significant stressor in its own right [28,29].

We took great care to be inclusive of the young sexual minority men for whom the intervention is intended. A recently published report that provides recommendations for tailoring eHealth interventions for sexual minority individuals supports our approach [30]. The recommendations highlight the need for

examples, characters, and imagery, especially around relationships, that reflect the unique aspects of the intended audience's lived experiences. TODAY! was designed with these young men's unique experience of minority stress in mind by, for instance, utilizing examples to show how common CBT techniques (eg, problem solving or cognitive restructuring) can be applied to these stressors [31]. We did so without using labels or focusing on sexual identity, an approach the report also recommends [30] and which was one of the fundamental principles that informed the development of TODAY!. Finally, the report highlights the usefulness of including helplines and other resources for sexual minority people, both of which have been included in TODAY! since the earliest versions.

This Study

To support the development of TODAY!, we conducted a series of usability testing sessions with young sexual minority men experiencing at least mild symptoms of anxiety or depression. The process of usability testing helped elucidate what this population desires from a mobile phone app designed to help young men like them cope with symptoms of anxiety and depression. During this study, we identified several recurring themes that shaped the design of the intervention as it underwent development.

Methods

Interpretation

To maximize transparency, we follow the consolidated criteria for reporting qualitative research (COREQ) in reporting our methods and results [32]. COREQ is a checklist of criteria, intended to be comprehensive, by which qualitative studies can be assessed and compared with one another and with which the results of qualitative studies can be better interpreted and understood in context [32]. The 32 items on the COREQ fall into three domains: (1) characteristics of the research team and their relationships with participants, (2) research study design, and (3) analysis and interpretation of data [32]. Addressing all COREQ criteria in our methods and results should aid interpretation by disclosing relevant details about the context in which the usability testing took place.

Recruitment

Young sexual minority men were recruited in a large Midwestern city through (1) flyers placed in general neighborhood locations, as well as at community organizations frequented by sexual minority people; (2) Facebook advertisements targeting males who reported interest in other males; (3) Web-based advertisements in general venues, as well as venues dedicated to sexual minority people; and (4) another researcher's database of sexual minority youth interested in research participation. Some youth also stated that they learned of the study through word of mouth. Interested youth completed a telephone screening with study staff to establish eligibility. Eligible participants were young cisgender men (ie, men who were assigned a male sex at birth and who presently identify as male) aged 17-20 years who endorsed sexual attraction to other males, experienced at least mild depressive or anxious symptoms per a verbally administered Patient Health Questionnaire for

Depression and Anxiety 4-item scale (PHQ-4) [33] score of 3 or greater, and were familiar with the use of a mobile phone. Potential participants were excluded if they reported a psychiatric history that suggested that the intervention, once developed, might be insufficient to meet the youth's needs or otherwise inappropriate (eg, a reported diagnosis of psychosis, post-traumatic stress disorder, substance dependence, or prior psychiatric hospitalization). We recruited participants in waves of 3-5, integrating participant feedback into the intervention on a rolling basis after each wave. We planned to conclude the study when three consecutive interviews failed to produce major new critiques or actionable suggestions.

Intervention

TODAY! is a 10-week mobile phone-based intervention designed to target clinically significant symptoms of depression and anxiety. It consists of a mobile phone app (see Figure 1 for the home screen) and an accompanying coaching protocol. The app content is informed by transdiagnostic CBT protocols that focus on factors that are common across internalizing disorders such as emotion regulation and cognitive appraisals [23]. The app is culturally tailored for young sexual minority men and consists of (1) short, sequential daily didactics called Daily Scoops (50 in total) that familiarize users with cognitive behavioral concepts, tools, and skills; (2) the Toolbox, a set of interactive tools to facilitate putting those concepts into action (eg, a Thought Record); (3) prompts for mood ratings and social context several times per day; (4) a retrospective daily review of important events, including high points, low points, and coping strategies employed [34]; and (5) feedback. This feedback includes data visualizations intended to show the user how his reported mood varies by social context and time (see Figure 2). Feedback also includes In-the-Moment tools, or tips to help manage current distress. These In-the-Moment tools are accessible on demand in the Toolbox but are also offered to the user after a negative mood rating. For example, when a user rates their mood and indicates that they are angry, TODAY! presents the In-the-Moment tools designed to help manage anger. After the user indicates he has completed one of the In-the-Moment tools, mood is assessed again to see if there has been any improvement. Figure 3 shows one of the In-the-Moment tools.

Not all of the intervention content is available from the beginning. Daily Scoops and the tools in the Toolbox are hidden at the start and unlocked over time, sequentially. For the first 50 days, a new Daily Scoop is unlocked each day. New tools in the Toolbox are unlocked when the Daily Scoop that introduces them is unlocked. As the intervention is intended to be used over a 10-week period, no new material is presented during the last 20 days. This is intended to give users room to miss some material and still catch up during the intervention period.

Throughout the app, we employ examples pertinent to the target population, such as

coping with negative societal views on same-sex attraction or deciding if, when, and how to disclose their same-sex attraction to friends and family. The intervention is also supplemented with inspirational material intended to help combat internalized

homonegativity, including inspirational quotes, accomplishments of influential sexual minority men, and affirming music videos. The intervention material is provided entirely within the TODAY! app but will be accompanied by weekly support (by telephone and email or text message [short message service, SMS]) from a master's level clinician who will employ motivational interviewing [35] techniques with the aim of enhancing engagement with the app. As the coach is not available around the clock and some youth may find they need to talk to someone urgently in crisis situations such as suicidal ideation or dramatically losing family support, TODAY! includes a Lifesaver feature accessible from the main screen. The Lifesaver allows for quick access to telephone support 24 hours a day, 7 days a week through a national crisis hotline for sexual minority youth, a national suicide crisis hotline, and 911.

There may be some questions as to why the app itself was designed for a very specific subpopulation of sexual minority youth, that is, individuals assigned male sex at birth, who identify as male, and who are sexually attracted to other males. First, a primary purpose of developing this intervention is to provide a culturally tailored intervention. As the group being targeted by such an intervention is expanded, the amount of cultural targeting possible grows smaller. Second, evidence suggests that models of minority stress may differ between sexual minority subpopulations [36]. In light of this and in such a preliminary study of a novel intervention, we decided to reduce the heterogeneity of the sample by focusing on a specific subpopulation. If future studies suggest this intervention is effective, it would be reasonable to expect that similarly targeted interventions might be effective among other sexual minority populations.
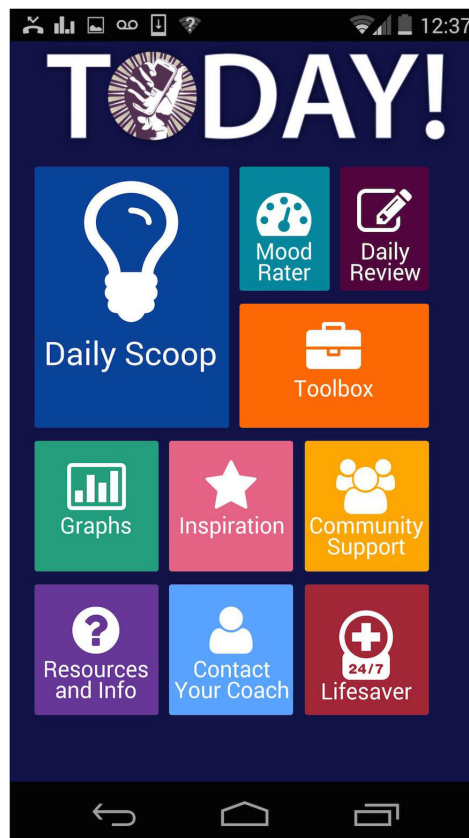
Figure 1. The TODAY! home screen.

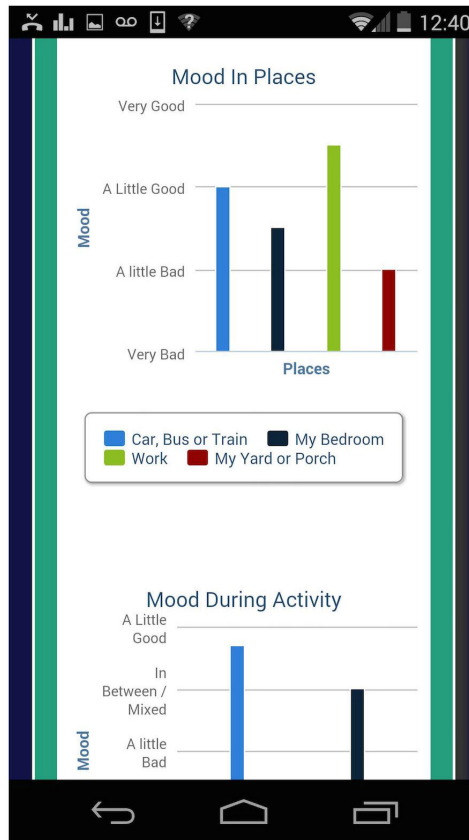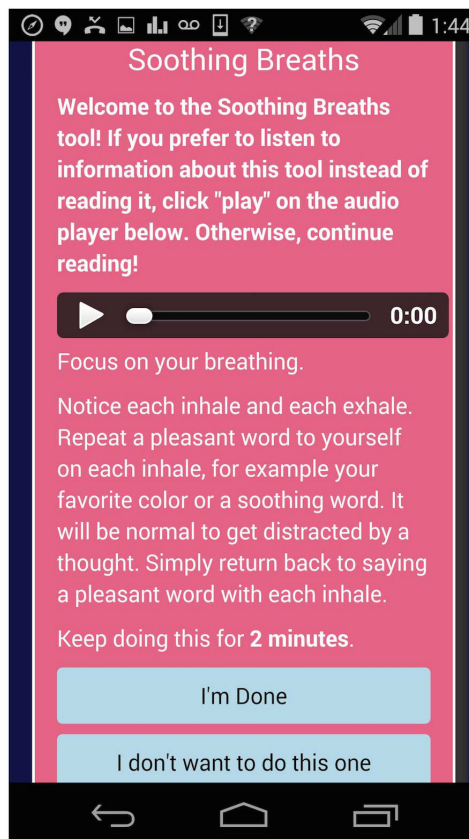**Figure 2.** Mood variation by social context visualization.

Figure 3. An In-the-Moment tool intended to help manage current anxiety.

Usage Flow

Typical usage of the app would consist of consuming any newly available didactic material from the Daily Scoops at the start of the day, followed by practice use of any tools discussed or introduced in that material. Throughout the day, he would rate his mood periodically and use the suggested In-the-Moment tools as needed to improve mood. There is no intended frequency that the Toolbox should be accessed. However, to gain maximum benefit from the app, we encourage regular use. Toward the end of the day, a typical user would reflect on his day and complete the Daily Review. After using the app for several days, he might also start periodically checking the Graphs section to see the patterns the app has recorded regarding his mood and behavior. Usage of TODAY! features that are not part of the core intervention is likely to be somewhat idiosyncratic, with users accessing these features when they determine a personal need or interest.

Procedure

Each youth who screened eligible for the study was invited to meet with us for one session, at their choice of our offices at an urban Midwestern university or at a local LGBT community center. All study procedures were approved by the university's institutional review board (IRB). The sessions lasted approximately 3 hours, with an additional 30 min available for breaks if participants desired them. Upon the arrival of each participant, the researcher discussed the study with him and obtained informed consent. An assent procedure and waiver of parental consent were prepared and approved by the IRB for any participants who were 17 years of age. As no 17-year-old participants enrolled, we did not have occasion to use that procedure. To characterize the sample, participants completed the self-report Patient Health Questionnaire for Depression 9-item scale (PHQ-9) and the Generalized Anxiety Disorder 7-item scale (GAD-7) to measure depressive and anxious symptoms, respectively [37,38]. Each participant also filled out a brief demographic questionnaire and surveys of his typical Internet and mobile phone usage.

Next, participants completed a semistructured interview (see Multimedia Appendix 1) with research staff. First, the intervention components were verbally described to the participant to elicit the youth's initial reaction to the concept and to discover which topics the participant believed would be helpful to include in such an intervention. Then, each participant interacted with various features of the app using paper prototypes or a partially functional version running on a mobile phone. This portion of the session was conducted using a think-aloud paradigm, where the youth were asked to verbalize the thoughts they were having, questions they had, and any decisions they were making (such as what to press on the screen when there were multiple actions that could be taken) as those thoughts, questions, or decisions occurred [39]. Afterwards, the semistructured interview resumed by asking each participant about his opinions after interacting with the app. To capture all the relevant data produced in a usability session, the interviews and think-aloud sessions were video recorded, with the exception of one session that was audio recorded due to technical issues. The interviewer kept field notes during the think-aloud exercise,

and otherwise when appropriate, to supplement the recorded data. Sessions were conducted privately, with only the interviewer and participant present. Each participant received US $60 in cash, as well as travel cost reimbursement up to US $7 at the conclusion of his usability feedback session.

Interviewers

The sessions were led by either a white, cisgender female Ph.D. level clinical psychologist and assistant professor (senior author) or a Hispanic, cisgender female predoctoral clinical psychology resident (second author). The senior author has previously conducted research with this population through partnerships with other researchers and institutes, and her perspective is informed by the minority stress theory [25,26]. Additionally, she has years of experience working with behavioral intervention technologies such as the one described here. The second author's clinical psychology residency had a primary focus of research and clinical work with sexual and gender minority individuals. No participant was familiar with either interviewer before his usability session, nor did the format of the usability sessions allow for participants to learn about the interviewers' personal motives for performing this research.

Analysis

We chose to recruit participants in waves of 3-5, making any iterative changes to the intervention after each wave, such that at least three participants would review the same version of the intervention. We ended recruitment when three consecutive interviews produced no distinct major critiques or actionable suggestions. These were our chosen criteria for determining when data saturation had been reached. Descriptive statistics calculated on the self-report data provided details regarding the makeup of our sample. We then subjected the comments obtained during the usability feedback sessions to thematic analysis using a general inductive approach [40]. Having only one contact with each person, participants did not have an opportunity to review and possibly correct our raw data. We used no a priori codes or codebook; rather, we looked for themes that emerged from the data itself. First, the second author reviewed the recorded sessions and transcribed participant comments when they constituted an identifiable item of usability feedback. These transcribed comments were combined with observed participant behaviors and technical issues that the first author noted at the time of the interviews. The second author then used Microsoft Excel to sort this data into initial proposed thematic areas. All three authors then reviewed the data together to come to an initial consensus on what the major themes were. Finally, the first and senior author individually coded each item of feedback, assigning each to one of the identified themes. Items not coded identically by both coders were discussed until consensus was reached as to which category each piece of feedback fit into. The themes that emerged during this analysis informed continued development of the intervention. This means that later participants interacted with more refined versions of the app than previous participants did. Participants did not have an opportunity to respond to the findings of this study once analysis was complete.

Results

Participants

We reached data saturation after 9 young men participated in usability sessions. Of these 9 participants, 44.4% (4/9) identified as black, 44.4% (4/9) as white, and 11.1% (1/9) as Latino. Participant ages ranged from 18 to 20 (Mean=19.00, SD=0.71). All participants (N=9) reported an exclusively gay sexual identity. Eight youth reported being sexually attracted only to males, with one reporting being attracted mostly to males but to some females. All participants reported owning a mobile phone that was nearly always with them. The mean PHQ-9 score of 8.67 (SD 3.35) was over the 90th percentile according to German studies, with representative samples of male adolescents and young adults [41,42] Likewise, the mean score of 8.44 (SD=4.33) on the GAD-7 was in the 92nd percentile [43]. All participants who came to their scheduled session gave informed consent and participated fully.

Usability Feedback

All participants expressed enthusiasm about an app created to help young sexual minority men like themselves with anxiety and depression. These general positive comments constituted one theme that emerged from our data. The analysis of more specific items of feedback revealed six more themes that, by highlighting what required improvement, informed the ongoing development of TODAY!: (1) Functionality, or comments concerning the features available in the app, as well as usability concerns such as navigation; (2) Personalization, or feedback regarding the extent to which interaction with the app was tailored to the individual and his circumstances based on input from the user; (3) Presentation, including the methods by which information was conveyed to the user; (4) Aesthetics, which covered the visual experience of using the app; (5) LGBT or Youth Content, comprised of suggestions of additional features or content that participants believed could benefit young sexual minority men; and (6) Barriers to Use, which described aspects of the intervention that participants believed could prevent themselves or other young men from participating in the intervention or deriving maximum benefit from it. What follows are some of the most frequently endorsed or most salient of these critiques. Because the intervention was updated between waves of participants, the number of participants endorsing any particular suggestion is not meaningful as a fraction of the sample size, and is thus not reported.

Functionality

Some participants indicated it was unclear from the home screen which features of the app they were supposed to use each day, since there was nothing to indicate which Daily Scoops and tools were unused or newly available. In response, the app was updated to add a glowing border around new or unaccessed material, visually guiding the user to content of interest. The participants who provided this feedback were among the first half of usability testers. Participants in later waves no longer expressed the same concern. One advantage of performing revisions on a rolling basis during testing was being able to see that users' concerns were being addressed.

Another concern that youth expressed was that providing a graph displaying mood over time could potentially be upsetting if it showed that their mood had been deteriorating. This is a risk of providing visualizations of users' mood data. We hope coaching will mitigate the possibility of the mood graph creating the iatrogenic effect of further demoralizing a user whose mood declines despite using the app regularly enough to provide mood ratings. The coach can discern with the youth what might be contributing to his mood decline and which features of the app (eg, an In-the-Moment tool) might help the youth to cope better. If concerns remain once the app has been evaluated in the field, we will consider removing the graph or making it accessible only to the coach, who could apply clinical judgment in choosing whether to share it with a given user.

Personalization

In general, participants did not react positively when they were asked to enter personal data into the app, and the app did not in return provide some kind of tailored response. One participant said the lack of personalized feedback made the Social Support tool (designed to help a youth assess his levels of various types of social support) feel like "just some survey" and that he thought it would be used more if it gave some kind of feedback based on the values entered. In response, we updated the Social Support tool to provide 24 unique combinations of feedback based on the unique needs of the user himself, suggesting how he might broaden or deepen his social support.

Another aspect of the intervention that participants found to be impersonal was that the asking of some questions seemed to not make sense based on information already entered by the user. An early version of the Mood Rater asked the user to endorse how intensely he was experiencing several emotions (eg, "How sad are you right now?"). One tester commented that if they had already endorsed sadness, it felt like they had not been heard when they were also asked, "How happy are you right now?" With the understanding that one can be happy and sad at the same time, we did agree that the sequence of questions was needlessly complex. We addressed the concern by streamlining the Mood Rater and replacing those items with two questions: one that asks the user to rate his mood valence on a scale of "very bad" to "very good," and one which presents a list of emotions and asks the user to check off those he is experiencing. This removed a source of impersonal-feeling content and reduced the amount of time necessary to complete the Mood Rater.

