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Contents

Viewpoints

- Texting Condolences: Adapting mHealth Programs After Unexpected Pregnancy and Infant Outcomes (e176)
Jennifer Unger, John Kinuthia, Grace John-Stewart. 4
- Medication Adherence and Technology-Based Interventions for Adolescents With Chronic Health Conditions: A Few Key Considerations (e202)
Sherif Badawy, Alexis Thompson, Lisa Kuhns. 214
- Methods for Evaluating the Content, Usability, and Efficacy of Commercial Mobile Health Apps (e190)
Danielle Jake-Schoffman, Valerie Silfee, Molly Waring, Edwin Boudreaux, Rajani Sadasivam, Sean Mullen, Jennifer Carey, Rashelle Hayes, Eric Ding, Gary Bennett, Sherry Pagoto. 248

Original Papers

- Detecting Smoking Events Using Accelerometer Data Collected Via Smartwatch Technology: Validation Study (e189)
Casey Cole, Dien Anshari, Victoria Lambert, James Thrasher, Homayoun Valafar. 7
- App-Supported Promotion of Child Growth and Development by Community Health Workers in Kenya: Feasibility and Acceptability Study (e182)
Alastair van Heerden, Debjeet Sen, Chris Desmond, Julia Louw, Linda Richter. 19
- Usage Pattern Differences and Similarities of Mobile Electronic Medical Records Among Health Care Providers (e178)
Yura Lee, Yu Park, Junetae Kim, Jeong Kim, Woo Kim, Jae-Ho Lee. 27
- The QardioArm App in the Assessment of Blood Pressure and Heart Rate: Reliability and Validity Study (e198)
Victoria Mazoterias Pardo, Marta Losa Iglesias, José López Chicharro, Ricardo Becerro de Bengoa Vallejo. 40
- Patients' Acceptance of Smartphone Health Technology for Chronic Disease Management: A Theoretical Model and Empirical Test (e177)
Kaili Dou, Ping Yu, Ning Deng, Fang Liu, YingPing Guan, Zhenye Li, Yumeng Ji, Ningkai Du, Xudong Lu, Huilong Duan. 65

Web-Based Interventions Supporting Adolescents and Young People With Depressive Symptoms: Systematic Review and Meta-Analysis (e180) Maritta Välimäki, Katriina Anttila, Minna Anttila, Mari Lahti.	79
Using mHealth Technology in a Self-Management Intervention to Promote Physical Activity Among Adults With Chronic Disabling Conditions: Randomized Controlled Trial (e185) Matthew Plow, Meghan Golding.	95
The Impact of a Mobile Diabetes Health Intervention on Diabetes Distress and Depression Among Adults: Secondary Analysis of a Cluster Randomized Controlled Trial (e183) Charlene Quinn, Krystal Swasey, J Crabbe, Michelle Shardell, Michael Terrin, Erik Barr, Ann Gruber-Baldini.	111
A Smartphone App to Reduce Sugar-Sweetened Beverage Consumption Among Young Adults in Australian Remote Indigenous Communities: Design, Formative Evaluation and User-Testing (e192) Emma Tonkin, Lauren Jeffs, Thomas Wycherley, Carol Maher, Ross Smith, Jonathon Hart, Beau Cubillo, Julie Brimblecombe.	124
Factors Influencing Engagement and Behavioral Determinants of Infant Feeding in an mHealth Program: Qualitative Evaluation of the Growing Healthy Program (e196) Eloise-Kate Litterbach, Catherine Russell, Sarah Taki, Elizabeth Denney-Wilson, Karen Campbell, Rachel Laws.	141
Insights From Google Play Store User Reviews for the Development of Weight Loss Apps: Mixed-Method Analysis (e203) Kerstin Frie, Jamie Hartmann-Boyce, Susan Jebb, Charlotte Albury, Rebecca Nourse, Paul Aveyard.	153
Developing mHealth Messages to Promote Postmenstrual Regulation Contraceptive Use in Bangladesh: Participatory Interview Study (e174) Elisabeth Eckersberger, Erin Pearson, Kathryn Andersen, Altaf Hossain, Katharine Footman, Kamal Biswas, Sadid Nuremowla, Kate Reiss.	1
	6
	7
How Do Infant Feeding Apps in China Measure Up? A Content Quality Assessment (e186) Jing Zhao, Becky Freeman, Mu Li.	178
Mobile Health Intervention to Increase Oral Cancer Therapy Adherence in Patients With Chronic Myeloid Leukemia (The REMIND System): Clinical Feasibility and Acceptability Assessment (e184) Amanda Pereira-Salgado, Jennifer Westwood, Lahiru Russell, Anna Ugalde, Bronwen Ortlepp, John Seymour, Phyllis Butow, Lawrence Cavedon, Kevin Ong, Sanchia Aranda, Sibilah Breen, Suzanne Kirsas, Andrew Dunlevie, Penelope Schofield.	199
Health App Use Among US Mobile Phone Users: Analysis of Trends by Chronic Disease Status (e197) Rebecca Robbins, Paul Krebs, Ram Jagannathan, Girardin Jean-Louis, Dustin Duncan.	218
Connected Health Devices for Health Care in French General Medicine Practice: Cross-Sectional Study (e193) Leila El Amrani, Agnes Oude Engberink, Gregory Ninot, Maurice Hayot, François Carbonnel.	227
The Swedish Web Version of the Quality of Recovery Scale Adapted for Use in a Mobile App: Prospective Psychometric Evaluation Study (e188) Ulrica Nilsson, Karuna Dahlberg, Maria Jaensson.	238
Predictors of Playing Augmented Reality Mobile Games While Walking Based on the Theory of Planned Behavior: Web-Based Survey (e191) Hyeseung Koh, Jeeyun Oh, Michael Mackert.	260

Reviews

Mobile Phone Apps for Quality of Life and Well-Being Assessment in Breast and Prostate Cancer Patients: Systematic Review ([e187](#))

Esther Rincon, Francisco Monteiro-Guerra, Octavio Rivera-Romero, Enrique Dorrnzoro-Zubiete, Carlos Sanchez-Bocanegra, Elia Gabarron. 5 2

Chinese Cardiovascular Disease Mobile Apps' Information Types, Information Quality, and Interactive Functions for Self-Management: Systematic Review ([e195](#))

Bo Xie, Zhaohui Su, Wenhui Zhang, Run Cai. 188

Corrigenda and Addenda

Addendum of: Fall Detection in Individuals With Lower Limb Amputations Using Mobile Phones: Machine Learning Enhances Robustness for Real-World Applications ([e167](#))

Nicholas Shawen, Luca Lonini, Chaithanya Mummisetty, Ilona Shparii, Mark Albert, Konrad Kording, Arun Jayaraman. 273

Viewpoint

Texting Condolences: Adapting mHealth Programs After Unexpected Pregnancy and Infant Outcomes

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Abstract

Mobile health (mHealth) short message system (SMS) interventions for maternal and child health (MCH) are being implemented globally. In many low- and middle-income settings in which these mHealth interventions are being rolled out, stillbirths and neonatal and infant deaths are common. It is important that mHealth solutions do not exacerbate emotional stress and pain by continuing with routine messaging for pregnancy or infant care when someone has experienced loss. In this brief viewpoint paper, we argue that SMS programs for maternal and child health need to adapt and make available messaging for miscarriage, stillbirth, and infant loss.

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KEYWORDS

mHealth; infant loss; miscarriage

Mobile health (mHealth) short message system (SMS) text messaging interventions such as Text4baby [1] and MomConnect [2] are increasingly incorporated within maternal child health (MCH) care systems globally. Evidence regarding effectiveness of these interventions to improve MCH health services uptake and outcomes is limited to date but accruing [3-5]. Studies suggest that these interventions may improve beliefs and attitudes about behaviors and preparedness during pregnancy [1,6] and that women appreciate access to information [7] throughout pregnancy and the postpartum period. Message development for MCH text message programs has involved tailoring messaging to the stage of pregnancy and infant age and targeting key behaviors that can improve health outcomes. As women connect to the health care system through text messaging, there is increasing programmatic responsibility to get the messaging right for these participants. Messaging needs to be culturally appropriate, accurate, and reflect realities to be

a credible resource that has positive impact on maternal and child outcomes.

An unanticipated challenge we faced during a recent mHealth randomized controlled trial (RCT), Mobile WACH (Mobile Solutions for Women's and Children's Health) [NCT01894126], was responding to the high number of neonatal and infant deaths, stillbirths, or miscarriages. Unfortunately, in many low- and middle-income settings in which mHealth interventions are being rolled out, stillbirths and neonatal and infant deaths are not infrequent [8]. Although mHealth MCH systems automate text messaging based on timing of gestation or postpartum status, most are not built to capture the real-time vital status of mother or infant. Thus, a woman may continue to receive messages from the program about actions to keep her pregnancy or baby healthy after the occurrence of a miscarriage, stillbirth, or infant death. Women could end messaging by sending a STOP message, but this leaves these women without access to

a potentially valuable source of support. Women with adverse outcomes may especially benefit from access to advice and encouragement at this difficult time. In our RCT, we found that when we contacted women for study follow-up, most women

who experienced a stillbirth or infant death wanted to continue receiving messages. In addition, women in the bidirectional text messaging group wanted to be able to continue a message dialog with the nurse.

Textbox 1. Example text messages for women participating in mHealth programs after a miscarriage or infant death.

Immediate message after infant loss:

[Name], this is [nurse] from [clinic]. We are very sorry to hear about your loss. It may be more difficult to take care of yourself but you need to make sure to take time each day for your health, even now. If you have any questions or concerns, please come in to the clinic. We are all here for you.

Week 1 postloss:

[Name], this is [nurse] from [clinic]. It may be difficult to cope after your loss. Try and do something each day to take care of yourself. Talk to your family and friends or go for a walk. Please come in and talk to the nurses if it helps.

Week 3 postloss:

[Name], this is [nurse] from [clinic]. It may be a very difficult time after your loss. Please continue to take care of yourself and know we are thinking of you. Please come in to the clinic if we can be of help.

Week 4 postloss:

[Name], this is [nurse] from [clinic]. It may be best to delay your next pregnancy just to make sure you are healthy and feeling your best. Even if you don't want to go to the maternal child health clinic, we can send you information about family planning or you can get family planning from another clinic.

With scale-up of mHealth in MCH systems, the intersection between messaging projects and infant deaths is not insignificant. For example, South Africa has rolled out MomConnect countrywide to improve maternal and child outcomes. The infant mortality rate in South Africa is 33 infant deaths per 1000 live births [9], and MomConnect has messaged over 700,000 pregnant women since its launch in 2013. Thus, an estimated 23,100 women receiving MCH-related text messages will also experience the loss of their baby. It is important that mHealth solutions do not exacerbate emotional stress and pain with perhaps unwanted reminders of this loss, and programs need to be thoughtful about how these women and their families could benefit from adapted messages tailored to this scenario.

One approach that may also lessen the stigma of miscarriage, stillbirth, and infant death is to develop messaging around these

sad events (Textbox 1). The messages in our trial were developed and revised after formative work, both pre-RCT focus group discussions and post-RCT interviews, with representative women from the communities where we work. Although there are limitations to all counseling messages and they may not address the concerns of all women, messaging could be designed to support women and encourage healthy behaviors around grief and depression. Women would then have the option to remain connected to the program and not experience a loss of support. Building such a system would require some design innovations to enable prompt notification of infant deaths by integrating more closely with primary health care workers but could ultimately provide valuable information about infant deaths and the needs and experiences of participating women and result in long-term improved outcomes for these families.

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Abbreviations

MCH: maternal child health

Mobile WACH: Mobile Solutions for Women's and Children's Health

RCT: randomized controlled trial

SMS: short message service

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Original Paper

Detecting Smoking Events Using Accelerometer Data Collected Via Smartwatch Technology: Validation Study

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Abstract

Background: Smoking is the leading cause of preventable death in the world today. Ecological research on smoking in context currently relies on self-reported smoking behavior. Emerging smartwatch technology may more objectively measure smoking behavior by automatically detecting smoking sessions using robust machine learning models.

Objective: This study aimed to examine the feasibility of detecting smoking behavior using smartwatches. The second aim of this study was to compare the success of observing smoking behavior with smartwatches to that of conventional self-reporting.

Methods: A convenience sample of smokers was recruited for this study. Participants (N=10) recorded 12 hours of accelerometer data using a mobile phone and smartwatch. During these 12 hours, they engaged in various daily activities, including smoking, for which they logged the beginning and end of each smoking session. Raw data were classified as either smoking or nonsmoking using a machine learning model for pattern recognition. The accuracy of the model was evaluated by comparing the output with a detailed description of a modeled smoking session.

Results: In total, 120 hours of data were collected from participants and analyzed. The accuracy of self-reported smoking was approximately 78% (96/123). Our model was successful in detecting 100 of 123 (81%) smoking sessions recorded by participants. After eliminating sessions from the participants that did not adhere to study protocols, the true positive detection rate of the smartwatch based-detection increased to more than 90%. During the 120 hours of combined observation time, only 22 false positive smoking sessions were detected resulting in a 2.8% false positive rate.

Conclusions: Smartwatch technology can provide an accurate, nonintrusive means of monitoring smoking behavior in natural contexts. The use of machine learning algorithms for passively detecting smoking sessions may enrich ecological momentary assessment protocols and cessation intervention studies that often rely on self-reported behaviors and may not allow for targeted data collection and communications around smoking events.

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KEYWORDS

machine learning; neural networks; automated pattern recognition; smoking cessation; ecological momentary assessment; digital signal processing; data mining

Introduction

Despite rapid adoption of many tobacco control policies around the world, cigarette smoking remains the greatest preventable cause of death [1]. Ecological momentary assessment studies

are increasingly popular for understanding smoking behavior in context [2-4]. Studies in this area have traditionally relied on participants to self-report smoking behaviors in real time, which can be particularly burdensome for heavier smokers and result in missing or biased information if participants are not

forthcoming about or forget smoking events [5]. In this study, a smoking event can be either an individual puff or an entire session, defined as the time it takes to smoke a single cigarette. Emerging technologies that allow for passive detection of stereotyped behaviors such as smoking may be able to decrease or eliminate reliance on burdensome and potentially biased self-reports to study when, how frequently, and under what circumstances smoking behavior occurs.

Mobile phones and, recently, smartwatch technologies have rapidly spread and are widely available [6]. Typical smartwatches house sophisticated sensors that accurately track simple activities, such as step counting. In recent years, methods have been developed that use these sensors to detect more complex activities, such as eating and drinking [7,8]. Previous research [9-12] has shown the possibility of detecting smoking using smart devices. However, these studies have employed highly intrusive devices such as respiration bands [10,13] worn across the chest and two-lead electrocardiographs worn under the clothes to achieve high accuracy in detection. In our previous, laboratory-based work [14,15], we have shown that smoking can also be detected by leveraging the accelerometer sensor found on a typical smartwatch in conjunction with common machine learning algorithms.

The utilization of smartwatches presents a nonintrusive means of smoking detection that potentially eliminates the need for reliance on self-reporting. The purpose of this study is to extend our previous laboratory-based work to determine the feasibility and accuracy of our detection method with a population of smokers wearing the device in the natural context of normal daily activities.

Methods

Overview

Adult smokers were recruited to wear a commonly available smartwatch while recording their daily activities, including smoking and other behaviors that are similar to smoking (ie, eating, drinking). The data from these recordings were then used in a machine learning exercise to develop an automated gesture detection algorithm. The accuracy of our automated detection was compared against the self-reported information on activities and manual inspection of smoking session data.

Recruitment of Participants

Participants were recruited through flyers, which included study information and a link to an online eligibility survey that was accessible via a clickable URL address and a QR code. The survey asked about participants' smoking behavior as well as age, gender, and contact information. Eligibility criteria included age older than 18 years, having smoked at least 100 cigarettes in their life, smoking more than 10 cigarettes daily, and preference for smoking with the right hand. The flyers were posted throughout Columbia, SC, in areas where smokers were likely to congregate (eg, coffee shops, bars), as well as online venues such as Craigslist. The incentive for completion of the study was a US \$100 Visa gift card that was given to each participant after concluding the protocol.

