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Original Paper

Attitudes and Preferences on the Use of Mobile Health Technology and Health Games for Self-Management: Interviews With Older Adults on Anticoagulation Therapy

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Abstract

Background: Older adults are at substantial risk for cardiovascular disorders that may require anticoagulation therapy. Those on warfarin therapy report dissatisfaction and reduced quality of life (QOL) resulting from the treatment. Advances in the area of mobile health (mHealth) technology have resulted in the design and development of new patient-centric models for the provision of personalized health care services to improve care delivery. However, there is a paucity of research examining the effectiveness of mHealth tools on knowledge, attitudes, and patient satisfaction with treatment, as well as self-management, adherence to therapy, and QOL in older adults with chronic illness conditions requiring long-term warfarin therapy.

Objective: The objective of the study was to explore the attitudes and preferences of older adults on warfarin therapy regarding the use of mHealth technology and health games to gain skills for self-management.

Methods: We conducted group and individual interviews with patients (60 years or older) on warfarin therapy at two anticoagulation clinics affiliated with an academic medical center. We held 4 group and 2 individual interviews, resulting in 11 patient participants and 2 family caregiver participants. We used structured questions on three topic areas including medication self-management strategies, mHealth technology use, and health games for exercise. We demonstrated some commercial health apps related to medication management, vitamin K content of food, and a videogame for balance exercise. Discussions were audiotaped and transcribed verbatim. Common themes were drawn using content analysis.

Results: The participants reported awareness of the importance of staying on schedule with warfarin therapy. They also acknowledged that negative experiences of friends or family members who were taking warfarin influenced their desire to keep on schedule with warfarin therapy. In addition, the participants expressed that the use of mHealth technology may be helpful for medication management. They also expressed the need for family support in the use of health technology devices. Moreover, the participants discussed concerns and challenges to use health technology and health games, and provided suggestions on ways to make mHealth technology and health games elder-friendly.

Conclusions: These findings indicate that our older adults on warfarin therapy are interested in mHealth technology specific to warfarin medication management and health games. Further research needs to be done to validate these findings. Elder-friendly designs, technology support, and physical safety using mHealth technology may be useful in this population. These findings can be used to inform a larger study to design and test an elder-centered mHealth technology in this target population.

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KEYWORDS

anticoagulation therapy; health apps; health games; mobile health technology; self-management

Introduction**mHealth Technology and Older Adults**

Advances in the area of mobile health (mHealth) technology and improvements in information technology have resulted in the design and development of new patient-centric models for the provision of personalized health care services [1]. Technological innovations in health care can potentially promote healthy aging and reduce disparities by providing more precise and individualized health care services to patients [1]. In addition, mHealth devices and telehealth platforms support disease management for patients who use the Internet and other electronic communication tools to connect with family and friends and communicate with health care providers [2]. Many mHealth apps available in the market were designed for pediatric patients (eg, asthma, diabetes) and adult patients with chronic conditions (eg, diabetes, heart failure) [3]. However, older adults with chronic diseases can also be end-users of such new health technologies. mHealth technology can potentially empower older adults in self-management and can simplify the complex care systems that many older adults with chronic conditions face [1].

Along with the rise of mHealth technology use in chronic disease treatment, health games including virtual reality and interactive gaming have gained increased popularity in the health care industry as a promising approach for the delivery of health education and services [4,5]. They are also being used as tools for enhancing self-care behaviors and for increasing adherence to therapy [4,6,7]. Research has also shown that the use of health games for exercise (eg, Wii) improves physical function such as balance [8-10], and enhances awareness of risk factors and self-management in a variety of patient populations [5,11,12].

Warfarin Therapy for Anticoagulation

Older adults who are at substantial risk for cardiovascular disorders including atrial fibrillation, valvular disease, venous thromboembolism, and heart failure require long-term oral anticoagulation treatment (ie, warfarin therapy) [13-15]. Warfarin has been used for several decades in a variety of clinical settings in many countries to prevent and treat patients with thromboembolic risk. Although new oral anticoagulants have been recently introduced and approved by the United States Food and Drug Administration, warfarin is still the most common anticoagulant for patients with thromboembolic risk. Wide spread coverage by health insurance plans in the United States to cover the new oral anticoagulants continues to be a challenge.

Despite the proven benefits from warfarin therapy, older adults report dissatisfaction and reduced quality of life (QOL) resulting from the treatment, leading to poor adherence and decreased treatment efficacy [16,17]. Dissatisfaction with treatment has been attributed to a variety of reasons including the need for frequent visits to health care provider clinics to monitor international normalized ratio (INR) [18], lifestyle limitations

(eg, restrictions on diet and activities) [19], and fear of potential side effects (eg, bleeding and/or bruising) [20,21].

Such obstacles, as reduced QOL, have prompted the search for alternative strategies (eg, mHealth) to improve attitudes toward warfarin therapy and reduce perceived barriers to ensure that older adults who require anticoagulation therapy are more optimally and consistently treated [22-25]. Moreover, studies showed that the relationship among patient, health care providers, and tailored educational programs in consideration of age differences should be taken into account for a better warfarin management [26,27]. However, there is limited research on the use of mHealth technology to promote adherence to anticoagulation therapy, and also enhance QOL in older adults on warfarin therapy.

The current study reported in this paper is part of a larger study proposing to expand current mHealth infrastructure, and to broaden its impact to older adults requiring warfarin therapy. The overall goals of the parent study are to design and test a theory-based, culturally appropriate, elderly centered mHealth intervention, and to examine patient satisfaction with and feasibility of the intervention. The purpose of the present study was to explore the attitudes and preferences of older adults treated with blood thinners regarding the use of health technology apps and health games to gain skills for self-management. We have used the findings reported here in the development of an mHealth-based intervention for the larger parent study.

Methods**Participants**

We held a series of group and individual interviews with older adults on warfarin therapy. The patients were eligible if they were 60 years or older, taking warfarin, and speaking English. Exclusion criteria were: (1) diagnosis of irreversible conditions likely to affect 6 month survival or ability to participate in the study, (2) living in a long-term care facility, or (3) cognitively impaired (evidenced by documentation of dementia or delirium in medical records). The level of cognitive impairment of the participants was also evaluated by health care providers (ie, pharmacists who encounter patients on anticoagulation) when referring the participants, and evaluated by the investigators at the time of interviews. In addition, caregivers (age ≥ 18) of the eligible patients were also included in the discussion if they accompanied the patient participants.

Procedures

After obtaining approval for the study from the University of California, Irvine Institutional Review Board (IRB), we used passive and active recruitment strategies from October 2012 through March 2013. First, we recruited the participants attending two anticoagulation clinics affiliated in an academic medical center via flyer postings. Second, pharmacists who encountered the patients at the anticoagulation clinics provided study information sheets to the potential participants. Last,

investigators obtained the eligible patient names and phone numbers from the pharmacists at the anticoagulation clinics and contacted the potential patients to inform them about the study and recruit them to participate.

Each group session lasted approximately 60-120 minutes and included 2-6 participants. We also conducted individual interviews if only one participant showed on the day of the scheduled group meetings. All of the group or individual interviews were held in conference rooms within the anticoagulation clinics or the hospital. All of the participants were provided with a study information sheet including the purpose of the study, research members' contact information, study procedures, and potential benefits and risks associated with study participation. The University of California, Irvine IRB, did not require written informed consent. Research members (1 moderator and 1 assisting research staff) conducted all sessions.

Prior to the discussion, the participants were asked to fill out a brief paper-based survey, including questions on demographic information and participants' experiences with computers, health technology aids, and health related computer/videogames. We provided magnet reading glasses for the participants to wear, or we read survey questions out loud as needed. During the session, the participants discussed strategies and barriers to medication self-management, as well as use of mHealth technology and health games. The questions asked are presented in Table 1. We demonstrated a few commercial health apps, including a medication reminder app and a Vitamin K food content app, as well as a commercial videogame for exercise. Then, we asked the participants to use each one briefly and share their opinion on each mHealth app. The patient participants received US \$30 cash each for their participation after the group meetings/interviews were completed. All discussions were audiotape recorded, and the recordings were then transcribed verbatim.

Table 1. Interview questions.

Interview questions	
I. Medication self-management related	
	1. Have you ever skipped taking your blood thinner?
	2. What are some reasons that you have skipped doses?
	3. What are some strategies that you have used to manage your medications?
	4. How well did those strategies work for you?
II. Health technology apps (including computers) related	
	1. How comfortable are you using computers or electronic devices?
	2. What are some of the reasons that you don't use computers or electronic devices more often? (barriers)
	3. What are some things that would help you feel more comfortable using these devices?
III. Computer/video health games related	
	1. What kinds of computer games or videogames have you played before?
	2. What things make videogames or computer games more enjoyable for you? (Do you like games to move around, do you like to play with other people?)
	3. What things make it more difficult for you to enjoy computer games or videogames?
The commercial apps that were demonstrated	
	1. Medication monitor app, the app is designed to manage any of person's pills or medications, taking pills on time with the app, preventing missing taking pills because of so many things to do or bad memory.
	2. Vitamin K app, the app is designed for people who take warfarin so they need to monitor their foods and warfarin interaction. The app provides Vitamin K level in foods. Users can search food by categories including fast foods, fruit and vegetables, meat and fish, dairy and egg, grain and pasta, and more. Vitamin K levels are rated by colors (Black-extremely high in Vitamin K, Red-high, Yellow-moderate, Green-low, White-extremely low).

Data Analysis

Data analyses were conducted using Atlas.ti 7.0 qualitative data management software (Atlas.ti Scientific Software Development

GmbH). The transcripts were analyzed for emergent themes using content analysis based on the principals of grounded theory [28]. Grounded theory allows for an inductive theory-building approach to coding, which does not require a

priori theory, but provides a road map through the process of analysis of qualitative data [28]. All transcripts were read and coded by 3 independent raters. The subsequent primary codes were discussed as a team by the 3 raters (including the moderator) and a qualitative research method expert to create consensus codes. There were 3 research team members (2 coders including the moderator, and 1 experienced qualitative methodologist) that reviewed the consensus codes and synthesized them into common themes, including main themes and subthemes. Then, another experienced qualitative nurse researcher independently reviewed the common themes and compared them with all of the transcripts to verify the quality of themes and relevant quotes.

Results

Participant Information

There is an appendix that presents the participant demographic information and their experiences with the use of computers, health technology, and health games (see [Multimedia Appendix 1](#)). An abbreviated version of this information is shown below in [Tables 2](#) and [3](#). There were 8 male patients and 3 female patients that participated in the study. A daughter who was a caregiver of a male patient, and a spouse caregiver of a male patient also participated in the discussion. The mean age of the 11 patient participants was 75 years (SD 7.5). The majority (8/11, 73%) completed high school or higher. There were 10/11 participants that reported that they lived with family.

Table 2. Participants' demographic characteristics.

Demographic characteristics	Frequency, N=11
Age (year)	
Mean (SD)	74.9 (7.5)
Median	75
Range	61-89
Gender (male)	8
Ethnicity/race	
Caucasian	6
Hispanic	3
Asian	2
Education- high school completion or above	8
Living situation- living with family (vs living alone)	10
Currently employed	2
Insured	10
Having a primary care provider	9
Comorbidities	
Stroke	4
Diabetes	3
Hypertension	3
Arthritis	3
Heart failure	2
Atrial fibrillation	1
Lupus	1
Multiple comorbidity (≥1)	5
Years taking blood thinner	
Mean (SD)	5.45 (4.8)
Median	5
Range	3 weeks-6 years
Have ever skipped taking blood thinner? (yes)	6

Table 3. Participants' technology related experience.

Computer experience	Frequency, N=11
Have a home computer	6
Use a computer at all including at home, library, community center, other places	6
Reasons for computer use	
Internet and email	6
Word processing	4
Scheduling (calendar or reminder)	2
Managing household finances	0
Photos or music	0
Playing games	0
Other	1
Frequency of computer use	
Never	5
Once per month or less	0
2-3 times per month	0
Every week	0
Every day	5
Have ever used a smart phone/tablet for health apps such as medication reminders or weight management (yes)	2
Frequency of health apps use	
Once per month or less	2
Have ever played computer/video games (yes)	
Computer games	3
Video games (eg, Wii, PlayStation, Xbox, etc)	2
Games on phones/tablets	1
Frequency of game playing	
Never	10
Once per month or less	1

Medication Self-Management

The participants discussed strategies that they used to manage all their medications including blood thinners (eg, warfarin), and reasons for skipping medications. In general, most of the participants reported that they were able to follow the medication regimens as prescribed, and were not prone to skipping medications. However, they described special circumstances that led to skipped medication doses.

Strategies for Managing Medications

Most of the participants attributed their adherence with their medication regimen to having developed consistent self-monitoring strategies, such as taking blood thinner pills at the same time every day or using tools to help keep track of their regimen. These tools include digital reminders on a cell phone or alarm clock, written reminders on index cards or calendars, and organizational devices such as pill boxes, dishes, jars, and bottles to divide up the correct type and number of pills to be taken in a given time period. There was one

participant that further elaborated that he created backup plans, such as keeping an extra dose of medication in the car, in case he forgot to take his pills at home. Some of the participants stated that they had the support of family members and caregivers who helped remind them to take their medication,

My wife, who works for the school system, has her smartphone with her 24 hours a day, and she programmed the time at 5:00pm and at 8:00pm an alert, and if I'm home, she tells me. If I'm not home, she will call me, "Take your medicine". So my wife actually reminds me every day...so that's my plan.
[Male participant, age 74]

Most of the participants also spoke about their awareness of the importance of staying on schedule with their warfarin. For some, learning about the negative experiences of friends or other family members who struggled to remember doses, and consequently had problems with clotting, served to heighten their awareness of the importance of warfarin. There was one

participant that shared a story about her daughter-in-law's experience,

She ended up with some clotting...That knowledge from dealing with my family having it, my daughter-in-law at first was taking it at different interims and then [her doctors] finally realized that she didn't realize and told us, "no, you have to take it at a specific time"...so I approached it with that knowledge. [Female participant, age 75]

For some, having clear instructions from their health providers about why and when to take warfarin was an important component to their adherence. Some of the participants stated that being knowledgeable about blood clots made them realize it was something they did not want, and so taking warfarin was seen as "good" and "preventive". Some of the participants reported that their doctors further provided them with information about foods high in vitamin K, which helped them to better manage the foods they ate to prevent drug interactions.

Reasons for Skipping Medications

The participants reported that from time to time, they might skip a dose of medication for a variety of reasons. The most commonly cited reason was that skipping occurred when their daily routine was interrupted or when they were distracted by something. There was one participant that explained, "You have a big break in your normal routine and you're out of your normal mode and it just slips by" [Male participant, age 74]. Sometimes the participants forgot a dose because they were "busy doing something" so that keeping up with the dose got "lost in the shuffle". For one participant, being on multiple medications and caring for his grandchildren sometimes meant that,

Once in a while, they run me around and sometimes I forget. I'll go all day long and I think, I didn't even take any pills. [Male participant, age 80]

For some, skipped doses were a result of being forgetful. This meant that they forgot to take a dose, or forgot whether or not they had already taken a dose. Skipping medications also occurred as a result of doctor's orders to prepare for surgery. However, the directions received from doctors for skipping medications was sometimes inconsistent and confusing. For instance, one participant stated that in preparation for a surgery, his surgeon directed him to be off warfarin for 5 days, but that another physician directed him to be off for 2 days. He stated,

So I go back to the [surgeon] and tell the nurse and the nurse says, "that would be all right". So I'm off maybe two days before and two days after. [Male participant, age 80]

Health Technology for Medication Management

The participants were asked about their level of comfort with using computers and various types of technological devices, including mobile phones and tablets. They were also asked to talk about their experience with playing computer or videogames, and to give their thoughts about a variety of health related games and medication management apps on mobile devices, such as mobile phones or tablet computers.

Participants Without Technological Experience

Those who expressed a lack of experience with computers and other technological devices, such as smart phones and tablets, mostly cited reasons such as lack of interest, patience, knowledge, training, or that it was challenging to learn or a "waste of time". Some felt that electronic devices were expensive for people on a "limited budget", and that these devices may be better suited for people with a "bigger salary". There was one participant that stated that others did not expect her to use or know how to use technology because of her age. She stated,

[My doctor] didn't ask me [about Skype]. Probably thought I was too old and didn't know how or something. [Female participant, age 75]

Participants Without Technological Experience for Health

When prompted to comment on their thoughts about technology specifically for health or medication management, the participants with no reported experience in using technology mostly stated that nontechnological methods were "simple" and easy to use. For example, some of the participants stated that although a pill monitor app on a phone or tablet may be useful for some people, a manual pill box was "convenient" and "works well". There was one participant that was only on one medication, so she was not concerned about her ability to manage her medication, and did not feel that it was necessary to use an app for reminders. Some of the participants talked about the ease of medication refills without the use of technological reminders or alerts because their doctor coordinates with the pharmacy, and they get telephone calls from the pharmacy when they have medications to pick up. However, some of the participants also said that medication management apps might be useful for those who are "forgetful", are cognitively impaired, or have a difficult time keeping track of appointments.

Most of the participants had positive reactions to apps that help monitor foods with vitamin K, but some expressed that it might be more useful for "someone else" because they felt they already had good knowledge about what foods are high in vitamin K. There was one participant that said,

I wouldn't be interested in that at all...once you've seen the list and you kind of focus on the ones that are high [in vitamin K], you've kind of got it. So in my own case, I don't worry about what I eat...but for other people, maybe they need it. [Male participant, age 73]

A few participants expressed interest in using a similar app for themselves. For instance,

That's very interesting. It would keep you where you're supposed to be, and what you're supposed to do by looking the different products up. I like that...because my family says, "You shouldn't eat that. You should eat more of this". With this here I can say, "Yep, don't need. Yep, do need", you know. That I like very much. [Male participant, age 75]

Participants With Technological Experience

The participants who reported having some level of comfort with technology had experience with a range of devices. This included things such as the use of mobile phones for taking pictures and texting, work experience with computers and touch screens, and regular use of a personal computer. Many of them stated that they used technology to communicate and keep in touch with friends and family. Some of them used the alarm function on their cell phones as medication or appointment reminders. Many of these participants also spoke about their familiarity with technology as being a result of the ubiquitous use of technology by those around them including friends and family.

Participants With Technological Experience for Health

The participants who had experience using technology had positive reactions to using technologies to manage health conditions and medications. Many of them expressed favorable views of technology for older adults, and also expressed interest in using or learning to use tablets and phone apps for health and medication management purposes. There was one participant that shared,

A medication monitor app might help the people who are on more than one medicine, because even my daughter-in-law, after she went back to work for a couple hours a day, she got back into the old thing of forgetting the warfarin...Where if she had something like this with her, it would have told her it's time. I think it would be a great asset to a lot of elderly people. [Female participant, age 75]

A few participants elaborated further on the appeal of using mHealth technology for health and medication management. They stated that devices such as computer tablets are “small”, “portable”, and easy to carry around and keep by their side.

Suggestions to Make Technology Elder-Friendly

Because technological devices can be expensive, a few of the participants suggested that being able to rent a tablet from their health provider would be helpful. Many of the participants were concerned about the specifications of devices and suggested that phones and tablets need bigger screens, bigger keyboards, and simple visual illustrations in order to make them more “age-appropriate”. Apps that can help people easily keep track of their diet and vitamin K consumption were viewed as something that can be useful for older adults. There was one participant that also suggested that since many older adults have multiple medications, a medication management app could be useful,

It would be a great way of seeing if you're being prescribed something that doesn't go with the other one...It's hard to keep track of what all you're on. That was like I went to my doctor after the surgery and showed him what all I was taking. I took them all in and then he had them on his little screen...I do think that it's a great way to monitor what the patient is having put in their body because, like you said, sometimes it's very hard for the doctor to look at a

piece of paper and keep a list of all these medications and everything. [Female participant, age 75]

However, most of the participants suggested that learning to use apps would be challenging for older adults with technology challenges, and that they would need to be provided with external help. For example, someone may need to help the patient enter all of their medications into an app before they are able to use the app for monitoring.

Health Games for Exercise

In asking the participants about exercise, the interviewers showed the participants a video clip of someone playing a videogame on the Nintendo Wii designed for exercise. They then elicited responses from the participants about their thoughts on using something similar. Some of the participants were familiar with it and said it was something that they would try for themselves, while some did not think it was something they wanted to try. Positive reactions were mainly elicited from those who had played on the Wii with their grandchildren. The participants offered some concerns and suggestions on how to make exercise games more elderly friendly.

Concerns About Health Games for Exercise

Many of the participants cited the risk of falls as a reason why they did not want to try videogames for exercise. Many of them were worried that they were too “uncoordinated” to play exercise games, and that they would get dizzy and fall. There was one participant that said,

I fall all the time, come running into stuff...It's the moving back and forth, I would totally lose my balance on that. [Male participant, age 75]

Some of the participants expressed that the idea of playing videogames was something that was not appealing to them, stating that they had “no desire” or in the case of one participant, “I can think of other things I should be doing that are much more important” [Male participant, age 80]. Many of the participants stated that walking was their preferred form of exercise.

Suggestions to Make Health Games Elder-Friendly

A variety of suggestions were made by the participants to make exercise games more appealing to older adults. Making the games multiplayer was a big appeal. Some of the participants said that they had no interest in playing games alone, but that if it were done with other people or in a group, they would be more interested in participating. Some of the participants also suggested that games be developed for people with varying degrees of physical activity levels. For example, one participant suggested that some older adults would need to perform exercises while sitting down. Another participant said of sitting exercises,

I am physically very active. I can do all of this stuff...This isn't enough for me. [Male participant, age 74]

Several of the participants were concerned that standing on the Wii platform could pose as a falling hazard, and suggested that the addition of a support bar or grab bar to hold onto while exercising would be useful.

Discussion

Older Adults and mHealth Technology

This study explored the attitudes and perceptions toward mHealth technology and health games in older adults on oral anticoagulation therapy using a qualitative research methodology. The findings suggest that the use of mHealth technology, such as health apps on mobile devices, may be helpful for managing medications since the participants experienced missing doses of medication occasionally. However, the participants also expressed the need for family support in the use of health technology devices. In addition, the participants discussed concerns and challenges to use, and provided suggestions on ways to make mHealth technology and games elder sensitive.

Medication Self-Management Strategies

Older adults deal with polypharmacy (multiple medications), due to multiple chronic conditions [29]. Factors contributing to medication adherence in older adults include physiological changes with the aging process such as decline in cognitive ability and multiple morbidities, psychosocial profile, health beliefs, patient-health provider communication/relationship, and social support [30]. Individuals develop their own strategies to keep track of their medications and for refills. The strategies that older adults on anticoagulation therapy used in this study included electronic reminders or calendars for refills, pill boxes, or other tools to store medications. Many of the participants reported family support for medication management. The use of mobile-based short message service (SMS) reminders has been shown in studies to improve adherence to medication in chronic disease conditions including acquired immune deficiency syndrome [31], diabetes [32], or polypharmacy [33]. None of the participants in this study reported use of SMS.

Awareness of the importance of taking medication (warfarin) everyday, and the consequences of not maintaining the regimen, seem to enhance adherence to anticoagulation therapy with warfarin. Such awareness was obtained through experiences and anecdotes from friends or family members who had taken warfarin or through good provider-patient communication. At our medical center, anticoagulation specialized pharmacists lead anticoagulation clinics. The patients with warfarin therapy in this study expressed satisfaction with the level of detail of instruction provided by the pharmacists, including which foods have high Vitamin K content, drugs to avoid while on warfarin therapy, the importance of taking blood tests regularly, and adjusting warfarin doses according to INR. For years, the clinical and economic benefits of pharmacy-led anticoagulation management have been demonstrated [34,35].

Most of the participants in this study confirmed the value of using mHealth technology in the management of medications, but commented that it would be more useful for other people, but not themselves. This may be because the mean length of warfarin treatment in this sample is long (5.5 years). The patients in this sample may have adapted and normalized their routine for warfarin management. mHealth technology may be better targeted to patients new to warfarin or to patients who have

unstable INR in order to aid the normalization of medication routines.

Mobile Health Technology

According to the Pew Internet Research report published in June 2012, slightly more than half of all older adults (65 years and older) in the United States used the Internet via computers, cell phones, or tablets [34]. Approximately 56% of older adults responded in the Pew Internet survey that they owned a cell phone [36]. However, the ownership of mobile phones or tablets is low (3%). There were 1 in 3 older adults who used the Internet that reported that they enjoyed social networking (eg, Facebook, LinkedIn) [36]. In this current study, the older adult participants reported similar experiences with computers and mobile devices. In particular, some of the participants raised concerns related to the economic burden for the use of tablets. Some who reported that they did not often use computers expressed little interest for learning to use mHealth technology for managing their medication or for self care. However, many of the participants commented that health apps specifically designed to promote adherence to warfarin therapy would be helpful. They also commented that family support in the use of mHealth technology would be favorable.

The concept and market for mobile technologies in health care have been developing rapidly in recent years [1]. Substantial interest toward mobile technologies in health care is growing alongside the movement toward individualized medicine. The mHealth industry seeks to fill the gap toward that movement with technologies that allow consumers to customize their preferences for alternative health care delivery beyond disease management alone [1]. Health apps on mobile phones or tablets have been designed to monitor, assist, and inform patients about individual disease conditions including diabetes, migraines, and asthma [37]. There are only a few specific apps designed to comprehensively manage anticoagulation therapy, although there is a substantial need for ongoing patient education and provider feedback during the course of therapy.

Another form of mHealth technology that is being used in health care is the remote monitoring systems (RMS) or telehealth systems [3]. For example, patients with heart failure living in rural areas or having limited mobility can monitor their blood pressure, heart rate, body weight, and blood oxygen level using peripheral devices (eg, weighting scale blood pressure device, or oximeter) [38]. Such clinical data are transferred to a RMS device that alerts health care providers of clinically meaningful changes in physiological data. Health care providers can then provide patients with immediate feedback based on the data transferred via the RMS system.

Despite the growing use of mHealth technology in health care, many challenges to widespread use remain due to the complexity of health care delivery system in the United States. Health care providers are concerned about the additional workload that the use of mHealth technology may generate, and are unclear about the impact on the provider-patient relationship [1]. Older adults may face more challenges to mHealth technology use due to relatively lower levels of technology proficiency compared to younger populations. However, in this study many of the patients expressed a basic understanding of how mHealth technology

works, particularly those related to anticoagulation therapy. Developers of mHealth technology should be aware that older adults can be savvy end users like other age groups, but that technological platforms should be designed with elder-friendly specifications to meet the specific needs of older adults. Elder-friendly suggestions from the participants in this study include simplifying the design of app interfaces, designing

bigger screens and keyboards, and providing technical support in using technology aids.

We have been developing a mobile app for older adults on warfarin therapy based on the comments from the participants in this study. The modules of this elder-centered app for warfarin therapy that our research team has developed are shown in the Table 4.

Table 4. Modules included in the warfarin therapy app for older adults, mobile app for savvy seniors (MASS), happy and safe life with blood thinners.

Module name	Description
My page	Users enter preferred information that will be useful for their care management. This includes doctor's information, pharmacy's information, and emergency contact information. The user for his/her identification can create an icon or picture.
Blood thinners	This educational component provides essential warfarin information that includes medication interactions and food-medication interaction. The information is evidence-based, and written in plain language for easy understanding by users.
Medication	Medication monitoring that creates reminders of dosage and when to take a medication. This schedule can be shared with trusted others such as family, caregivers, or close friends.
Foods	A vitamin K content food list that includes a listing of foods high in vitamin K including ethnic foods.
Body	This module allows users to monitor adverse symptoms such as bruising or bleeding on body. A picture can be taken and saved to the app in order to log the episodes to show a health care provider at an office visit.
Blood test	Monitor and log of the results of blood tests, such as INR level, to track whether they are in the recommended therapeutic range.
Safety tips	Easy and specific safety tips related to warfarin therapy, such as injury prevention and when to call a doctor.
Share	All information logged in the MASS can be shared with trusted other via email. Users are empowered to manage their own health information.
Resources	Additional resources regarding anticoagulation therapy, such as information from federal agencies (eg, Agency for Healthcare Research and Quality, U.S. Department of Agriculture, National Nutrient Databases).

Health Games for Physical Activities in Older Adults

Games designed to promote exercise (eg, Nintendo Wii, Sony EyeToy, Dance Dance Revolution, or Xbox Kinect, etc) have been studied in community-dwelling older adults and patients with stroke for rehabilitation [4,39]. Many commercial apps for physical activities that are available in the market are targeted to those who want to lose body weight [40,41]. In addition, there are health apps for diabetes that include a physical activity component along with diet and blood glucose monitoring [42]. Physical activity games can be included in a health app for those on anticoagulation therapy, but designs need to take into account specific safety measures. Older adults on warfarin therapy are at a higher risk for bleeding, and may be limited in engaging in physical activity due to the fear of falling. The participants in this study expressed that they had some experience with commercially available balance games or group games. However, they were concerned about safety issues in regards to the design of the game platforms, and made suggestions for safety strategies to prevent falling while playing games.

Limitations

There are several limitations to take into consideration. First, the participants were recruited from two anticoagulation clinics affiliated with an academic medical center, and findings may not be generalized outside of the population in this sample due to regional differences in practice. Furthermore, the small sample size and exploratory nature of this qualitative study further limits the generalizability of the findings across all

segments of the population. Consequently, the findings from the study are a journalistic representation of the sample's perceptions and beliefs related to anticoagulation (ie, warfarin), and the potential role of mHealth in promoting self-management. Second, we experienced challenges to recruitment that may have affected the demographics of our sample. Many of the scheduled participants did not show up to the group meetings because of transportation problems or urgent health issues. Therefore, our sample may be more representative of those in better health or those who are more independent. Nevertheless, the findings from this study provide a rich source of data to examine the use of mHealth technology specifically within the context of anticoagulation therapy.

Conclusions

This study was conducted to generate formative information on the use of mHealth technology among older adults on warfarin therapy, and identify themes that could be captured when designing a valid and reliable instrument based on input from stakeholders. These findings can be used to inform a larger study to design and test mHealth technology in this target population. The next study will include an iterative process to refine the design and effectiveness of the health app in a real life clinical environment. The findings indicate that our older adults on warfarin therapy are interested in mHealth technology specific to warfarin medication management and health games. Further research needs to be done to validate these findings. Elder-friendly designs, technology support, and physical safety using mHealth technology may be useful in this population.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Patient characteristics.

[[DOC File, 16KB - mhealth_v2i3e32_app1.doc](#)]

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Abbreviations

INR: international normalized ratio
IRB: Institutional Review Board
MASS: mobile app for savvy seniors
mHealth: mobile health
NCATS: National Center for Advancing Translational Sciences
NCRR: National Center for Research Resources
NIH: National Institutes of Health
QOL: quality of life
RMS: remote monitoring systems
SMS: short message service

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Original Paper

Supporting Cancer Patients in Illness Management: Usability Evaluation of a Mobile App

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Abstract

Background: Mobile phones and tablets currently represent a significant presence in people's everyday lives. They enable access to different information and services independent of current place and time. Such widespread connectivity offers significant potential in different app areas including health care.

Objective: Our goal was to evaluate the usability of the Connect Mobile app. The mobile app enables mobile access to the Connect system, an online system that supports cancer patients in managing health-related issues. Along with symptom management, the system promotes better patient-provider communication, collaboration, and shared decision making. The Connect Mobile app enables access to the Connect system over both mobile phones and tablets.

Methods: The study consisted of usability tests of a high fidelity prototype with 7 cancer patients where the objectives were to identify existing design and functionality issues and to provide patients with a real look-and-feel of the mobile system. In addition, we conducted semistructured interviews to obtain participants' feedback about app usefulness, identify the need for new system features and design requirements, and measure the acceptance of the mobile app and its features within everyday health management.

Results: The study revealed a total of 27 design issues (13 for mobile apps and 14 for tablet apps), which were mapped to source events (ie, errors, requests for help, participants' concurrent feedback, and moderator observation). We also applied usability heuristics to identify violations of usability principles. The majority of violations were related to enabling ease of input, screen readability, and glanceability (15 issues), as well as supporting an appropriate match between systems and the real world (7 issues) and consistent mapping of system functions and interactions (4 issues). Feedback from participants also showed the cancer patients' requirements for support systems and how these needs are influenced by different context-related factors, such as type of access terminal (eg, desktop computer, tablet, mobile phone) and phases of illness. Based on the observed results, we proposed design and functionality recommendations that can be used for the development of mobile apps for cancer patients to support their health management process.

Conclusions: Understanding and addressing users' requirements is one of the main prerequisites for developing useful and effective technology-based health interventions. The results of this study outline different user requirements related to the design of the mobile patient support app for cancer patients. The results will be used in the iterative development of the Connect Mobile app and can also inform other developers and researchers in development, integration, and evaluation of mobile health apps and services that support cancer patients in managing their health-related issues.

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KEYWORDS

mobile applications; patients; cell phone; smartphone; symptom assessment; self-care; user-computer interface

Introduction

Mobile Health Apps—Opportunities and Challenges

Mobile devices are continuously present in people's everyday lives [1], and many individuals have a deeply personal relationship with their mobile phones, which are typically customized to their specific needs [2,3]. Evolving technical capabilities of mobile devices enable delivery of various services independent of the user's time and place, and their dynamic adaptation to current context of use and users' personal preferences [4]. These features make mobile devices well-suited terminals for easier monitoring and managing of pre-existing health conditions, the delivery of more efficient, individually tailored care at the point-of-need, and promotion of better collaborative work between patients and health care providers [5-10].

However, mobile devices' hardware limitations (eg, small screen, limited input capabilities) introduce numerous challenges when migrating from an existing eHealth Web-based system to a mobile platform. Some of the general guidelines are to (1) provide support only to a limited number of features to eliminate the variety of options that are not core to the mobile use case, (2) show only limited content to reduce word count and provide better visibility and glanceability, and (3) enlarge interface elements to enable easier input of data and accommodate the "fat finger" problem [11,12]. Research has explored methods of automating the migration process from Web-based to mobile-based systems (eg, [13,14]), but such work has mainly focused on increasing efficiency of translation techniques, rather than identifying system requirements in the new context. When designing and developing mobile health apps, special care must be taken to address patients' specific needs, which often vary greatly across different contexts beyond type of access terminal (eg, type of illness and diagnosis, phase in treatment, and patient demographics and literacy). For example, literacy, health literacy, and previous experience with technology can significantly influence patients' usage and navigation through (mobile) health apps and their ability to apply the knowledge gained to managing health conditions [15,16]. Also, the granularity of data that is captured on the mobile device and used for monitoring of health conditions and behaviors is highly dependent on the patient's condition. While a simplified 5-point scale describing the size of the meal is good enough for logging food intake of persons who are trying to get in shape and lose weight, it is not sufficient for diabetes patients who need to carefully monitor relation of food intake and blood glucose level [7]. Another example includes the use of metaphors and graphical representations to show the user's progress towards some predefined goal or current (health) status. While metaphors on glanceable displays are shown as highly effective for maintaining and increasing the physical activity of users [8,17], their use for presenting the status of more serious health-related conditions are not well accepted by patients (eg, neutral graph visualization metaphors were found to fit better for patients with mental illness [18]).

Previous research has also shown that advanced age and lack of experience with mobile technology decreases peoples' ability

to create accurate and useful spatial mental models of a mobile app's menu and navigation structure [19]. A mental model is defined in cognitive psychology as a user's internal representation of an external system's structure and functions [20]. Mental models are usually formed by combining previous knowledge and experience with similar systems, cognitive schemes, and problem-solving strategies [21]. The absence of an accurate mental model can significantly influence a user's task performance on mobile devices and can lead to disorientation in menu selection [19,22].

In system development, the user-centered design (UCD) approach is used to identify and address end-user requirements and adjust (mobile) system design and functionality to user's capabilities, needs, and expectations [23-26]. UCD incorporates a range of methods ranging from focus groups to iterative usability testing and participatory design [27]. Applying UCD principles to development of mobile health information services for patients can support users in changing their health-related behavior [26,28].

Mobile Apps for Cancer Patients

Cancer patients often experience a wide range of physical, functional, and psychological symptoms during treatment and rehabilitation. Failure to identify and address these symptoms during hospital admissions can lead to considerable distress [29,30]. Also, the side effects of treatments usually cause a range of new symptoms that are often worse after patients have been discharged from the hospital. Therefore, Web-based systems that can support management of symptoms and health care-related issues at home could be beneficial for this patient group [31]. However, few projects can be found in the literature that address the design and implementation challenges of mobile information services intended to support cancer patients in managing their illness and health-related issues. For example, Leimeister et al researched how standard features of personal digital assistants—such as diaries, SMS (short-message service), email, messaging—can be used to support adolescent cancer patients in illness management [32]. The results showed that using the mobile devices helped patients in coordinating their extensive treatment schedules and medication plans. To achieve this goal, the calendar function was found especially useful. The diary function was not well accepted due to the limitation of a small keyboard. Communication features such as SMS and email messages were well accepted but mostly for communication with family members and friends rather than health care personnel [32].

Klasnja et al described the design of HealthWeaver Mobile, an app that helps patients manage care-related information during treatment [33,34]. The study outlines the general design and functionality requirements for developing mobile systems that target cancer patients, such as the ability to install the mobile app on a personal phone, the importance of standard integrated features (eg, camera, microphone), and useful system functionalities (eg, calendar, notes, registration). The mobile app is developed as part of a greater symptom-management system that also includes a Web app. The authors argued that the use of a native Web hybrid approach offered a more

cost-effective way to provide cross-platform support in mobile health tools.

The ASyMS system supports remote monitoring and symptom management of chemotherapy-related symptoms in cancer patients [35,36]. Using their mobile phones, patients fill out and send a report with their symptoms and then immediately receive feedback consisting of tailored self-care advice directly related to the severity level of the symptoms they just reported. An additional evidence-based risk assessment tool alerts clinicians when an incoming patient-reported symptom is considered critically important. A randomized control trial showed that the mobile app can provide valuable support to chemotherapy patients for symptom management and improve patient-provider communication. The feasibility of a similar system for monitoring chemotherapy-related issues is reported in [37], demonstrating the benefits of real-time telemedicine with remote nurse support.

A Wireless Health Outcomes Monitoring System (WHOMS) and the electronic Edmonton Symptom Assessment System (e-ESAS) are additional examples of mobile systems that provide remote monitoring of cancer patients' health issues by health care providers. In WHOMS [38], the medical management team sends structured questionnaires to the patient's mobile phone, and the completed questionnaire is then reviewed by the medical team. The e-ESAS system [39] was developed and adapted for use in developing countries to enable patients to easily report symptoms, as well as to enable palliative doctors to preview and process data.

In summary, research has addressed a range of issues related to the design and development of a mobile information system that enables the remote monitoring of cancer patients by health care providers while also supporting patient's self-management of health-related issues and preparation for clinic consultations. The evolution of social media and advances within communication technology provide new opportunities for patients to become more engaged in different types of discussion and reflections regarding their own health issues. The importance of these functionalities is discussed in previous research [7,32,40,41]. However, to our knowledge there is no research addressing issues regarding design and development of mobile app(s) for cancer patients that support a wider range of system features including advanced online communication among patients and between a patient's health care provider as well as symptom management tools.

To address issues related to design and development of mobile apps for cancer patients that provide a greater variety of system features (both symptom management and communication), we present the design, development, and evaluation of the Connect Mobile app. The Connect Mobile app is part of the previously developed and deployed Connect system, which provides support to cancer patients in managing health-related issues and promotes better patient-provider communication, collaboration, and shared decision making. The goal of this work was to (1) identify design challenges and issues related to providing mobile access to a patient support system such as the Connect system, (2) evaluate perceived usefulness and user acceptance of the system and its features across different access terminals, (3)

investigate the new context of use and new system requirements introduced by enabling mobile access to the patient support system, and (4) contribute to a robust and extensible mobile app design framework for patients with chronic illness.