At the same time, some youth wanted to be able to provide a fuller account of how they were feeling, and why, than the Mood Rater allowed. While we were streamlining the Mood Rater, we also created the Daily Review, intended to be used once each evening, to give the user a chance to reflect on high and low points of their day, what triggered them, and how they responded to those situations. The addition of the Daily Review also addressed the concern inherent to ecological momentary assessment (EMA) [44] that periodic assessment of current states may fail to capture some important events. Figure 4 shows a visualization displaying the types of coping strategies the user tends to use, gathered during the Daily Review.

Figure 4. Categories of coping strategies endorsed in the Daily Review.
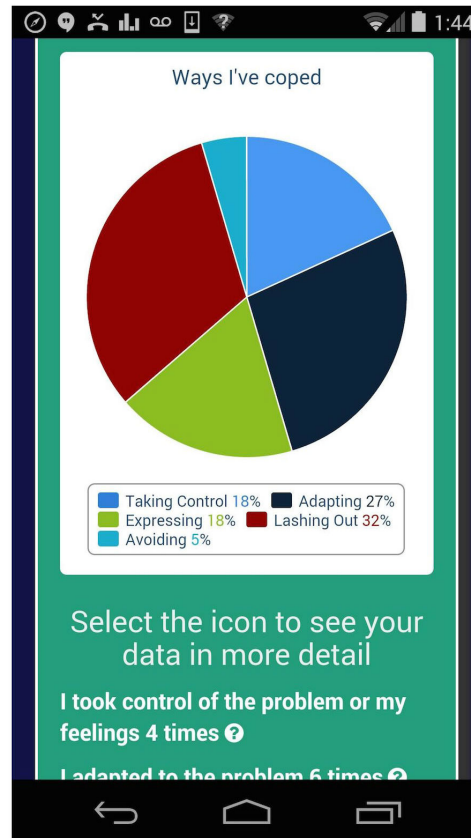
Presentation

Feedback on the methods used to deliver information tended to be more idiosyncratic, with each tester expressing personal preferences regarding how they would prefer to engage with the app. Even so, some themes recurred in feedback from the youth which did guide further development of the intervention in this area.

One common theme was that the Daily Scoop material was perceived as being too lengthy, despite our attempts to keep it brief from the outset. Aside from perceptions that there was too much written material, one participant stated straightforwardly that he would "never" read it because doing so felt like homework. Some users expressed a preference for the inclusion of audio or video to replace or supplement the written Daily Scoops. In response, we did supplement some Daily Scoops with audio and video. We added spoken versions of some of the Daily Scoop content, making some Daily Scoop content accessible by listening rather than reading. We also added short videos to some of the first Daily Scoops, where it seemed especially important for users to grasp the concepts presented in order to derive maximum benefit from later material. The videos depicted a male in his late twenties talking about his own personal experiences that related to the concepts being presented. Testers had mostly positive responses to these videos. Some feedback indicated a sensitivity to the notion that video content was scripted or inauthentic in some way. However, this did not seem to render the videos useless, as one youth with authenticity concerns regarding one video also reported a positive reaction to its message.

Early usability testers were exposed to test videos produced using different paradigms (animated characters discussing Daily Scoop concepts, a solo actor acting as a guide to the concepts, and vignettes with several actors demonstrating the concepts) to assess general format preferences. Participants expressed a diversity of opinions, but there were some commonly repeated themes. Several youth thought the single actor videos were more effective. Usability testers in subsequent waves were shown more single-actor videos, which continued to be better received than video vignettes with multiple actors. Some participants commented on how attractive the characters in the video were:

> He was cute, so that was a plus for keeping me interested in the video. [Participant #4, 19-year-old gay Latino male; high-school equivalent education]

Attractive characters may not be enough to maintain engagement, however. One participant who found one of the animated characters to be "gorgeous" still said he found the video boring.

It seems that presenting key material as concisely as possible should be a guiding principle when developing material for this population. It also became evident that simply replacing text with multimedia content would not have solved this problem. Some participants stated a preference for reading the didactic material, one stating that in general he is only interested in watching videos when a visual is required for learning. Some participants suggested that the Daily Scoops be presented as text supplemented with other media:

> I kind of grew up watching like the "It gets better" videos...my generation maybe relates more to

watching videos and stuff. But I think that you could honestly do both. I think like have a video link and have the story. There are so many times that I can't watch a video and I'll just want to read it, so I think that having both would be cool. [Participant #2, 19-year-old gay white male; college student]

Since preference for media type varied from individual to individual, it appeared that presenting information in more than one medium would maximize a given user's likelihood of engaging with it. Whereas it may not be appropriate or feasible to provide all intervention content in multiple modalities, the feedback we received indicated that adding multimedia content when feasible would maximize the impact of didactic material.

Aesthetics

Feedback on the app's aesthetics played a crucial role in helping us determine what would be the most broadly appealing to this population. A substantial number of our earlier usability testers stated that the colors should be brighter. We made the app's background solid and dark blue so it would provide high contrast to the colors used for buttons, images, and other parts of the user interface, and we replaced colors that were dull or did not stand out from the background. This effort was ultimately rewarded with an overall aesthetic that is more cohesive across the app and appears more lively. After these changes, subsequent usability testers no longer offered any critiques regarding the app's aesthetics.

Another set of aesthetic issues that came up several times related to the fact that early versions of TODAY! were running as a Web application on a mobile phone browser. Depending on how a user interacted with the screen, sometimes the browser's URL bar would appear and reveal this fact. This happened in several early usability sessions. One participant said the URL bar made the app "ugly" and urged us to offer the intervention as a "legit app" instead. Another youth (not referencing the URL bar) also expressed a preference for an app that was not running in the browser. It is notable that the youth were not commenting on content at all. In one case, the accidental discovery that the app was running inside the mobile browser provoked the strong reaction, and in the other, it was just the idea that it was running inside the mobile browser that elicited a preference for a different paradigm. These participants did not articulate exactly what felt illegitimate to them about the intervention being delivered as a Web application. TODAY! is now packaged as a standalone Android app like the apps in an Android app store.

Lesbian, Gay, Bisexual, and Transgender (LGBT) or Youth Content

Despite taking care from the outset to design TODAY! for young sexual minority men, usability testers still had a wealth of suggestions for topics they would like to see addressed in this kind of app. One of the most often-suggested topics was coming out:

because...you obviously come out to your parents like one time, but you have to come out on like a daily basis as a gay man. It kinda wears on you or you'll be in a situation like I went to a new school for a year and then I transferred and then I had to like do it all

over again and it was like, you kinda forget a little bit... [Participant #2, 19-year-old gay white male; college student]

The young men that TODAY! is intended to help do not necessarily identify as gay or bisexual, and it is possible this material would not be helpful to all users of the app. The relationship between disclosure of sexual orientation and well-being is also somewhat complex [45], and addressing this issue clinically, particularly with this age group, is not simple. We are certainly in no position to recommend any particular course of action to any individual. Thus, we added eight optional Daily Scoops and three tools that deal solely with aspects of coming out, including assessing available social support and weighing all options. For youth who choose to come out, the supplemental material covers preparatory steps, the disclosure itself, and coping with potential consequences. Our goal was to provide a structure whereby a youth could thoughtfully determine for himself whether coming out is the best choice at this time, and if so, prepare in a comprehensive way. Figure 5 shows the Coming Out Game Plan tool being used.

Another frequently mentioned topic was social isolation or inadequate peer social support. These issues are especially salient in a population who may feel set apart from their peers, who may conceal their sexual orientation, and who may have limited contact with other sexual minority youth. In response, we highlighted the Social Support tool that was already part of TODAY!, encouraging youth to return to it and reassess their levels of support as they move through the program. This feedback came while the Social Support tool was already being updated to give personalized feedback (see Personalization, above), so it now can offer ideas about shoring up social support in areas where it is lacking. We also added a new category of In-the-Moment tools to manage loneliness. These tools focus on ways one might reach out to others when feeling lonely, as well as making the most of time alone.

Another feature that youth often mentioned as desirable was a social networking component. One repeated suggestion was that this could be a forum where they could discuss issues and receive tips from peers:

Like they say like I'm feeling this kinda way...like an instant message thingy and we'd be able to talk to them through that...they don't know who we are, we don't know who they are...like [some screen name] said this and I feel much better...I'm dealing with the same situation...It's like a message board.. [Participant #5, 19-year-old gay black male; high school graduate]

Another idea floated was a messaging system where users of TODAY! could receive support from other users after posting about their day or how they were feeling. One youth stated he would like to share his accomplishments within the app with other app users. Although we lacked the resources to add social networking features at this time, we intend to provide an indirect connection between users by allowing participants to volunteer a narrative about their experience with TODAY! each week. Narratives perceived by study staff to be of potential value to other users will be deidentified and made visible to other users.

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Figure 5. The Coming Out Game Plan tool after a user has entered data.
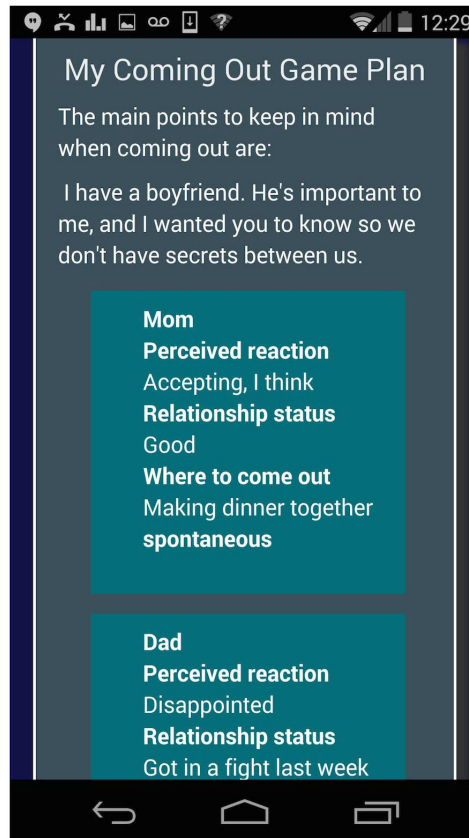
Barriers to Use

The usability testers were also queried about factors that might hypothetically prevent themselves or other young sexual minority men from using and staying engaged with the TODAY! program. The topic that came up most frequently as a possible barrier was the idea of having weekly phone calls with the coach. A number of our participants indicated scheduling this call could be difficult due to their schedule, the desire to remain discreet, or other factors:

> Me personally, I probably wouldn't want to use the coach because if it's an app...like everything will be on the phone. Cause if I'm at work or something and I want to use it, I may not have time to talk to someone...maybe that could be an optional thing in the app...I don't think it should be mandatory cause some people...may be benefiting by just using the app. Or maybe they don't feel comfortable talking to someone. [Participant #1, 20-year-old gay black male; has trade school certificate]

In response, we have made it possible for the youth to contact their coach via telephone, text message (SMS), or email to communicate between calls or schedule their phone conversations, which can take place at different times each week according to the user's schedule. Relating to the coach, being able to open up with the coach, and possibly not getting along with the coach were also concerns. A participant who was concerned about the relatability of the coach said that it might help just to see the coach's face. We created a video of the coach introducing herself to the participants and integrated it into a "Meet the Coach" section of the intervention. We hope that revealing the person behind the word "coach" early in the program will help youth feel more comfortable with the idea. Although several participants voiced concern about some aspect of the coaching protocol, some offered suggestions to mitigate those concerns.

There are a few other possible barriers worth noting. As mentioned above (see Presentation), one usability tester stated outright that he would not look at any of the Daily Scoops because they felt like homework. Another youth believed that using certain tools (eg, the Thought Record and Problem Solver) could get tedious, so he did not think he would use them. Understanding that individual differences may lead different participants to prefer Daily Scoops to using tools or vice versa, we have since tried to make the tools as usable as possible on their own, adding introduction screens to each tool with brief summaries of the tool's purpose and the concepts it employs. Although we expect individuals who make use of both the didactic material and the tools to remain the most engaged and have the most success, we also want individuals with different preferences to derive as much benefit from the app as possible.

Positive Feedback

Whereas all participants had positive reactions to the app, individual participants believed different aspects of TODAY! would be the most helpful to them, personally. The graphs providing feedback based on Mood Rater and Daily Review input were cited by one user as the most helpful feature; he believed seeing the patterns in his mood could over time help him learn how to improve his mood in the future (but also see

above, Functionality, for concerns about the mood over time graph). One participant was most positive about the Daily Scoops, which he found to be informative. He also found great value in the community resources referenced in the app:

> *I didn't even know there was a hotline for lesbian, gays, bisexuals. It's very informative.* [Participant #5, 19-year-old gay black male; high school graduate]

Another commented on the Lifesaver button and said it was a great idea. Others cited the tools as most likely to be helpful. One agreed that the Toolbox sounded useful but believed that he himself would only respond well to the In-the-Moment tools.

That each individual highlighted different aspects of TODAY! as being the most helpful validates to some extent the comprehensive design of the intervention. One participant commented on this directly:

> *I don't think I've seen such a comprehensive stress, anger, depression app like this. It's a really great idea.* [Participant #3, 19-year-old gay white male; college student]

Discussion

Principal Findings

The participants expressed enthusiasm for a comprehensive mobile phone app designed to treat clinically significant symptoms of anxiety and depression among young sexual minority men. These young men tended to prefer bright colors, presentation of didactic content in multiple media formats, brief text content, personalized feedback, and features allowing them to record their mood quickly, yet with options to provide deeper responses. Some of them further suggested that caution should be taken when presenting visualizations of mood data due to the potential to demoralize youth whose mood is negative or deteriorating. Participants also indicated that it was very important to them that an intervention culturally tailored for young sexual minority men like themselves address the topics of social isolation and coming out.

It also became clear that an intervention that intends to include human supports meant to increase engagement (such as a coach) might overcome many obstacles to participation by introducing those supports early on and facilitating flexible scheduling with them. Participant feedback also suggested that future studies should explore the potential for social networking features to enhance such apps. Providing a peer network would pose many potential challenges that would have to be considered [46]. However, given the frequently voiced concern about isolation and the importance of social support, having such a feature may be of benefit.

Human Supports

The feedback we received on human supports raises a bigger issue that reaches beyond the specifics of our intervention and targeted population. Our usability testers raised many potential problems they saw with having an expert coach guide them through the intervention, and at the same time requested that they be able to interact in some way with peers who are using the same intervention. Adding a social networking feature was beyond the scope and budget of this version of TODAY!, but we intend to explore the possibility of adding social networking to future versions; we have begun preliminary research to attempt to determine the broad outlines of a social networking feature that would be appropriate, effective, and meet youth's expectations of peer interaction. Meanwhile, requiring coach support as we currently do does potentially restrict access to the intervention relative to a standalone mobile phone app with no clinician involvement. If expanding access to care is one of our goals, and feedback from usability testers has been mixed, why do we not consider removing or replacing the coaching protocol? We know from the broader literature that eHealth interventions for anxiety and depression have been plagued by low levels of adherence that limit their potential [47] and that addition of human coaching protocols increases adherence [48] and efficacy [49] in the general population. There is unfortunately no formula to guide us in determining the appropriate balance between what the literature to date tells us, what individuals from a target population tell us about themselves, and our goal to expand access to those who are presently underserved. This decision thus highlights a fundamental tension that can arise in usability testing.

Generalizability

The other known technology-delivered CBT intervention for young sexual minority individuals with depressive symptoms, Rainbow SPARX, targets depressive symptoms only, is presented as a computer game, and was tested in non–gender-specific sexual minority youth in New Zealand. In contrast, the TODAY! app targets symptoms of depression and anxiety, is presented as a mobile phone app, and was tested in sexual minority males in the United States. Even so, most of the usability feedback received about Rainbow SPARX that differed substantially from feedback we received on TODAY! was based on these differences in intervention format and target population, or on items very specific to one intervention or the other. In any domain they could both be evaluated in, the youth who usability tested TODAY! and the youth who participated in focus groups and feasibility trials for Rainbow SPARX gave similar feedback on these two different interventions [17,50]. Areas where similar feedback were given include that both were generally received positively, youth requested that more be included in both about coming out, and testers for both emphasized in some way the value of friendships and community in coping with their problems [50]. The similarity in feedback regarding quite different interventions lends support to both sets of findings and indicates they may be generalizable to a broader population of sexual minority youth.

Consistency With Recently Published Guidelines

The positive reception given TODAY! by the young men in our study supports the value of tailoring interventions specifically to young men who are attracted to men. This inclusiveness was always a guiding principle in the design of TODAY!, but two of the recently published recommendations for tailoring eHealth interventions for sexual minority individuals [30] that did not guide the development of this intervention did arise during usability testing, lending support to their importance. First, while we do stress the importance of social support and have

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an entire tool devoted to assessing and enhancing social support, we did not originally consider a social component to the intervention itself. A social networking component was recommended by several of our participants during usability testing. Second, while the entire intervention is tailored for young men who are attracted to men, we did not originally intend to include significant material devoted to the topic of coming out. Early feedback we received from participants made it clear that this information was highly desired.

Limitations

Eligibility requirements for our usability testing sample required the presence of only mild depressive or anxious symptoms on a brief screener, whereas the intervention is intended to treat symptoms that are clinically significant. The more mild nature of the symptoms endorsed by many youth in the current sample was reflected in one case by a usability tester declaring he would not be likely to use TODAY! simply because he was "not that depressed." This should be taken into consideration when interpreting the responses in this study, especially when generalizing them to youth with more severe symptoms of depression or anxiety.

Another limitation of the study is that we reached saturation after only 9 youth had participated. Small sample sizes may be effective in uncovering most usability issues [51,52] when the total number of testers is distributed into waves of 3-5 as in this study. More waves, as opposed to more testers per wave, are of greater benefit due to features of the iteration process [52]. Similarly, a review of usability testing studies using the think-aloud protocol indicated that nine testers can detect approximately 80% of usability problems [53]. However, these conclusions have been criticized [54], and thus, the small sample size may have resulted in failure to detect important usability issues. Other, more definitive sampling issues are that none of the youth in this study identified as bisexual, the sample was divided between black and white participants but did not include multiple Latino youth or any youth from other racial backgrounds, and our results also may not generalize to sexual minority youth living in other cities or in nonurban areas.

Finally, the feedback that we elicited reflects the participants' personal preferences. There may be a disparity between stated user preferences during our usability sessions and actual usage behaviors and mental health outcomes.