Only participants who met all eligibility requirements were contacted and invited to a study briefing. In the briefing, participants' eligibility was reconfirmed with a smoke carbon monoxide breathalyzer. A level of 8 ppm was used as the cutoff, which is slightly higher than cutoff levels of 5 to 6 ppm suggested for distinguishing smokers from nonsmokers in other studies [16-18]. Participants were provided with an Asus Zenwatch and Android mobile phone to complete the trial. A 15-minute tutorial was given to each participant on how to use the data collection app and smartwatch and how to fill in the smoking logs using their mobile phone to register the times when they began and finished smoking. Fourteen smokers attended a briefing; two did not meet the criteria of 8 ppm after taking the smoke carbon monoxide breathalyzer measure and were excluded from the study. Of these 12 participants, data from two were inconsistent and excluded from the analysis because they did not follow the study procedures. In one case, the participant wore the watch on the left hand instead of the right hand and therefore did not collect data from the hand used to smoke. In the second case, large sections of data were missing due to the participant losing Bluetooth connectivity between their watch and their phone by moving more than 30 feet away from the phone. Hence, data from 10 participants were analyzed.

After the study was completed, these 10 participants were asked to fill out a brief demographic survey. The survey included basic questions about age, race, ethnicity, gender, and intentions to quit or continue smoking.

Data Collection and Annotation

The data analyzed in this study consisted of the three-dimensional accelerometer data collected from the Asus Zenwatch (first generation). The accelerometer onboard the Asus Zenwatch is triaxial and therefore capable of recording acceleration in three principal axes x, y, and z. These three axes are situated on the watch as shown in Figure 1, where the z-axis (in green) is perpendicular to the watch face.

Although a few apps exist for recording accelerometer data on both Apple and Android platforms, none of them contained the required features, such as recording and transmission of the data to cloud storage or alteration of sampling frequency. Therefore, we developed an app capable of recording, maintaining, and transmitting data to Dropbox as the means of data collection and storage across our cohort of participants. The use of a customized app allowed for control over the sampling frequency of the data. During this investigation, a fixed sampling frequency of 20 Hz was used.

Each participant was asked to record a total of 12 hours of data over the course of three days. The total of 12 hours was partitioned into seven periods: four 1-hour periods, two 2-hour periods, and one 4-hour period. The participants were instructed to schedule these seven periods such that each would contain at least one full smoking session. Due to the large data transfers occurring between the watch and the phone, the battery life of the watch was not able to achieve the full 4 hours in most cases. In these cases, the participants were asked to record as long as they could until the battery power was nearly depleted.

Figure 1. An illustration of accelerometer axes on a typical smartwatch.



In addition to the accelerometer data, the participants were instructed to record the beginning and end times of each cigarette in an online logbook using the provided mobile phone. A bookmark on the phones linked to a brief Google form that served as their logbook. The protocol involved recording the starting timestamp immediately before beginning a smoking session. In addition, each participant was asked to indicate whether the cigarette was the first from a new pack. After each smoking session, they were asked to report the end of their smoking session as well as the approximate number of puffs during their smoking session.

Smoking sessions were extracted and inspected based on the start and end times recorded in each participant's log entries. The duration of these sessions ranged from 2 to 20 minutes in length. However, these ranges are misleading in some ways. For instance, some of the longer sessions (>10 minutes) clearly consisted of more than one smoking event. This behavior is typical for chain-smokers but, as per our defined protocol, should have been recorded as two separate sessions instead of one. Any other gesture that was not within one of the reported sessions was classified as a nonsmoking session.

A Hierarchical Approach to Detection of the Smoking Gesture

Machine learning techniques have been commonly used in the broad field of pattern recognition. Common machine learning techniques consist of naive Bayes, support vector machine, decision tree, random forest, artificial neural network, and rule-based artificial intelligence (AI), to name a few. In this study, we have integrated artificial neural networks and rule-based AI in a hierarchical fashion to improve recognition of smoking activity.

Artificial Neural Networks

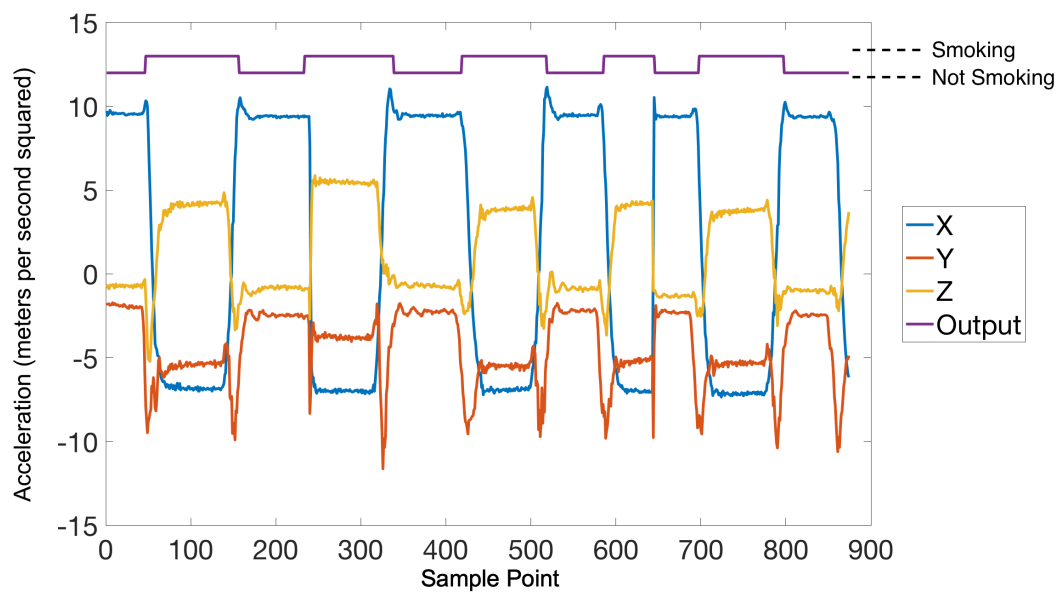
In this study, two-layer, feed-forward artificial neural networks [19] with 10 hidden neurons were used as the core engine for

detection of smoking gestures. Typically, the creation of an artificial neural network occurs in two main steps: training and validation. Details about the training and validation processes can be found in our previous works [14,15]. In general, the artificial neural network was trained to produce an output of 1 during the smoking gesture and a 0 during all other activities. Figure 2 provides an illustration of a sample smoking session (with five distinct puffs) and the expected ideal output. In this figure, the patterns illustrated in blue, red, and yellow correspond to the x, y, and z dimensions of the accelerometer data and the pattern shown in purple denotes the ideal output.

Rule-Based Artificial Intelligence

Rule-based AI constitutes the earliest form of the machine learning techniques. Rule-based techniques can be very efficient in circumstances where the actions taken by the AI core can be deduced based on a set of definable rules. The cooperation between the artificial neural network and rule-based cores can be structured in a variety of ways. In our study, we chose a hierarchical model, where the artificial neural network operates as the core of the smoking detection and rule-based AI operates in a layer above the artificial neural network. In this arrangement, the rule-based core is responsible for establishing the beginning and the end of a "puff" gesture, counting the number of puffs, and establishing the beginning and end of a new smoking session. The rule-based layer also addresses some of the shortcomings of our previous studies [14], where several nonsmoking gestures (eg, scratching the nose and yawning) caused high numbers of false positives for the artificial neural network. By utilizing the rule-based layer to establish a minimum number of puffs within a smoking session, single gestures such as a yawn will be eliminated as a smoking event. The operational directives of the rule-based core are described later in the paper.

Figure 2. An example of a smoking session. Each dimension of the accelerometer data is shown in blue (x), red (y), and yellow (z). An ideal output of the artificial neural network is shown in purple where each bump denotes a smoking gesture.

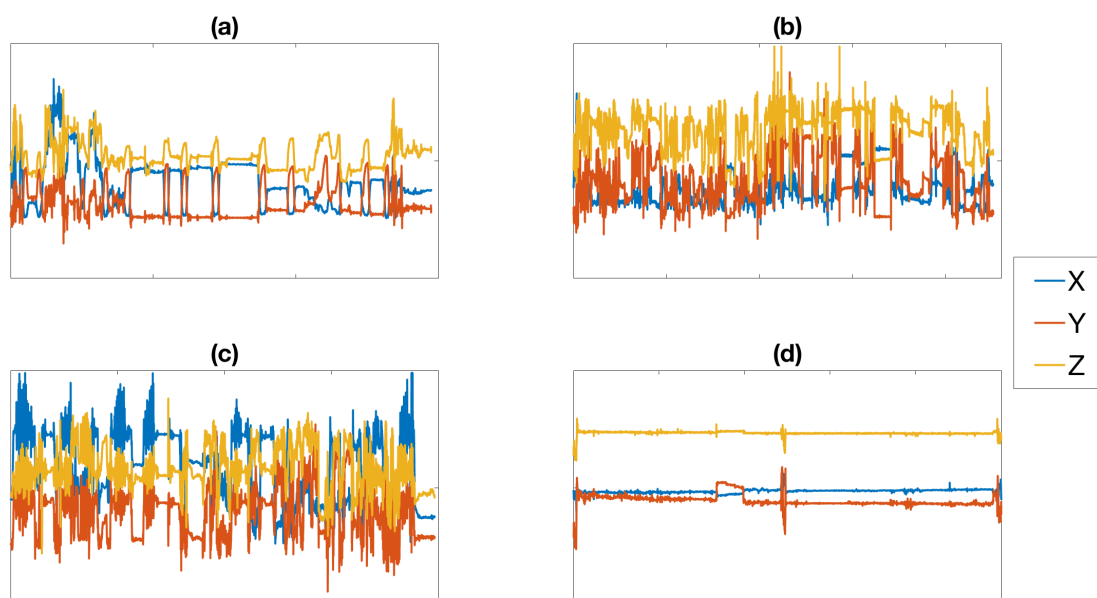


Training of the Artificial Neural Network

It is typical to train the artificial neural networks on a separate set of data than what is used during the validation step to establish its full functionality (to enforce generalization). This process eliminates the possibility of memorization [19] by the AI. Therefore, the training of the artificial neural network was performed with smoking data collected from 10 volunteers that were not part of the data collection mentioned in the “Recruitment of Participants” section. These volunteers were instructed to use the same mobile phone and smartwatch used in the trial to record smoking and nonsmoking sessions in a laboratory setting. The training set consisted of 13 smoking sessions that were collected from 7 of 10 participants and 12

nonsmoking sessions from 3 of the remaining participants. The nonsmoking sessions included a variety of activities such as eating (3 sessions), drinking (3 sessions), walking (3 sessions), tying shoes (1 session), and typing on a computer (2 sessions). An example of each gesture is shown in Figure 3. Inputs to the network were extracted using a 5-second rolling window, which resulted in a total of 177,450 smoking gestures and 174,080 nonsmoking gestures. The smoking gestures were then coded as positive responses and the nonsmoking gestures as negative responses. The artificial neural network was trained and validated with this set of data, achieving an accuracy of 95%. Here we define accuracy to be the percentage of correctly predicted smoking and nonsmoking gestures.

Figure 3. Examples of the following nonsmoking sessions: (a) drinking, (b) eating, (c) walking, and (d) typing on a computer.



Development of the Rule-Based Artificial Intelligence From a General Model of a Smoking Session

Precise definition of a smoking session is critical for evaluation of a predicted model and development of any rule-based criteria. Development of a template for a smoking event is beneficial in a number of ways. First, such a definition can be used to compare the output from our detection mechanism to the actual smoking session recorded by participants. Second, the existence of such a model will help to better define the operating rules of the rule-based AI in improving the detection rates.

A smoking session can be defined in terms of its dependent components such as the number of individual gestures and their time dependencies. Figure 4 describes the model of smoking that was empirically derived based on our observations of the participants' data. Based on this model, a smoking session is described by five main parameters: minimum puff duration, minimum and maximum rest time between puffs, maximum session duration, and the minimum number of puffs per session. A "puff" was defined as the time it takes a person to raise the cigarette to their lips, inhale, and then lower their arm back to the resting position. Therefore, we conservatively define a minimum puff duration consisting of 0.75 seconds (shown in Figure 4a). Any puff shorter than 0.75 seconds in duration was therefore rejected as a valid puff by the rule-based AI system.

A minimum of 2.5 seconds and a maximum of 4 minutes were used as the rest time that separated two adjacent puffs (Figure 4b) belonging to the same smoking session. Two adjacent puffs in violation of the minimum separation criterion were classified by the rule-based system as the same puff that was incorrectly separated from each other. Correspondingly, two adjacent puffs in violation of the maximum separation criterion are classified to belong to two separate smoking sessions.

Finally, a smoking session was defined to consist of at least 3 puffs that satisfy the previous gesture criteria (eg, puffs must

be longer than 0.75 seconds in duration and more than 2.5 seconds and less than 4 minutes from the next puff) and not exceed 8 minutes in duration (Figure 4c-d). The 8-minute rule was implemented to have a higher precedence over all other rules. A sequence of appropriate puffs that exceed 8 minutes in total length was counted as two separate smoking sessions. This rule was primarily implemented to address chain-smoking behavior.

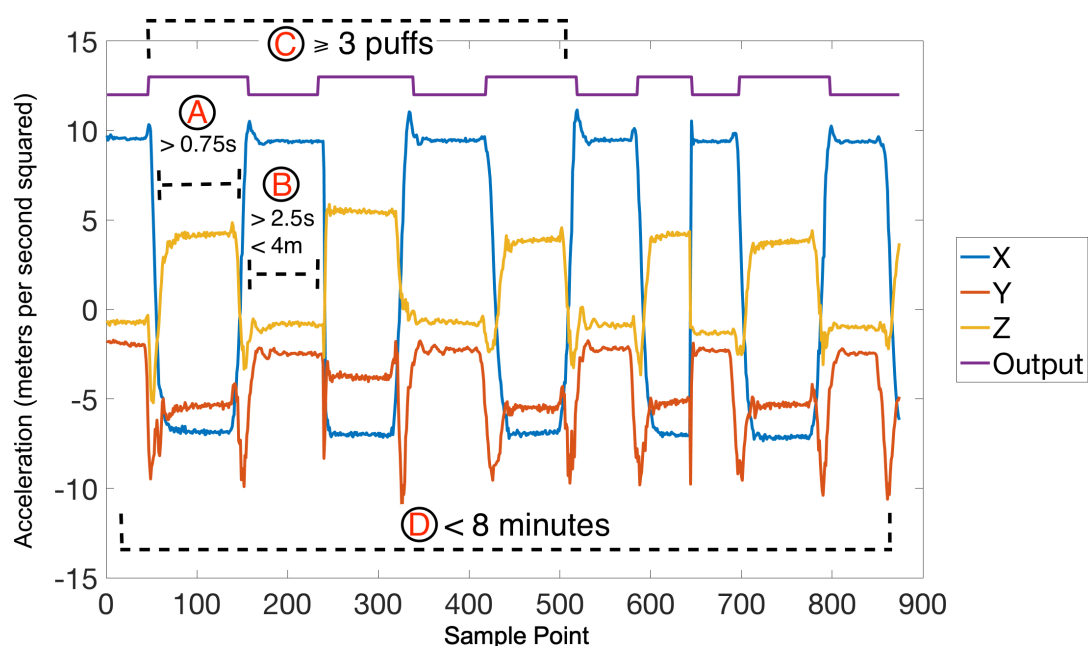
In our data, puff duration never exceeded 5 seconds in length. Therefore, the input to the artificial neural network's gesture recognition system consisted of a set of accelerometer data that spanned 5 seconds of observation sampled at 20 Hz (100 points of data). Each set of data included x, y, and z components of the accelerometer, which necessitated an artificial neural network architecture with 300 input points and one output point. The single output of the artificial neural network was interpreted based on a threshold of a probability of 0.85, above which signified a smoking gesture. For more details related to the interpretation of the artificial neural network's output, refer to our previous articles [14,15].

During the supervised training of the artificial neural network, the onset and offset of the smoking gesture was loosely defined by the supervisor. Loose interpretation of the edge is not consequential because it is a very quick event (in comparison to the gesture itself) and therefore makes very little impact on the duration of a gesture.

Evaluation Techniques

Evaluation of automated methods for detection of smoking gestures can be performed at various levels of granularity. At the finest point, every sampled data point (20 points every second) can serve as the subject of evaluation, whereas at the coarsest point an entire smoking session can be the subject of evaluation.

Figure 4. Model of a smoking session: (a) puff duration >0.75 seconds, (b) maximum rest time between puffs <4 minutes and minimum rest time >2.5 seconds, (c) minimum number of puffs in a session = 3 puffs, (d) session duration <8 minutes.