The Connect System

The work reported in this paper is part of the Connect research project. Its goal is to promote timely, secure, and seamless collaboration between chronically ill patients and health care providers on different levels of care by using a device-independent, mobile, and multifunctional Internet platform called Connect (formerly known as WebChoice). The Connect system and its components were developed based on patient-centered principles and designed to support cancer patients in self-managing their illnesses and to enhance patient-centered care. The Connect system's design and functionalities were developed in cooperation with system stakeholders (ie, patients, health care providers) using numerous user-centered and participatory design methods (eg, focus groups, usability evaluation, heuristic evaluation) [31,42,43]. The system incorporates a series of modules designed to support patient-provider communication, collaboration, and shared decision making in different environments (eg, hospital, outpatient clinic, and patients' homes). Patients can access the Connect system through a Web browser on their personal computers or laptops (Figure 1) to (1) report and monitor their symptoms and health problems by selecting from predefined categories and rate their level of distress and priority for support (assessment module), (2) obtain individually tailored evidence-based self-management support (symptom self-management support module), (3) get access to other reliable Internet resources (information module), (4) ask questions and receive advice and professional support (messaging module), (5) share and discuss their experiences with other patients (communication module), and (6) note their private health-related information as free text (diary module).

The Connect system was tested in a randomized clinical trial with 325 breast- and prostate-cancer patients from all over Norway. The results showed that the system improved patient-provider communication, decreased symptom distress and depression, and provided better self-efficiency for patients [31,42,44]. Additionally, system logs analysis showed that all system components were used independently of users' diagnosis type, stage of disease, age, or previous computer experience [41]. However, usage patterns differed for patient subgroups. For example, even though the functions that enabled patient-patient and patient-provider communication were used the most frequently, in general breast-cancer patients used the system more for seeking health-related information while prostate cancer patients focused more on features that helped them to prepare to talk with health personnel. Patients with a long-term illness history were more active in communication (both patient-patient and patient-provider) and exhibited more information-seeking behaviors than patients who received a diagnosis for the first time [41,45]. Additionally, messaging and symptom self-management support functionalities were used more by patients with a low level of social support and a high level of symptom distress and depression [40]. The general conclusion was that there is no "one size fits all" system, and

user preferences and use patterns are dependent on numerous factors including personal characteristics, illness type, disease stage, social support, and illness burden.

Since the Connect system provides a device-independent, multifunctional Internet platform, in the current research project we investigated how the system's functions could be further translated to new contexts of use by enabling access over mobile devices such as mobile phones (which refers to smartphones but not regular cell phones) and tablet computers. The work presented in this paper addresses different design and implementation challenges that surfaced during the development and evaluation of Connect Mobile, a mobile app that enables access to the Connect system. The initial version of the Connect Mobile app design was developed to adhere to general and widely accepted usability guidelines for different types of mobile devices (eg, design guidelines from device and software manufacturers [46,47] and general guidelines for development of user-friendly mobile apps and interfaces [12,48]). Since basic design rules for development of a mobile app underline the importance of simplicity due to device limitations (eg, small displays and limited input characteristics), the Connect Mobile app was implemented to allow access to only a subset of all functionalities offered by the Connect system. Based on previous research on the Connect project that identified patients' usage patterns and functional requirements, we endeavored to incorporate the following modules and features in the Connect Mobile app:

- The messaging module where patients can exchange messages with health care personnel (eg, primary and specialist care physicians and nurses).
- The assessment module where patients can record and keep track of problems that are bothering them. The symptoms assessment module requires the following four steps: (1) patients select the symptoms that are bothering them from the list of predefined symptoms organized in groups and subgroups, (2) for each selected symptom, the patient selects how bothersome it is, (3) the patient selects how important it is to address the symptom in the meeting with health provider, and (4) before submitting the report, the patient can review the list and go back to previous steps and perform changes if needed. The mobile app also gives the patient an option to see the list of previously reported symptoms.

- The symptom self-management support module where patients can get information about managing self-reported symptoms, how to psychologically deal with the illness, the challenges it brings, and their rights as a patient. Patients can also create a personalized list of advice and activities that they find most useful and valuable.
- The communication module/forum functionality where a patient can exchange information and experiences with other patients using the Connect system.

The Connect Mobile app was developed using PhoneGap, an opensource framework for building cross-platform mobile apps [49]. The PhoneGap platform supports development of a single mobile app using standard Web-based technologies (such as HTML, cascading style sheet, and JavaScript), which can run as a native app on various mobile platforms and operating systems (such as Android, iOS, Windows Phone). We chose the development of a native app because they are better accepted by end users than Web pages and provide better support for customization to device characteristics [50]. Additionally, the native apps can make use of the mobile devices' features (eg, camera, positioning).

For implementation of the mobile app design, we used JQuery Mobile framework, which provides support for development of HTML5-based user interfaces for all popular mobile device platforms as well as a library of standard and widely accepted mobile app widgets and interface elements. We applied a responsive Web design approach that supports dynamic adaptation of app interface design to a device's characteristics (screen size, platform type, device orientation), while the app logic was the same for both types of devices (mobile phones and tablet computers). For example, while the bottom tabs are used to enable transition between features on mobile phones, the left side menu was used for the same type of navigation on tablet devices. Additionally, the design of interface elements (eg, size, order, positioning on the screen) was adjusted to fit characteristics of these two types of devices. The communication with underlying Connect system uses hypertext transfer protocol and follows representational state transfer architecture guidelines for designing networked apps.

A preview of Connect system main menu interface is shown on different access terminals in [Figures 1-3](#).

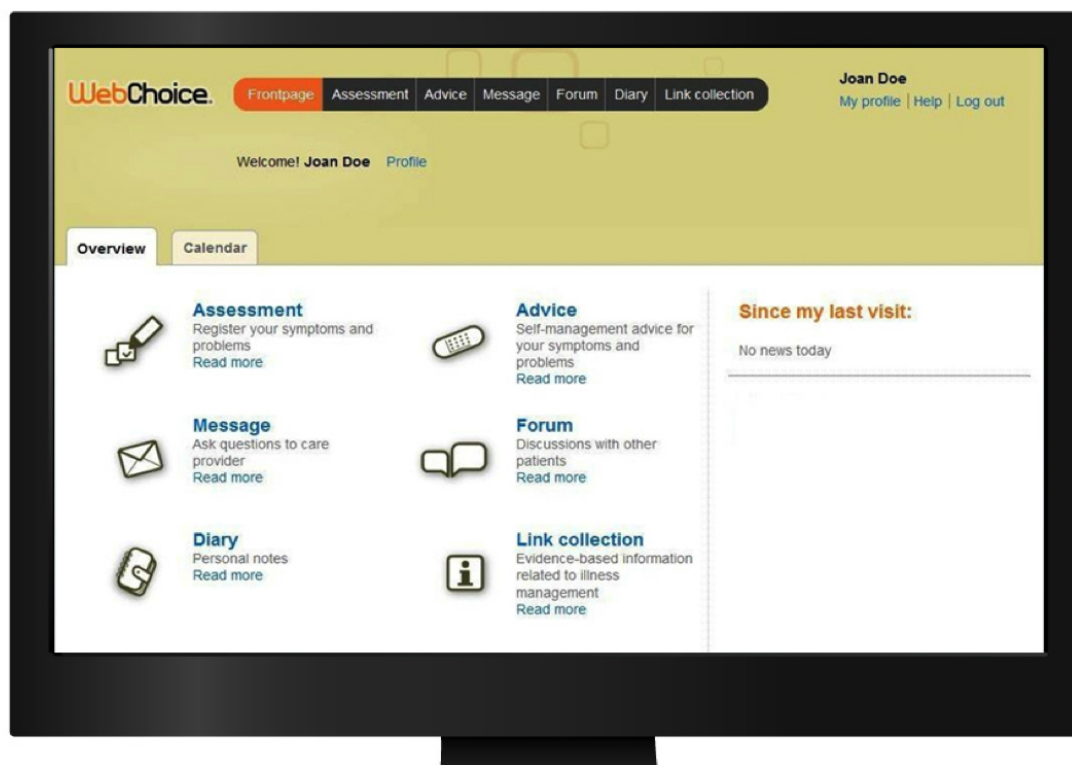
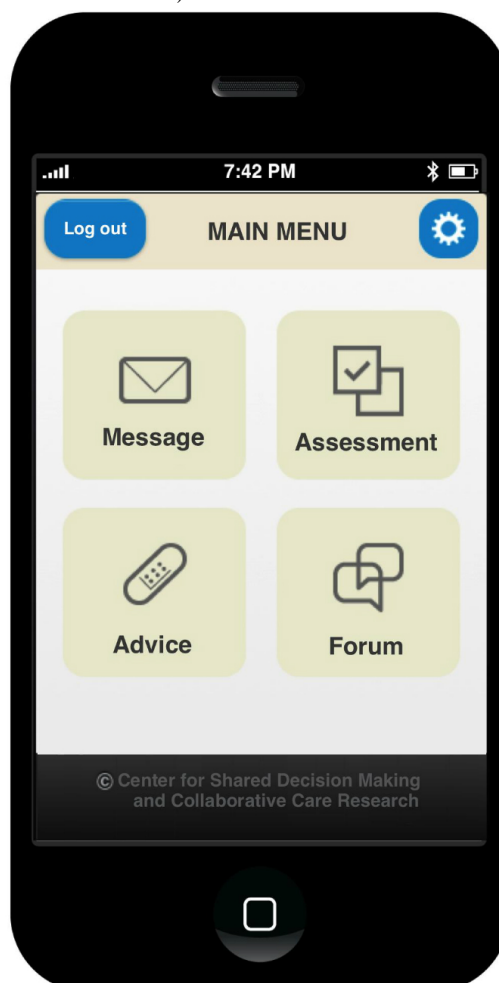
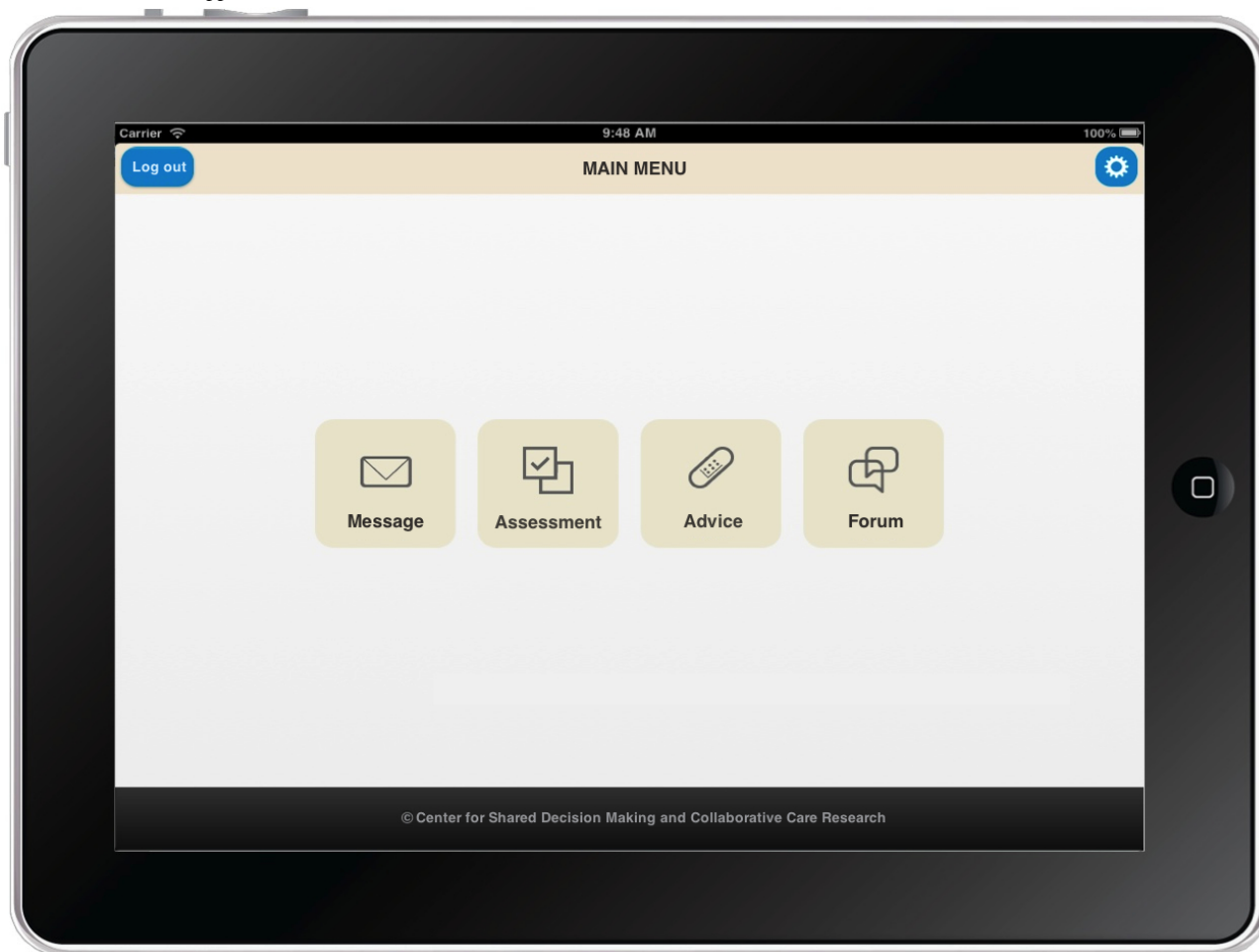
Figure 1. Connect Web app (screenshot of the main menu).**Figure 2.** Connect smartphone app (screenshot of the main menu).

Figure 3. Connect tablet app (screenshot of the main menu).

Methods

To evaluate the Connect Mobile app, we performed a usability evaluation study of both the mobile phone and tablet computer versions of the app. The study consisted of usability testing of a high fidelity prototype where our objectives were to identify existing design and functionality issues along with usability problems and to provide patients with a real look-and-feel of the mobile system. In addition, we conducted semistructured interviews to solicit responses from participants about app usefulness, identify the need for new system features and design requirements introduced by the new context of use, and determine the acceptance of the mobile app and its features in everyday health management.

Our study sample consisted of 7 cancer patients from a rural municipality in the northern part of Norway. Inclusion criteria were that patients were participants in the larger study where they were given access to the Connect system on their private computers, and that they had previous experience using the system.

The usability study was conducted on two devices: (1) an iPod device that simulated a mobile phone with access to a wireless network and (2) an Asus Transformer tablet computer. The devices were tested as follows: 2 participants tested the mobile phone version of the app, 3 participants tested tablet PC version, and 2 participants tested both versions. Since the 2 participants

were tested in separate sessions separated by 3 months, we concluded that first testing session did not considerably affect the users' efficacy in the second testing session. In addition, the app interface and navigation elements were implemented to fit different device characteristics, and this should serve to further differentiate their user experience. All evaluation sessions except one took place in a quiet room at a community center with a moderator (JM). Only one participant was visited at home. The study was performed in the Norwegian language. The moderator guided the participants through the testing procedure but did not intervene or disrupt the thinking process. Help was provided to participants only if they explicitly requested it, and only the essential amount of information to enable them to move on to the next task was provided.

All participants completed a demographic questionnaire that asked about their age, gender, education level, and previous experiences with mobile phone and tablet devices, and previous use of the Connect system. A tutorial of the Connect system and its functionalities was not given beforehand, since the initial assumption was that participants were already familiar with the system from prior use on the Web-based app on a personal computer. We also wanted to understand the nature of challenges involved in translating knowledge and procedures from one platform to another. The participants were offered pre-training exercises on the testing device prior to testing, with the goal of enabling participants with little to no experience with mobile touchscreen devices to gain a general understanding of the

standard mobile system design and its navigational characteristics.

Throughout testing, each participant was asked to perform nine tasks of varying levels of complexity. The following tasks covered the full range of functions offered by the mobile app:

- Login/Logout to the app (Tasks 1 & 9).
- Reply to a message from the nurse (Tasks 2-3).
- Report the predefined set of health related symptoms (Task 4).
- Find self-management activities that can be performed to address new and previously reported health symptoms (Tasks 5-7).
- Share predefined text with other patients in forum (Task 8).

The participants were asked a set of follow-up semistructured questions following each group of tasks, with the goal of obtaining the participants' immediate interpretation of a given task scenario and system design and to facilitate the elaboration of usability issues and increasing insight and design suggestions [51]. During this phase, the participants were encouraged to discuss the situations where they encountered problems or expressed concerns and then discuss the possible causes of the situation or possible design changes that could be implemented to address the identified issues.

After testing, the participants were asked to fill out the System Usability Scale, a standardized questionnaire used to assess participants' perceptions of usability [52]. This robust and reliable scale consists of a 10-item questionnaire with each item rated on a 5-point Likert scale. The scores for each question were converted to a new number (odd questions score is calculated as scale position minus 2, and even-numbered questions are calculated as 5 minus the scale position), added together, and then multiplied by 2.5 to get the final score (ranging from 0 to 100).

At the end of testing, participants were asked follow-up questions about the full app design and its features, its usefulness, participants' intention to use it, and barriers to the use of the mobile app in the future.

The participants were video-recorded and analyzed using Morae usability and analytic software (Techsmith). In addition, notes taken during observation of the sessions served to inform the analysis. During the analysis, we quantified and characterized a set of variables related to user performance. Specifically, we identified the number of requests for assistance, the types of errors participants made, and the time taken to complete the task. We also noted the feedback provided by participants in relation to their user experience. The list of identified events (request for help, errors, participant feedback, and moderator's observation) was then used to assemble a list of usability issues.

Each of the usability issues was categorized according to problem type and frequency of occurrence. The videos were reviewed and coded by the first author (JM). All identified issues were also reviewed by the second author (DK), and all differences were resolved through iterative viewings and discussions.

Each of the usability issues was mapped to usability heuristics for mobile devices to note any violations of usability principles. We employed usability heuristics for mobile computing as defined by Bertini et al [53]. The heuristics reflect a modification of Nielsen's heuristics [54] with the goal to capture contextual factors in mobile computing. The usability heuristics are (1) visibility of the system status, (2) match between system and the real world, (3) consistency and mapping, (4) good ergonomic and minimalistic design, (5) ease of input, screen readability, and glanceability, (6) flexibility, efficiency of use, and personalization, (7) aesthetic, privacy, and social conventions, and (8) realistic error management.

All participant and moderator comments along with feedback were transcribed and analyzed using thematic analysis. Thematic analysis was used to code the data based on main categories identified in the user feedback and to gain a more structured set of user needs and expectations from this type of mobile system.

Results

Overview

In this section, we first present the results of the quantitative analysis of the usability study, including demographic data and usability scale questionnaire results. The results of semistructured interviews and observations captured during the testing follow. The results are categorized in groups based on the main topic and subtopics they address.

Participant Characteristics

Table 1 lists the characteristics of the study participants. Of the 7 participants, 4 were women and 3 were men. The average age of the participants was 61 years (range 49-75). For education, 6 participants had completed grade school or high school education, and only one had higher education. All of the participants owned a private cell phone (5 had smartphones and 2 had regular cell phones), while only 3 participants owned a tablet. The most commonly used function on the Web version of the Connect system was the exchange of messages between patients and health care provider (7 participants), the diary where they note their private information (5 participants), and the forum where they can share information with other patients (4 participants). Among the least used functions were symptom assessment and self-management support (3 participants) and the information module (2 participants).

Table 1. Characteristics of the study participants.

Characteristics	n (%)
Age, median (range)	61 (49-75)
Gender	
Male	3 (43)
Female	4 (57)
Education	
Elementary/high school	6 (86)
University/college	1 (14)
Own a phone	
Smartphone	5 (71)
Regular cell phone	2 (29)
Experience with the phone	
Low	0 (0)
Medium	3 (43)
High	4 (57)
Own a tablet computer	
Yes	3 (43)
No	4 (57)
Experience with a tablet computer	
Low	2 (67)
Medium	1 (33)
High	0 (0)
Use of Connect system features on the Web version	
Assessment module	2 (29)
Symptom self-management support module	3 (43)
Information module	2 (29)
Messaging module	7 (100)
Communication module	4 (57)
Diary module	5 (71)

Quantitative Results

The task completion times with numbers of errors participants made while performing tasks and number of times they requested assistance are provided in Table 2. Although the sample size was too small to do reliable tests of significance, it is apparent that the tasks were completed consistently faster on the tablet than on the mobile phone. However, as the standard deviations suggest, there was substantial variation between users. All the tasks required more time on the mobile phone except for the logout task (Task 9). Tasks related to performing symptoms assessment (Task 4) took the most time for all participants to complete. They also yielded the highest number of errors and requests for help. Perhaps the primary reason is that this task is more complex and requires the user to go through four different steps: (1) symptom selection, (2)

assessment of symptom bother (eg, a rating of perception of pain or irritation), (3) assessment of importance to address the problem during meeting with health provider, and (4) review of assessment summary. Additionally, symptom assessment was one of the least used functions on the Web version of the Connect system. Since participants were not previously acquainted with this system feature, they encountered problems in understanding the organization of functionality and step sequence without an initial introduction. The task of asking a user to reply to a message from the nurse and attach a picture to the message also took more time for patients to perform, even though the messaging function is one of the most frequently used features on the Web version for all participants. The high completion time and number of errors and requests for help indicate possible usability issues in implementation of the new picture attachment option.

Table 2. Quantitative results (time and standard deviation, errors, and requests for help) for both mobile phone and tablet app across nine tasks.

	Time (SD), seconds		Errors, n		Requests for help, n	
	Mobile phone	Tablet	Mobile phone(n=4)	Tablet (n=5)	Mobile phone (n=4)	Tablet (n=5)
Task 1 ^a	101.25 (60.7)	67.6 (29.6)	1	4	2	4
Task 2 ^b	321.75 (120.2)	293.2 (58.2)	7	5	11	20
Task 3 ^b	42.75 (37.3)	28.4 (21.1)	2	0	3	2
Task 4 ^c	682.75 (186.4)	403 (81.3)	10	5	26	30
Task 5 ^d	191.75 (88.7)	116.6 (48.9)	2	2	7	16
Task 6 ^d	116.75 (40.4)	108.0 (41.2)	2	1	7	11
Task 7 ^d	132.75 (85.4)	69.4 (77.94)	2	2	4	3
Task 8 ^e	186.75 (80.6)	142.8 (32.5)	1	1	4	4
Task 9 ^f	13.75 (8.5)	22 (4.9)	0	0	1	1
Sum			27	20	65	91

^aTask 1: Login to the app.

^bTasks 2-3: Reply to a message from the nurse.

^cTask 4: Report the predefined set of health related symptoms.

^dTasks 5-7: Find self-management activities that can be performed to address new and previously reported health symptoms.

^eTask 8: Share predefined text with other patients in forum.

^fTask 9: Logout.

The number of requests during testing was very high, with participants making more requests for help when using the tablet app. One explanation could be that a majority of them owned mobile phones and had prior experience with these types of devices, which resulted in increased levels of self-confidence and fewer requests for help. However, 4 patients did not own a tablet and of the 3 patients who owned a tablet, 2 had limited experience and needed routine guidance. Frequency of requests across tasks was highest for the symptom assessment and messaging module, which also required the most time for participants to complete (as previously discussed).

The number of errors participants made during testing was higher for the mobile phone app and, consistent with previous observations, was the highest for the symptom assessment and messaging module. Additionally, in the tablet app, participants made a greater number of errors while logging into the app. The errors in this task were related to the participant's lack of experience with the use of the virtual keyboard (eg, they frequently used the wrong buttons on the keyboard or the navigation bar, which either hid or displayed the keyboard).

The average subjective usability ratings from the System Usability Scale questionnaire were 71.25 (SD 14.8) for the mobile phone app and 72.5 (SD 15.3) for the tablet app. On the System Usability Scale, 68 is considered an average score [55]. From the results, we can conclude that participants, on average, rated both apps as being slightly above average. However, from the patients' individual ratings, we observed that 4 patients rated mobile apps rather high with scores over 80 and the other participants rated the mobile app as below average (lower than

68). This result demonstrated that patients had a variable experience in using the app. In addition, it was apparent that the app did not support the full range of their requirements.

Qualitative Results

Overview

The thematic analysis of the interview transcript and users' feedback during the usability testing process revealed two main themes: (1) mobile app user-friendliness, with subtopics of Mobile app design and functionality issues, Self-efficacy and training, and Ease of use, and (2) usefulness of the Connect system, with subtopics of Context dependent usefulness of system features, System usefulness and intention to use, and Integration of new features.

Connect Mobile App User-Friendliness

Mobile App Design and Functionality Issues

The quantitative and qualitative analysis of the usability testing results together with the qualitative analysis of interviews with participants revealed design and functionality issues of the Connect Mobile app that have a potential to influence its effective and efficient use. The testing revealed a total of 27 design issues with the apps (13 for mobile phone and 14 for tablet version) (see Tables 3 and 4). Each of the identified issues was mapped to source events (ie, errors, requests for help, participant's concurrent feedback, and moderator observation) used to identify the issue. Additionally, each of the issues was categorized in one of eight usability heuristics for mobile devices defined by Bertini et al [53].

Table 3. Usability issues identified in the Connect app for mobile phones.

App module	Problem	Source (frequency)	Heuristic
General	Color consistency between mobile and Web app	Feedback (1)	3 – Consistency and mapping
	Navigation issue—support more advance options for expert users (eg, swiping screen)	Feedback (1)	3 – Consistency and mapping
Messaging	The option for adding a picture to the message difficult to find and use	Errors (1); Request for help (2)	5 – Ease of input, screen readability, and glanceability
	The feedback about attached image is difficult to find	Request for help (3)	5 – Ease of input, screen readability, and glanceability
	Problems writing/editing a message—support in-putting text in horizontal mode	Feedback (2)	5 – Ease of input, screen readability, and glanceability
	Unnecessary popup	Request for help (2)	4 – Good ergonomic and minimalistic design
	Popup screen options not intuitive	Errors (1)	2 – Match between system and the real world
Symptom assessment	Collapsible set widgets not intuitive	Feedback (2); Errors (3); Request for help (12)	5 – Ease of input, screen readability, and glanceability
	Slider widgets not intuitive	Request for help (5)	5 – Ease of input, screen readability and glanceability
	Introduction screen not intuitive nor informative enough	Errors (1); Request for help (4)	2 – Match between system and the real world
	Symptom assessment values in the summary screen not intuitive	Request for help (1)	2 – Match between system and the real world
Symptom self-management support	Color of the bottom tab menu not intuitive	Errors (1); Request for help (3)	5 – Ease of input, screen readability and glanceability
	Option for removing item from the list misleading	Errors (1)	2 – Match between system and the real world

Table 4. Usability issues identified in the Connect app for tablets.

App module	Problem	Source (frequency)	Heuristic
General	Color contrast across platforms	Feedback (4); Observations (1)	5 – Ease of input, screen readability, and glanceability
	Navigation issue—provide support for hardware back option	Errors (4); Request for help (2)	3 – Consistency and mapping
	Small font size	Feedback (1)	5 – Ease of input, screen readability, and glanceability
	Navigation issue—provide support for more intuitive navigation buttons (eg, text in navigation buttons)	Feedback (1)	3 – Consistency and mapping
Messaging	The option for adding a picture to the message difficult to find and use	Errors (1); Help (3); Observations (1)	5 – Ease of input, screen readability, and glanceability
	Font size too small for screens with more information (message info, content of the message)	Feedback (2); Observations (3)	5 – Ease of input, screen readability, and glanceability
	The feedback about attached image is difficult to find	Requests for help (2)	5 – Ease of input, screen readability, and glanceability
	Popup screen options not intuitive	Requests for help (1); Observation (1)	2 – Match between system and the real world
	Problems writing/editing a message	Observations (1)	5 – Ease of input, screen readability, and glanceability
	Difficult to answer to the message if the original content is not shown	Observation (1)	2 – Match between system and the real world
Symptom assessment	Collapsible set widgets not intuitive	Feedback (1); Help (10)	5 – Ease of input, screen readability and glanceability
	Slider widgets not intuitive	Observations (2); Requests for help (2)	5 – Ease of input, screen readability, and glanceability
	Introduction screen not intuitive nor informative enough	Requests for help (1); Observations (1)	2 – Match between system and the real world
Symptom self-management support	Font size too small for screens with text describing advices	Feedback (3)	5 – Ease of input, screen readability, and glanceability

As suggested by the results of the quantitative analysis, the majority of identified usability issues were related to messaging (11) and symptom assessment (7) modules. In the messaging module, participants had the most problems with a new feature that allowed them to attach a picture to the message. The option for attaching a picture, placed at the bottom of screen as a link, was hard to find and hard to use ([Multimedia Appendix 1](#)). Additionally, when the picture was added to the message, the feedback to the user in the form of a thumbnail image at the bottom of the screen was not visible since the user could not see it without scrolling down the page. Some participants who tested the tablet app commented that they would prefer to have a larger font size for screens when there is more information, for example, a screen showing health related advices and activities ([Multimedia Appendix 2](#)). Additionally, we observed that some of the participants experienced problems with inputting information. They also suggested the need for introducing additional affordances, such as writing text in a horizontal mode and quoting the original text of the sender's message when writing a reply.

For the symptom assessment module, the participants struggled the most with understanding the collapsible set widgets that are used to present different categories and subcategories of symptoms ([Multimedia Appendix 3](#)). The main issue related to

collapsible set is that participants had problems differentiating between different levels of hierarchical organization provided by the widget functionality. Additionally, one participant misinterpreted the standard plus/minus icons that are used to indicate that the categories are opened or closed. Some of the participants had problems understanding how to use slider widgets to set level of bother and importance for specific symptom. In the introduction screen, most participants did not understand the meaning of the text and often confused images in the text with buttons ([Multimedia Appendix 4](#)). Additionally, general design issues not related to specific system functionality were identified, most of which related to providing more intuitive or advanced navigations. For example, one of the participants with extensive mobile device experience commented that she was accustomed to navigating between separate parts of the apps by performing a swiping motion on the screen. Additionally, participants often wanted to use a hardware back button (if it exists on the device), and one participant proposed using both text and icons on the navigation buttons on the tablet app to support easier recognition and recall of options.

Most of the identified issues (15 issues) were related to usability heuristics addressing ease of input, screen readability, and glanceability (Heuristic 5). Such issues indicate that throughout the study participants mainly struggled with options related to

inputting data (such as previously mentioned issues for attaching picture or selecting symptoms and botherness and importance level), and previewing information on the device's small screen (eg, organization of symptoms in collapsible sets, font size). Additionally, the high number of usability issues that violated Heuristic 2, describing mismatch between system and real world (7 issues), and Heuristic 3, describing inconsistency and wrong mapping (4 issues), showed that understanding and interaction with system features were additionally challenging in some parts of the apps (eg, meaning of icons and system feedback, support for advanced navigation options). It should be noted that we did not identify any violations to the following heuristics: visibility of system status of the mobile device (Heuristic 1), flexibility and personalization (Heuristic 6), aesthetic, privacy, and social conventions (Heuristic 7), and error management (Heuristic 8). Problems associated with Heuristic 7 were not likely to emerge given the nature of the tasks.

Self-Efficacy and Training

As discussed previously, participants often felt insecure about their actions and asked for help and confirmation before performing tasks (Table 2). This is partially attributable to their lack of experience with mobile devices and perhaps their age as well. All participants commented that they would need some time to learn and get used to the system and its features before they could start to use it regularly. Some indicated a need for training prior to use. A couple also noted that they often ask for help from people in their surroundings (eg, family, friends) when using new functions on mobile device:

I have a lot of grandchildren that are really helpful to me in understanding the system. But they do it a little too fast. Since they [already] know it. And that is exactly my problem. When they are trying to explain [things] to me, I do not manage to follow them.
[Patient 5, Tablet]

During the testing, a couple of participants commented that for a younger generation with more experience with technology, the mobile app would be easier to use and more widely accepted for everyday health management than for an older user group:

Fortunately I have a smartphone [with touch screen]... So I am used to [this type of systems]... If I were 69 years old, and had an older Nokia phone with regular keyboard, it would be more challenging to use touch [screen]...And also I am not afraid to press something wrong. And this would be more difficult for people that that are maybe a little fearful.
[Patient 1, Mobile phone]

By the end of testing, most of the participants had gained some experience with the system and mobile app features, which led to much faster task completion times and a reduced number of requests for help. Two of the participants even commented that they were very satisfied with how they performed the tasks. All of the participants agreed that by using the app regularly they would be better acquainted with its features and use it more efficiently:

I think I will be able to use [the app], but it will take time. These tasks...When it is new then there are a lot [of new things]. However, I did this in the Connect [Web app]. So I can find what I want now [in the system]. [Patient 3, Tablet]

Ease of Use

After testing, all participants commented that it was not hard to perform the tasks and they were able to find the right functions in the app menus. They concluded that the mobile app is simple to use, and one participant stated that it is much easier to perform and understand tasks on a mobile phone app than on the Web version. After testing the tablet version, the same patient additionally concluded that the tablet version is even easier to use compared to the mobile phone and Web apps.

Most of the participants commented that they did not want more functions on the mobile phone and tablet apps because they would be more complicated and harder to use. However, other participants suggested that supporting further functionalities on mobile app(s) could be useful for users with greater expertise in these emerging technologies.

Usefulness of the Connect System

Context Dependent Usefulness of System Features

As noted before, all participants in the study were involved in the larger study and had previously used the Connect system on a Web browser on a personal computer. The background questionnaire showed that the symptom assessment and self-management support and information modules were the least used functions on the Web app (Table 1). Most participants in this study reported that the main reason for not using the symptom assessment and self-management support modules was that they did not have the need for these functions in their phase of illness. They commented that these features would be better suited for patients who were recently diagnosed since they would be experiencing a range of new symptoms and have numerous emerging concerns related to their health condition. Only one participant said that she did not possess strong enough knowledge of the system, which influenced her use of the different system features:

I always said that is important to get access [to the Connect system] when you are in the treatment, when you are new cancer patient. When some time passes, then you usually go beyond this part (points to the screen with registration process). Then this [symptom assessment and self-management support functions] is not what it is important. There are other things that are a little more important. But for people that get cancer, and are new cancer patients, this [functions] is very important. [Patient 3, Tablet]

In addition to their previous comments about how usefulness of system features are related to the phase of the illness, after testing the mobile app some of the participants concluded that the usefulness of the system features could also be influenced by different contexts of use such as terminal type. They commented that symptom assessment and self-management support features, which were not frequently used on the Web app, could be used on mobile devices to overcome limitations

introduced by the mobile device's characteristics. For example, since writing text is more difficult on a mobile device, symptom assessment functionality can be used for easier registration and management of health problems instead of the diary functionality. Additionally, the symptom self-management module can be used to find practical advice on how to address health issues and presents an alternative to writing messages to the nurse.

System Usefulness and Intention to Use

Regarding Connect system functionalities, the participants commented that Connect system provides a lot of quality information, which is obviously important for this type of system. One participant additionally commented that for her one of the main goals of the Connect system was to provide support for easier patient-provider communication and higher levels of cooperation between patients:

When I had acute problems I had to go to the doctor. But for more chronic problems, like thoughts, emotions, experiences, physical problems... And when I finally sat down and wrote and defined all my problems... I could relax and be home. And not have to go to the doctor, and get appointments as I did [before]. And I knew I will get the answer and that there is somebody there who heard me. And then you as a cancer patient do not feel so alone... And that's where you can get support through SMS or system as Connect. [Patient 1, Mobile phone]

It is not just the fact that health care personnel should be available and give you answer in 24 or 48 hours. But we should be help to each other... I think the overall goal of the system and its functionalities is the meeting point for cancer patients... So we can share experiences about our anxiety, treatment, diagnose... And they [the patients] can be of help to each other. [Patient 1, Mobile phone]

All participants agreed that both phone and tablet versions of the app are useful and that they would use them in future. Some of the participants even commented that they previously thought about or tried accessing the Connect system over mobile device(s). Some of the participants also commented that if they could have the opportunity to use the Connect system on a mobile device, they probably would not need to use the Web version.

Most of the participants commented that they would use the same features on the Connect Mobile app as they currently use

on the Web app, but they identified new contexts of use that were enabled by mobile terminal characteristics:

So I got the [notification] message on my mobile phone [that I received a new message in Connect system], and only when I came home in the afternoon could I log in [and read it]. But tablet or mobile phone people have them with them all the time so they can log in and see [the message] right away. [Patient 4, Tablet]

Integration of New Features

In addition to testing standard features of the Connect system on the mobile app, we also investigated how they can be further expanded with new functions that better fit mobile terminals, such as tools for sending pictures to health care providers as attachments to messages. All participants agreed that this function would be very useful and that they would use it since adding a picture to email or text message is a commonly performed action on their own mobile devices. One participant additionally suggested that rich media (such as pictures and video) could be integrated with blog or forum modules to support easier sharing of different information between patients. The same patient commented that since she does not have a good memory as a result of her treatment, she frequently takes pictures of her medications with the camera on her phone to facilitate management and recall of the medication information during consultations with her health care provider.

Discussion

Design Recommendations

Mobile devices are ubiquitous tools in everyday life and are increasingly becoming part of the armaments for patients in their efforts to manage chronic disease. However, the available tools often do not support the needs of patients. There is a need to better understand obstacles in order to use these tools more productively and to fashion appropriate design solutions to better suit user needs. We identified a set of design issues in our findings that could also be used to further improve mobile app functions and design in health care contexts. From these issues we defined a set of general design recommendations that can be used when developing patient support mobile apps with similar design and functionality requirements. The design recommendations, grouped by the device type (mobile phone app, tablet app, or both), and usability heuristics are presented in [Table 5](#).

Table 5. The design recommendations grouped by the device type and usability heuristics.

App type	Heuristic	Design recommendations	Useful design features
Mobile phone and tablet	5: Ease of input, screen readability, and glanceability	Make sure the contrast between colors is clearly noticeable across different devices types	Easy identifiable back option
		Most important options/buttons/feedback to users must be visible on the screen without scrolling	Support buttons with both icons and text
		Collapsible sets and slider widgets may be problematic to use and understand	
		Implement support for using templates when writing messages to avoid requirement for too much writing	
	3: Consistency and mapping	Use the same colors across both Web and mobile systems	Implementation of system features to resemble to standard mobile app(s) options
		Enable both software and hardware back buttons (if device supports it)	System features should resemble across all apps (Web, mobile phone, tablet)
	2: Match between system and the real world	Make sure images and icons used in the app do not resemble of buttons	
		Text and options in dialog boxes must be easy understandable and intuitive	
		Enable user to preview original message content when writing reply	
	4: Good ergonomic and minimalistic design	Avoid use of not required popups/dialogs	
Mobile phone	5: Ease of input, screen readability, and glanceability	Provide support for writing message in horizontal mode	Option to customize main menu features
	6: Flexibility, efficiency of use, and personalization		
	3: Consistency and mapping	Implement advanced navigation options (eg, swiping screens) for expert users	
Tablet	5: Ease of input, screen readability, and glanceability	Use bigger font size (compared to the app for mobile phones) and additionally allow users to adjust text size themselves by zooming on screens with much text	Organization of the content on the screen in the two areas: menu on the left side and the main content on the right side
	3: Consistency and mapping	Use both text and icons on buttons	

Results showed that when performing tasks, patients mostly relied on their prior experience with mobile devices and Web versions of the Connect system and used knowledge along with analogies of these more familiar domains in order to build robust mental models of less familiar domains on the Connect Mobile app. The patients usually made mistakes or requested help when interface elements were not shown in a way that matched their previous experience with similar systems and real world perception (Heuristic 2). Inconsistency in mapping of system functions and interactions to standard mobile systems and the Connect system's design and functions (Heuristic 3) also contributed to incorrect mappings across different mental models and served to diminish task performance. For example, one patient commented that the use of consistent colors across apps and more advanced standard navigation options on mobile phone app (swiping screens) would help her to transfer knowledge from one context to the other. Most of participants during

interviews commented that they perceived the system features they previously used in the Web version or on private mobile device(s) as easier, since they were able to recognize the same features across different apps and/or devices. The previous experience with the Connect Web app also influenced the effectiveness of task performance. Based on these results, we can conclude that use of some standard design rules (eg, colors, system icons, option names) across all apps (Web, mobile phone, tablet) can help users transfer their knowledge of the Connect system to different contexts. Also, the development of a native mobile app that could be used on patients' private mobile devices, and adapting its features to resemble ones on the standard mobile devices (eg, organization of content, menus, navigation) can further support users to create more accurate mental models of the mobile app and its features while providing a better match between system features and the real world. This conclusion is consistent with findings from related research

work that also underline the importance of developing mobile health care apps for use on patients' private phones while complying with standard mobile design and functionality rules that patients are familiar with, rather than compelling users to learn to interact with additional mobile device(s) [23,33].