Conclusions

TODAY! is a comprehensive, culturally tailored mobile phone app for symptoms of anxiety and depression and constitutes one of the first steps forward in the call for technology-delivered, transdiagnostic minority stress treatment [12], and it elicited positive responses from young sexual minority men. Their critiques of the app may also prove useful in the development of other apps for this population. Such apps may be more helpful and appealing to young sexual minority men if they feature bright colors, personalized feedback, brief content, and the options to obtain content through multiple media, as well as to provide depth in their responses to queries. Developers of behavioral apps for young sexual minority males should also consider addressing social difficulties and challenges related to coming out. Finally, future studies should explore the potential for social networking features to enhance such apps.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The interview guide used to conduct the semistructured interviews that were the source of the data analyzed.

[PDF File (Adobe PDF File), 43KB - humanfactors_v4i3e22_app1.pdf]

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Abbreviations

CBT: cognitive behavioral therapy
COREQ: consolidated criteria for reporting qualitative research
EMA: ecological momentary assessment
GAD-7: Generalized Anxiety Disorder 7-item scale
HIV: human immunodeficiency virus
IRB: institutional review board
LGBT: lesbian, gay, bisexual, and transgender
PHQ-4: Patient Health Questionnaire for Depression and Anxiety
PHQ-9: Patient Health Questionnaire for Depression 9-item scale
SD: standard deviation
SMS: short message service

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Original Paper

Modeling Patient Treatment With Medical Records: An Abstraction Hierarchy to Understand User Competencies and Needs

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Abstract

Background: Health care is a complex sociotechnical system. Patient treatment is evolving and needs to incorporate the use of technology and new patient-centered treatment paradigms. Cognitive work analysis (CWA) is an effective framework for understanding complex systems, and work domain analysis (WDA) is useful for understanding complex ecologies. Although previous applications of CWA have described patient treatment, due to their scope of work patients were previously characterized as biomedical machines, rather than patient actors involved in their own care.

Objective: An abstraction hierarchy that characterizes patients as beings with complex social values and priorities is needed. This can help better understand treatment in a modern approach to care. The purpose of this study was to perform a WDA to represent the treatment of patients with medical records.

Methods: The methods to develop this model included the analysis of written texts and collaboration with subject matter experts. Our WDA represents the ecology through its functional purposes, abstract functions, generalized functions, physical functions, and physical forms.

Results: Compared with other work domain models, this model is able to articulate the nuanced balance between medical treatment, patient education, and limited health care resources. Concepts in the analysis were similar to the modeling choices of other WDAs but combined them in as a comprehensive, systematic, and contextual overview. The model is helpful to understand user competencies and needs. Future models could be developed to model the patient's domain and enable the exploration of the shared decision-making (SDM) paradigm.

Conclusion: Our work domain model links treatment goals, decision-making constraints, and task workflows. This model can be used by system developers who would like to use ecological interface design (EID) to improve systems. Our hierarchy is the first in a future set that could explore new treatment paradigms. Future hierarchies could model the patient as a controller and could be useful for mobile app development.

KEYWORDS

clinical decision-making; health services research; qualitative research; primary health care; medical records systems, computerized

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Introduction

Health care is considered a complex sociotechnical system [1]. Additionally, there is a trend to move away from paternalistic health care approaches to treatment [2,3] and engage patients in their own care. For example, there is currently a trend to adopt shared decision making (SDM) [4,5] to improve patient care through engagement. Similarly, new health care laws are promoting patient-centered care as a priority paradigm shift (eg, the Ontario's Patients First Act). As the health care delivery environment incorporates new constraints and develops new goals, clinicians have unique needs and require a rich set of competencies to practice medicine. As a complex sociotechnical system, using the cognitive work analysis (CWA) framework can be an effective approach to understand and describe the complexities of care in this challenging world.

Cognitive Work Analysis

CWA is a conceptual framework that facilitates the analysis of complex systems at various levels of detail. It can help assess how the environment impacts and shapes human-information interactions [6]. Work domain analysis (WDA) is the first step of CWA that focuses on ecology. It can provide valuable information about the structure of work, articulate abstract concepts such as professional values and culture, and describe the constraints that operate in the work domain. WDA can describe how structures, abstract values, and constraints affect the normal functions of a system [7]. There are many examples of using CWA in health care [1,8-14].

The abstraction hierarchy (AH) is a modeling tool that describes the results of a WDA [6]. The AH is intended to be a full depiction of the necessary constraints that need to be taken into consideration in order for the system to achieve its purpose, while describing the system's underlining ecology and limitations [15]. Using AHs can help bridge the psychology-culture-medicine gap in health care. These hierarchies can be used to develop representations of patient care that align with biomedical knowledge, support medical problem solving, and act as a frame of reference [16]. As a structured approach to WDA, the AH includes a layer to describe the system's functional purposes, abstract functions, generalized functions, physical functions, and physical forms. Lines are shown between each layer to show means-end or how-why relationships [15].

Work Domains, Patients, and Patient Care

Many AHs have been developed to describe patient health. Some of these AHs were developed through a WDA, whereas others were developed within the context of a fuller CWA exercise. Some of these abstractions treat patients as biomedical machines with physiological processes [16-20]. For example, some models represent the human body in its resting state during anesthesia [19], decompose the human body into systems and organs [10], or describe the cardiovascular system as an independent system [20]. The scope of these analyses is more biomedical in nature because they describe treatments and procedures, and are modeling biomedical treatments after the consultation phase. This scope makes sense within the confines of emergency or surgical care when patients are unconscious;

naturally patient values and personal wishes fall out of the scope of such an analysis. In these contexts, "aberrations in physiological and biological regulatory processes" are the "domain upon which clinicians work" [17].

In other cases, patients are conscious and therefore capable participants in their own health care. Ashoori and Burns [12] modeled the patient-as-an-actor approach effectively during a study of a birthing unit. The CWA showed rich coordinative points, shared artefacts and adjusting structures, and described the patient as an active partner that engaged in their own health. In particular, the AH modeled the patient as a physical function of prescription, assessment, and consulting. In another example, Rezai and Burns [13] modeled patient values, skills, support systems, and abilities in a home health care scenario with WDA and Control Task Analysis (ConTA). The scope did not include the patient within clinical practice. Regardless, both examples demonstrate that CWA is capable of characterizing patients as emotionally complex, social creatures, and that CWA can successfully describe patients as decision makers with rich sets of values and capabilities to support their own health care. Within CWA, WDA can describe many complex relationships that are both biomedical and patient-related.

Building a model of patient treatment is challenging, and it is further complicated by the nuances of effectively treating patients with the assistance of electronic medical records (EMRs). At present, no CWA models or AHs of patient treatment address this context and need.

Model Objective and Scope

The objectives for the AH was to capture the complexities, balances, and challenges regarding patient treatment from a clinician's perspective. Such a model could be specific to an individual physician, practice, or specialty. In an effort to offer a breadth of utility, the goal of this AH is to capture generic and common health care processes and priorities, without worrying about specific or unusual use cases. The goal is to develop a model that could represent all types of clinicians involved in providing and triaging care.

To represent current and modern approaches to patient treatment, the model must go beyond the laymen's and paternalistic impression of medicine as a purely biomedical process. Whereas physicians are experts in disease, patients are experts in their own experience of disease and in their preferences [3]. One of the challenges of patient care is incorporating the patient's values and preferences into decision making [5]. The model must articulate the challenges of treating patients in a modern world that is subject to contradictory sources of health information, conflicting personal values, and complex determinants of health. In this sense, the model needs to describe the biopsychosocial constraints and nuances of patient treatment in the Internet age.

Finally, the model must capture the impact and role of EMRs in delivering health care. The model needs to describe the complex processes associated with using EMR records and how they interact with clinical practice.

Intended Uses

As an insightful model of patient treatment, the AH should serve several purposes. The goal of developing this AH was to support many use cases, including the following.

Change Management

The AH should provide greater context when trying to plan for the implementation of new systems, new processes, and new workflows.

EMR Development

As patient treatment complexities evolve, so must EMRs. Providing a better context and understanding of patient treatment could offer valuable insights to EMR developers. Developing a current and modern model of patient treatment addresses a gap and could lead to the design of improved EMR systems.

Additional AHs

Clear value is seen in understanding health care as a complex system. An AH of patient treatment could provide a basis for additional analysis. For example, understanding patient treatment would be a precursor to understanding the management of health information and data.

Methods

Study Context

The study was conducted through collaborations with subject matter experts (SMEs) such as managers and clinicians in Ontario. The intent of the model was to capture patient treatment in a general way that could encompass different types of patient care situations. To capture a broad set of ideas and clinical processes, SMEs who worked at medium-sized hospitals within primary care clinics and within family health teams were interviewed. The concepts that were included in the model are reflections of a single-payer system in Canada and reflect a Canadian perspective on social determinants of health [21]. The scope of the study included the development of a model to represent all types of clinicians including, but not limited to, physicians, physiotherapists, nurse practitioners, dietitians, mental health workers, and pharmacists.

Information Gathering and Validation

The development of the AH took place over the span of 12 months. As an initial step, information for our WDA was collected by reviewing textbooks (such as pathophysiology textbooks [22] and health system textbooks [23]), best practice guidelines, professional standards [24,25] and literature [1,4,26-33]. Insightful information and anecdotes were also gathered during previous research [34].

After reviewing literature, we collaborated with 8 SMEs, iterated through various model concepts, re-interviewed SMEs to collect additional feedback and reworked the model as required. Our strategy was to link concepts in the WDA to comments from SMEs. In addition to gathering input from a large group of SMEs, a family physician volunteered to provide feedback after seeing several drafts. While practicing over the course of a week, this physician took notes about the AH and verified that all important concepts, processes, and decision-making tasks

he experienced throughout a week were generally included in the model. This helped confirm the insight we collected from the larger group of SMEs. There were 10 iterations and versions of the AH before the development of the final version.

Abstraction Hierarchy Development

The development of AHs is challenging because there are many ways to model abstract concepts and ideas. Practitioners need to engage and observe users and articulate thoughts and suggestions into the AH. Often, the literal suggestions and ideas from SMEs need to be abstracted into high level concepts and ideas. AHs are intended to be helpful, but not perfect, and managing the scope and level of detail of the modeling exercise is a challenge in itself.

The first phase of a WDA is to determine the system boundary. There is a balance to achieve in the analysis: a domain boundary that is too narrow will leave out connections and interactions that exist outside the boundary, whereas a broad boundary can distract the modeling effort as time is spent developing concepts that are not germane to the modeling objective [10]. As the operator of the system domain was the patient's clinician, the boundary was restricted to activities that were within the clinician's control during a patient's use of services, even if they were indirect. The patient and their attributes were included in the scope of the analysis. Patient flows and activities outside of an encounter with a clinician were excluded from the scope (eg, patient opting not to take medicines, choosing to perform exercises, adjusting diet, and consulting with family).

Workflows representing patient flows (see Figure 1) and information processes (see Figure 2) were developed with SMEs to describe the generalized activities of the clinic and its clinicians. As generalized workflows, not all components of the workflow are necessarily "activated" during each patient encounter but represent possible workflows during a visit. In the case of patient flows, most use cases within the clinic (involving a combination of triage, assessment, treatment, care transfer, and scheduling) were captured. In the case of information flows, most use cases involving the EMR (involving a combination of summarization, sharing, updating and interpretation) were also captured. These workflows were later translated into the 'generalized function" layer of the AH. Using our boundary definition, previous work regarding medical records [34], and discussions with SMEs, 5 goals were developed to describe the purpose of treatment. These formed the "functional purpose' layer of the AH. Whereas a purely biomedical treatment goal would be to "improve health," concepts such as patient education and public safety were included in the scope of patient treatment.

After describing goals and processes, a list of concepts that linked these layers was developed with help from SMEs. This included articulating abstract concepts such as values and balances, and showing how system goals were mediated to perform functions. These concepts were translated into the "abstract function" layer of the AH.

The physical functions layer of the AH represented concepts, objects, and actors that were needed to perform the processes. The physical form represented details and attributes of the

objects and actors that were relevant to the system processes. For example, the social status and severity of symptoms were

relevant attributes of the patient.

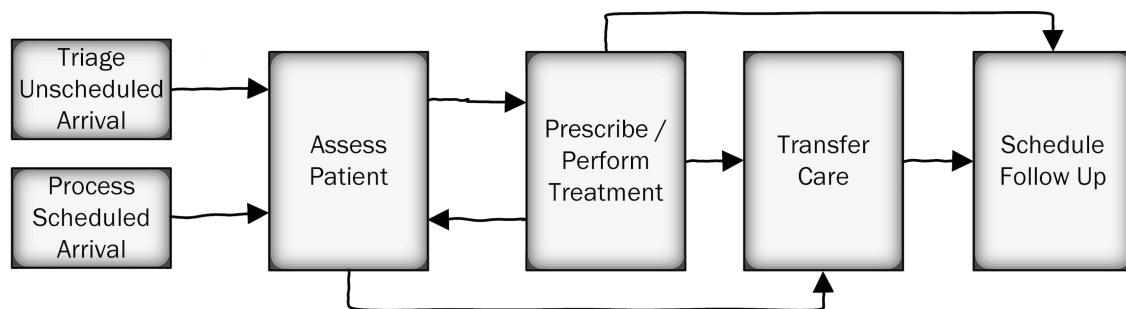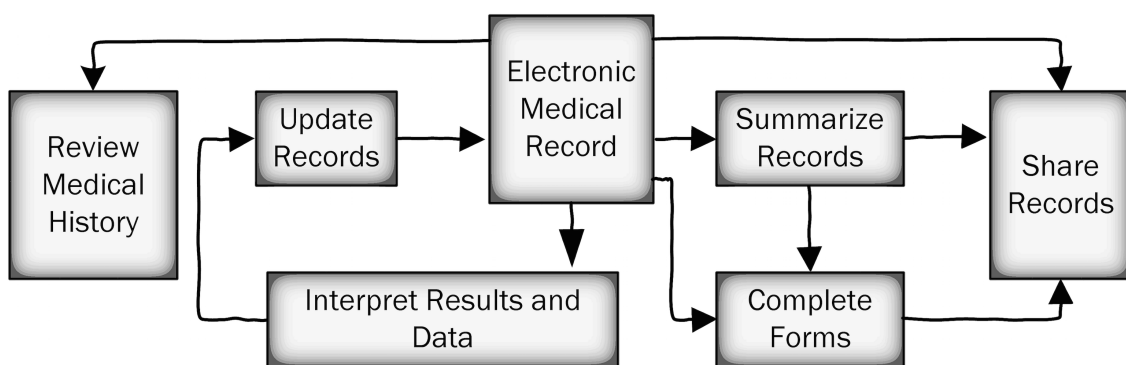**Figure 1.** General patient workflow functions.

Figure 2. General information workflow functions.

Results

The patient flows and information flows each were placed into separate views of the same AH (see Figures 3 and 4). Showing two views increased the readability of the hierarchy and allowed each type of process to be displayed separately. Other than the generalized functions and specifically noted omissions, all elements of the model are shown in each view.

Functional Purpose and Treatment Goals

Five functional purposes were identified in the AH. The treatment purposes (eg, goals) included concepts of patient education, financial compensation, health improvement, sustainable care, and public safety. These goals are linked to abstract functions which represent constraints to be respected in achieving each goal. In some situations, each goal is met during treatment. In some situations, one goal may take priority over the other. For example, a patient with a communicable disease may need to be quarantined to ensure public safety at the expense of their individual wellness and freedom. However, the goal of the modeled system generally is to achieve all goals simultaneously outside of fringe cases. The details underlying these concepts were developed in consultation with SMEs.

Patient Education

As part of treating patients, clinicians aim to educate patients. This includes providing information about health conditions,

treatments, and lifestyle. Educating patients is an important goal in their treatment since poor education or incorrect information can interfere with treatment and must be considered as a goal. For example, SMEs mentioned that some patients may not wish to be vaccinated based on individual patient beliefs about vaccines. In this context, the overall goal of treating a patient is a combination of education, improving their health, and ensuring public safety from communicable diseases.

As shown in the AH, during treatment, patient education is mediated by patient means and abilities (eg, patients who cannot afford physiotherapy might be educated about exercises instead of receiving a referral) and patient values (eg, not being willing to accept a certain treatment).

Financial Compensation

In Ontario, fee-for-service payments are provided by the Government, a third party insurance provider, or the patients themselves. In other situations, such as clinicians who are part of a FHT or physicians who work at a community health center, clinicians are salaried and employed by the Government to provide health care services and treat patients. Sometimes physicians are compensated through a combination of patient-capitation (eg, payment per patient per year), by the services provided and according to special bonuses for achieving specific care practices [23].

Figure 3. Abstraction Hierarchy 1.A, describing patient functions.
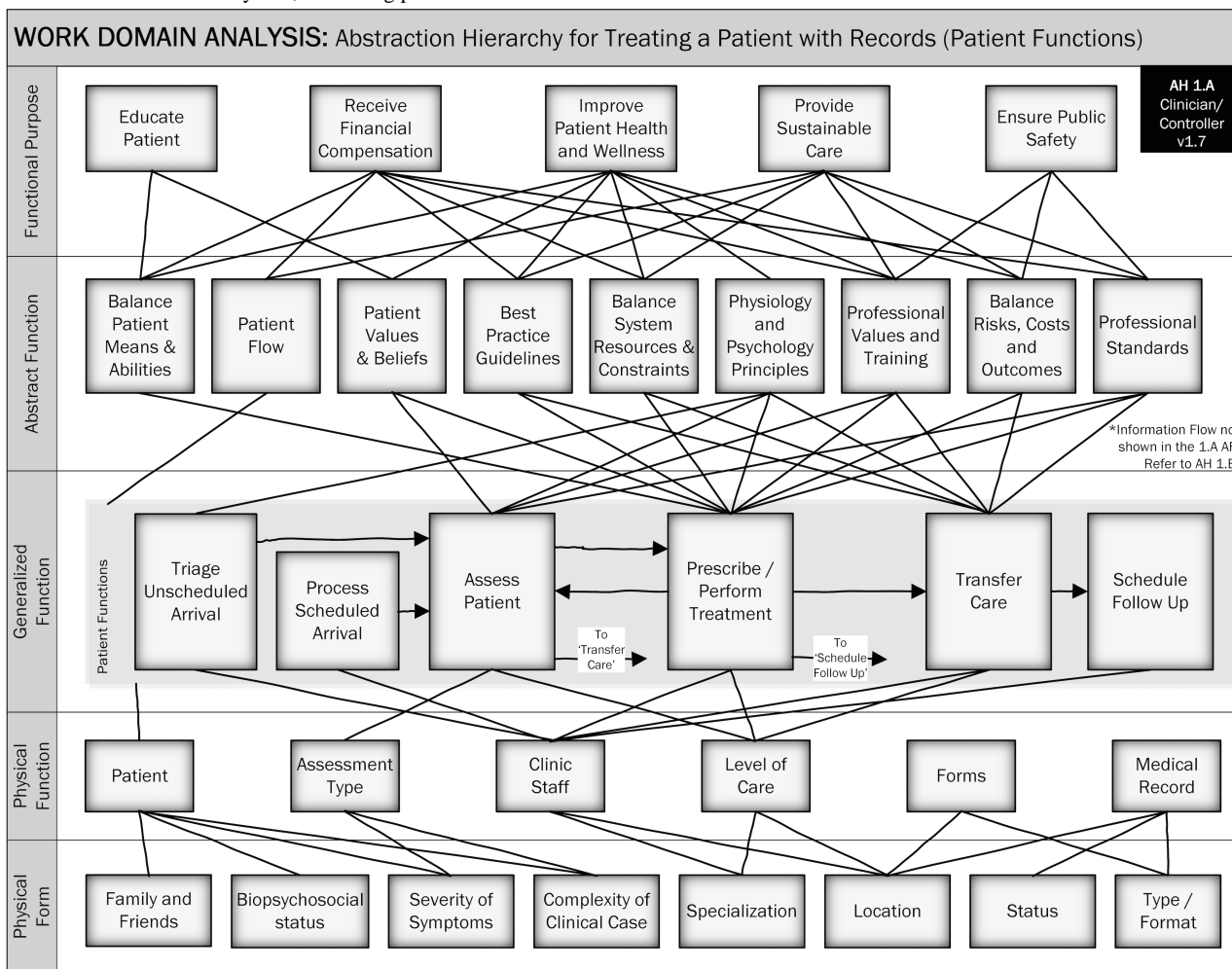
While treatment could be modeled altruistically, payment to clinicians impacts the treatment approach. As mentioned by SMEs, some doctors in the fee-for-service model adopt a "one visit, one problem" approach to maximize potential remuneration. Since this decision is influenced by financial remuneration and not driven by best practice or health outcomes, this concept is important to capture in the AH and show as a treatment goal that impacts clinical processes through abstract functions.