In this work, we define our objective as successful detection of each smoking session. The interpretation rules of a smoking session (Figure 4) were used to quantify the output of the smoking detection mechanism. The validity of each detected session was established based on comparison to the self-report by the participants. A detected smoking session was categorized as a true positive if it was corroborated by the timestamps of the self-report and false positive otherwise. The true positive rate was measured by the number of detected true positive sessions divided by the total number of smoking sessions reported by the participants.

It is common to provide a measure of false positive rate to form a more complete evaluation of a predictive system's performance. Calculation of the false positive rate is the total number of nonsmoking sessions that were predicted as smoking divided by the total number of nonsmoking sessions. However, in this instance proper calculation of the total number of nonsmoking sessions term became ambiguous. Within a 12-hour of recording session, a total of 854,400 nonsmoking sessions (of 8 minutes length at 20 Hz of sampling rate) can be extracted via a rolling window. Given that the smoking detection mechanism produced on average two false smoking sessions per participant, the estimated false positive rate would be 2.34×10^{-6} . A more meaningful measure of the false positive rate can be achieved by calculating the number of nonsmoking sessions as the total number of contiguous nonsmoking sessions (ie, the number of 8-minute nonsmoking sessions that had no overlap with other ones). The number of nonsmoking sessions was calculated as the total number of minutes recorded by a given participant divided by the window size (in our case 8 minutes) and subtracting the total number of smoking sessions recorded by the participant from this value: number of nonsmoking sessions = (total number of minutes recorded sessions / window size) - total number of smoking sessions. Using

this calculation, for a given 12-hour period in which a participant smoked 10 times, the number of smoking sessions would be 80.

Results

Summary of Data

Participant Demographics

Three of the 10 participants did not complete the demographic survey. Of the participants who completed the survey, the mean age was 32 (SD 6) years, the minimum age was 27 years, and the maximum age was 46 years. There were four females and three males. Six participants were non-Hispanic white, whereas one was African American. Only one participant indicated that they intended to quit smoking within the next 6 months.

Participant Data

In total, 120 hours of data were collected from the 10 participants, in which 123 smoking sessions were reported. Each data file was first subjected to a low-pass filter to eliminate the high-frequency noise caused by movements such as walking or shaking. The effect of the filter can be seen in Figures 5 and 6. Following the smoothing step, the inputs to the artificial neural network were prepared by using a rolling window of 5 seconds.

Within the 12 hours of recording, participants typically smoked 12 times. On average, the duration of a smoking session was 8 minutes based on the self-report data and 5 minutes based on visual inspection of the recorded sessions. These discrepancies were most likely a consequence of both the additional time required for manual entry in the self-report protocol and human error. Requiring the participants to log their smoking session in an electronic form may have taken some participants a few extra minutes, thus inflating their reported session window.

Figure 5. A noisy nonsmoking session is shown before the smoothing filter with the output of the detection mechanism shown in purple.

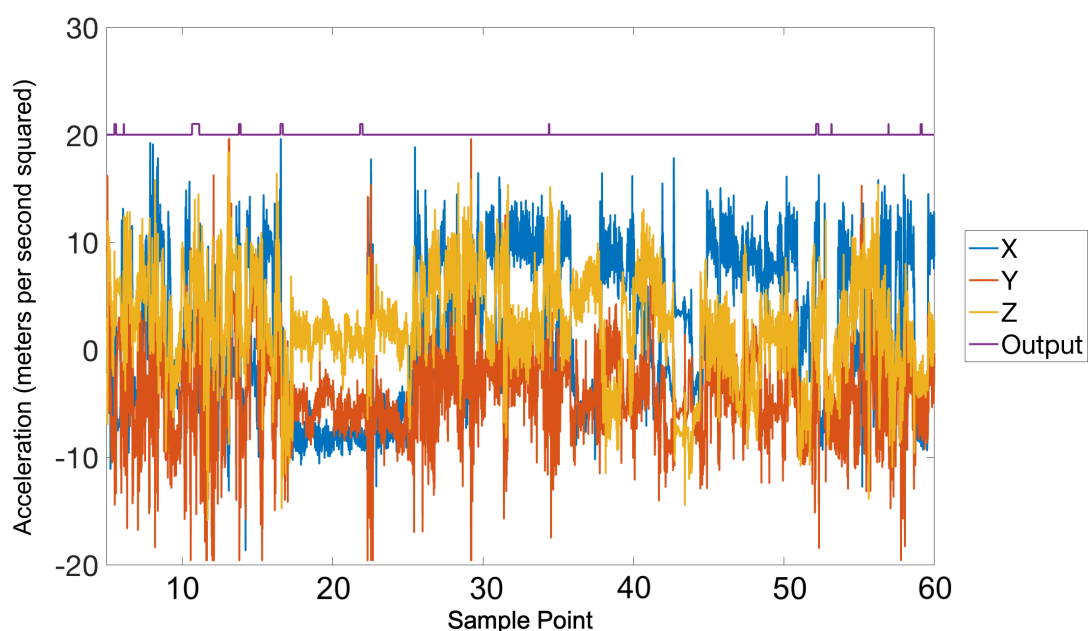
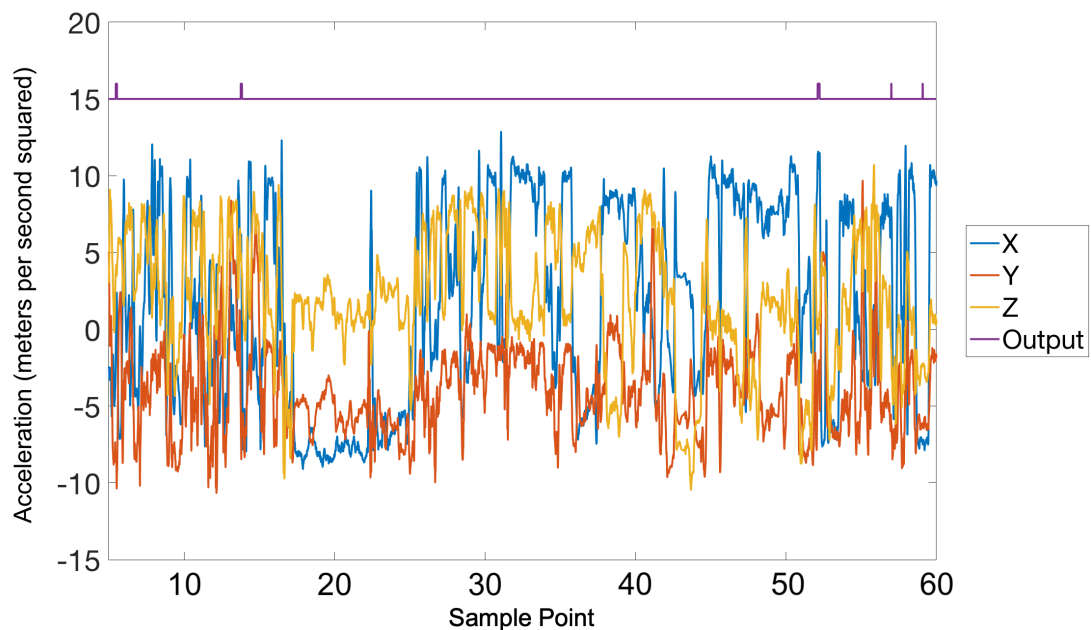


Figure 6. A noisy nonsmoking session is shown after the smoothing filter with the output of the detection mechanism shown in purple.



Evaluation Outcomes

Self-Reporting Accuracy

In total, of the 123 recorded sessions, 27 entries were missing either a start or end time. In these cases, a window of 8 minutes was given preceding an end time with a missing start time or following a start time with a missing end time. Using this metric, the accuracy of self-report (ie, the rate of correctly logged smoking entries) was approximately 78% (96/123). However, it should be noted that we expect the self-report to be lower than the estimated 78%. This expectation is based on close examination of the raw recorded data that would otherwise be impossible to ascertain from self-report data. One such example

is shown in [Figure 7](#), where the participant did not report a clear smoking session. However, by a close comparison of the recorded session to the model of smoking, one can make a reasonable determination that it is indeed an unreported smoking event. The omission of this session in the log resulted in an increase of the false positive rate, where it should have contributed to an increase in the true positive rate. The opposite of this phenomenon also occurred; that is, a smoking session was reported in a given period yet on careful inspection no valid smoking event was found in the recorded data (an example is shown in [Figure 8](#)). If both of these phenomena were included in the calculation of the self-report accuracy, then it would drop to 71% (88/123 correctly reported sessions).

Figure 7. This session was not reported by the participant, but is an unmistakable smoking session with 13 clear puffs.

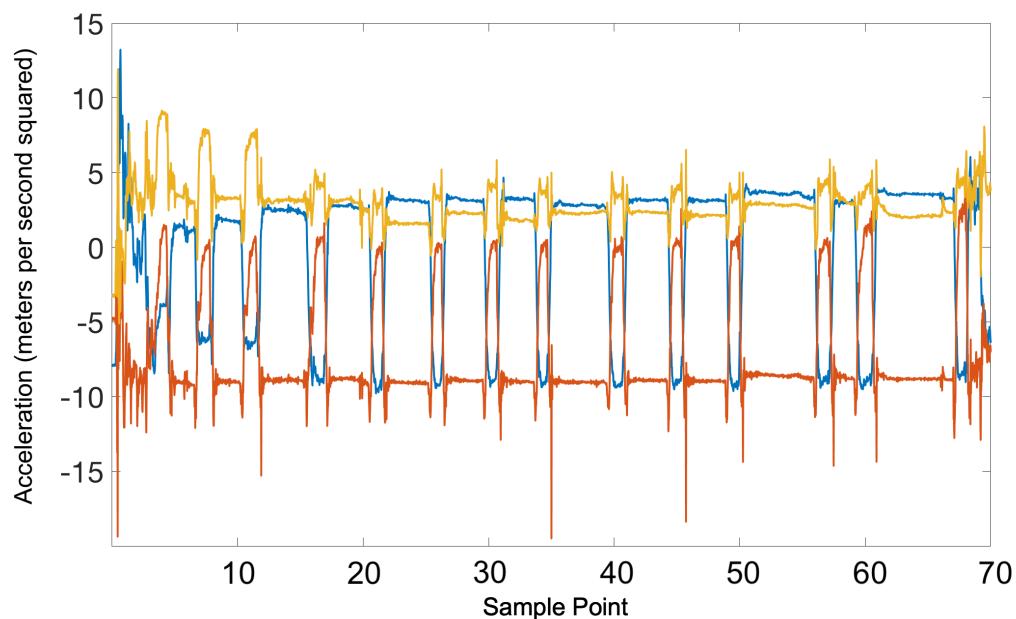
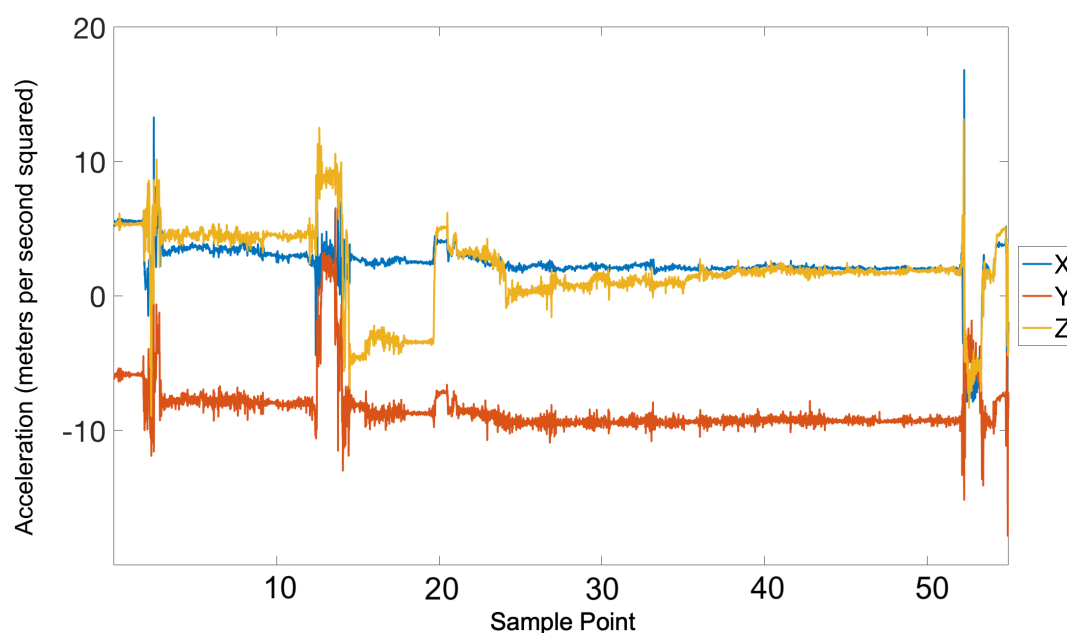


Figure 8. This session was reported as a smoking session, but no clear smoking gestures can be identified.**Table 1.** Values for the true positive rate calculated by iteratively excluding sessions from the four categories producing false negatives.

Category	Detected smoking sessions, n	Excluded smoking sessions, n	Corrected smoking sessions, n	True positive rate, %
Ground assumption	100	0	123	81
No smoking	100	2	121	82
Improper use	100	9	112	89
Abnormal gesture	100	9-11	101-112	89-99
True false negative	100	0	101-112	89-99

Detection Accuracy

The evaluation of the results was not as intuitive as expected. Our initial approach to evaluation (first entry in Table 1) was to compare the outcomes of the automated detection mechanism to that of self-reported smoking. However, this approach presumed 100% accuracy of self-report, for which we have cited some contradictory examples (refer to the previous section). If we assume that self-report is 100% accurate, then real errors in self-report (see previous section) lead to underestimating true positive detection rates and overestimating false positive rates. Therefore, it is paramount to examine and categorize the sources of discrepancy between the two methods. To that end, we define the following categories of discrepancies: “no smoking,” “improper use,” “abnormal gesture,” and “true false negative.” All subsequent investigations of the self-report data were performed by visual inspection of the recorded signals. All detection estimates were adjusted incrementally as each source of error was eliminated. The modified results are shown in Table 1.

The first category of no smoking denotes no visual presence of a smoking event during the reported smoking period (an example is shown in Figure 8). Two such sessions belonged to one participant. These sessions were excluded from the total number of self-reported smoking sessions, which resulted in a new true positive rate of 82% (100/121).

The second category, improper use, was one of the biggest contributors in reducing the true positive rate in this study. Improper use denotes the condition where the participant did not wear the watch as dictated by the protocol of the study (either not on the right wrist or not in the protonated position). This condition can easily be identified and corrected [15], although the correction mechanism was not implemented and incorporated into this study. A total of nine sessions were identified via visual inspection to be in violation of proper adherence to the study protocol and could therefore be excluded from the study. A corrected true positive rate value of 89% (100/112) was estimated after elimination of these violations.

Table 2. Values for the false positive rate calculated by iteratively excluding sessions from the two categories producing false positives.

Category	Detected false smoking sessions, n	Excluded sessions, n	Corrected false smoking sessions, n	Total possible sessions, n	False positive rate, %
Ground assumption	22	0	22	777	2.8%
Clearly smoking	22	6	16	771	2.1%
True false positive	22	0	16	771	2.1%

The third category, abnormal gesture, denotes the occurrence of smoking gestures that could not be reproduced in the laboratory setting. These gestures had a clear periodicity consistent with smoking behavior, but had no other resemblance to our database of smoking gestures. Such conditions may be indicative of smoking in unusual positions, such as smoking while lying in the facedown position (possibly from the edge of the bed) or hanging upside down. Various reclined positions, laying down in the face-up position, or lying down on the left or right side were investigated without any success in recreating the recorded anomalous smoking gestures. In future iterations of the detection mechanism used in this study, smoking in these positions should be included in our training session of the artificial neural network. However, before retraining the artificial neural network, these curious gestures need to be confirmed as valid smoking sessions and be reproducible in laboratory settings. Depending on whether such gestures can be excluded from this study or not, an upper bound of 99% accuracy can be estimated for the performance of the automated detection mechanism.

The fourth and final category, true false negative, represented the cases where the self-reporting data were correct, but the automated detection mechanism misidentified the sessions. Our thorough investigation identified only one such session. We suspect the abnormally short puffs by this participant as the culprit for this misclassification. The likelihood of this type of misclassification can be reduced in the future by allowing personalization of the puff duration based on a given person's smoking profile.