Due to the limited characteristics of mobile devices (eg, small screen, limited input capabilities), different issues influencing ease of input, screen readability, and glanceability (Heuristic 5) are identified. For example, participants did not always remember to scroll down, which caused them to miss some of the options that were not visible on the top of the page. Similarly, collapsible sets and slider widgets were problematic to understand and use. Due to both age and ongoing health treatments, several participants reported physical problems that limited their use of mobile devices (eg, swollen hands that introduced additional difficulties when navigating and using touch screen; memory problems). In the literature, different research projects have investigated how universal design rules and guidelines should be applied to support the development of mobile apps for users with special needs. For example, Kane et al proposed more general guidelines for developing mobile services for people with visual and motor disabilities, such as support for highly flexible interface customization to arbitrary settings, and dynamic adaptation of user interface to increase accessibility in different outdoor environments [56]. More specific design approaches have been created to facilitate interactions for people with specific needs, such as sliding fingers on the screen instead of tapping for people suffering from tremors [57] or using pens and edges on the screen for people with motor issues [58]. Participants in our study also gave us some suggestions on how they usually address these problems when using their private mobile devices and proposed how the Connect Mobile app could be adapted to be more suitable to their needs. For example, a couple of patients suggested that the horizontal view mode must be enabled when writing text on mobile phones since in this manner the buttons are bigger and easier to press. In menus, both icons and text should be used, since remembering meanings of just icons can be difficult. Additionally, different options can be used to facilitate inputting text in forms (eg, using template text, bigger font size of input fields).

Aside from the design issues and problems observed in the study, patients also identified navigation and design features that they found particularly useful. For example, on the tablet app, participants were very satisfied with organization of the content on the screen in the two areas (menu on the left side and the main content on the right side) since it provided a better overview of page content and required less action from the user (Heuristic 5).

The results of the study showed that it would be useful to have customization options that enable users to manually adjust the visibility of app modules on the main menu. This option could be used to preserve mobile app simplicity, which is identified as one of the most important app features. The customization option would be especially useful if the mobile app were to be expanded to support more system features. In general, the customization of system options is a regular feature of mobile apps (the app world in particular) that enable users to adjust the

content and features of the app to better fit their needs. This finding is consistent with several other mHealth studies that underscore the importance of enabling user customization [7,33,59,60]. Of course, unbridled customization would lead to app inconsistency and result in possible user confusion, so it is necessary to strike a balance between consistency and flexibility [61].

Connect System in the New Context of Use

The results from our study showed us patient needs for different system features on mobile phones and tablet devices, and how they differ from their Web app needs. Some patients said that they would use mainly the same functionalities on the mobile device as on the Web app, but also identified how the same features can be useful in the new contexts introduced by mobility of access terminal (eg, having the option to read the message from the health provider as soon as the SMS notification arrived, enabling access to the forum and blog features when traveling or away from home). Other patients identified features that they had not previously used on the Connect Web app as more useful on the mobile app. For example, since typing text was a demanding task for this patient group, some of them proposed using alternative system features such as menus that require selection from a predefined list (eg, using symptom assessment functionality for monitoring and reporting health symptoms from predefined lists instead of writing and describing symptoms in free text in the diary module). This is a classic problem in design that reflects the tension between flexibility/expressiveness and the need for standardization and structure [62]. Additionally, the symptom self-management support module can be used by patients to find advice and identify possible solutions related to reported symptoms instead of having to write messages to the nurse to solicit their advice. These results showed us how patients change and adapt their health management needs based on the current context, and how these new needs are influencing perception of usefulness and acceptability of different system features in the new contexts of use.

The results of this study were consistent with some of the common usage patterns for the current Web version of Connect system [41,45]. For example, this group of patients used the Web app more as a communication tool that enabled them to communicate with other patients and to provide each other with support, as well as to exchange information with their health care provider. In fact, one of the participants erroneously believed that the symptom assessment module generated a summary report that was automatically shared with his health care provider. Additionally, two other participants asked if it was possible to share lists of report problems in Connect with their health care provider. The feedback we gained during the study underlined the importance of system features that enable patients to involve health care personnel in health issues management and leverage socialization and sharing experience with other patients [7,40,41]. This is a prerequisite for effective shared decision making, which is especially important for cancer patients [63].

The participants reported that the acceptability of patient support systems and its features are influenced by the phase of illness.

For example, system features that enable patients to self-manage their symptoms and health-related issues are particularly important for patients in the early phases of their illness and/or treatment. This is consistent with results from previous studies [31,40,45,64,65].

Mobile App Usefulness and Directions for Further Development

All participants agreed that the Connect Mobile app is useful and that they would use it in the future for managing their health conditions. The results of the study support the notion that patient support systems for cancer patients, such as the Connect system, should be available across multiple modalities including Web and mobile devices. Integration of different mobile devices that provide the new context of use and advanced features are required to enable the full potential of patient support systems (such as personal health records and patient portals). Such systems would serve to increase use and accessibility for patients and promote shared decision making with health providers.

Participants also provided feedback on how different system features could be further developed and improved to support more efficient communication and collaboration. For example, using new information formats such as images in messages and blog modules can help patients to share their experience and health issues with others. The related research work on use of rich media as pictures [66,67], voice [33], and videos [68] in managing health conditions showed positive results and identified mobile devices as suitable tools to more quickly capture richer data, which was not previously possible using stationary computers. The results of our study are consistent with these findings and show patients' preferences on how rich media can be integrated as part of different functions of the Connect system for both sharing and managing personal health information. Also, integrating symptom assessment modules with electronic health care records supports more efficient symptom monitoring and enhances shared decision making between patient and health care provider.

User Training

The results of the study identified existing misunderstandings about Connect system functionalities showing that the patients' mental models of the system do not completely correspond with the real system functions. For example, as reported previously, one patient used the symptom assessment module because he believed that this information was visible to his health care provider and complained that he never received any return communications. He did not understand that the reported symptom should be used for self-management and that he can use symptom self-management support module himself to find advice addressing previously reported symptoms. One other patient was reluctant to write and share thoughts and comments with other patients since she was concerned about privacy issues and did not realize that only her nickname (and not identifiable information) was shown to others in the discussion forum.

These misunderstandings suggest that better training for new users, including a more detailed explanation of the system functions, is necessary for both proper use of the system and its acceptance. This is especially important with older users

with limited prior experience with technology [69,70]. This study is a precursor to a large-scale clinical trial of the Connect Mobile app. The findings of the study highlight the need for effective training to avoid possible mismatch between user mental models of the system and system. The fact that a majority of the participants became proficient during a 1-hour testing period showed us that the training period does not need to be very long, but it should focus on the system features that are more problematic and complex for potential users.

Some participants argued that the mobile technology is more suited for younger patients than for older users due to their limited experience with aspects of these devices such as the touchscreen display. However, even though most of the participants in this study were middle aged or older and not proficient users of mobile devices, all of them showed interest in using these apps to access the Connect system. This trend is also shown by some of the previous research, which demonstrated that older adults are also interested and capable of using emerging devices and advanced services for managing health care issues [71-73]. Additionally, the lower level of education of most participants did not influence the acceptance of the mobile app in our study, contrary to previous research findings [38].

Limitations and Future Work

We recognize that the user group of 7 patients who were involved in this evaluation study constitutes a small sample and may not adequately represent the larger user population. However, the sample size is more or less consistent with general recommendations for usability testing that state that the majority of usability issues can be identified with smaller number of participants (eg, 5-7 participants) [74,75]. It provided us with valuable feedback about the current app design and identified significant usability issues that will be addressed in the iterative design process. Additionally, we believe that participants' prior knowledge and experience with the Connect system enabled them to more readily assess the Connect mobile app's usefulness, evaluate potential new contexts of use, and suggest new functions to augment the existing system.

Although we can learn a lot about the usability of a mobile app in a controlled setting, it is important to test it in real-world situations, which are highly variable [76]. In the future, and prior to the clinical trial, we are planning to organize a feasibility study (outside a laboratory context) to further identify implementation issues and context-related concerns about the system features and design.

Previously we noted that there is limited related research on how mobile devices can be used in the context of health care information systems for cancer patients. These patients have special needs and unique problems. Further work is needed to identify the primary factors and design issues influencing acceptability and usefulness of different system features of mobile health care information services. In our future research, we are planning to continue work on development of Connect Mobile app and investigate how apps for mobile phones and tablets can be designed and adjusted to best fit users' needs in the new contexts of use. Some of the potential new app features have been identified during testing, as well as the need for

further exploration of how we can add rich media to the Connect Mobile app.

Conclusions

This work describes the results of our study of the design and functionality requirements for developing a mobile app to support cancer patients' management of health-related symptoms and problems.

The study has shown the need for and potential of integrating mobile phones and tablets in patient support systems and identified design recommendations and useful features that can be applied during mobile app design and development processes. The results of this study demonstrated how potential use and acceptance of different patient support system features could

be influenced not just by usefulness of specific functions but also by current context of use. The results from the study will be used in the iterative development of the Connect Mobile app and can also be used by other developers and researchers in the development, integration, and evaluation of mHealth apps and services that support cancer patients in managing their health-related issues and problems. mHealth is a burgeoning area of research and application. However, we are not yet at the point where system development is based on a stable paradigm that factors in a host of usability and idiosyncratic user needs. Nevertheless, it is becoming more apparent that even users who are typically considered to be disadvantaged, including older adults and those with lower levels of education, will not only accept the technology but also embrace it.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

App screen with the option for attaching a picture on the bottom of the page that was hard to find and use (in norwegian).

[[JPG File, 187KB](#) - [mhealth_v2i3e33_app1.jpg](#)]

Multimedia Appendix 2

App screen showing the small font size on pages containing lots of text (in Norwegian).

[[JPG File, 276KB](#) - [mhealth_v2i3e33_app2.jpg](#)]

Multimedia Appendix 3

App screen with the collapsible set widget that was problematic for participants to understand (in Norwegian).

[[JPG File, 263KB](#) - [mhealth_v2i3e33_app3.jpg](#)]

Multimedia Appendix 4

App screen with images that were confused as buttons (in Norwegian).

[[JPG File, 152KB](#) - [mhealth_v2i3e33_app4.jpg](#)]

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Abbreviations

CSS: Cascading Style Sheet
e-ESAS: electronic Edmonton Symptom Assessment System
HTML: hypertext markup language
HTTP: hypertext transfer protocol
PDA: personal digital assistant
REST: representational state transfer
SMS: short-message service
UCD: user-centered design
WHOMS: Wireless Health Outcomes Monitoring System

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Original Paper

Sexual and Reproductive Health for Young Adults in Colombia: Teleconsultation Using Mobile Devices

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Abstract

Background: Sexual risk behaviors associated with poor information on sexuality have contributed to major public health problems in the area of sexual and reproductive health in teenagers and young adults in Colombia.

Objective: To report our experience with the use of DoctorChat Mobile to provide sexual education and information among university students in Bogota, Colombia, and knowledge about the sexual risk factors detected among them.

Methods: A mobile app that allows patients to ask about sexual and reproductive health issues was developed. Sexual and reproductive risk behaviors in a sample of young adults were measured before and after the use of the app through the validated survey Family Health International (FHI) Behavioral Surveillance Survey (BSS) for Use With Adults Between 15 and 49 Years. A nonprobabilistic convenience recruitment was undertaken through the study's webpage. After completing the first survey, participants were allowed to download and use the app for a 6-month period (intervention), followed by completion of the same survey once again. For the inferential analysis, data was divided into 3 groups (dichotomous data, discrete quantitative data, and ordinal data) to compare the results of the questions between the first and the second survey. The study was carried out with a sample of university students between 18 and 29 years with access to mobile phones. Participation in the study was voluntary and anonymous.

Results: A total of 257 subjects met the selection criteria. The preintervention survey was answered by 232 subjects, and 127 of them fully answered the postintervention survey. In total, 54.3% (69/127) of the subjects completed the survey but did not use the app, leaving an effective population of 58 subjects for analysis. Of these subjects, 53% (31/58) were women and 47% (27/58) were men. The mean age was 21 years, ranging between 18 and 29 years. The differences between the answers from both surveys were not statistically significant. The main sexual risk behaviors identified in the population were homosexual intercourse, nonuse of condoms, sexual intercourse with nonregular and commercial partners, the use of psychoactive substances, and lack of knowledge on symptoms of sexually transmitted diseases and HIV transmission.

Conclusions: Although there were no differences between the pre- and postintervention results, the study revealed different risk behaviors among the participating subjects. These findings highlight the importance of promoting high-impact educational strategies on this matter and the importance of providing teenagers and young adults with easily accessible tools with reliable health information, regardless of their socioeconomic status.

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KEYWORDS

mobile health; youth and adolescents; telemedicine; remote consultation; Colombia; Latin America.

Introduction

Sexual risk behaviors associated with poor information on sexuality, such as the early onset of sexual intercourse and a high number of sexual partners, is one of the factors contributing to the status of sexual and reproductive health in teenagers and young adults as a public health problem [1,2].

In Colombia, the pregnancy rate was estimated to be 2.4 children per woman from 2002-2005, which is equivalent to 20 births per 1000 women. In teenagers, the pregnancy rate was estimated at 90 births per 1000 women (79 per 1000 in urban communities and 128 per 1000 in rural populations) [3]. This rate is one of the highest compared with the rest of Latin America and the United States. Regarding socioeconomic status (SES) as an influence factor for sexual risk behaviors, one study conducted in two cities in Colombia with 1100 teenagers from all socioeconomic backgrounds showed that there are indeed significant differences in patterns of sexual activity, cohabitation, and pregnancy between teenagers with varying SES in the country. The study showed a higher frequency of teenage pregnancy among low-level SES women, due to earlier onset of sexual intercourse, cohabitation, and less willingness to use contraceptive methods [4].

According to the National Demographic and Health Survey (ENDS) conducted by Profamilia in 2010 among 49,562 women between 15 and 49 years, it was determined that 99% had heard about HIV/AIDS, but knowledge was lower in those between 15 and 24 years old [5]. The level of knowledge was lower in rural areas (96%) than in urban areas (99%). Likewise, knowledge was lower among women who have no education (84%) and those at a lower economic level (95%). However, another study conducted in the country concluded that higher SES women share HIV and sexually transmitted diseases (STDs) risk characteristics with lower SES women, especially regarding cultural aspects and gender roles in relationships [6].

Various strategies of education for prevention have been explored, but their impact has not been as great as expected. From 2007, the Colombian Ministry of Health and Social Protection has been implementing the national adoption of the World Health Organization (WHO) Adolescent Friendly Health Services (AFHS) model. The model aims to facilitate the access and essential attention of young people and teenagers to sexual and reproductive health, in the context of the rights of health [7]. On the other hand, the United Nations Fund for Population Activities (UNFPA) Colombia promotes favorable conditions for the informed and protected exercise of sexuality in several cities of the country (not including Bogota). The UNFPA aims to do this by the promotion of comprehensive sexual and reproductive health services. The UNFPA also promotes the improvement of the socioeconomic determinants that contribute to HIV vulnerability [8,9]. Nonetheless, the rates of pregnancy and sexually transmitted diseases among young adults and teenagers have not decreased in the last 20 years in Colombia [8,10].

This situation has motivated the search for innovative programs through the use of emerging information technologies. These programs promise benefits in the diffusion of information and guidance toward prevention. However, their potential and impact have not been studied sufficiently in Latin America.

Specifically, in the field of sexual health for behavioral change, literature on the applicability of mobile technologies is limited. In 2010, The Cochrane Collaboration published their review on interactive, computer-based interventions for sexual health promotion [11]. In this report that analyzed 15 studies, a moderate positive effect was found on sexual health knowledge, a small effect on self-efficacy, and a small effect on sexual behavior. In the past years, there have been several studies and reviews that indicate that short message service (SMS) may be an effective low-cost method to promote sexual health among young people [12,13]. However, very few of these studies have been conducted in developing countries and most of them leave aside the use of mobile phone technologies and Web-based mobile apps. The WHO's report "mHealth—New horizons for health through mobile technologies" [14] summarizes the global efforts through mobile devices for health promotion. The report showed many successful programs in health promotion using SMS even in Colombia, but it does not mention interactive mobile systems or mobile app-based programs. Yet it showed how this kind of system can raise awareness in sexual health problems and solutions. In 2006, Zhao et al concluded, "providing sexual education to students in Shanghai over the Internet is feasible and effective" [15]. His statements suggested that Web-based sexual education programs increased the students' knowledge of reproductive health and led to significant changes in their attitudes toward sexuality, particularly on issues related to sexual freedom. The author concluded that the Internet offers significant potential to provide sexual education to students and teenagers in China. Furthermore, one study assessed the perception of a group of teenagers regarding technology for enhancing sexual health education, showing that young people can be enthusiastic and open to innovative ways of education [16].

Fundacion Santa Fe de Bogota is a private, nonprofit health organization located in Bogota, Colombia. The research group that conducted this study is part of the Education and Knowledge Management Department of the institution. This department is in charge of the Telehealth Center and all its related activities [17]. In September 2006, our research group started a Web-based medical counseling program service called DoctorChat. It is a free-access, online consulting service for Spanish-speaking users that allows them to submit health-related inquiries and to receive personalized and accurate responses from a well-known group of physicians through a simple, Internet-based form [18]. As previously reported [19,20], most queries were related to sexual health in the young population. Teleconsultation in Colombia has proved to be an innovative, low-cost, effective method to provide accurate and useful health information. The program also allows unrestricted open discussion on sensitive topics such as sexually transmitted diseases and sexual risk

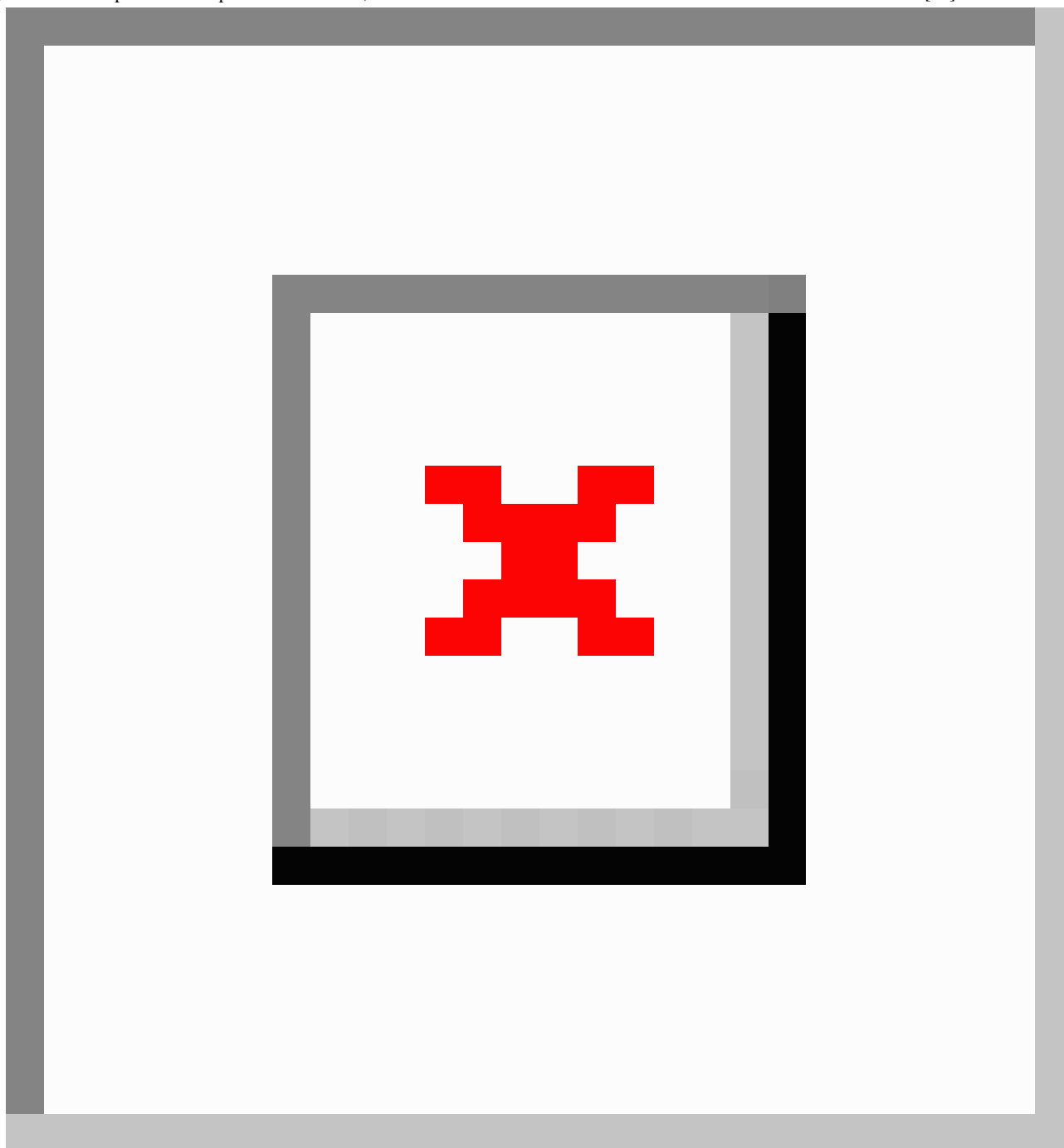
behaviors. With these findings we concluded that the expansion of the service into new platforms could enhance DoctorChat potential and positively impact key health indicators in Colombia, such as the rate of teenage pregnancy and spreading of diseases, through innovative educational services. With that in mind, the Web-based, mobile teleconsultation platform for DoctorChat was designed and developed in partnership with a software development group from the Universidad de los Andes, a private university in Colombia [21]. The ultimate goal of the app is to promote and deliver accurate sexual health information among young adults. Assessing a target population of young adults in Colombia, including their behaviors and knowledge regarding sexual health, can lead to future innovative interventions on sexual health education, thereby increasing its success. In this study, we tested the intervention in this convenience sample before expanding access to the intervention by a broader population.

In Colombia and Latin America in general, penetration of cellular phones among the population reached 100% (Figure

1), and 32% of the population was found to have access to the Internet, including mobile access [22]. Given that the effectiveness of behavioral interventions on sexual health is generally higher with measures on a specific target population and with clear expected outcomes [2], it is of great importance to assess intervention strategies through mobile device apps such as DoctorChat Mobile. Furthermore, medical services in Colombia are costly, and for those under the age of 18, medical appointments can only be scheduled by their parents or their legal guardians. These legal and financial restrictions on the ability of young people to access medical advice are very important when considering the utility of these kinds of strategies, which should be considered to be of high-potential and high-efficacy for the promotion of access to accurate and timely health information among young people.

In this paper we report our experience with the use of DoctorChat Mobile to provide sexual education and information among university students in Bogota, Colombia, and the sexual risk factors detected among them.

Figure 1. Mobile phone subscriptions in Colombia, 2000-2012. Data taken from the International Telecommunication Union [22].



Methods

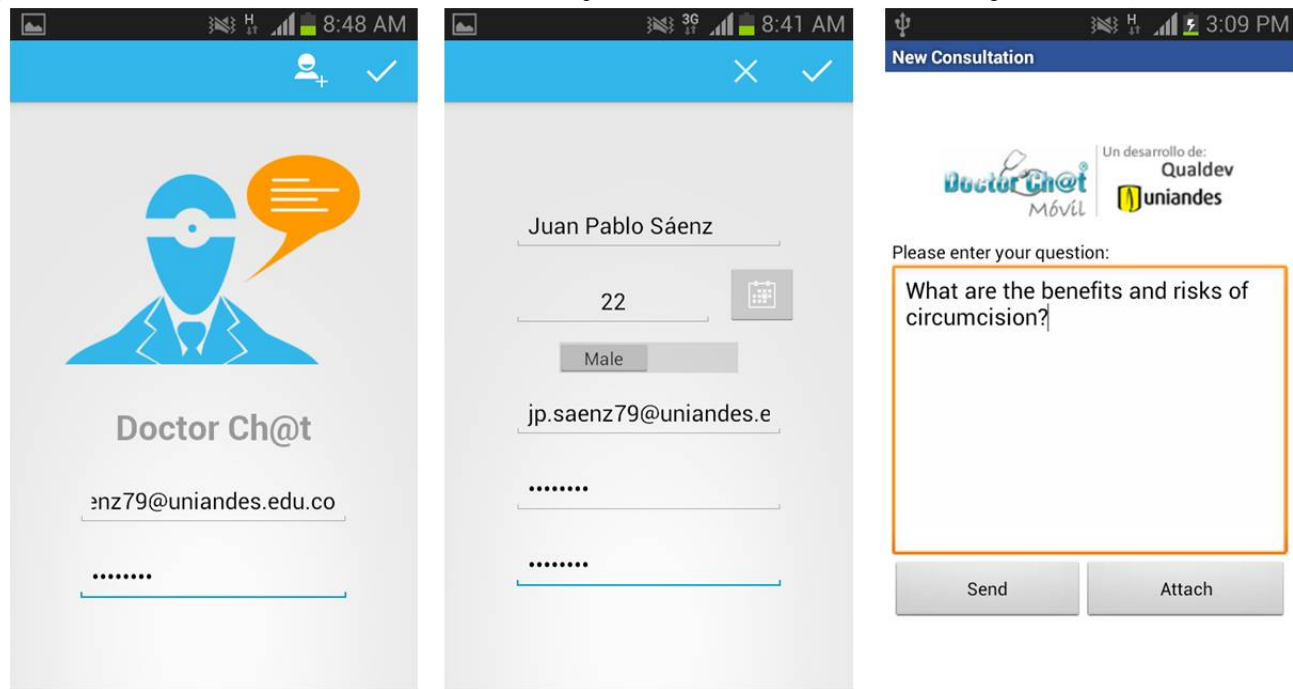
Study

Based on our previous experience with DoctorChat and in alliance with the Systems and Computing Engineering Department of the Universidad de los Andes, we developed an app that allowed users to send inquiries on sexual and reproductive health topics through their mobile phones, and to receive personalized and accurate responses from a knowledgeable group of physicians. Users had to type their questions into a free text field with the possibility of attaching multimedia files (Figure 2). All questions were individually answered asynchronously by the medical team from the

Telehealth Center in Fundacion Santa Fe de Bogota with a response rate of 24 to 48 hours. The app ran on 4 mobile platforms (iOS/iPhone, Android, RIM/Blackberry, and Symbian) and 27 mobile devices most used by a cohort of 371 potentially eligible subjects. Potential subjects responded to a short email-based survey which questioned their interest in the project and the type of mobile device they owned.

The reference population was established from our previous experience with the DoctorChat Web platform [19,20]. A nonprobabilistic convenience sampling was performed with the aim of recruiting at least 261 individuals, representing the number of annual average users of DoctorChat posing sexual and reproductive health questions.

Figure 2. DoctorChat on a mobile device; home screen (left), user profile screen (middle), and free text field (right).



Recruitment and Process

For this study we recruited university students from Universidad de los Andes with access to mobile phones. An invitation to participate was sent via email to a total of 12,463 students from different departments of the university. Participation in the study was voluntary and anonymous. If the subjects decided to participate, they had to register at a specific website, confirm all inclusion and exclusion criteria (Table 1), give their informed consent, and accept the terms and conditions of the project.

Once registered, they received an automatic confirmation via email with their personal username and password to access the online survey. After completion of the preintervention online questionnaire [23], they were able to download and use the mobile app.

The recruitment period took 5 months and the app was available for 6 months for each participant. After the 6-month period, participants were invited to complete the postintervention survey, which included questions on satisfaction with the app, to conclude the process.

Table 1. Selection criteria for participation in the study.

Inclusion criteria	Exclusion criteria
Aged 18-29 years	Health students and professionals
Reside in Colombia.	People who planned to leave the country for more than 20% of the time available to use the service during the teleconsultation time
Have access to a mobile device that: - allows navigation using a wireless network or an owned data plan, and - allows the installation of the app (installation requirements were provided)	Sex workers.
Have read, understood, and accepted the terms and conditions of the study	Intravenous drug users

Survey

The survey Family Health International (FHI) Behavioral Surveillance Survey (BSS) for Use With Adults Between 15 and 49 Years [23] was chosen to evaluate knowledge on sexual and other risk behaviors in young adults. This survey has been used and validated for more than 10 years in 20 countries, and has generated significant results in this matter. The BSS was conducted for the first time in Bangkok in 1993, and since then has been conducted mostly on people at high risk of contracting HIV and other sexually transmitted infections in developing countries. The data obtained from these surveys worldwide have enabled the implementation of more robust monitoring and control systems of sexually transmitted diseases such as HIV

[23]. The questions were limited to those of the validated survey and were not modified. The second survey included four additional questions on satisfaction with the tool.

Statistical Analysis

To ensure consistent analysis, data was initially collected and compared with the selection criteria (Table 1). Data with inconsistencies or lacking internal integrity was eliminated. Subsequently, the data was normalized following the second normal form as defined by Kifer et al [24], which ensured consistency and helped with the analysis process by dividing the results into work domains. This normalization also allowed the authors to relate data with the DoctorChat app database, determining which users used the app and how often. Thus, an

initial descriptive analysis of the information could be performed.

To perform the inferential statistical analysis, data was divided into three groups based on the nature of the questions on the instrument used. This division permitted comparison of results between the first and second survey. Samples were considered to be independent and, in most cases, followed a normal distribution.

The three analysis groups were as follows: dichotomous data (with positive or negative answers), discrete quantitative data, and ordinal data (such as the Likert scale). For all tests, a confidence interval of 95% was established. For dichotomous-nature data, the Chi-squared test was used, not assuming the Yates correction for continuity. This test was used due to its statistical power and to construct contingency tables. For quantitative data, and given the paired nature of the results, the Student's *t* test was used, which allows a statistical approach in small samples. This approach allowed the comparison of the variances and means of each sample. Finally, for the ordinal-class data, the measurement scale was established and the Mann-Whitney-Wilcoxon test was used, allowing the determination of differences between two scalar samples given their ranges. All statistical tests were performed using the

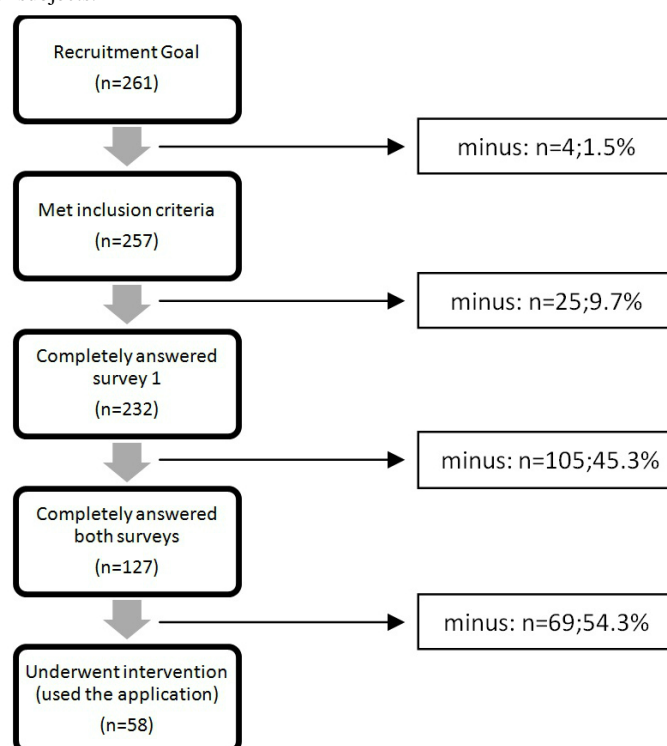
standard package from the statistical software R (The R Project for Statistical Computing, Institute for Statistics and Mathematics, Wirtschaftsuniversität Wien).

Results

Recruitment

Of the recruitment goal of 261 subjects, 257 registered voluntarily on the virtual platform and met the selection criteria. Of these, 232 completely answered the preintervention survey and, therefore, were eligible to advance to the intervention phase. At the end of the intervention phase, 127 subjects fully answered the postintervention survey. Of the 127 subjects that completed both surveys, 69 of them (54.3%) did not use the mobile app. As the intent was to compare the results from both surveys and their relationship with the use of the mobile tool (intervention), these subjects were excluded, leaving a final effective sample of 58 subjects to be analyzed (Figure 3). As a side analysis, the sexual behavior of those 69 subjects who completed both surveys but did not use the app was performed to compare the results with those who did use the app. In general, there were no statistically significant differences between the groups. Relevant results will be discussed in each subsection.

Figure 3. Recruitment and subsets of subjects.



Demographic Data

Demographic information was taken from the baseline survey. Of the total analyzable subjects, 53% (31/58) were women, and 47% (27/58) were men. The mean age was 21 years, ranging from 18 to 29 years. The subjects had lived in Bogota (the city

where the study was performed) for 13.3 years on average, ranging from 0 to 29 years and most were from mixed ethnic groups (mestizos). Regarding religion, most subjects were Catholic (41/58, 71%), followed by nonreligious affiliation (11/58, 19%). Table 2 summarizes the demographic data from the subjects.

Table 2. Demographic information of the subjects (n=58).

	Mean (SD) or n (%)
Age in years, mean (SD)	
Male	20 (2.9)
Female	21 (4.1)
Total	21 (3.6)
Years residing in Bogota, mean (SD)	13.3 (9.4)
Gender, n (%)	
Male	27 (47%)
Female	31 (53%)
Total	58 (100%)
Religion, n (%)	
Catholic	41 (71%)
None	11 (19%)
Don't know	3 (8%)
Protestant	2 (3%)
Other	1 (2%)
Total	58 (100%)
Ethnic group, n (%)	
Mestizos	41 (71%)
Caucasian	15 (26%)
Other	2 (3%)
Total	58 (100%)

Consultation Through the Mobile Service

Of the 58 subjects who used the mobile app, 48 of them (83%) consulted 1 to 3 times. Of 58 subjects, 9 of them (16%) made

4 or more consultations, and 1 person (2%) made 29 consultations ([Table 3](#)).

Table 3. Number of consultations per number of subjects (n=58).

Number of consultations	Number of subjects	%
1	24	41
2	16	28
3	8	14
4	2	3
5	1	2
6	1	2
7	1	2
8	2	3
16	2	3
29	1	2

Sexual Background

In answer to the question “Have you ever had sex?”, 91% (53/58) replied “yes”, 7% (4/58) replied “no”, and 2% (1/58) did not answer. Of the 58 subjects, 12 women (21%) and 17 men (29%) had sexual intercourse for the first time under the

age of 18. Overall, 50% (29/58) of the subjects had sexual intercourse for the first time under the age of 18, ranging between 13 and 22 years, with a mean of 18 years and a standard deviation of 3.3. When comparing both groups, men had sexual intercourse for the first time at a mean age of 16 years, while

women started sexual activity at a mean age of 18 years (Figures 4-6). The differences between those who did not use the app but did complete both surveys (Group 1), and those who did use the app (Group 2) were not statistically significant ($P=.97$), and are shown in Table 4.

Figure 4. Age and gender comparison of first experience of sexual intercourse.

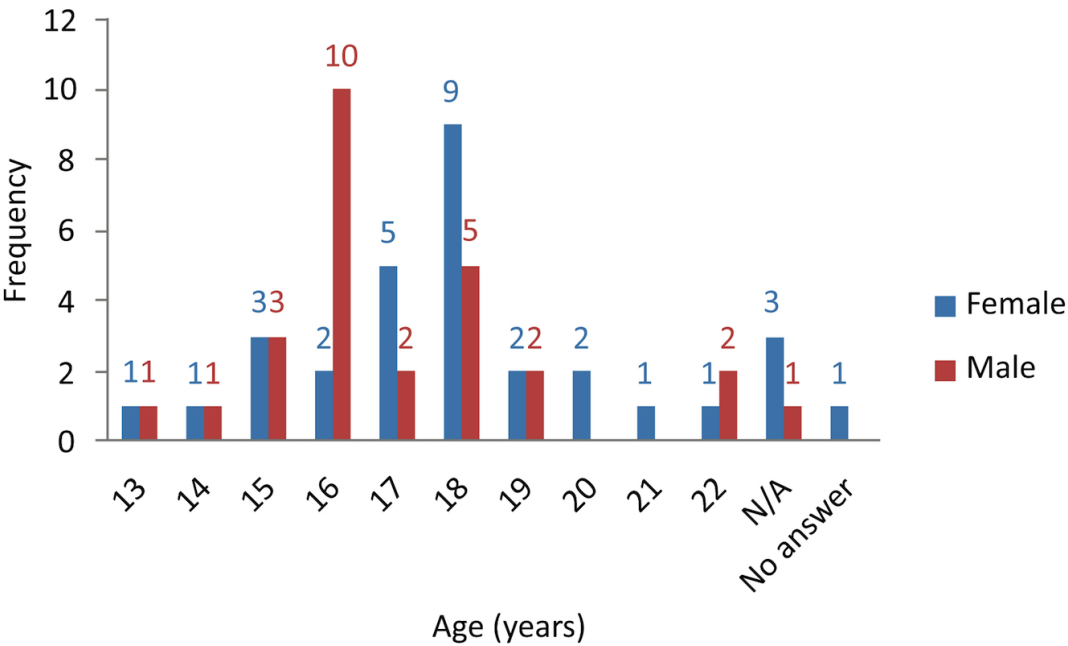


Figure 5. Age of first experience of sexual intercourse for males.