As shown in the AH, compensation is mediated by a patient's resources (eg, ability to pay uncovered costs and fees), best practice guidelines (eg, government bonuses for specific additional interventions, which are based on best practice guidelines), patient flow (eg, volume and theoretical maximum billable time), system resources (eg, the government budget), professional values and training (eg, what services can be performed and opting to select strategies favoring maximum remuneration), balancing risks versus benefits (eg, determining whether receiving compensation for the treatment is worth any potential risks or benefits to the patient), and professional standards (eg, what actions are permitted, ethical, and appropriate).

Figure 4. Abstraction Hierarchy 1.B, describing information functions.
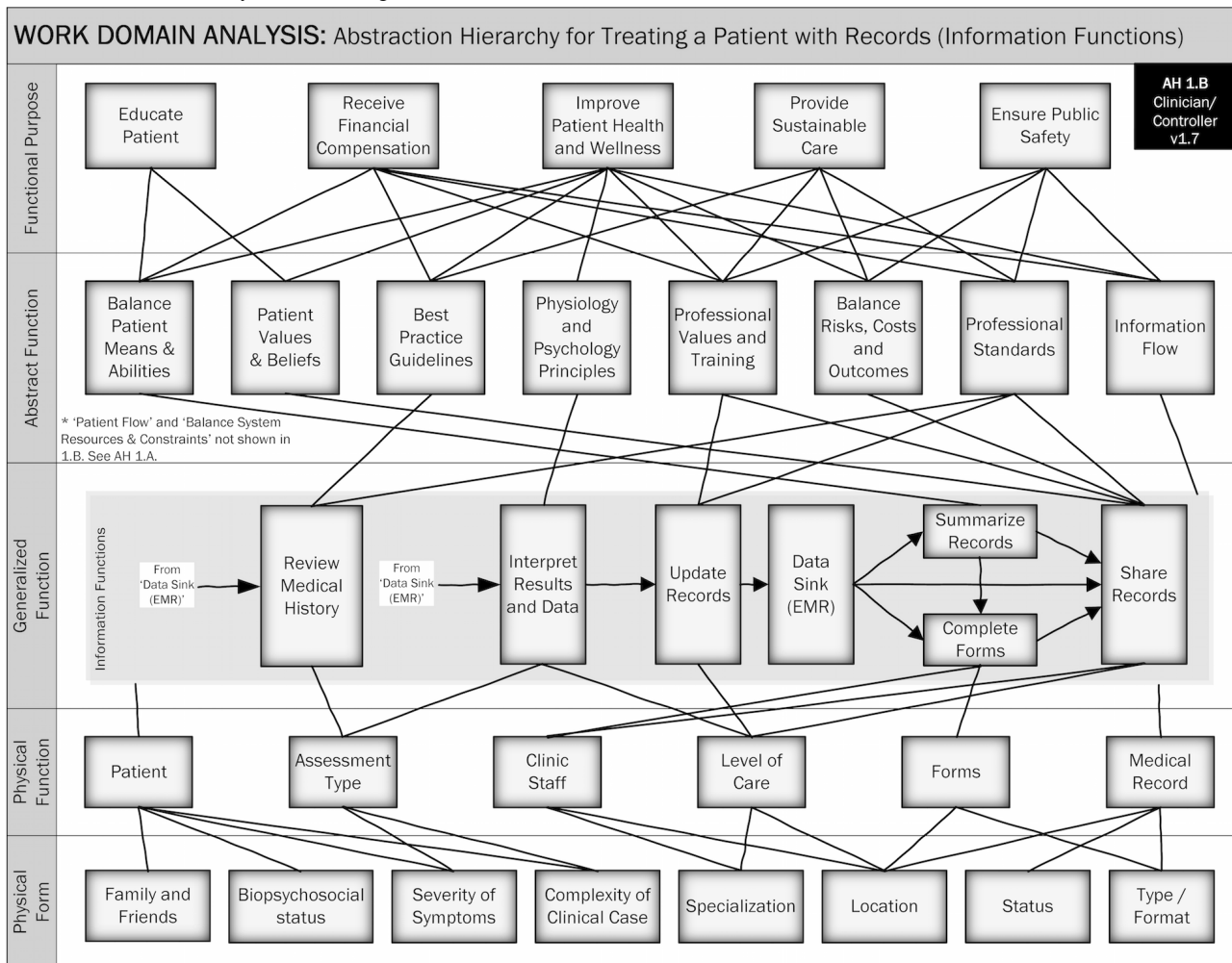
Patient Health and Wellness

An obvious goal of patient treatment is to improve patient health and wellness. Patients who are not looking to improve their health or wellbeing (directly or indirectly) will not seek treatment. SMEs mentioned that sometimes patients seek assistance for social reasons and not for strictly medical reasons; the biopsychosocial nature of care accords services to patients who are isolated socially or are experiencing significant life challenges such as job loss or homelessness.

Improving patient health is mediated by patient resources (eg, financial ability to pay clinicians when required, afford drugs, or have social supports to support care), the ability to actually see the patient (eg, patient flow), patient values and beliefs (eg, willingness to accept recommendations), best practice guidelines, health system constraints (eg, scheduling constraints for referrals), physiology and psychology principles, professional values and training (eg, what treatment can be performed), and balancing the costs and benefits of a treatment plan.

Sustainable Care

In Ontario, clinicians need to select appropriate tests and treatments that support a sustainable health care system. Clinicians also need to avoid unnecessary procedures that are of limited clinical value. For example, SMEs described patients

who request "fad" bloodwork, such as a vitamin test, without a clinical reason. Unlike the fully privatized health care systems, clinicians need to make treatment choices that respect the public purse and support a sustainable health care system by ensuring diagnostics are medically necessary. This type of conflict resolution is challenging [3] and is important to include as a constraint in treatment. Patients are not always able to receive the tests and treatments that they want because of limited health resources.

Sustainable care is moderated by best practice guidelines, patient flow (eg, volume and capacity), system constraints (eg, budgetary limits), professional values (eg, caring about the public purse), and professional standards of care (eg, guidelines).

Public Safety

Clinicians must place individual patient treatment into the context of public safety. Patients who are a danger to others, have communicable diseases, or could endanger their community in other ways (eg, poor eyesight in a senior citizen who drives) require interventions that are not necessarily in the patient's best interest. For example, SMEs discussed that taking a senior citizen's driver's license may protect public safety, but may also result in social isolation and poor medical outcomes for the individual patient. Public safety is an important element to model in health care. Ensuring public safety is moderated by professional values and training, the balancing of risks versus

outcomes, and professional standards. This also has an impact on many information flows, such as mandatory reporting requirements [25].

Abstract Functions and Treatment Constraints

Abstract functions represent constraints that need to be respected during clinical processes (eg, generalized functions) to achieve the system's treatment goals. These concepts were created in consultation with SMEs.

Patient Means and Abilities

Patient means (eg, financial and social) and abilities (eg, mental competency and self-care) need to be balanced and considered in their treatment. For example, SMEs mentioned that a physician will need to take a patient's ability to pay for drugs into consideration when issuing a prescription or recommending physiotherapy. Likewise, an elderly patient's access to peer groups and family would impact their ability to live at home or require homecare. This constraint influences treatment functions and plays a role in how medical records are processed (eg, looking up patient details and social circumstances) and summarized for sharing (eg, summarizing data for a referral).

Patient Values and Beliefs

Patients have varying worldviews and values that need to be understood and balanced during treatment. For example, SMEs mentioned that some religions would object to blood transfusions, some cultures will not tolerate birth control, some peer groups adhere to false information about vaccines, and some female patients may be uncomfortable with a male doctor performing certain medical procedures. This abstract concept plays a role in patient assessment and treatment procedures. Patient beliefs also may play a role in how information is shared with other providers based on patient perspective about privacy rules and regulations [35].

Best Practice Guidelines

Best Practice Guidelines suggest health screenings, preventative tests, and appropriate actions for patients with specific characteristics (eg, age and diagnosis). SMEs referred to guidelines that recommend specific treatment functions (eg, recommending a test), or specify that a patient be transferred to another level of care (eg, sending a patient to a stroke unit from the emergency room). Best practice guidelines have a significant impact on the review of medical history. The constraints on treatment that are associated with best practice guidelines are represented through this abstract function, but guideline documents were not included in the Physical Function of the AH in order to manage project scope.

Patient Flows

Patient flow is a representation of patients entering, moving through, and exiting the treatment process. Patient flow represents limits related to patient volume and throughput. Patient volume is an important constraint on the system, as the flow of the patient through the clinic and the health care system must be taken into consideration and is important for all generalized functions. Without capacity, treatment is not possible.

System Resources and Constraints

As a single-payer, publicly-funded health care system, health care dollars and resources in Ontario must be taken into consideration during treatment. Not all drugs or treatments are available, and some procedures have significant waiting lists due to insufficient system resources (eg, number of beds and number of surgeons). This abstract function describes a constraint in selecting treatment options for patients while achieving treatment goals.

Physiology and Psychology Principles

Human anatomy, physiology, and pathophysiology principles are important constraints to be considered during treatment. When patients are suffering from situations that are not strictly biomedical in nature (eg, social distress, isolation, and stress), psychological principles need to be taken into account. This abstract function helps describe constraints during triage, patient assessment, treatment, and transfer of care. From an information perspective, these principles are important when clinicians interpret results and data and update the medical record.

Professional Values and Training

Clinicians are not uniform in their decisions. As with patients, clinicians have worldviews, professional values, and priorities. For example, physicians may choose to see more patients in a day (eg, volume) and provide care to a large number of patients, or may choose to see fewer patients for full assessments to provide higher-quality care. Worldviews also may impact ethical decisions, such as valuing the public purse. A professional's scope of practice, practice style, and set of priorities is based on training and personality characteristics. This abstract value system plays a role in assessing patients, performing treatments, and deciding when it is appropriate to transfer care. It also plays a role in a clinician's interest in creating high-quality documentation that is above minimum standards. Patient and documentation processes are constrained by professional values and training.

Risks, Costs, and Outcomes

Whenever treatment is provided to a patient, there are risks, possible outcomes, and costs. If a clinician determines that the risk is high and the probability of a positive outcome is low, another treatment option may be selected. Similarly, a clinician may balance the health care costs of surgery for an arthritic patient versus a prescription, and make a treatment determination that is based on total costs, recovery periods, and quality of life. Risk balancing takes place in consultation with patients who describe their preferences and capabilities. In situations where patients pose a risk to public safety, a clinician must make an appropriate determination between risks and potential negative outcomes to the patient and public.

This abstract concept plays a role in assessments and treatments. Risks also are evaluated when choosing to transfer care. Information functions assist in determining risk.

Professional Standards

All clinicians are governed by professional associations and colleges. For example, physicians in Ontario are governed by the College of Physicians and Surgeons of Ontario (CPSO).

The CPSO establishes specific conditions and training requirements for all physicians in Ontario. They have policies on medical records [24] and provide guidelines regarding reporting information to third parties [25]. The concept of professional standards constrains patient assessment; prescription and treatment; transfer of care; and maintaining, reviewing, updating, and sharing medical records. To manage the scope of the domain analysis, the standard documents were not included in the scope of the model and are not included in the physical function of the AH as well.

Information Flow

Information flow is a representation of information that enters the system and is used and stored in an EMR. Information flow is important in managing care and impacts decision making and timing. If information is not available when needed, it will affect many aspects of treatment. As an abstract concept, information flow is important through all information functions in the generalized function layer of the model. Information flow impacts financial compensation (eg, ability to bill and document encounters), patient health (eg, improved care quality through information), and public safety (eg, reporting mandatory information to appropriate authorities).

Generalized Treatment Processes

The generalized functions represent the general processes in health care, as described in Figures 1 and 2. Each generalized function was linked to abstract function constraints that had to be respected to achieve the system goals and to the appropriate physical components of the processes.

Physical Treatment Elements and Attributes

The physical functions layer of the AH represents concepts, objects, and actors that were needed to perform the processes modeled in the generalized functions. The physical form represents details and attributes of the objects and actors that are relevant to the system processes. Keeping in mind that the clinician is the system controller (and is not represented in the physical form), the relevant actors and objects in the AH include the patient, type of assessment, clinic staff, level of care, forms, and medical records.

Patient

The patient is obviously an important actor associated with all generalized functions. The patient's attributes that are relevant in treatment include patient's family and friends (eg, presence of social supports to facilitate treatment), the patient's biopsychosocial status (eg, social circumstances such as employment and stressors), the severity of the patient's symptoms or problems, and the complexity of the clinical case. The patient and their most important attributes are included in the model as they affect the entire treatment ecosystem.

Assessment Type

Different types of assessments are used. A physical exam would be detailed, whereas a 10-minute assessment would be problem-oriented. Other assessments may play the role of triage and refer a patient directly to the hospital (from primary care) or admit a patient (from the emergency room). Severity and complexity play roles in the type of assessment that will be used with the patient.

Clinic Staff

The clinical staff supports many processes. Depending on the specializations and location of the care delivery, resources may be greater or fewer. Larger clinics with multiple clinicians will have a larger support staff with specific roles and responsibilities. Smaller clinics with an individual doctor may only have a single support resource who plays a generalist role. The type of staff and their abilities varies according to location of the practice.

Forms

Many forms are employed to support the information processes during treatment. The location of the forms and their type (paper or electronic) are relevant attributes to the information flows and processes described in Figure 4.

Medical Record

Medical records support all the information flow processes. The location of the status (eg, availability), record type (eg, paper or electronic), and location of the system are relevant attributes.

Discussion

Comparisons With Other Models

Our WDA and AH is interesting because it describes patient treatment in the context of a complex biopsychosocial ecosystem (Figure 3) and patient treatment in an electronic health record context (Figure 4). Each view shows how the rich ecosystem system influences patient treatment and records management.

The view showing patient treatment flows is different compared with existing models in the literature; as an AH, the model can articulate complex ideas within the treatment ecology and is a formative reference model. No existing AH describes how treatment takes place with clinician-controllers and modern, Internet-enabled patients. As a macro-level view of patient treatment, our model is similar to a model of medication administration in home care, which facilitated an in-depth understanding of medication safety problems and analyzed medication errors [14].

The view showing records management flow is also unique in the literature. To our knowledge, there are no WDA in the literature that describe records management with a complex sociotechnical perspective. The results of this view could be very interesting to health information management professionals who are concerned with data quality, and to EMR developers trying to understand the work context of their users.

Design Implications

WDAs and AHs are consumed during design by using the ecological interface design (EID) approach [11,36]. The AH can support system designers by properly articulating the ecosystem and clinician decision making in context. The model supports system thinking and can help articulate how changes may impact the ecosystem through linear and ripple effects [37]. Based on our work domain analysis, the decision support

requirements for health care are becoming increasingly complex. The challenge for system engineers will be to determine how electronic systems could support, and not hinder, the treatment process. In addition, the analysis is a reminder that technology-centric solutions and implementations that do not take the larger health care ecology into consideration during the entire treatment process will likely fail to thrive. Creating a product that is compatible with the nuances that are described in the AH would be a competitive advantage.

Limitations

Our AH is intended to be helpful, but it is not perfect. The model is limited to a clinician's perspective and aims to provide a high-level overview of treatment. Obvious opportunities are present for a deeper analysis of the work domain in special areas. For example, complex nuances to medication, prescription, and administration have been simplified and abstracted in our model as "Prescribe and Perform Treatment." It would be possible to do a more detailed WDA on this specific issue. For example, Lim et al developed a detailed analysis of medication administration in home care [14], and this could be performed in primary care. In this sense, our work is incomplete. In this same sense, the amount of modeling to be performed is infinite, and our hierarchy is a contextual overview that could serve as a blueprint for additional work.

One potential limitation of our work was the availability of SMEs and volunteers to validate the model in clinical practice. Though we interviewed several SMEs with different backgrounds and roles in the health care system, we did not adopt a formal grounded theory approach to our information gathering. Though the use of techniques such as grounded theory may have improved and formalized our qualitative data collection, formalized approaches are not standard practice for conducting CWAs and building AHs. In this sense, this limitation is not uncommon in the literature. Based on the concept of our WDA being a helpful, but not perfect, model, this is not a significant or unusual limitation.

Future Work

The current AH describes patient treatment and takes a biopsychosocial perspective over a biomedical one. Taking a patient-centered perspective further, the AH could more formally incorporate aspects of SDM thinking. This would be compatible with the current work, as general qualities of treatment with SDM include deliberation with patients, an individualized approach, information exchange, involvement of multiple parties, finding middle ground, espousing mutual respect, developing patient education, encouraging patient participation,

and following a process with stages [38]. Adopting SDM is a desirable approach to care; improved patient involvement in decision making can result in improved health outcomes, provide a better ethical framework for clinicians to deliver appropriate care and can improve the health system's efficiency [39]. However, it is important to note that SDM is not always easy for clinicians to implement, and barriers exist to its use in patient care: in addition to requiring new time management strategies, it also might not apply to the patient's characteristics or their clinical situation [40]. Thus, a goal would be to capture SDM and non SDM procedures, values, and concepts.