In our evaluation of the false positive rates, we faced the same challenges as in our evaluation of the true positive rate. A progressive evaluation of the false positive rate is shown in [Table 2](#). Under the simplified conditions (assumption of 100% accuracy in self-reporting), a total of 22 smoking sessions were identified within nonsmoking regions of the 120 hours of total recording time. Based on the definition of false positive rate presented in a previous section, 120 hours of recording time translated into 777 windows of observed nonsmoking behavior. Similar to the case of true positive rate, the following categories of false positive rate were investigated to understand the nature of the detection mechanism's performance better: clearly smoking and true false positive. The results of this classification are summarized in [Table 2](#).

Under the conventional technique of assuming 100% confidence in self-reporting data, on average, the detection mechanism achieved a false positive rate of 2.8% (22/777). However, due to clear presence of errors in self-reports, 2.8% served as an upper bound estimate of performance, and the actual performance can be expected to be lower than 2.8%.

To obtain a better estimate of the false positive rate, the first category of clearly smoking was scrutinized ([Table 2](#)). The clearly smoking category denotes sessions in which at least one smoking event was indisputably present, yet no smoking event was logged during the self-reported period of smoking. An example of the phenomenon is shown in [Figure 7](#). A total of six such sessions were identified during a careful manual inspection of the recorded data. It is unclear whether such instances should be included in the evaluation of the true positive rate or false positive rate. Here we have chosen the latter and have excluded them from the calculation of the false positive rate. With these excluded, the false positive rate was reduced to 2.1% (16/771).

The second category, true false positive, signified the cases where the smoking detection mechanism performed a true misclassification and thus could not be excluded. A total of 16 such sessions fell into this category. The majority of these sessions contained very jittery and erratic motions, which may be the cause of their misclassification. If so, a more rigorous filtration of high-frequency signals may remove or reduce this category of error in future iterations of the software.

Discussion

Principal Results

The presented automated smoking detection mechanism demonstrated a conservative true positive rate of more than 82% for identifying smoking sessions, while achieving a negligible false positive rate of 3%. Furthermore, the true positive rate increased to approximately 90% when considering only the smoking sessions that participants adhered to study protocols. Approximately 10 of the smoking sessions were not reproducible in the laboratory session, which will be the subject of future studies to assess how different smoking positions (eg, while lying down) are accompanied by different gesture patterns or otherwise influence accelerometer readings. Once confirmed as valid smoking sessions, similar gesture patterns can be included in future training sessions of the detection mechanism's underlying artificial neural network. A new true positive rate can be estimated for the newly trained artificial neural network by assuming 50% successful detection of the anomalous gestures (although, based on the current true positive rate, 80% is more realistic). A 50% success rate in detecting anomalous gestures will increase the true positive rate to 93% accuracy. In contrast, a liberal assessment of the traditional self-report had a maximum accuracy of 71% to 78%. However, we speculate actual accuracy of self-report may be lower if our analysis of the data from our study is indicative of normal self-report behavior.

Limitations

There are two primary limitations of the automated, machine learning-based approach to detection of smoking: technological and methodological. Technological aspects include the battery life span, which is of primary interest for apps that require continuous monitoring over waking hours. The wearable device used in our studies (Zen watch) has a limited practical battery life of nearly 20 hours. However, this battery life span may be significantly reduced under high-throughput data exchange conditions, where data are continuously transmitted to another device via a Bluetooth connection. Although a limitation for practical deployment of an automated smoking detection approach, limited battery life can be mitigated in two ways. First, the identification of puffs, smoking gestures, and smoking sessions can be translocated on the watch and therefore eliminate excessive Bluetooth communication. We anticipate a substantial reduction in the power consumption of the smartwatch, returning its life span to nearly 10 hours a day. The second mitigation of limited battery life is newly arriving smartwatches with battery life spans of more than a week. Therefore, the prospect of continuously monitoring smoking behavior for a day or more is highly positive.

A number of methodological issues also limited this study. The first issue is related to study protocol adherence, which requires participants to wear the smartwatches in a particular fashion (eg, wearing the watch on the dominant hand). Although these protocols may be acceptable during the early stages of a study, they may be cumbersome during the broader dissemination of this approach. To that end, our existing algorithm should be improved to detect the orientation of the smartwatch (left hand versus right hand, supinated or pronated) either automatically

or during the initial setup stages. Our subsequent work [15] has demonstrated the possibility for automatic correction of the accelerometer data if the watch is worn incorrectly. In addition, study procedures can warn the user if the watch is not worn correctly. The second issue is related to the anomalous and irreproducible smoking gestures we observed. These gestures need to be further studied and, once confirmed as valid smoking gestures, examples need to be included in future iterations of the smoking detection mechanism.

Conclusions

The potential benefits of developing an automated system for detection of human activities are vast. Based on our observations, two distinct conclusions can be stated. First, it is possible to detect smoking behavior based on triaxial accelerometer data and this behavior can be distinguished from other similar gestures. Second, an automated smoking detection approach to the study of smoking behavior may be substantially more reliable than approaches that rely on traditional self-report. Third, with an accurate, automated system in place, reliance on self-reporting could be eliminated, thus decreasing the burden on a participant without losing any benefits. The resulting data collection system could allow for a range of unobtrusive studies of how context, including that which can be captured by global positioning systems, influences smoking behavior, targeted surveys around smoking events, and targeted communications for those who are trying to quit. Furthermore, this automated system may easily be expanded to detect increasingly popular electronic cigarette smoking, for which behavioral gestures accompanying consumption are very similar to cigarette smoking but for which the patterns of behavior and their context are much less well understood.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence

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Original Paper

App-Supported Promotion of Child Growth and Development by Community Health Workers in Kenya: Feasibility and Acceptability Study

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Abstract

Background: Early childhood is a critical phase of development. In low resource settings, monitoring this stage of development and providing appropriate and timely feedback is a challenge. Community-based service providers play a key role in promoting early childhood development in areas where government services are weak. These community-based service providers are also tasked with the collection of monitoring and evaluation data for donors and local government. Usually, collection of these data aims to provide accountability, learning, and correction leading to improvement. However, such data is rarely used beyond the accountability stage.

Objective: The purpose of this study was to test the feasibility and acceptability of the Information for Action (IFA) mobile phone app. The IFA app was designed for use by community health volunteers (CHVs), and repackages routinely collected data about children into useful, offline decision support for caregivers and program managers.

Methods: The IFA app was tested with a convenience sample of 10 CHVs in West Katweng'a, a sublocation of Rarieda subcounty in western Kenya. CHVs used the IFA app for 5 months as part of their regular home visits to households containing children aged 0 to 5 years, after which a qualitative assessment of the app was conducted. A total of 16 caregivers who received services from the CHVs were randomly selected to participate in 1 of 2 focus group discussions about their experience.

Results: The app was reported to help facilitate interactive dialog between CHVs and caregivers, leading to improved quality of home visits. Caregivers described the app as shifting the relationship from feeling harassed by CHVs to experiencing genuine interest from CHVs. CHVs reported feasibility challenges primarily related to infrastructure. The limited battery life of mobile phones combined with the lack of readily available electricity made it difficult to keep the phones charged. CHVs reported initial anxiety as first-time mobile phones users, including concerns about using the IFA app. With time, increased levels of confidence were seen.

Conclusions: Acceptability was high with both CHVs and caregivers, who reported an improvement in their client-provider relationship. A number of feasibility challenges were experienced.

KEYWORDS

child health; child development; monitoring and evaluation; parent support; mHealth

Introduction

Background

Early childhood is a critical period in human development [1]. Strong causal evidence suggests that delayed or disrupted early development has long-term negative consequences for children. Impoverished nutritional, emotional, and cognitive circumstances result in risks for ill health, as well as social and psychological difficulties in adulthood [2]. In response, increased efforts are being carried out globally to protect and promote children's early experiences. These initiatives, aimed at supporting early development, typically take place at health facilities, early child development centers, or through community health volunteers (CHVs) [3,4]. The role of CHVs varies, but typically they are responsible for strengthening the links between the community and health services. Primary responsibilities of CHVs in Kenya include the identification and registration of pregnant women and their young children, assisting in the registration of births, monitoring child growth and vaccination schedules, and reporting notifiable diseases and deaths [5].

Community and home visitors can play a critical role in addressing gaps in the coverage of health services by relaying health education messages, conducting basic health assessments, and providing referrals. However, in reality, they seldom have the tools, support, and feedback required to carry out these functions. Even when data are immediately available, for example, when measuring a child's height or weight, CHVs do not traditionally have the knowledge or skill to interpret the measurements and data in relation to the child's age or gender, nor do they necessarily have training in what feeding, nutrition, and health care recommendations to make on the basis of the measurement [6]. In addition, their core function ends up shifting away from the above, primarily toward data collection for donors and government, with no clear benefit perceived by CHVs or families. Under these conditions data quality suffers, further reducing the likelihood that data will be able to be used meaningfully or for quality improvements [7]. A key challenge identified in many programs (both governmental and nongovernmental) is the almost exclusive focus on collecting data on field activities and outputs and sending this information upward to governmental and nongovernmental stakeholders—often located at a distance from the data collection sites. The underutilization of monitoring and evaluation data is generally attributed to top-down designs for routine reporting rather than a focus on learning and improvement of existing systems [5]. There are usually few systems in place which would enable front-line workers and their supervisors to use the data they collect to improve their performance.

In light of the above, this paper reports on a field test of the Information for Action (IFA) mobile phone app developed by a team at the Human Sciences Research Council (HSRC) in

South Africa. The app was designed to use CHV data collection activities as an opportunity to provide useful information to families and caregivers about their children's development.

Information for Action App

With a view to transforming some of the challenges outlined above, we prototyped and developed an easy-to-use mobile phone IFA app that can simultaneously collect data on growth and child development and provide tailored information and targeted messages to parents and other caregivers, health and social community-based service providers, workers and volunteers, case managers, program managers, and funders.

Harnessing mHealth solutions in the support of maternal and child health is not a new idea. Launched in February 2010, Text4baby, for example, has gained wide media attention, winning awards from the United States Office of Science and Technology in 2010 and the Public Relations Society of America in 2011. The Text4baby program uses the health belief model to support mothers through prenatal care text messages [8]. More recently, a consortium of partners including Johnson & Johnson, United States Agency for International Development, United Nations Foundation, and the mHealth Alliance created an alliance to improve maternal health by leveraging mobile technology to deliver health information to mothers in India, South Africa, and Bangladesh [9]. A number of mobile phone-based data collection apps are also available that facilitate the collection of data in low-resource settings [10-13]. A multitude of studies review and test mHealth apps designed to collect health data and provide feedback for the self-management of chronic disease [14-17].

A review of mHealth apps in low- and middle-income countries (LMICs) found that the majority of apps still focus on only one of the following areas: data collection, education, communication, or information sharing [18]. Apps targeting LMICs that integrate multiple functionalities do exist, but resource-limited environments present an additional challenge with the low availability of high-speed, stable, mobile Internet [19]. The implication of this is that all data processing and decision support needs to reside on the device rather than on a central server. This study adds to this growing body of literature by examining the acceptability and feasibility of the maternal and child health IFA app, which was designed specifically for women and young children living in LMICs.

Participants

The IFA app was piloted in the West Katweng'a sublocation of Rarieda Subcounty in western Kenya. The community-based organizations (CBOs) in this sublocation had 10 CHVs under their supervision. All 10 were invited to participate in the study. No new CHVs were hired or trained for the purposes of the field test. All CHVs were already working in the area and were familiar with the terrain and households in their catchment area. No direct financial incentives were offered for participation.

However, the CHVs participating in the field test were allowed to purchase the phones used in the study by paying a price that was well below market value (4500 Kenyan Shillings or US \$50 at the time of the study). In the local context, this was still a high price, as CHVs are currently (2017) paid 2000 Kenyan Shillings a month for their work in the same sublocation. A total of 16 caregivers, selected at random from among the households visited by the CHVs, were also contacted after the study period and invited to participate in 1 of 2 caregiver focus group discussions.

Methods

Information for Action App

The IFA app includes a child growth and development assessment function, which produces useful information that is provided to parents, caregivers, and front-line home visitors providing community-based services. At the same time as pushing data for action down to where it matters most, the information is also aggregated and stored on a central server where it can be used for timely training and supervision of community-based service providers and adjustments to program implementation.

For illustrative purposes, we selected 2 critical domains for monitoring young children's development—growth (height and weight), a proven measure of both child well-being and development [14], and a measure of psychosocial development (Figure 1). The World Health Organization (WHO), which sets guidelines on child development milestones, provides standardized growth charts by age for gender [15]. These standards were embedded in the IFA app for reference. Although specialized equipment is needed for gold-standard growth monitoring, an inexpensive bathroom scale that can be calibrated and a stadiometer (or measuring tape) is used in this context of home- and community-based service delivery.

Psychosocial development is assessed with the Ages and Stages Questionnaire, Third Edition (ASQ-3), a widely used early childhood development tool that was tested for applicability in the context [16]. The ASQ-3 is an easy to use, reliable, and valid screening instrument to identify potential developmental delays among children aged 2 months to 5 years. It taps into 5 domains of children's development: communication, gross motor, fine motor, problem solving, and personal-social, with each domain consisting of 6 developmentally appropriate items at 21 time points. Caregivers respond to each item by selecting yes, sometimes, or not yet (see Multimedia Appendix 1).

Using the IFA app, a community-service provider inputs identifying information about a child which can be anonymized at any level of data output. For example, name, photograph, date of birth, gender, location, and other required social and demographic information would be added. Age-appropriate items and reference standards are retrieved from the IFA app database, and the items are displayed for completion by the CHV and caregiver. Collected data are compared to norms by the app, and immediate feedback is provided to caregivers and parents about their child's growth and development using simple messages and diagrams (for example, a range of smiley faces

that indicate good vs potentially problematic development). Feedback is then generated in the form of simple, targeted counseling messages relevant to the specific child. The messages were extracted from international feeding guidelines based on recommendations by the Indian Academy of Pediatrics [17] and the WHO–United Nations Children's Fund Care for Child Development Package [18] (see Figure 1 D and Multimedia Appendix 1). Historical information for the child is stored, and longitudinal assessments are available to CHVs to track and demonstrate progress through time. Additional information such as a map of the households under the care of the CHV and an indication of the length of time since their last visit are also available (Figure 1 C).

Procedures

The field test used 14 mobile phones donated by Google, running on the Android platform. Ten phones were provided to the CHVs for implementation during the field test, and 4 were given to their supervisors. For the purpose of the field test, the app contained 2 child development tools. The first tool was based on a modified version of the ASQ, and the second included 9 questions based on indicators collected by CHVs in Kenya as part of routine household visits (Multimedia Appendix 2).

A training-of-trainers approach was adopted to train the CHVs. First, a team from the HSRC met with and explained the study and IFA app to the Rarieda District Health Management Team (DHMT) to build their capacity as trainers. Thereafter, 3 members of the Rarieda DHMT and the Community Health Extension Workers (CHEWs) of West Katweng's sublocation trained CHVs over the course of 2 days. The training curriculum included instruction on the use of mobile phones and on the specific use of the app. The curriculum also included a mix of both theory and practice sessions, such as role-plays involving CHVs using the app in mock household visits.

The CHVs were then asked to use the app as part of their regular home visits between May and September 2014. Each home visit took between 45 and 60 minutes depending on the amount of feedback that was required. During this 5-month period, the research team made 3 visits to the site in order to provide feedback and support to the CHVs and their managers. An information and communication specialist from the DHMT also volunteered time to troubleshoot any technical issues that emerged during the study. CHVs were expected to visit each household in their catchment area at least once a month. The growth indicator tool was completed at each visit and the ASQ-3 completed on every second visit to allow the child opportunity to progress to the next ASQ age range.