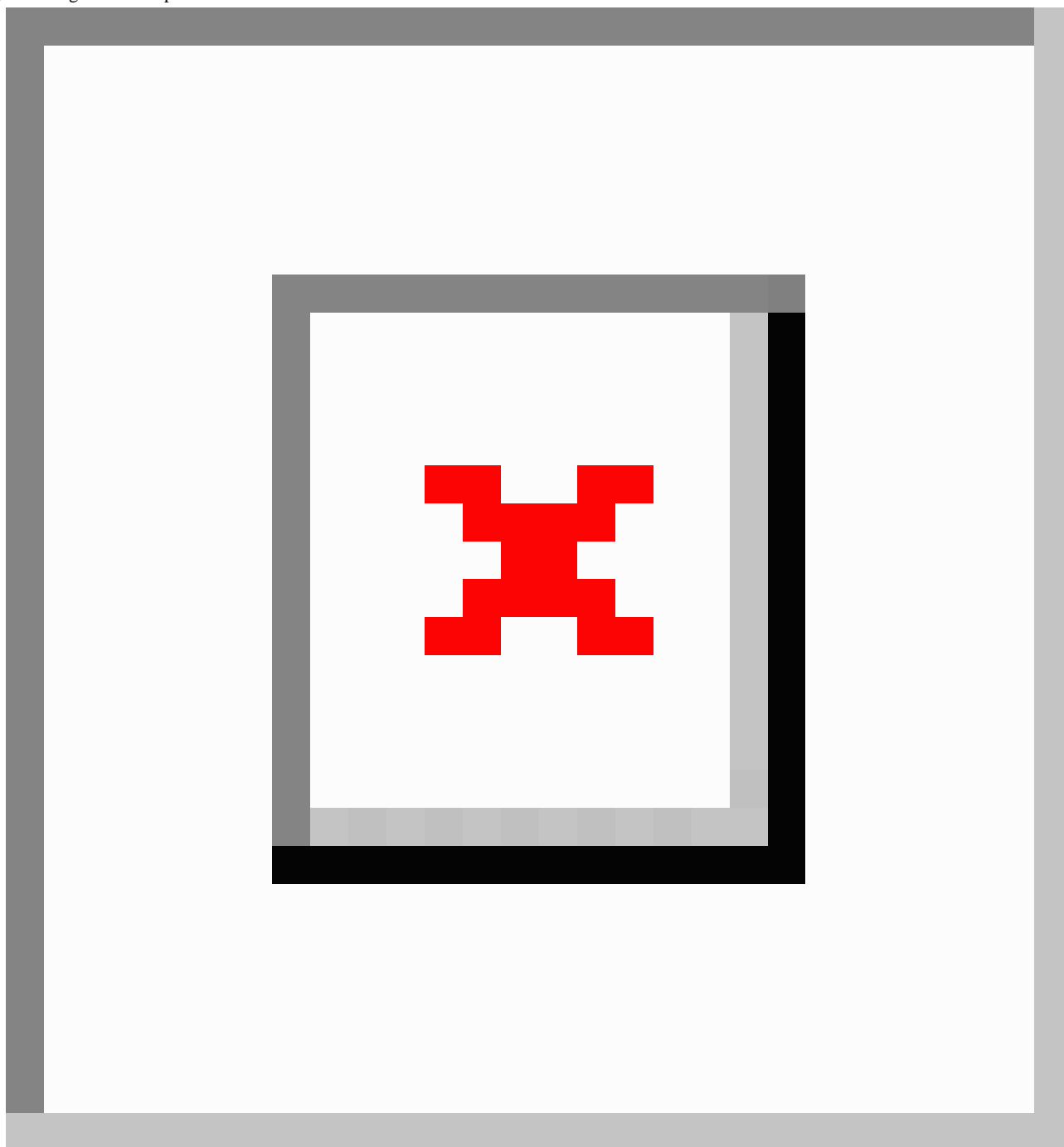
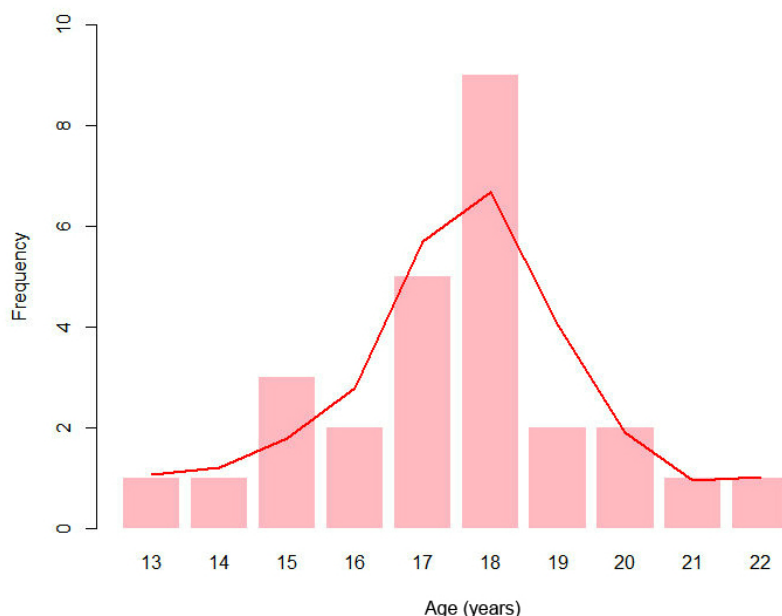


Figure 6. Age of first experience of sexual intercourse for females.**Table 4.** Comparison of age of first sexual intercourse experience between groups.

	Group 1 ^a (n=69)	Group 2 ^b (n=58)
Answered “yes” to the question “Have you ever had sex?”, n (%)	60 (87)	53 (91)
Age in years of first experience of sexual intercourse, mean (SD)	17(1.9)	18(2.1)
Age range in years ^c	12-23	13-22

^aSubjects completed both surveys, but did not use the app.

^bSubjects completed both surveys and used the app.

^cAge range of first experience of sexual intercourse.

By comparatively analyzing the answers given by the subjects in the preintervention versus the postintervention survey, no statistically significant differences were found. However, risk behaviors among subjects could be identified in both. All results reported in this section are taken from the baseline survey.

Regarding the sexual background of the subjects (Table 5) and the main sexual risk behaviors identified, the surveys demonstrated that over 80% (survey 1, 50/58; survey 2, 47/58) of the subjects had sex in the 6 months prior to the surveys. In the first survey, 2 men out of 27 (7%) claimed to have had sex with another man, whereas in the second survey, 3 out of 27 (11%) did so, with an average of 3 partners in the past 6 months in the second survey. Furthermore, in the first survey, 12 men out of 27 (44%) and 8 women out of 31 (26%) claimed to have had sex with nonregular partners (to whom they were not married, whom they had never lived with, and who did not receive any payment), whereas in the second survey, 13 out of 27 men (48%) and 9 out of 31 women (29%) did so. From these data, there was an average of 2.6 partners for men and 1.6 partners for women. This last difference was statistically significant ($P=.15$). On average, men had sexual intercourse 2.6 times in the past 30 days with their last nonregular partner, and women had sexual relations 2 times (nonstatistically

significant difference, $P=.64$ and $P=.38$, respectively). Likewise, 3 men out of 27 (11%) and zero (0%) women claimed to have had commercial sex partners in the last 6 months, with an average of 1.7 commercial partners for men in the last 6 months for the first survey and 3 partners in the second. In the first survey, none of the subjects answered how many times they had sexual intercourse with their last commercial sex partner in the past 30 days. However, in the second survey, the subjects claimed to have had sexual intercourse twice on average with their last commercial partner.

Regarding the use of condoms, 18 subjects out of 58 (31%) reported having sexual intercourse without a condom in the last 6 months. Out of 58 subjects 1 person (2%) reported in the second survey not having used a condom during his last sexual intercourse experience with a commercial partner. Of 58 subjects, 7 (12%) in the first survey and 6 (10%) in the second reported not using a condom the last time they had sexual intercourse with a nonregular partner. Finally, 34% (20/58) of the subjects did not use a condom the last time they had sexual intercourse with their regular partner. Results of sexual background between those who did not use the app and those who did were similar.

Table 5. Sexual background of subjects (n=58).

Questions posed in surveys	Survey 1 ^a n or mean (SD)	Survey 2 ^b n or mean (SD)	P value P value
Have you had sexual intercourse in the last 6 months?, n			
Yes	50	47	.23
No	4	8	
Commercial Partners^c			
Men: Think about the female sexual partners you've had in the last 6 months—were any of them commercial?, n			
Yes	3	3	N/A ^d
No	20	20	
Both genders: How many commercial partners have you had sex with in the last 6 months?, mean (SD)			
	1.7 (1.15)	3 (0)	.18
Both genders: Think about your most recent commercial sexual partner—how many times did you have sexual intercourse with this person over the last 30 days?, mean (SD)			
	0 (0)	2 (2.83)	N/A ^d
Nonregular partners^e			
Men: Think about the female sexual partners you've had in the last 6 months—were any of them nonregular partners?, n			
Yes	12	14	.55
No	11	19	
How many nonregular partners have you had sex with in the last 6 months?, mean (SD)			
Men	1.25 (0.46)	1.86 (0.69)	.06
Women	1.5 (0.84)	1.22 (0.67)	.49
Think about your most recent nonregular sexual partner—how many times did you have sexual intercourse with this person over the last 30 days?, mean (SD)			
Men	3 (4.44)	2.11 (3.82)	.64
Women	2.44 (2.24)	1.43 (0.78)	.38
Women: Think about the male sexual partners you've had in the last 6 months—were any of them nonregular partners?, n			
Yes	8	9	.75
No	17	15	
Use of Condoms			
Both genders: The last time you had sex with your regular partner, did you and your partner use a condom?, n			
Yes	21	21	.91
No	20	19	
Both genders: The last time you had sex with a commercial partner, did you and your partner use a condom?, n			
Yes	3	0	.15
No	2	1	
Both genders: The last time you had sex with a nonregular partner, did you and your partner use a condom?, n			
Yes	13	15	.66
No	7	6	
Both genders: During the last 6 months, did you ever have sex without a condom with any commercial sexual partner or any other sexual partner with whom you have never lived nor been married to?, n			
Yes	18	18	.94
No	30	29	
Male homosexual relations^f			

Questions posed in surveys	Survey 1 ^a	Survey 2 ^b	<i>P</i> value
	n or mean (SD)	n or mean (SD)	<i>P</i> value
Men: Have you ever had any male sexual partners in the last 6 months?, n			
Yes	2	3	.81
No	1	1	
Men: How many male partners have you had anal intercourse with in the last 6 months?, mean (SD)			
	1 (0)	3 (2.64)	.32

^aPreintervention survey.

^bPostintervention survey.

^cPartners with whom you had sex in exchange for money.

^dNot applicable.

^eSexual partners that you are not married to, who you have never lived with, and did not pay—do not include current spouse(s) or live-in sexual partners.

^fSexual intercourse defined as penetrative anal sex.

Sexually Transmitted Diseases

Regarding knowledge of STDs (Table 6), 100% (58/58) of subjects were aware of the existence of STDs. In the first survey, 69% (40/58) of the subjects answered that foul-smelling discharge is a symptom that can occur in both men and women. However, 26% (15/58) answered that this symptom manifests in only men or only women, and 5% (3/58) answered that this symptom does not occur. For this same question in the second survey, 86% (50/58) answered that this symptom can occur in both men and women, 9% (5/58) answered that it manifests in only men or only women, and 5% (3/58) answered that this

symptom does not occur. This change represented a statistically significant difference between both surveys ($P=.04$). However, this statistically significant difference was not observed in the group of those who did not use the app ($P=.25$).

Of the 58 subjects, 41% (24/58) in the first survey and 31% (18/58) in the second survey did not consider anal irritation or discharge to be a symptom of STDs.

In the first survey, 19% (11/58) of the subjects answered that itching is a symptom present in only men or only women, and 12% (7/58) answered the same in the second survey.

Table 6. Knowledge of sexually transmitted diseases (n=58).

Questions posed in surveys		Survey 1 ^a , n	Survey 2 ^b , n	P value
Have you ever heard of diseases that can be transmitted through sexual intercourse?				
Yes		58	58	N/A ^c
No		0	0	
Can you describe any symptoms of STDs in women and/or in men? ^d				
Genital discharge				
Women and men		44	46	.75
Only in women or only in men		10	8	
None		4	4	
Foul-smelling discharge				
Women and men		40	50	.04
Only in women or only in men		15	5	
None		3	3	
Genital ulcers/sores				
Women and men		46	48	.81
Only in women or only in men		11	5	
None		1	5	
Anal swelling or discharge				
Women and men		23	35	.06
Only in women or only in men		11	5	
None		24	18	
Itching				
Women and men		46	47	.99
Only in women or only in men		11	7	
None		1	4	
Flu-like symptoms				
Women and men		25	30	.40
Only in women or only in men		1	1	
None		32	27	
Abdominal pain				
Women and men		11	21	.24
Only in women or only in men		18	25	
None		29	12	
Burning pain on urination				
Women and men		49	48	.74
Only in women or only in men		8	7	
None		1	3	
Headache				
Women and men		20	19	.88
Only in women or only in men		0	3	
None		38	36	
Diarrhea				

Questions posed in surveys		Survey 1 ^a , n	Survey 2 ^b , n	<i>P</i> value
Nausea and vomiting	Women and men	18	21	.69
	Only in women or only in men	2	1	
	None	38	36	
	Women and men	16	19	.93
	Only in women or only in men	10	6	
	None	32	33	

^aPreintervention survey.

^bPostintervention survey.

^cNot applicable.

^dThese questions are meant to assess whether participants think that STD symptoms may occur only in one gender. The questions were taken from the validated FHI survey and were not modified.

HIV/AIDS

With regard to HIV awareness (Table 7), 1 person out of 58 (2%) claimed not to have ever heard of HIV. Of 58 subjects, 7 individuals (12%) in the first survey and 4 (7%) in the second survey claimed that a person can contract HIV by sharing food

with someone who is infected. Out of 58 subjects, 11 (19%) that answered the first survey and 10 (17%) that answered the second survey did not know whether a woman with HIV or AIDS can transmit the virus to her newborn child through breastfeeding.

Table 7. HIV knowledge by subjects (n=58).

Questions posed by the surveys	Survey 1 ^a , n	Survey 2 ^b , n	P value
Have you ever heard about HIV or the disease called AIDS?			
Yes	57	58	.32
No	1	0	
Can people protect themselves from HIV, the virus that causes AIDS, by using a condom correctly every time they have sex?			
Yes	56	57	.32
No	1	0	
Can a person get HIV from mosquito bites?			
Yes	7	4	.51
No	42	37	
Don't know	8	17	
Can people protect themselves from HIV by having one uninfected faithful sex partner?			
Yes	46	45	.64
No	8	10	
Don't know	0	0	
Can people protect themselves from HIV by abstaining from sexual intercourse?			
Yes	38	41	.64
No	19	17	
Don't know	0	0	
Can a person get HIV by sharing a meal with someone who is infected?			
Yes	7	4	.36
No	46	48	
Don't know	4	6	
Can a person get HIV by getting injections with a needle that was already used by someone else?			
Yes	56	58	.31
No	1	0	
Don't know	0	0	
Do you think that a healthy-looking person can be infected with HIV, the virus that causes AIDS?			
Yes	56	58	.31
No	1	0	
Don't know	0	0	
Can a pregnant woman who is infected with HIV or AIDS transmit the virus to her baby?			
Yes	56	56	.32
No	0	1	
Don't know	1	1	
Can a woman with HIV or AIDS transmit the virus to her newborn child through breastfeeding?			
Yes	20	25	.55
No	11	10	
Don't know	26	23	

^aPreintervention survey.^bPostintervention survey.

Substance Use

Regarding the use of substances (Table 8), 26% (15/58) of subjects that answered the first survey and 31% (18/58) that answered the second reported consuming alcohol at least once a week in the last 6 months.

Of 58 subjects, 24 (41%) in the first survey and 22 (38%) in the second survey claimed to have used a psychoactive substance at least once. The most common substances used were marijuana (22/58, 38%), tobacco (19/58, 33%), and cocaine (5/58, 9%).

Table 8. Substance use by subjects (n=58).

Questions posed by the surveys	Survey 1 ^a , n	Survey 2 ^b , n	P value
During the last 6 months, how often have you ingested drinks containing alcohol?			
Less than once a week	40	36	.49
At least once a week	15	18	
Have you ever tried any psychoactive substance?			
Yes	24	22	.70
No	34	36	
Which of the following, if any, have you tried?			
LSD			
Yes	2	5	.17
No	22	17	
Ecstasy			
Yes	0	0	N/A ^c
No	24	22	
Cocaine			
Yes	5	6	.61
No	19	16	
Marijuana			
Yes	23	21	.95
No	1	1	
Tobacco			
Yes	19	19	.52
No	5	3	
Poppers			
Yes	4	5	.60
No	20	17	
Injectable drugs			
Yes	0	0	N/A
No	24	22	

^aPreintervention survey.

^bPostintervention survey.

^cNot applicable.

Satisfaction With the Mobile Tool

Of the participants who answered the postintervention survey, 142 of them answered all four satisfaction questions included in the survey. These results are summarized in Table 9. Of these subjects, 92.3% (131/142) of them considered having access to a mobile-based teleconsultation tool on sexual health to be important or very important. Of the respondents, 69.7% (99/142)

of them considered the use of the app to be easy or very easy, in contrast with the remaining 30.3% (43/142) that found the app difficult or not so easy to use.

Regarding the subjects' preferences on learning methods for sexual and reproductive and health topics (degree of perceived effectiveness with the different learning methods), 74.6% (106/142) of the subjects considered that in-person lessons/workshops in a classroom are ineffective and 50.7%

(72/142) considered virtual lessons/workshops to be ineffective as well. Of the participants, 54.9% (78/142) thought that a mobile-based teleconsultation tool could be effective, and 54.2% (77/142) had the same perception regarding face-to-face medical consultations. The participants' overall experiences with DoctorChat Mobile were reported as Excellent, 26.8% (38/142),

Good, 50.0% (71/142), Fair, 15.5% (22/142), and Bad, 7.7% (11/142).

Finally, participants were allowed to write free comments about the app. The positive comments alluded to the clarity of the responses, the response time, and the option to send queries anonymously. On the other hand, the negative comments were related to the installation process and the correct use of the tool.

Table 9. Satisfaction survey results (n=142).

Questions posed by the satisfaction survey	n	%
How important is it to you to have access to a mobile teleconsultation tool such as DoctorChat Mobile?		
Very important	72	50.7
Important	59	41.5
Not important	11	7.7
How easy was it for you to send queries through your cell phone?		
Very easy	43	30.3
Easy	56	39.4
Not very easy	32	22.5
Difficult	11	7.7
For each of the following four methods, indicate whether you consider it effective or not as a learning method on reproductive and sexual health related topics:		
1. In-person lessons/workshops in a classroom		
Effective	36	25.4
Not effective	106	74.6
2. Virtual lessons/workshops		
Effective	70	49.3
Not effective	72	50.7
3. Teleconsultation using a mobile device		
Effective	78	54.9
Not effective	64	45.1
4. Face-to-face consultation with a health care professional		
Effective	77	54.2
Not effective	65	45.8
How would you qualify your overall experience with the use of DoctorChat Mobile?		
Excellent	38	26.8
Good	71	50.0
Fair	22	15.5
Bad	11	7.7

Discussion

Principal Findings

This study provides results regarding not only the use of a mobile teleconsultation service to provide sexual education and information for young adults, but also about sexual risk behaviors among university students in Colombia.

In terms of usage of the app, with a loss rate of 77.8% (58 subjects to be analyzed out of 261) of the subjects and with 41%

(24/58) of subjects using the app only once, we can predict, as we have reported in our previous studies, that this behavior reflects the law of attrition described by Eysenbach in 2005 [25]. This law states that eHealth initiatives suffer from a common problem that involves a loss of users over time. This effect is most likely due to a decrease in motivation of the user after their curiosity toward the app has been satisfied by using the app a few times.

When performing the consolidated comparative analysis of changes in sexual risk behaviors pre- and postintervention, most

of the results were not statistically significant. However, this study did not intend to change risk behaviors but rather to obtain a descriptive dataset regarding risk behaviors. On this matter, this study confirms that risk behaviors including heterosexual and homosexual unprotected sex, sex with nonregular and commercial partners, substance consumption, and lack of knowledge regarding sexuality are still very frequent problems among young adults regardless of their socioeconomic status [6].

On the other hand, analyzing the details of the effect of the use of the mobile app on sexual behaviors, we noted some interesting issues worth mentioning. It is clear that the use of the tool did not influence sexual practice. Of the 50 subjects who claimed to have had sexual intercourse 6 months prior to the preintervention survey, 92% (46/50) maintained their sexual activity during the postintervention period. Only men reported having had sexual intercourse with commercial partners. It is notable that these men did not answer how many times in the past 30 days they had had sexual intercourse with their last commercial partner in the first survey. However, in the second survey, these men answered this question. Additionally, it is clear that men in this study had more nonregular partners than did women, and this difference was statistically significant.

Likewise, there were no differences regarding sexual practices among homosexual men or the use of condoms. However, there was a difference of only 1 additional person who used a condom with his regular partner between the pre- and postintervention surveys. Moreover, 3 additional subjects reported using condoms with irregular partners in the second survey, and 2 additional subjects reported not using a condom with a commercial partner in the second survey. There were no differences regarding the use of condoms in heterosexual men, with a difference of only 1 additional person who reported having used a condom in the past 6 months with a noncommercial or nonregular partner.

Interestingly, although all subjects had heard about sexually transmitted diseases, 1 person had never heard about HIV/AIDS before the intervention, but this status changed after the use of DoctorChat Mobile. Likewise, 1 person learned that this infection can be prevented with the proper use of condoms. Furthermore, 2 to 3 people learned that HIV/AIDS can be prevented with sexual abstinence, whereas another 3 people learned that the risk of infection is minimal after sharing food with an infected person. In addition, 2 subjects learned that they can become infected after sharing a needle with someone who is infected and at the end of the intervention all participants knew this fact. Similarly, 2 subjects learned that an HIV-infected person can appear healthy, and all subjects were aware of this fact by the end of the intervention.

Paradoxically, 2 additional subjects, after the intervention, did not think they could protect themselves from HIV by having 1 uninfected faithful sex partner, whereas previously they thought they could. Additionally, doubt about the vertical transmission of HIV persisted in the only person who reported doubt at the beginning of the study. However, doubt did not persist in the case of breastfeeding, as 1 to 3 people learned of the causal relationship.

Although the differences in knowledge and risk behaviors for HIV/AIDS were subtle, they are nonetheless important, considering that in 2011 approximately 2.5 million people became infected and 1.7 million died from AIDS-related causes [26]. Other indicators, such as those concerning knowledge of the symptoms of sexually transmitted infections, seemed to improve with the intervention. Specifically, 10 people learned, with the intervention, that malodorous discharge may be a symptom of sexually transmitted infections, which represented a statistically significant difference.

Comparison With Prior Work

More than 5 years ago, we reported the first experience since the release of DoctorChat, a free-access service of virtual medical orientation in Spanish [19,20]. From September 2006 to March 2007, 270 teleconsultations were received, mostly from women (167/270, 61.9%) and users 18-29 years old (146/270, 54.1%). The main topics of consultation were those related to sexual and reproductive health [19]. Subsequently, the 2-year follow-up of the experience was reported [20]. We observed a tendency similar to that of the first report—between 2007 and 2009, 1624 consultations were received from users, mainly those 18-29 years old (861/1624, 53.02%). The main topic of consultation remained sexual and reproductive health (422/1624, 25.99%). We concluded, in both reports, that the service could be an innovative way to improve community access to health information, particularly sexual and reproductive health. Observing the rapid increase in the spread of mobile devices in Colombia and Latin America, we also concluded that mobile-based interventions could positively impact the delivery of health information. This encouraged us to develop DoctorChat Mobile, an app to support the service of DoctorChat on mobile devices.

Studies like the one conducted by Formigos have shown that "1 in 6 patients consult the Internet before going to the doctor, and 1 in 4 do so afterwards to contrast or complete the information" [27]. On the other hand, the Health Information National Trends Survey (HINTS) [28], a US National Institutes of Health initiative, reported that the first source consulted by patients when consulting specific information is the Internet, despite the fact that the physician is the most trustworthy source of health information.

According to Kirby et al [29], educational strategies aimed at sexual health have a positive impact on sexual risk behaviors without negative effects. This positive impact is associated with increased use of condoms and oral contraceptives, delay in the onset of sexual life, and reduction in the frequency of sexual activity. There are several reasons why young people would request guidance in sexual and reproductive health through a mobile teleconsultation service. The first could be age. Although the computer culture is not yet fully consolidated in Colombia, it is likely that young people make the most use of the Internet to address their health information needs compared with other age groups. Second, in Colombia the parents or legal guardians are responsible for scheduling medical appointments for minors (defined as those less than 18 years of age). Hence, social embarrassment and other limitations may restrict teens from asking their parents or guardians or requesting a medical

appointment to solve issues considered taboo, typically those related to sexual and reproductive health. Moreover, and related to the above statement, monetary issues could also be an important factor—few teenagers can afford a private face-to-face consultation. For the group over 18 years old with purchasing power and access to the health care system (which represents the minority), waiting times for a face-to-face consultation can be extensive, and the administrative process necessary to request an appointment can be rather complex. Finally, another possible explanation could be supported by the desire of the users to evaluate the severity of their symptoms before scheduling a face-to-face consultation.

In this context, we think that it is worth insisting on the modeling of strategies for sexual education and guidance aimed at young people through their most-used tools, including mobile devices. As information technologies ultimately become more accessible to the least favored, these strategies could enhance patient empowerment, improve macroeconomic indicators, and achieve Millennium Development Goals such as improving maternal health and combatting diseases such as HIV/AIDS [30].

Limitations

Regarding the recruitment process, the goal of reaching 261 individuals was not met and the analysis was limited to 58 people, thereby limiting the statistical power to detect changes between both surveys. However, being a descriptive report, the information can be of great interest as a baseline for more robust studies. The demographic characterization of the sample population in this study, in particular the high socioeconomic profile of the participants, can be considered as a limitation. However, as reinforced by the results of this study and other Colombian reports, this population still has sexual risk behaviors and is susceptible to receive innovative sexual educational strategies [3,6].

As for the survey, the original questionnaire was intended for in-person interviews. When applying it online as a self-evaluation tool without an interviewer, some questions could lose their effectiveness. This is particularly evident in those that refer to STD symptoms. The original survey asks openly if the individual can describe any symptoms of STDs in women or men without giving them any evident options. In this study we did not assess whether participants knew that a person could be infected without having symptoms.

Among other limitations of this study, we must mention that the DoctorChat Mobile app works only on smartphones, versus mobile phones with more basic features. This limitation may have contributed to the low use of the mobile teleconsultation service, given that it was necessary to exclude a great percentage of the subjects initially recruited to the study that didn't meet the technical criteria. Moreover, more than 80% of the 58 subjects that did use the service accessed the app 3 times, and less than 20% of them accessed the service 4 or more times. Unfortunately, the paradoxical situation of telemedicine suggests that the population that is most likely to benefit from such information technology services is the population that has the least access to them [31]. However, this study proves that it is still important to encourage the use of these new technologies among people that can have access to them, given that they are

rising steeply in developing countries [14, 22], and given that youngsters are very fond of them. In addition, it's very important to encourage and spread the use of simpler technologies that have proven to be in some way effective, such as texting or SMS, or in-person educational strategies [11-13].

Thus, it would be useful to repeat this study in other populations that are more vulnerable in terms of age, educational level, and socioeconomic status compared to this study's subjects. However, this task would involve a mobilization of resources and a much greater budget than that available for our study. Repeating this study in a new population could reveal interesting results, especially considering that in Latin America, at least 30% of women aged 15 to 19 have had some type of sexual experience. Additionally, in Colombia 33% of women under the age of 18 and 70% under 20 have had a sexual experience, with only 7% having used a contraceptive method [32].

Taking into account that obtaining an answer from the DoctorChat Mobile service could take up to 48 hours, it may be inferred that people may not be willing to wait that long for basic information on sexual and reproductive health. However, having access to a professional medical staff giving personalized answers to specific anonymous questions through mobile devices was very well rated among the participants. In addition, most of the positive comments on the app were related to the response time.

Ethics

This study was conducted with previous approval from Fundacion Santa Fe de Bogota and Universidad de los Andes' Ethics Committees. In addition, all subjects were provided with an informed consent document and a document containing all terms and conditions of the service prior to their enrollment. This consent was recorded online as the first step in the registration process.

Conclusions

DoctorChat Mobile seems to be an innovative and well-accepted tool to provide personalized sexual health-related information and education. This study revealed that sexual risk behaviors are frequent among young Colombian adults of high socioeconomic status. This finding confirms the importance of promoting education strategies on this topic and the importance of encouraging the empowerment of young patients with easy access to reliable information, regardless of their origin. However, it would be worthwhile to repeat this study in a more vulnerable population than the one hereby included, such as teenagers with low education levels and socioeconomic status.

DoctorChat Mobile did not result in significant changes in sexual and reproductive risk behaviors in the population studied. Although the recruitment was satisfactory, the loss of subjects was high, and the rate of the use of the service was low. Nonetheless, user satisfaction with the tool was very encouraging and confirmed that these kinds of strategies are well-accepted among young adults, and can be considered as innovative and effective tools to provide accurate and useful health-related information to a new generation of well-informed and empowered patients.

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Conflicts of Interest

None declared.

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Abbreviations

AFHS: Adolescent Friendly Health Services

BSS: Behavioral Surveillance Survey

ENDS: National Demographic and Health Survey

FHI: Family Health International

HINTS: Health Information National Trends Survey

SES: socioeconomic status

SMS: short message service

STDs: sexually transmitted diseases

UNFPA: United Nations Fund for Population Activities

WHO: World Health Organization

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Original Paper

Development of an Evidence-Based mHealth Weight Management Program Using a Formative Research Process

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Abstract

Background: There is a critical need for weight management programs that are effective, cost efficient, accessible, and acceptable to adults from diverse ethnic and socioeconomic backgrounds. mHealth (delivered via mobile phone and Internet) weight management programs have potential to address this need. To maximize the success and cost-effectiveness of such an mHealth approach it is vital to develop program content based on effective behavior change techniques, proven weight management programs, and closely aligned with participants' needs.

Objective: This study aims to develop an evidence-based mHealth weight management program (Horizon) using formative research and a structured content development process.

Methods: The Horizon mHealth weight management program involved the modification of the group-based UK Weight Action Program (WAP) for delivery via short message service (SMS) and the Internet. We used an iterative development process with mixed methods entailing two phases: (1) expert input on evidence of effective programs and behavior change theory; and (2) target population input via focus group (n=20 participants), one-on-one phone interviews (n=5), and a quantitative online survey (n=120).

Results: Expert review determined that core components of a successful program should include: (1) self-monitoring of behavior; (2) prompting intention formation; (3) promoting specific goal setting; (4) providing feedback on performance; and (5) promoting review of behavioral goals. Subsequent target group input confirmed that participants liked the concept of an mHealth weight management program and expressed preferences for the program to be personalized, with immediate (prompt) and informative text messages, practical and localized physical activity and dietary information, culturally appropriate language and messages, offer social support (group activities or blogs) and weight tracking functions. Most target users expressed a preference for at least one text message per day. We present the prototype mHealth weight management program (Horizon) that aligns with those inputs.

Conclusions: The Horizon prototype described in this paper could be used as a basis for other mHealth weight management programs. The next priority will be to further develop the program and conduct a full randomized controlled trial of effectiveness.

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KEYWORDS

weight loss; intervention; Internet; mobile phone; focus groups

Introduction

There is a critical need for weight management programs that are effective, cost efficient, accessible, and acceptable to adults from diverse ethnic and socioeconomic backgrounds. Global rates of overweight and obesity have increased sharply in the last decades, and over 750 million individuals worldwide are estimated to be overweight and more than 300 million people are obese [1]. The global burden of disease attributable to excess body weight in adults continues to rise. Ischaemic heart disease and stroke collectively killed 12.9 million people in 2010 which relates to one in four deaths worldwide, compared with one in five in 1990. Moreover, compared to 1990, in 2010 twice as many deaths globally were due to diabetes [2]. The direct health care costs are estimated to be about 2-7% of annual health care budgets [3], but the true costs related to obesity are thought to be significantly higher [4]. Obesity and overweight show large and persistent social gradients and are more prevalent in disadvantaged socioeconomic groups in many Organisation for Economic Co-operation and Development (OECD) countries [5]. In New Zealand, the highest obesity rates ($\text{BMI} > 30 \text{ kg/m}^2$) are reported among Pacific Islanders (64%), Māori (42%), and adults living in the most deprived areas (35-40%), compared with the population average of 25-26% [6].

Weight loss has been shown to improve many obesity-related illnesses and to reduce all-cause mortality [7]. However, the menu of evidence-based weight loss interventions currently available is limited. Pharmacotherapy has modest beneficial effects, but these are often lost once the medication is stopped [8]. Surgical interventions are more successful, but are expensive, unsuitable for large-scale use, and restricted to the morbidly obese [9]. Diet and/or physical activity interventions have variable effects [10], and interventions in primary care have reported mixed results [11]. More intensive behavioral interventions generate small but sustainable weight loss, which can engender clinically worthwhile long-term health benefits [12]. However, such interventions are generally limited to research contexts, are costly, and not widely available. Similar limitations apply to commercial weight loss programs such as Weight Watchers and Jenny Craig. While there is some evidence showing that these programs are effective, they are generally very intense and costly. Also, there is uncertainty whether the observed weight loss is clinically relevant and whether it would be sustained long-term [13]. A study by Cobiac et al, on the cost-effectiveness of Weight Watchers and the Lighten up to a Healthy Lifestyle Program revealed that such behavioral counseling interventions are not very cost-effective, and the potential benefits for population health are small [14].

International weight management guidelines (eg, New Zealand [15], United States [16], and Australia [17]) for overweight and obese adults recommend programs using “three key interventions in combination: changes to food/diet, increased physical activity, and behavioral strategies”. The Weight Action Programme (WAP) is a weight management program developed

in the United Kingdom (UK) consistent with this multi-component, behavioral approach [18]. It entails a comprehensive package of cognitive, behavioral, and educational interventions including dietary advice, self-monitoring, exercise targets, and cue management, and is delivered in a group-based format over eight weeks. WAP was evaluated in two short-term pilots involving 162 overweight adults (mean BMI 35 kg/m^2) from multiethnic areas of high deprivation in London. Average weight loss was 4.5 kg at 3-month follow-up [18]. Significant increases were also seen in physical activity levels, and knowledge of healthy eating.

While face-to-face approaches such as WAP or Weight Watchers are effective [19,20], they are relatively expensive to implement, difficult to scale up, and do not suit those who work or live some distance from venues. mHealth behavior change programs (delivered via mobile phones and Internet) offer a practical and potentially cost-effective solution to these barriers. There is broad population penetration of mobile and wireless technologies [21]. Globally, there were 6.8 billion mobile phone subscriptions in 2013, with mobile devices now exceeding traditional computers in unit sales [22]. In 2009, 89% of households in New Zealand had access to a mobile phone and in 2012, 80% had access to the Internet. There are no significant differences in Internet access across the country, gender, or level of education, and there are few differences in age below 65 years (>90% internet access in the age groups 15-34; around 90% in the age group 35-54; just below 80% in the age group 55-64; and around 60% in the age group 65-74) [23]. Previous research in New Zealand demonstrated strong support for an mHealth weight management intervention; with 75% of Māori and 65% of non-Māori saying they would use a mobile phone-based weight management intervention [24]. In line with this trend, a growing number of commercial programs including Weight Watchers and Jenny Craig deliver online/mobile tools as an alternative or extra support to their traditional programs. However, these mobile components are mostly an integrative part of the larger (traditional) programs and therefore still very expensive and the potential benefits for population health are small [14]. Also, it is unclear how effective these mobile components would be on their own (eg, separate from the traditional program components) and, as outlined in more detail below, there is a general lack of comprehensive randomized controlled trials on the effectiveness of these weight loss apps.

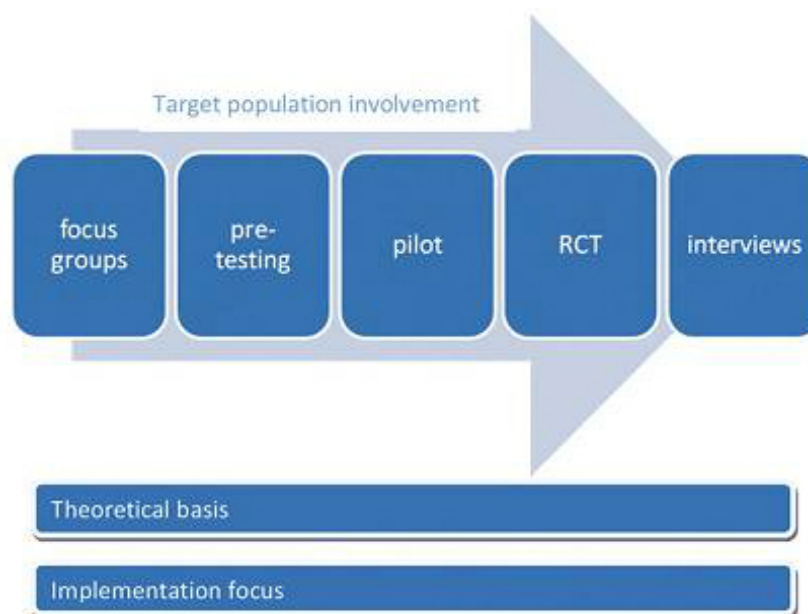
The aim of this study was to develop an evidence-based mHealth weight management program appropriate for ethnically and socioeconomically diverse target groups (Horizon), using a structured content development process (involving the target audience in the development stages) and formative research [25].

Methods

Development of the Horizon mHealth Weight Management Program

The development of the Horizon mHealth weight management program followed the steps of the mHealth framework (Figure 1) [25]. It involved the modification of the UK Weight Action Programme (WAP) for delivery via short message service (SMS)

Figure 1. mHealth framework [25].



Expert Input

The project team included members from New Zealand (CNM, RW, RM), the United Kingdom (KMS, HMR) and Australia (KB, DC) with extensive expertise in nutrition, physical activity, mHealth, and behavior change. Conceptualization included review of existing WAP modules and key theoretical models of behavior change, including the Theory of Planned Behaviour [26] and the self-regulatory process action planning and coping planning [27]. The review also considered the outcomes of a meta-regression analyzing 122 behavior change interventions and classifying these interventions according to component and theoretical-based techniques [28]. This phase produced agreement on core components and functionality of the Horizon program, including mode of delivery.

mHealth programs can be delivered via various channels including texting, a website, and Smartphone apps. The expert panel decided that SMS text messaging and an interactive website would be the most appropriate mode of delivery for the Horizon program. There is already some evidence showing that SMS text messaging and Internet-delivered interventions have positive effects on some health-related behaviors, including physical activity [29,30] and weight-related behaviors [31]. Two recent systematic reviews support the use of texting [32] and Internet [30] interventions for achieving behavior change.

and the Internet. In this paper we report an iterative development process with mixed methods entailing the first two phases of the framework: (1) conceptualization using expert input on evidence of effective programs and behavior change theory; (2) formative research with target population input using focus groups and an online survey. Incorporating the findings from these phases, we present the prototype mHealth weight management program (Horizon).

Also, while the use of health-related smartphone apps has been rapidly increasing over the last several years (ie, in the United States, 674,000 free apps categorized in the “Healthcare and Fitness” category were downloaded via the Apple App Store in September 2013 [33]), there are some important limitations of these apps. A recent review conducted by our team (unpublished data) assessed the concordance of weight loss apps with the New Zealand clinical guidelines for weight management [15] and revealed that of the 20 most popular weight loss apps just 22% met the New Zealand guidelines criteria. Few apps included important components such as a comprehensive approach (including food, activity and behavior) or emphasized “permanent weight management change”. None of the apps reported any testing or evaluation with consumers, and no published research on the apps could be found. Other studies found similar results by showing that weight loss apps typically included only a minority of the behavioral strategies found in evidence-based weight loss interventions [34]. Other disadvantages of weight loss apps include the requirement for ownership of a smartphone or tablet and the fact that they rely on consumer initiative to use them. SMS text messaging on the other hand, is reactive, more direct and can be delivered in a timely manner as initiated by the program not the consumer. Also, SMS text messaging is available on every type of mobile

phone and has great penetration into low socioeconomic populations.

In addition to the SMS text messaging module, it was decided that Horizon should include an interactive website and a hard copy toolkit. The website was important for additional effective program components including self-monitoring of progress and peer support. Likewise, since text messages only allow 120 characters, it was decided to develop a hard copy toolkit which participants could refer to for more detailed information. These three modules (eg, texting, website, and toolkit) were the basis for target population input.

Target Population Input

Target population input was obtained by focus group and one-on-one phone interviews which were used to develop the initial content of the program modules (ie, text messages, toolkit and webpages) followed by an online survey to obtain in-depth feedback on the proposed content.

Focus Group and Phone Interviews

Three focus groups were conducted in Auckland, New Zealand, supplemented with five one-on-one phone interviews. Purposive sampling methods were used to recruit participants via advertisements in local newspapers and posters in community venues. A local mailbox drop was also conducted. Phone interview participants (n=5) were recruited via the assistance of the Department of Pacific Health at the University of Auckland. Inclusion criteria were that people had to be aged 18 years or older, overweight (BMI \geq 25), own a mobile phone, and want to lose weight. Participants needed to be able to provide informed consent and to converse in English. All participants received a gift voucher for their participation.