It would be interesting to compare SDM and non SDM perspectives with patient care. Inviting SMEs to comment and develop a similar AH could lead to an interesting comparison of work, as the current work does include an SDM expert in its development. Such a comparison could help to describe the perceptions and realities of what shared decision making is and how it is (or is not) incorporated in routine clinical care. The idea of drawing comparisons has previously been discussed [41].

Another interesting perspective about SDM is that it is a shared process between at least two actors; colloquially, SDM has been described as a dance between providers and patients [42]. Thus, developing a full perspective of SDM will require at least one other AH describing patients as a controller. Work by Rezai and Burns [13] could provide a good starting point for developing an AH from a patient perspective. Team perspectives to patient care modeled with SOCA [12] also could be helpful for understanding SDM in care teams comprised of family physicians, nurse practitioners, pharmacists, medical specialists, caregivers, and patients [40,43]. Generally, further work on this AH and line of inquiry could lead to interesting contributions to SDM research.

Conclusions

Our AH links treatment goals, decision-making constraints, and task workflows. The model articulates the immense task complexity and nuanced user needs in today's patient treatment by describing the system's goal, abstract functions, workflows, and physical characteristics. The model can be used by system developers to improve systems by better supporting complex decision making in context. The model could support the development of EMRs that incorporate the cognitive processes associated with patient treatment by transferring the knowledge from our WDA into design concepts through EID. Currently, the hierarchy is a contextual overview of the treatment domain from a clinician's perspective and additional models could further articulate depth and details in subdomains of the system.

Conflicts of Interest

None declared.

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Abbreviations

CWA: cognitive work analysis
ConTA: control task analysis
CPSO: College of Physicians and Surgeons of Ontario
EID: ecological interface design EMR: electronic medical record
SME: subject matter expert
WDA: work domain analysis
SDM: shared decision making

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Original Paper

Perceptions of Patients With Chronic Obstructive Pulmonary Disease and Their Physiotherapists Regarding the Use of an eHealth Intervention

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Abstract

Background: If eHealth interventions are not used (properly), their potential benefits cannot be fulfilled. User perceptions of eHealth are an important determinant of its successful implementation. This study examined how patients with chronic obstructive pulmonary disease (COPD) and their physiotherapists (PHTs) value an eHealth self-management intervention following a period of use.

Objective: The study aimed to evaluate the perceptions of COPD patients and their PHTs as eHealth users.

Methods: In this study, an eHealth self-management intervention (website and mobile phone app) aimed at stimulating physical activity (PA) in COPD patients was evaluated by its users (patients and PHTs). As participants in a randomized controlled trial (RCT), they were asked how they valued the eHealth intervention after 6 months' use. Interview requests were made to 33 PHTs from 26 participating practices, and a questionnaire was sent to 76 patients. The questionnaire was analyzed in Excel (Microsoft). The interviews with the PHTs and text messages (short message service, SMS) sent between patients and PHTs were transcribed and independently coded in MAXQDA 10 for Windows (VERBI GmbH).

Results: A total of 60 patients with COPD filled out the questionnaire, and 24 PHTs were interviewed. The mobile phone app was used 89.0% (160.2/180 days) (standard deviation [SD] 18.5) of the time by patients; 53% (13/24) of PHTs reported low or no use. Patients scored the ease of use of the app 5.09 (SD 1.14) (on a 7-point scale). They found the presentation of the PA information in the app to be clear, insightful, and stimulating. All PHTs judged the website as explicit and user-friendly but had trouble devising a new PA goal for their patients. Patients mostly sent informative, neutral messages concerning the PA goal, and PHTs sent mostly motivating, positive messages concerning the PA goal. Messages were not perceived as supportive in reaching the PA goal according to the patients. Perceived usefulness of the intervention for the PHTs was the objective measurement of PA, the ability to see PA patterns over time, and the ability to use the intervention as a tool to give their patients insight into their PA. For patients, it was that the intervention supported them in increasing their PA and that it made them feel fitter. Barriers to use of the intervention according to the PHTs were time constraints and financial reasons. Seventy-nine percent (19/24) of the PHTs and 58% (35/60) of the patients mentioned they would be interested in using the intervention in the future.

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Conclusions: PHTs and COPD patients had positive feelings regarding the functionality and potential of the eHealth self-management intervention. This paper addresses a number of topics that may aid in the successful development and implementation of these types of eHealth interventions in the future.

Introduction

eHealth is a relatively new field, and its emergence is causing a shift in health care. Whereas health data have historically been in the hands of health care professionals (HCPs), eHealth apps now provide this information directly to the patient [1]. Furthermore, data collection, insights into the data, and the person that subsequently takes action shifts from the HCP to the patient when using self-management apps.

eHealth has the potential to address the issue of increasing numbers of older adults [2] with relatively fewer HCPs available to provide the required level of service [3]. Moreover, eHealth may also address the increasing number of persons living with chronic conditions such as chronic obstructive pulmonary disease (COPD) [4], who are in need of long-term health care.

In addition to its potential benefits, there are limitations of eHealth that must be mentioned. The limited evidence base is a challenge, as are concerns regarding the privacy of data and the use of eHealth in daily practice. Also, the question of how to engage older adults in eHealth interventions remains an issue [5]. If the interventions are not used (properly), their potential benefits cannot be fulfilled. Furthermore, understanding disease-specific factors to determine how various populations may benefit from eHealth seems important in increasing their use and, subsequently, their efficacy [6]. For example, persons with COPD are generally older adults and are more prone to have a low socioeconomic status [7]. This could negatively impact the (effective) usage of eHealth self-management interventions in this patient group.

User perceptions are an important determinant of the successful use of eHealth. According to the Unified Theory of Acceptance and Use of Technology (UTAUT) model, there are four main constructs that influence the intention to use technology: performance expectancy, effort expectancy, social influence, and facilitating conditions. Additionally, gender, age, voluntary nature of use, and experience with the technology moderate the relationship between the four main constructs and the intention to use [8]. According to the extended expectation-confirmation model in the information technology (IT) domain (extended expectation-confirmation model [ECM]-IT), important predictors of the continued use of technology are perceived usefulness and ease of use, confirmation of expectations, and satisfaction [9]. Continued use of eHealth technologies is especially important when targeting patients with chronic conditions such as COPD. Most eHealth projects begin with little insight regarding user needs and perceptions, which can be an important barrier to implementation [10].

We previously developed an eHealth self-management intervention with the aim to improve or maintain physical activity (PA) in patients with COPD [11]. It comprises a mobile phone app for the COPD patients and a website for their physiotherapists (PHTs). The intervention was tested for efficacy in a randomized controlled trial (RCT) [12] that revealed that the eHealth intervention did not have an effect on PA in this patient group. Based on these unexpected results, the question as to why it was ineffective was raised. This study examined how the users (patients and PHTs) valued the eHealth intervention following a 6-month period of use. The results may help in the future development and successful implementation of similar eHealth self-management interventions.

Methods

Study Design

Participants

In this study, patients with COPD and their PHTs were asked to evaluate an eHealth self-management intervention. The PHTs worked in primary care physiotherapy practices in the Netherlands and had expertise in treating people with COPD. Patients were diagnosed with COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage 2 or 3 (forced expiratory volume in 1 s (FEV1) 30 to 80%, FEV1/forced vital capacity (FVC) <70% after bronchodilatation), aged ≥40 years, had completed a pulmonary rehabilitation program of 3 months, and lived independently. PHTs and patients were participants of a RCT [12] and used the intervention for 6 months.

eHealth Intervention

The goal of the eHealth self-management intervention is to increase or maintain PA in daily life using step-count goals set by the PHT for each individual COPD patient. The intervention consists of two components: (1) a mobile phone app for patients with COPD for the self-management of PA and (2) a website for PHTs for remote monitoring of their patients.

1. The app (Figure 1) logged and visualized PA in real time in quantitative (steps taken) and qualitative (progress bar) forms as measured by an accelerometer embedded in the mobile phone. Patients were encouraged to reach their personalized PA goal by automatically generated encouraging messages and an emoticon. The automated messages and emoticon in the app were programmed to correspond with the current PA status toward reaching their daily PA goal. The app icon on the home screen indicated current PA status with traffic light colors and an emoticon.

2. PHTs could monitor their patients via the (secure) website (Figure 2) that showed an overview of the PA data from all

participants from their practice and a more detailed view of individual patients. The PHT was able to adjust each patient's PA goal and send group or individual text messages to persuade patients to be physically active and to stimulate them to attain their PA goal [11]. A daily PA goal consisted of the number of steps to be reached, amount of steps per minute that would

classify it as an intensive minute of PA, and the number of intensive minutes to be reached. Text messages were synchronized with the mobile phones via an Internet subscription, as were the PA data from the patients to the website of the PHT.

Figure 1. Application. The bar on the left side combines amount and intensity of steps. The physical activity (PA) goal is met when the horizontal stripe (representation of current PA status) is kept in the rising rectangle at all times until the green area is reached. Absolute number of steps and automated encouraging messages linked to current PA progress are also shown.

Methodologies

Participants of the RCT were enrolled in the study for 12 months (from May 2012 to October 2014). This included 6 months of using the intervention and a follow-up measurement at 12 months. After 12 months, interviews were conducted with the PHTs (relating to the total intervention, website, and app), and the patients with COPD received a questionnaire (related to the app). Furthermore, the text messages that were sent during the trial via the website (PHTs) and the mobile phone app (patients) were analyzed.

Interviews were chosen as a method for the PHTs because this group showed low use with the intervention, and it was expected that interviews were the best opportunity to find out the reasons why. The patients were sent a questionnaire to minimize strain on this group, for practical reasons (the group was much larger than the PHTs), and to create a low threshold to participate in this additional study.

Figure 3 provides an overview of the methodologies used in this study.

Physiotherapist (PHT) Interviews

PHTs that treated patients who were included in the intervention group of the RCT were invited for a semistructured interview.

The interview structure was based on the rational choice theory [13] and the theory of planned behavior [14]. The first theory states that individuals make choices with the objective of attaining the maximum achievable for themselves or of realizing a certain goal. The second theory accounts for the influence of circumstances and personal and social factors on choices. Interview questions can be found in Multimedia Appendix 1.

The interviews were transcribed and semi open coded by the second author and two research assistants. Based on the interview questions, a basic code list was made. The basic code list consisted of items that were addressed during the interviews such as the app, the website, and the text messages. With the basic code list, the second author and one of the research assistants open coded the interviews until there was a saturation of codes. Open coding was done to ensure that all topics discussed in the semistructured interviews were properly analyzed. The resulting final code list was discussed with the first author. With this final code list each interview was coded twice (by different coders) with the use of MAXQDA 10 for Windows (VERBI GmbH) software package. Differences were discussed between the coders and the first author, after which final decisions were made. The final code list can be found in Multimedia Appendix 2.

Figure 2. Website for the physiotherapist in Dutch. Above: anonymized overview of the physical activity (PA) goal attainment status of all patients connected to the physiotherapist. Below: detailed PA information of a single subject. The graph on the left shows the PA with the red line and the set PA goal in a blue line. On the upper right scores on PA intensity are shown and on the lower right physiotherapists can sent patients text messages and see an overview of sent and received messages with the current patient.
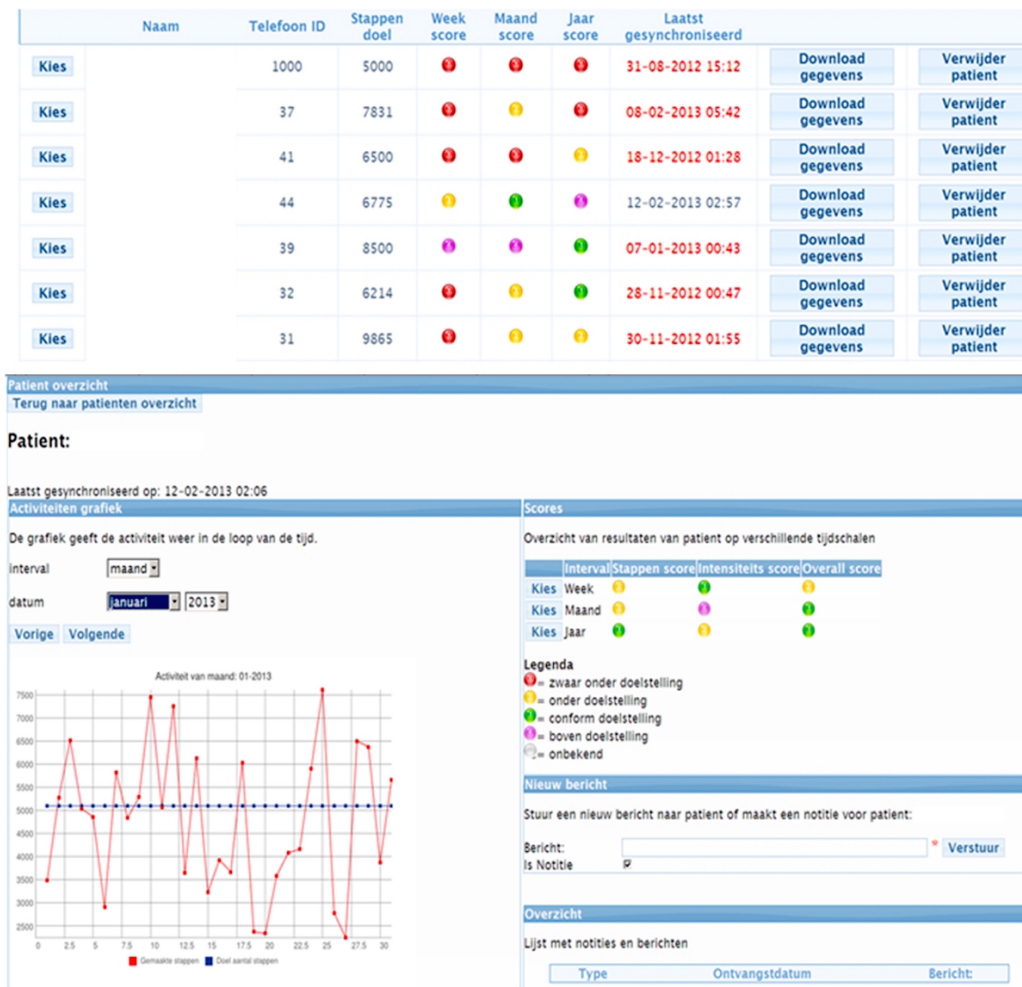
Patient Questionnaire

After completion of the RCT, questionnaires were sent by postal mail to patients with COPD who participated in the intervention group. A week later, one of the researchers discussed all of the questions with the patients during a phone appointment to ensure that they were properly understood. The questionnaire was composed of three existing questionnaires: the Usefulness, Satisfaction, and Ease of Use (USE) questionnaire on usability [15], which results in total scores for the domains of usability, ease of use, ease of learning, and contentment; the Florida State University (FSU) mobile device feedback preferences scale; and the FSU physiological monitoring privacy scale (inspired by Beach et al [16] and Kwazney et al [17]). Eight out of 38 questions from the USE questionnaire, 15 from the FSU feedback scale, and 14 from the FSU privacy scale were slightly adjusted to be specifically directed toward the intervention at hand. We added 6 questions regarding circumstances influencing the ability to reach the PA goal and whether patients would like to continue to use the intervention (questions 68-73). The questionnaire can be found in Multimedia Appendix 3. The results of the USE questionnaire were summarized per its instructions [15]. For the other results, averages and standard deviations (SDs) were computed in Excel (Microsoft). For the 8-point scales (0-7), a score of 3.5 or higher was seen as satisfactory, and for the 7-point scales (1-7), a score of 4 or higher was seen as satisfactory.

Figure 3. Overview of the methodologies used.
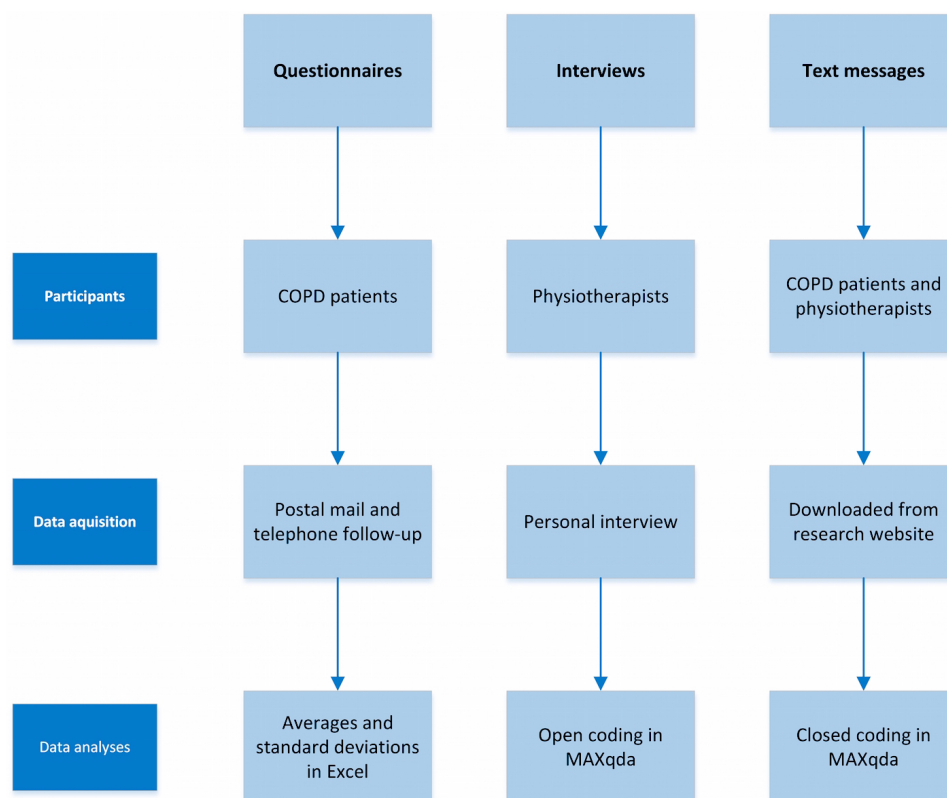
Text Messages and Use of the Intervention

The frequency of text messages sent between the PHTs and the COPD patients was recorded. Content was analyzed by coding similar to the interviews. However, three final code lists were established in advance by the second author after a read through of the messages and discussion with the third author; one for tone (positive, negative, and neutral), type (motivating, informative, fun or social, and question), and topic (PA goal, mobile phone or app, health, study related, and other). Tone was chosen to give insight into the ways in which patients were motivated by their PHTs to reach their PA goal. The second author and a colleague independently coded the messages, after which differences were discussed with the third author, and final decisions were made.

Adherence to the intervention was measured as the percentage of days that the intervention was used and as the percentage of days that the PA goal was attained.

