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Original Paper

Satisfaction and Usability of a Commercially Available Medication Adherence App (Medisafe) Among Medically Underserved Patients With Chronic Illnesses: Survey Study

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Abstract

Background: Research supports the use of mobile phone apps to promote medication adherence, but the use of and satisfaction with these apps among medically underserved patients with chronic illnesses remain unclear.

Objective: This study reports on the overall use of and satisfaction with a medication adherence app (Medisafe) in a medically underserved population.

Methods: Medically underserved adults who received care for one or more chronic illnesses at a federally qualified health center (FQHC) were randomized to an intervention group in a larger randomized controlled trial and used the app for 1 month (n=30), after which they completed a web-based survey. Objective data on app usage were provided as secondary data by the app company.

Results: The participants were very satisfied with the app, with all participants (30/30, 100%) somewhat or strongly agreeing that they would recommend the app to family and friends. Participants strongly agreed (28/30, 93%) that the reminders helped them remember to take their medications at the correct time each day, and they (28/30, 93%) found the app easy to use. Additional features accessed by some included educational features and the adherence report. Participants noted the helpfulness of having a medication list on their phones, and some used it during medication reconciliation at doctor visits. Use of the Medfriend feature, which alerts a social support person if a medication is missed, was low (n=2), but those who used it were very positive about the feature.

Conclusions: A commercially available medication adherence app was found to be useful by participants, and they were satisfied with the app and the additional features provided. The use of medication adherence mobile phone apps has the potential to positively influence chronic disease management in a medically underserved population on a large scale.

Trial Registration: ClinicalTrials.gov NCT05098743; https://clinicaltrials.gov/study/NCT05098743

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KEYWORDS

medication adherence; mHealth; mobile phone; app; medically underserved; chronic disease; satisfaction; usage; health disparities

Introduction

Background

Medication adherence is vital for those with chronic illnesses who require long-term medication therapies to maintain optimal health. For example, medication adherence and persistence with high blood pressure medications are known to significantly decrease the risk of both cardiac events and stroke [1,2]. In those with type 2 diabetes, medication adherence with hypoglycemics reduces microvascular complications [3]. Unfortunately, the burden of chronic diseases is increasing, with an estimated 60% of adults in the United States having 1 chronic disease and 40% having 2 or more chronic diseases [4]. The growth of chronic disease burden coupled with a lack of medication adherence is associated with increased health care expenditures due to increased demands on health care resources [5,6] and poor health outcomes such as worsening disease status and even death [5]. The economic impact of low medication adherence is estimated to cost the US health care system between US $100 billion and $290 billion annually [5-8].

Medication adherence is therefore particularly important in medically underserved populations who seek care at federally qualified health centers (FQHCs). These centers serve communities and populations with a demonstrable unmet need for health services [9]. These centers are reporting growth in more complex patient populations because their patients have higher rates of chronic conditions and social risk factors associated with poorer health outcomes [10]. Additionally, lower rates of medication adherence are seen in lower socioeconomic populations [11,12] and those with multiple chronic conditions [13]. The reasons for this are influenced by social determinants of health and the material and social conditions in which people live [14]. Adverse social determinants of health are associated with lower medication adherence [15].

Mobile health (mHealth) interventions, defined as the use of mobile wireless technologies for public health [16], have been cited as a potential way to reduce health disparities among chronically ill and medically underserved populations [17,18]. However, despite the promise of these technologies, researchers indicate that mHealth interventions remain understudied in medically underserved populations [17,18]. This is true of medication adherence apps, which can support patients in adhering to their medications through reminders, medication educational information, adherence data, and social support. Studies have shown mixed results for the interest in mobile phone interventions in vulnerable populations [18,19]. Furthermore, research testing commercially available apps to manage chronic disease in a racially and ethnically diverse sample found that the usability of the tested apps in this population was suboptimal [20]. Understanding and gathering detailed data from diverse perspectives regarding the user experience of medication adherence apps will provide important information that is needed to support wider implementation.

A recent meta-analysis of the effectiveness of mobile apps on medication adherence in adults with chronic illnesses found that medication adherence mobile apps, which are designed to be used across a range of multiple chronic health conditions, remain underexplored [21]. This meta-analysis reported that in general, patients have a high acceptance of medication apps, but none of the studies analyzed included medically underserved populations [21]. Eight studies have demonstrated increased medication adherence with the use of medication adherence apps [22-29], but only 3 of these were conducted in low-income medically underserved populations [27-29]. Two of those studies in underserved populations were focused on hypertension [27,28], and the other included hypertension and type 2 diabetes and was a post hoc analysis of a digital health offering using a cluster-randomized design [29]. Only 1 of these studies, conducted in an urban low-income population with hypertension, obtained satisfaction information on the intervention [28]. Satisfaction with the app was high, and most participants felt they would use the app or a similar program in the future. Participants agreed that the app made it easier to keep track of their medications and that having a medication list on their phone made it easier to take care of themselves. More detailed feedback from the participants or information on which features of the app were used was not gathered [28].

A high-quality, free, commercially available smartphone medication adherence app called Medisafe supports patients in adhering to their medication regimen across disease states [30]. It uses a variety of advanced features, such as daily reminders, which can be snoozed, rescheduled, and marked as taken or missed; medication educational information in the form of medication cards and videos; an interaction checker; customizable refill reminders; adherence reports; and the ability to designate a social support person to be notified if a medication is skipped [23]. A randomized controlled trial (RCT) mixed methods evaluation in patients with coronary artery disease examined the efficacy [23] and the utility, acceptability, and engagement [31] of the Medisafe app. This study was conducted in a large urban tertiary hospital in Sydney, Australia and did not focus on a medically underserved population. In addition to improving self-reported medication adherence, overall utility was rated positively, with participants indicating that having their medication list on their phone and receiving timed reminders were useful. Most participants engaged with the app and its features; found the app acceptable, convenient, and easy to use; planned to continue using the app; and would recommend it to a family member or friend [31].

A qualitative study explored the potential benefits and barriers of using a mobile medication app in a medically underserved population in the United States [18]. The researchers found that patients were willing to try smartphone apps but expressed concerns about affordability, the technology being too complicated, not keeping phones with them all the time, and not being able to use all the features [18]. That study exposed a knowledge gap regarding the perceptions and user experiences of medically underserved patients with chronic illnesses who use free commercially available medication adherence apps.

Purpose

To address the knowledge gaps, a larger RCT investigating the efficacy of the Medisafe app (reported elsewhere) [32] was performed for evaluating the overall use and satisfaction of patients with a variety of chronic illnesses in a medically

underserved population in an FQHC in the United States. The efficacy portion of the RCT found significant improvements in both medication adherence (Cohen *d*=0.52; *P*=.01) and medication self-efficacy (Cohen *d*=0.43; *P*=.04) for participants assigned to use the app compared to the usual care group [32]. As part of this RCT, participants assigned to the intervention arm provided feedback and usage data regarding their experience using the Medisafe app [32]. This manuscript presents the summaries of the perceptions of patients enrolled in the intervention arm of the RCT regarding the usefulness of and satisfaction with the app features after 1 month of use. Given the improvements observed in medication adherence and self-efficacy, understanding patients perceived usefulness and satisfaction with the app is important to address potential barriers for uptake and use in larger medically underserved patient populations who often receive care for chronic illnesses in FQHCs.

Methods

Setting and Recruitment

Participants were recruited from November 2021 through June 2022 from an outpatient adult medicine department in an FQHC in the northeastern United States. The inclusion criteria for the RCT study were as follows: (1) adults aged 18 years or older, (2) having the ability to speak and understand English, (3) personally owning and using an Android smartphone (version 5.0 or above and at least 88 MB of phone space) or iOS smartphone (version 13 or later and at least 165 MB of phone space), and (4) taking at least one medication for a chronic condition based on the computerized medical record at the health center. Patients were excluded if they: (1) were already using a medication reminder app or other electronic reminder system such as phone alarms, (2) owned a smartphone not capable of downloading the app, (3) had a diagnosis of severe dementia or serious mental illness, or (4) were otherwise unable to use a mobile phone or the medication reminder software either physically or cognitively. For this study, only those participants who were randomized to the intervention group and used the Medisafe app were invited to participate in the survey.

Recruitment involved an informational flyer, a referral form from clinicians at the health center, and in-person recruitment. The flyer and referral forms were available to clinicians, staff, and patients in the FQHC offices and at the reception desk. The form contained study information, the contact information of the principal investigator (PI), and a place for patients interested in participation to provide their contact information. The form also contained a section for health care providers (HCPs) to refer potential patients and a section for their signature to verify that the patient's medications listed in the electronic health record were correct and current. The PI (CH) conducted in-person recruitment at the FQHC on multiple days per week and worked with clinic staff to identify potentially eligible patients. Although a convenience sample was used (ie, patients visiting the clinic on any given day), the risk of selection bias was reduced by using the aforementioned 2-prong approach to identify eligible patients for recruitment, inviting all patients meeting the eligibility criteria to participate, and using random assignment to either the intervention or control group. The 2 groups were not statistically different [32]. The PI approached eligible patients at the end of the health center visit to inform them of the study. Once the PI confirmed participant eligibility and obtained informed consent, participants were randomized to either the intervention or control group. Additional details of study procedures for the RCT have been previously published [32].

Statistical Analysis

Based on a preliminary efficacy study for the RCT [33], a total sample of 60 participants was estimated to enable the detection of differences between the groups with Cohen *d* effect values of 0.6-0.7 (80% power; α=.05) for the quantitative study variables [32]. As 30 participants were randomized to the app intervention group, their usage and satisfaction data are presented in this manuscript. Descriptive statistics and frequency distributions were used to describe the sample and determine if the data were normally distributed. Qualitative participant responses were transcribed into an Excel spreadsheet, and the content was coded and summarized as themes by the researcher (CH) and PhD faculty advisor (DPS).

Ethical Considerations

This research was approved by the Vanderbilt University Institutional Review Board (IRB #211409) and is registered with ClinicalTrials.gov (NCT05098743). All participants received a copy of the consent form. Based on participant preference, informed consent was completed as either an IRB-approved e-consent form or a hard copy. The consent form contained a privacy and confidentiality protection description ensuring that all study data are deidentified. Participants received a US $25 gift card after completion of the baseline survey and a US $35 gift card after completion of the follow-up survey.

Medisafe App Intervention

The Medisafe app is a Health Insurance Portability and Accountability Act (HIPAA) compliant medication adherence app that is available at no cost in the iTunes and Google app stores. In previous studies, Medisafe was ranked highly among medication reminder apps [30,34]. The Medisafe app provides interactive and customizable daily timed reminders to reinforce medication taking at a set time every day through a push notification, equivalent to an alarm or text message. The reminders can be snoozed, rescheduled, or marked as taken or skipped, and they are repeated a total of 3 times in 10-minute intervals if the participant does not mark the medication dose. Additional features include educational information in the form of a medication database that includes written and video content [30]. The written content is in the form of a medication card, which Medisafe terms a leaflet, and it reviews what the medicine is used for, medication interactions, what to do if the user misses a dose, what the user should watch for, possible side effects, how it should be used, and where to store the medication. Some medications also have video content, consisting of a brief clip of an HCP reviewing the most important considerations when taking the medication, which can be viewed on tapping the information icon. There is also an interactions tab that lists possible interactions with the medications or food/alcohol.

Lastly, there is an interaction checker where participants can check for interactions between their medications. The app also has a Medfriend feature, which allows participants to designate a family member or friend as their support person. The Medfriend feature will alert the designated Medfriend who can provide peer support and additional reminders through text messages, emails, or a telephone call if the patient misses a dose. The language mode of the app can be switched, if desired, to multiple foreign languages, including Spanish.

The PI helped consented participants set up the app using a copy of the patient's medication list extracted from the electronic health record. The PI also reviewed how participants could access and edit their medications; access medication educational content; and indicate when a medication was taken, skipped, or rescheduled. The PI reviewed with participants additional app features such as Medfriend, medication interaction checking, adherence reports, and refill reminders. Participants were also shown how to access the help and support section in the app. Following the app set up, the PI provided previously developed educational materials as a take-home resource. These materials, specific to either an iPhone or Android smartphone, included a laminated "quick tips" card with short instructions on the reviewed features and how to access them. Additional detailed instructions on how to use the app were printed in a question-and-answer format and distributed to participants.

Data Collection and Study Procedures

All study data were collected using observation, a REDCap web-based survey, and secondary data provided by the app company and were obtained using a data-sharing agreement between institutions. REDCap is a secure web-based software platform designed to support data capture for research studies [35,36]. Following consent, all participants completed the baseline study survey. Those randomized to the intervention group also completed a survey at study end to obtain feedback on the app, including usability and satisfaction.