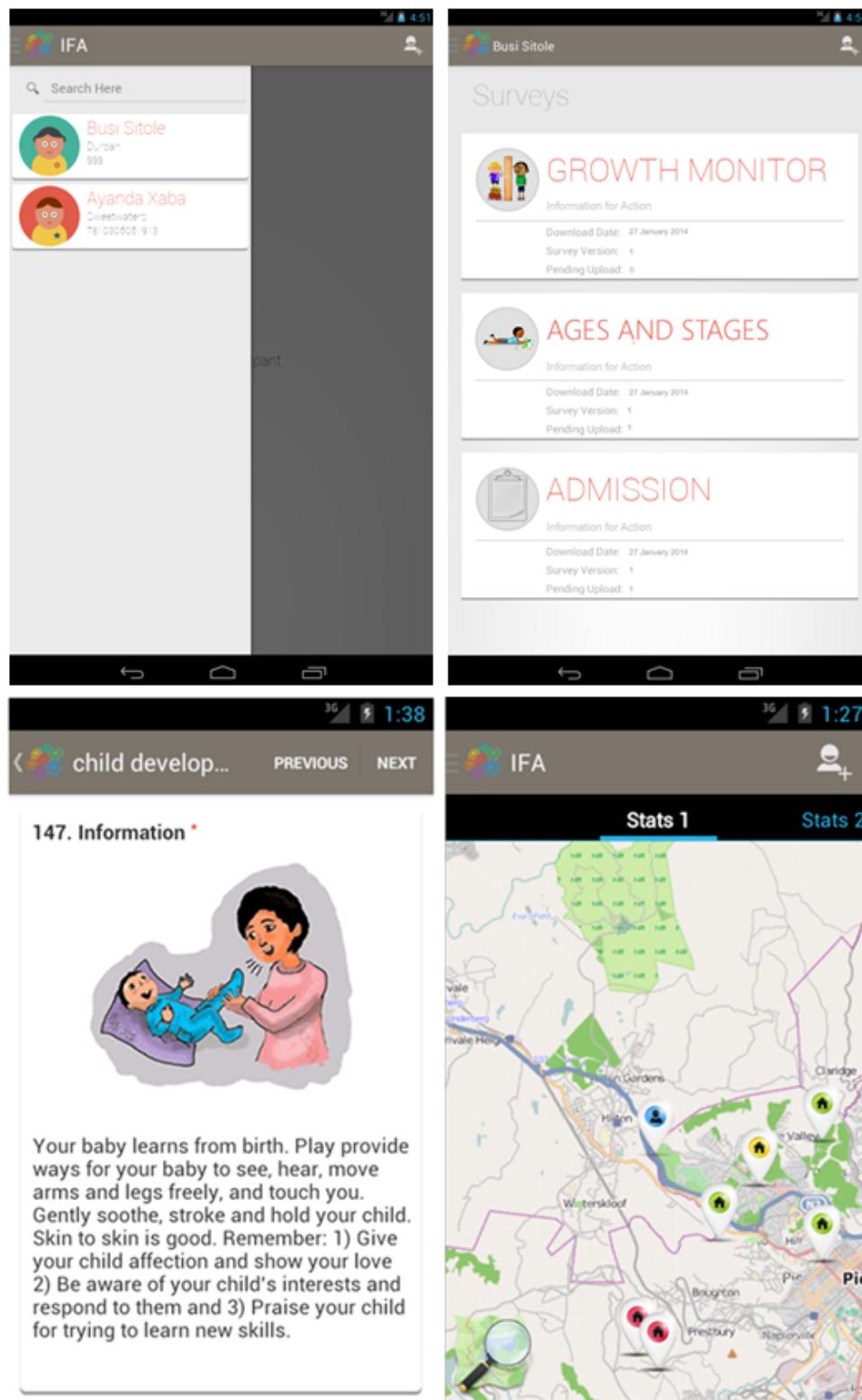
Institutional review board approval was obtained in Kenya from the Ethics Review Committee of the Jaramogi Oginga Odinga Teaching and Research Hospital (accreditation number 01713) and in South Africa through the HSRC's Research and Ethics committee (REC 22/19/02/2014). All participants were required to provide their written informed consent. If the participant was illiterate, best practice was followed and a trusted literate family member or friend was asked to participate in the consenting process and ensure all information was provided accurately before the participant signed or made their mark.

Data Analysis

All conversations were audiotaped, transcribed, and translated for thematic analysis [20]. Informed by the literature and the preliminary analysis of transcripts, a coding framework was developed. Following this step, the codes underwent another

phase of thematic analysis [21] using Atlas Ti 7.5 (ATLAS.ti Scientific Software Development GmbH) software. Two researchers manually analyzed conversation transcripts. If codes were inconsistent, consensus was reached after reanalyzing the transcripts.

Figure 1. From top left clockwise, the screen shots illustrate (A) selecting a participant, (B) selecting an assessment domain, (C) community-based mapping, and (D) caregiver feedback.



Results

Overview

The 10 CHVs collected data on 313 children living in 140 households in Rarieda. Children ranged in age from 2 to 8 years with a mean age of 5 years and 2 months. Just under half (149/313, 47.6%) of the children and the majority of caregivers (123/140, 88.1%) were female. Focus group participant demographics are provided in [Table 1](#).

Acceptability

Training and Uptake

Overall, CHVs and caregivers reacted positively to the app. In particular, CHVs were enthusiastic and excited about the use of both the mobile phone and the app. In the beginning, learning how to use the functionalities of a mobile phone (eg, using a touch screen and selecting apps) proved challenging for several CHVs. Given their initial discomfort with using a mobile phone, CHVs also felt that using the phone for counseling caregivers was slower compared to using paper-based tools. With time and support, CHVs gradually became more confident in using mobile phones. They felt the number of questions provided by the app was optimal, with some respondents mentioning that they would be comfortable with more questions added to the survey. A common perception was that the use of the app reduced the need to carry around heavy counseling materials. Due to its ability to convert collected data into actionable information, respondents felt that the app helped CHVs to remember key messages.

The phone is the way to go, some CHVs used to forget some information that was important and that was supposed to be passed to the caregivers. The phones nowadays have all the information and it is not possible to forget something. [Caregiver, FGD]

Increased Level of Confidence

The improved quality of home visits together with the possession of a fairly sophisticated phone and the ability of CHVs to use them for their work raised the profile of CHVs within their communities.

It [the app] gives feedback depending on how you talk to the caregiver, it gives you specific response and this has built a lot of confidence. [CHV, FGD]

Some caregivers mentioned a change in their own attitude toward home visits.

My attitude changed because now I get their help more than it used to be. One used to harass me so much but now...they ask me questions from the form. I have now loved their work. [Caregiver, FGD]

Improved Communication and Behavior Change

A consequence of increased caregiver satisfaction and acceptance toward CHV home visits was an increase in self-reported uptake of desired behaviors and practice.

The advice I received from the CHV helped me a lot. I used not to use nets, I used to buy mosquito coils but upon the advice of the CHV I started using nets. [Caregiver, FGD]

The question-and-answer format of the app was found to facilitate interactive dialog during home visits.

What I think is that the CHVs go beyond what they want from the caregivers. They can ask how you are doing, how the children are doing. [Caregiver, FGD]

This shift toward an interactive dialog held other benefits for caregivers.

I was so happy because it gave me the knowhow; I was enlightened by the data collection process, which was also a learning process. [Caregiver, FGD 2]

Feasibility

Feasibility challenges were experienced. Most had to do with the infrastructure required to keep phones operational and linked to the Internet.

That is a big challenge to us I think, because like since yesterday, I have not been able to charge my phone and that is very difficult. I may just continue asking for help from others who have electricity. Even one of my colleagues has electricity and I just charge there. Our CHEW [Community Health Extension Worker (supervisor)] told us that there is a solar charger for ksh. 900 that we can purchase and use it during data collection; can we be given any support from you guys so that we can buy this charger that can hold power for a long time. [CHV, FGD]

While decision support was available offline, CHVs reported experiencing challenges when it came to trying to upload data.

I have enjoyed using this phone, these days I read news over the phone, anything I need I find it online, the other day I got some information from Wangapala in south Nyanza and that was very good to me. I also take photos using this phone and I think it's a good phone. The negative side of this phone is that, if you carry it like that and you want to use it, it 'hangs' a lot and sometime you want to send data and the phone 'hangs' a lot. [CHV, FGD]

After these initial challenges, the Rarieda DHMT offered their support by providing technical assistance to the CHVs through their information and communication technology (ICT) specialist. The inclusion of specialized support had a significant beneficial impact on the implementation of the field test. CHVs mentioned seeking the ICT specialist's assistance from time to time to troubleshoot issues with running the phone and the app.

...it was like starting to learn how to walk, but with continuous mentorship they have absorbed how to use the smart phones and my assessment is that they now like to use them. [CHV, FGD]

Table 1. Demographic details of focus group discussion participants.

Characteristic	CHV ^a (n=10)	Caregiver (n=16)
Age, years, mean (SD)	33 (7.7)	26 (10.1)
Gender, n		
Female	7	13
Male	3	3

^aCHV: community health volunteer.

Discussion

Principal Findings

The IFA app was developed and piloted as part of an effort to enable community-based program staff to both access the data they collect as part of routine monitoring and provide on-the-spot counseling messages and guidance. This was a significant advancement on the parallel systems present in many of the mHealth apps designed for LMICs at that time (ie, the collection of data and the delivery of messages through short message service). Currently, the app is able to convert growth measurements into field-usable data, provide child development assessments using the ASQ-3, and deliver care and feeding messages appropriate to the assessment. We have also developed field management tools that facilitate improved planning and supervision of the work responsibilities of community-based service providers.

The pilot indicates good reception and use of the app by community-level workers, their supervisors, and the health management team. In addition, qualitative follow-up with a small group of mothers and other caregivers who received home visits during which the app was used reported that they felt they received more targeted assistance and had more confidence in the CHV. Functions of the app that were particularly appreciated by all stakeholders in this field test (beneficiaries, service providers, and supervisors) were the ability of the app to facilitate dialog during home visits and the ability of the app to convert routinely collected data into actionable information and facilitate use of data for decision making at the point of data collection. The app thus addresses common gaps in community health services in low-resource settings. These two functions need to be emphasized in future projects involving the app. These advantages should be weighed against the potential negative consequences of moving data collection to a mobile app. One clear risk is that these data, if stored online, could be accessed, stolen, and leaked or sold. If sensitive data such as

the caregiver name, contact number, home Global Positioning System coordinates, and HIV status were included in the dataset, it could be used to extort money from the caregiver. Some feasibility challenges remain, but they are not insurmountable. For example, purchasing solar-powered chargers as a one-off investment can help mobile phones remain consistently charged without having to incur recurring expenses of charging phones at a commercial charging station. Network coverage is improving at a fast pace as demand for and uptake of mobile phones increases in African countries and elsewhere. Also, in resource-poor environments data is becoming cheaper. Further pilot work will address the challenges identified and explore the use of the app by mothers and other caregivers themselves to monitor their own child's growth and development and to report on indicators tracked by local health and social services.

Limitations

This study has 3 main limitations. First, the IFA app was only tested for feasibility and acceptability with a small number of CHVs and caregivers. It is not possible to draw broad conclusions on how other CHVs in Kenya would view the app. Second, the donated devices were a few years old, and the poor battery life experienced may partially be due to this fact. Testing the app using recently purchased mobile phones may improve the user experience. Finally, longitudinal data was not available to support the qualitative findings of improved counseling and subsequent outcomes.

Conclusion

Data collection instruments are often designed as a 1-way process. Questions are asked of participants and their answers extracted for aggregation and analysis. We show in this work that the process can be reimagined as a bidirectional engagement. Using the IFA, it was possible to both collect data and provide feedback to participants about the growth and development of their child, resulting in improved CHV-facilitated dialog during home visits.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

App Ages and Stages Questions and Feedback.

[[PDF File \(Adobe PDF File\), 551KB - mhealth_v5i12e182_app1.pdf](#)]

Multimedia Appendix 2

Key indicator tool completed by community-health volunteers in the Information for Action app.

[[PDF File \(Adobe PDF File\), 45KB - mhealth_v5i12e182_app2.pdf](#)]

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Abbreviations

ASQ-3: Ages and Stages Questionnaire, Third Edition
CBO: community-based organization
CHEW: community health extension worker
CHV: community health worker
DHMT: District Health Management Team
HSRC: Health Sciences Research Council
ICT: information and communication technology
IFA: Information for Action
LMIC: low- and middle-income country
WHO: World Health Organization

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Original Paper

Usage Pattern Differences and Similarities of Mobile Electronic Medical Records Among Health Care Providers

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Abstract

Background: Recently, many hospitals have introduced mobile electronic medical records (mEMRs). Although numerous studies have been published on the usability or usage patterns of mEMRs through user surveys, investigations based on the real data usage are lacking.

Objective: Asan Medical Center, a tertiary hospital in Seoul, Korea, implemented an mEMR program in 2010. On the basis of the mEMR usage log data collected over a period of 4.5 years, we aimed to identify a usage pattern and trends in accordance with user occupation and to disseminate the factors that make the mEMR more effective and efficient.

Methods: The mEMR log data were collected from March 2012 to August 2016. Descriptive analyses were completed according to user occupation, access time, services, and wireless network type. Specifically, analyses targeted were as follows: (1) the status of the mEMR usage and distribution of users, (2) trends in the number of users and usage amount, (3) 24-hour usage patterns, and (4) trends in service usage based on user occupations. Linear regressions were performed to model the relationship between the time, access frequency, and the number of users. The differences between the user occupations were examined using Student t tests for categorical variables.

Results: Approximately two-thirds of the doctors and nurses used the mEMR. The number of logs studied was 7,144,459. Among 3859 users, 2333 (60.46%) users were nurses and 1102 (28.56%) users were doctors. On average, the mEMR was used 1044 times by 438 users per day. The number of users and amount of access logs have significantly increased since 2012 ($P < .001$). Nurses used the mEMR 3 times more often than doctors. The use of mEMR by nurses increased by an annual average of 51.5%, but use by doctors decreased by an annual average of 7.7%. For doctors, the peak usage periods were observed during 08:00 to 09:00 and 17:00 to 18:00, which were coincident with the beginning of ward rounds. Conversely, the peak usage periods for the nurses were observed during 05:00 to 06:00, 12:00 to 13:00, and 20:00 to 21:00, which effectively occurred 1 or 2 hours before handover. In more than 80% of all cases, the mEMR was accessed via a nonhospital wireless network.

Conclusions: The usage patterns of the mEMR differed between doctors and nurses according to their different workflows. In both occupations, mEMR was highly used when personal computer access was limited and the need for patient information was high, such as during ward rounds or handover periods.

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KEYWORDS

mobile applications; electronic health records; physicians; nurses; communication; rounds; patient handoff

Introduction

For health care providers, mobile phones are emerging as clinical tools comparable in value to the stethoscope [1]. They are handheld tools that can be transported in a pocket, carried anywhere, and helpful in collecting valuable patient information [2,3]. However, smartphones are tools that are more ubiquitous than a stethoscope. Moreover, they can be linked to the hospital information system to identify patient information, deliver clinical knowledge, and assist in clinical decision making [4-7]. Smartphones are expected to play a role as potential medical devices beyond their conventional use for communication between health care providers [7-9]. Mobile health, manifested in part by smartphone use, is changing the paradigm of medical care with its mobility, compatibility with other devices, and powerful computing capability [4-7,10-13]. Health care providers, as well as patients, are beneficiaries of mobile health through various devices and apps [14-17].

Among the various applications for health care providers, mobile electronic medical records (mEMRs) are expected to be a solution to the lack of mobility of personal computer (PC)-based electronic medical records (EMRs) [18-22]. Correspondingly, mEMRs enable health care providers to freely exchange patient information and decision-making content irrespective of time and place in a secure environment [11,12,15,22,23]. According to recent reports on the acceptance of mEMRs or its effects, the users were found to be satisfied with the performance, efficiency of workflow, and improvement of communication [7,11,12].

Although previous studies on mEMRs have reported positive technological prospects and potentials, the studies were investigated with the collections of subjective assessments via user survey [7,11,12]. Moreover, studies that analyze usage log data were limited to simple log data, such as log-in or log-out, or stationary data [11,12,22]. The evaluations of the location of user access, or the mEMR usage according to time, were insufficient in determining the inherent value of the mobility [1,11,12,15,22].

Additionally, the analyses for the differences of mEMR usage among health care providers were insufficient, although there are a lot of documented differences for workflows by doctors and nurses [24-26]. Typically, doctors are full-time workers, with a few night shifts in their work schedule. Decision making and treatment plans for patients are determined mainly during the morning rounds [27-29]. However, the nurses work in three shifts that are carried out even in the middle of the night [30,31]. The differences in information needs, working hours, and workflow will be revealed as differences in usage patterns [26]. EMRs specialized in nursing are efficiently used by nurses with

satisfaction [32]. Similarly, mEMRs require occupation-specific services. For more efficient use by each occupation in real-world practice, a detailed analysis of mEMR usage patterns and collection of related data are necessary.

In this study, we analyzed the usage pattern of health care providers and the wireless network access in the mobile environment based on mEMR data logs over a period of 4.5 years in an effort to overcome limitations of previous studies. Specifically, we investigated the peak time of usage and the differences and similarities in usage patterns between user types.