The focus group interviews were carried out according to standardized procedures. All focus groups were audiorecorded and conducted by a psychologist experienced in facilitating focus groups and qualitative research methods. Prior to the interviews, basic demographic information including ethnicity, gender, and age was recorded. During the interviews, an effort was made to involve all participants and they were encouraged to express their opinions. The focus groups followed a semi-structured format (allowing for unscripted ideas to surface and for a reflexive discussion to take place) and lasted approximately 60 minutes each. Their purpose was to gain in-depth information on participants' past experiences of weight management, and their perceptions around an mHealth weight management program. Topics that were explored included: mobile phone usage, positive and negative experiences of previous weight management attempts, perceived acceptability of the proposed mHealth program (barriers and benefits), preferred style of messages, frequency of messages and feedback on specific components of the program (eg, interest in being able to text a question). After the three focus groups, a preliminary analysis was carried out and results were fed back to the study investigators. At this point it was decided that further information was needed around family dynamics and more Pacific Islander input into the program development was required. Questions on family shopping/cooking were added. Five phone interviews were subsequently carried out with

Pacific Islanders by the same interviewer. These were also audiotaped and the same semi-structured interview technique was used.

Following transcription, all data (focus groups and phone interviews) were analyzed using a general inductive thematic approach to identify common themes and meanings. NVivo9 software was used to manage the transcripts and facilitate the analysis. Data were read and re-read as they were collected. Each focus group and phone interview was coded separately. Once all data were collected, categories and subcategories were organized and refined. Subsequently, all categories were grouped into themes and discussed with members of the research team.

Online Survey

The results of the focus group interviews were used to inform the development of the initial content of the Horizon program modules (eg, text messages, toolkit, and website). Subsequently, a quantitative online survey was conducted to obtain in-depth feedback on drafts of the module content and delivery format. Particular emphasis was placed on aspects such as preferred text message frequency, integration of social support, and response to different message styles and content. Participants were recruited via similar methods used for the focus group interviews supplemented with email networks and the aim was to include n=150 participants. The survey was undertaken using LIME software (open source survey application). Data were analyzed and summarized using descriptive statistics and findings were reported back to the expert group to refine development of the prototype program.

Results

Expert Input

Review of existing WAP modules and key theoretical models of behavior change determined that the core techniques for the program should include: (1) self-monitoring of behavior; (2) prompting intention formation; (3) promoting specific goal setting; (4) providing feedback on performance; and (5) promoting review of behavioral goals [28]. These techniques were integrated in each of the modules of the program; the text messages, the website and the hard copy toolkit. Moreover, it was agreed that the small steps approach for weight management should be an integral part of the program. Recent findings suggest that it is more motivating for people to set small short-term goals that they can successfully achieve (eg, eat one piece of fruit per day), instead of failing large long-term goals (lose 10 kg of weight in the next month). Also, small steps are more likely to evolve into a sustainable healthy lifestyle (eg, creating a habit) [35].

Target Population Input

Focus Group and Phone Interviews

There were 20 participants (18 female; 2 male) in three focus groups (5 to 8 participants per group), and 5 (2 female; 3 male) participated in the phone interviews. Most (n=16) were New Zealand European, two were Māori (indigenous), and all phone interviewees were of Pacific Island ethnicity. The majority of

focus group participants were aged between 35 and 64 years (n=17).

Table 1. Focus group themes.

Theme #	Focus group themes
1	Weight management is a roller coaster
2	More than just energy-in/energy-out: psychological factors
3	A lifestyle change
4	Goal setting: set us up for success
5	Support us on all levels
6	Cultural considerations
7	Perceived benefits and barriers of mHealth

During focus groups, seven themes emerged (Table 1). When participants were asked to describe positive and negative experiences they had when trying to manage their weight (Theme 1), they were unable to clearly differentiate between the two. For most, attempts to manage weight were described as always starting off positive and then ending negatively. Many had tried several different weight management programs (eg, Weight Watchers, Jenny Craig, etc). These programs were generally described as having unrealistic goals and being not sustainable. Some felt these programs were boring, repetitive, expensive, and involved eating processed tasteless food. For some, having to go to meetings and get weighed in front of others was described as embarrassing and degrading as they felt they were being judged. One participant described a workplace competition to lose weight that has been working well for her as she liked the nonconfrontational positive support she received from her colleagues. Group support was a feature that was predominantly found to be valuable, at least in the first instance while it was still novel.

I can't afford it and I found Weight Watchers was really successful for about a year and then it became too boring and you just go to those meetings and you listen to the same old stories, the same old people, same people talk – it's just nothing's new, nothing, it's not that motivating. And the other thing I've tried is the Green Prescription, which is the reduced cost one that you can get through your GP but the only times you can do it are during work hours, that's the only time that the gym is available and things like that so it's completely out of limits, off limits to people who work.

The majority of participants felt they knew and had repeatedly heard educational information around weight management (Theme 2). They discussed that despite knowing what they “need to do”, they still struggled to make changes and expressed an awareness of there being more to weight management than exercising and eating healthy. Words that came up throughout discussions of weight management included guilt, shame, embarrassment, emotional eating, feeling judged, secret eating, and bingeing.

I would imagine that quite a few of us here, have um, we're all overweight and we all know we are, and we all know how to eat healthy and everything like that.

I'm sure somewhere inside there's something that's just not letting us mentally.

There was a strong desire among all participants for something to be developed that could guide them as to how they make sustainable lifestyle changes (Theme 3). They wanted a long-term cost-effective solution for not only themselves, but also for their families. Also, they would like practical tips on exercise and useful recipes to cook at home.

I think it's best to have menus and food or dishes that one are the run of the mill kind of foods that we would generally eat, whereas to make it so that the whole family can eat those so that you're not having separate things. I think when you have separate, first of all it creates a culture within the family that you're different and that you've got a problem and they don't. And it also sets up um a kind of understanding that in fact they can eat all the bad things and you can't, and so later on you're probably causing weight problems for your kids and people in your family.

Participants expressed feeling fed up due to not succeeding at weight management programs (Theme 4). The “all-or-nothing” strategies they had tried in the past left them feeling demoralized when they either failed to lose weight, hit a plateau, or regained the weight they had lost. They expressed a desire for a program that was realistic and would allow them to slip up once in a while.

It's not a 100% stick to a diet, it's really got to be 75% and you can fall off the wagon. If you're going to tell me I've got to be 100% then I think we're all kidding ourselves.

When discussing goal setting, almost all participants expressed a preference for lifestyle-based goals, with their level of effort reflected in recognition of achievement of their goal. Participants were predominantly against the sole use of weight-related goals, but were open to having a small and realistic weight goal (for example, ½ kg per week) alongside lifestyle-based goals. The use of body mass index (BMI) as a way of prescribing behavior change and measuring success was perceived negatively, as often being daunting and unachievable, and not taking into consideration their individual situation and level of fitness.

Family support for weight management was not something that was desired, although participants could see the benefit of a

family attempt (Theme 5). A few participants said that in the past, their family members had sabotaged weight loss attempts and that they preferred support from professionals and from others going through similar experiences through an online forum, group meetings, or a buddy system where they can text each other. Additionally, the majority of participants did not want to be involved in another program which would tell them educational weight management information they already knew. One described this as patronizing. Another participant stated:

So I don't want nutritional information. Other people might disagree. I want the little person on my shoulder telling me have a little bit more strength and motivation. As you say, motivation or inspiration or whatever it is.

In contrast, a few participants expressed that although they had heard many of the educational health messages before, it would be beneficial to be reminded of them. There was also a desire to have conflicting messages clarified by a credible professional. They liked the concept of being able to text someone with questions regarding physical activity or healthy eating. However, there was a strong preference for an immediate reply at the moment they needed support. Professional support was also wanted in the form of someone tracking their progress on meeting goals.

None of the five Pacific Island participants that were interviewed had engaged in any of the organized weight management programs (Theme 6). Adapting lifestyle changes was seen as something that needed to be done at the family level. In terms of physical activities, one participant suggested that it would be best to have a variety of options for people to choose from. He made the suggestion that traditional dance classes may appeal to some people as they are fun and undertaken in a "safe" environment. It was thought by one participant that an mHealth program might be very suitable to Pacific Islanders who may not feel comfortable in a public weight loss support group.

Yeah I think as a um Pacific Islander they're not really into, most Pacific Islanders are pretty laid back and they're not confrontational, they're not comfortable sitting face to face with people and having discussions. And this type of message will go a lot easier, well it will be more acceptable to them than sitting and talking with somebody face to face because they'll feel shy and they'll say yes, yes, yes and all the time they don't really want to do this type of thing.

Two of the phone interview participants expressed an interest in testimonial stories of people who have been through similar ups and downs and are now successfully making lifestyle changes.

Mobile phones are the technology that most people were comfortable with and the majority of participants were very positive and excited about the potential of an mHealth program (Theme 7). Nonetheless, a few concerns about such an approach were raised, including technological limitations (eg, areas with poor network coverage), lack of tailoring, and potential reduced accountability to a phone.

Online Survey

A total of 171 people accessed the online survey of which 120 (70.17%) consented and completed the questionnaire (Table 2). Of these, 18 reported having normal weight and two reported not owning a mobile phone. These were excluded from further analysis. Of the 118 mobile phone owners, 41% owned a smartphone.

Of all the participants, 13.7% (16/117) said that they would like to receive program text messages less frequently than daily, the remainder expressed preferences for once a day (44/117, 37.6%) or more often (57/117, 48.7%). Almost all participants (115/119, 96.6%) said that they would reply to text messages if asked.

Table 2. Participant characteristics online survey (n=120).

Characteristics	n (%)
Sex	
Male	16 (13.3)
Female	104 (86.7)
Age	
18-24	10 (8.3)
25-34	27 (22.5)
35-44	36 (30.0)
45-54	28 (23.3)
55-64	16 (13.3)
65+	3 (2.5)
Ethnicity	
New Zealand European	34 (28.3)
Māori	53 (44.2)
Pacific Island	22 (18.3)
Asian	5 (4.2)
Other	6 (5.0)
Weight (self reported)	
Normal	18 (15.0)
Overweight	102 (85.0)

Ten sample text messages were presented to the participants with only one message receiving more than 12.5% (14/112) negative feedback. For the message content, participants reported that these should have a personal touch, give tips straightaway (eg, not just a link to another source), use trustworthy language (eg, no texting language/abbreviations) and offer peer support. With regard to the toolkit (hard copy folder with additional information), 13 potential information

items were proposed and for all items a large majority (>86%) of participants said that they would like to see information on these items included (Table 3). The two most popular items were “Snacks: cutting down, healthy options” and “Healthy, quick and easy recipes”. In addition, participants requested information on reading nutrition labels, local options for physical activity, tools to track progress, and information on the energy content of foods.

Table 3. Responses to proposed items in the toolkit (descending order).

Item	Should be included (yes) (n/n) %
Snacks: cutting down, healthy options	(116/116) 100.0
Healthy, quick, and easy recipes	(107/110) 97.3
How to cut down portion sizes and energy intake	(108/112) 96.4
Temptation and how to deal with it	(112/117) 95.7
How to cook and eat healthy when you don't have time	(108/113) 95.6
Exercise, physical activity, TV watching	(106/113) 93.8
Fat, sugar, carbs and protein: understanding the basics	(104/113) 92.0
My personal plan and goals for a healthy life	(106/116) 91.4
Breakfast: fuel yourself for the day	(100/114) 87.7
Drinks: more water and less sugar	(97/112) 86.6
Energy (calorie) content of common foods	(99/114) 86.8
5 pieces a day: eating more fruits and vegetables	(94/109) 86.2
Myth busting	(97/113) 85.8

Horizon Prototype Development

The outcomes of the expert and consumer studies were used to develop the Horizon prototype weight management program. The Horizon prototype comprises three main modules: (1) text messages; (2) toolkit; (3) website. These three modules all link together (eg, the text messages refer to information in the toolkit) and are designed in line with the five core components (eg, self-monitoring of behavior; prompting intention formation; promoting specific goal setting; providing feedback on performance; and promoting review of behavioral goals [28]).

A library of 130 different text messages which focus on motivation, goal setting, getting social support, monitoring and use of other study components (eg, toolkit and website) was developed with the goal of sending participants an average of two text messages per day (Table 4). The text messages are designed to encourage participants to set new well-specified

goals each week (such as “I will bring fruit to work and eat this every day with morning tea”) and are tailored according to whether the participant is the main household shopper/cook and/or whether the participant has children. At the end of each week, participants receive a monitoring text message asking them to review how well they accomplished their goal and to text a number from 1 (not successful at all) to 10 (very successful). This information will be displayed graphically on the Horizon website, showing the participants’ individual score compared with the average score of the entire study population. In a similar way, participants will be asked to text in their step count for graphical display on the website (Figure 2). In addition to these monitoring and motivational components, participants will be provided with the opportunity to send their questions using text messages to the study team which will be answered within 24 hours.

Table 4. Text messages in the Horizon prototype for the first week.

Text category/type ^a	Example
Motivational/small steps	<i>Small steps add up to important changes. This is not a quick fix but developing new habits to last a lifetime</i>
Goal setting/reference to toolkit/ Motivational/monitoring behavior	<i>It is important to set small goals each week. The toolkit has suggestions. Pick one goal to get started on this week, write it down and go for it!</i>
Pedometer/monitoring behavior	<i>Ralph^b here, wearing your pedometer and recording your daily step count in your toolkit is a great way to track your progress, start today!</i>
Motivational/monitoring behavior	<i>Hi (name), we are here to support you along the way. Each week we will ask about your step count and goals, and you can track your progress online.</i>
Monitoring behavior	<i>Cliona^b here, writing down what you eat can help you understand your eating patterns. Try it for the next 7 days to see where you can make changes</i>
Reference to toolkit/reference to website/monitoring behavior	<i>Hi (name), this is Cliona your nutrition coach. You may find the food diary and the weight tracker in the toolkit to be useful tools.</i>
Motivational/goal setting/small steps	<i>Have you reduced the sugar in your tea and coffee? It can taste funny at first but you will soon get used to it. Try it now. Cliona</i>
Getting support	<i>Hi (name), where can you get support? Making changes is easier with the help of others. See if your friends or family will join in too.</i>
Pedometer/monitoring behavior/reminder	<i>Hi this is Ralph your activity coach. Have you been wearing your pedometer? I will text you in 3 days for your daily step count.</i>
Getting support/reference to the website	<i>If you are finding it hard to get people to support your efforts, ask others on Horizon to help via the horizon study weblog</i>
Motivational/goals setting	<i>Hi (name), remind yourself daily why you are doing this by writing your reasons somewhere you can see them everyday.</i>
Motivational/getting support/ reference to the toolkit/reference to the website	<i>Did you read about Jamie in the toolkit/online. He removed all snacks and sweets from his house to help him in the early days.</i>
Monitoring success	<i>Hi. Overall, how well do you think you did with your goal this week? Reply with a number from 1 (not well at all) to 10 (brilliantly).</i>
Motivational/reference to the toolkit	<i>Cliona again. If you are starting to get bored with your healthy meals, the toolkit has recipe websites to inspire new ideas.</i>

^a The messages were slightly tailored; we developed specific texts according to: (1) whether the participant was the main household grocery shopper/cook; (2) whether participants had children or not.

^b Horizon includes a physical activity coach (Ralph) and a nutrition coach (Cliona) who were incorporated in the program to give it a more personal feel.

The toolkit serves as a source of more detailed information and contains eleven sections, including: goals and tips, personal plan (writing down weekly goals), monitoring resources (eg,

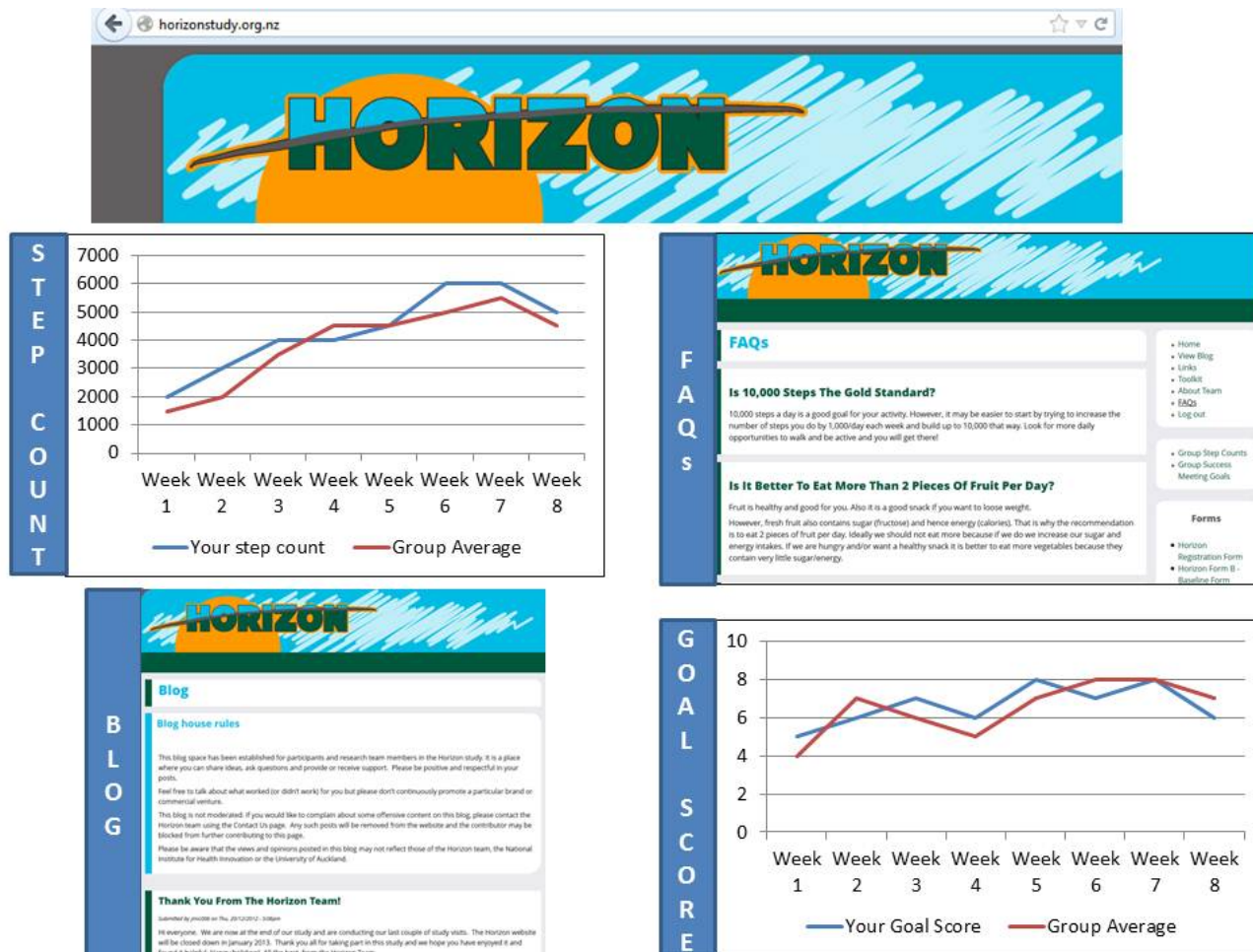
food diary, step count diaries, weight records), recipes, and stories of successful weight loss. The toolkit focuses on ideas for short-term goals and practical suggestions on how to reach

these goals. The website serves as a further source of information, and focuses on providing a blogging space to enable participants to share their stories and experiences with each other and the researchers, and provides a graphical display

of their self-monitoring of daily step counts and success in reaching the weekly behavioral goals (Figure 2).

Following this study, the Horizon program will be further refined and subsequently tested in a full randomized controlled trial of the effectiveness of the final Horizon program.

Figure 2. Horizon website.



Discussion

Principal Findings

The aim of this research was to develop an mHealth weight management program based on behavior change techniques, proven effective weight management programs, and closely aligned with participants' needs and preferences [25]. The resulting Horizon prototype program involved modification of the UK Weight Action Programme (WAP) for delivery via SMS text messaging and the Internet. Expert review of the evidence of effective programs determined that core components of a successful program should be: (1) self-monitoring of behavior; (2) prompting intention formation; (3) promoting specific goal setting; (4) providing feedback on performance; and (5) promoting review of behavioral goals.

We started our development by applying the theory and philosophy behind WAP, the specified necessary components, and our experience in behavior change support via technology, to delivery of a program via mobile phones and the internet. Subsequent target group input confirmed that participants liked

the concept of an mHealth weight management program and would like the program to have a personal touch, immediate and informative text messages, practical and localized physical activity and dietary information, culturally appropriate language, social support (group activities or blogs), and weight tracking functions. These individual constructs (eg, self-efficacy; goal setting) and environmental characteristics (eg, localized information; social support) have previously been identified as crucial in developing effective physical activity [36] or dietary interventions, and confirm the complexity of developing successful behavior change programs [37].

Our study revealed that the majority of participants were very positive and excited about the potential of an mHealth program. The sample text messages (presented to the online panel) received very positive feedback and the majority of participants expressed preferences for at least one text message per day. Moreover, 97% of participants indicated they would reply to a text message if asked to do so. These results are promising and show that mHealth could potentially provide a practical and cost-effective alternative to face-to-face approaches (eg, WAP or Weight Watchers [19,33]) that are relatively expensive to

run, difficult to scale up, and do not suit those who work or live some distance from venues.

Strengths and Limitations

A limitation of our study was that the ethnic mix was not as diverse as originally intended; thus we conducted an additional five phone interviews with Pacific people. However, the online survey was successful in recruiting an ethnically diverse sample. Results showed that Horizon would appeal to different ethnic groups, including Pacific Islanders who may not feel comfortable in a public weight loss support group.

The strength of our structured iterative development process [25] is that the program builds on effective programs and behavior change techniques, ensures that the program is engaging and useful to the target audience (by including target audience input at early development stages and by evaluation of prototypes), and then follows up with gold standard research methods to determine the effectiveness of the intervention [25]. In publishing the findings of this development process and formative research, we envisage that this information will be useful to other developers and researchers, and that our process is replicable in significantly different target populations and adaptable across multiple platforms and technologies. However, an important limitation of this development process is the time required. In this case, the formative research and prototype development took six months. A randomized controlled trial of effectiveness would add at least another 2 years to the total timeframe. Technology continues to evolve at a rapid pace and the way people use technology continues to change over time [25]. By the time evidence on the effectiveness of Horizon is obtained, the technology and mode of delivery might be outdated. While existing smartphone apps are likely to have been developed more rapidly, our research-based user-informed

development process aims to deliver a more proven and acceptable intervention. A second potential issue comes from building on insights from behavior change theories developed for other less immediate and on-going, less proactive and less dynamic media. Whether these theories hold with innovative technological advances in mHealth is yet to be determined [38]. The success of using a new technology is likely to depend on its ease of use, engagement, and level of appeal to different consumer groups. Therefore, it seems relevant to consider other models, such as research and development processes used by successful consumer technology product companies.

The mHealth components used in the Horizon prototype (eg, text messages and an interactive website) are technologies that most people feel comfortable with and have widespread access to. However, as we progress our development, we will consider also modification for a smartphone app to allow participants to opt for the technology that suits them. The Horizon prototype can as such be viewed as a basis for other mHealth weight management programs and can be updated in accordance with the newest technological innovations as required.

Conclusions

mHealth weight management programs have the potential to assist in weight loss; however, well-designed high-quality pilot and subsequent scaled up RCTs evaluating the long-term benefit and cost-effectiveness of interventions employing mobile technology are needed. This paper describes an iterative development process to create a feasible and acceptable mHealth weight management program. The presented prototype (Horizon) can be used as a basis for future mHealth weight management programs and we envisage that this information is useful to other developers and researchers.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
OECD: Organisation for Economic Co-operation and Development
SMS: short message service
WAP: Weight Action Program

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Original Paper

FoodSwitch: A Mobile Phone App to Enable Consumers to Make Healthier Food Choices and Crowdsourcing of National Food Composition Data

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Abstract

Background: Front-of-pack nutrition labeling (FoPL) schemes can help consumers understand the nutritional content of foods and may aid healthier food choices. However, most packaged foods in Australia carry no easily interpretable FoPL, and no standard FoPL system has yet been mandated. About two thirds of Australians now own a smartphone.

Objective: We sought to develop a mobile phone app that would provide consumers with easy-to-understand nutrition information and support the selection of healthier choices when shopping for food.

Methods: An existing branded food database including 17,000 Australian packaged foods underpinned the project. An iterative process of development, review, and testing was undertaken to define a user interface that could deliver nutritional information. A parallel process identified the best approach to rank foods based on nutritional content, so that healthier alternative products could be recommended.

Results: Barcode scanning technology was identified as the optimal mechanism for interaction of the mobile phone with the food database. Traffic light labels were chosen as the preferred format for presenting nutritional information, and the Food Standards Australia New Zealand nutrient profiling method as the best strategy for identifying healthier products. The resulting FoodSwitch mobile phone app was launched in Australia in January 2012 and was downloaded by about 400,000 users in the first 18 months. FoodSwitch has maintained a 4-plus star rating, and more than 2000 users have provided feedback about the functionality. Nutritional information for more than 30,000 additional products has been obtained from users through a crowdsourcing function integrated within the app.

Conclusions: FoodSwitch has empowered Australian consumers seeking to make better food choices. In parallel, the huge volume of crowdsourced data has provided a novel means for low-cost, real-time tracking of the nutritional composition of Australian foods. There appears to be significant opportunity for this approach in many other countries.

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KEYWORDS

smartphone technology; traffic light labeling; food choices; public health nutrition; processed food

Introduction

Growing rates of overweight and obesity around the world, in conjunction with a rise in nutrition-related diseases [1,2], mean that the food industry has an increasingly important role to play in public health. In high-income countries, the majority of food eaten is processed or pre-prepared by the food manufacturing, food retail, and catering industries [3]. These industries and their associated distribution networks have enabled a constant supply of affordable food in much of the world with consequent alleviation of many nutritional deficiency disorders [4]. However, a large proportion of the world's population is now exposed to foods that are excessively energy dense and high in saturated fat, sugar, and salt [5,6]. Higher intakes of energy, saturated fat, added sugars and salt, such as that provided by a typical Western-style diet through a higher intake of processed food products, are risk factors for chronic disease, particularly cardiovascular disease, type 2 diabetes, and obesity [7-9].

It is difficult for consumers to make healthy food choices because the nutritional information available on packaging is not easily interpretable [10]. While packaged food in Australia is required to display a nutrient declaration [11], the format of the information provided can make it difficult for consumers to use this to make a quick and easy assessment of how healthy a product is [12]. It has been suggested that interpretive front-of-pack nutrition labeling systems have the potential to help consumers choose products on the basis of healthiness both by enabling an understanding of the nutrient data and allowing direct comparison across products [12]. There is widespread support from public health organizations for front-of-pack nutrition labels that provide "at a glance" information that consumers can act on [13]. This is based on evidence indicating that front-of-pack labels (FoPL) are much better understood than the nutrient declaration, particularly among disadvantaged groups who have the most to gain from making better decisions about the foods they buy [12]. There is, however, currently no requirement for FoPL in Australia. Australian industry has implemented "daily intake guides" [14] on some products, but market penetration is limited and the absence of any interpretive element is likely a major weakness [10]. It has been suggested that multicolored traffic light labels could be a better option for informing Australian consumers [10]. The Australian government is also currently exploring the use of a "star" system to rate products in terms of healthiness. However, this has not yet been implemented and industry is resisting the work program.

Mobile phone technologies offer an innovative way for consumers to access all manner of information. Mobile phones have become widely available in Australia over the last few years with more than 65% of Australians aged 15-65 years (8.6 million people) now owning some form of smartphone. This is a higher proportion of the population than in the United States and Britain [15]. In Australia, 90% of all smartphones use either an iOS or Android operating system, and 76% of Australian smartphone owners currently use their phones to get recommendations for health and other lifestyle-related factors [16]. A number of mobile phone apps have used the traffic light

signposting system, but most have required the user to manually enter nutritional information about the product.

In the absence of standardized FoPL on Australian foods, and with processed foods largely responsible for excessive intakes of saturated fat, energy, added sugars, and sodium in the diet, we sought to develop a mobile phone app that would provide Australian consumers with access to easy-to-understand nutritional information about packaged and processed foods. To this end, we began a program of research and development to define how to use evolving mobile phone technology to deliver Australian consumers with better information about the packaged foods they eat. We intended that this project would ultimately improve the healthiness of the food choices made by Australian consumers and therefore enhance the health of the Australian population.

Methods

Objective

This project was planned and executed as a collaboration between researchers based at The George Institute for Global Health, developers from Xyris Software Pty Ltd, and the health communications team at Bupa Australia. The objective was to deploy a mobile phone app that would allow users to access quick and easy-to-understand information about the nutritional characteristics of packaged foods and, where possible, would suggest healthier alternative products.

Identification of Required Nutritional Information

Packaged foods in Australia are required to display a Nutrition Information Panel (NIP) that includes information about seven key nutrients. The information in the NIP is known to be mostly accurate [17], and these label data were identified as the most likely source of comprehensive nutritional information to support the proposed mobile phone app. It was recognized, however, that food composition tables that collate this information at the level of the stock keeping unit (SKU) are scarce, and those that do exist are owned by commercial entities and can be expensive to access. In addition, we noted that a food categorization system that could divide food into comparable subsets of products would be required. A search was done using the Internet and by inquiry among colleagues to identify possible data sources. We also noted that the universal product code (UPC) (barcode) values for each SKU would be required for the delivery of an app based on barcode scanning, and thus the search was broadened to also capture databases of Australian UPCs.

Selection of Display Format for Nutritional Information

There are a broad range of different formats that have been proposed for FoPL systems [12], and these were identified through a review of the literature. A series of criteria were developed to support the format that would be selected for the app based primarily on (1) the quality of the supportive evidence, (2) the likely acceptance of the format by consumers, (3) current FoPL practices around the world, and (4) congruence with local Australian standards and recommendations.

Method of Product Comparison and Identification of Healthier Products

This project sought both to provide easily understandable nutritional information and to support consumers in their efforts to make healthier food choices. To better deliver on the second of these objectives, it was determined that it might be necessary to compare products against one another and develop a method of suggesting alternative products that were likely to be healthier. Fundamental to this requirement was a mechanism for ranking foods on the basis of their healthiness, and a review was undertaken to identify the different methods to achieve this. Once again, a series of criteria were considered in making the choice and these were based primarily on (1) the quality of the supportive evidence, (2) the likely acceptance of the method by the nutrition community, (3) current methods being used around the world, and (4) congruence with local Australian standards and recommendations.

Choice of the Technological Solution

The project was launched with the goal of developing a mobile phone app. While we recognized early on that aspects of the solution might subsequently be deployed on other platforms, the focus of the work program was on the development of a mobile phone app for Australia. The key considerations in developing the technological solution were the method of user interaction with the mobile phone app and the platforms the app would be developed for. In regard to the user interaction, decisions were informed primarily by reviewing the functionality of other mobile phone apps—this review covered apps available in the broader retail space as well as those addressing specific health and nutrition issues. We chose the platforms the application should be developed for based on an analysis of the

current and projected market penetration of the iOS, Android, Windows, and BlackBerry, in Australia.

The Mobile Phone App Development Process

Development of the mobile phone app was led by individuals who are expert in research and public health, ensuring that the solution was underpinned by strong science and retained a primary public good objective. The findings of the reviews done during the development process were, however, reviewed by all participating groups (research, public health, developer, and health insurer) to ensure that decisions were informed by a broad range of perspectives. The development process was broken down into key components (eg, user interface, supporting data systems, and nutritional algorithms) that were formulated in parallel by working groups that were expert in the respective area. Weekly meetings were held to review progress and iteratively refine each component of the work. An initial test version of the mobile phone app was built and deployed for user acceptability testing by a limited group of individuals associated with the development team. Once feedback had been incorporated, a subsequent iteration of the app was deployed to a broader group of external stakeholders for further evaluation. Ultimately a launch version was completed and placed in the public domain.

Results

The development process commenced in August 2011, and the initial iOS version of FoodSwitch was deployed in January 2012 (Figure 1). This was followed by a launch on the Android platform in March 2012 with subsequent upgrades made to both platforms.

Figure 1. Splashscreen for FoodSwitch.



Food Composition Database and Product Categorization

A branded food composition database compiled by The George Institute for Global Health and updated on an annual basis was identified as the source of nutritional information that was most complete and readily accessible for the FoodSwitch project. The 2012 database was compiled from in-store surveys done by George Institute staff at large stores in Sydney, Australia: ALDI, Coles, Independent Grocers of Australia, and Woolworths. During the surveys, the nutritional information provided on the NIP was transcribed into the database. A random selection of 5% of records was verified against the original NIP (by viewing product photos within the online database system). The 2012 dataset held records for about 17,000 SKUs and included nutrient information on energy, protein, total fat, saturated fat, carbohydrate, sugar, fiber, sodium, and calcium. The database also contained information on the UPC for each item. Each SKU in this database is assigned to one of about 700 different food categories, and this categorization system was adopted as the standard for FoodSwitch.

Display Based on Traffic Light Labels

The review of possible display formats identified multiple colored traffic light labels as the preferred format. Using this approach, foods are signposted with respect to each of total fat, saturated fat, sugar, and salt using a high (red), medium (amber), or low (green) indicator in conjunction with a fifth circle without color containing information about energy density. The decision to select this approach was driven primarily by the report on the Australia and New Zealand Review of Food Labelling Law and Policy, “Labelling Logic”, which recommended that this system be adopted in Australia (Recommendation 51). The decision was further supported by the ready availability of detailed technical specifications provided by the UK Food Standards Agency in their 2007 document “Traffic light signpost labelling, Technical Guidance, Issue 2” [18]. This guidance details the method for front-of-pack traffic light signpost labeling including the thresholds for total fat, saturated fat, sugars, and salt at which red, amber, and green traffic light colors are applied for foods and beverages (Tables 1 and 2) [18].

Table 1. Food labeling.

	Green (low)	Amber (medium)	Red (high)	
Total fat	≤3.0 g/100 g	>3.0 to ≤20.0 g/100 g	>20.0 g/100 g	>21.0 g/portion
Saturated fat	≤1.5 g/100 g	>1.5 to ≤5.0 g/100 g	>5.0 g/100 g	>6.0 g/portion
Sugars	≤5.0 g/100 g	>5.0 to ≤12.5 g/100 g	>12.5 g/100 g	>15.0 g/portion
Salt	≤0.30 g/100 g	>0.30 to ≤1.50 g/100 g	>1.50 g/100 g	>2.40 g/portion

Table 2. Labeling for drinks.

	Green (low)	Amber (medium)	Red (high)
Total fat	≤1.5 g/100 ml	>1.5 to ≤10.0 g/100 ml	>10.0 g/100 ml
Saturated fat	≤0.75 g/100 ml	>0.75 to ≤2.5 g/100 ml	>2.5 g/100 ml
Sugars	≤2.5 g/100 ml	>2.5 to ≤6.3 g/100 ml	>6.3 g/100 ml
Salt	≤0.30 g/100 ml	>0.30 to ≤1.50g/100 ml	>1.50 g/100 ml

Ranking by Nutrient Profile Score

The method selected to enable the comparison of food products was the nutrient profiling system (Nutrient Profiling Scoring Calculator - NPSC) developed by Food Standards Australia New Zealand (Textbox 1) [19]. This is an across-the-board scoring system where “baseline” points are allocated for increased amounts of energy, saturated fat, sodium, and total sugars [19]. These baseline points are then offset by “modifying” points allocated for the increasing percentage of the product that is fvnl (fruit/vegetables/nuts/legumes) and the amount of

fiber, and for selected food categories, also protein and calcium. Foods are scored within three separate categories—edible oils, spreads, and certain cheeses; other foods; and beverages—with lower values indicating healthier products. Some scoring criteria (such as fiber and calcium) are not required on the standard Australian nutrient declaration and were therefore not completely available in the food composition database, requiring imputation of proxy values for some products (Table 3). All foods in the database were assigned a nutrient profile score using this system (Textbox 1).

Textbox 1. Nutrient profiling method.

Step 1: Determine the NPSC category of the food.
<ul style="list-style-type: none"> 1: beverages 2: all food not in category 3 3: cheese and processed cheese >320 mg calcium/100 g, edible oil, edible oil spread, margarine, and butter
Step 2: Calculate baseline points.
<ul style="list-style-type: none"> 0-10 for energy 0-30 for saturated fat 0-10 for sugars 0-30 for sodium calculate total baseline points = X + X + X + X
Step 3: Calculate modifying points.
Fruit and vegetable (V points) (0, 1, 2, 5, or 8)
Formula used: $(\% \text{ non-concentrated fvn1}) + (2 \times \% \text{ concentrated fruit or vegetables}) \div (\% \text{ non-concentrated fvn1}) + (2 \times \% \text{ concentrated fruit or vegetables}) + (\% \text{ non fvn1 ingredient}) \times 100/1$
Protein points (P points)
<ul style="list-style-type: none"> Calculate protein points (1-5)
Fiber points (F points)
<ul style="list-style-type: none"> Calculate fiber points (1-2)
Step 4: Calculate the final score.
Final score = Baseline points – (V points) – (P points) – (F points)

Table 3. Data availability and imputation for nutrient profile scoring.

Nutrient	Availability
Energy	Complete
Protein	Complete
Total sugar	Complete
Saturated fat	Complete
Sodium	Complete
Dietary fiber	Partial data were available: products in a food category known not to contain fiber (eg, eggs) were assigned a fiber score of 0; products with data available were assigned an individual fiber score; and products with no data but in a category of foods known to contain fiber were assigned an imputed value. The imputed value was the average for all products in the category with data.
Calcium	Partial data were available for cheese and processed cheese categories, which require a calcium value for the calculation of the nutrient profile score: products with data available were assigned an individual calcium score, and products with missing data were assigned an imputed value. The imputed value was the average for all products in the category with data.
Percentage content of fruit, vegetables, nuts, and legumes (%F&V)	No data were available: products in food categories known not to contain appreciable amounts of fruit and vegetables (eg, dairy milk) were assigned a %F&V score of 0; and products in food categories known to contain fruit and vegetables were assigned imputed %F&V scores.

Selection of the Technological Solution and Mobile Phone App Functionality

In Australia, the iOS and Android platforms comprise more than 90% of smartphones in circulation with only small numbers of users with Windows or BlackBerry platforms. The decision was therefore made to develop the mobile phone app only for

the iOS and Android platforms. Initial development was done in iOS with subsequent transfer of the app to the Android environment. The transfer to Android involved moderate re-working of the user interface to achieve the best possible integration of the app into the Android environment.

The over-riding design philosophy for the functionality of the app was simplicity of use and clarity of messaging. Accordingly, the primary operation of the app requires only that users turn it on and hold the mobile phone camera over the barcode of the product that they want information on (Figure 2). This action results in the automatic acquisition of the UPC, the immediate display of traffic light labels for the selected product, and the concurrent listing of similar alternative products with a more favorable nutrient profile (Figure 3). For some product categories where similar healthier alternative products are not recommended (such as sugar-sweetened soft drinks), a standard message provides high level advice about how to make a healthier choice (“Sugar-free drinks and water are healthier choices” in the case of sugar-sweetened soft drinks). Users are

also able to compile lists, see the results of recent scans, and share their observations using social media. [Multimedia Appendix 1](#) outlines the overall FoodSwitch process.

A particular innovation in the app was the incorporation of a crowdsourcing function whereby users are able to contribute information on missing products. If a barcode is scanned but the corresponding UPC is not identified in the database, then the user is asked to photograph the front of the package, the NIP, and the ingredients list (Figure 4). The data are then forwarded to the data management center, and the information is added to the database. Periodic updates to the database are then made to ensure that the app is supported by complete and contemporary product information.

Figure 2. Scan function in FoodSwitch.



Figure 3. Switch function in FoodSwitch.**Figure 4.** Crowdsourcing function in FoodSwitch.