Observation

While setting up the app for the intervention group, the PI completed a study-specific observational behavioral checklist. The purpose of the checklist was to inform the researchers if participants had difficulty setting up the app and how long it took them to do so. The checklist included documenting whether the participant had difficulty visualizing the app and had difficulty with dexterity while setting up the app, and mentioning the number of times the participant's input of medications needed to be corrected. The length of time in minutes from starting the download of the app to completing app set up and reviewing the app was also documented.

Survey

After 1 month, based on preference, participants completed the follow-up survey online, by phone, or in-person at the health center. Participants who did not complete the follow-up survey within 10 days of the 1-month follow-up date received 2 reminders via phone, email, or text message.

Measures

The end-of-study survey included 11 questions that assessed satisfaction and usability using a 5-point Likert scale with responses ranging from "strongly disagree" to "strongly agree." The survey questions were developed and pilot tested before use [33]. Seven of the first 11 questions were developed by Santo et al [31] and were used with permission in this study, while the remaining 4 were developed by the researchers. Six additional questions asked about the use of additional features such as the educational information, Medfriend feature, interaction checker, adherence report, refill reminder, and additional morning reminder of the Medisafe app. These questions asked participants whether they used a given feature, and if they did, whether they found the feature useful. There were open-text response options available to elicit qualitative data from the app participants such as how a feature helped them manage their medications and what they found most useful about the feature. The remainder of the survey included 6 general use questions previously developed and pilot tested, 4 of which were "Yes/No" questions (eg, did you use the refill reminder and did you have technical issues with the smartphone app?). The remaining 2 questions assessed how often medication reminders were received each day and which language the participant used.

Secondary Data

Deidentified usage data were obtained from the Medisafe company at study completion. Medisafe provided the PI with objective user interactions with the Medisafe app, such as whether educational information in the form of a leaflet was accessed by participants and whether the Medfriend feature was used.

Analysis

Descriptive statistics and frequency distributions were used to describe the sample and determine if the data were normally distributed. Open-ended survey question responses were imported into an Excel (Microsoft Corp) spreadsheet, and the content was coded and summarized as themes by the researcher (CH) and the PhD faculty advisor (DPS). This approach was taken given the short, free-text, and limited responses received. Since the qualitative data came from the open-ended survey responses, data collection was based on sample size rather than data saturation.

Results

Participant Characteristics

Complete details are included in Table 1, and information can also be found in the app efficacy manuscript [32]. A flowchart of study participants in the main RCT can be found in Figure 1. The median age of the 30 participants using the app was 53.5 years (IQR 37-76 years). Most participants in the intervention group were non-White (23/29, 79%). Races/ethnicities were as follows: Asian (5/29, 17%), Black or African American (10/29, 35%), Hispanic/Latino (4/29, 14%), Native American or Alaska Native (1/29, 3%), and other (3/29, 10%). More than 75% of the participants had government insurance (25/30, 83%), and a small number of participants were uninsured (2/30, 7%). Brief

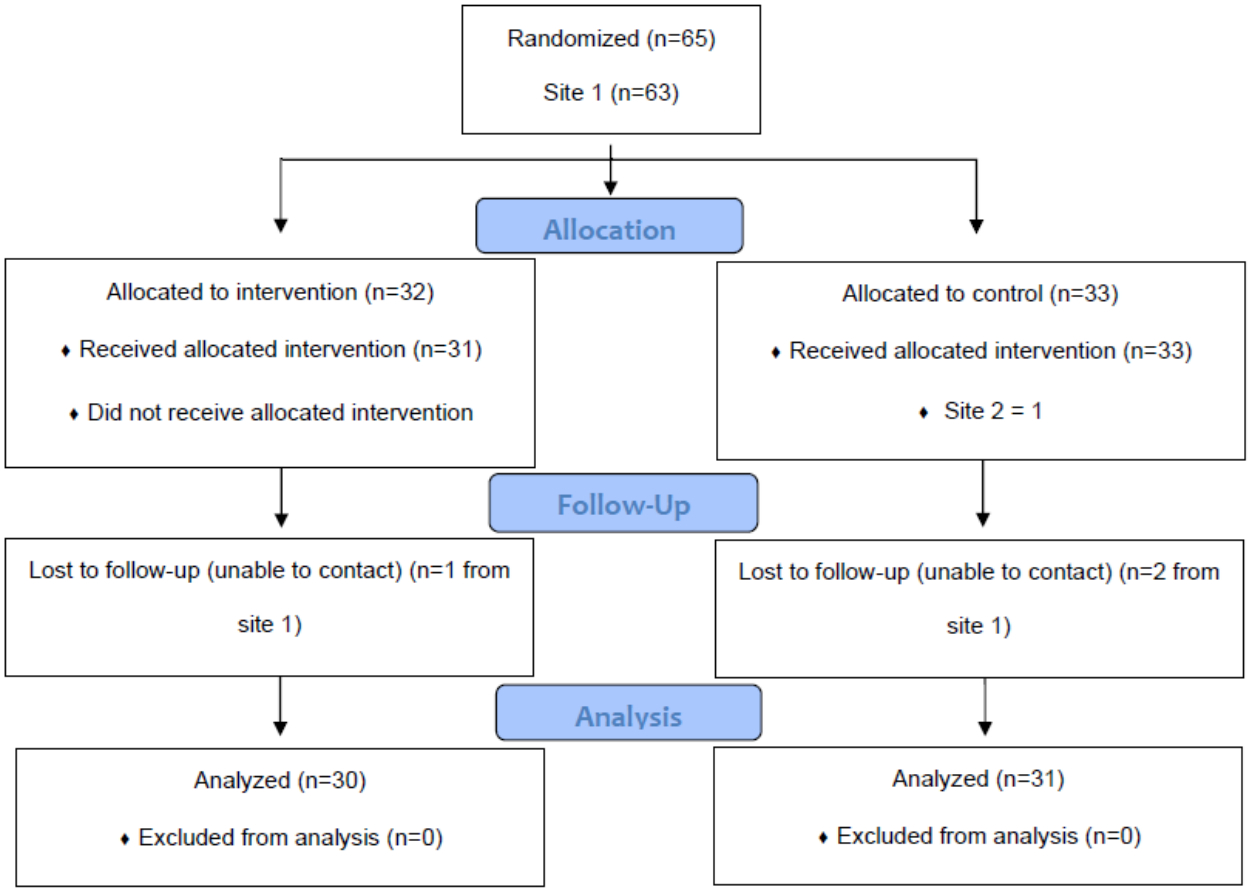
health literacy scores were generally high (median 12.0 of a possible score of 15, IQR 5-15). Slightly more than half of the participants (16/29, 55%) reported that it was either very or somewhat difficult to pay their monthly bills. The most common chronic illness was hypertension (22/30, 73%), followed by hyperlipidemia (19/30, 63%) and type 2 diabetes (14/30, 47%). Most participants (25/30, 83.3%) had 2 or more chronic illnesses.

Table 1. Sociodemographic characteristics of the participants using the app.

Characteristic	Value, n (%)
Race/ethnicity (N=29)	
Asian	5 (17)
Black or African American	10 (35)
Hispanic/Latino	4 (14)
Native American or Alaska Native	1 (3)
White	6 (21)
Other	3 (10)
Marital status (N=30)	
Married/partnered	15 (50)
Single/never married	15 (50)
Employment status (N=30)	
Employed	15 (50)
Unemployed	12 (40)
Retired	3 (10)
Education (N=30)	
Some high school or less	8 (27)
High school graduate	4 (13)
College credit, no degree	8 (27)
Trade/vocational training	4 (13)
Associate’s degree	2 (7)
Bachelor’s degree or higher	4 (13)
Difficulty paying bills (N=29)	
Very difficult	6 (21)
Somewhat difficult	10 (35)
Not very difficult	8 (28)
Not at all difficult	5 (17)
Type of health insurance (N=30)	
Uninsured (sliding scale)	2 (7)
Government insurance	25 (83)
Private insurance	3 (10)
Current chronic illness (N=30)	
Hypertension	22 (73)
Type 2 diabetes	14 (47)
Hyperlipidemia	19 (63)
Asthma	5 (17)
Other[a]	11 (37)

[a]Includes depression (n=1), type 1 diabetes (n=1), chronic obstructive pulmonary disease (n=1), heart disease (n=1), cirrhosis (n=1), anxiety (n=1), gout (n=1), rheumatoid arthritis (n=1), thyroid disorder (n=1), hypothyroidism (n=2), gastroesophageal reflux disease (n=1), arthritis (chronic pain) (n=1), and fibromyalgia (n=1).

Figure 1. Flowchart of study participants in the larger randomized controlled trial of the efficacy of the app intervention.



Behavioral Observations While Setting Up the App

During app set up, some participants (4/30, 13%) expressed difficulty visualizing the app owing to the unavailability of their eyeglasses, which they stated were either in their car or left at home. No participants had difficulty with dexterity while setting up the app, and the median time it took from starting the app download to completing the set up and reviewing the app was 15 minutes (IQR 10.0-25.0; minimum 10, maximum 30 minutes). The majority of participants (21/30, 70%) did not need to be corrected when they entered the medications. However, 4 (13%) were corrected by the researcher once, 3 (10%) were corrected twice, and 2 (7%) were corrected thrice. Patients were corrected when they spelled the medication name incorrectly, chose the incorrect medication dose, or set an incorrect time for the reminder.

Satisfaction and Utility

Summaries of the participants' reports of satisfaction are presented in Table 2.

Most participants (27/30, 90%) strongly agreed that they liked the app design, while most (25/30, 83%) strongly agreed that it was useful to have their medication list on their smartphone. Some participants (2/30, 7%) mentioned the usefulness of the app when seeing other HCPs to indicate the medications they were taking during medication reconciliation. Furthermore, a large proportion of participants (28/30, 93%) strongly agreed that the reminders helped them to remember to take their medications at the correct time each day. The majority of participants strongly agreed that the app was easy to use (27/30, 90%) and convenient (28/30, 93%) and that they would continue using the app (26/30, 87%). A small number of participants (2/30, 7%) somewhat agreed that they would continue using the app. It is important to note that some participants (2/30, 7%) strongly disagreed that they would continue using the app, because they found the reminders annoying. All the participants (30/30, 100%) somewhat agreed or strongly agreed that they would recommend the app to family and friends.

Table 2. Satisfaction with the app (N=30).

Satisfaction information	Value (N=30), n (%)
Liked the app design	
Neutral	1 (3)
Somewhat agree	2 (7)
Strongly agree	27 (90)
It is easy to tap the correct icon with my finger	
Neutral	1 (3)
Somewhat agree	1 (3)
Strongly agree	28 (93)
I am able to see all the options in the app	
Neutral	3 (10)
Somewhat agree	1 (3)
Strongly agree	26 (87)
It is useful to have a medication list on the smartphone	
Somewhat disagree	1 (3)
Neutral	1 (3)
Somewhat agree	3 (10)
Strongly agree	25 (83)
Reminders helped me remember to take my medications at the correct time each day	
Neutral	1 (3)
Somewhat agree	1 (3)
Strongly agree	28 (93)
Found it easy to use the app	
Somewhat disagree	1 (3)
Neutral	1 (3)
Somewhat agree	1 (3)
Strongly agree	27 (90)
Found it easy to set up reminders in the app	
Neutral	3 (10)
Somewhat agree	2 (7)
Strongly agree	25 (83)
Found it convenient to have the app	
Strongly disagree	1 (3)
Somewhat disagree	1 (3)
Strongly agree	28 (93)
Found it useful to snooze the reminder	
Strongly disagree	1 (3)
Somewhat disagree	1 (3)
Neutral	10 (33)
Somewhat agree	3 (10)
Strongly agree	15 (50)
Will continue using the app	
Strongly disagree	2 (7)

Satisfaction information	Value (N=30), n (%)
Somewhat disagree	1 (3)
Neutral	1 (3)
Strongly agree	26 (87)
Will recommend the app to family and friends	
Somewhat agree	2 (7)
Strongly agree	28 (93)

The 2 participants (10%) who were dissatisfied with the app described the reasons why. One said:

> *It is annoying when you get a reminder and you are in the middle of doing your work. This is not for everybody. I work on the computer and on my cell phone and it is very distracting to receive the reminder in the middle of working on something. It might be better for someone who doesn't have as much going on. I find it very distracting.*

The other participant had technical difficulties but blamed it on the type of phone they had:

> *The bug thing with the notification alarms was a problem. I have an android - a cheap phone. My phones get destroyed because of the type of work I do.*

Use of Educational Information

Almost half of the participants (12/30, 40%), self-reported accessing educational information. To the contrary, objective usage data from Medisafe indicated that only 3 participants (10%) accessed the educational content, which was defined as cards termed “leaflets” or videos. According to Medisafe, this was done for a total of 14 medications. Additionally, Medisafe reported that only 1 participant accessed 4 different videos and 1 leaflet, 1 participant accessed 1 leaflet, and 1 participant accessed 6 different videos and 2 leaflets. Although not all participants actually accessed the information, those who reported accessing the educational information (12/12, 100%) found the information useful. When asked about how they used the educational information in the app, the participants reported learning about the side effects of the medications (6/12, 50%), reported that it was helpful for general knowledge (4/12, 33%), and mentioned using it to learn more about medication and food interactions (2/12, 17%).