Methods

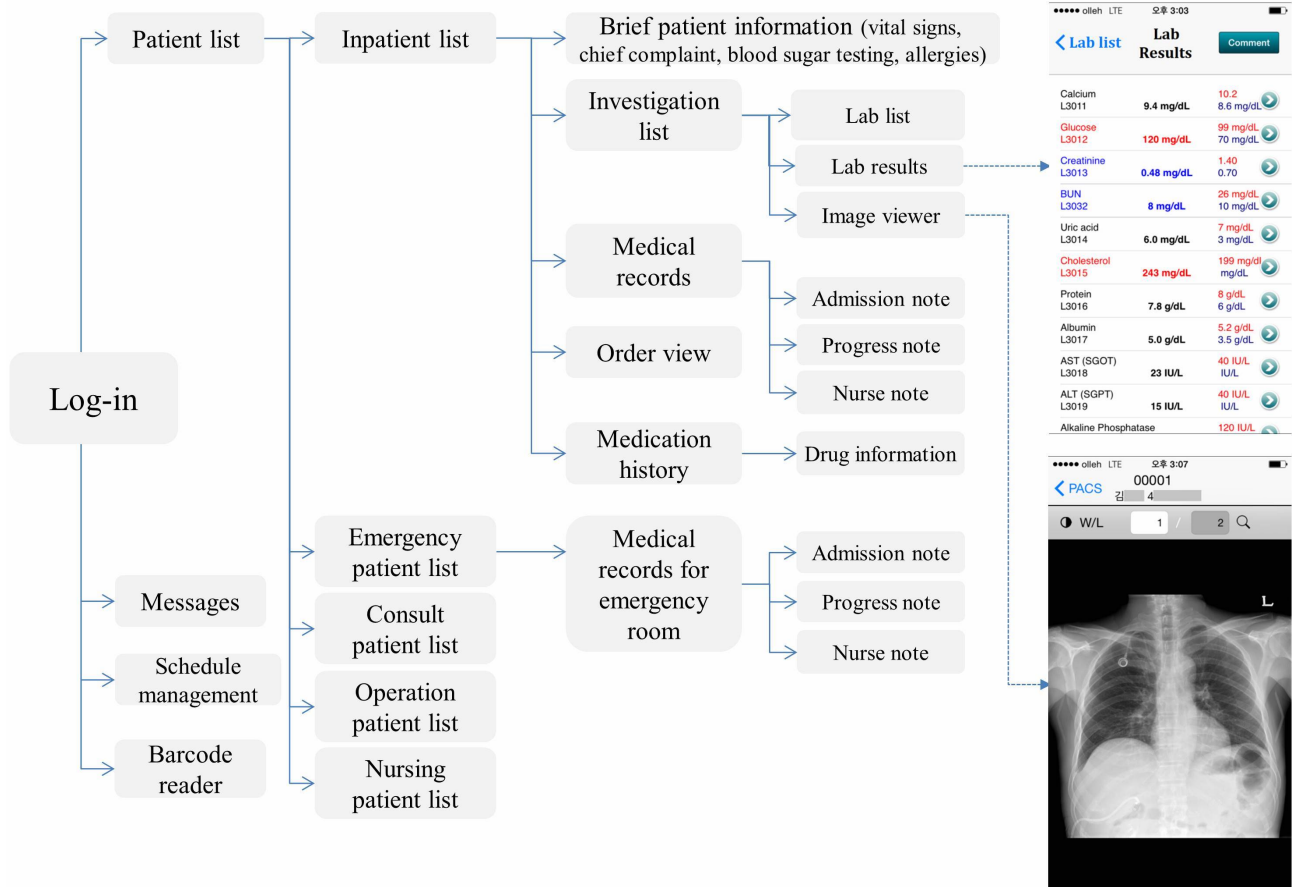
Study Design

To identify and verify the usage pattern of the mEMR according to time, user type, and wireless network, the mEMR usage log data were analyzed from March 2012 to August 2016. Usage log data were classified according to user occupations. Specifically, the analysis of the usage data determined the following: (1) the status of the mEMR usage and the distribution of users, (2) trends in the number of users and usage amount as a function of time (over a period of 4.5 years), (3) dissemination of 24-hour usage patterns (that exhibited differences based on yearly trends, trends based on user occupations, and usage patterns according to network access), and (4) trends in service usage based on user occupations. After analyzing the mEMR usage logs, the usage status of the system and the peak time usage between user occupations were described.

Study Subjects and the mEMRs

This study was performed at the Asan Medical Center (AMC), the largest medical center in South Korea with more than 2700 beds, including 205 beds in intensive care units. The average count of daily outpatient visit was more than 11,600, and the average count of daily emergency room visit was more than 300 in 2016. The total number of employees in 2012 was 7408 (doctors: 1614, nurses: 3249), which increased to 7921 (doctors: 1676, nurses: 3605) in 2016. Since its establishment, the hospital information system, known as the Asan Medical Information System (AMIS), has been actively used [33]. The mobile version of the AMIS, the mobile AMIS (mAMIS), was launched in November 2010 (Figure 1) [10,16,22]. The functions and menus were selected and developed after gathering the opinions of health care workers based on surveys. The mAMIS version 2.0 was launched in March 2012 with extended functions, particularly for the usage of nurses. Additionally, three regular and three minor updates have been performed from the time of the launching to August 2016 [16,22]. It was initially based on iPhone operating system (iOS, Apple Inc), but the Android version was launched in 2013 [16].

Figure 1. Function list and screen captures of the mobile Asan Medical Information System application. This application includes functions that allow viewing of all medical records, including medications, laboratory results, and images of radiologic studies.



Users can access patient information with the mAMIS in or out of the hospital based on implemented security and privacy systems. Using a certified user’s identification number and password, users could download the app from the app store of AMC via the hospital intranet (Wi-Fi network). Using JavaScript object notation, the app communicates with the hospital gateway server that controls direct access to the legacy database via device certification and encryption functions. Thereafter, the gateway server communicates with the legacy system (hospital information system) [8].

Collection and Analysis of Usage Data

All system event logs were automatically stored in the mAMIS database server with the information of the user occupation, the event time, access page, and Internet protocol (IP) address (Wi-Fi information). To check the status of the system usage, the mAMIS version 2.0 log data were retrieved collectively from the server. No personal identifiers were gathered. The IP address was used to determine hospital network access. Only the mAMIS version 2.0 log data were used because of the difficulty of interpretation of log data acquired by different software versions.

We investigated the log data to identify trends regarding the actual usage of the mAMIS, overall usage patterns, usage characteristics of certain user occupation groups, and Wi-Fi network access patterns. To characterize the trend of the mAMIS usage, we analyzed the log data using linear regressions, and

plotted the resulting trend lines in the corresponding figures. To determine the peak usage hour within a 24-h usage cycle, we investigated the time and usage amount of each local maximum point, that is, the point at which the value is greater than those of the adjacent points [34]. The differences between the groups were examined via a Student *t* test for categorical variables. All reported *P* values were two-sided, and *P* values less than .05 were considered significant. Data analyses were conducted with the R software version 3.3.1(The R Project for Statistical Computing).

This study was approved by the institutional review board of the hospital (IRB no. 2016-0287). The need for informed consent was waived by the ethics committee, as this study utilized routinely collected log data that were anonymously managed at all stages, including data cleaning and statistical analyses.

Results

User Characteristics

The mAMIS log data comprised 7,144,459 accumulated logs created by 3859 users between March 2012 and August 2016. Among the 3859 users, 2333 (60.46%) were nurses and 1102 (28.56%) were doctors. In 2015, the numbers of AMC doctors and nurses who used the mAMIS were 1882 and 3504, respectively, representing almost two-thirds of the health care workers (65.5% of the total number of doctors, and 66.6% of the total number of nurses). Other health care providers, such

as health care assistants (n=194), pharmacists (n=68), and other staff members in management departments (n=162), accounted for the remaining users. Among the doctors, more than half of the users were trainees, that is residents and interns (58.90%, representing a ratio of 649/1102).

Overall Usage Trend

The access frequency and number of users increased throughout the period of data collection (Figure 2). To ascertain whether the access frequency and the number of users continuously increased, linear regressions were performed to model the relationship between the time and access frequency, and the number of users. The access frequency and the number of users exhibited abrupt and significant increases over time (estimated slopes=23.03 and 29.33 for the number of users and access frequency, respectively, $P<.001$ for both variables). The

correlation coefficient for usage per month was high ($R^2>.9$) in all cases.

Hourly Usage Pattern According to User Occupation

Overall, the mAMIS was accessed, on average, 1044 times per day by 438 users. Of the 438 daily users, doctors accounted for 28.5% (125/438), and nurses accounted for 60.5% (265/438). When we examined the hourly usage according to user occupation, we found that on average, the nurses used the system 3 times more often than the doctors (60,481.9 vs 21,646.1) per day (Table 1).

The patterns of usage of the mAMIS between doctors and nurses were very different in terms of usage rates based on year and time (Figure 3). Initially, the use of mAMIS by nurses increased by an annual average of 51.5%, but the number of doctors who used it decreased by an annual average of 7.7%.

Figure 2. Monthly trends of the number of mobile Asan Medical Information System users and access frequencies from March 2012 to August 2016. The corresponding trend line and the correlation coefficient for usage per month present significant increases over time.



Table 1. Comparison of hourly wireless network access to the mobile Asan Medical Information System in according to user occupation.

Access count	Doctors	Nurses	Total
Total access, n (%)			
Hospital Wi-Fi	144,303 (42.24)	197,286 (57.75)	341,589
Nonhospital network	375,204 (23.02)	1,254,280 (76.97)	1,629,484
All wireless networks	519,507 (26.35)	1,451,566 (73.64)	1,971,073
Average access per hour (SD)			
Hospital Wi-Fi	6012.6 (4858.3)	8220.3 (3732.6)	14,232.9 (7161.2)
Nonhospital network	15,633.5 (7350.4)	52,261.7 (26,075.2)	67,895.2 (30,143.7)
All wireless networks	21,646.1 (11,660.8)	60,481.9 (29,431.8)	82,128.0 (35,393.1)
Minimum access period^a (times^b)			
Hospital Wi-Fi	541 (4-5)	1946 (6-7)	3710 (3-4)
Nonhospital network	2056 (3-4)	13,267(3-4)	15,323 (3-4)
All wireless networks	2668 (3-4)	15,772 (6-7)	19,033 (3-4)
Highest peak usage period^c (times)			
Hospital Wi-Fi	19,095 (8-9)	15,159 (12-13)	26,284 (8-9)
Nonhospital network	27,989 (7-8)	97,182 (20-21)	115,973 (20-21)
All wireless networks	46,739 (8-9)	108,276 (20-21)	130,920 (20-21)
Second peak usage period (times)			
Hospital Wi-Fi	11,124 (17-18)	12,309 (17-18)	23,541 (12-13)
Nonhospital network	22,906 (17-18)	87,509 (12-13)	105,435 (12-13)
All wireless networks	34,030 (17-18)	102,668(12-13)	128,976 (12-13)
Third peak usage period (times)			
Hospital Wi-Fi	8382 (12-13)	11,094 (20-21)	23,433 (17-18)
Nonhospital network	19,832 (21-22)	33,890 (5-6)	40,653 (5-6)
All wireless networks	26,308 (12-13)	38,710 (5-6)	46,552 (5-6)

^aMinimum duration (in hours) of user access during a 24-hour period.

^bTime presentation follows a 24-hour notation.

^cMaximum duration (in hours) of user access during a 24-hour period.

Figure 3. Annual trends in hourly usage of the mobile Asan Medical Information System. The access count for nurses increased by an annual average of 51.5%; however, for doctors, the access count decreased by an annual average of 7.7%.

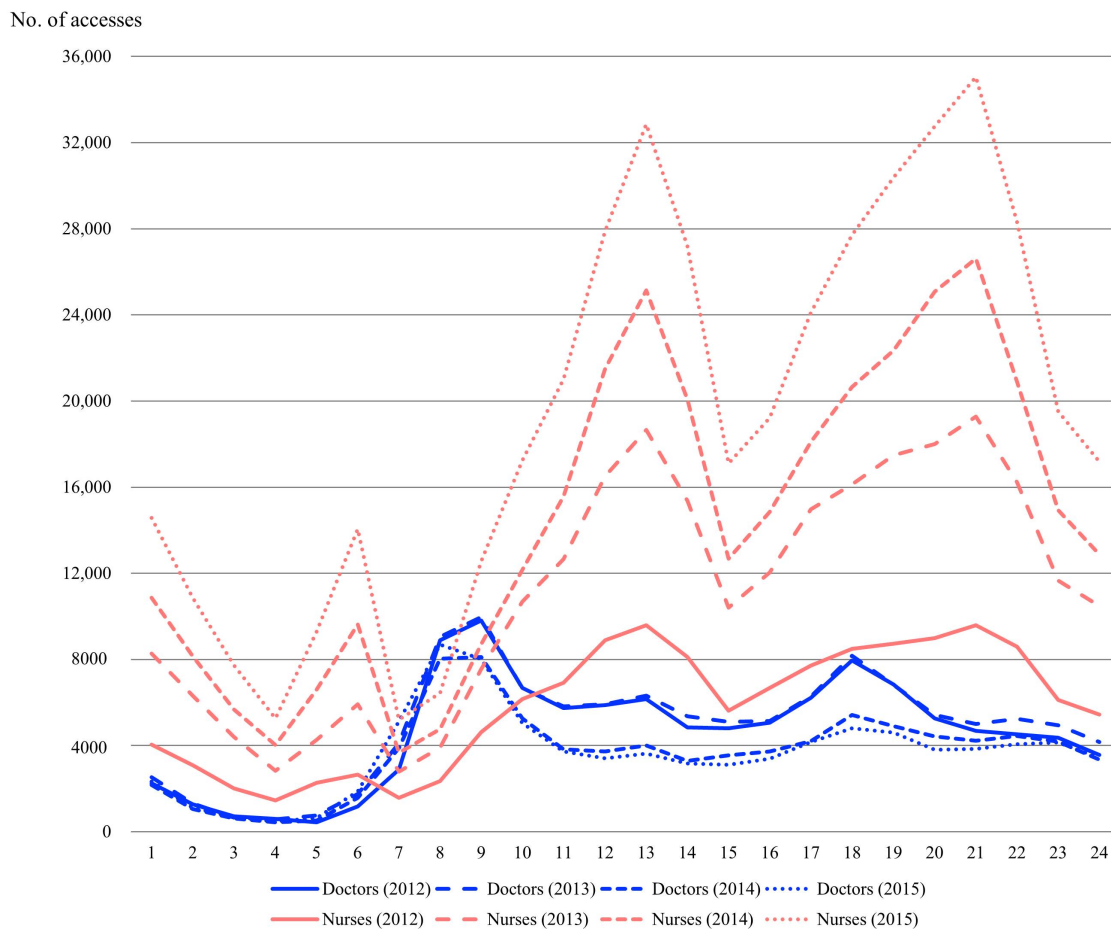


Figure 4 indicates that the peak use time differs in the case of doctors and nurses. Specifically, we analyzed the usage rates according to the time of the day and found that the peak usage periods were different for each occupation (Table 1; Figure 4). The time periods in which definite peak usage was observed for doctors occurred from 08:00 to 09:00 and 17:00 to 18:00, with two minor peaks observed between 12:00 and 13:00 and 21:00 and 22:00. Conversely, peak usage for nurses was observed between 05:00 and 06:00, 12:00 and 13:00, and 20:00 and 21:00. The peak usage periods for doctors overlapped with times for ward rounds, whereas the peak usage periods for nurses occurred 1 to 2 hours before the handover time in a three-phase rotation system beginning at 07:00. Among the doctors, the usage associated with the highest peak (08:00-09:00) was 2.2 times higher than the average usage (46,739/21,646.1). Among the nurses, the usage associated with the highest peak (20:00-21:00) was 1.8 times higher than the average usage (108,276/60,481.9).

Throughout the data collection period, the mAMIS was accessed 1,971,073 times via a wireless network (Table 1). According to the network log data, more than 80% of accesses occurred

via a nonhospital wireless network (1,629,484, 82.67%). Figure 5 illustrates the network access frequency of the hospital's Wi-Fi and other nonhospital networks according to time and user occupation. On the basis of the hospital's Wi-Fi use, there was no significant difference in access rates and averages between doctors and nurses (access rate: 42.2% vs 57.8%, average: 6012.6 vs 8220.3). Conversely, with nonhospital network use, nurses were found to access the system nearly 4 times more than doctors (access rate: 77.0% vs 23.0%, average: 52,261.7 vs 15,633.5).