Downloads, User Feedback, and Post-Launch Development

In the approximate 2-year interval between the launch of the FoodSwitch app in January 2012 and the preparation of this paper, FoodSwitch has been downloaded by more than 400,000 users. Some 2000 have provided comments, mostly positive, and the app has retained a 4+ score in the iTunes store since launch. In addition to updating the underlying food composition database, there have been two major upgrades that have added new functionality—SaltSwitch, targeted at individuals seeking

to lower their dietary salt intake, which recommends healthier alternative products primarily on the basis of the sodium level, and GlutenSwitch, targeted at people with celiac disease and those wanting recommendations for gluten-free foods. Both developments were based on user feedback and a series of further upgrades that will address health problems such as diabetes and dyslipidemia are under development. The crowdsourcing tool within FoodSwitch has enabled substantial expansion of the underlying database from an initial 17,000 SKUs to over 50,000. More than 26,000 photographs, equating to 6000 additional SKUs, were received in the first 48 hours

after launch, and 2 years later more than 200 photographs of new SKUs are still sent in by FoodSwitch users every day. While the initial photographs were mostly of products missing from the launch database, the photographs now received are of new items released into the market.

Discussion

Principal Results

The success of FoodSwitch with Australian consumers is likely a direct reflection of the enormous community interest in the foods they eat and the great difficulty they have in obtaining easy-to-understand nutritional information. The FoodSwitch experience provides strong support for the introduction of a standardized, interpretive front-of-pack food labeling system for all foods marketed in Australia. Last year, the Australian government indicated that it will launch a “star”-based FoPL system that will be mandated if widespread voluntary uptake by industry is not forthcoming. While data to define the impact of the proposed star-based system are sparse, the application of a single FoPL system across all foods is an important first step in providing consumers with the information they require to make healthier food choices. Plans are in place to provide users of FoodSwitch with the option to select the new star-based labeling system as the display mode, as soon as the criteria underpinning the system are finalized. Funds have also been received to conduct large-scale randomized trials using the FoodSwitch technology that will, for the first time, objectively define the impact of different labeling systems on real world food purchases.

The implementation of FoodSwitch in Australia was initially done with the objective of providing consumers with a tool that would enable them to make better food choices, both by providing nutritional information in an at-a-glance, easy-to-understand format and by suggesting healthier alternative products within the same category. The app has been successful in this regard with a large number of downloads and a significant number of regular users. However, almost all of the Australian population consumes a diet that is suboptimal in nutritional content, and even if every individual who downloaded FoodSwitch made radical changes to their diet, the net effect on population health would be only small. While this does not mean that FoodSwitch is without direct value to some users, the direct benefits are likely to be restricted to the households of a relatively few motivated individuals.

Fortunately, individual behavior change is not the only means by which FoodSwitch might have public health impact. Indeed, the real value of FoodSwitch is likely to be in the data collected through crowdsourcing and a consequent new capacity to define and track the nutritional composition of the food supply over time. These data will make it possible to hold the food industry to account, as a group and at an individual company level, for the nutritional quality of the products they sell. It will also be possible to objectively evaluate the extent to which the food industry and government deliver on commitments to improve the quality of the food supply through initiatives such as the Food and Health Dialogue. Another postulated effect of FoPL is that it will drive reformulation of products towards healthier

formulations; for example, manufacturers might reduce the levels of adverse nutrients such that the product displays an amber instead of a red, or a green instead of an amber traffic light. It will be possible to directly test this hypothesis using the data collected by FoodSwitch in the coming years.

For the first few years of operation, compilation of the branded food composition database that FoodSwitch was based on a highly labor-intensive exercise that incurred significant costs, while achieving only partial coverage of the Australian processed food supply. By crowdsourcing data collection through FoodSwitch itself, the data collection costs have been optimized, the database is much more comprehensive, and new products are added soon after they appear on the supermarket shelves rather than during an annual round of data collection. With streamlined data management systems in place, and plans to develop optical character recognition for data entry and automated algorithmic categorization of foods, it should be possible to further reduce costs and enhance data processing. It is also hoped that this will provide for scalability and offer a practical means of delivering on the ambitions of organizations like the Global Food Monitoring Group [20] and INFORMAS [21], who seek to track the food supply in multiple countries around the world.

FoodSwitch was initially launched in Australia but is now also available in New Zealand and the UK, with well-developed plans for release in multiple other countries in the short-to-medium term. Each country requires its own database for the operation of FoodSwitch because UPC codes, product ranges, and the nutritional content of even apparently identical products vary from one jurisdiction to another. In practice, this means that the launch of FoodSwitch requires access to an initial “priming” branded food composition database for that country, which can then be made complete by post-launch crowdsourcing. The priming dataset needs to ensure an initial rate of successful scans that is sufficiently high to persuade early adopters of the value of submitting photographs of missing items. Just how high that successful scan rate must be is uncertain, although it is clear that the approximate 70% success rate achieved at launch in Australia was more than adequate. The potential for crowdsourcing data collection of the initial priming dataset is also under investigation through the engagement of special interest groups willing to submit photographs of items with the promise of a future launch of FoodSwitch in their country.

Limitations

Even with mandated nutrient declarations on processed foods in Australia, access to the full data required for nutrient profiling was a challenge for the FoodSwitch project, with incomplete information available for calcium, fiber, and the fruit and vegetable content for many products. In each case, the missing values were imputed to enable a score to be calculated for each product. In several cases, this resulted in the same average value being applied to multiple products, which may have reduced the capacity to discriminate between the healthiness of the products within a given category. In particular, this resulted in little capacity for the fruit and vegetable content of a product to influence the ranking of products because the same score was

applied to many products. Future iterations of FoodSwitch may make recommendations for healthier alternatives outside of category, in which case this limitation will be reduced. As with many databases of this scale, despite rigorous quality assurance being undertaken regularly on the data, errors may exist, either in data entry itself, or in the values displayed by the manufacturer on product labels. Within FoodSwitch, users are able to send feedback on data errors directly to the FoodSwitch team so that the next database update can include fixes to existing data. Another limitation is that nutrient values per serving of product are not displayed within FoodSwitch. However, there are plans for future versions of the app to display this information.

Conclusions

FoodSwitch has greatly exceeded our expectations both in regard to numbers of downloads and the crowdsourcing of data. Based on this success and the clear potential for scalability, there are a series of further upgrades planned and we hope to launch the app with partners in multiple developed and developing countries around the world. The proposed model is one whereby the local partner organization takes leadership of the project in their country with the Australia-based team providing technical support and advice about how to achieve launch and the requirements for post-launch support. We hope that local partners will also take the lead in using the data that derive from the project to advocate for in-country improvements in the food supply, as well as contributing to the wider global effort to control the harms caused by the consumption of unhealthy processed foods.

Authors' Contributions

E Dunford was responsible for drafting of the manuscript, E Dunford, J Webster, B Neal, S Goldstein, and A Mills were involved in the design and development of FoodSwitch, O Huguinot was responsible for the modification of the nutrient profiling criteria underpinning FoodSwitch, HK Ng, and C Goodsell were responsible for management of the data underpinning FoodSwitch. All authors were involved in reviewing of the manuscript.

Conflicts of Interest

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Multimedia Appendix 1

FoodSwitch process.

[[JPG File, 208KB](#) - [mhealth_v2i3e37_app1.jpg](#)]

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Abbreviations

FoPL: front-of-pack labeling
fvnl: fruits, vegetables, nuts and legumes
NHMRC: National Health and Medical Research Council
NIP: nutrition information panel
NPSC: nutrient profiling scoring calculator
SKU: stock keeping unit
UPC: universal product code

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Original Paper

ClereMed: Lessons Learned From a Pilot Study of a Mobile Screening Tool to Identify and Support Adults Who Have Difficulty With Medication Labels

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Abstract

Background: In order to take medications safely and effectively, individuals need to be able to see, read, and understand the medication labels. However, one-half of medication labels are currently misunderstood, often because of low literacy, low vision, and cognitive impairment. We sought to design a mobile tool termed ClereMed that could rapidly screen for adults who have difficulty reading or understanding their medication labels.

Objective: The aim of this study was to build the ClereMed prototype; to determine the usability of the prototype with adults 55 and over; to assess its accuracy for identifying adults with low-functional reading ability, poor ability on a real-life pill-sorting task, and low cognition; and to assess the acceptability of a touchscreen device with older adults with age-related changes to vision and cognition.

Methods: This pilot study enrolled adults (≥ 55 years) who were recruited through pharmacies, retirement residences, and a low-vision optometry clinic. ClereMed is a hypertext markup language (HTML)-5 prototype app that simulates medication taking using an iPad, and also provides information on how to improve the accessibility of prescription labels. A paper-based questionnaire included questions on participant demographics, computer literacy, and the Systems Usability Scale (SUS). Cognition was assessed using the Montreal Cognitive Assessment tool, and functional reading ability was measured using the MNRead Acuity Chart. Simulation results were compared with a real-life, medication-taking exercise using prescription vials, tablets, and pillboxes.

Results: The 47 participants had a mean age of 76 (SD 11) years and 60% (28/47) were female. Of the participants, 32% (15/47) did not own a computer or touchscreen device. The mean SUS score was 76/100. ClereMed correctly identified 72% (5/7) of participants with functional reading difficulty, and 63% (5/8) who failed a real-life pill-sorting task, but only 21% (6/28) of participants with cognitive impairment. Participants who owned a computer or touchscreen completed ClereMed in a mean time of 26 (SD 16) seconds, compared with 52 (SD 34) seconds for those who do not own a device ($P < .001$). Those who had difficulty, struggled with screen glare, button activation, and the “drag and drop” function.

Conclusions: ClereMed was well accepted by older participants, but it was only moderately accurate for reading ability and not for mild cognitive impairment. Future versions may be most useful as part of a larger medication assessment or as a tool to help family members and caregivers identify individuals with impaired functional reading ability. Future research is needed to

improve the sensitivity for measuring cognitive impairment and on the feasibility of implementing a mobile app into pharmacy workflow.

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KEYWORDS

low vision; legibility; prescription labelling; medication labels; usability; cognitive impairment; visual impairment

Introduction

Background

The Institute of Medicine (IoM) estimates that each year at least 1.5 million deaths in the United States are caused by preventable adverse drug events with patient confusion as a major contributor [1-6]. To save lives, the IoM and others, including the Institute for Safe Medication Practices (ISMP) and the American Foundation for the Blind, have urged health professionals to communicate more clearly, improve the legibility of medication labels, and provide information in ways that are accessible to adults with low vision and low literacy [2,7,8]. Patients are also being encouraged to take a more active role by maintaining careful records and double checking their own prescriptions [2].

Yet, to use, record, double check, and understand a prescription, a patient or caregiver must be able to see, read, and understand their medication labels. An estimated 1 in 12 North American adults have a self-reported “seeing disability,” with eye diseases, such as cataracts, glaucoma, diabetic retinopathy, or macular degeneration being major causes of vision loss [9-11]. In a study of simulated vision loss, 3-point font is at the limit of legibility for healthy vision, whereas mild- to moderate-simulated vision loss renders anything smaller than 8 to 14 points illegible [12]. The result is that regular prescription medication labels cannot be read accurately by those with moderate-simulated visual impairment. Many older adults also have difficulties reading if there is glare or dim lighting, and struggle with low-contrast reading materials [13].

Individuals over age 65 who are visually impaired are 2 to 3 times more likely to need help managing their medications [14-16]. Specifically, older adults have more difficulty recalling and understanding information printed on prescription labels in 7-point font than in 10-point font [17]. Older adults also read labels less accurately when printed material is in 9- or 12-point font rather than 14-point font [18]. However, Leat et al [19] found that while reading speed is slower for participants with visual impairment, accuracy of reading is high if participants are allowed to use their magnification devices, suggesting that simple interventions can improve prescription label readability.

Patients who can see medication labels must also be able to read and understand the presented information. Just under one-half of North American adults have low literacy (47% in the United States and 48% in Canada) meaning they lack the literacy skills needed for everyday life [20,21]. Between 46% and 60% also have low health literacy and struggle to “obtain, process, and understand basic health information and services needed to make appropriate health decisions” [22,23].

In addition, 1 in 5 community-dwelling adults aged 65 and older have cognitive impairment, including 5-7% who have dementia [24-26]. Compared with individuals with healthy cognition, those with cognitive impairment are 2 to 4 times more likely to be nonadherent to their medication therapy [27,28]. Because 1 in 4 home-dwelling adults with cognitive impairment also have vision problems [29], many patients have multiple barriers to taking medications safely and effectively.

Identifying the Problem

Considering that one-half of all prescription labels are misunderstood, there is a significant need to identify individuals who require additional support with their medication therapy [6]. For chronic conditions such as diabetes, cardiovascular disease, and mental illness, at least one-half of patients are nonadherent to prescribed therapy often because they have a poor understanding of the purpose, safety, and effect of the medications they have been prescribed [30-34].

Despite the high prevalence of medication misunderstandings, adverse events, and nonadherence, there is no gold standard screening tool that health professionals can use at the point-of-care to identify people who need additional support to use medications safely and effectively. In fact, results from Leat’s lab show that 94% of participants (older adults and adults with low vision) reported not being asked by their pharmacist whether they had difficulty reading labels, while 90% of pharmacists reported that there were either no guidelines or they did not know if there were guidelines on when to ask patients if they would like large print (Susan J Leat, PhD, email communication, June 22, 2014).

In research studies of patient comprehension and adherence, the most common screening strategies have been to ask patients to use standard dosing instructions to either calculate the total daily dose being prescribed or to fill a pillbox [35-37]. In a recent study, Anderson et al [38] compared both methods in 65 multi-ethnic patients with type 2 diabetes and found that the pillbox fill was a more conservative method for identifying patients with low cognition [38]. Another strategy that has been proposed is for pharmacists to assess health literacy using the Very Short Test of Functional Health Literacy in Adults, which is positively correlated with pharmacy comprehension ($r=.72$, $P\leq.001$) [39]. However, neither of these strategies have been widely adopted in front-line pharmacies.

Making Medication Information More Accessible

One of the first steps to making medication information more accessible is to identify individuals who simply cannot see the medication information or instructions. On a typical pharmacy label, the most prominent and legible information is the pharmacy logo, which has a mean font size of 13.6 points [40].

By comparison, medication instructions, medication names, and warning labels are 9.3, 8.9, and 6.5 points, respectively [40]. In a recent study of Canadian prescription labels, 44% of medication instructions and all drug and patient names were smaller than 12-point font [41].

To improve legibility, the United States Pharmacopeia recommends that pharmacists label prescriptions with a high contrast print, a simple uncondensed large font (eg, 11-point font, Arial), and adequate white space [42]. Health Canada also recommends pharmacists use a minimum 10-point font [43]. More specific to patients with low vision, the American Foundation for the Blind, the American Society of Consultant Pharmacists Foundation, and ISMP have recommended that pharmacists give patients the option of having large print prescription labels in at least 18-point font [7,8].

In recent years, there has also been considerable effort put toward creating accessible health information. Health Canada has begun producing plain language medication handouts that are more accessible to patients [44]. In the United States, the National Patient Safety Foundation is promoting the “Ask Me 3” campaign that encourages patients to improve their health literacy by preparing questions ahead of physician visits [45]. The Agency for Healthcare Research and Quality has also developed an in depth pharmacy health literacy assessment process to better understand health literacy by guiding pharmacies in collecting information from patients, staff, and objective auditors through a series of surveys and focus groups [46].

The ClereMed Mobile App

The purpose of the study was to build a mobile tool that could be easily used by health care providers or caregivers to identify individuals who have difficulty reading or understanding medication labels and to study the accuracy, usability, and acceptability of the device. To guide content, development, and usability, we convened an advisory committee including a pharmacist and pharmacy professor (Kelly Grindrod); a representative from the Canadian National Institute for the Blind (Deborah Gold); an optometry professor and researcher in the area of low vision, visual assessment, and reading (Susan Leat); an optometrist working with low vision patients (Shamroze Kahn); a pharmacy business expert (Roderick Slavcev); a community pharmacist (Bryan Hastie); and a pharmacy student with a special interest in eHealth technologies (Calvin Poon). The committee met monthly until the final prototype was developed. This approach is consistent with the third generation participatory design framework for health informatics development [47].

As described above, the overall goal was to study one approach to help pharmacists identify patients over age 55 who have difficulty reading and/or understanding the instructions on prescription medications. We designed the app by focusing on the users, the task, and the outcome.

We began by writing use-cases for patients we encountered who had struggled to read prescription labels. We defined our patient users as individuals over age 55 who use at least one chronic medication, including narrow therapeutic index drugs, such as

warfarin and insulin. In describing our users, we made several assumptions. First, we assumed some individuals over age 55 may not be familiar with computers and may require extra support to use a touchscreen device. We also noted some individuals with functional impairments find it difficult to complete paper questionnaires and find touchscreen devices more user-friendly [48]. Given that we were hoping to influence the legibility of prescription labels, we also assumed that it would be most effective to have the pharmacist administer the screening test to the patient rather than having the patient complete the task at home. Our rationale was that the pharmacist could screen the patient when they filled a new prescription and immediately apply the findings to prescription labeling.

We originally intended to design an app that could rapidly screen patients for visual impairments. With the use-cases, we put together several ideas including questionnaires, vision screening tests, and simulations. In consultation with the advisory committee, we chose to develop an app to simulate medication taking and hypothesized it would also capture individuals who could see a label, but could not understand the instructions due to low literacy or cognitive impairment. Although a paper screener or an actual pill vial may have some advantages (simplicity, less expense), an electronic version has the advantage that the results could potentially be stored in the patient's e-record, be shared with other health care providers, automatically print large-print labels, or generate a recommendation for an eye examination.

The researchers worked with a systems design trainee (Behzad Aghaei) to mock-up the app using the Balsamiq platform. To maximize usability, we highlighted the importance of large fonts, large buttons, and intuitive colors (eg, green buttons to move to the next screen). In addition, to help pharmacists act on the results of the screening tool, we developed a prescription-labeling algorithm using the recommendations from the American Foundation for the Blind and the American Society of Consultant Pharmacists Foundation (Figure 1) [7].

The app prototype was built through the Communtech Apps Factory in Kitchener ON, by co-op students from the University of Waterloo computer science program. The app was programmed using hypertext markup language (HTML)-5 and designed for the Apple mobile Operating System (iOS) [49].

We termed the app “ClereMed” (Figure 2). The final prototype included two phases and was designed to take 2 minutes to complete. During the first phase (patient-directed), patients were asked about their perceived ability to read prescription and nonprescription labels. Patients then completed a 1-minute simulation where they read a hypothetical prescription label written in 6.5-point font and followed the instructions to correctly drag and drop “tablets” into the correct times on a “pillbox”. If the patient could not accurately and easily complete the task, the patient was prompted to repeat the activity using progressively larger font sizes. Participants were allowed to increase the print until they felt they could undertake the task comfortably. Of interest, on analysis we identified that, despite programming ClereMed to use default font sizes of 9, 12, 15, and 18 points, the font-sizes in the actual app appeared as 6.5,

9, 11, and 13 points, respectively. The “drawing and print guide for iOS” confirms that font sizes are device-dependent [50].

In the second phase (pharmacist-directed), the pharmacist was asked to identify any common medication-related issues that could reduce visual acuity (the smallest detail that an eye can discern), such as uncontrolled diabetes or chronic corticosteroid use. A participant was considered to have failed the visual aspect of the app if they required the print to be larger than the second

largest print size on the app (ie, >9 points in actual size). This cut point was chosen as then a patient would be able to read most patient-critical information on current prescription medication labels. A cut point of 11 points would mean that the majority of information would not be legible [40]. The app closed with patient-specific recommendations to improve prescription label legibility based on the outcomes of the screening questions and simulation.

Figure 1. Flow chart linking ClereMed prescreening and screening test results to recommendations. (a): Although a participant may report requiring large print material or having difficulty reading prescription or OTC labels and/or worn labels, screening results may indicate that the participant has the ability to complete the screen game using 9-12pt font. In this case, the pharmacist should discuss the results with the participant and decide on the best option. (b): When applicable based on screening results, prescription(s), or disease condition(s) (eg, if participant reports difficulty with both worn and glossy labels, the benefits and risks of taping the label should be discussed).

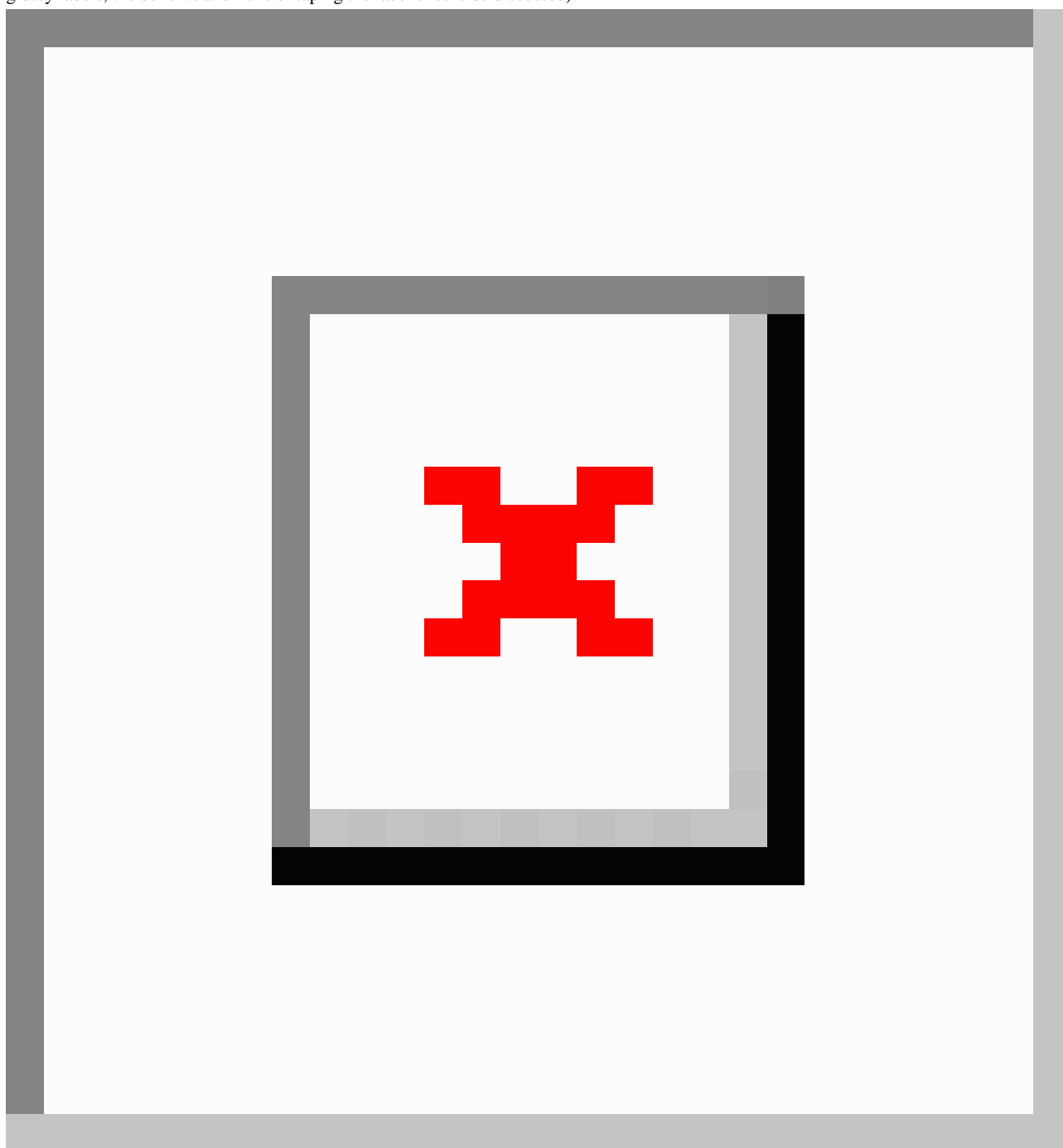
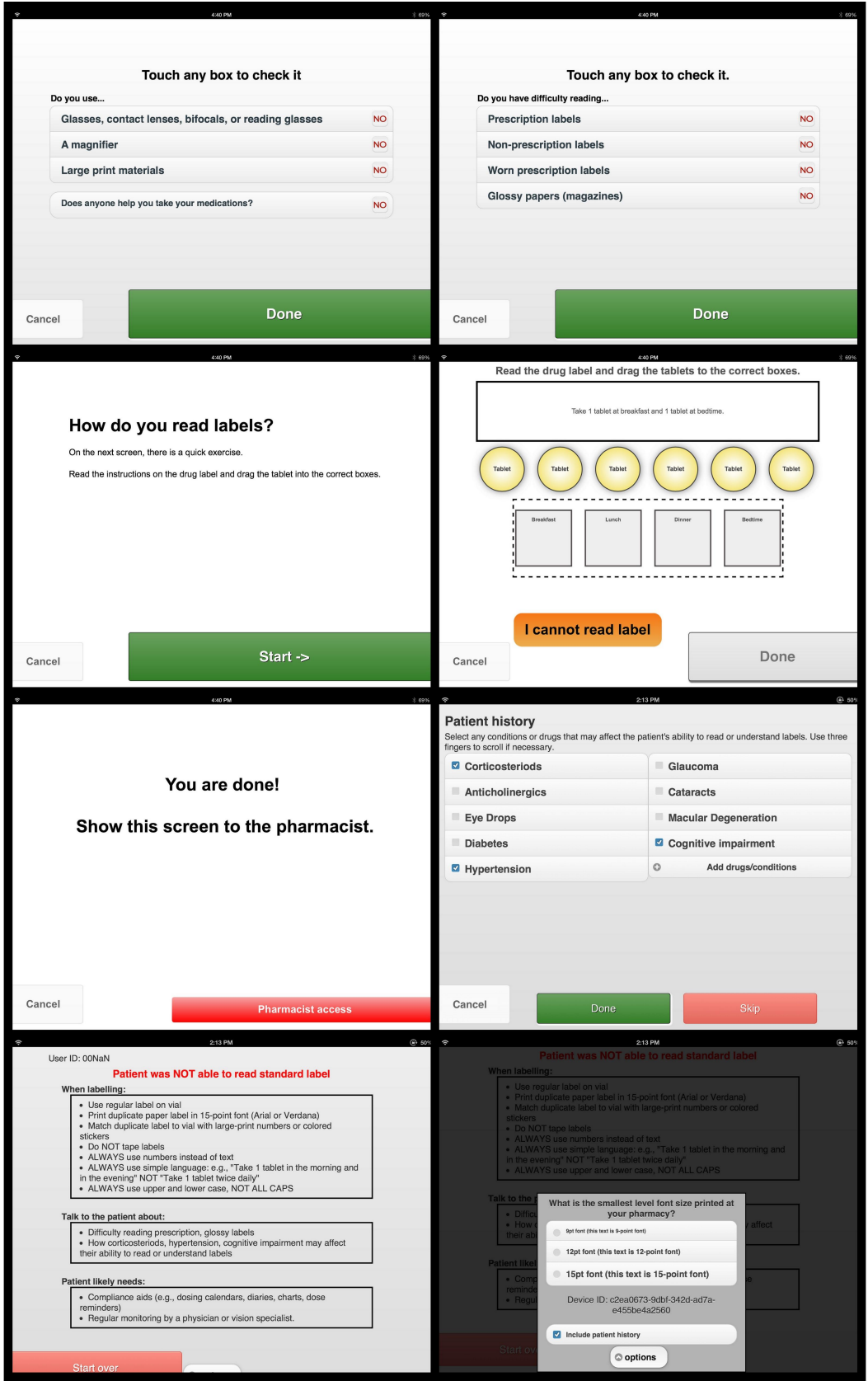


Figure 2. Screenshots of ClereMed.



Research Question and Objectives

Our research question asks, can an easy-to-use mobile app be designed to help pharmacists identify and support adult patients over age 55 who may have difficulty reading or understanding

prescription labeling? The goal of the app was to provide patients and pharmacists with realistic and individualized recommendations to improve the legibility of labels before their patients leave the pharmacy and to assess their ability to follow instructions.

The specific objectives of this pilot study were to build the ClereMed prototype, to determine the usability of the prototype with adults 55 and over, and to assess its accuracy for identifying adults with low-functional reading ability, poor ability on a real-life pill-sorting task, and low cognition. We also wished to assess the acceptability of a touchscreen device with older adults with age-related changes to vision and cognition and to provide recommendations for future mobile app development.

Methods

Participants

Our methods and results are reported according to the CONSORT-EHEALTH statement [51]. This study was reviewed and received ethics clearance through the Office of Research Ethics at the University of Waterloo on January 6, 2012 (Application #17596).

We pilot-tested ClereMed with individuals age 55 and over, who could speak and read English and who were taking at least one chronic medication. We recruited participants from the Waterloo Region, which is a large urban center in Southwestern Ontario with a population of over 500,000.

We began our pilot testing by asking pharmacists to test the app in their pharmacy. We asked pharmacists to approach patients who were filling a prescription and ask if they would be willing to test a new mobile app. After very poor initial uptake, we moved the pilot testing out of the pharmacy and into local retirement residences and a low-vision clinic at the University of Waterloo School of Optometry and Vision Science. Results for the pharmacist directed portion of the ClereMed will not be described due to low uptake of ClereMed by pharmacists. Potential participants were contacted by telephone, mail, and using posters and were invited to schedule a time to meet with a research assistant. They were given the option to test ClereMed at their home, in the common areas of their retirement home (if applicable), or in the clinical spaces of the University of Waterloo Schools of Pharmacy, Optometry, and Vision Science. All participants provided written consent prior to taking part in the study and were provided with a \$10 gift certificate in appreciation of their time.

Halfway through pilot testing we made minor updates to the app. Participants were originally required to tap radio buttons. In response to user difficulty with the tapping action, we changed radio buttons to yes/no “sliders”. We also enlarged the button sizes and participants were offered the choice of using a stylus.

Data Collection

Immediately before trying ClereMed, the research assistant asked participants to complete a paper-based background questionnaire that included questions on patient demographics and computer experience. Participants tested ClereMed on an iPad using any assistive devices they would typically use to read a prescription label (eg, spectacles, a magnifying glass). The research assistant provided little guidance and only offered a prompt if the participant could not move forward with a task after several attempts.

After completing the app, participants assessed usability with the Systems Usability Scale (SUS) and by providing written feedback [52]. The SUS is a validated tool that uses a 5-point Likert scale to provide a quantitative measure of the usability and learnability of a system and provides an overall score between 0 and 100 [52]. A trained research assistant administered a vision and cognitive assessment. We assessed reading visual acuity using the MNRead Near Vision Chart. Participants used the same spectacles as were used for the app and held the chart at 40 cm with good, even illumination. To achieve the clearest vision for the testing, +2.00 lenses were held over the participant’s habitual distance prescription or in a trial frame if this provided clearer vision. Functional visual impairment was designated as visual acuity >1 M on the MNread chart (equivalent to Arial >8.5-point font, which is similar to the cut off used for the app).

We assessed cognition using the Montreal Cognitive Assessment tool (MoCA) [53]. The MoCA is a validated, paper-based test that is used to detect mild cognitive impairment. It has short questions that test the areas of visuospatial, naming, memory, attention, language, abstraction, delayed recall, and orientation. It was chosen because it has a greater sensitivity for detecting mild cognitive impairment compared with the Mini-Mental State Examination [53]. MoCA scores of $\leq 25/30$ were defined as mild cognitive impairment.

Lastly, as a true-life task, participants completed a real-life prescription vial simulation. Participants were handed a pill bottle with instructions written in Arial, 9-point font (eg, “Take ONE tablet THREE times daily”) and asked to place the pills into a pillbox in accordance with the instructions. Participants who could not complete the activity were given pill bottles labeled with incrementally larger font sizes and asked to try again, until they were able to do the task correctly. A research assistant recorded the time taken to complete the activity using a digital timer.

Statistical Analysis

Data were analyzed using SPSS. We used descriptive statistics to summarize demographic data. For each factor of the SUS, participant responses to the 5-item Likert agreement scale were scored by subtracting 1 from odd numbered factors, subtracting the even numbered factors from 5 and multiplying each factor by 2.5 for a total possible score of 100 for the entire 10-item scale [54]. The total mean usability score as well as the scores for learnability (factors 4 and 10) and usability (factors 1-3 and 5-9) [55] were compared between the populations of participants who did and did not own a computer/touchscreen device using a Mann-Whitney test for nonparametric data.

We converted the MNRead scores (which are in a Times Roman font) to the Arial font size equivalent. Both MNRead scores and app print size were log transformed, as is usual for vision data. The correlation between the near-visual acuity score and the smallest font size required by the participant to complete the app was calculated using a Pearson product-moment correlation coefficient. We assessed agreement using a Bland-Altman plot. To determine the accuracy of ClereMed, participants’ ability to complete the app without help was compared against the MNRead, real-life pill bottles, and MoCA

results (sensitivity and specificity). Statistical significance for all tests was determined a priori at a level of $P < .05$.

Results

Participants

Over a 2-month period, a total of 4 participants were recruited through two pharmacies. The study protocol was expanded to nonpharmacy environments and within 2 months, 39 participants were recruited from retirement residences and 4 additional participants were recruited from the low-vision clinic.

Of the 47 participants who completed the study, 60% (28/47) were female, the mean age was 76 (55-93 years), 15% (7/47) had functional visual impairment based on the MNread visual acuity, and 62% (29/47) had mild cognitive impairment based on the MoCA (Table 1). Of participants, 77% (35/47) reported

having at least one condition that could affect ability to see and/or understand prescription labels. Further, 32% (15/47) of participants did not use a computer, tablet, e-reader, or mobile phone at home. Participants who had access to a computer or touchscreen device at home completed ClereMed in a mean time of 26 (SD 16) seconds, compared with 52 (SD 34) seconds for those who did not ($P = .001$).

In their daily life, nearly all participants wore spectacles, while 21% (10/47) used a magnifier and 21% (10/47) used large print materials. Of the participants, 14% (6/44) needed assistance to take their medications and 36% (16/44) reported having difficulty reading medication labels or nonprescription labels. Worn or glossy labels were also a problem for 39% (17/44). The most common complaints about the legibility of prescription labels were that the fonts were too small and that the contrast was poor. Many participants reported that labels are easier to read when large letters, bold fonts, and high contrast were used.

Table 1. Participant demographics, technology in the home, and self-reported difficulty reading medication labels (N=47).

Demographics	N	%
Age, years, mean (range)	76 (55-93)	
Female	28	60
Highest education level completed		
High school	20	43
Trade school	1	2
Post-secondary	21	45
Graduate degree	5	10
Annual income (\$CAD)		
<20,000	7	15
20,000-49,000	15	32
50,000-79,999	4	9
>80,000	4	9
Prefer not to respond	17	36
Technology in the home		
Computer	30	63
Tablet	4	9
e-Reader	10	21
Mobile phone	4	9
Assistive devices for daily living		
Spectacles	42	89
Magnifier	10	21
Large print	10	21
Self-reported difficulty		
Taking medications	6	13
Reading prescription labels	12	26
Reading nonprescription labels	14	30
Reading worn labels	15	32
Reading glossy paper	9	19
Concerned about ability to read or understand medication labels	10	21
Medical conditions that could affect ability to read medication labels		
Diabetes	7	15
Hypertension	13	28
Glaucoma	6	13
Cataracts	12	26
Macular degeneration	4	9
Total with at least one condition affecting vision	35	77
Medications that could affect ability to read medication labels		
Corticosteroids	0	0
Anticholinergics	1	2
Medicated eye drops	13	27
Cognitive impairment (MoCA <25/30)	29	62
Functional visual impairment (MNRead <1M)	7	15

ClereMed Usability

Overall, the mean SUS was 76/100 (Table 2), with 84% (37/44) of participants agreeing the app was easy to use on item 3. Participants who owned computers or touchscreen devices found ClereMed to be more usable than those who did not own a computer or touchscreen (mean SUS score difference 16.22, 95% CI 11.59-20.86, $P<.03$; Table 3).

The difference may be largely attributable to the learnability of ClereMed (items 4 and 10), with 60% (9/15) of those with no technology ownership agreeing or strongly agreeing they would require some kind of technical support to get through it (SUS Factor 4) and 47% (7/15) agreeing or strongly agreeing they needed to learn a lot before using ClereMed (SUS Factor 10), compared with a respective 24% (7/29) and 17% (5/29) in the technology ownership group.

In written feedback, most participants found the app to be simple and thought it could quickly identify patients with visual impairment within a pharmacy. Some positive comments included that the screen was a nice size, the app had good

contrast, instructions for the simulation activity were clear, and the process was quick and concise. Of participants who found the app difficult to use, many had trouble navigating the touchscreen, either due to lack of dexterity, hand tremor, or simply because the screen did not respond to their touch. This problem was often alleviated with the use of a stylus.

Some participants noted that the font sizes for the simulation instructions were too small and felt larger, bolder fonts would make it easier to complete the app. Many participants also had trouble with screen glare. Of the visually impaired participants, some noted that the yellow color used for the tablets in the simulation was hard to see. They also noted that white fonts on a black background might be easier to read. Finally, some participants noted that radio buttons (for yes/no responses) were confusing, while others were not familiar with the term “drag” for the drag and drop simulation.

With regards to the minor updates made to the app during the pilot, the larger buttons did appear to reduce user difficulties but the change from radio buttons to a yes/no slider did not.

Table 2. Participant agreement with Systems Usability Scale (SUS) items after using ClereMed (1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree) and mean SUS score (n=44^a).

	Mean Agreement (SD)	MeanSUS Score (SD) ^b
1. I think that I would like to use ClereMed frequently	3.05 (1.71)	5.11 (4.28)
2. I found ClereMed unnecessarily complex	1.70 (1.42)	8.24 (3.56)
3. I thought ClereMed was easy to use	4.39 (1.35)	8.47 (3.38)
4. I think that I would need the support of a technical person to be able to use ClereMed	2.52 (1.59)	6.19 (3.98)
5. I found the various functions in ClereMed were well integrated	4.25 (1.24)	8.13 (3.10)
6. I thought there was too much inconsistency in ClereMed	1.45 (1.04)	8.86 (2.61)
7. I would imagine that most people would learn to use ClereMed very quickly	4.14 (1.37)	7.84 (3.44)
8. I found ClereMed very cumbersome to use	1.55 (1.23)	8.64 (3.07)
9. I felt very confident using ClereMed	4.16 (1.29)	7.90 (3.23)
10. I needed to learn a lot of things before I could get going with ClereMed	2.27 (1.72)	6.82 (4.29)
Learnability score ^c	-	65.06 (35.72)
Usability score ^d	-	78.98 (20.19)
Total SUS score	-	76.19 (20.67)

^aThree participants who had severe vision impairment tried but could not test the app.

^bOdd numbered items (1, 3, 5, 7, 9) were scored by subtracting 1 from the mean agreement and multiplying by a factor of 2.5. Even numbered items (2, 4, 6, 8, 10) were scored by subtracting the mean agreement from 5 and then multiplying by a factor of 2.5.⁵¹

^cLearnability is represented by factors 4 and 10.

^dUsability is represented by factors 1-3 and 5-9.

Table 3. Responses to Systems Usability Scale (SUS) components according to computer and touchscreen ownership for participants who could use ClereMed (n=44^a).

Responses	Mean SUS score (SD)	
	Technology ownership (n=29)	No technology ownership (n=15)
1. I think that I would like to use ClereMed frequently ^b	6.55 (3.68)	2.33 (4.06)
2. I found ClereMed unnecessarily complex ^b	9.22 (2.23)	6.33 (4.81)
3. I thought ClereMed was easy to use	9.05 (2.45)	7.33 (4.58)
4. I think that I would need the support of a technical person to be able to use ClereMed	7.07 (3.60)	4.50 (4.25)
5. I found the various functions in ClereMed were well integrated	7.59 (3.57)	9.17 (1.54)
6. I thought there was too much inconsistency in ClereMed	9.14 (2.03)	8.33 (3.49)
7. I would imagine that most people would learn to use ClereMed very quickly	7.76 (3.36)	8.00 (3.68)
8. I found ClereMed very cumbersome to use	8.79 (2.80)	8.33 (3.62)
9. I felt very confident using ClereMed ^b	8.79 (2.07)	6.17 (4.32)
10. I needed to learn a lot of things before I could get going with ClereMed	7.76 (3.68)	5.00 (4.91)
Learnability score ^b ($P=.04$)	74.14 (28.53)	47.50 (42.31)
Usability score ^c ($P=.06$)	83.62 (16.32)	70.00 (24.26)
Total SUS score ($P=.03$)	81.72 (15.78)	65.5 (25.06)

^aThree participants who had severe vision impairment tried by could not test the app.