Medfriend Feature

Based on usage data from Medisafe, only 1 participant (3%) used the Medfriend feature. That participant was very positive about the feature and reported that her husband would call her to say, “Are you taking your medicines?” She stated:

> *It gets him involved. It makes him recognize that I need support and I need to take the medicine. It makes me know he loves me.*

Another participant self-reported using the Medfriend feature, but there was no indication of use in the Medisafe data. The participant reported that when her husband was notified, he would send a text about her forgetting her medications and she would remember to take them. Those who did not use the Medfriend option were asked, “who might that person be for you?” Among those who responded (18/30, 60%), the top 3 most common responses were their sibling (4/18, 22%), their child (4/18, 22%), and their husband or wife (4/18, 22%).

Interaction Checker

All participants who used the interaction checker (5/30, 17%) agreed that it was useful. One participant reported that 2 of the medications she had been taking together should be taken separately and stated, “It was a lifesaver!” The other 4 participants expressed an appreciation for being able to have access to this type of information. The use of the interaction checker was distinct from the educational content and could not be verified in the Medisafe data as Medisafe does not register or track the use of the interaction checker.

Adherence Reports and Reminders

Participants (8/30, 27%) who checked their adherence report agreed it was useful. The adherence report provided them with a history of their daily missed and taken medications as well as a weekly adherence percentage based on what they reported when marking medication reminders in the app. Participants reported experiencing positive reinforcement for adhering to their medications through the adherence report, mentioned the affirmation they received when they saw a high percentage of adherence, and reported appreciating the positive reinforcement as useful. Some participants (2/30, 7%) mentioned that it incentivized them to reach higher levels of adherence.

Slightly less than half of the participants (13/30, 43%) received reminders to take their medications 2 times a day, while around one-third (9/30, 30%) received reminders 3 or more times a day. Reminders were generally well received:

> *I like the reminder. The shaking of the pill bottle helps me. Sometimes I will wake up at night and remember hearing the shaking pill bottle that day and I will get out of bed and check if I took my pills that day. I might be cooking with the grandkids and the first reminder goes off. I might ignore it but with the second reminder I might put the bottles on the counter so I can remember.*

Three participants (15%) mentioned the app’s helpfulness, particularly for those who have multiple chronic illnesses and take multiple medications.

> *This app was a lifesaver. I take a lot of different medication so sometimes I forget whether I took the*

> *medication or not. I can check the app to see if I took it or not.*

One of those 3 participants commented as follows:

> *It is perfect for people who have multiple illnesses and take a lot of different medications. I take eight different medications a day.*

Most of the participants (27/30, 90%) did not use the refill reminder. In their comments, a number of participants said they received automatic refill reminders from their pharmacy and therefore did not need this feature of the app. All participants (30/30, 100%) used the app in English, and the majority (24/30, 80%) did not make any changes, such as changing the time of a reminder, removing or adding a medication, or changing the medication dose in the app. Many participants (13/30, 43%) said they would use the app to manage someone else's medications.

Technical Difficulties Using the App

Some participants (4/30, 13%) mentioned they had technical difficulties. Of those who reported difficulties, 3 (75%) needed to allow notifications from the app to hear the reminders. Another user mentioned that they had to tap the "take all" icon a number of times before it registered and suggested that it should be made bigger or be more centrally placed. Participants gave additional feedback about the app when asked (20/30, 67%). In this section, participants (7/20, 35%) specifically mentioned liking the reminder.

> *It was really nice to hear that shaking sound. It was fun.*

Some participants (2/20, 10%) reported that the snooze function was particularly helpful when they were away from home.

> *The snooze option is helpful to use when I am out and don't have my medications. When I come back home it reminds me so I remember to take it.*

Social Support

The 2 participants (7%) who self-reported using the Medfriend feature were very enthusiastic.

> *It's a great app and I love it. My husband is on it for his meds and I am his Medfriend. I am also going to get my mother hooked up on it.*

The other participant shared her thoughts about the feature, highlighting her increased feelings of self-efficacy and social support.

> *This app is about being a team player. You are able to help me and I am able to help you. I can now say "I did it" "I can do this." This is a good app. I can't see anyone who is interested in their health not using this app. Since being introduced to this app I know that it is there for me.*

Discussion

Principal Findings

As part of an RCT using the Medisafe medication adherence app in a medically underserved population with a variety of chronic illnesses, behavioral observations on app use and satisfaction and usage data were gathered from participants in the intervention arm of the study and the Medisafe company. The quantitative RCT results (reported elsewhere) [32] found significant improvements in both medication adherence and medication self-efficacy for participants who used the app. The portion of the RCT presented in this manuscript, which collected behavioral observations and satisfaction and usage data from the intervention arm, identified that participants were satisfied with the app and found it useful. Even though the use of the additional features was generally low, those who used them found them useful. Most participants did not need help setting up the app. An important strength of this RCT is that it explored patients' perceptions of the usefulness of the app and their satisfaction with the app and therefore fills an important knowledge gap. This was done by collecting both quantitative and qualitative data through open-response questions, which gave voice to the perspectives of a low-income racially and ethnically diverse sample of adults with chronic illnesses receiving care in an FQHC [17,18]. As FQHCs are reporting a growth in the rates of treating complex chronic conditions [10] and there are lower rates of medication adherence among populations with lower socioeconomic status and those with multiple conditions [37], the implementation of tools to enhance medication adherence is imperative. Understanding the user experience with the Medisafe mobile app demonstrated that wider-scale use of the Medisafe app is feasible in a low-income population with multiple chronic illnesses. Systematic literature reviews have pointed out a gap in implementation studies of mobile app interventions in this population [38]. This study addressed an important knowledge gap by demonstrating that the use of a commercially available free medication adherence app is a viable option for medically underserved adult patients with chronic diseases.

Prior research found that medically underserved patients expressed reluctance about paying for a medication adherence app [18]. While not directly addressed in this study, some participants anecdotally asked before enrolling in the study if they would need to pay for the app, and when told it was free, they expressed interest in participating. This underscores the importance of not having patients incur additional costs for the technology and was a strength of this intervention.

Most participants were able to set up the app with minimal assistance, with a median duration time of 15 minutes during the behavioral observation. It is important to note that 30% of the participants needed to be corrected 1-3 times when setting up the app, thus pointing to the importance of helping some patients set up the app initially and checking that the medications are entered accurately. This highlights a difficulty with individuals setting up the app. Although not implemented in this study, another option is to import medications from other databases, such as Apple Health, or a pharmacy directly. This may shorten the time it takes to set up the app. Once the app is set up properly, in addition to HCPs assisting patients, the help and support page and the company contact could serve as a resource for patients.

Survey data indicated that satisfaction with the app was high, with most patients strongly agreeing it was easy to use. All

intervention group participants (30/30, 100%) strongly agreed that they would recommend the app to family or friends. This was higher than the proportion in the study by Santo et al [31], which used Medisafe and found that 78.6% of patients with coronary heart disease would recommend it [31], and the study by Anglada-Martinez et al [24], which used a similar app and found that 71.4% of patients receiving treatment for hypertension, dyslipidemia, heart failure, or HIV would recommend it [24]. Both these studies were, however, conducted outside of the United States. It may be that Americans are more familiar with app technologies and feel more comfortable recommending apps to others.

Qualitative research conducted in a medically underserved population with chronic illness regarding the use of medication adherence apps found that technical issues and complexity were concerns when setting up and using these apps [18]. One study involving a medication adherence app similar to Medisafe indicated that 50% of participants reported problems receiving reminders [24]. The Medisafe app used in this study is a commercially available app with high-quality assessment ratings [30,39], and in this study, technical issues were rare. The most common issue was not receiving the reminders until the participant allowed notifications from the app in their phone settings. No participants expressed that the app was technically complex, which was previously cited as a concern in this population but was not an issue in this study [18]. One participant had ongoing technical issues receiving reminders. These findings suggest that the Medisafe app can be implemented in this population from a technology standpoint, and participants did not find it difficult to use.

Similar to other studies involving the Medisafe app, feedback results point to receiving timed medication reminders as the most used aspect of the app [31]. Furthermore, feedback regarding the app aligns with the findings of other studies linking medication reminders with medication adherence [22,25,28,29]. Participants found the snooze function of the reminder helpful when they were not home to take their medications and used this function as a reminder to take their medications when they got home. The snooze function therefore was an important component of the app when participants experienced disruptions in their routines, such as being away from their medications. The findings also align with a previous study in a medically underserved population where participants indicated that disruptions in their daily routines negatively affected their medication adherence [18]. This study demonstrated that patients used the reminder feature when available, and the majority of patients found it helpful in improving medication adherence. The 1 participant who was bothered by the reminders used his phone for work and found the reminders distracting if he was using his phone for work purposes. The reminders predominantly targeted the phenomenon of forgetting, which has been found by a study to be the most likely cause of reported nonadherence in low-income uninsured patients with multiple chronic illnesses [13].

Research has shown that both patient knowledge of medications and their satisfaction with the information provided about their medications can improve medication adherence [40]. There was a discrepancy between the data reported by Medisafe and the number of participants who self-reported accessing educational information. Although the reason for this discrepancy is not clear, several possibilities exist. First, participants could have overstated the use of educational features. Another potential reason might be related to the specific data Medisafe defines as educational data. Medisafe does not collect data on the use of the interaction tracker or the “For You” tab at the bottom of the app and only collects data if a participant clicks on the educational leaflet and opens it up. In contrast, participants might have perceived content under the “For You” tab and drug interaction materials or videos as educational materials, resulting in a discrepancy between patient self-reported data and Medisafe data regarding accessing educational content. The feedback received demonstrated that participants who reported accessing the educational information (less than half) were very positive about doing so. The educational information was found to be useful for learning about side effects and food and medication interactions. Because individuals have different preferences for the amount of medication information they receive and the way that information is delivered [41], the modularity of the Medisafe app is useful to facilitate patient education in a practical and less burdensome way. The information is available at the patient’s fingertips and can be accessed as frequently as needed to learn what they want at their convenience. The educational app feature is also advantageous to HCPs as it alleviates some of the burden and time commitment associated with educating patients about their medications.

Social support has been found to have a positive effect on medication adherence [42-44]. Studies deploying digital technologies in the form of web-based online communities to provide social support have generally demonstrated that they can support people emotionally, socially, practically, and politically [45]. However, using technology to provide social support has not been studied in the context of a commercially available medication adherence mobile app. This study addressed this gap by studying social support via a commercially available app in the context of medication adherence. The Medisafe app offers social support in the form of Medfriend, and this is the first known study to incorporate this feature as part of the study intervention. Some studies have pointed out that online social support networks for those with specific chronic illnesses lessened the burden on relationships with family and friends, who are referred to as “offline” support persons [45,46]. However, despite asking and offering to demonstrate how to set up the Medfriend feature, usage of the Medfriend feature was very low. This study did not gather information on why participants chose not to set up the Medfriend feature, and this is a limitation of the study. It may have been because this feature was seen as too burdensome by the patients or their support people, most of whom were identified as family members. Patients might have avoided using Medfriend due to confidentiality concerns associated with this feature, which entails giving access to the user’s medication list, as many participants (13/30, 43%) were willing to use the app to manage someone else’s medications but chose not to share their own medication information. Another challenge regarding the Medfriend feature was that there was a discrepancy between Medisafe data and self-reported data on the use of the Medfriend feature. Despite the aforementioned concerns, the 2

participants who reported using the Medfriend feature were satisfied with it as they perceived that the app fostered social support. To further explore the social support feature of the app, research on dyads who use the app to manage the medications of family members might shed new light on the phenomenon of incorporating social support into mobile apps. By studying a subset of the population, including patients and their caregivers, the social support feature may be used more frequently. If the confidentiality of medication lists proves to be a barrier, a feature that dissociates specific medications from the reminder might address that concern. Support persons could receive a general text that their online Medfriend has not taken their medications without sharing details on the specific medications.