Service Menu Usage Pattern According to User

Table 2 provides a list of highly ranked mAMIS services and frequencies according to occupation. The highly ranked services list shows that the doctors and nurses utilize different services. For doctors, the "inpatient list" service was highest in frequency, followed by "lab results" and "lab list" services. Over 60% of system usage comprised these three services. For nurses, the "order view" service was highest in frequency, followed by "nurse note," "nursing patient list," and "EMR view" services. Approximately 90% of system usage by nurses comprised these four services.

Figure 4. Hourly usage trends of mobile Asan Medical Information System according to user occupations.

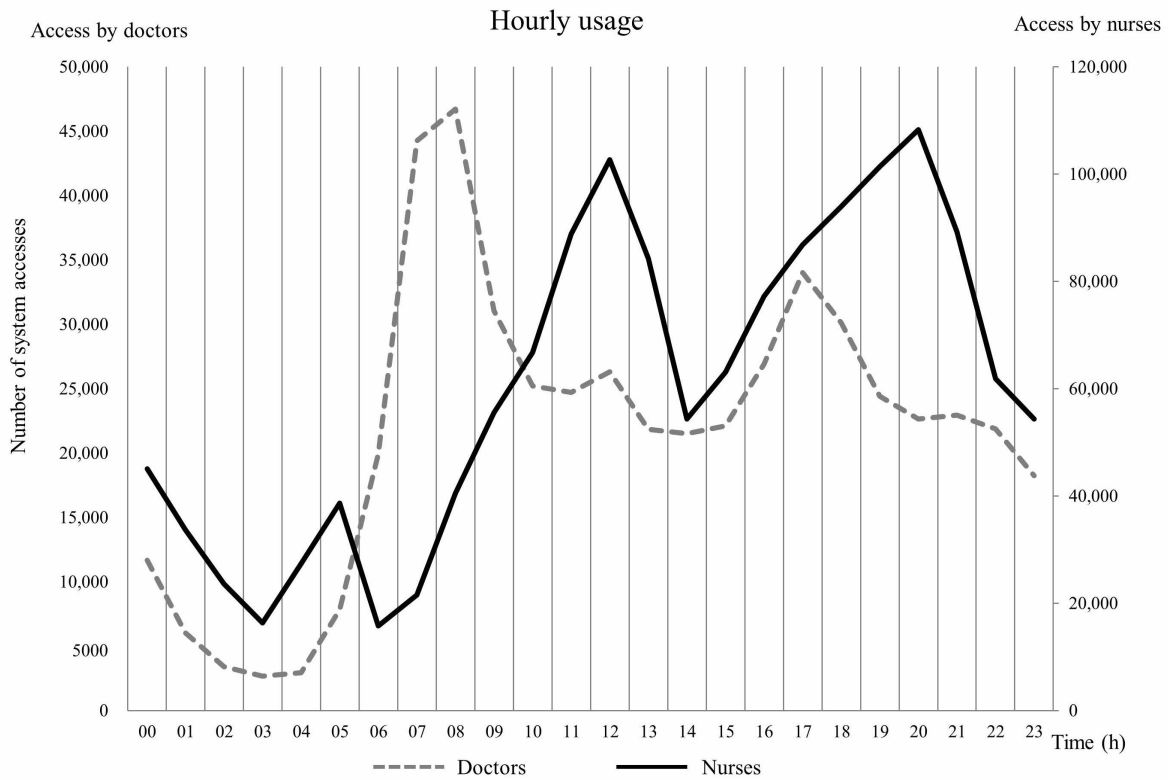


Figure 5. Network access frequency according to time and user's occupations for (a) hospital's Wi-Fi, and (b) a nonhospital network.

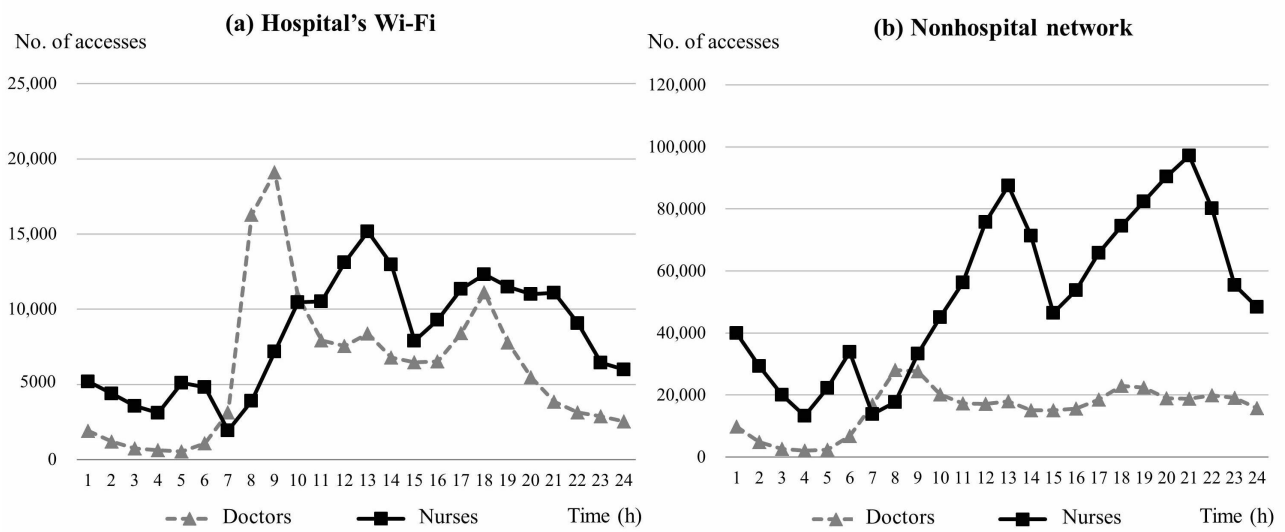


Table 2. Ranking of mobile Asan Medical Information System services based on user occupations.

Function list	Nurse		Doctor	
	Rank	Access frequency, n (%)	Rank	Access frequency, n (%)
Order view	1	1,322,717 (23.90)	9	46,491 (2.90)
Nurse note	2	1,229,581 (22.22)	6	84,532 (5.24)
Nursing patient list	3	1,183,876 (21.39)	14	0 (0.00)
EMR ^a view	4	1,096,258 (19.81)	4	134,721 (8.36)
Lab results	5	219,285 (3.96)	2	389,156 (24.14)
Lab list	6	142,787 (2.58)	3	201,535 (12.50)
EMR for ER ^b	7	87,077 (1.57)	10	27,670 (1.71)
Emergency patient list	8	85,549 (1.54)	8	48,705 (3.02)
Investigation list	9	53,235 (0.96)	5	128,507 (7.97)
Inpatient list	10	39,798 (0.71)	1	421,103 (26.13)
Operation patient list	11	28,859 (0.52)	12	23,976 (1.48)
PACS ^c viewer	12	28,193 (0.50)	7	74,680 (4.63)
Drug information	13	15,376 (0.27)	13	3333 (0.20)
Consult patient list	14	433 (0.00)	11	27,026 (1.67)
Total		5,533,024		1,611,435

^aEMR: electronic medical record.

^bER: emergency room.

^cPACS: picture archiving and communication system.

Discussion

Principal Findings

According to the analyses, daily users increased from 200 in 2012 to 438 in 2016. The number of users and connections steadily increased over time. The steady use of approximately two-thirds of all health care providers over a 4-year period implies that the mAMIS had been well implemented and used reliably. Additionally, the differences in working hours and workflow between user occupations (doctors vs nurses) were reflected in the usage patterns. The doctors used the mAMIS more during the morning rounds, and the nurses used it more before the handover time. In both occupations, the users intensively used the mAMIS at the time when communication and information needs were high.

Annual Usage Trends of the mAMIS

Compared with nurses where increase in usage was continuous, the usage by doctors decreased year by year. Although usage by nurses steadily increased at all time intervals, usage by doctors declined from 08:00 to 22:00, particularly between 2013 and 2014. The noted increase for nurses implies that the version with extended functions reflects user demands and leads to an increase in the actual usage. The first version of the mAMIS exhibited a higher proportion of doctor users than nurse users (doctors 66.0%; 416/630, nurses 31.0%; 195/630), and the percentage of users reversed in the early 2013. However, there was little difference in yearly usage by doctors from night time (10:00) to morning peak hours (08:00), which means that there

were essential demands in the morning, regardless of the number of floating users.

The second version of the mAMIS was upgraded on the basis of user surveys. If we consider an mEMR based on the concept of the personal digital assistant, which was launched in 2004 and accessed only twice a day on average, the access rate of the mAMIS has markedly increased (2 vs 82,217), whereas the number of health care providers in AMC increased 1.6 times during the past 10 years (5092/3195) [22]. The improvement of function reflecting user feedback is essential for the hospital information system, which also applies to mEMRs [35]. Moreover, the number of doctor users is expected to increase through service improvements.

Hourly Usage Pattern of the mAMIS

The peak usage periods of doctors overlapped with the starting times of morning and evening ward rounds (Figure 4). The highest peak occurred early in the morning when doctors evaluated the overnight events and the current status of patients before they began their rounds. The second peak occurred between 17:00 and 18:00, which was associated with most of the evening rounds. The two peak usage periods generally occurred when most of the doctors were actively moving through the hospital, and the access to patient information was needed to check the patient status. Timely usage of the mAMIS occurred during the peak hours, as the usage during the morning peak hour was more than twice as high as the average (46,739/21,646.1). This implies that the mAMIS has a unique value for doctors in assisting the preparation or execution of ward rounds.

The attendance of ward rounds necessitates the conduct of physical examinations, retrieval of patient information, and communication with other health care providers to make optimal decisions [27-29,36]. Because the ward round is such an active process, the most updated information should be exchanged, as doctors visit each patient [37]. Moreover, efficient information exchange and communication can lead to effective work and rational decision making [38,39]. Active users provided feedback via user surveys administered by the medical information office, indicating that they frequently used the system during rounds. However, it was not investigated whether the system was universally used during ward rounds.

The peak usage periods by nurse groups occurred between 05:00 and 06:00, 12:00 and 13:00, and 20:00 and 21:00. These time periods were 1 to 2 hours before handover times in a three-phase rotation system. The working patterns of the day-shift workers seemed to be reflected in the usage logs. The peak usage period and the use of a predominantly nonhospital network imply that users access the mAMIS while they are in transit to work. Additionally, the user survey revealed the mAMIS usage during commuting time. Correspondingly, the mAMIS possesses a unique role as a buffer between shifts, as the users prepare for the handover process during their spare time.

There was speculation that a flexible work time schedule can increase work efficiency; however, this cannot be applied to health care providers in a hospital [40,41]. An mEMR could compensate for the lack of flexibility, particularly for nurses who are obliged to adhere to a strict three-shift schedule. As a significant amount of information is exchanged within a short period of time during handover, checking information in advance could reduce the memory load. With the assistance of mEMRs, nurses can access the information of patients who will be under their care as they commute to work. This implies that nurses seemed to use the mAMIS as a tool for efficient workflow, particularly during the preparation for the handover. Moreover, as a successful handover influences patient safety, mEMR can improve patient safety, ensuring an efficient handover and reducing memory load [30,31,42]. Therefore, the development of specialized services that help nurses to precheck the tasks during the next shift could increase the usage by nurses.

Despite the extensive use of PC-based EMRs, there were several disadvantages [18-21,43]. PC-based systems are stationary, whereas health care providers are obliged to be mobile [19,43,44]. Furthermore, it can impede face-to-face communication [21]. For both doctors and nurses, the mAMIS was highly used in situations relevant to patient information access, and efficient communications were critical, such as ward rounds or handover. In addition, the peak usage time corresponded to the times when the users were actively moving. As the mAMIS was actively used during ward rounds or handover, mEMRs could fill in the gap between bedside and workstation, as well as promote work efficiency.

Wireless Network Access of the mAMIS

Nurses accessed the mAMIS using a nonhospital wireless network manifested by the overwhelming usage majority. The nonhospital network access pattern of the nurses was comparable with the total wireless access pattern. It means that the system

was used several times before or after regular business hours. As mentioned earlier, it is presumed that it was caused by usage during commuting time. Nurses accessed the system nearly 4 times more than doctors via a nonhospital network. Furthermore, more than 80% of accesses were via a nonhospital wireless network. This means that nurses did not use it much during their regular work.

Among the doctors, the amount of nonhospital network access began to increase compared with hospital Wi-Fi access, which was more prominent during the morning and evening peak usage periods. The hospital's Wi-Fi access pattern for the doctors was comparable with their total wireless access pattern, although nonhospital network access was more common. The third usage peak of the hospital's Wi-Fi that occurred during lunchtime implies the retrieval of information in a PC-free environment (Table 1). After the evening rounds, and up to midnight hours, negligible change in usage was observed via nonhospital network access (Figure 5). Nonhospital network access seemed to be used as a means of patient information access before and after working hours. This implies that because of the continuity of the patient care, doctors cannot be completely free of responsibility for their patients, even during off-duty time [42].

A low percentage of in-hospital usage means that the nurses did not sufficiently use the mAMIS during their work in the hospital. According to the studies showing that PC on wheels is efficient in rounds for nurses, nurses also have needs for mEMR in the hospital [45]. There is still plenty of room for improvement for in-hospital usage, such as new functions for nurse rounds. More efforts are needed to converge and reflect active user feedback, as the number of nurse users is growing.

The increased use of the nonhospital network by doctors may indicate the connections from outside, but it could be caused by troublesome hospital Wi-Fi. Nonhospital network access during regular work hours implies that doctors were reluctant to use the hospital's Wi-Fi. Hence, the immediate access to patient information is the key value for the mAMIS, and hesitation for use because of network accessibility is a critical drawback. Increased nonhospital network access suggests the need to provide a more accessible Wi-Fi environment by adding Wi-Fi access points and implementing Wi-Fi interference solutions.

According to the majority of the mAMIS usage that occurred through the use of the nonhospital network, it is important to maintain a high level of security and to strengthen the information protection policies. Building stronger protection and security mechanisms will enable mEMRs to be used in a safer environment for both occupations [46-48]. Moreover, an improved network environment will enable the mEMRs to be used in a timely manner, reducing the working time. Therefore, regardless of whether the mAMIS is accessed inside or outside the hospital, security should be concerned when a nonhospital network is used [15,46-48].

Usage Pattern According to Service Menus

The menus accessed by doctors and nurses were significantly different. Among the doctors, the most frequently accessed service was the "inpatient list," followed by "lab results" (Table

1). These results showed that checking real-time lab results is important, as it may require immediate action [37]. Moreover, this implies that easier access to the lab results of patients of special concern, such as patients in critical conditions, may facilitate a more efficient workflow [11]. With the exceptions of “inpatient list” and “lab list” functions, a gradual decline in the usage amount was observed. Additionally, the increased usages of “EMR views” and “nurse notes” among the doctors suggest the existence of the need to identify overnight events for the patients in their care, before the onset of routine work. Similar findings were observed in the case of the nurse group. However, because there was no information on time-service usage, it was not possible to confirm this assumption. Considering the increased usage of certain services during the peak periods, it would be helpful to add a quick menu option that is customized for rounds or shortcuts to frequently used menus.

Conversely, the usage logs from the nurse group showed increased utilization over specific services (order list, nurse notes, nursing patient list, and EMR views). The usage log count of the fifth most highly used service among the nurses, namely, “lab results,” equaled one-fifth of the fourth most highly used service (219,285/1,096,258), that is “EMR views.” Due to the nature of their work, “order view” seems to be the most frequently accessed menu option among the nurses. Among the top five menu options accessed by the doctors, “EMR views” was the only menu option that was also included in the “top four” menu options accessed by the nurses. This finding confirms the necessity for a more simplified but specialized service menu for nurses. Furthermore, it is necessary to actively develop useful menus for more practical use, considering that the use of menus among the nurses was limited, and that most of the services were accessed via a nonhospital network. Considering that there is increased use during the handover preparation, it would be helpful to develop a menu customized for efficient handover.

The mAMIS system should be used more frequently in clinical practice or point of care as was originally intended [22]. Diverse functions for use at bedside could be implemented, such as structured data entries for doctors, medication administration records for nurses, and barcode applications for patient identification. A user-customized service, or menu arrangement, could also facilitate task-oriented usages.