^bOdd numbered items (1, 3, 5, 7, 9) were scored by subtracting 1 from the mean agreement and multiplying by a factor of 2.5. Even numbered items (2, 4, 6, 8, 10) were scored by subtracting the mean agreement from 5 and then multiplying by a factor of 2.5.⁵¹

^cLearnability is represented by factors 4 and 10.

^dUsability is represented by factors 1-3 and 5-9.

Accuracy

In terms of vision, ClereMed correctly identified 71% (5/7, sensitivity) of participants who had functional vision impairment and 86% (31/36, specificity) who had healthy, functional vision (Table 4). There was a positive correlation between the log MNRead visual acuity and the log smallest app print size read

($r=.56$, $n=45$, $P<.001$). However, this was strongly influenced by one outlier who had extreme low vision (MNRead reading acuity value of 1.5), and when this was removed the correlation fell to $r=.43$ ($n=45$, $P=.003$). Of particular note, it was not apparent that the individual had such poor vision until they were asked to complete ClereMed and indicated they could not see the iPad.

Table 4. Sensitivity and specificity of ClereMed for identifying individuals with functional vision impairment, mild cognitive impairment, and who failed the real-life simulation (N=43^a).

	Functional vision impairment	Mild cognitive impairment	Failed real-life simulation
Sensitivity	0.71 (5/7)	0.21 (6/28)	0.63 (5/8)
Specificity	0.86 (31/36)	1.00 (15/15)	0.97 (34/35)

^aDue to a system error, results data was not collected for the first four participants who tested ClereMed.

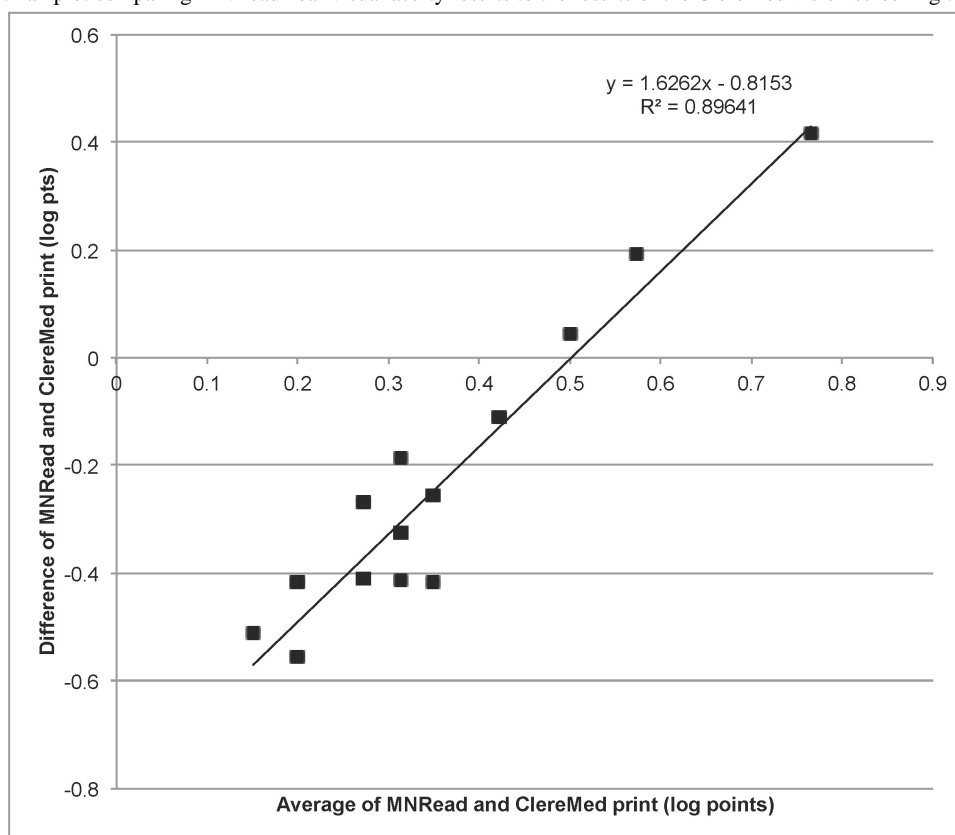
The Bland-Altman analysis (Figure 3) showed that there was moderate agreement between the measures in terms of reading print. On average, the point print chosen for the app tended to be larger than the reading acuity measured with the MNRead. However, there was a strong trend toward those with better vision choosing a larger print on the ClereMed, while 2 participants with poorer vision chose smaller print on the app.

Compared with the real-life prescription vial simulation, ClereMed correctly identified 63% (5/8) of people who could not complete the simulation and 97% (34/35) of participants who could complete it (Table 4).

Of the 62% (29/47) of participants identified by the MoCA as having cognitive impairment, 2 individuals could not complete the ClereMed tool. One participant with healthy cognitive ability also had difficulty comprehending the instructions for the

simulation activity. ClereMed correctly identified only 21% (6/28) participants with mild cognitive impairment but identified 100% (15/15) of participants who had healthy cognition.

Figure 3. Bland Altman plot comparing MNRead near visual acuity results to the results of the ClereMed vision screening test (N=43).



Discussion

Principal Findings

ClereMed was moderately accurate for identifying participants who could not read prescription labels compared with the MNRead reading test and the real-life prescription vial simulation. It was not accurate for detecting mild cognitive impairment. Given ClereMed's reported ease-of-use for adults 55 and over, the app may be a convenient option to estimate a patient's ability to read a medication label. Although visual acuity can be measured simply on a reading card, the app has the advantage of not getting soiled or losing its contrast and can measure a variety of functions in addition to visual acuity. However, further development and testing of ClereMed is necessary before it could be integrated into the workflow of pharmacies and other health care settings.

Though there was moderately good correlation with reading acuity, most participants preferred print that was larger than their visual acuity threshold as measured by the MNRead. This is not surprising as the MNRead measured the participant's acuity limit, while ClereMed allowed participants to increase the print until they felt they could undertake the task comfortably. It is known that to obtain reasonable fluency in reading, the print needs to be at least twice as large as the acuity threshold [56] and patients prefer print that is somewhat larger than their acuity limit. The 2 participants who preferred smaller print on ClereMed may have been using a spectacle with a strong reading

addition or holding the ClereMed closer than when their near reading acuity was measured with the MNRead.

Though the sensitivity of ClereMed was high for functional vision impairment, the sensitivity was very low for mild cognitive impairment. ClereMed was not designed to measure cognition directly, but the practical ability to understand and follow instructions. This finding is consistent with a small study by Anderson et al [57] who, in 2008, found that the well-validated Mini-Mental State Exam for cognition was poorly correlated with the patient's ability to fill a pillbox ($r^2=.15$, $P=.046$). Stilley et al [58] has also shown attention/psychomotor speed are cognitive domains that most consistently predict medication adherence. Executive function is also considered to be a good predictor of everyday functioning and includes behaviors such as purposive action/self-regulation, planning/attention, volition/inhibition, and effective performance/self-monitoring [59]. In 2013, Zartman et al [60] developed the "Pillbox Test" to assess executive function. Using five pill bottles with different colored beads, patients were asked to fill a pillbox using a range of common instructions ranging from "take one tablet daily" to "take one tablet in the am and pm" and "take one tablet every other day" [60]. Initial testing with 120 patients showed that the Pillbox Test was well correlated with the Direction Assessment of Functional Status score for executive function and that it had a sensitivity of 75% and a specificity of 87.5% for adults with neurological disorders including dementia and stroke compared with healthy adults [60]. For assessing cognition, future research on tests such as

ClereMed should consider the role of the different cognitive domains.

ClereMed Usability

In terms of usability, interacting with new technology at an older age without any previous experience can, understandably, be daunting. Many of the participants had previous computer experience, though much fewer had experience with touchscreen devices. The majority of participants, regardless of their previous experience with touchscreens, reacted positively to ClereMed. In general, participants found the app to be simple and easy to use and felt most people would learn to use it quickly. Given that many adults 55 and over would not have any previous experience using a touchscreen device, the reported usability of ClereMed is encouraging. Certainly, previous research has shown that many adults 55 and over, especially those with motor difficulties (eg, rheumatoid arthritis) may actually prefer using touchscreens over traditional pen and paper when completing questionnaires [48].

Many participants also expressed their apprehension prior to participating, stating their lack of experience as a reason to fear using an app. A review by Broady et al [61] reported that this is a typical reaction for adults 55 and over. Despite lack of experience that may lead them to feel less comfortable and competent using a new technology, personal relevance of the technology is an important factor in encouraging adults 55 and over to make use of such services [61]. In this study, most participants were pleasantly surprised at how quickly they picked up on the new technology. Knowing the relevance of the app to their everyday lives seemed to help participants want to learn how to use it.

Although most of the feedback provided about ClereMed was positive, some participants had difficulty interacting with the touchscreen. Many could not get the screen to respond to their touch and reported difficulty when finer movements were required (ie, when trying to tap a radio button). Most commonly, problems were encountered when there was a long lag time between touching the screen (pressing) and letting go (releasing). When this occurred, the system would not recognize the tap or would activate a copy/paste function until participants mastered the required technique. Leonardi et al [62] observed a similar problem when testing a touchscreen interface for older adults. They found that many misunderstood the tapping gesture. For some participants, up to a 1-second gap was measured between the “press” and the “release”. In other instances, the finger would move slightly while pressing, leading the system to interpret the motion as a dragging gesture, rather than a tap [62].

Research by Wacharamanotham et al [63] also found that elderly users with a hand tremor may have difficulty interacting with

touchscreens due to finger oscillation. Instead of tapping, a “swabbing” or swiping motion can decrease error rates and improve user satisfaction. Future research is needed to investigate tools and methods to improve the user-friendliness of mobile apps for adults 55 and over, especially those who have little to no experience with touchscreens for whom certain functions may not be completely intuitive.

Limitations and Lessons Learned

There were some limitations to the current study and some lessons learned. It was a pilot study designed to test a concept. Although ClereMed was designed for use in pharmacies, only 4 participants were actually recruited through a pharmacy. Most recruitment occurred in independent living retirement homes with a research assistant. As a result, our sample population may not be representative of all individuals who pharmacists would assess with ClereMed. Community-dwelling adults who are younger, for example, may differ in their experience with and willingness to adopt new technologies.

On follow-up, pharmacists told us they felt over-burdened recruiting participants and testing the app in the pharmacy setting. For a multi-user app such as ClereMed, the user experience needs to be positive for both experienced and new users. In our design processes, we had input from pharmacists but focused on the patient user and not the pharmacist user. With ClereMed, it is the pharmacist who would make the decision to adopt the app into their practice. The diffusion of innovation model posits that, for a technology to be adopted, it must provide users with a relative advantage over their current circumstances [64]. In hindsight, we should have focused on providing pharmacists with a relative advantage over their current practice. This is an important consideration for future research.

Further, though our goal was to build on the rapid advances in mobile technologies to build a novel tool, another approach would have been to use a simple paper-based tool. The other issue that requires consideration is the motivation of pharmacists to use any tool, be it paper or electronic, to assess and support their patients. Currently, it is likely that many patients who have difficulty reading their prescription labels go unnoticed. More research is needed to explore the ways to work with pharmacists to identify patients who need help. The lack of sensitivity of ClereMed for cognitive impairment also requires further investigation. Nevertheless, if used correctly, an app such as ClereMed has the potential to reduce medication mismanagement in adults 55 and over by rapidly allowing the pharmacist to identify a patient’s inability to read a medication label or understand instructions and provide practical solutions to the problem.

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Authors' Contributions

Kelly Grindrod and Susan Leat were lead researchers responsible for the study design, data acquisition, analysis and interpretation, drafting and revising the final article. Allison Gates was a research assistant responsible for data acquisition, analysis, interpretation and drafting the article. Lisa Dolovich, Roderick Slavcev, Shamrozé Khan, and Calvin Poon provided input on the study design and the article drafts. Rob Drimmie and Behzad Aghaei were responsible for the development of the ClereMed tool and provided input on the article drafts. All authors reviewed the final draft.

Conflicts of Interest

None declared.

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Abbreviations

HTML: hypertext markup language
IoM: Institute of Medicine
iOS: Apple mobile operating system
ISMP: Institute for Safe Medication Practices
MoCA: Montreal cognitive assessment tool
SUS: systems usability scale

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Review

Commercially Available Mobile Phone Headache Diary Apps: A Systematic Review

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Abstract

Background: Headache diaries are often used by headache sufferers to self-monitor headaches. With advances in mobile technology, mobile electronic diary apps are becoming increasingly common.

Objective: This review aims to identify and evaluate all commercially available mobile headache diary apps for the two most popular mobile phone platforms, iOS and Android.

Methods: The authors developed a priori a set of 7 criteria that define an ideal headache diary app intended to help headache sufferers better understand and manage their headaches, while providing relevant data to health professionals. The app criteria were intended as minimum requirements for an acceptable headache diary app that could be prescribed by health care professionals. Each app was evaluated and scored against each criterion.

Results: Of the 38 apps identified, none of the apps met all 7 app criteria. The 3 highest scoring apps, meeting 5 of the app criteria, were iHeadache (developed by Better QOL), ecoHeadache (developed by ecoTouchMedia), and Headache Diary Pro (developed by Froggyware). Only 18% of the apps were created with scientific or clinical headache expertise and none of the apps reported on psychometric properties.

Conclusions: Despite the growing market and demand, there is a concerning lack of scientific expertise and evidence base associated with headache diary apps.

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KEYWORDS

headache; diary; apps; smartphone; mobile phone; technology; mHealth; review

Introduction

Headache disorders are highly prevalent, with 46% of adults and 51% of children and adolescents presenting with an active headache disorder worldwide [1]. Headache disorders are among the most disabling conditions for both men and women, and a major public health concern [1-3].

Keeping a diary on a regular basis to track headache-related information such as occurrence, symptoms, triggers, and medication intake is often recommended by health care professionals [4,5]. A diary helps both users and health care professionals assess headache impact, make a diagnosis, and inform health care decision making [4,5]. Typically, paper diaries have been used. However, paper diaries can be bulky,

data must be entered by hand, and they can be lost or forgotten. Compliance with paper diaries can be a problem, and individuals may be completing multiple diary entries concurrently at a later date, leading to reliability concerns [6]. The limitations of paper diaries, along with recent advances in mobile technology, have led to the increasing adoption of electronic diaries (e-diaries) on mobile devices such as mobile phones [7,8].

The use of mobile e-diaries has several advantages over paper diaries. Mobile e-diaries allow users to conveniently take the diary with them at all times, they make it possible to incorporate branching questions which makes data entry more efficient, and they have the capability of automatically building reports from the data entered, which may help users to identify patterns and predict trends. E-diaries are also beneficial to health care professionals by allowing them to access patient data in real time, verify actual entry times, and ultimately user compliance rates. E-diaries have been shown to be more reliable than paper-based diaries, and they are associated with increased levels of compliance and satisfaction when compared to paper diaries in both adults and children [9,10]. For instance, Stone et al found that the compliance rate for an electronic pain diary was 94%, compared to 11% for a paper diary [6]. They also found that out of the 710 days analyzed, the paper diary was not used on 230 (32%) of the days, yet participants reported a level of compliance over 90% on those days.

E-diaries and other medical apps on mobile phones are rapidly expanding, especially outside the academic setting. The number of available mobile health apps across major mobile phone app stores increased from 17,000 in 2010 to 97,000 apps in 2013 [11,12]. In 2014, 4.55 billion people are expected to use mobile phones overall, with worldwide mobile phone usage predicted to increase by 25% to 1.76 billion people [13]. By 2017, nearly 50% of mobile phones are expected to be smartphones [14]. In addition, it is estimated that by 2015, 500 million mobile phone users will be using a medical app [11].

Concerns are commonly raised around the quality of such mobile health apps, due to the low levels of involvement by health care professionals, and failure to use a scientific evidence base in app development [15,16]. However, no systematic review of many of the available medical apps, including headache diary apps, has been conducted. Recently, Stinson et al systematically reviewed headache diaries used in the research setting only [8]. A previous review by Rosser and Eccleston demonstrated the popularity of pain apps in the commercial app market [16]. They found headache pain was the most common type of pain targeted and found that diary tracking features were included in 24% of the identified pain apps. However, the pain apps were not downloaded and evaluated as part of the review. Since Rosser and Eccleston's review, the number of headache diary apps has increased dramatically. Our goal was to systematically identify and evaluate all commercially available headache diaries for Apple (iOS) and Android devices. Together, these two platforms represent the majority of devices, with more than 90% (81% Android, 13% iOS) of the global mobile phone market in 2013 [17,18]. The results of this review will help inform health care professionals and potential users on the best available e-diary apps for headache. It will also provide researchers with new electronic assessment tools if apps are found with evidence of

reliability and validity. A lack of high-quality apps would demonstrate a need for researchers and health care professionals to improve the existing apps, or develop quality diary apps to fill the current gap in demand.

Methods

Search Strategy

The two most popular mobile phone platform app stores were used to identify all available headache diary apps. The Canadian Google Play (Android) and Apple iTunes App (iOS) stores were searched using the following search terms: headache, headache diary, headache tracker, migraine, migraine diary, and migraine tracker. The final app search was conducted on November 2, 2013 by 2 reviewers (ASH, Hayley Stinson, BA). ASH identified a total of 41 apps, while HS identified 42. Agreement between the reviewers was 96.4%. Any discrepancies were resolved by a discussion with a third reviewer (AH).

Inclusion and Exclusion Criteria

All of the apps identifying themselves in the Canadian Google Play or Apple iTunes App store description as headache logging or tracking tools were included. The apps were then downloaded and excluded from the review if they failed to log or track headaches, despite their associated description. When both a version requiring payment and a free version of an app was available, the version requiring payment was purchased and used, while the free version was excluded. This was done to ensure that the best available version of the app was considered. The apps not available in English were also excluded. Identical apps available in both the Google Play and Apple iTunes App stores were counted only once.

Data Extraction

One reviewer (ASH) downloaded all of the apps meeting the criteria. The apps were installed on a Google LG Nexus 4 running Android 4.3 and an Apple iPod Touch ME178C/A (4th generation) running iOS 6.1.2. The reviewer extracted the following information for each app: date and version of last update, price, developer, technical requirements, language, assessment schemes (time contingent, signal contingent, or event contingent), presence of reports, reports linking multiple variables, type of reports (plain text, table, graphs/charts), presence of headache entry log (list of previous headache entries), ability to edit previous headache entries, ability to export data from app (eg, email, PDF), reminders, headache characteristics and related variables measured (eg, headache severity, triggers, headache quality), inclusion of customization and personalization features, ability to use the app without Internet connection, the need to create an account to use the app, and presence of advertisements in the app. Any associated components not directly part of the app, such as website components, were not evaluated, given that our main focus was to evaluate the diaries as stand-alone apps.

App Quality Assessment

Overview

Given that no standards exist for evaluating these apps, the authors consensually defined a set of criteria for an ideal

headache diary app intended to help headache sufferers better understand and manage their headaches, while providing relevant data to health professionals. Based on the authors' judgment, an ideal headache diary app should (1) be created with clinical and/or scientific headache expertise, (2) have undergone testing to ensure the diary is a feasible and reliable method of data collection, (3) measure clinically relevant headache variables, (4) be usable, (5) include customizable answer options and reports, (6) include reports linking multiple variables, and (7) have the ability to export headache data from the app. See below for how each of these criteria, intended as minimum requirements for an acceptable headache diary app, were evaluated.

App Criterion #1: Apps Created With Headache Expertise

An appropriate app does not necessarily need to be developed by headache experts themselves, but it is important that experts be involved at least in advising development. For this reason, we *a priori* defined that an ideal app be created with headache expertise. The app description available in the app store and any websites linked to the developer, creator, or institution affiliated with app development were examined for scientific or clinical headache expertise. The apps found to be supported by academic or clinical institutions, or created by individuals with MDs or PhDs practicing or doing research in the fields of neurology or pain were considered to have been created with headache expertise. The method used to identify expert involvement was chosen as a feasible strategy. It is possible that headache experts may have been involved in development but not identified in the app descriptions or associated websites. We also acknowledge that headache sufferers can be considered experts in creating diary apps. However, they were not included in this criterion as it was not possible to reliably confirm whether the app creators held this type of expertise.

App Criterion #2: Formal Psychometric and Feasibility Testing

To examine whether the feasibility—described in terms of adherence, acceptability, learnability, efficiency, or accuracy—and psychometric properties of the existing apps could have been formally tested, a search of the following databases was conducted: PubMed, Web of Knowledge, and

PsychINFO (2000 to October 24, 2013). The search did not include publications prior to 2000; the oldest app versions included in this review were released in 2010. The search terms included “headache or migraine or cephalalgia” and “diary or diaries”. A total of 1442 abstracts were retrieved from our search strategy. Two reviewers (ASH, AH) independently screened all retrieved abstracts (n=723 after removing duplicates) for e-diaries or mobile phone diaries matching the names of the apps, their developers' names, or descriptions of the content of the apps included in this review. The systematic review of the headache e-diaries developed and used in the academic setting was conducted recently by several members of this research team and was taken into account [8]. Using Cohen's kappa, the level of agreement between the 2 reviewers screening the abstracts was 1.00, indicating perfect agreement [19,20]. We also acknowledge that the apps may have undergone psychometric or feasibility testing that was not published in the scientific literature. However, it was not possible to verify whether such testing had occurred.

App Criterion #3: Clinically Relevant Headache Variables Measured

There is no consensus on a standard set of core variables that should be assessed in a headache diary. Consequently, the authors created and conducted an online survey among headache experts to define what the most clinically relevant headache variables for a headache diary app should be. Headache experts were required to (1) have an MD or PhD, (2) be affiliated with recognized universities, (3) be currently conducting research and/or practicing in the field of neurology or pain, and (4) be published in peer-reviewed journals on the topic of headaches. We identified and invited 35 headache experts to participate. Of the 35 experts contacted, 10 responded. Experts were independently asked to create a list including all variables they believed should be measured in a mobile headache diary. Responses were compiled and comparable responses grouped under the same variable (eg, headache severity, headache intensity, and pain level were grouped together). For a complete list of headache variables recommended by the experts, see Table 1. Those variables suggested by 50% or more of the headache experts were considered clinically relevant. A reviewer (ASH) assessed each of the apps for inclusion of the clinically relevant variables suggested by the experts.

Table 1. Headache variables recommended by headache experts (n=10).

Headache variable ^a	Number of experts recommending, n (%)
Headache severity/intensity	10 (100)
Headache triggers	9 (90)
Medication/treatment taken for headache	9 (90)
Associated headache symptoms	7 (70)
Headache frequency (derived from headache occurrence)	6 (60)
Headache-related disability	5 (50)
Headache duration	5 (50)
Response to medication/treatment	3 (30)
Ongoing preventative medication	2 (20)
Time of headache onset	2 (20)
Date of headache	2 (20)
Presence of aura	2 (20)
Menses	2 (20)
Headache pain location	2 (20)
Headache pain quality	2 (20)
Side effects of treatment	1 (10)
Time of treatment	1 (10)
Nonpharmacological treatments	1 (10)
Life events (eg, travel, exercise)	1 (10)
Prodrome symptoms	1 (10)
Sought care from health professionals	1 (10)
Worry/anxiety/fear rating	1 (10)
Stress/mood rating	1 (10)
Sleep rating	1 (10)

^aVariables recommended by 50% or more of the experts were considered clinically relevant.

App Criterion #4: Usable Apps

An ideal app was expected to be usable. Usability is a qualitative attribute which assesses how easy user interfaces are to use and understand [21]. Usability was assessed using a heuristic evaluation, which consists of a small number of expert evaluators assessing the user interface against a list of heuristics, defined as general principles for interaction design [21]. Heuristic evaluation is one of the most common methods of usability assessment. It benefits from being an efficient evaluation method for obtaining high-quality results in a short amount of time, and at a low cost [21-23]. Usability can also be assessed using a variety of methods by users themselves, such as the think aloud protocol, which consists of verbal reports from users [23].

In the current review, each app user interface was systematically inspected, and its compliance with a common list of 10 well-established usability heuristics (see Table 2 for a description of each heuristic) was judged by trained reviewers [21]. Each app user interface was rated on a scale of 1 to 5 (1=poor, 5=excellent) against each of the 10 heuristics and a total usability score was obtained by summing the individual

scores (maximum score of 50). The calculated usability score for each app was not intended to be used as a precise indicator of its usability; instead it was intended to be used as an approximate indicator, with higher scores indicating higher perceived usability. One reviewer (ASH) was trained for usability evaluation and evaluated all included apps. For the purpose of exploring interrater reliability, a second reviewer (MW), a software developer with expertise in developing medical apps and testing usability, evaluated the usability of a random selection (9/38, 24%) of the apps. Usability scores are subjective and slight variation between reviewers is expected. Interrater reliability of the total usability scores was assessed using a two-way mixed, absolute agreement, average-measures intraclass correlation (ICC) [24]. Unlike kappa, ICC incorporates magnitudes of disagreement, making it more suitable for evaluating interrater reliability of ratio variables [24]. The resulting ICC was .95, indicating excellent agreement between reviewers [25]. Given that strong agreement was identified between reviewers, it was not considered necessary for the second reviewer (MW) to evaluate more than 24% of the apps. For all of the apps, the first reviewer's (ASH) scores were used in the presented data. Usability scores of 75% (equivalent to a

score of 37.5 out of a maximum score of 50) or higher were considered acceptable for meeting the app criteria.

Table 2. Nielson usability heuristics [21].

Heuristic	Description
Visibility of system status	The system should always keep users informed about what is going on, through appropriate feedback within reasonable time.
Match between system and the real world	The system should speak the user's language, with words, phrases and concepts familiar to the user, rather than system-oriented terms. The system should follow real-world conventions, making information appear in a natural and logical order.
User control and freedom	Users often choose system functions by mistake and will need a clearly marked "emergency exit" to leave the unwanted state without having to go through an extended dialogue. The system should support undo and redo.
Consistency and standards	Users should not have to wonder whether different words, situations, or actions mean the same thing. The system should follow platform conventions.
Error prevention	Even better than good error messages is a careful design which prevents a problem from occurring in the first place. Either eliminate error-prone conditions or check for them and present users with a confirmation option before they commit to the action.
Recognition rather than recall	Minimize the user's memory load by making objects, actions, and options visible. The user should not have to remember information from one part of the dialogue to another. Instructions for use of the system should be visible or easily retrievable whenever appropriate.
Flexibility and efficiency of use	Accelerators—unseen by the novice user—may often speed up the interaction for the expert user such that the system can cater to both inexperienced and experienced users. The system should allow users to tailor frequent actions.
Aesthetic and minimalist design	Dialogues should not contain information which is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.
Help users recognize, diagnose, and recover from errors	Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution.
Help and documentation	Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation. Any such information should be easy to search, be focused on the user's task, list concrete steps to be carried out, and not be too large.

App Criterion #5: Customizable Answer Options and Reports

Customizable answer options are important in making the apps relevant to each user. This feature allows users to create their own inputs when filling out a diary entry. For example, the possibility for the user to add a custom trigger (eg, chocolate, caffeine, or stress) in case the desired trigger does not appear in the default list. To meet this criterion, the apps were required to have at least one headache variable answer option input be customizable and to contain some level of customization in the reports. Customizable reports allow users to better understand their headaches by allowing them to examine the trends that are a concern to them. Examples of customizable reports include controlling the time span of a report or choosing the variables contained in a report. One reviewer (ASH) extracted the required information by reviewing the content of the apps.

App Criterion #6: Reports Linking Multiple Variables

Reports allow users to understand trends associated with their headaches. This criterion required that the apps include reports simultaneously linking multiple variables in tables or graphs. For example, a report displaying information about both time of day and headache occurrence was considered to be a report linking multiple variables (time of day and headache

occurrence). One reviewer (ASH) extracted the required information by reviewing the content of the apps.

App Criterion #7: Ability to Export Headache Data From App

The final app criterion required that the apps include an export feature, allowing users to export logged headache data directly to email, PDF, etc, and allowing the data to be viewed and saved outside the app. This feature is important as it facilitates sharing users' headache data with their health care professionals. One reviewer (ASH) extracted the required information by reviewing the content of the apps.

Results

Overview

In total, 38 apps were identified as headache diaries. For a list of included apps and their characteristics see Table 3. Of the 38 apps, 24 (63%) were available on iOS only, 11 (29%) were available on Android only, and 3 (8%) were available across both platforms. Of the apps identified, 19 (50%) were free, while 19 (50%) required purchase. The average price among the paid apps was Can \$2.74. All of the apps used an event-contingent assessment scheme and focused only on tracking headache episodes; none gathered data on days when no headache events occurred. Only 2 apps (5%) included the ability to set reminders.

Table 3. Available headache diary apps (n=38) and their characteristics, ordered by number of app criteria met.

Name	Platform/ Version tested	Price, Can\$	App criteria			Usability score (%)	Custom answer options ^a / Custom reports	Reports ^b / Reports linking multiple variables	Export data from app	Number of app criteria met (out of 7)
			Created with headache expertise	Published in scientific literature	Headache variables measured / Clinically relevant variables measured (out of 7)					
iHeadache	iOS/1.45	4.99	Yes	No	8/7	90	Few/Yes	Yes/No	Yes	5
Headache Diary (ecoHeadache)	iOS/2.3	1.99	No	No	13/7	94	Many/Yes	Yes/Yes	Yes	5
Headache Diary Pro ^c	Android/3.7	2.99	No	No	10/7	82	Few/Yes	Yes/Yes	Yes	5
Headache Diary Pro ^d	iOS/1.5	3.99	No	No	12/7	94	Many/No	Yes/Yes	Yes	4
Migraine Diary	iOS/2.4.1	1.99	No	No	10/7	90	Many/No	Yes/Yes	Yes	4
PainCal	iOS/2.0	1.99	No	No	9/6	80	Many/Yes	Yes/Yes	Yes	4
A Migraine Diary for You	iOS&Android /1.1.3 & 1.1	4.99 / 4.95	No	No	13/7	62	Many/Yes	Yes/Yes	Yes	4
Migraine	iOS/1.1	Free	Yes	No	7/6	72	Few/No	Yes/Yes	Yes	3
Migralex	iOS/1.1	Free	Yes	No	10/5	84	Few/No	Yes/No	Yes	3
Oh, My head	iOS/1.0	1.99	No	No	5/2	76	Few/Yes	Yes/Yes	No	3
Migraine Free	iOS/1.1	Free	Yes	No	5/5	74	None/No	Yes/Yes	Yes	3
Cluster Headaches	Android /2.0.04	Free	No	No	4/3	80	Few/No	Yes/Yes	Yes	3
Headache Relief Log	Android/1.07	1.00	No	No	7/4	80	Few/No	Yes/Yes	Yes	3
Headache App	iOS&Android /1.4.5 & 1.5	Free	No	No	9/6	76	Many/No	Yes/Yes	Yes	3
Headache Note ^e	iOS&Android /1.2.1 & 1.0.3	Free	No	No	6/5	84	Few/No	Yes/Yes	Yes	3
Migraine Meter	iOS/2.6	Free	Yes	No	9/7	82	Few/No	Yes/No	Yes	3
PainTrek	iOS/1.1	Free	Yes	No	8/5	66	None/Yes	Yes/Yes	No	2
American Migraine Foundation	iOS/1.0.1	Free	Yes	No	7/5	74	No/No	No/No	Yes	2
PainCalendar	iOS/1.0	5.99	No	No	9/6	86	Few/No	Yes/Yes	No	2
Headache & Migraine Diary	iOS/2.5.0	1.99	No	No	5/3	74	No/Yes	Yes/Yes	Yes	2
Migraine Journal	iOS/0.9.1	Free	No	No	4/4	86	Few/No	No/No	Yes	2
MigraineMate	iOS/2.198	Free	No	No	3/2	94	No/No	Yes/Yes	No	2
Migraine Diary	iOS/1.0	Free	No	No	8/6	86	No/No	No/No	Yes	2
Headache ^f	iOS/1.1.0	4.99	No	No	6/4	82	Few/No	Yes/Yes	No	2
Migraine Stop	iOS/1.0	Free	No	No	9/6	92	No/No	Yes/No	Yes	2
Migraine tracker!	iOS/4.0	Free	No	No	2/1	82	No/No	No/No	No	2
Headache diary ^g	Android/1.3.0	1.34	No	No	7/6	72	Few/No	Yes/Yes	Yes	2

Name	Platform/ Version tested	Price, Can\$	App criteria			Usability score (%)	Custom answer options ^a / Custom reports	Reports ^b / Reports linking multiple variables	Export data from app	Number of app criteria met (out of 7)
			Created with headache expertise	Published in scientific literature	Headache variables measured / Clinically relevant variables measured (out of 7)					
Migraine Calendar	Android/4.0	1.96	No	No	10/6	86	Few/No	Yes/No	Yes	2
HeadacheDiary	Android/1.0	2.04	No	No	6/6	76	No/Yes	Yes/Yes	No	2
Headache Diary ^h	Android/1.25	Free	No	No	7/4	74	Few/No	Yes/Yes	Yes	2
MyGraine	iOS/1.1	Free	No	No	9/5	70	Few/No	Yes/Yes	Yes	2
Migraine Institute	iOS/1.4	0.99	Yes	No	8/6	74	No/No	No/No	Yes	2
Ubiqi Health Migraine Tracker	Android/2.1	Free	No	No	7/5	82	Many/No	No/No	No ⁱ	1
Migraine Tracker	Android/0.9b	Free	No	No	4/3	86	No/No	No/No	No	1
My Headache Di- ary	iOS/1.1	Free	No	No	7/5	72	No/No	No/No	No	0
migraineDiary	Android/0.1	Free	No	No	5/4	72	No/No	No/No	No	0
Headache Diary ^j	Android/1.1	0.99	No	No	6/5	64	No/No	No/No	No	0
Headache & Migraine Tracker Pro	iOS/1.2	0.99	No	No	5/3	0 ^k	Few/No	No/No	No	0

^aFew: 3 or less headache variables allow for custom answer options; Many: more than 3 headache variables allow for custom answer options.

^bRefers to the app's ability to create reports in general, not necessarily custom reports or reports linking multiple variables.

^cDeveloped by Froggyware.

^dDeveloped by appcellent GmbH.

^eFull name: Headache Note – You can manage headache by recording the pain and the taken medicine (iOS name); Headache Note-be healthier- (Android name).

^fFull name: Headache – migraine and headache journal/log/calendar.

^gDeveloped by Marcel Shroder.

^hDeveloped by Benjamin Gerfelder.

ⁱAble to export data from website component associated with app.

^jDeveloped by Tmoney.

^kNot usable; unable to load headache entries.

App Quality: App Criteria

Overview

The quality of the apps was determined by how many app criteria were met. The apps with the highest quality were iHeadache (developed by Better QOL), ecoHeadache (developed

by ecoTouchMedia), and Headache Diary Pro (developed by Froggyware), each of which met 5 of the 7 app criteria. See [Figure 1](#) for a screenshot of the 3 highest scoring apps. Only 7 of the 38 available apps met 4 or more of the app criteria. The median number of app criteria met was 2. [Table 4](#) shows the number of apps meeting each criterion.

Table 4. Number of apps meeting each app criterion (N=38).

Criterion	Number of apps meeting the criterion, n (%)
1. Created with headache expertise	7 (18)
2. Formal psychometric and feasibility testing	0 (0)
3. Clinically relevant headache variables measured	7 (18)
4. Usable	24 (63)
5. Customizable answer options and reports	9 (24)
6. Reports linking multiple variables	22 (58)
7. Export headache data from app	25 (66)

Figure 1. The home screen of iHeadache (left), ecoHeadache (middle), and Headache Diary Pro (right).

App Criteria #1 and #2: App Created With Headache Expertise and Formal Feasibility and Psychometric Properties Testing

Only 7 apps (18%) were found to have been created with scientific or clinical expertise and met criterion #1. None of the apps in this review were found in the scientific literature search, and as a result none of the apps were considered to have undergone formal psychometric or feasibility testing (criterion #2).

App Criterion #3: Clinically Relevant Headache Variables Measured

Of the 38 apps, 7 of them (18%) measured all 7 clinically relevant headache variables as defined by app criterion #3. The

average number of headache variables measured in each app was 7 out of 24. The average number of variables measured per app that were identified as clinically relevant by the experts was 5 out of 7. The most common variable measured was headache intensity (37/38, 97%), followed by medication usage (30/38, 79%), triggers (27/38, 71%), time of headache (27/38, 71%), notes/comments (26/38, 68%), other headache symptoms (25/38, 66%), headache duration (25/38, 66%), location of headache (21/38, 55%), headache disability (12/38, 32%), headache quality (11/38, 29%), and other coping strategies (11/38, 29%). Other variables less frequently measured were geographical location, weather, mood, and headache type. For a complete list of headache variables measured by those apps meeting 4 or more app criteria, see [Table 5](#).

Table 5. Headache variables measured by all apps (n=7) meeting 4 or more app criteria.

Headache variables measured	App						
	iHeadache	Headache Diary (eco-Headache)	Headache Diary Pro ^a	Headache Diary Pro ^b	Migraine Diary	PainCal	A Migraine Diary for You
Headache severity/intensity	✓	✓	✓	✓	✓	✓	✓
Headache triggers	✓	✓	✓	✓	✓	✓	✓
Medication/treatment taken for headache	✓	✓	✓	✓	✓	✓	✓
Associated headache symptoms	✓	✓	✓	✓	✓	✓	✓
Headache frequency	✓	✓	✓	✓	✓	✓	✓
Headache-related disability	✓	✓	✓	✓	✓		✓
Headache duration	✓	✓	✓	✓	✓	✓	✓
Time of headache onset	✓	✓	✓	✓	✓	✓	✓
Headache pain location		✓	✓	✓	✓	✓	✓
Headache pain quality		✓		✓		✓	✓
Nonpharmacological treatment and coping strategies		✓		✓	✓		✓
Type of day (eg, work, school)		✓					
Type of headache		✓	✓				
Weather when headache occurred							✓
Activity when headache occurred							✓
Geographical location when headache occurred				✓			

^aDeveloped by Froggyware.^bDeveloped by appcellent GmbH.**App Criterion #4: Usable Apps**

Of the 38 apps, 24 (63%) met this criterion, which consisted of scoring a total usability score of at least 75%. Usability scores ranged from 0% to 94% with a median score of 80%.

App Criteria #5, #6, and #7: Customizable Answer Options and Reports, Reports Linking Multiple Variables, and Ability to Export Headache Data From App

Most of the apps (27/38, 71%) contained reports on headache data, with 58% (22/38) of the apps containing reports linking multiple variables, while customizable reports were less common (9/38, 24%). The ability to modify existing lists of answer options for a headache variable (eg, adding a new trigger to the preexisting list) was seen in 63% (24/38) of the apps. Many of the apps (25/38, 66%) also allowed data entered into the diary to be exported, often via email or by creating PDF documents.