Participants reported that having a list of medications on their phone was beneficial, which was also noted in a population of patients with coronary heart disease who used the Medisafe app in Australia [31]. When managing chronic illnesses, patients are often referred outside of the FQHC setting or require hospitalization to receive care. Some participants mentioned using the phone medication list for medication reconciliation when seeing other HCPs. This finding is in contrast to that of another study of patients presenting to an emergency department setting, which found that emergency department patients rarely used their mobile phones to share their medication list during medication reconciliation [47]. Medication reconciliation can be facilitated through the adoption of these technologies. HCPs in both primary care and tertiary care settings should suggest and support patients with implementing researched medication adherence mobile apps. The sample of this study included many patients with multiple chronic conditions. These participants appreciated the ability of the app to work across multiple chronic illnesses and its helpfulness when taking multiple medications. This finding underscores the importance of advocating for the use of medication adherence apps like Medisafe, which can work across a range of illnesses and medications and can be easily adjusted when medications change over the disease trajectory. Additionally, participants who used the adherence report felt that it provided positive reinforcement and was an incentive to reach higher levels of adherence. Similar to what has been reported in other studies, a majority of participants reported not using the refill reminder because they already received text alerts from their pharmacy, which they found helpful [18]. When HCPs select apps for patients to enhance their medication adherence, careful attention to app features and evaluation of existing research findings, such as the findings of this study, are important.

Limitations

This study had several limitations. First, the study duration of 1 month does not provide insights regarding long-term patient satisfaction and continued use of app features, which are important aspects of chronic disease management. Though this study found high satisfaction and usability of the app during the first month of use, future studies should evaluate the role of time in app usage and satisfaction. Medisafe data and self-reported data showed that the uptake of educational information and the Medfriend social support feature was low. There was an unresolved discrepancy in the number of participants who reported accessing educational information and the actual usage identified from the Medisafe data. The discrepancy might be because Medisafe data only captured if the leaflet was accessed. Patients may have perceived accessing educational information as clicking the interaction button or clicking the “For You” tab at the bottom of the app, which Medisafe data did not capture. This can be clarified in the future by a more detailed definition of what constitutes the educational features of the app. Incorporating interviews to clarify subsequent survey results would strengthen future research studies. Another limitation of the study is that we did not gather participants’ inputs about why they chose not to use the Medfriend feature. Therefore, this study cannot speak about the potential benefits of this feature. Finally, although the app can be used in several languages and many patients who seek care at FQHCs speak a primary language other than English [48], the researchers were not able to incorporate multiple languages into the study protocol.

Future Research

FQHCs and primary care settings working with adults who are chronically ill should consider medication adherence mobile phone apps as acceptable and practical tools to support medication adherence. Future studies could include a larger sample, consider the use of the available provider portal, and consider the experiences of both providers and patients. Cost analysis could be performed, and hospitalization rates and long-term usage and health outcomes over time could be studied. This study was for a 30-day period, but a study with a longer duration is necessary to see if the use of the app is sustained over time. In this study, only 2 participants reported barriers to using the app, and a larger long-term study could further explore barriers to sustained use and strategies for maintaining engagement in this population. Future research should use mixed methods to provide insights into app modification, the nature of barriers to use, and how app features, such as the Medfriend feature, could more easily be implemented among patients who might benefit the most from such features. As uptake of the additional features of the app, such as educational information and the Medfriend option, was low in this study, future research using larger datasets could explore what types of patients chose to use specific features and why they did. We purposefully did not require certain features to be used because we wanted to organically discover which features were most often used, if any.

Studying the usability of the app and its associated effects in ethnic populations in various languages is an important area of future research as community health centers serve a large number of patients with limited English proficiency [48].

Conclusion

This study demonstrated that the medication adherence app is a useful, convenient, and feasible intervention in an FQHC setting. The various features of this app positively influenced the medication-taking behaviors of adults with one or more chronic illnesses. Participants were satisfied with the app and the features they chose to use. Reminders were viewed as helpful by the majority of participants. The medication list feature was particularly useful for patients who had multiple chronic

conditions and saw multiple providers, and some used it to facilitate medication reconciliation. The findings of this study have important clinical implications, as clinicians can recommend the use of medication adherence apps as tools to provide support in adhering to medication regimens and as additional tools to use during medication reconciliation.

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Data Availability

Limited deidentified data are available upon request from the corresponding author.

Conflicts of Interest

None declared.

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Abbreviations

FQHC: federally qualified health center
HCP: health care provider
PI: principal investigator
RCT: randomized controlled trial

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Gender-Inclusive Language in Public-Facing Labor and Delivery Web Pages in the New York Tristate Area: Cross-Sectional Study

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Abstract

Background: Transgender and nonbinary (TGNB) individuals are increasingly intentionally becoming pregnant to raise children, and hospital websites should reflect these trends. For prospective TGNB parents, a hospital website is the only way they can assess their safety from discrimination while receiving perinatal care. Cisnormativity enforced by communication gaps between medical institutions and TGNB patients can and has caused delays in receiving urgent care during their pregnancy.

Objective: The aim of this study was to evaluate the current prevalence of gender-inclusive terminology among labor and delivery services in the New York tristate area.

Methods: The labor and delivery web pages of 189 hospitals from New York, New Jersey, and Connecticut were examined for gender-inclusive language. “Fully inclusive” websites explicitly acknowledged lesbian, gay, bisexual, transgender, queer, intersex, and asexual plus other gender- and sexual-oriented (LGBTQIA+) parents, “inclusive” websites did not use gendered terminology for parents, and “noninclusive” websites used gendered terms at least once in the text reviewed. The hospitals’ web pages were further stratified by Healthcare Equality Index scores and population classifications defined by the 2013 National Center for Health Statistics Urban-Rural classification given to the county that each hospital was located in.

Results: Of the 300 hospital websites reviewed, only 189 websites met the criteria for inclusion. Overall, only 6.3% (n=12) of labor and delivery web pages were “inclusive” or “fully inclusive.” No geographic areas (*P*=.61) or Healthcare Equality Index scores (*P*=.81) were associated with inclusive or fully inclusive language.

Conclusions: Hospitals need to use inclusive language to help TGNB people identify hospitals where their existence and needs are acknowledged and thus feel more comfortable in their transition to parenthood.

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KEYWORDS

OBGYN; transgender; nonbinary; pregnancy; maternity; transmasculine; observational study; gestational; perinatal care; communication; labor; USA; United States; New York City; sexual orientation; inclusion; parents; obstetrician gynecologist; delivery

Introduction

Within the last 2 decades, as transgender and nonbinary (TGNB) people have gained greater legal and social recognition, those in the TGNB community who want to become pregnant have become increasingly more common, as have the number of families with same-sex, transgender, or nonbinary parents [1]. Despite this trend, the field of medicine has mostly maintained the heteronormative model of a “mother” and “father” as opposed to a more fluid, freeform reality that accompanies the rise of lesbian, gay, bisexual, transgender, queer, intersex, and asexual plus other gender- and sexual-oriented (LGBTQIA+) couples who raise children.

As pregnant TGNB people attend numerous prenatal visits, they make repeated contact with heterosexist health care systems without the ability to hide their transgender status. Pharr [2] explains that heterosexism is not an active form of discrimination but rather “a belief that the world is and must be heterosexual.” According to the heterosexist worldview, every couple contains—or should contain—only 2 gender-conforming people of the opposite sex [3].

Heterosexism works with homophobia to make health care inaccessible for LGBTQIA+ populations. Current literature has

found that these parents and couples are often invalidated and marginalized throughout the health care process through obstacles like registration forms, comments from ancillary staff, and physicians who are unprepared to deal with LGBTQIA+ couples [4-6]. These experiences can take a deep mental and emotional toll—doubly so during the sensitive transition to parenthood [7].

Beyond these mental health impacts, the invisibility of TGNB parents can negatively affect pregnancy outcomes. LGBTQIA+ patients were less likely to trust providers and divulge important medical information when they received heteronormative medical treatment [8,9]. Patients may also experience delays receiving urgent pregnancy care due to the systematic heterosexism built into the health care system.

For example, Parker et al [6] discuss the experiences of a transmasculine patient who was delayed in seeing the doctor because the receptionist argued that he was not the intended person. These patterns are not limited to individual heterosexist health care workers but also integrated into hospital software. Berger et al [10] describe another scenario where a transmasculine patient's care was delayed, this time because the hospital's electronic medical record required that he reregister as female to document the pregnancy, regardless of his actual gender identity. A delay in care to circumvent cisnormative systems can be dangerous for all pregnant TGNB people. Ultimately, discrimination has often necessitated that prospective TGNB parents discern a "safe" hospital before seeking care.

Historically, LGBTQIA+ people have relied on word of mouth from their personal social circles to find safer health care [11]. However, younger LGBTQIA+ people, especially ones without LGBTQIA+ support networks, also rely on the internet to search for health information and providers that are inclusive of LGBTQIA+ people [12,13]. This vetting of hospitals, along with the increase of patient choice and consumerism for perinatal care in general, has prompted hospitals to advertise their unique benefits, such as low cesarean rates, "baby-friendly" designations, and private rooms [14-19]. Hospitals have tailored their advertisements for other demographics around them, but there is a dearth of literature showing how hospitals advertise their services for LGBTQIA+ populations, who rely on publicly available information to find inclusive care and preserve their health and safety [20].

Purdie-Vaughns et al [21] point to purposeful word choice as one safety cue that, when recognized, signals protection from identity-based discrimination. Hospitals might therefore attract pregnant LGBTQIA+ parents by crafting more inclusive obstetrical web pages. These pages could signal inclusivity by explicitly referencing LGBTQIA+ care or by avoiding gender-exclusive language like "mother and baby," "mom," or presumptive she/her pronouns for parents. Through the words chosen on these public-facing web pages, hospitals thus enable parents to choose to give birth in places where their existence is actively supported during the physically dangerous and psychologically difficult transition to parenthood.

The states surrounding New York City—New York, New Jersey, and Connecticut—boast an exceptionally high population density of LGBTQIA+ individuals, who make up between 3% to 5% of the total adult population [22]. This geographical region is viewed as more inclusive towards LGBTQIA+ people than average, so hospitals may have more incentive to provide inclusive care [23,24]. This study aims to evaluate the current prevalence of LGBTQIA+ inclusion and gender-inclusive terminology among labor and delivery (L&D) service web pages in the New York tristate area.

Methods

Study Design

The targeted words used to assess gender-inclusiveness for this study were largely adapted from the Jennings et al [25] study of gender-inclusive language on National Health Service websites.

The official public-facing obstetric web pages of nonfederal, short-term, acute-care hospitals from Connecticut, New Jersey, and New York were analyzed (n=300). Hospitals without L&D services or web content describing these services were excluded (n=189). Websites were reviewed from late November 2022 to January 2023.

Hospitals were categorized by state, 2013 National Center for Health Statistics Rural-Urban classification, and Healthcare Equality Index (HEI) score. The National Center for Health Statistics Rural-Urban classification is a tool used to identify urban and rural areas of the United States. It was used to analyze any association between urbanization and hospital-based inclusiveness of LGBTQIA+ people. The HEI score is the national LGBTQIA+ benchmarking criterion that assesses health care facilities' policies and practices regarding equity and inclusion of LGBTQIA+ patients, visitors, and employees. It was also used to identify if there was any association between a hospital's publicly perceived LGBTQIA+ inclusivity and word choice on the web pages.

For each hospital, at least 1 web page was examined alongside up to 2 additional pages as supplementation for language analysis. The gendered language used was recorded and analyzed by a single reviewer. The complete L&D-related text was analyzed and the types of gendered language used were recorded. (Explicit discussion of related services, such as chestfeeding, within the same site was excluded.) Any non–gender-inclusive descriptors for the name of the building or third-party services were also excluded from analysis, as these are often not controlled by hospital administration.

Language Analysis

Each web page was reviewed independently by the chief reviewer to minimize any discrepancies. Each hospital's L&D web page was rated as "fully inclusive," "inclusive," or "noninclusive." "Fully inclusive" websites explicitly acknowledged LGBTQIA+ or TGNB parents. "Inclusive" websites did not use gendered terminology or pronouns for prospective parents. "Noninclusive" websites used the terms "woman" or "women"; "mom" or "mother"; other terms for women; "father" or "dad"; or she/her pronouns at least once in the text reviewed.