Ethics

According to the Central Committee on Research Involving Human Subjects, interviews or questionnaires do not require ethics approval unless the questions are very *detailed*, *burdensome*, or *intimate* [18].

Table 1. Demographics of the chronic obstructive pulmonary disease (COPD) patients (N=60).

Outcome		Mean (SD) or number
Age in years, mean (SD)		62 (8)
Gender	Female	25
	Male	35
Body mass index (kg/m2), mean (SD)		27 (5)
Forced expiratory volume in 1 second (liters), mean (SD)		1.71 (0.60) (59 [SD 20]% predicted)
Forced vital capacity (liters), mean (SD)		3.61 (0.95) (99 [SD 19]% predicted)
6-minute walking distance (meters), mean (SD)		486 (84) (83 [SD 15]% predicted)
Average steps/day (weekday), mean (SD)		5980 (3035)

Results

Demographics

PHTs from 26 physiotherapy practices (with patients in the intervention group during the RCT) were invited for the interviews. A total of 76 COPD patients (that were randomized into the intervention group) were invited to fill out the questionnaire (Figure 4). The questionnaire for the patients did not contain missing values.

The average age of the participating PHTs was 44 years (SD 11). In total, 16 females and 8 males were interviewed. Demographics of the participating COPD patients and their baseline measurements during the RCT [12] are shown in Table 1.

The results are presented in five segments: the use of the intervention, the app, the website, text messages, and the results of the eHealth intervention in general. Multimedia Appendix 4 provides more detailed results of the questionnaire for the patients with COPD regarding use, privacy, feedback preferences, and personal circumstances. Below, the most important findings are described. At the end of the results, the key findings are summarized in Table 6.

Use

Patients with COPD used the eHealth self-management app on 89.0% (160.2/180) (SD 18.5) of the days that it was in their

possession (6-month period). They attained their personal PA goals on 33.8% (61/180) (SD 16) of these days [19]. The reported use of the website by PHTs varied from 5-60 min per session. Nine practices used it every week, 3 used it every other week, 4 used it mostly at the start of the RCT, and 3 did not use it at all. Ten practices mentioned having spent barely any time on the website. Three PHTs scheduled time in their agenda to use the website. PHTs mentioned that patients' and their own motivation to use the intervention diminished over time.

Application

Patients considered the app to be fairly easy to learn and use (Table 2). Training on the use of the app was not reported as highly necessary. The presentation of the PA information in the app was considered to be clear, insightful, and stimulating. Desired options included the possibility to measure cycling, swimming, and distance walked.

Patients liked the fact that PA was presented in steps, thought the bar and graph provided extra insight into their PA status, and that the emoticon and written advice were stimulating. The widget on the home screen clearly stated current PA status, and they thought it was pleasant to have various choices of emoticons. Patients think their PA information should be visible to them and not only to their PHT.

Health status, energy level, personal circumstances, and timeconstraints did not negatively influence patient ability to reach the PA goal (Multimedia Appendix 4).

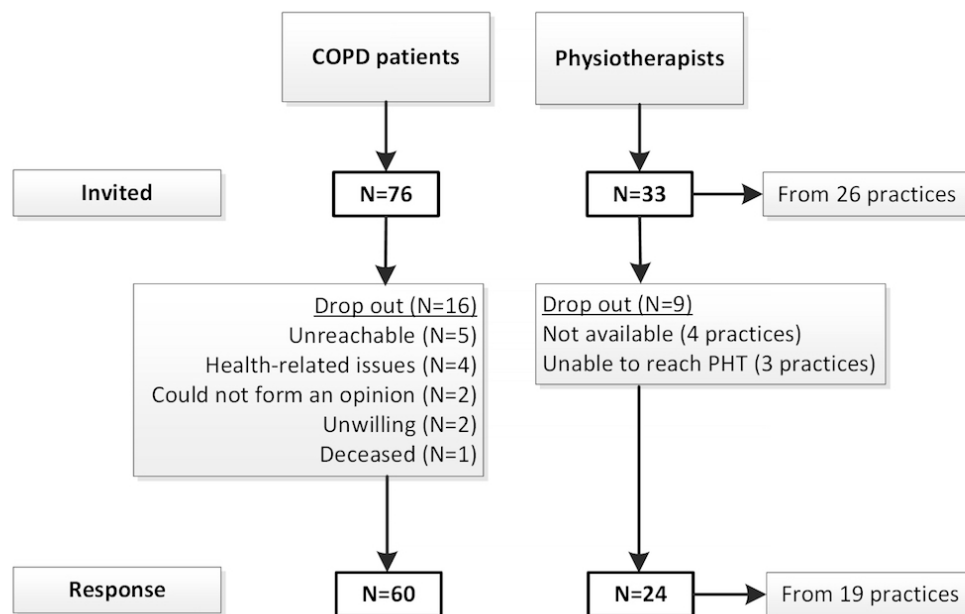**Figure 4.** Consort flowsheet participants.

Table 2. Application: Usefulness, Satisfaction, and Ease of use (USE) questionnaire scores (mean [SD]). Scores range from 0-7 (0: totally disagree and 7: totally agree).

Outcome	Mean (SD)
Ease of learning	5.55 (1.46)
Ease of use	5.09 (1.14)
Contentment	5.06 (1.54)
Usability	4.97 (1.32)

Table 3. Feedback on website by physiotherapists.

Remark	Number of practices
There should be a mobile version of the website to use on your mobile phone	3
Integrate into standard patient software	3
Patients should receive message notifications	2
Show intensity scores also in patient overview	2
Remove year scores (not relevant)	2
Meaning of scores not always clear (colors)	2
Add Borg score (rating of perceived exertion)	1
Graphs were difficult to read	1
Show week scores in patient overview	1
Show medication use and other types of exercise on the website	1
"I don't trust the intensity scores"	1

PHTs mentioned that the app was explicit and user-friendly for their patients. Six PHTs mentioned that some of their patients had trouble sending text messages as a result of the small keyboard or overlooked the possibility. Nine PHTs mentioned that there were differences among the patients with regards to digital skill level. Personal instruction on the use of the intervention was deemed important, especially for older users. PA status was often viewed by patients and was regarded as stimulating. PHTs suggested that patients should have the option to indicate if they were having a bad day and, subsequently, that their daily PA goal would be adjusted accordingly.

Mobile Phone

Patients scored the ease of use of the mobile phone as 5.7 (SD 1.65) (on a 7-point scale). A total of 32% (19/60) of patients owned a mobile phone before the start of the study, and 18% (11/60) purchased one after the study. Technical failure of the mobile phone or app or forgetting to bring the phone was not a major issue (Multimedia Appendix 1).

Six PHTs mentioned that the use of the mobile phone, as well as continuously wearing the mobile phone, was considered troublesome for one of their patients (but not for the rest of their patient group). Personal instruction regarding the use of the mobile phone was considered important, but they found it important not to give too much information at one time.

Website

All interviewed PHTs considered the website to be explicit and user-friendly. They used it to view PA data, adjust PA goals, and send text messages. However, reported use was low due to time constraints. The additional log-in was considered tedious, and the PHTs mentioned that a website that could be incorporated into their usual patient software would be better.

Five practices adjusted PA goals via the website, and one adjusted PA goals via the researchers, whereas seven reported that they did not adjust PA goals. Devising a new goal was considered difficult, especially regarding PA intensity, which was seen as an important outcome and thought to predict exacerbations. However, the intensity scores of the daily PA goal (see Methods) were not always well understood.

PHTs noted that they would like to receive a notification when a patient was deteriorating over a longer time period. Table 3 shows PHTs feedback on specific website items and suggestions for improvement.

Text Messages

Fifteen practices sent text messages to their patients. Group messages were sent by 8 practices. Thirty-five patients sent text messages to their therapists. Information on the number of messages sent between the PHTs and the patients can be found in Table 4.

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Table 4. Number of messages sent by physiotherapists and patients.

Users	Text messages sent	Erroneous messages
	Type/N	N (% of total)
Physiotherapists	Personal: 382	41 (10)
	Group: 12	
COPD[a] patients	162	16 (9)

[a]COPD: chronic obstructive pulmonary disease.

Table 5. Types of messages sent. Results are given as frequencies and percentages of total messages sent.

Type of message	By the physiotherapists (N)	Percentage of total messages (%)	By the COPD[a] patients (N)	Percentage of total messages (%)
Motivating	241	56	0	0
Informative	68	17	117	66
Question	43	10	11	6
Fun or social	20	8	34	19
Total	372	100	162	100

[a]COPD: chronic obstructive pulmonary disease.

The messages sent by the PHTs mostly concerned the PA goal (72.8%, 287/394). The remaining messages were related to the mobile phone or app (10.9%, 43/394), the study (7.1%, 28/394), health (4.5%, 18/394), or other topics (3.8%, 15/394). For the patients, this was more evenly divided, with 30.2% (49/162) of the messages concerning the PA goal; 19.7% (32/162), the mobile phone or app; 9.3% (15/162), the study; 19.1% (31/162), health; and 22.2% (36/162), other topics. PHTs mostly sent motivating messages, whereas patients mostly sent informative messages. Table 5 presents the distribution of the types of messages sent. The tone of the messages sent by the PHTs was mostly positive (63.9%, 252/394), followed by neutral messages (36.0%, 142/394), and 2 negative messages (0.5%). For patients, positive (55.0%, 88/160) and neutral (43.1%, 69/160) messages were more evenly divided. They sent 15 (3%) negative messages.

Patients mentioned that sending messages to and receiving them from the PHT was rare and was not seen as supportive in reaching their PA goal (Multimedia Appendix 4). PHTs from 6 practices explained that they used text messages to inform patients, to motivate them, and to determine the reason why the PA goal was not met. One PHT emailed patients instead of texting. During the RCT, the PHTs contacted all subjects but mentioned that if the intervention was implemented, they would contact only those who did not reach their PA goals.

eHealth Self-Management Intervention in General: Perceived Usefulness, Applicability, and Privacy

Perceived Usefulness

PHTs mentioned that the intervention provided them insight into the objective PA data of their patients outside the clinical setting, whereas previously they had to rely on the account of the patient. This was regarded by them as a major advantage. It also enabled them to see patterns in PA. Nine PHTs mentioned that the ups and downs in the PA of patients with COPD are important to monitor in light of exacerbations. The data can be used to start a conversation with the patient about their PA level and to give them insights and tips. One PHT mentioned that his patients learned how far they needed to walk to reach their PA goal during the intervention period and continued to do so after the study ended. Nine PHTs found it pleasant and necessary to follow patients after pulmonary rehabilitation (PR), whereas two PHTs did not see this as a task for the PHT. Patients thought that the eHealth intervention helped them to increase their PA and made them feel fitter. It was rewarding for patients to reach their PA goal (Multimedia Appendix 4).

Applicability

PHTs from 15 practices mentioned they would be interested in using the intervention, provided that it proved effective and that the helpdesk would remain available. Two practices stated that they would not be interested in using the intervention. Two practices were unclear on this matter. Additionally, 58% (35/60) of the patients mentioned that they would like to start using the intervention again. The PHTs believe that the eHealth intervention may be useful in preventing relapses and subsequent repeated PR. PHTs from 8 practices thought that the intervention should already be used during PR, and 4 practices preferred to start after the program.

PHTs believe that face-to-face contact every 2-3 months is necessary, in addition to monitoring from a distance. Additionally, the use of the intervention should be individually tailored to each patient.

There were questions regarding the financing of the intervention. PHTs were concerned that they would not be paid by health care insurers because monitoring is not seen as a consultation; therefore, expenses cannot be claimed. Additionally, they considered it an issue that not all patients owned a mobile phone.

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Privacy

Patients reported that they did not worry about privacy with regards to their PA data. Interested parties such as family and PHTs are welcome to access the data; however, local authorities are not. It is important that patients have control over who can see their data (Multimedia Appendix 4). Two PHTs mentioned that privacy is an important consideration when using eHealth.

Table 6. Key findings

Topic		Patients	Physiotherapists
App		The intervention was used on 89.0% (160.2/180) (SD[a]18.5) of the days in their possession	10 out of 19 practices spent little time on the intervention
		Easy to learn and use	
		Explicit and user-friendly to patients	
		Training not necessary	Training necessary
		Clear, insightful, and stimulating	
Mobile phone		Easy to use	Use of and continuously wearing the mobile phone troublesome for a few patients
		32% (19/60) owned a mobile phone, 18% (11/60) purchased one after the RCT[b]	
Website			Explicit and user-friendly
			Used to look at PA[c]data, adjust PA goals, and to send messages
			Setting PA goals was considered difficult
			Reported low use was attributed to time-constraints
			Tedious additional log-in
Text messages		Sent mostly informative, neutral messages concerning the PA goal	Sent mostly motivating, positive messages concerning the PA goal
		Messages were not perceived as supportive in reaching the PA goal	
eHealth self-management intervention general	Perceived usefulness	Felt it helped to increase PA	Measure of objective PA data outside the clinical setting
		Made them feel fitter	Ability to see patterns in PA (to monitor exacerbations)
			Tool to start a conversation about PA with the patient
	Applicability	58% (35/60) would like to continue to use the intervention	15 out of 19 practices were interested to use the intervention
			Could be useful in preventing relapse
			Financing concerns
			Face-to-face is necessary in addition to monitoring
			Intervention should be individually tailored to the patient
	Privacy	Important to have control over the distribution of their data	Important aspect to keep in mind when working with eHealth

[a]SD: standard deviation.

[b]RCT: randomized controlled trial.

[c]PA: physical activity.

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Discussion

This study evaluated the perceptions of patients with COPD and their PHTs and the text messages both groups sent regarding the use of an eHealth self-management intervention aimed at stimulating PA in patients with COPD.

Principal Findings

Use

Measured use among patients was high, whereas PHTs reported low use. Barriers to use the intervention according to the PHTs were time constraints and financial reasons. Implementation of the intervention in daily practice was challenging. PHTs suggested various features that may enable its use such as a mobile phone app for the PHT, a notification when a patient deteriorates, and a website that is incorporated into the standard patient software.

Application

Patients scored the mobile phone and app satisfactory with respect to ease of learning and use. Contentment with and usability of the app was also scored as satisfactory.

Patients were disappointed that the app could not measure cycling or swimming and that it did not capture the intensity of walking the stairs. There were quite a few patients who cycle a lot and were disappointed when this was not added to the overall PA goal attainment. For COPD patients living in countries with a strong cycling tradition, this activity is seen as an important part of PA, whereas it is not relevant for individuals living in other countries [20]. This shows that nationality or culture can also influence the needs and wishes of the end user and should be considered.

As of the time of the study, battery capacity was too low to add global positioning system (GPS) measurements or other features that could measure these activities. As the development rate of mobile phone technologies and accompanying batteries is high, this seems likely to be possible in the near future. For example, identifying the activity of "walking the stairs" has recently become possible [21]. Also, waterproof mobile phones are now available, so swimming can be measured as well [22].

According to the PHTs, there were some patients who had trouble using the mobile phone. With proper instruction and training, mobile phone and other technology use in older adults has not shown to pose many problems [23].

Face-to-face instructions are usually preferred by older adults [24]. The PHTs warned us of an information overload at the initial instruction for the patients. We may have provided too much information at once. The written instructions and help desk were helpful in this regard.

One-third of the patients owned a mobile phone, and 18% (11/60) purchased one after the study. This was in 2012, 2013, and 2014 when mobile phone use among older adults (65+ years) in the Netherlands was 11, 17, and 26%, respectively [25]. This result, combined with the high use rate in patients, is promising in light of mobile phone–based eHealth self-management interventions for older adults and patients with COPD in particular.

Website

PHTs considered the website to be explicit and user-friendly. Several suggestions were made to improve usability of the website (Table 3). Important with regard to the aim of the intervention were the results on setting or adjusting the PA goals.

Only 6 out of 19 practices that were interviewed adjusted the PA goals of their patients. If there were patients in the other practices that had trouble achieving their PA goals or their goals were too easy for them, they may have been demotivated. Three PHTs mentioned that they found it difficult to set a new goal. Despite the personal instructions for the PHTs regarding the intervention, some did not completely understand the intensity scores of the PA goal. Furthermore, as there are no COPD-specific PA guidelines available, PHTs had to rely on their own practice-based expertise. This can be difficult, especially because minor changes in the frequency, intensity, and time of general PA guidelines for older adults can have major consequences for patients with COPD regarding their ability to comply with these guidelines [26]. Furthermore, automated PA goal setting with the option of an override by the PHT could prove the best option.

The PHTs mentioned that it would be beneficial if patients had the opportunity to indicate whether they are having a bad day. During the measurements, a few patients also mentioned that there were days that they wanted to attain the PA goal but were too tired or were too affected by dyspnea to do so. The option to adjust daily PA goals to account for fluctuating physical capacity may improve goal attainment in this patient group. As a result, positive feedback may increase, and patients may be more motivated to use the intervention long-term.

Text Messages

The text messaging function was not used to its full potential. Only 15 out of 26 practices sent messages. Additionally, only 10 group messages were sent. Similar to the PHTs, there was a large portion of patients who did not use this function (53%, 32/60). Patients did not perceive messaging as supportive in reaching their PA goal, which is not surprising considering its low use rate. Low use could stem from a suboptimal interface (eg, the letters on the mobile phone keyboard were small), as we found that both PHTs and patients sent erroneous messages in approximately 10% (39/394) of cases. One PHT used email instead of messaging, choosing the technology she is more familiar with.

In looking at the correct messages, we see that the messages sent by the PHTs mainly focused on the PA goal and were positive and motivating. This was the intention of this aspect of the intervention. Perhaps if all PHTs had sent these messages, patient PA outcomes would have improved. Automatic reminders could assist in this regard. Responses from patients would likely have been higher as well. On the other hand, 80% (48/60) of patients were still seeing their PHT once or twice a week. During these meetings, the PA measurements of the

intervention were discussed and patients motivated. This would have rendered (some) messages superfluous.

Intervention General

Interestingly, patients thought that the intervention helped them to increase their PA and made them feel fitter. However, the data from the RCT does not show a difference in PA over time compared with the usual care group, and PA actually diminished in both groups equally over the 1-year study duration [12].

Although, in general, the reported use of the website and messaging function was low, PHTs were positive about the functionalities of the intervention. Thus, one could argue it was not the intervention itself but rather its cumbersome implementation that caused the low use by PHTs. Financing concerns were expressed regarding implementation. These may stem largely from a lack of awareness regarding the financing options of the Dutch Health Authority concerning eHealth. Educating PHTs on funding for eHealth could remove this barrier for use.

PHTs mentioned that face-to-face contact every 2-3 months is necessary, in addition to long-term monitoring. eHealth should be seen as an addition to current health care instead of as a replacement. Clearly indicating this to HCPs might help in eHealth acceptance since it can be seen as a threat to their job.