Discussion

Available Apps

Clinicians often recommend that headache sufferers use a diary to record headache events, and e-diaries have been growing in popularity. Despite this, e-diaries created and tested by headache experts in academic settings are not available to the general

population. As a result, consumers are restricted to what is available in the app stores. Despite the large volume of apps available commercially, none of the apps met all 7 app criteria. It is especially concerning that none of the apps identified in this review were found to have undergone formal feasibility or psychometric property testing. It is essential when developing mobile health apps to test feasibility and, later on, psychometric properties in order to offer consumers high-quality assessment tools. Additionally, only 2 apps included the ability to set reminders, despite research demonstrating that reminders can increase adherence in health interventions [26,27]. Overall, this review has demonstrated the lack of quality headache diary apps available to consumers.

Of the 3 highest scoring apps (iHeadache, ecoHeadache, and Headache Diary Pro), iHeadache, developed by Better QOL for iOS, was the only app created with scientific or clinical headache expertise and is available for Can \$4.99. The app records all clinically relevant variables without recording other nonessential information, making it easy to use with fast data input. However, it has not been formally tested for feasibility or psychometric properties and the in-app reports are in plain text format that can be difficult to interpret. The app developed by ecoTouchMedia for iOS, ecoHeadache, is available for Can \$1.99. While it offers good levels of customization, it tracks significantly more information than what has been defined as essential. This app can track 13 headache variables and can

generate 24 chart reports, in addition to customizable reports. Headache Diary Pro, developed for Android by Froggyware, costs Can \$2.99 but was not rated as usable as were the 2 other apps mentioned above. However, it was the highest rated Android offering.

Recommendations and Future Directions

A long-term strategy is needed to begin offering validated evidence-based medical apps to the general population. As a first step it is essential to disseminate the state of the current apps to headache sufferers and their health care professionals. Currently, this can be done through educating health care professionals on the existing app environment, allowing them to inform patients. In addition, findings can be distributed using social media to educate consumers on the quality of existing apps. Given the fast-growing number of medical apps available, it is not realistic to propose regulating the full marketplace. As well, systematic reviews such as this will become more complex as the number of apps increases, especially taking into account the rate at which apps are being developed and upgraded.

We recommend that headache experts and the research community partner with app developers to test high-quality, popular apps currently available to consumers. Another solution would be giving developers the opportunity to have their apps evaluated by an independent third party organization with mobile health expertise. There are current initiatives moving in this direction, for example, the National Health Service (NHS) in the United Kingdom has begun reviewing medical apps and currently offers a growing list of approved apps online [28]. In addition, the United States Food and Drug Administration (FDA) recently released its recommendations for medical apps [29]. The FDA will regulate only those apps that can be used as an accessory to regulate a medical device (eg, an app that controls the delivery of insulin through a pump), or those apps that are similar to currently regulated medical devices, by transforming a mobile platform into a medical device using attachments (eg, attachment of electrocardiograph electrodes to a mobile platform).

We have evaluated the apps taking into account current knowledge. However, it is critical for apps to advance along with research, which will require continual updates to the apps to satisfy the newest developments and discoveries.

We intend to work toward filling the gaps identified in this review. We are currently developing the Wireless Headache Intervention (WHI) diary app called myWHI. The myWHI diary is designed to meet all 7 app criteria. It has been developed using a participatory design process involving both headache sufferers and headache experts [30]. The app has been shown to be usable and feasible and we are currently testing its psychometric properties [31]. The myWHI diary has been designed to be used as a stand-alone app and will also be offered as part of an online comprehensive cognitive behavioral therapy (CBT) intervention for chronic headaches.

Strengths and Limitations

Information on pain apps (including headache diaries) has been synthesized in a previous review by Rosser and Eccleston [16]. The app evaluation in Rosser and Eccleston's review, along with other app reviews [32,33], was limited to the app descriptions, without downloading the apps. The authors of the current review found that the app description can insufficiently, and sometimes incorrectly, describe the app function. In this review, the authors downloaded and used all of the existing headache diary apps for a more comprehensive evaluation.

The scope of the review was limited to the English-language apps available in the Canadian app stores, and looked only at the 2 most popular platforms. Different apps may be available in other countries, and other apps may exist on less popular platforms. This review focused on mobile apps, and did not consider e-diaries available only as general websites. The authors focused on mobile diary apps because they are portable, which is key for a self-monitoring tool, allowing users to use them on the go. This in turn may facilitate increased adherence [34,35]. However, the development and sustainability of mobile apps may be more economically expensive, especially when apps must be developed for multiple platforms [36].

The app evaluation method had several limitations. First, the method for evaluating the quality of these apps was developed by the authors and the criteria have not been validated. Second, the app criteria were each given equal weight in evaluating the apps, despite the fact that some criteria might be more significant than others in terms of the effectiveness of the app. Third, we made the assumption that the more app criteria met, the higher the app quality, but this may not be the case. Fourth, when reaching a consensus on the most relevant clinical variables that should be collected by a headache diary, only scientific or clinical experts were used—headache sufferers were not consulted and may have suggested other relevant variables. Fifth, in determining if the app was created with headache expertise the authors were limited to the information made available to them in the app store description and developer websites, and these descriptions can be of poor quality. Finally, the literature search seeking to identify formal feasibility or psychometric testing of the apps could not confirm that this type of testing had not occurred, only that it has not been published.

The limitations to this review reflect limitations and concerns with the medical app market in general. It is an emerging field lacking quality standards with poor transparency in the app development process.

Conclusions

In summary, although a proliferation of headache diary apps exists, the majority do not meet reasonable quality standards. More emphasis on the quality of these tools is needed as they are easily accessed and used by the general population, often for self-managing health conditions. The demand remains for a high-quality, evidence-based headache diary app.

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Conflicts of Interest

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Abbreviations

CBT: cognitive behavioral therapy
FDA: Food and Drug Administration
ICC: intraclass correlation
WHI: Wireless Headache Intervention

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Corrigenda and Addenda

Metadata Correction: Smartphone Ownership and Interest in Mobile Applications to Monitor Symptoms of Mental Health Conditions

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The authors of “Smartphone Ownership and Interest in Mobile Applications to Monitor Symptoms of Mental Health Conditions” (*JMIR Mhealth Uhealth* 2014;2(1):e2) inadvertently misspelled Matcheri Keshavan’s name as Keshvan. This was corrected in the online version of the paper on July 7, 2014,

together with publishing this correction notice. This was done before submission to PubMed, and the corrected full-text has been resubmitted to Pubmed Central and other full-text repositories.

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Original Paper

Study of the Usability of Spaced Retrieval Exercise Using Mobile Devices for Alzheimer's Disease Rehabilitation

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Abstract

Background: Alzheimer's disease (AD) is an irreversible brain disease that slowly destroys memory and thinking skills, and eventually the ability to carry out the simplest daily tasks. Recent studies showed that people with AD might actually benefit from physical exercises and rehabilitation processes. Studies show that rehabilitation would also add value in making the day for an individual with AD a little less foggy, frustrating, isolated, and stressful for as long as possible.

Objective: The focus of our work was to explore the use of modern mobile technology to enable people with AD to improve their abilities to perform activities of daily living, and hence to promote independence and participation in social activities. Our work also aimed at reducing the burden on caregivers by increasing the AD patients' sense of competence and ability to handle behavior problems.

Methods: We developed ADcope, an integrated app that includes several modules that targeted individuals with AD, using mobile devices. We have developed two different user interfaces: text-based and graphic-based. To evaluate the usability of the app, 10 participants with early stages of AD were asked to run the two user interfaces of the spaced retrieval memory exercise using a tablet mobile device.

Results: We selected 10 participants with early stages of AD (average age: 75 years; 6/10, 60% males, 4/10, 40% females). The average elapsed time per question between the text-based task (14.04 seconds) and the graphic-based task (12.89 seconds) was significantly different ($P=.047$). There was also a significant difference ($P<.001$) between the average correct answer score between the text-based task (7.60/10) and the graphic-based task (8.30/10), and between the text-based task (31.50/100) and the graphic-based task (27.20/100; $P<.001$). Correlation analysis for the graphic-based task showed that the average elapsed time per question and the workload score were negatively correlated ($-.93$, and $-.79$, respectively) to the participants' performance ($P<.001$ and $P=.006$, respectively).

Conclusions: We found that people with early stages of AD used mobile devices successfully without any prior experience in using such devices. Participants' measured workload scores were low and posttask satisfaction in fulfilling the required task was conceivable. Results indicate better performance, less workload, and better response time for the graphic-based task compared with the text-based task.

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KEYWORDS

Alzheimer disease; Alzheimer disease rehabilitation; spaced retrieval exercise; usability study; mobile human computer interaction

Introduction

Background

Alzheimer's disease (AD) is an irreversible brain disease that slowly destroys memory and thinking skills, and eventually the ability to carry out the simplest daily tasks. Currently, there is no cure for the disease, which worsens as it progresses, and eventually leads to death. The Alzheimer's Association estimates that 1 in 8 older Americans is living with AD totaling approximately 5 million Americans [1].

AD is the most common cause of dementia among older people. Dementia is the loss of cognitive functioning including thinking, remembering, and reasoning and the loss of behavioral abilities, to such an extent that it interferes with a person's daily life and activities. Dementia ranges in severity from the mildest stage, when it is just beginning to affect a person's functioning, to the most severe stage, when the person must depend completely on others for basic activities of daily living [2].

Health care professionals have tended to overlook the needs and the requirements of Alzheimer's individuals for physical exercises and activity programs. Because of the memory retention problems, many health care professionals feel that the majority of persons with AD have little, if any, rehabilitation potential. Besides retention problems, many clinicians also take the "they're just going to get worse anyway" approach in their clinical decision making [3].

Recent studies [3] have shown that people with AD may actually benefit from physical exercises and rehabilitation processes. Studies showed that rehabilitation would also add value in making the day for an individual with AD a little less foggy, frustrating, isolated, and stressful for as long as possible. In addition, rehabilitation helps the individual with AD on living as fully as possible with whatever time he has. In general, rehabilitation is about the quality of life; it adds life to the years, not more years to the life.

For individuals with AD, rehabilitation should focus on people's abilities, rather than their disability. The goal is to maintain as high a quality of life as possible for as long as possible [3]. This may help to enhance people's ability to take part in meaningful activities within their environment and enjoy family events.

In recent years, mobile devices have improved rapidly in processing power, embedded sensors, storage capacity, and network data rates. Mobile devices today have evolved from merely being phones or simple personal digital assistants to full-fledged computing, sensing, and communication devices. These advances in mobile device technology have paved the way for exciting new apps. Mobile devices can be used as medical devices for measuring blood pressure, measuring glucose levels, performing portable ultrasounds, and even testing for sexually transmitted diseases.

In previous research [4], we have focused on developing ADcope, an integrated app that includes several modules that target individuals with AD, using mobile devices. The goal for ADcope is to maximize the patients' remaining capabilities and avoid excess disability, improving their overall quality of life.

In this paper, we focus on the usability aspects of ADcope. Specifically, we studied the usability of the Spaced Retrieval Exercise module on a group of people who are diagnosed with early stage AD.

Approach

AD is currently an incurable disease and worsens progressively. Our approach in dealing with this disease focuses on two aspects: finding ways to help the patient cope with the disease, and slowing down the pace of decline in quality of life as the disease worsens. A combination of advanced mobile devices equipped with near field communication (NFC) and NFC tags will be used to meet the challenges of the two focus areas. Mobile devices running the Google Android operating system (OS) have been selected because currently, many mobile devices supporting NFC are running the Android OS.

General Requirements in Dealing With AD Patients

Our approach was based on general standards recommended when dealing with people with dementia [3]. This includes: (1) using simple language when interacting with AD patients; (2) repeating instructions several times; (3) instructions should be broken into simple steps and given one at a time; (4) allow the AD patient ample of time to respond or react; and (5) all messages should be as short as possible.

Helping the Patient Cope With the Disease

Since AD is not a curable disease, our approach focused on maintaining the highest possible quality of life of AD patients. An app, named ADcope, with several modules was developed on mobile devices to support this approach [4]. Figure 1 is a block diagram of the app showing the modules and mobile device interfaces. The app and its modules were designed to help the patient in many aspects of the daily life. The continuous interaction of the patient with the mobile device as he moves through his daily life ensures that the patient does not forget about using the mobile device. In addition, ADcope provides an option to remind the AD patient to use the mobile device.

The first module is a memory wallet, as suggested by Bourgois et al [5]. They suggested the use of a wallet that contained 30 pictures and sentences about familiar persons, places, and events. The patients managed to learn to use the wallet to improve their conversations by making more accurate factual statements. The module allows the user to take photos of the familiar people, places, and events. The patient is then given a chance to tag the photos with phrases that reminds him of the subject of the photo. Photos of people can also be tagged with voice samples of the person in the photo. The patient can go back to the wallet as frequently as needed to be reminded of these people, places, and events. The memory wallet also use the tagged voice samples to automatically play back the photo and tagged phrases anytime the voices in the background match the tagged voice samples helping the patient to refer to the wallet to instantly get help on recognizing the people around him without having to sift through the wallet.

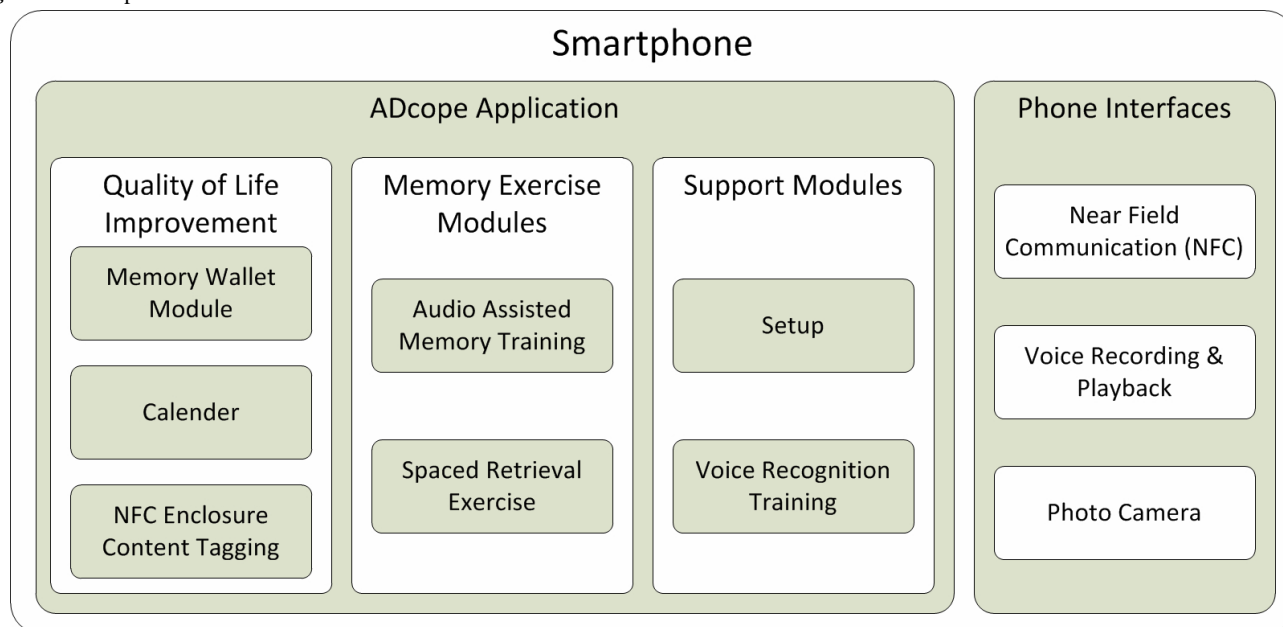
The second module is a calendar with reminders of all daily activities that need to be performed. The events can refer to information in the memory wallet such as photos to help the

patient recognize the person he needs to talk to or the place he needs to go. The calendar also includes the recurring event to review the memory wallet.

The third module uses NFC tags that are placed on various things, including drawers and doors. As the person touches these

with the mobile device, the mobile device displays a list of content of the drawer or room. This saves the person from having to open them for inspection when looking for something. This can also be used by a new caretaker to facilitate fetching items requested or needed by the patient since they may not have prior knowledge of how things are arranged.

Figure 1. ADcope modules and interfaces.



Exercising the Patients' Memory

Although AD is an incurable disease, some memory exercises may help in retaining critical information longer. Researchers have identified several exercises and training techniques that patients with dementia should perform periodically. The exercises include Audio Assisted Memory Training as identified by Arkin [6] and Spaced Retrieval, which was first described by Landauer and Bjork in 1978 [7]. In Audio Assisted Memory Training an audiocassette recorder was used to playback narratives of biographical information then interactive quizzes are performed to exercise the retrieval process. This technique has resulted in substantial learning with most patients. The Spaced Retrieval exercises are based on asking a questions and requiring an immediate response. The questions are then repeatedly asked with the time between each repetition systematically lengthened until the patient demonstrates the ability to recall information in everyday life. This technique has been increasingly used with AD patients to teach important information and skills needed to improve daily life.

These exercises have been integrated into the ADcope app as separate modules. The Audio Assisted Memory Training module replicates the audiocassette recorder approach by playing back audio files of the biographical information and quizzing the patient regarding the information. The targeted answers are very short and mostly consist of one or two words. The simplicity of the answers is critical for successful exercises based on the general recommendations when dealing with AD patients. The simplicity of the answers also enables the use of voice recognition techniques to automatically validate correctness of responses.

The Spaced Retrieval exercise module has been designed to execute in two phases: an assessment phase and a training phase. During the assessment phase, the current memory recall ability is assessed by presenting a piece of information, and then the patient is quizzed about it at a later time. If the recall fails, the information is reiterated, and quiz repeated again later. The length of time between quizzes is reduced until memory recall is successful. The final duration between information presentation and successful recall is stored as the basis for initial duration in future training. The second phase is the training phase in which the module follows the Spaced Retrieval recommendations for training recall of information. The module starts with the duration of time between information presentation and quizzing as determined in the first phase and the length of time between information presentation and quizzing is lengthened with every successful retrieval and maintained with every failure.

Supporting Modules

The modules described in the previous sections require substantial setup and training. The ADcope app includes a setup module, which will guide the caregiver (or patient if he is able to) through all of the setup steps, which is outlined in [Textbox 1](#).

The app needs to be able to recognize voices and match voice replies with correct answers. The ADcope app includes a separate module for training the voice recognizer. The module displays words and asks the patient to read them. A spectral analysis is then done on the words and stored for future voice recognition.

Textbox 1. ADcope setup module.

- Recording audio files of biographical data: the user is asked to narrate the desired biographical phrases and signal the termination of recording. The user can record several audio files that are randomly played back in the Audio Assisted Memory Training module.
- Recording of biographical quiz questions and answers: the user is repeatedly asked for questions that are recorded. After each question, the user is asked to type in the correct answer. The answers are currently limited to numbers (such as age, year, and quantities) or single words due to the limitation of the voice recognition libraries used in the development of the app.
- Spaced retrieval exercises: the ADcope app has some built-in spaced retrieval exercises based on general knowledge facts. However, the setup module allows the user to add additional fact-question pairs. The user also has the option to setup the Spaced Retrieval module to exclusively use the user-added facts.
- Memory Wallet initialization: the user is asked to take photos of people, places and events and type in a word or a phrase for each one. The user can also optionally tag the photo with a voice sample of the person in the photo. The user is allowed to defer this part of the setup to later and build the memory wallet as he meets people or visits places.
- NFC tagging: The user is asked to enter a note that describes the item being tagged. For example, this could be contents of drawers. The user is then asked to place the smartphone next to the tag and the ADcope app uses the internal NFC writer of the smartphone to write the information to the tag.
- Calendar: In the last step of the setup procedure. The user is asked to enter recurring calendar event with optional photos for each event.

Methods

Study Scope

In this study, we evaluate the usability of the proposed ADcope app. Specifically our main objective is to evaluate the usability of the Spaced Retrieval exercise. The following section describes in details the selected participants, apparatus, study procedure, and the collected measures.

Participants

The participants considered in the study were volunteers from Darat Samir Shamma, a senior residential care facility and housing located in Amman, Jordan. The participants were primarily seniors, with early stages of AD. It is important to note that finding participants with early stages of AD was very challenging. Ten participants were asked to perform the Spaced Retrieval exercise on a tablet device while sitting in a room

(NCT02005380). The mean age of the participants was 75 years and the SD was 9.6. Basic demographic characteristics were recorded for each participant. [Table 1](#) summarizes the demographic factors for the participants' age, mobile device ownership, mobile device usage frequency, and familiarity with tablets along with their current ability of using mobile devices.

As shown in [Table 1](#), most of the participants in this study were not frequent handheld mobile devices users and had no familiarity with tablets. However, the experimental tasks performed on the tablet device were designed in which prior experience with handheld mobile devices or tablets was not required. Additionally, all participants were initially acquainted and instructed on performing the experiment goals and tasks. Tasks were designed with minimal input needed to accomplish the exercise. Each participant had been assigned to perform the same set of tasks on a tablet device while sitting at a table.

Table 1. Participants' demographics summary (N=10).

Characteristics		
Age, years		
	Average	75.1
	SD	9.6
Gender, n (%)		
	Male	6 (60)
	Female	4 (40)
Handheld mobile device owner? n (%)		
	Current	7 (70)
	Never	3 (30)
Handheld mobile device use frequency, n (%)		
	>1/day	4 (40)
	1/day	3 (30)
	<1/day	3 (30)
Familiarity with tablets, n (%)		
	Yes	3 (30)
	No	7 (70)

Apparatus

Seven-inch Samsung Galaxy Tab 2 devices running Android OS were used in this study. The app was developed using the Android software development kit (SDK). The app kept a log of participants' response times, total time of each trial, and the total time for each participant to complete his/her overall task. At the beginning of each experiment, participants were briefed about the goal of the study and instructions on how to use the device and run the app to complete the required task. Upon completion of the trials, participants were requested to fill in a posttask questionnaire to rate the performed task degree of difficulty along with the National Aeronautics and Space Administration task load index (NASA-TLX) workload assessment [8].

NASA-TLX [8] is a subjective workload assessment tool that allows users to perform subjective workload assessments on operators working with various human-machine systems. NASA-TLX is a multidimensional rating procedure that derives an overall workload score based on a weighted average of ratings on six subscales. These subscales include mental demands, physical demands, temporal demands, own performance, effort, and frustration.

Procedure

As described in the Approach Section, the Spaced Retrieval exercise has been designed to execute in two phases; an assessment phase and a training phase. During the assessment phase, the current memory recall ability is assessed by presenting a piece of information, and then the patient is quizzed about it at a later time. If the recall fails, the information is reiterated, and the quiz is repeated again later. The length of time between quizzes is reduced until memory recall is successful. The final duration between information presentation

and successful recall is stored as the basis for initial duration in future training.

In the assessment phase of our developed spaced retrieval exercise, one sentence piece of information along with a text button at the bottom of the screen labeled "tap the screen to continue" was displayed on the tablet's screen. Participants were instructed not to move onto the question until they felt they had known the content of the presented information. When the participant taps on the screen, the sentence disappears and a question with four choices related to the previously presented sentence appears on the screen after some delay. The delay was initially set to 90 seconds at the first trial. Once the participant taps on the screen, s/he was not allowed to go back to the passage. If the participant taps on the correct answer, the time space between the presented information and the related question for the next trial was increased by 10 seconds. If the participant taps on the wrong answer or fails to answer within 60 seconds, the same information was represented again and the time space was decreased by 10 seconds for the next trial. The assessment phase was limited to 10 different questions or 30 minutes of time. The delay time between the presented piece information and the display of the question for the last trial was used for the training phase of the program and was referred to as the recall time for the participant.

The second phase was the training phase, in which the same procedure as the assessment phase was repeated where one sentence piece of information was presented followed by a question with four different choices. The recall time logged at the end of the assessment phase is used for the duration of time between information presentation and quizzing. The length of time between information presentation and quizzing is lengthened with every successful answer and maintained with every wrong answer. Once the participant selects a correct

answer, a feedback appears for 5 seconds on the screen, which read "correct answer" before moving to the next question. If the selected answer was incorrect a "wrong answer" feedback appeared on the screen for 5 seconds before repeating the same information for the failed trial. The training phase for our experiment was limited to 10 questions. Upon successfully completing all of the trials, a feedback appears at the bottom of the page, which read "well done, task completed."

The ADcope Spaced Retrieval exercise offers two types of quizzes: text-based and graphic-based scenarios. In this study, participants performed both of the two scenarios.

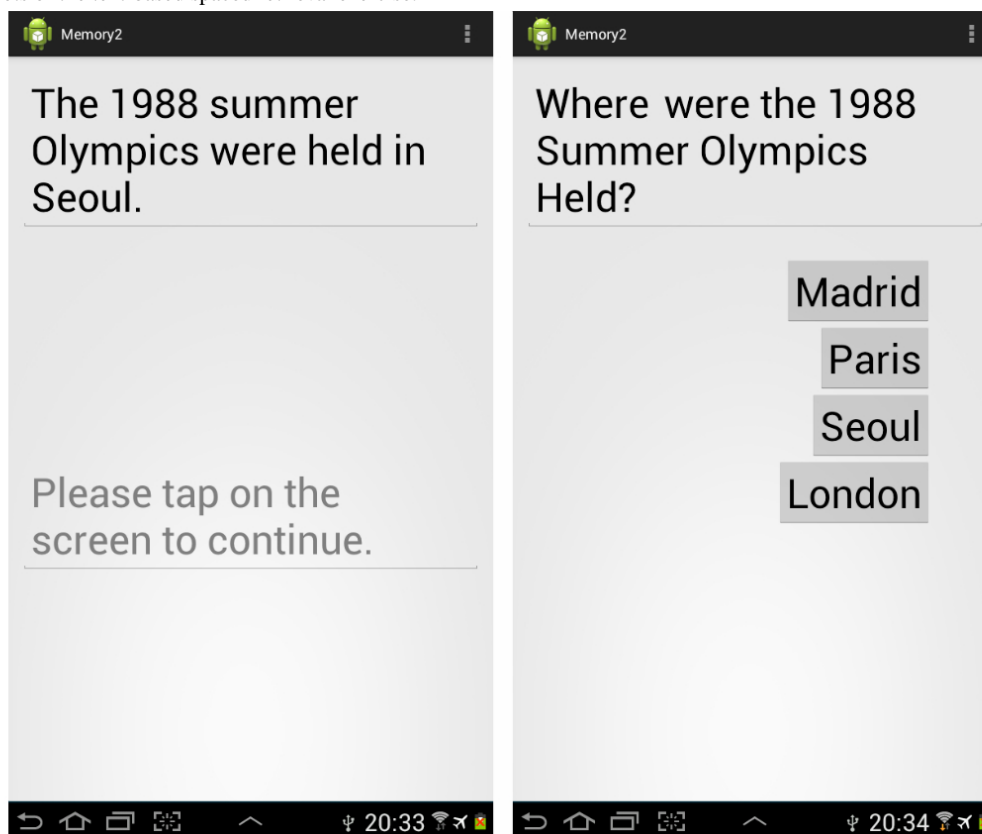
Task 1: Text-Based Spaced Retrieval

In this scenario, a one sentence piece of information was displayed on the tablet's screen. The sentence was composed of 5 to 9 long words. After a delay, a question related to the

previously presented sentence appears on the screen with four choices. Each of the answer choices consists of 1 to 2 words. The questions were general knowledge questions in sports, history, geography, and movies. Both of the assessment phase and training phase consist of 10 different questions each. The same presented sentences' order along with the same multiple choices were used for all participants. A screenshot of one of the presented information and the multiple-choice question screens are shown in [Figure 2](#).

As some of the participants in our study have difficulties in reading text, we have used text to speech Android SDK to read the information, the questions, and the associated multiple-choices aloud. The developed app also supports two languages: English and Arabic. Participants were instructed to use their preferred language.

Figure 2. Screenshots of the text-based spaced retrieval exercise.



Task 2: Graphic-Based Spaced Retrieval

In this scenario, a shape or image was displayed on the tablet's screen followed by a four multiple-choice images of which one matched the earlier presented image. The questions were created using simple geometrical shapes, flags, and traffic signs. The same 10 presented images order along with the 40 multiple choices were used for all participants. A screenshot of one of

the presented information and the multiple-choice question screens are shown in [Figure 3](#).

Experimental Measures

The recorded measures during the experiments are presented in [Table 2](#). The measures are divided into objective and subjective measures and presented in [Textbox 2](#).

Table 2. Collected measures.

Measure	Description
Average response time	The elapsed time between the question presentation and the participant selection of one of the answer choices.
Average elapsed time per question	The average elapsed time for answering presented question, excluding the recall delay time.
Correct answer score	Percentage of questions answered correctly from the first trial.
Posttask questionnaire score	Participants' feedback related to his/her overall satisfaction in fulfilling the required task (between 0 and 7).
NASA-TLX ^a score	The overall NASA-TLX subjective workload score (between 0 and 100).

^aNational Aeronautics and Space Administration task load index.

Textbox 2. Objective and subjective experimental measures.

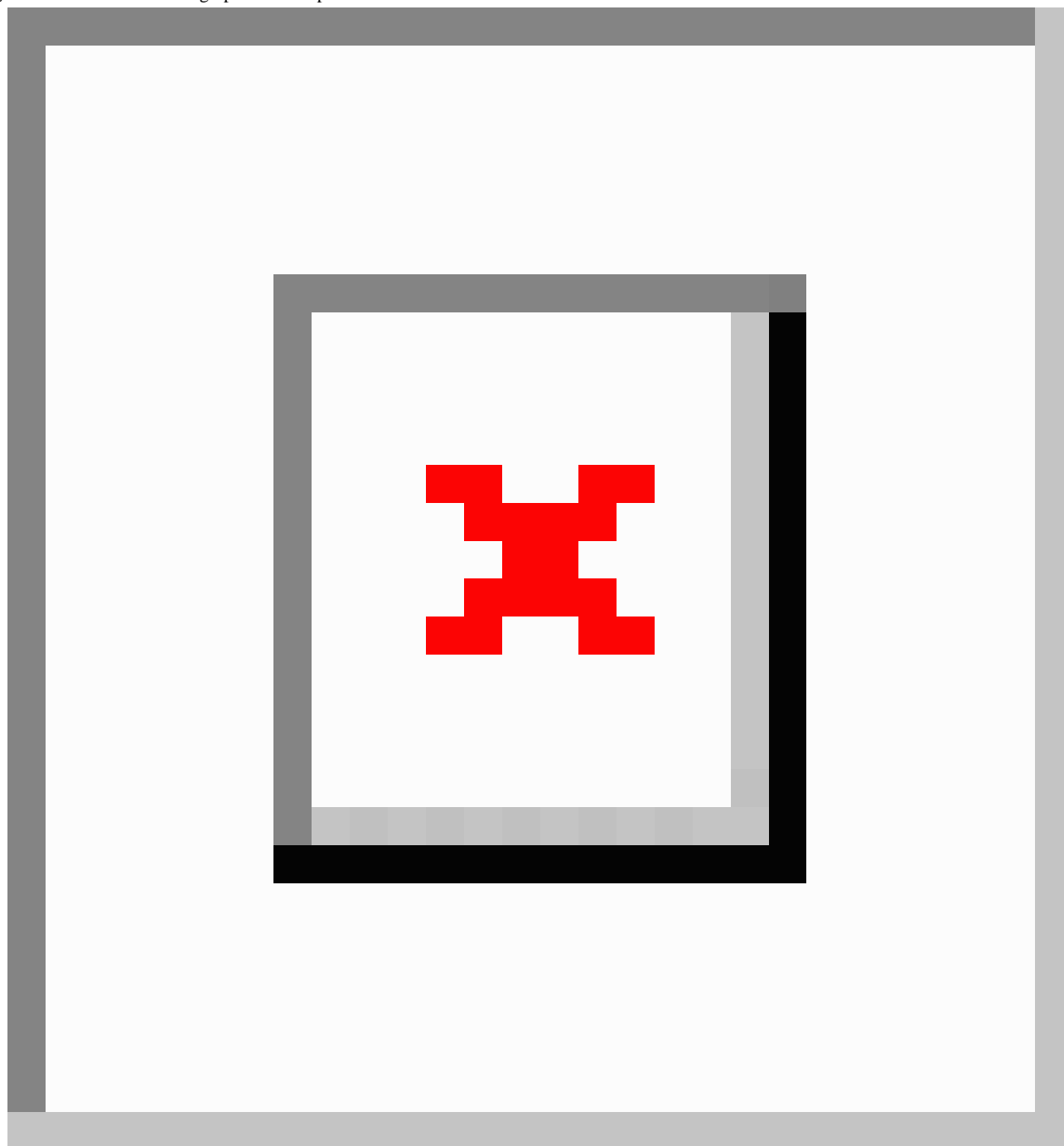
The objective measures are:

- The average response time: the elapsed time between the question presentation and the participant selection of one of the answer choices. It measures the average time it takes the participant to comprehend the question and select one of the four multiple-choice answers.
- Average elapsed time per question: the average elapsed time for answering presented question excluding the recall delay time. This measures the average time it takes the participant to successfully answer the question correctly excluding the delay between information presentation and quizzing.

Correct answer score: measures the percentage of questions answered correctly by the participants from the first trial.

The subjective measures are:

- Post task questionnaire score: measure the participants' feedback related to his/her overall satisfaction in fulfilling the required task.
- NASA-TLX: measures the overall participants' workload score in fulfilling the required task.

Figure 3. Screenshots of the graphic-based spaced retrieval exercise.

Results

Table 3 presents the mean, minimum, maximum, and standard deviation for the average response time, average elapsed time per question, correct answer score, posttask questionnaire score, and NASA-TLX score for both the text-based and the graphic-based exercises. The mean average response time and the mean average elapsed time per question for the text-based task are higher than the graphic-based task (14.04 and 53.81 vs 12.89 and 34.84 seconds, respectively). Participants also scored higher correct answers with the graphic-based task compared with the text-based task (8.30/10.00 and 7.60/10.00, respectively). The mean values for the posttask questionnaire score for both of the text-based and graphic-based tasks were

high (5.8/7.00 and 6.00/7.00, respectively) indicating that participants were satisfied in completing their two tasks successfully. The mean values for the NASA-TLX scores for both the text-based and graphic-based are relatively low (31.5/100 and 27.2/100, respectively) indicating that the two tasks require low workload.

To investigate the between-groups (text-based and graphic-based) difference, analysis of variance (ANOVA) test was conducted (**Table 3**). The results indicate significant differences between text-based and graphic-based tasks for average elapsed time per question ($P=.047$) and posttask questionnaire score ($P=.02$). The results also indicate significant differences between text-based and graphic-based tasks for

average response time ($P=.001$), correct answer score ($P<.001$), and NASA-TLX ($P<.001$).

Table 3. Results comparison between text- and graphic-based experiments.

Measure	Mean	Minimum	Maximum	SD	<i>F</i>	<i>P</i>
Average response time					23.94	.001
Text-based	14.04	6.60	20.50	4.98		
Graphic-based	12.89	5.90	19.50	4.49		
Average elapsed time per question					5.48	.047
Text-based	53.81	9.30	186.00	54.67		
Graphic-based	34.84	9.30	82.50	25.21		
Correct answer score					26.87	<.001
Text-based	7.60	4.00	10.00	2.32		
Graphic-based	8.30	6.00	10.00	1.70		
Posttask questionnaire score					7.69	.02
Text-based	5.80	4.50	7.00	0.89		
Graphic-based	6.00	4.50	7.00	1.03		
NASA-TLX^a					104.44	<.001
Text-based	31.50	10.00	48.00	14.77		
Graphic-based	27.20	10.00	40.00	10.64		

^aNational Aeronautics and Space Administration task load index

In order to investigate the relationship between the experimental measures and the participants' performance in fulfilling their required task successfully, correlation analyses were run among all pairs of the experimental measures. The correlation results are shown in Table 4 for the text- and graphic-based tasks. The correlation between the posttask questionnaire and the participants' performance in fulfilling the required task successfully did not identify any significance. For the text-based task, the average response time is negatively correlated ($-.84$)

to participants' performance and significant ($P=.002$). Similarly, the average elapsed time per question and the NASA-TLX score are negatively correlated ($-.72$ and $-.66$, respectively) to participants' performance and significant ($P=.02$ and $P=.04$, respectively). For the graphic-based task, the average response time, average elapsed time per question, and NASA-TLX score are negatively correlated ($-.78$, $-.93$, and $-.79$, respectively) to the participants' performance and significant ($P=.008$, $P<.001$, and $P=.006$, respectively).

Table 4. Correlation analysis for the text- and graphic-based tasks.

Measure	Correlation value	<i>P</i>
Text-based task		
Average response time	$-.84$.002
Average elapsed time per question	$-.72$.02
NASA-TLX ^a	$-.66$.04
Graphic-based task		
Average response time	$-.78$.008
Average elapsed time per question	$-.93$	<.001
NASA-TLX ^a	$-.79$.006

^aNational Aeronautics and Space Administration task load index

Discussion

Principal Findings

Our study showed that patients with early stages AD could use mobile devices successfully without any prior experience. Participants were able to comprehend, recognize, and recall

information from our mobile app ADcope, and performed better in the graphic-based tasks compared to text-based tasks with a lower response time. The workload for completing these tasks was low, and participants were satisfied in completing the tasks successfully based on the posttask questionnaire scores. These are good indications for the app, as Yurko et al [9] showed that increased workload during task performance may increase

fatigue and facilitate errors, which could affect the app's overall effectiveness.

Comparison With Prior Work

Many researchers have focused on using mobile devices and social networks for monitoring elderly patients by relatives and health professionals [10-12]. Chan et al [13] investigated the use of smart homes for elderly where intelligent devices including sensors and assistive robotics are implanted into their homes for continuous mobility assistance and nonobtrusive disease prevention.

Some researchers proposed various devices to help AD patients to cope with the symptoms. Imbeault et al [14] proposed using an electronic organizer to help individuals with AD to organize their daily activities. Tapus [15] suggested using socially assistive robotic system that aims to provide a customized protocol through motivation, encouragement, and companionship for users suffering from cognitive changes related to aging and/or AD.

Bouchard et al [16] proposed guidelines for designing and implementing effective serious games targeting Alzheimer's patients. The suggested guidelines include designing appropriate interaction mechanisms for cognitively impaired people, implementing artificial intelligence for providing adequate assistive prompting and dynamic difficulty adjustments, and producing effective visual and auditory assets to maximize cognitive training.

Lim et al [17] explored the usability of tablet computers within the early-stage dementia context as a source of leisure for people with dementia. The authors' results indicated that one-half the participants with dementia were able to engage with and use the tablet computer independently, which proved to be helpful to their caretakers.

Much research has focused on usability studies of devices, apps, and games that are targeting Alzheimer's patients. Boulay et al [18] conducted a usability study of MINWii, a music therapy game for patient suffering from mild to moderately severe AD. The authors demonstrated that patients were satisfied with the game and expressed a desire to repeat the experience. Granata et al [19] completed a usability testing of the graphical user interface for robot service for elderly with cognitive impairment. The authors concluded despite that cognitive profile, age, and computer experience were found to impact task performance, the interfaces and contents of the services assessed were usable by older adults with cognitive impairment. Nugent et al [20] carried a usability study for mobile phone-based video reminding system along with a qualitative collection of pre- and postevaluation questionnaires. The authors suggested that caretakers played a significant role in terms of the success of the solution and that an initial settling was required before users felt comfortable using the technology.

Conclusions

AD is the most common cause of dementia among older people causing the loss of cognitive functioning including thinking, remembering, and reasoning. Currently, there is no cure for the disease, which worsens as it progresses, and eventually leads to death. In this paper, we have conducted usability study for the spaced retrieval memory exercise using mobile devices on 10 participants with early stages of AD. We have found that people with early stages of AD have been successfully able to use the mobile device without having any prior experience in using such devices. Participants' measured workload was found to be low and posttask satisfaction in fulfilling the required task has shown to be conceivable. Results also indicated better performance, less workload, and better response time for the graphic-based user interface compared with the text-based user interface.

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Conflicts of Interest

None declared.

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Abbreviations

AD: Alzheimer's disease

ANOVA: analysis of variance

NASA-TLX: National Aeronautics and Space Administration task load index

NFC: near field communication

OS: operating system

SDK: software development kit

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