Statistical Analysis

Categories were analyzed using χ^2 tests presented as frequencies with percentages. *P* values <.05 were considered statistically significant, and all tests were 2-sided.

Ethical Considerations

Ethics and insitutional review board approval were not required since the study did not include human or animal subjects and all data were collected from publicly available websites.

Results

Of the 300 hospital websites reviewed, 111 hospital websites did not have a L&D web page or did not have content describing their L&D services (Multimedia Appendix 1). Of the remaining 189 websites analyzed, 12 (6.3%) of them used fully inclusive or inclusive language (Table 1). Only 1 hospital (0.5%) was considered fully inclusive because it acknowledged "same-sex" couples in its L&D content. The most common noninclusive terms used were "mom" or "mother" (n=166, 87.8%) and "woman" or "women" (n=94, 49.7%). No geographic areas (*P*=.61) or HEI scores (*P*=.81) were associated with inclusive or fully inclusive language (Tables 2-4).

Table . Labor and delivery web pages that used each type of language (N=189).

	Fully inclusive, n (%)	Inclusive, n (%)	Noninclusive, n (%)	Total, n (%)
Websites	1 (0.5)	11 (5.8)	177 (93.7)	189 (100)
Language used				
woman or women	1 (1.1)	0 (0)	93 (49.2)	94 (49.7)
mother or mom	0 (0)	0 (0)	166 (87.8)	166 (87.8)
she/her (parent)	0 (0)	0 (0)	42 (22.2)	42 (22.2)
she/her (staff)	0 (0)	0 (0)	9 (4.8)	9 (4.8)
synonyms for women (ladies, etc)	0 (0)	0 (0)	1 (0.5)	1 (0.5)
father or dad	0 (0)	0 (0)	33 (17.5)	33 (17.5)

Table . Summary of HEI[a] scores and gender-inclusive language used on L&D[b] web pages .

	Fully inclusive (n=1), n (%)	Inclusive (n=11), n (%)	Noninclusive (n=177), n (%)	Total (N=189), n (%)
HEI score=100%	0 (0)	5 (45.5)	60 (33.9)	65 (34.8)
HEI score <100%	0 (0)	1 (9.1)	25 (14.1)	26 (13.9)
HEI score not applicable	1 (100)	5 (45.5)	92 (52)	98 (52.4)

[a]HEI: Healthcare Equality Index.

[b]L&D: labor and delivery.

Table . Summary of gender-inclusive language used on labor and delivery web pages and population data.

	Fully inclusive (n=1), n (%)	Inclusive (n=11), n (%)	Noninclusive (n=177), n (%)	Total (N=189), n (%)
Large central metro	0 (0)	6 (54.5)	53 (30.6)	59 (31.2)
Large fringe metro	0 (0)	3 (27.3)	65 (37.6)	68 (36)
Medium metro	1 (100)	1 (9.1)	31 (17.9)	33 (17.5)
Small metro	0 (0)	0 (0)	7 (4)	7 (3.7)
Micropolitan	0 (0)	1 (9.1)	17 (9.8)	18 (9.5)
Noncore	0 (0)	0 (0)	4 (3.9)	4 (2.1)

Table . Examples of suggested gender-inclusive language [19,25].

Non–gender-inclusive language	Gender-inclusive language
"Mothers"	"Birthing parents" OR "women and birthing parents"
"Pregnant woman"	"Pregnant patient" OR "pregnant person"
"Mother and baby unit"	"Maternity unit" OR "birthing unit"

Discussion

Principal Findings

These results demonstrate that there is a large barrier for TGNB parents to search for and identify potentially inclusive pregnancy care. Out of the 12 inclusive and fully inclusive L&D web pages, 92% were inclusive not because they included gender-additive language or LGBTQIA+ topics but rather because they omitted the pregnant person's gender altogether by addressing the reader in the second person. The websites may have been inclusive not by intention but by coincidence. In stark contrast, there are multiple private reproductive endocrinology and infertility clinics that specifically target LGBTQIA+ couples using specific gender-inclusive language on their websites [26]. TGNB parents who are accustomed to a purposefully inclusive experience during their fertility journey and early pregnancy may be caught off guard by the sudden invisibility of their identities as they progress further through their pregnancy.

Interestingly, none of the hospitals that are acknowledged for their excellence in LGBTQIA+ care in other specialties discussed serving prospective TGNB parents for L&D care on their websites. This likely reflects a wider societal trend of "repronormativity," by which society at large does not recognize reproductive sex between TGNB parents as possible or legitimate [27].

The accessibility of websites and web-based platforms is important for TGNB people to find services and connect to similar parents. Our above findings suggest less than 10% of hospitals use gender-inclusive language when representing their services. Thus, TGNB parents who are not connected to a wider LGBTQIA+ community may struggle to find inclusive prenatal care and delivery services due to the lack of representation.

Limitations

The use of multiple surrogate end points may limit this study. The analyzed web pages, while used as a proxy for the culture in L&D departments, may not fully represent institutional attitudes and practices once parents start using their providers. This is exacerbated by delays between institutional attitude changes and hospital website updates. HEI scores were ineffective in predicting the LGBTQIA+ inclusivity of hospitals' web pages because HEI scores are determined purely through institutional measures like nondiscrimination policies; they do not directly address subtler, underlying heterosexism that hopeful TGNB parents try to avoid in their health care. Finally, the methodology used in this study makes it impossible to establish a causal link between gendered terminology and the quality of LGBTQIA+ inclusive care.

Additionally, it is important to note that individual TGNB people may feel varying levels of dysphoria around maternal terms; some TGNB parents may not consider the words "mom" or "mother" to be exclusively for women. However, using gender-inclusive language and terminology is an important step towards providing a more welcoming and inclusive environment for TGNB parents, regardless of those individuals' personal dysphoria triggers.

Conclusions

Using gender-inclusive language and terminology is the first step towards providing a more welcoming and inclusive environment for pregnant TGNB parents. Hospitals that want to be recognized as more inclusive towards LGBTQIA+ people can integrate gender-additive language into their L&D web pages (eg, "mothers and birthing parents") rather than omit mentions of gender entirely [28]. US hospitals should consider expanding this language to meet the needs of a growing group of people who are having children. Future research should be done including LGBTQIA+ patient advocate groups on the use of inclusive language within health care providers' obstetrical and gynecology departments, specifically in L&D units and on how this language impacts TGNB parents' health outcomes and rapport with physicians.

Conflicts of Interest

None declared.

Multimedia Appendix 1
List of hospitals reviewed for analysis, along with a list of hospitals where labor and delivery pages were missing for various reasons.
[XLSX File, 77 KB - humanfactors_v12i1e53057_app1.xlsx]

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Abbreviations

HEI: Healthcare Equality Index
L&D: labor and delivery
LGBTQIA+: lesbian, gay, bisexual, transgender, queer, intersex, and asexual plus other gender- and sexual-oriented identities
TGNB: transgender and nonbinary

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Effectiveness of Using a Digital Wearable Plantar Pressure Device to Detect Muscle Fatigue: Within-Subject, Repeated Measures Experimental Design

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Abstract

Background: Muscle fatigue, characterized by reduced force generation during repetitive contractions, impacts older adults doing daily activities and athletes during sports activities. While various sensors detect muscle fatigue via muscle activity, biochemical markers, and kinematic parameters, a real-time wearable solution with high usability remains limited. Plantar pressure monitoring detects muscle fatigue through foot loading changes, seamlessly integrating into footwear to improve the usability and compliance for home-based monitoring.

Objective: This study aimed to investigate the effects of muscle fatigue on plantar pressure measurements using a self-developed wearable plantar pressure system.

Methods: Twelve healthy participants completed a 5-minute calf muscle fatigue protocol. The plantar pressures and surface electromyography (sEMG) activity of the gastrocnemius muscles were recorded before and after exercise. The plantar pressures at 6 regions and the median frequency (MDF) of sEMG were analyzed to quantify fatigue.

Results: The self-developed foot pressure system showed a significant decrease in plantar pressure peak values at the heel of the left (P=.003) and right feet (P=.001) and at the lateral toe of the left (P=.001) and right feet (P=.026). A significant increase was observed at the metatarsal head of both the left foot (P=.001) and the right foot (P=.017). The MDF of sEMG signals significantly decreased in the left (P=.001) and right gastrocnemius (P<.001).

Conclusions: Plantar pressure changes and sEMG signals effectively detect gastrocnemius muscle fatigue using the proposed wearable system, supporting the development of a wearable solution for detecting muscle fatigue suitable for home-use.

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KEYWORDS

muscle fatigue; plantar pressure sensors; wearable devices; home-based monitoring

Introduction

Muscle fatigue, characterized by the reduced ability to generate adequate force during repetitive contractions [1], affects performance across different groups and activities including daily activities of older adults as well as athletes during sports. Muscle fatigue disrupts the neuromuscular system and affects different aspects such as muscle strength, force production, and movement patterns, resulting in stiffness of the muscles and joints, impaired motor control, and poor balance [2], thereby increasing the risk of injuries. For instance, in badminton players, muscle fatigue impairs neuromuscular coordination, by reducing input from the foot sole receptors, and muscle force production, leading to weaker responses and decreased reaching distance performance [3]. Running-induced fatigue reduces lower limb muscle activity, decreases shock absorption capacity, and alters plantar pressure distribution [4], thus increasing the risk of running-related injuries such as stress fractures in the foot [5]. Mello et al highlighted how fatigue delays the gastrocnemius muscle's activation by 1 second relative to the center of pressure, thus impairing balance [6]. Furthermore, Morrison et al found that muscle fatigue in older adults (aged 60 - 79 years) significantly increased reaction times, postural sway, and fall risk compared to younger individuals (aged 30 - 59 years) [7].

Muscle fatigue can be detected through various methods, including blood lactate concentration [8], electromyography (EMG) [9], mechanomyography (MMG) [10], near-infrared spectroscopy (NIRS) [11], and kinematic parameters using inertial measurement units (IMUs) [12]. While the lactate concentration provides an estimation of global fatigue, it cannot monitor fatigue in real-time [8]. MMG, NIRS, and IMUs can be used in wearable forms; however, the use of NIRS and MMG has challenges owing to issues such as time lags, the use of

MMG has susceptibility to motion artifacts [13], and the use of IMUs needs further research regarding the relationship between kinematic parameters and muscle fatigue [14]. Surface electromyography (sEMG) is a widely used wearable method for real-time monitoring of local muscle fatigue by measuring myoelectric activity [15]. Fatigue reduces muscle fiber conduction velocity, shifting the sEMG power spectrum to lower frequencies (eg, decreased median frequency) and increasing signal amplitude. sEMG captures these changes and quantifies muscle fatigue using time-domain or spectral parameters [8]. However, the use of sEMG in a home setting is difficult, owing to the challenges of correctly attaching the electrodes and regularly wearing the device without assistance [16].

Adherence is a critical factor for effective daily monitoring, as meaningful and continuous data are required for accurate analysis [17]. Wearable devices integrated with mobile apps present promising healthcare solutions for home-based monitoring. The integration of hardware sensors and software mobile apps enables continuous and unobtrusive monitoring, thereby providing real-time data analysis that can support timely interventions [18]. A suitable alternative wearable approach for muscle fatigue monitoring is the use of plantar pressure sensors, which can be seamlessly integrated into a shoe's insole for daily comfortable wear. Wearable plantar pressure sensors in the foot insole are widely used for the detection of diabetic foot ulcers [19], gait analysis, and the measurement of the ground reaction force [20] and the center of pressure [6]. Muscle fatigue impacts body mechanics and alters foot loading patterns, measurable through plantar pressure at different foot regions. Considerable research has explored changes in plantar pressure following various physical activities linked to lower limb muscle fatigue, such as badminton [21], walking [22], and long-distance walking [23].