In the introduction, we mentioned that perceived usefulness and ease of use, confirmation of expectations, and satisfaction with the technology are important predictors of continued use [9]. Perceived usefulness for the PHTs was that the PA data was objectively measured, the ability to see PA patterns over time, and that they could use this data to give their patients insight in their PA. They mentioned that they used the intervention as a tool to start a conversation with their patients about their PA. For patients, it was that the eHealth intervention helped them to increase their PA and made them feel fitter. This shows that the intervention has the potential to help patients self-manage their PA. Reported ease of use by patients and PHTs was satisfactory with regard to the app and the website. We cannot draw any conclusions regarding confirmation of expectations because this was not measured at the start of the RCT. For a measure of satisfaction in patients, we can examine the contentment score of the app, which was adequate. For PHTs, this is more difficult because they reported low use. However, they were positive on the functionality and potential of the eHealth intervention.

Limitations

We thought it would be important to pay extra attention to the patients to ensure that they would use the intervention. The PHTs were the ones who initially signed up their practice to participate in the RCT and were thus thought to need less attention. They were given one face-to-face instruction session, written instructions, and access to a helpdesk. In hindsight, they may have needed more prompting and training to use the intervention. For successful use of eHealth interventions, HCPs need new competencies such as composite skills and technology-specific competencies [27]. Inadequate training and education of HCPs can function as a barrier to implementation [10]. Coaching skills, the ability to combine clinical experience

with technology, communication skills, clinical knowledge, ethical awareness, and a supportive attitude are seen as core competencies needed by HCPs to effectively use eHealth technologies [28]. Future studies may benefit from training the HCPs to improve these competencies.

PHTs were interviewed by a member of the research group. This may have led to more favorable answers toward the intervention to please the researchers. The same holds true for the patients who were telephoned to ensure that they understood all of the questions in the questionnaire. Furthermore, the PHTs (9) and patients (16) that were not interviewed or did not fill out the questionnaire may have had a lower use rate and more negative opinions.

The interviews and text messages were coded by the research team and one colleague. To avoid any bias, it would have been preferable if coding was done by people without further knowledge of the study.

Because the RCT had a follow-up measurement at 12 months, interviews and questionnaires were conducted 6 months after the period of use. This could have caused recall bias.

Comparison With Prior Work

For eHealth self-management apps, we found user evaluation studies for diabetes [29-31] and dementia [32]. Bender et al [33] performed a systematic review on mobile phone apps for the prevention, detection, and management of cancer. They concluded that even though there are hundreds of cancer-focused apps, there is a lack of evidence on their utility, effectiveness, and safety. This seems to hold true for COPD-focused apps as well. However, we did find some user evaluations of Web-based applications for COPD (in-home PR [34,35] and a self-management support application [36]). One study evaluated the use of a similar mobile phone-based app to stimulate PA in COPD [37]. Eighty-eight percent (53/60) of the patients used it until the end of the intervention period, in spite of high numbers of technical problems. Our study similarly showed high adherence rates to the intervention. Another similarity was that the monitoring HCPs struggled to fit the extra consultations into their busy daily practice.

As in this study, other studies also stress the importance of training of patients [29] and HCPs [38] on the proper use of the eHealth technology. Besides training, studies propose several important elements to incorporate in the design of eHealth apps, such as automatic data transfer when possible, motivational and visual user interfaces, peer support, individual tailoring, and considerable health benefits in relation to the effort required [30,35]. Furthermore, Bitterman et al [39] mention that it has to be taken into account that, compared to the use of medical equipment in the standardized hospital environment used by experienced and well-trained HCPs, users of home medical devices and services are a heterogeneous, primarily nonprofessional group that operate the device in an unpredictable and uncontrolled environment.

Often, some patients benefit more from eHealth self-management apps than others [29]. Jalil et al [29] propose the Clinical User-Experience Evaluation (CUE) methodology to unpack the variations in outcome of individual patients using

the technology. This is a three-step process where first, the user uses the device while using the "think-aloud" method; second, the user is interviewed; and third, is given an anonymous survey to express opinions without reservations. Having a standardized method might assist researchers in performing more (comparable) user evaluations.

Conclusions

PHTs and patients were positive regarding the functionality and potential of the eHealth self-management intervention. Patients used the intervention on 89.0% (160.2/180) of the days that it was in their possession. Fifty-three percent of PHTs reported low or no use. Patients rated the mobile phone and app as easy to use. They found the presentation of the PA information in the app to be clear, insightful, and stimulating. PHTs considered the website to be explicit and user-friendly. Perceived usefulness of the intervention for the PHTs was the objective measurement

of PA, the ability to see PA patterns over time, and the ability to use the intervention as a tool to give their patients insights into their PA. The patients reported that it supported them in increasing their PA and made them feel fitter.

Fifty-eight percent (14/24) of PHTs and 47% (28/60) of patients used the messaging function. PHTs sent mostly motivating, positive messages concerning the PA goal, whereas patients sent mostly informative, neutral messages concerning the PA goal. The messages were not perceived as supportive in reaching the PA goal by patients.

Barriers to use of the intervention according to the PHTs were time constraints and financial reasons. Devising a new goal was considered difficult. However, 79% (19/24) of the PHTs and 58% (35/60) of the patients mentioned they would be interested in using the intervention in the future.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview questions physiotherapists.

[PDF File (Adobe PDF File), 415KB - humanfactors_v4i3e20_app1.pdf]

Multimedia Appendix 2

Final code list.

[PDF File (Adobe PDF File), 32KB - humanfactors_v4i3e20_app2.pdf]

Multimedia Appendix 3

Patient questionnaire.

[PDF File (Adobe PDF File), 353KB - humanfactors_v4i3e20_app3.pdf]

Multimedia Appendix 4

Results patient questionnaire.

[PDF File (Adobe PDF File), 49KB - humanfactors_v4i3e20_app4.pdf]

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Abbreviations

COPD: chronic obstructive pulmonary disease
ECM-IT: expectation-confirmation model in IT domain
FSU: Florida State University
GPS: global positioning system
HCP: health care professional
IT: information technology
JMIR: Journal of Medical Internet Research
PA: physical activity
PR: pulmonary rehabilitation
PHT: physiotherapist
RCT: randomized controlled trial
SD: standard deviation
USE: Usefulness, Satisfaction, and Ease of Use questionnaire
UTAUT: Unified Theory of Acceptance and Use of Technology

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Original Paper

Remote Monitoring Systems for Chronic Patients on Home Hemodialysis: Field Test of a Copresence-Enhanced Design

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Abstract

Background: Patients undertaking long-term and chronic home hemodialysis (HHD) are subject to feelings of isolation and anxiety due to the absence of physical contact with their health care professionals and lack of feedback in regards to their dialysis treatments. Therefore, it is important for these patients to feel the "presence" of the health care professionals remotely while on hemodialysis at home for better compliance with the dialysis regime and to feel connected with health care professionals.

Objective: This study presents an HHD system design for hemodialysis patients with features to enhance patient's perceived "copresence" with their health care professionals. Various mechanisms to enhance this perception were designed and implemented, including digital logbooks, emotion sharing, and feedback tools. The mechanism in our HHD system aims to address the limitations associated with existing self-monitoring tools for HHD patients.

Methods: A field trial involving 3 nurses and 74 patients was conducted to test the pilot implementation of the copresence design in our HHD system. Mixed method research was conducted to evaluate the system, including surveys, interviews, and analysis of system data.

Results: Patients created 2757 entries of dialysis cases during the period of study. Altogether there were 492 entries submitted with "Very Happy" as the emotional status, 2167 entries with a "Happy" status, 56 entries with a "Neutral" status, 18 entries with an "Unhappy" status, and 24 entries with a "Very unhappy" status. Patients felt assured to share their emotions with health care professionals. Health care professionals were able to prioritize the review of the entries based on the emotional status and also felt assured to see patients' change in mood. There were 989 entries sent with short notes. Entries with negative emotions had a higher percentage of supplementary notes entered compared to the entries with positive and neutral emotions. The qualitative data further showed that the HHD system was able to improve patients' feelings of being connected with their health care professionals and thus enhance their self-care on HHD. The health care professionals felt better assured with patients' status with the use of the system and reported improved productivity and satisfaction with the copresence enhancement mechanism. The survey on the system usability indicated a high level of satisfaction among patients and nurses.

Conclusions: The copresence enhancement design complements the conventional use of a digitized HHD logbook and will further benefit the design of future telehealth systems.

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Introduction

End stage renal disease (ESRD) is the most severe form of chronic kidney disease (CKD), and patients suffering from this condition have poor life expectancy if left untreated. Patients who are not suitable for a transplant have to remain on dialysis for the rest of their lives, making dialysis an essential life-prolonging treatment modality for patients with ESRD [1]. Dialysis replaces kidney function through the removal of accumulated metabolic waste products, by a process of diffusion, as well as removal of excess fluids from the body, by a process of ultrafiltration [2]. Dialysis can essentially be performed by two modalities: peritoneal dialysis, which uses the patients' own peritoneal membrane, and hemodialysis, which uses a synthetic membrane for diffusion and ultrafiltration to occur. While chronic peritoneal dialysis is usually performed by patients at home, hemodialysis is typically conducted for 4-5 hours 3 times a week in a hospital setting (in-center hemodialysis) or in a community setting (satellite hemodialysis). In addition, patients (or their families) can also be trained to conduct hemodialysis treatments at home (home hemodialysis).

Home hemodialysis (HHD) has a number of advantages over other forms of dialyses as it leads to better patient survival, better quality of life, greater independence and opportunity for rehabilitation [3], and is more cost effective [4]. However, HHD is not without its drawbacks. Although patients and their families are trained to deliver these seemingly complex treatments at home, patients on HHD often feel abandoned by the health system because of a constant lack of real-time oversight by trained health professionals, which may increase patients' anxiety [5]. This lack of oversight may also promote noncompliance, such as violating dietary and fluid intake restrictions [6,7], noncompliance to medications [6], and skipping or shortening dialysis sessions [8]. Moreover, the feelings of isolation and difficulty in accessing assistance may also lead to lack of confidence and poor decisions, including abandoning this otherwise very useful and effective dialysis modality [9] and increasing the risk of complications [6]. The common practice to address some of the limitations associated with HHD is to make frequent phone calls or home visits and use paper-based logbooks to record a number of dialysis-related parameters of hemodialysis treatments conducted at home. However, these paper-based logs can be reviewed only when a patient sees their health care professional face-to-face. The problem with this approach is that it could take a long time until the patient sees their health care professionals, rendering it impossible for them to take early corrective actions for any worrisome deviations in these parameters. Additionally, patients may forget to bring their logbooks at the time of consultations or logs could be lost or unintentionally erased before their health care professionals have a chance to review them.

Although there is no system specifically designed for HHD, there are multiple attempts at addressing the identified limitations above for other health conditions. There are a number of mobile phone apps developed to be used as simple self-monitoring or logging apps. Medical professionals are also devoting efforts to building customized computer-based self-monitoring systems [10,11], with features such as summative information of health signs, and electronic reminders sent at a predefined frequency. Some of those apps are similar to paper-based logs, while others may have additional functions to remind patients to report their vital signs in a timely manner. Although with the setting of reminders, noncompliance might be improved. However, the lack of presence of health care professionals onsite (ie, at home for patients on HHD) may still make patients feel isolated and anxious about whether their dialysis-related parameters are stable and within expected range and anxious about whether treatments are being monitored by trained health professionals. Prior study has pointed out that addressing social isolation and emotional needs of users is a major challenge to the emerging telemonitoring and smart care technologies [12].

In this study, we propose an exemplar design for an HHD system optimized for HHD patients with novel mechanisms to enhance patient's perceived "copresence" with their health care professionals. Our design addresses the social and emotional needs of the patients. The pilot deployment of the HHD system employs multimethod data collection including system entries, survey questionnaire, and interview. The study aims to reveal how patients perceive and utilize the functions related to emotion sharing and copresence enhancement. The results will demonstrate how the feelings of being connected with their health care professional can be improved to enhance patients' experience on HHD. This study presents the system design and the analysis of the impact of the copresence enhancement mechanism. The clinical improvements from the pilot, such as change in dialysis prescription, patient and staff time-saving associated with consultation and travel times, and user satisfaction, were presented as a separate study [13]. The rest of the paper is organized as follows: related work on information technology (IT) enabled self-monitoring is reviewed, followed by a discussion of theoretical foundation informing the design. System development will then be discussed, followed by system usability evaluation.

Background

IT-enabled patient monitoring systems play an important role in well-being and chronic illness management. They are changing the way health services, patient data, and medical interferences interact and are able to reduce the number of hospitalized patients, minimize the load on clinical staff, and lower the total caring costs for governments. In general, IT-enabled patient monitoring systems would benefit both patients and medical professionals by providing digitization of and rapid access to health information. They have been used to monitor various types of illness, including cardiac and heart illness [14-16], diabetes [14,17,18], mental illness [19,20], asthma [21], obesity [22], and other types of illness.

Prior studies on patient monitoring systems usually consist of three main components: (1) tracking physiological parameters,

such as respiration rate, heart rate [23], blood pressure, and blood glucose level [24], some of which are able to be captured by wearable sensors [25] while others rely on patients' self-input [26]; (2) a dashboard for clinicians to view data through a Web interface or mobile interface enables authorized personnel to monitor the patients' condition and facilitate remote diagnosis; and (3) a messaging function to provide reminders or alerts to both patients and physicians. These systems are continuously being enhanced, but challenges remain to improve their clinical impact. Data security and privacy are believed to be major threats to IT-enabled patient monitoring systems, especially in terms of patient identification and confidentiality of medical information [27]. Another concern is the battery life or energy consumption of the design, as continuous data collection and processing can impose on a phone's battery runtime [27].

Prior research suggests that addressing social isolation and emotional needs of users is a challenge to the emerging telemonitoring and smart care technologies [12]. The feeling of isolation is also a serious problem in patients on HHD [5] as there is a lack of face-to-face communications between patients and health care professionals. As the HHD procedures require patients to perform the complex dialysis treatments autonomously, the feeling of isolation from health care professionals may cause anxiety and lower their mood and self-confidence. When patients feel disconnected from their health care professionals, their compliance to medical advice drops and their confidence of self-care also comes down [5]. Thus, in this study we have paid attention to the social nature of using technology and introduce the concept of copresence. We discuss how we designed a remote-monitoring system for patients on HHD to reduce patients' feelings of isolation.

Copresence, referring to the sense of connection with another interactant [28], exists when people feel that they are actively perceiving others and feel that others are also actively perceiving them [29]. Specifically, copresence refers to the perception by a communicator that another person in a mediated or online environment is real, immediate, or present [30]. Thus, copresence is a reflection of psychological connection to and with another person. It is required that interactants feel they were able to perceive their interaction with a partner and that their interaction partner actively perceived them [28].

Copresence was widely studied in the field of human-computer interactions, and its application has been used in the context of virtual team collaboration [31] and online shopping experiences [32]. Higher perceived copresence directly influences the satisfaction of the communication medium [28]. However, existing studies of remote patient monitoring have not yet capitalized on the importance and capabilities of copresence.

Methods

A field trial involving 3 nurses and 74 participants was conducted to evaluate the copresence-enhanced HHD system, over a 6-month period.

The Home Hemodialysis System Architecture

The home-monitoring system consisted of three main components. The first component is the HHD app installed in the patient's mobile device. The second component is the cloud server built on Windows Azure services with SQL storage as the database. The third component is the Web app also hosted on the Azure server. Azure provides industry-leading protection and privacy of the data. Patients use their own mobile device to record their hemodialysis-related data. These data are sent immediately whenever the mobile device has an Internet connection. After the Azure cloud service retrieves the data, it is stored in its database. Patients' health care professionals (including their HHD nurses and renal specialists) can choose to access the website at any time. The website provides the patient's up-to-date status with regards to their HHD treatment parameters, along with trends in these parameters over time, enabling the clinical team to make appropriate decisions on a patient's dialysis prescription, blood pressure, and body weight that are a surrogate of their body fluid status. Reports along with trends in various parameters over time can be generated and saved as printable documents. Figure 1 illustrates the described functionality, users, and the exchange of information and emotion between the patients and the health care professionals. The detailed functions of the HHD system and the copresence enhancement features will be described below.