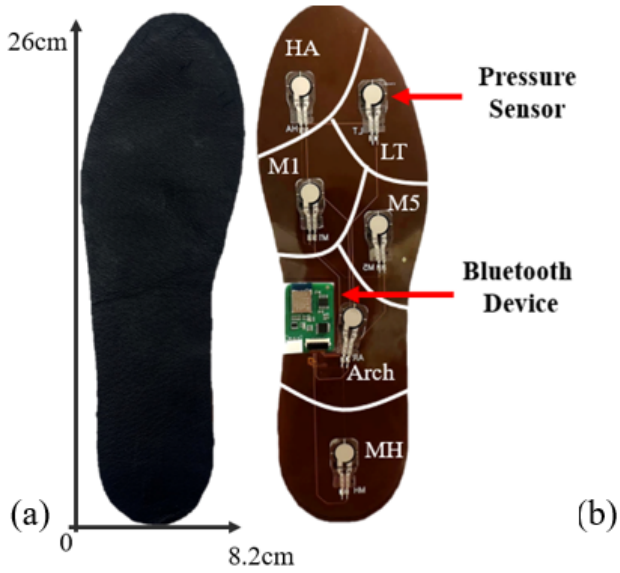
Despite the aforementioned advancements, wearable foot plantar systems for detecting muscle fatigue in everyday physical activities have yet to be designed. In this study, the effect of calf muscle fatigue in healthy participants was investigated using a self-developed wearable plantar pressure system that was suitable for daily use. The results can provide a muscle fatigue detection method for developing a wearable plantar pressure monitoring system

Methods

The Digital Foot Pressure System

A self-developed digital foot pressure system was utilized in this study. Figure 1 shows the wearable plantar devices for both the left and right feet as well as the measurements of the devices. Each device, designed to be worn comfortably with shoes, is equipped with 6 pressure sensors (A301 Flexiforce, Tekscan Inc.). The system also has a nRF52840 microprocessor (Nordic Semiconductor) used for the analog-to-digital converter measurement of foot plantar pressure, a wireless Bluetooth 5.0 module for data transmission, and a lithium-ion battery for power supply. The system operates with a sampling rate of 100 Hz, ensuring high-resolution data capture. The data from the 6 pressure sensors in both the left and right devices can be transmitted wirelessly in real time via Bluetooth to a custom-developed Android mobile app. This app facilitates real-time data display, analysis, and cloud storage, as shown in Figure 2. The pressure sensors are strategically arranged on the foot insole to cover 4 main plantar anatomical areas: the toes, metatarsals, arch, and heel. This general layout enables accurate measurement of natural gait; the layouts of the toes and metatarsals are further divided into 2 parts to capture plantar pressures along the mediolateral axis during walking [24].

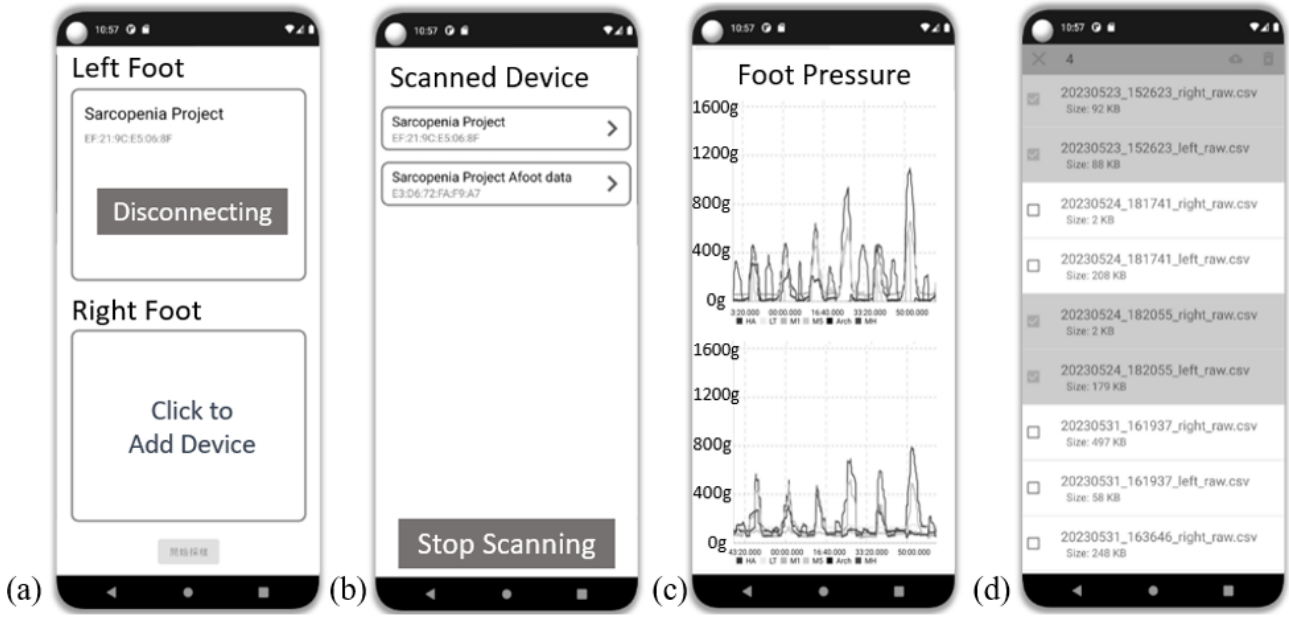
Figure 1. Wearable plantar pressure device in an insole format. (**A**) Foot insole with 6 regions of pressure measurements: hallux (HA), lesser toe (LT), first metatarsal (M1), fifth metatarsal (M5), arch, and medial heel (MH); (**B**) Coordinates of the 6 pressure sensors on the insole.



(b)

	X axis (cm)	Y axis (cm)
Hallux (HA)	5.8	21.3
Lesser Toes (LT)	2.4	21.1
First Metatarsal (M1)	6.2	16.2
Fifth Metatarsal (M5)	2.7	14.5
Arch	4.2	4.2
Medial Heel (MH)	4.7	3.9

Figure 2. Overview of the digital mobile app for the wearable plantar pressure device. (**A**) Bluetooth connection page for the devices on the right and left feet; (**B**) Bluetooth connectable device page; (**C**) real-time streaming graph showing plantar pressure data; and (**D**) Cloud storage for historical data.



Ethical Considerations

The research was approved by the Ethics Review Board of the Chung Yuan Christian University for Human Subjects Research (No. 8800-4-07-002). The participants were informed of the requirements and procedures of the entire experiment, and written consent was obtained before testing.

Subjects

A briefing session was conducted to familiarize the participants with the fatigue protocol and the walking test to be used in the research. Twelve healthy participants from the Chung Yuan Christian University, Taiwan, were recruited for the research. The mean (SD) age of the participants was 23.7 (2.6) years, and their mean (SD) weight was 62.4 (6.3) kg. The dominant limb of each participant was determined by identifying which foot would step out first once they started walking. The exclusion criteria included participants with plantar fasciitis or flatfoot and those who could not run independently for 5 minutes. Given that these foot disorders were excluded, experiments for minimizing variability could be performed. Then, suitable foot insole sizes were given to the participants.

Experimental Procedures

The experimental procedures were divided into 4 main steps. First, baseline tests were performed to measure the EMG of muscle activity and foot plantar pressure in both the legs. During the baseline test, the sEMG activities of the participants' gastrocnemius and rectus femoris muscles in the right and left legs were recorded using sEMG electrodes (T709, Comepa, France) and a data acquisition instrument (MP36, Biopac Inc., USA). The skin of each participant was cleaned with alcohol before the electrodes were attached. The sEMG muscle activities were recorded at a sampling rate of 2000 Hz. The plantar pressures at 6 locations in the left and right legs were measured simultaneously with sEMG. The plantar pressures were recorded using the wearable foot plantar device that was developed specifically for this study. Then, timed up-and-go and 10-meter walk tests were conducted; the participants were asked to rise from a standard chair, walk for 10 meters at their most comfortable speed, turn around, walk back. and sit down again [25].

After the baseline test, each participant was instructed to perform a fatigue exercise. All the participants were asked to place a weight-bearing apparatus on each leg and perform forefoot running for 5 minutes. The weight-bearing apparatus was 1/20th of a participant's weight [26]. sEMG data were collected from the gastrocnemius and rectus femoris muscles to capture the electrical activity associated with muscle contractions, and the wearable foot plantar pressure device was used to monitor changes in pressure distribution under the feet. This dual approach allowed the fatigue levels in both the muscles to be evaluated and quantified. After the exercise, the rating of perceived exertion (RPE) scale was used to assess and document each participant's perceived level of fatigue. Postfatigue measurements were recorded immediately after the fatigue protocol, while the participants performed timed up-and-go and 10-meter walk tests, and sEMG and foot plantar pressure measurements for both legs were collected.

EMG Muscle Fatigue Analysis

Three consecutive sEMG signals from the gastrocnemius and rectus femoris muscles were averaged for prefatigue and postfatigue analyses. The sEMG envelope was calculated from the raw sEMG signal through a 20 - 500–Hz finite impulse response bandpass filter. The signal was then processed via fast Fourier transformation to calculate the power spectrum median frequency (MDF) of the sEMG. A shift in the MDF to a lower frequency during exercise is considered localized muscle fatigue [27]. This method allowed researchers to determine whether muscle fatigue was induced in the gastrocnemius muscles, thereby increasing confidence in these data's correlation with foot plantar pressure data. The MDF is the frequency at which the EMG power spectrum is transmitted, and it is given by

(1)∑j=1MDF Pj=∑j=MDFM Pj=12∑j=1M pj,

where Pj is the power spectrum of the EMG at frequency bin *j*. The MDF splits the power spectrum of the EMG into two equal-amplitude regions.

The RPE Scale Analysis

The RPE scale was utilized to assess each participant's self-reported fatigue level. This subjective measurement tool is widely employed in the fields of physical activity, exercise, and sports to evaluate an individual's perceived effort and fatigue during physical tasks [28]. Participants rate their exertion based on sensations such as increased heart rate, breathing rate, muscle fatigue, and overall physical strain. The Borg RPE Scale, ranging from 6 to 20, is one of the most commonly used versions, with higher scores indicating greater levels of exertion [29].

Foot Plantar Pressure Analysis

Foot plantar pressure data, obtained using the developed digital foot plantar system and the commercial system, were simultaneously collected with the EMG data. The 6 plantar pressures in the left and right feet obtained in this research represent 6 anatomical areas of the foot: hallux (HA), lesser toe (LT), first metatarsal (M1), fifth metatarsal (M5), arch, and medial heel (MH). The peak pressures (Pa) in these 6 anatomical areas were analyzed and calculated from the raw plantar pressure data via MATLAB version R2022a (Mathworks Inc.). The measurements for the three consecutive prefatigue and postfatigue tests were averaged and compared. On the basis of the preliminary results, changes in the mean peak pressure of the 6 anatomical areas before and after the fatigue protocol were determined.

Statistical Analysis

In this study, the MDFs of the sEMG signals and the mean peak plantar pressures in each anatomical area for each participant before and after the fatigue protocol are presented as the means (standard errors). A paired *t* test with repeated measures was used to compare the MDFs of sEMG signals from the gastrocnemius and rectus femoris muscles before and after fatigue exercise. Then, a paired *t* test with repeated measures was used to detect significant differences in the 6 anatomical areas (ie, HA, LT, M1, M5, arch, and MH) before and after muscle fatigue exercise for the wearable plantar pressure system. All the statistical tests were performed with the significance level of $P<.05$.

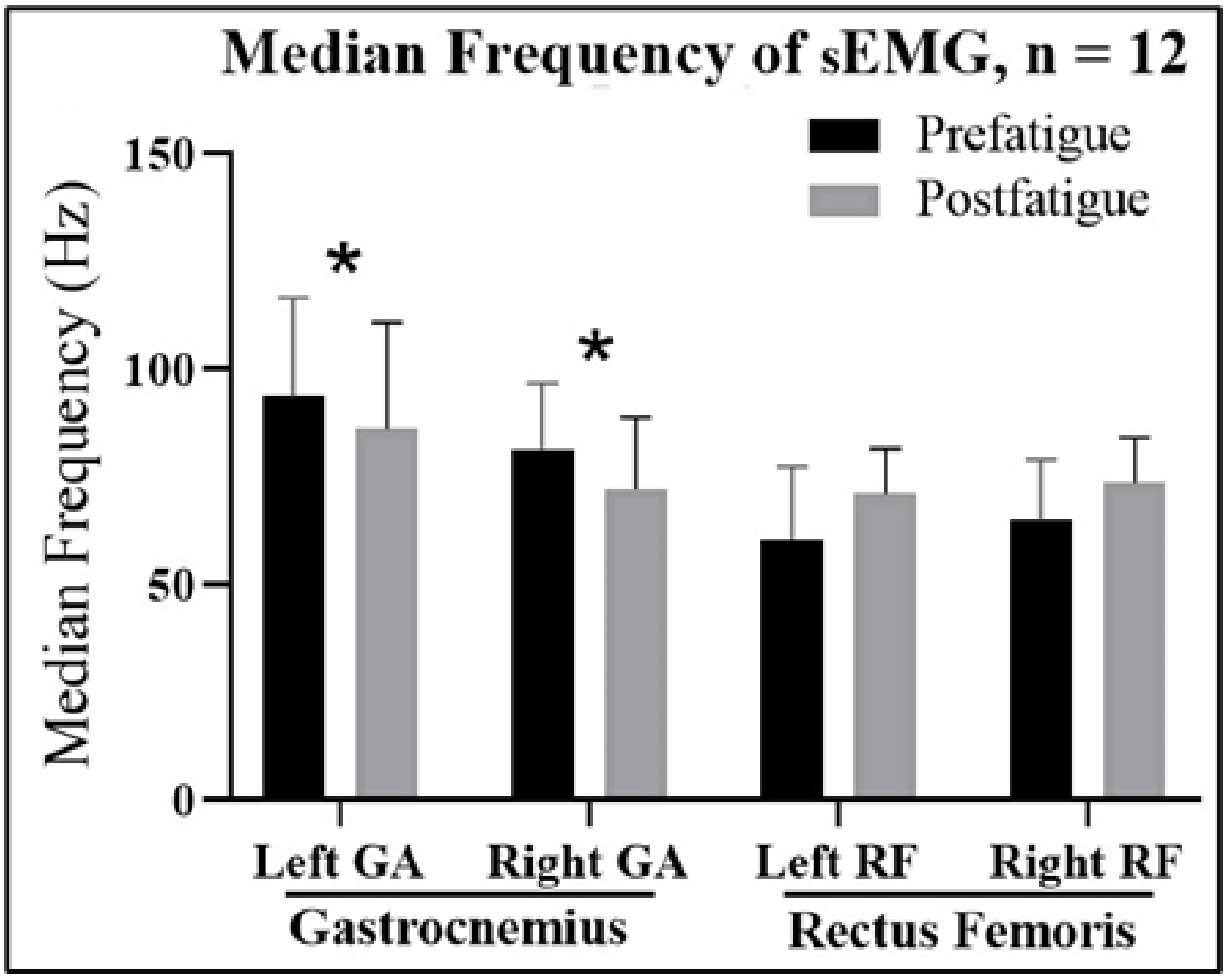
Results

The data for muscle fatigue, RPE, and mean plantar pressure were collected and analyzed using a paired *t* test.

MDFs of sEMG in Detecting Muscle Fatigue

The MDFs of the sEMG data of the gastrocnemius and rectus femoris muscles are presented in Figure 3. The MDFs (SD) of the sEMG data of the left and right gastrocnemius muscles significantly decreased from 93.6 (22.8) Hz to 86.1 (24.6) Hz in the left foot and from 81.3 (15.5) Hz to 72.1 (16.6) Hz in the right foot after exercise for muscle fatigue ($P=.001$ and $P<.001$, respectively). However, the MDF of the sEMG before and after muscle fatigue exercise did not significantly differ between the left and right rectus femoris muscles.

Figure 3. Medium frequency of the sEMG for the gastrocnemius (GA) and rectus femoris (RF) muscles in the left and right legs before the fatigue exercise (prefatigue) and after the fatigue exercise (postfatigue). sEMG data of the left and right gastrocnemius muscles significantly decreased after the exercise for muscle fatigue (*P*=.001 and *P*<.001, respectively).



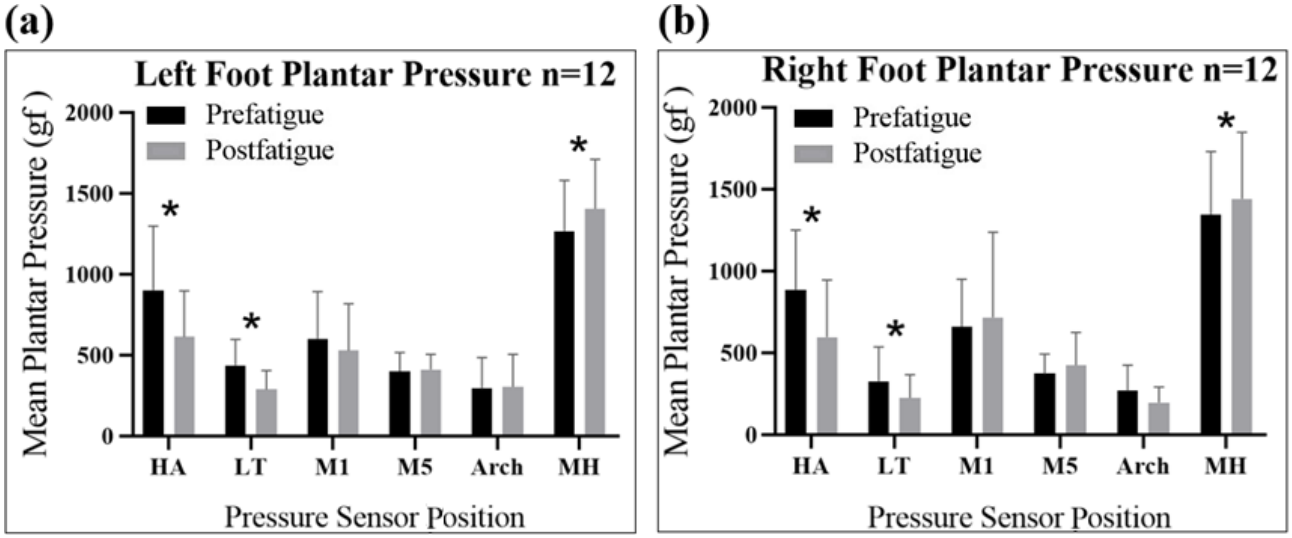
The RPE Scale in the Muscle Fatigue Protocol

The RPE scale was used in the experiment to assess the muscle fatigue levels of the 12 participants. All the participants reported that the level of fatigue in the gastrocnemius muscle was greater than that in the rectus femoris. The analysis of the average RPE scores revealed that the mean fatigue level for the gastrocnemius muscle was 14.3 (SD 1.3), whereas the mean fatigue level for the rectus femoris was 7.0 (SD 1.3). The significant difference in fatigue levels (P <.001) between the two muscles aligns with the analysis of MDF in the sEMG data. These findings confirmed that the gastrocnemius muscle experienced greater fatigue than the rectus femoris did during the experiment.

Foot Plantar Pressure in Detecting Muscle Fatigue

The data for the left and right feet (Figure 4A and B, respectively) were obtained using a developed digital plantar pressure measurement system. Figure 4 shows the changes in plantar pressure before and after fatigue. The changes were noticeable in terms of the plantar pressure at the HA, LT, and MH on both feet after gastrocnemius muscle fatigue. The pressure values at other locations also changed, but they were not statistically significant.

Figure 4. Mean peak plantar pressure before the fatigue exercise (prefatigue) and after the fatigue exercise (postfatigue) by sensor positions: hallux (HA), lesser toe (LT), first metatarsal (M1), fifth metatarsal (M5), arch, and medial heel (MH) in the (**A**) left foot: a statistically significant decrease in the mean plantar pressure peak values was observed in the HA (*P*=.003) and LT (*P*=.001), while the MH showed a statistically significant increase (*P*=.001) after the fatigue exercise; and (**B**) right foot: a statistically significant decrease in the mean plantar pressure peak values was observed in the HA (*P*=.001) and LT (*P*=.026). A significant increase was noted in the MH position after fatigue (*P*=.017).



The mean plantar pressure values were measured using the self-developed foot pressure system. A significant decrease was observed in the mean plantar pressure peak values in the HA of the left foot (*P*=.003) and right foot (*P*=.001) and in the LT of the left foot (*P*=.001) and right foot (*P*=.026). A significant increase was observed in the mean plantar pressure peak value in the MH position after fatigue in both the left and right feet (*P*=.001 and *P*=.017, respectively). The mean plantar pressure peak value in the right HA decreased by 32.6%, from 883.2 (366.8) gf to 595.1 (349.2) gf, and that in the left HA decreased by 31.9%, from 900.7 (396.2) gf to 612.8 (284.0) gf. The mean plantar pressure peak value in the right LT decreased by 31.1%, from 325.8 (210.6) gf to 223.7 (141.4) gf, and that in the left LT decreased by 33.9%, from 435.6 (162.0) gf to 287.8 (115.8) gf. The mean plantar pressure peak value in the right MH increased by 7.2%, from 1343.4 (385.7) gf to 1440.3 (406.8) gf, and that in the left MH increased by 11.0%, from 1265.5 (313.0) gf to 1404.9 (304.4) gf. The changes in the mean peak pressure in the M1, M5, and arch positions were not significant. However, the M1 and arch positions showed a change in the mean peak pressure in both the left and right feet. In contrast, we observed an increase in the mean peak pressure in the M5 position in the left and right feet of 12.5 (24.5) gf and 52.0 (79) gf, respectively. The details of the changes in the mean peak plantar pressures before and after fatigue exercise by sensor position via the wearable plantar pressure system are shown in Multimedia Appendix 1.

Discussion

Principal Findings and Comparison With Previous Works

The results of this study demonstrated that muscle fatigue in the gastrocnemius significantly affects the plantar pressure in the HA, LT, and MH regions in both the legs. In particular, the mean peak plantar pressure in the HA and LT regions significantly decreased and that in the MH regions significantly increased after 5 minutes of muscle fatigue exercise in the gastrocnemius compared with the value before the fatigue exercise. This finding was determined using the self-developed wearable foot plantar pressure system proposed in this research. Muscle fatigue exercise in this study induced muscle fatigue solely in the calf area, which corresponded with a significant decrease in the MDF of the sEMG of the gastrocnemius muscle but not in the MDF of the sEMG of the rectus femoris. As presented, sEMG is highly muscle-specific and effective for detecting localized muscle fatigue; it is not useful to detect muscle fatigue in deeper muscles like the tibialis posterior in the calf area [5]. Pressure sensors offer an alternative by measuring the fatigue in muscles through shifts in loading patterns, providing a broader and more accessible assessment.

The findings of this study align with existing literature, showing that muscle fatigue in the lower limb induces a significant decrease in the mean pressure in the HA area and a shift in plantar pressure from the forefoot to the hindfoot [21,23,30,31]. This could be due to individuals starting to adapt their plantar pressure pattern from the forefoot to the hindfoot to avoid overuse of the forefoot [23]. The literature also revealed a significant decrease in the first metatarsal region. Similar findings were observed in this study, but the results in the first and fifth metatarsals and arch regions were not statistically significant. This discrepancy could stem from differences in fatigue protocols, as more intensive activities, such as 30-minute runs, lead to greater pronation and increased medial midfoot loading, whereas walking shows no such midfoot differences [32-35]. Additionally, subject variability, including anatomical factors such as arch height and leg-length differences, may contribute to variance in medial midfoot pressure [30,36]. For instance, flat feet increase loading on the medial longitudinal arch, while high arches shift the load to the lateral edge [37].

In this study, a shift in loading from the forefoot region including the HA and LT to the hindfoot including the MH after 5 minutes of fatigue exercise results in gastrocnemius muscle

fatigue. This finding could serve as an indicator for real-time monitoring of lower limb muscle fatigue, aiding in the prevention of injuries or falls in older adults and athletes. When a healthy person participates in sports such as badminton or running, muscle fatigue of the lower limb may be expected. These fatigued muscles can result in compromised reaction times, joint stability, and dynamic balance, thereby reducing impact absorption, which heightens the risk of injuries [21,38]. Athletes and coaches should monitor for fatigue alerts and ensure timely rest to recover muscle strength, preventing performance issues and injuries [39]. For older populations, particularly those at high risk of falls, such as patients with sarcopenia [40] or stroke [41], this system enables continuous home-based monitoring of plantar pressure patterns. A shift in plantar loading from the forefoot to the hindfoot could trigger alerts for rest to individuals or caretakers, minimizing fall risks associated with muscle fatigue.

Usability is a key factor in the adoption of digital health technologies such as the proposed wearable plantar pressure system [42]. Compared to sEMG, MMG, NIRS, or IMU wearable devices, its shoe-based form offers a user-centered design for daily wear, eliminating the need for users to remember and attach it correctly, thereby enhancing acceptance and compliance in home settings. A previous study highlighted the importance of face-to-face interactions with physicians in increasing their trust in digital health technologies [43]. Clinical or expert recommendations play a critical role in encouraging patients to adopt the device. The system's ability to support effective remote patient management allows both users and experts to review and monitor past performance or clinical conditions, thus fostering engagement [44]. These features, combined with its user-friendly design and portability, enhance the system's feasibility and scalability for home-based applications, promoting widespread adoption.