Figure 1. Design of the copresence-enhanced home hemodialysis system.
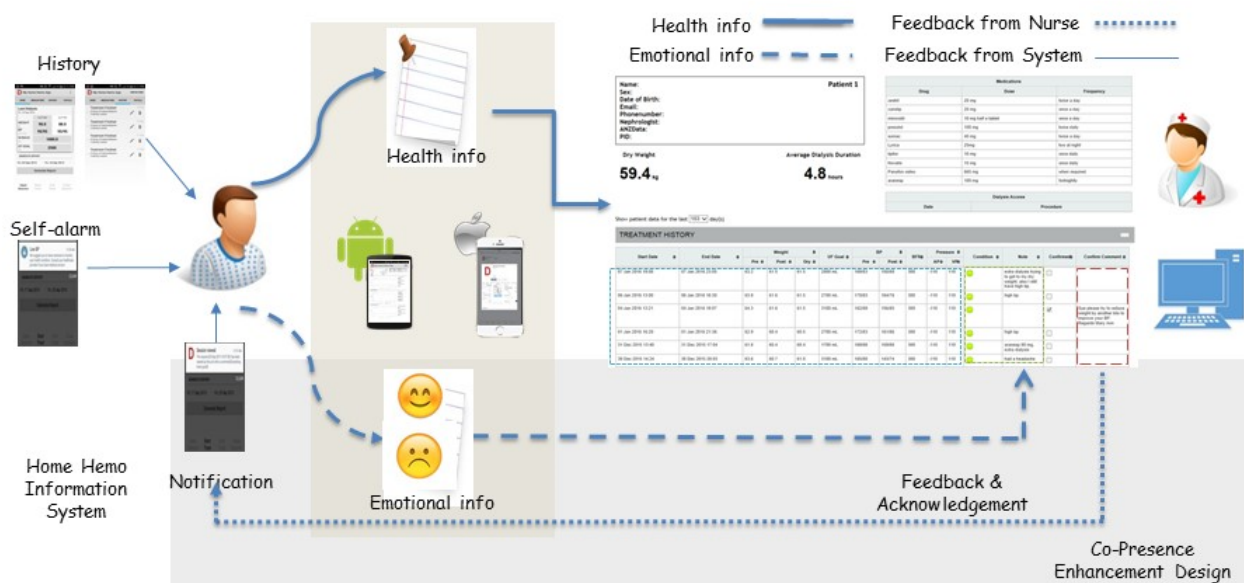
The Basic Functions

The basic functions of the self-monitoring system allow patients to record their hemodialysis session data (eg, pre- and postdialysis body weights, blood pressures, ultra-filtration volumes, blood flow rates, venous and arterial pressures, session times) to the system and get alerts on abnormal parameters or if they did not perform dialysis within a certain amount of time. At the end of each dialysis session, patients report their status on how they are feeling on a 5-point sliding scale, to flag if future dialysis sessions may need to be modified. Patient are also able to enter shorts notes in the textbox of the app for each entry submission. Health care professionals can review patient data, either in real time or at intervals based on patients' clinical needs, thereby allowing monitoring of patients' parameters as well as noncompliance to dialysis regimens, skipping dialysis sessions, or shortened dialysis sessions. They can also get a list of patients who have an abnormal status at the end of hemodialysis sessions, prompting remote analysis of their dialysis data to take remedial actions for their subsequent hemodialysis treatments.
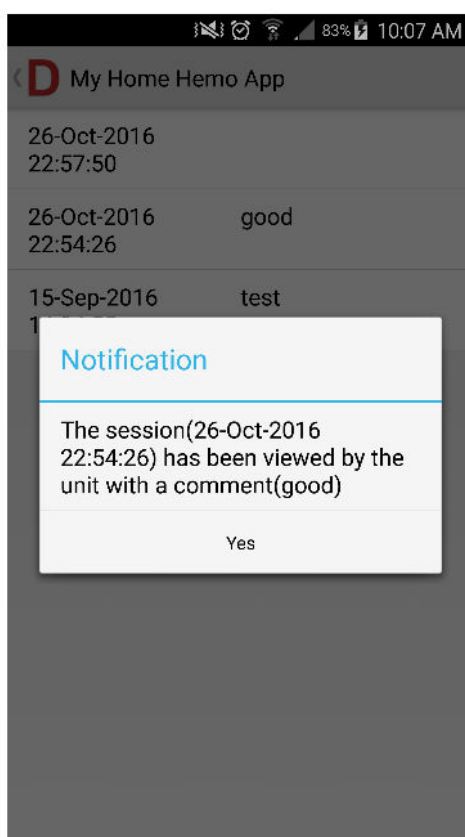
The Copresence Enhancement Mechanisms

Besides the basic functions that provide the digital data log and enable remote monitoring of patients, copresence enhancement mechanisms are related to the feeling of connection between two people. Given its dual nature, this usually consists of two perspectives, including a participant's perception of their partner's involvement in the interaction (perceived others' copresence) and a participant's own involvement in the interaction (self-reported copresence) [33]. The realization of copresence requires mutual synchronization attention and emotion in a computer-mediated environment [34]. Our system enables patients to rate their emotions at the end of the dialysis session as part of the self-health reporting exercise, so that health care professionals can have a general understanding of patients' feelings at the end of their dialysis sessions. The emotions are reported on a 5-point scale, with 1=Very Happy, 2=Happy, 3=Neutral, 4=Unhappy, and 5=Very Unhappy. Figure 2 shows the interface in the app that allows patients to share their emotions. Patients are also allowed to include text as additional comments to each submission (Figure 2). Figure 3 provides an interface of the dashboard on how the emotions are reviewed from the health care professionals' side. Dialysis data of patients expressing a low mood are reviewed as a priority.

Health care professionals can also send feedback (with or without comments) by simply clicking the confirmed function in the system, to let patients know their dialysis data have been reviewed (Figures 4 and 5).

The features of sharing emotions and one-click feedback functions were designed to collectively enhance the mutual attention and emotion between patients and health care professionals, while not increasing staff workload significantly.

Figure 2. Patients' interface to input their emotions.

Figure 3. Dashboard view of patients' emotions.

Figure 4. Sending feedback to patients.

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Figure 5. Patients' view of health professional's feedback.

Timeline of the Study and Data Collection

In order to evaluate the effectiveness of the system in general and the copresence enhancement mechanisms, a field trail was conducted with users at the Home Hemodialysis Unit at the Regional Dialysis Unit, Blacktown Hospital in Sydney. The Home Hemodialysis Unit is part of the Western Renal Service in Western Sydney that has a philosophy of promoting home dialysis and is one of the largest home dialysis services in Australia.

A 2-week trial to test the app's functionality on an Android platform commenced initially with 10 patients and 2 health care professionals (nurses). Improvements were made based on the feedback received, and an iOS version was launched along with updated Android version. Patient recruitment was scaled up to 74 patients and also to 3 nurses. The timeline of the study is summarized in Figure 6.

Once the HHD system was implemented within the Unit, an audit was conducted wherein qualitative data were collected through semistructured interviews to understand the efficacy of the copresence enhancement mechanism with nurses and patients. The interview was structured based on the system evaluation: ease of use, reliability and performance, and usefulness. The patients were allowed to give general comments along these three dimensions. They were further probed to explain whether they felt better connected with the health care professionals and whether they were more confident in doing their dialysis at home. Content analysis techniques were used for analyzing the qualitative data obtained. Content analysis is a research tool used to determine the presence of certain words or phrases within texts, and from these, infer the meanings that underlie these passages of text [35]. Researchers use these techniques to make inferences about the messages within the texts by analyzing the presence, meanings, and relationships of certain words and concepts [35]. The purpose is to reveal the insights related to the system usage rather than establishing casual relationships.

Basic quality assurance surveys were also conducted with the patients, where patients were required to answer a few questions in a 5-point Likert form to evaluate the systems along three dimensions: ease of use, reliability and performance, and usefulness. The questions were adopted from prior validated instruments with minor modification to the context of dialysis patients. Sample survey questions and interview protocols are included in Multimedia Appendix 1. The interview data were analyzed together with basic quality assurance survey to look at patients' and nurses' feedback on general system usage, copresence enhancement mechanisms, and effectiveness of the system. System data including the frequency of self-reporting and the time being acknowledged are also analyzed.

Figure 6. Timeline of the study.
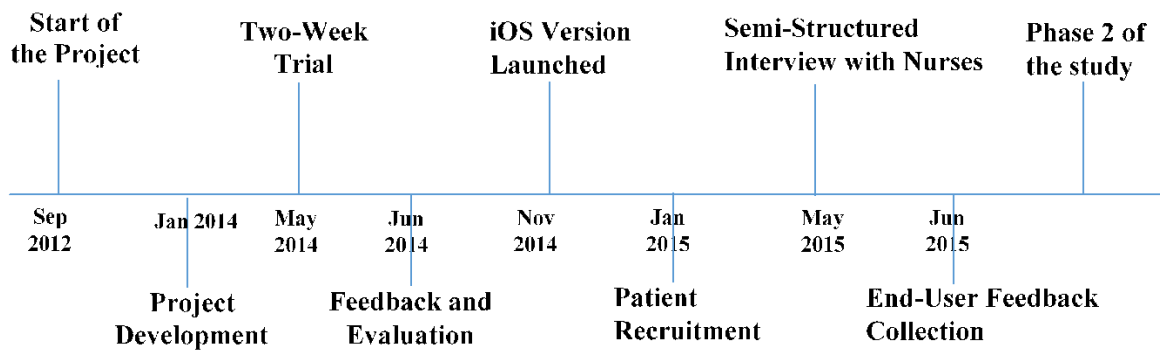
Results

General Information

Among the 74 participants of the study, there were 25 female and 49 male patients. The age distribution is shown in Figure 7 with more than half of the patients over 50 years old. The oldest patient was 78 years old and the youngest 21 years old.

There were altogether 2757 entries created by the patients during the trial period (Table 1). The average duration for the patients participating in the study was 128 days, with a standard deviation of 46.5 days. The minimum duration of participation is 9 days while the maximum is 180 days. Based on the results of the quality assurance survey and semistructured interview, both patients and nurses reported high ease of use and usefulness of the system. The results were further analyzed by patients and staff.

Analysis of Patients

Frequency and duration of using the app was dependant on the date the patient was enrolled in the trial. The total number of entries reported with a different emotional status is summarized in Table 1. Altogether there were 492 entries submitted by indicating "Very Happy" as the emotional status, 2167 entries with a "Happy" status, 56 entries with a "Neutral" status, 18 entries with an "Unhappy" status, and 24 entries with a "Very unhappy" status. On average, each patient had 37 entries for hemodialysis cases during the period of pilot study, with a standard deviation of 27.8. The maximum number of entries created by patients is 91, and the patient duration of participation is 180 days.
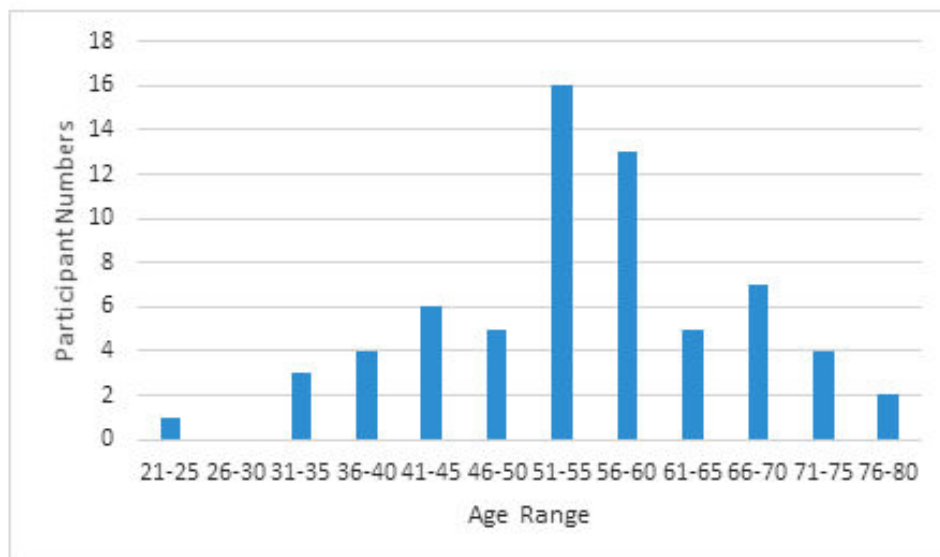
Figure 7. Participants' age distribution.

Table 1. The number of entries patients made during the evaluation period.

	Entries	Very happy	Happy	Neutral	Unhappy	Very unhappy
Entries, total N	2757	492	2167	56	18	24
Percentage of different emotional status, %	100	17.8	78.6	2.03	0.65	0.87
Average entries per patient, n	37	6.6	29.3	0.76	0.24	0.32

Patients reported an average of 4.2 on ease of use of the system (SD 0.77). Patients also reported an average of 4.1 for reliability and performance of the system (SD 0.87). The average perceived usefulness of the system was 4.1 (SD 1.4). They also gave positive feedback regarding the usage of the system during their interviews.

The patients also showed greater awareness of copresence enhancement design mechanisms that we associate with the interview responses such as "not feeling alone," "knowing I am monitored," and other similar phrases. They reported that they felt relaxed to know that their dialysis parameters and treatments were being monitored, especially when they received acknowledgements from the nurses after submitting their dialysis-related data. When asked about the functions of entering notes and emotions into the system, one of the patients mentioned, "It is comforting to know that my results are being monitored and you are not alone." As the negative modes (Very unhappy and Unhappy) usually get the fastest response from the health care professionals, the patients who expressed negative emotions also expressed that they felt "care and responsiveness from the health care professionals all the time." The copresence enhancement design of the system was shown to improve the mutual attention and mutual emotion for patient-nurse communication. The patients mentioned being "motivated to keep dialysis schedule" by the features in the app. In addition, the patients mentioned that they may append some notes to some submitted entries as they know "the nurse will get the message."

We further analyzed the entries with notes appended. Out of the 2757 entries created during the study period, 989 entries were submitted with short notes. We compared the notes entered against the emotion status submitted (see Table 2). Among 492 entries with the "Very Happy" status, 256 entries were supplemented with patients' short notes. For the "Happy" status, 30.69% (665/2167) of entries had additional notes. For "Neutral" status, 59% (33/56) had text notes in the entries. For the "Unhappy" status, all 18 entries consisted of notes input from the patients. For the "Very unhappy" status, 71% (17/24) of entries had notes input. The result shows that when patients are in negative mood, they would like to express themselves with the support of text messages and to improve nurses' understanding on their status. The patients also expressed that: "When I am not feeling well, I want to get the nurses' immediate attention" and "I am glad that they are paying attentions to our problems and emotions."

We also coded the notes entered by the patients into the system, which fell into three categories: (1) describing health status, such as "a bit dizzy in the last hour," "notice my BP increasing," "my bleeding didn't stop quickly it took almost 2 hrs," "all good," (2) greeting to health care professionals, such as "thanks, Maryann," "have a nice day," "A big smile"; this type of message is very common for the entries "Very happy" and "Happy" emotions, and (3) expressing technical difficulty, such as "Power failure after 30 mins." The patients mentioned that that by entering notes to the system, their queries can be quickly attended by the health care professionals and they do not need to wait till next consultation. They also mention it is an effective way to communicate with staff and feel they are "virtually connected" with the staff all the time.

Table 2. The number of entries submitted with text notes.

	Notes	Entries with notes for "Very Happy"	Entries with notes for "Happy"	Entries with notes for "Neutral"	Entries with notes for "Unhappy"	Entries with notes for "Very Unhappy"
Total N	989	256	665	33	18	17
Percentage by type of emotions, %	100	25.9	67.2	3.3	1.8	1.7
Average per patient, n	13	3.5	9.0	0.45	0.24	0.23
Note average per emotion entry, %		52	31	59	100	71

Analysis of Clinical Staff

With the implemented system, there were on average 12 patients remotely reviewed per week. It resulted in savings of 7 hours in nursing and patient times each, from reduced home and/or unit visits, equating to a total saving of 11 hours of travel time and 544 kilometres of travel distance. This paper focuses on the copresence mechanism; additional details about the operational benefits can be found in another paper [13]. The nurses reported satisfaction with the system features during the interview, especially by mentioning it is a "time saving tool."

The nurses mentioned that getting a glimpse of patients' emotional status with a simplified rating was reassuring. They reported a positive feeling of being able to "reach out" to more patients. The notes entered by the patients also provide a better understanding of whether the problem was technical or illness-related. When seeing some greeting messages, the nurse

also said that these patients were also treating them as friends, so the system still maintains a certain level of connection between patients and them. The digital log kept a history of patients' dialysis-related data and allowed nurses to track changes in the patient's dialysis parameters over time. The system also enabled nurses to change dialysis prescriptions and patients' dry weights in a timely manner, prompting patients to know that they were continuously monitored by nurses.

Discussion

Principal Considerations

This study is one of the first studies on copresence in remote monitoring in health care settings. Despite many efforts devoted to building and understanding the effectiveness of computer-based self-monitoring systems [10,11], few studies have looked at the importance of enhancing the social emotional needs of patients. Our study indicates that equipped with the copresence enhancement mechanisms, the HHD system received positive feedback from both patients and nurses. The field trial implies that HHD might reduce patients' feeling of isolation and anxiety caused by independently conducting hemodialysis treatments at home.

Although the system usage was voluntary for the patients and they could still enter their HHD-related data into the conventional exercise books without using the app, this mixed method study revealed that the app usage has achieved its effectiveness as designed. With the feeling of being monitored and connected to their nurses at all times, patients' motivations to adherence was increased. The system empowered patients to better understand and take care of their health care and therefore suggests that the system has the potential to improve patient uptake and retention on HHD programs and improve relationships with their nursing staff. The nurses also felt assured to have a simplified view of patients' emotions and dialysis parameters.

Our study has demonstrated the effectiveness of copresence enhancement mechanism in the context of remote monitoring of dialysis parameters in patients on HHD. IT-enabled patient monitoring is a trend and the benefits have been demonstrated including reducing nurse-patient ratio, reducing operational cost, and improving data accuracy. There are also issues and challenges with the use of technology, and a significant one is that patients are not able to have face-to-face communication with health care professionals and may feel isolated and lose compliance and confidence through the self-disease management process. While current ways to reduce patient isolation require additional investment of physicians' and nurses' time, such as increasing standby hours or having a video conferencing call, our study proposes a concise design by introducing functions like sharing emotions using emojis, sending quick notes, sending acknowledgment, and having a prioritized response to patients' records. The features provide health care professionals a preliminary filtering of patients' situations and provide patients the feeling that they are cared for and monitored constantly.

Our study also highlighted the importance of communicating emotions with health care professionals. Prior studies on telecare

suggest that social and emotional needs of users are overlooked in current solutions [12]. Patients expressed that better connections were built with staff through submitting emotional feedback for the dialysis session. The design of one-click feedback function is also highly regarded by the nurses.

Limitations and Future Work

This study has a few limitations, but it opens up exciting avenues for future research. First, there is no comparison group in the study, since the aim was not to establish causal relationship, but rather to reveal in-depth insights based on a combination of subjective and objective data. Future study can plan for a randomized controlled trial and draw causal relationships between system usage and clinical benefits. In the future, we plan to conduct a prospective study to measure the long-term benefits to patients and on the efficacy and productivity of health care professional's care delivery with the use of our copresence enhancement mechanisms. Second, feelings such as isolation were not directly measured using questionnaires. The current study only interpreted such meanings based on the qualitative data collected through interview. Future studies should include quantitative measurements of feelings and emotions. Third, there might be other possible features that can be implemented to enhance copresence. For example, studies have found that using an avatar can enhance perceived copresence in the context of teleconferencing and virtual learning [36]. As this study was to test the idea of copresence enhancement mechanisms while not overloading patients with too many functions, these features were not implemented in the HHD system. Future study can definitely implement and test the effectiveness of different copresence enhancement features. Additionally, we plan to further complement our copresence mechanism by incorporating a video conferencing tool to improve communication between patients and health care professionals and to ensure the safety of patients doing dialysis at home, as videoconferencing can enable assessment of patients' fluid status, visual inspection of vascular access integrity, dialysis machine malfunctions, and alarms.

Conclusion

In this paper, we propose an exemplary design of an HHD system by incorporating copresence enhancement mechanisms. The design was able to address the challenges of monitoring patients' dialysis-related parameters while they are on HHD and their feeling of isolation when conducting these treatments. Our user-centered HHD system was designed to enhance nurse-patient mutual attention and emotion without overloading them with complicated functions. The proposed mechanisms were shown to improve the feeling of connectedness with clinicians for the patients, improve adherence to their dialysis treatments and schedules, and also enhance emotional well-being of patients. It is one of the first studies to address social concerns and emotional feelings for patients on home dialysis. Our results from patients and the health care team have been positive and affirm that the proposed copresence-enhanced mechanisms have many benefits to HHD. We suggest that our copresence enhancement mechanisms are relevant to other remote chronic disease management systems.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Survey and interview instruments.

[PDF File (Adobe PDF File), 26KB - humanfactors_v4i3e21_app1.pdf]

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Abbreviations

CKD: chronic kidney disease
ESRD: end stage renal disease
HHD: home hemodialysis