Limitations

This study has some limitations. First, direct evidence for the development of muscle fatigue in the gastrocnemius could not be provided by this study, given that muscle force was not directly measured. Instead, the MDF of the sEMG signal, which shifted to a low frequency, was used as an indicator of muscle fatigue; this approach is a common research method for measuring muscle fatigue [45-47]. The decrease in MDF was likely caused by changes in the properties of the muscle fibers, such as decreased conduction velocity and increased muscle fiber recruitment [48]. The MDF of the sEMG measurement might also be affected by factors other than fatigue, such as the muscle fiber type [49] and motor unit firing rate [50]. However, this limitation was compensated by the RPE scale questionnaire. Second, the effects of fatigue were measured only in the rectus femoris and calf gastrocnemius muscles; the effect of upper leg fatigue on plantar pressure was ruled out. sEMG measurements of other calf muscles, such as the tibialis anterior, can provide insights into a particular calf muscle's interaction with plantar pressure. The short test duration and limited wearing time (10 - 20 min) in this study may not accurately represent real-life scenarios, necessitating extended testing to better simulate prolonged activities. In addition, wearable devices must adapt to various environments and wearing conditions, as factors such as daily wear and tear, temperature, humidity, flooring, and uneven terrain can impact sensor performance.

Conclusions

The results of this study demonstrated a significant decrease in the mean plantar peak pressure in the HA and LT and an increase in the mean plantar peak pressure in the MH as an indicator of the onset of muscle fatigue in the gastrocnemius. This work is an exciting proof-of-concept outcome showing that muscle fatigue in the gastrocnemius can be detected via a wearable plantar pressure system. These findings can be used to further develop a wearable lower limb muscle fatigue monitoring system for minimizing injury risk in sports or during the daily activities of older adults.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Mean peak plantar pressures before and after fatigue exercise by sensor position via the wearable plantar pressure system system.
[DOCX File, 8 KB - humanfactors_v12i1e65578_app1.docx]

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Abbreviations

EMG: electromyography
HA: hallux
IMU: inertial measurement unit
LT: lesser toe
M1: first metatarsal
M5: fifth metatarsal
MDF: median frequency
MH: medial heel
MMG: mechanomyography
NIRS: near-infrared spectroscopy
RPE: rating of perceived exertion
sEMG: surface electromyography

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Enhancing Methodological Rigor in Mobile Health Care Research

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KEYWORDS

letter to the editor; health care professionals; mobile health care; technical training; cross-sectional survey; mobile; China; web-based questionnaire; logistic regression; mhealth; mobile health

Tang et al's recent study published in *JMIR Human Factors* [1], titled "The Use of Mobile Health Care Among Medical Professionals in the Sichuan-Chongqing Region: Cross-Sectional Survey Study," captured my attention. Their analysis of mobile health (mHealth) device use and influencing factors, using chi-square and multivariable logistic regression analyses, revealed a significant association between age and mHealth use. This study provides valuable insights from China's western region.

However, I would like to offer a few comments and suggestions that I believe would further enhance the study's methodology and findings.

First, the study's reliance on a web-based questionnaire may introduce potential selection bias, as respondents, by nature of accessing web-based surveys, may be more likely to use digital devices and have a stronger interest in digital health in general. A more diverse, mixed-methods approach to questionnaire distribution could help mitigate this potential self-selection toward mHealth use and prevent the exclusion of individuals with limited experience or interest in mHealth.

Second, the study could benefit from a standardized and rigorous methodological framework for survey design and reporting. For instance, categorizing age into three broad groups may overlook essential trends. A finer measurement scale for satisfaction and usage, such as a Likert scale, could provide deeper insights into health care professionals' attitudes. Furthermore, for questions where "uncertain" responses outweigh "yes" or "no" responses, a qualitative or mixed-methods research approach could yield a more nuanced understanding of the underlying reasons. Finally, incorporating years of work experience as a variable could add valuable insights, given its potential correlation with age. Unlike professional titles, years of work experience could provide a more direct measure of professional tenure, potentially enriching the data analysis.

Third, ethical considerations of this study merit further attention. Identifying specific hospitals in the report may compromise confidentiality. Additionally, the exemption of review by an institutional review board (IRB) raises concerns, as the study involves gathering potentially sensitive information from human participants (ie, health care professionals) regarding personal perspectives, workflows, and technology use. Such studies often warrant an ethics board review to protect participant privacy, minimize psychological or social risks, and ensure adherence to ethical standards [2].

Fourth, before conducting logistic regression analysis, normality tests on both independent and dependent variables are recommended to confirm the validity of the chosen statistical methods [3]. If data are not normally distributed, adjustments should be considered.

Lastly, as noted in the "Limitations" section [1], the reliance on convenience sampling may affect the study's generalizability. Only public, district-level hospitals were included, excluding primary and tertiary institutions—this limits the representation of China's complete health care hierarchy in the analysis. Furthermore, only urban areas were sampled, overlooking rural populations. Women comprised 77.1% of the study sample, raising questions about gender representation. A multi-level sampling approach would likely yield a more comprehensive and representative dataset.

To conclude, I would like to highlight that these feedback points are not to challenge the integrity of the authors' work. Instead, I hope they can contribute to ongoing discussions on mHealth research and the development of robust methodologies in this field.

Conflicts of Interest

None declared.

Editorial Notice

The corresponding author of the publication "The Use of Mobile Health Care Among Medical Professionals in the Sichuan-Chongqing Region: Cross-Sectional Survey Study" declined to respond to this letter.

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Abbreviations

IRB: institutional review board
mHealth: mobile health

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Research Letter

Older Adults' Experiences With an Online Survey

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Abstract

The study explored older adults' perceptions after participating in an online survey about medication decisions, finding that approximately 80% of participants provided positive feedback about the research methodology and their experience.

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KEYWORDS

older adults; gerontology; geriatric; older; aging; online; internet; survey; questionnaire; research engagement; engagement; study subject; participant; medication decisions

Introduction

Older adults are underrepresented in research, often due to age-related biases and stringent exclusion criteria; this limits generalizability and leaves knowledge gaps [1].

The increasing prevalence of online research has the potential to increase older adult participation, given the rising internet use among this demographic [2]. While research has primarily focused on improving recruitment of older adults, an understanding of their experiences of online research is needed to effectively engage older people [3]. While most surveys include some form of piloting, they rarely capture or share participants' perceptions of the research process. We sought to explore older adults' perceptions after participating in an online experimental survey, given the potential high accessibility of this type of research.

Methods

Overview

We previously reported the main findings from a vignette-based online experiment conducted among adults aged 65 years and older from Australia, the Netherlands, the United Kingdom, and the United States [4]. Participants were recruited for this 15-minute survey through a panel of internet users administered by Qualtrics Research Panels. The study focused on contextual factors influencing how older adults (mean age 71.5, SD 5.1 years) think about deciding to stop a cardiovascular disease medication. In this study, we conducted a content analysis of free-text comments (Textbox 1). The final analysis framework included 17 codes that were subsequently consolidated into 14 themes. Descriptive statistics were used to assess the frequency of each theme.

Textbox 1. Summary of methodology for the content analysis.

1. A vignette-based online experiment was conducted among adults aged 65 years and older from Australia, the Netherlands, the United Kingdom, and the United States using sampling quotas to ensure balanced representation by country and gender. This study was registered at ClinicalTrials.gov (NCT04676282). At the end of the survey, participants were provided the opportunity to leave "any comments about this study."
2. A content analysis was conducted among participants who received the vignette about a hypothetical patient, Mrs EF. Participants from the Netherlands were excluded, as the study team for the content analysis was not fluent in Dutch.
3. Study authors read through the comments to inductively generate codes.
4. Two investigators (SEV and YM) independently coded comments, resulting in >80% agreement.
5. All discrepancies in codes were discussed until consensus was reached.

Ethical Considerations

The online experiment was registered at ClinicalTrials.gov (NCT04676282) and was deemed exempt by the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board (HUM00183129); by extension, a waiver of consent was granted. All data were collected anonymously. Participants were compensated based on the terms of their panel agreement.

Results

Participants (N=1789) most frequently did not provide any feedback in the free-text comment field (n=784, 43.8%) or wrote that they had no comments (n=487, 27.2%). Three participants (0.2%) gave unclear statements.

Participants' comments (n=515, 28.8%) were primarily positive (415/515, 80.6%), such as that the study was interesting (116/515, 22.5%). Themes and representative quotes are reported in Table 1. Participants said it made them think about their health (80/515, 15.5%) and some participants shared further health information about the study topic (48/515, 9.3%). Participants provided feedback on how to improve the study, categorized as question-specific comments (21/515, 4.1%), general suggestions (12/515, 2.3%), or country-specific comments (3/515, 0.6%). Few participants (16/515, 3.1%) provided negative feedback about the survey.

Table 1. Older adults' feedback about an online survey using a hypothetical vignette by theme, with representative quotes among respondents who provided feedback (n=515).

Themes	Representative quotes (participant code)	Participants, n (%)
Positive feedback (n=415, 80.6%)		
Interesting	• "An interesting study" (919) • "This was an interesting survey to complete" (2200)	116 (22.5)
Thought provoking	• "Interesting and insightful. Made me think a little more about how best to manage my health" (1872) • "Very good survey to ponder thoughts and beliefs" (481)	80 (15.5)
Positive feedback	• "Great stuff. Keep up the good work" (2574) • "Very good" (764)	67 (13)
Thanks for opportunity to participate	• "Thanks" (42)	43 (8.3)
Positive feedback about survey questions or structure	• "Love the format, so easy to see, follow, and understand" (1904) • "Very good questions regarding whether or not to stop a medication when you've been on it for an extended time" (2026)	35 (6.8)
Enjoyed taking survey	• "Enjoyed it" (328) • "Love doing your studies" (287)	34 (6.6)
Unusual study design	• "Very different enjoyed the variety" (540) • "Unusual but interesting" (1853)	19 (3.7)
Interested in results	• "Interested in purpose of results" (1863) • "Very interesting! Now I need to see the final results" (3481)	15 (2.9)
Interested in future studies	• "Great study, I'd do more" (4815) • "Need more like this" (2516)	6 (1.2)
Neutral feedback (n=48, 9.3%)		
Shared personal experience	• "I am afraid of going to see the dr for worries about my health" (1526) • "Thanks; my prescription drugs fall under the Federal Government program where they are funded nearly 100%" (2645)	48 (9.3)
Negative feedback or suggestions for improvement (n=52, 10.1%)		
Question-specific feedback	• "The percentage charts were confusing" (2403) • "One question said check all that apply but only one was allowed" (4279)	21 (4.1)
Negative feedback	• "Boring" (1409) • "Too many generalizations" (1102)	16 (3.1)
General suggestions for improvement	• "Consider adding a progress bar to the survey" (2027) • "Good study could be shorter" (2433	12 (2.3)
Country-specific feedback	• "Some questions are designed for the USA" (1471) • "Prescription insurance? In UK if you are over 65 prescriptions are free" (4075)	3 (0.6)

Discussion

Among older adults who provided feedback about their experiences completing an online survey, approximately 80% (415/515) of the comments were positive. Our findings signal general acceptability of the methodology, and we have implemented the practical feedback to improve our online surveys. We have become more mindful of the survey length, selected straightforward question types, and have conducted pilot testing in all target countries to ensure that questions are appropriate for all participants.

Our study had several limitations. First, less than one-third of the study participants provided any comments. Second, participants were asked if they had any comments, as opposed to more specific questions about their experience taking the survey. Finally, we acknowledge that we coded a single primary theme per comment given the short statements that were provided.

With an aging population who may spend many years in retirement, participating in research can offer benefits such as reducing social isolation and loneliness, fostering a sense of

purpose, and providing mental stimulation, and it may provide monetary incentives [5]. While our online study lacked the social benefit of in-person interaction typical of traditional research, participants reported enjoying the survey; they found it prompted self-reflection on their health, and they expressed interest in the study's outcomes and future research.

Online research is becoming more prevalent; therefore, it is important to make sure this methodology is inclusive of older adults [5]. More than half of adults older than 65 years use the internet, yet they are the least likely to have a home computer [6]. While some researchers attribute this limited use to age-related functional decline, others argue that the main barriers are negative attitudes such as fear, anxiety, and low motivation—barriers that are modifiable. Anxiety about using the internet and digital technologies often leads to self-imposed limitations and low confidence, with older adults frequently underestimating their knowledge and abilities compared to younger users [6]. This underscores the importance of studies like ours that highlight the positive experiences of older adults in online research.

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Authors' Contributions

Concept and design: KRW, SEV
Acquisition, analysis, or interpretation of data: all authors
Drafting of the manuscript: all authors
Critical review of the manuscript for important intellectual content: all authors
Statistical analysis: SEV
Obtained funding: SEV
Administrative, technical, or material support: KRW
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Conflicts of Interest

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