Limitations

As this study was performed with usage data from a single medical center, there are several limitations to extrapolating these results to all medical centers. First, most functions of the mAMIS are for reading or viewing, and not for writing or data entries. Analysis of mEMRs that contain balanced writing and viewing functions could be considerably different. Second, although access logs of menus were displayed, detailed usage logs were not analyzed because the user-specific access data were insufficient. If we could obtain such data, we would be able to investigate which users most often accessed the mAMIS, which menu options were most accessed during peak usage times, and so on. Third, active user surveys or interviews would be helpful to demonstrate our assumption; however, the pursuit of these studies was outside the scope of our study. The results of surveys on user perception and usage patterns, in addition to coordinating these results with actual log data, could provide definitive evidence of the value of the mEMRs.

Conclusions

The usage data of the mAMIS proved valuable for communication between health care providers and continuity of patient care. Although the usage pattern considerably varied between doctors and nurses, the mAMIS was accessed by users in circumstances of active movement. To improve the usability of the mAMIS, more user-centered service developments are required in addition to improvements to the user environment, such as a more accessible Wi-Fi network and increased security. Additional studies based on real-world data and clinical preferences should be considered to evaluate user satisfaction and the clinical implications of the mEMR.

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Conflicts of Interest

None declared.

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Abbreviations

EMRs: electronic medical records
IP: Internet protocol
mEMR: mobile electronic medical record
mAMIS: mobile Asan Medical Information System
PC: personal computer

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Original Paper

The QardioArm App in the Assessment of Blood Pressure and Heart Rate: Reliability and Validity Study

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Abstract

Background: Self-measurement of blood pressure is a priority strategy for managing blood pressure.

Objective: The aim of this study was to evaluate the reliability and validity of blood pressure and heart rate following the European Society of Hypertension's international validation protocol, as measured with the QardioArm, a fully automatic, noninvasive wireless blood pressure monitor and mobile app.

Methods: A total of 100 healthy volunteers older than 25 years from the general population of Ciudad Real, Spain, participated in a test-retest validation study with two measurement sessions separated by 5 to 7 days. In each measurement session, seven systolic blood pressure, diastolic blood pressure, and heart rate assessments were taken, alternating between the two devices. The test device was the QardioArm and the previously validated criterion device was the Omron M3. Sessions took place at a single study site with an evaluation room that was maintained at an appropriate temperature and kept free from noises and distractions.

Results: The QardioArm displayed very consistent readings both within and across sessions (intraclass correlation coefficients=0.80-0.95, standard errors of measurement=2.5-5.4). The QardioArm measurements corresponded closely to those from the criterion device ($r>.96$) and mean values for the two devices were nearly identical. The QardioArm easily passed all validation standards set by the European Society of Hypertension International Protocol.

Conclusions: The QardioArm mobile app has validity and it can be used free of major measurement error.

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KEYWORDS

blood pressure; heart rate; reliability; validity; mobile apps

Introduction

Blood pressure (BP) plays a major role in the development of cardiovascular disease, which is the leading cause of premature death worldwide [1]. For patients who have or are at risk for high BP, regular monitoring of BP is useful [1,2].

Successful BP management depends to a large extent on the patient's willingness and capacity to make certain lifestyle

changes [3]. As demonstrated in studies by the UK National Health System, self-measurement of BP is a priority strategy for managing BP [4]. Self-measured BP monitoring has many advantages. It enables diagnosis of hypertension or hypotension, helps patients control BP, improves therapeutic compliance, and minimizes the "white coat" and "masked hypertension" syndromes and observation biases caused by the health care professional being aware of the patient's characteristics during the measurement [5-8].

Figure 1. QardioArm is a device with a cuff used with an app for visualization of blood pressure known as Qardio.



Therefore, increased use of self-measured BP in the care of patients with arterial hypotension or hypertension could be beneficial. Recent clinical practice guidelines identified several indications for self-measured BP, which may provide for more standardized measurement of BP [5-17]. Today's powerful mobile technologies can greatly facilitate self-measured BP by giving individuals more control over their health and well-being than conventional clinic-bound medical devices and allowing clinicians to evaluate the patient's status and provide timely feedback remotely [18-28].

In a recent market study of mobile phone apps for managing hypertension, most were focused on health management. Only 14% of these Android and iPhone apps transformed a mobile phone into a BP measuring device [22]. QardioArm (Atten Electronic Co Ltd, Dongguan, China) is a device with a cuff used with an app for visualization known as Qardio [29] (Figure 1), and it may be a good alternative to enable self-measurement of BP by patients. None of these apps involved a BP cuff nor had any been validated against a gold standard. Only 3% of these apps were developed by health organizations, such as universities or professional organizations [18,20,22,23,25-28]. Nonetheless, consumers downloaded these apps for measuring BP and heart rate (HR) and evaluated them favorably, even though they had not been validated [22,24,26,30].

Self-measured BP devices are only useful and beneficial to the extent that they are user-friendly and accurate [6-9,11,13,14]. Self-measured BP devices should be validated by independent experts according to accepted protocols designed specifically for this purpose, such as those established by the British Hypertension Society [31], the Association for the Advancement of Medical Instrumentation [32], and the European Society of Hypertension (ESH) [33,34]. The ESH called for self-measured BP devices to be validated with the 2010 version of the ESH

International Protocol [35]. Accordingly, we evaluated the accuracy of self-measured BP and HR measurements obtained with one such mobile app, the QardioArm, with the ESH International Protocol.

Methods

We examined the concordance between two European Community-certified devices for measuring BP and HR in a study involving repeated measurements conducted in the city of Ciudad Real, Spain, between May and August 2016. The Clinical Research Ethics Committee of Hospital Clínico San Carlos in Madrid, Spain, approved this study (number 16/179-E). This study complies with the ethical principles of the Declaration of Helsinki [36], including amendments from 2000 to 2013.

Participants

We recruited 125 participants from the general population of Ciudad Real using snowball sampling, from May to August 2016. A total of 100 participants completed the study; 25 participants did not return for the second measurement. According to the ESH International Protocol [35], a minimum of one-third of the total number of participants must be men and a minimum of one-third must be women. The participants satisfied the eligibility criteria in the latest revision of the ESH International Protocol [33-35], which are as follows:

Inclusion criteria:

1. Demographic: men and women aged at least 25 years. Of the total number of participants, at least one-third must be men and one-third must be women.
2. Temporal and geographic: healthy adult volunteers able to attend assessments in Ciudad Real.
3. Clinical: ideal BP range of 90 to 180 mm Hg for systolic blood pressure (SBP) and 40 to 130 mm Hg for diastolic

blood pressure (DBP), and arm circumference of 220 to 320 mm.

Exclusion criteria:

1. Clinical: sustained arrhythmia, circulatory problems in which the use of a cuff is contraindicated, and/or pregnancy.
2. Cognitive impairment that leads to inability to follow instructions.

All participants gave their written informed consent to participate in this study.

Before recruitment, we calculated with the GRANMO sample size calculation program (Institut Hospital del Mar d'Investigacions Mèdiques, Barcelona, Spain) that a sample size of 125 would give 80% statistical power ($\alpha=.05$) and two-tailed test to detect a difference equal to or greater than 0.9 mm Hg in BP. This calculation was based on the assumptions of a standard deviation of 3.2 mm Hg [37] and a loss to follow-up rate of 20%.

Procedure

Participants visited the study site for two measurement sessions separated by 5 to 7 days. The first author (VMP) collected all the data. Both BP and HR were measured in the left arm. The central portion of the cuff was placed at heart level, with the bottom edge 1 to 2 cm above the elbow.

During the first session, each participant reported his/her sex and date of birth. Measurements were taken of the participant's weight (with an automatic digital scale), height (with a wall-mounted measuring rod), and arm circumference (with a tape measure at the midpoint between the acromion and olecranon). The participant then relaxed for 10 minutes before baseline BP and HR were measured with the criterion BP

monitor Omron M3 (HEM-7200-E, Omron Healthcare Co Kyoto, Japan) (Figure 2). Next, BP and HR were measured with the test device QardioArm only to confirm that the test device was working correctly on the participant (these were not included in analysis).

The rest of the first session involved seven BP and HR measurements, alternating between the criterion and test devices, with 2 to 3 minute intervals between measurements. The first, third, fifth, and seventh measurements were made with the criterion device; the second, fourth, and sixth measurements were made with the test device. The second measurement session involved the same series of seven measurements, with identical procedures carried out by the same researcher, which occurred on the same day of the week and at the same time after lunch, in the same room with identical conditions, as far as it was possible.

During measurements, participants were calm and quiet while sitting with their feet parallel and flat on the floor, their legs uncrossed, and their left hands resting palm side up on a flat surface. The room was maintained at an appropriate temperature and kept free from noises and distractions during the sessions [33,34].

Of the 125 participants who completed the first session, 100 also completed the second session. Our analysis focused on data from just these 100 participants.

Study Devices

The Omron M3 Intellisense was the criterion device used as a benchmark in our study. It has CE 0197 certification and has been validated by the ESH between the Omron M3 and a different criterion device with mean 1.7 (SD 3.2) mm Hg for systolic and mean -0.9 (SD 2.6) mm Hg for diastolic [36].

Figure 2. The Omron M3 blood pressure monitor.



The Omron M3 is a fully automatic BP monitor operating on the oscillometric principle. It has a range of 0 to 299 mm Hg for BP and 40 to 180 beats per minute (bpm) for HR. The cuff is inflated using an electric pump and deflated by means of a pressure release valve.

After each measurement, the SBP, DBP, and HR are shown on the Omron M3's LCD screen. The device can also display a symbol on the screen indicating an irregular heartbeat, which is detected during measurement of SBP and DBP.

The QardioArm app for mobile phones and tablets was the test device in our study. It has CE 0734 certification and is a fully automatic, noninvasive wireless BP monitor for measuring SBP, DBP, and HR in adults. The QardioArm also operates on the oscillometric principle and has an inflatable cuff, which is placed around the upper arm. The cuff is inflated automatically and deflated using a controlled pressure release valve. The cuff is suitable for an arm circumference of between 22 and 37 cm. The measuring range is 40 to 250 mm Hg for BP and 40 to 200 bpm for HR.

The QardioArm has an automatic screen with graphics and visuals to facilitate interpretation of the data. The monitor connects to the free Qardio app on any device with Bluetooth 4.0 that runs iOS 7.0 or later or Android 4.4 or later. It can be used with iPhones, iPods, iPads, Apple Watches, and Android mobile phones and tablets. The data are stored on the mobile phone or tablet and therefore the pattern of values over time can be viewed. The app can be configured to issue reminders and warnings, and the measurements and progress can be shared in real time with other users.

The QardioArm weighs approximately 310 g without batteries and measures 6.8 cm in width, 3.8 cm in height, and 14 cm in length, with the cuff closed. It requires four AAA batteries.

Statistical Analysis

All data were analyzed using SPSS version 19 (IBM Corp, Armonk, NY, USA). Statistical significance was set at $P < .05$.

We computed univariate summary statistics on participants' characteristics. Body mass index (BMI) was defined as weight in kilograms divided by height (in meters) squared. To assess whether the BP and HR variables were normally distributed, we conducted one-sample Kolmogorov-Smirnov tests, applying the Lilliefors significance correction. Significant probability values in this test indicate nonnormality.

To evaluate the reliability of the QardioArm, we computed the intraclass correlation coefficient (ICC) for comparing measurements taken within the same session (intrasession) and in different sessions (intersession) [38]. The participants were the groups in each ICC analysis. Each intrasession evaluation involved the three measurements obtained using the test device for a particular primary variable (SBP, DBP, and HR). We used the session means of a variable in calculating the intersession ICC.

We interpreted ICC values with the guide proposed by Landis and Koch [39]: ≤ 0.20 =slight agreement, $0.21-0.40$ =fair agreement, $0.41-0.60$ =moderate agreement, $0.61-0.80$ =substantial agreement, and ≥ 0.81 =almost perfect

agreement. We also followed the recommendations of Portney and Watkins [40], who suggested that an ICC of 0.90 or higher for clinical measurements indicates they are reliable.

We also calculated the standard error of measurement (SEM) for each intrasession and intersession primary variable. SEM values indicate the degree of error, with low values indicating low error. We used the SEM formula of the standard deviation multiplied by the square root of $(1-ICC)$. To identify systematic error over time, we also compared first and second session means on each primary variable with paired-sample Student t tests.

To determine the validity of the QardioArm, we compared the QardioArm measurements with those made by the Omron M3, using both the ESH's International Protocol for the validation of BP measuring devices and the Student t test. Following the ESH protocol [33,34], we computed the absolute values of the differences between successive pairs of the seven measurements in a session (second–first, second–third, fourth–third, fourth–fifth, sixth–fifth, and sixth–seventh). This gives three paired differences for each variable (SBP, DBP, and HR), participant, and session. We classified whether the paired differences were ≤ 5 , ≤ 10 , ≤ 15 , or > 15 mm Hg for BP and ≤ 3 , ≤ 5 , ≤ 8 , or > 8 bpm in the case of HR. The four levels of difference correspond to very accurate, slightly inaccurate, moderately inaccurate, and very inaccurate, respectively [33,34]. If the device passed during both sessions, it could be recommended for clinical use. If it did not pass during the second session, it could not be recommended for clinical use.

We compared the observed number of differences (out of 300: three paired differences for a variable \times 100 participants in a session) falling into these categories with the standards specified in the ESH International Protocol. There were two phases of this comparison. If a test device did not pass during the first session, the validation process was terminated. If it passed during the first session, the second session was started.

In addition to following the ESH International Protocol, we computed Student t test for independent samples to check whether there were differences between devices in BP and HR measurements. For these tests, we used the mean values of the three study variables obtained from both sessions for the different devices. We also compared the mean intersession differences for the two devices. Furthermore, we calculated the Pearson correlations between the devices for the mean participant values on the three primary variables [41].

Finally, we produced Bland-Altman plots [42] to display the agreement between the two devices. These plots show the difference between each pair of measurements on the y-axis against the mean of each pair of measurements on the x-axis.

Results

Table 1 shows the sociodemographic characteristics of the study participants ($N=100$). There were significant mean differences between men and women in weight ($P < .001$), height ($P < .001$), and BMI ($P = .009$), but no differences in age ($P = .10$) and arm circumference ($P = .08$). The Kolmogorov-Smirnov tests showed

that SBP ($P=.14$), DBP ($P=.20$), HR ($P=.20$), as well as weight ($P=.17$) and BMI ($P=.20$) were normally distributed

Table 2 shows the intrasession and intersession reliability results for the QardioArm. In every case, reliability was high for SBP, DBP, and HR, and there was no evidence of systematic error from one session to the next.

Table 3 shows the validity results for the QardioArm, with the Omron M3 as the criterion. The QardioArm passed both sessions of the ESH validation process for SBP, DBP, and HR.

Table 4 shows the comparisons between the devices in terms of mean values on the primary variables as well as the Pearson

correlations between them at the participant level. The two devices produced very similar mean BP and HR estimates. The differences in mean BP values for the QardioArm and Omron M3 were less than 2 mm Hg and the differences in mean HR values between devices were less than 0.1 bpm. All intrasession and intersession Pearson correlations were greater than .96.

Figures 3, 4, and 5 display the Brand-Altman plots for the BP and HR variables in the first session. For each variable and almost every participant, the difference between device means fell within the 95% confidence interval of all measurements. The plots for session 2 (not shown) gave very similar results.

Table 1. Sociodemographic and clinical characteristics of the sample.

Variables	Total group (N=100)		Male (n=37)		Female (n=63)	
	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range
Age (years)	52.2 (18.8)	25.0-89.0	52.3 (20.9)	25.0-89.0	52.2 (17.6)	25.0-83.0
Weight (kg)	76.2 (14.6)	49.5-125.1	84.6 (13.1)	65.3-125.1	71.3 (13.2)	49.5-102.4
Height (cm)	167.3 (8.1)	151.0-187.0	172.1 (7.1)	160.0-184.0	164.5 (7.4)	151.0-187.0
BMI ^a (kg/m ²)	27.1 (4.2)	18.9-38.2	28.5 (3.8)	22.2-38.2	26.3 (4.2)	18.9-37.7
Arm circumference (mm)	295.5 (35.2)	234.0-320.0	302.7 (33.9)	245.0-320.0	291.4 (35.6)	234.0-320.0
Baseline SBP^b						
Omron	130.9 (17.3)	88.0-180.0	136.0 (17.7)	101.0-180.0	127.9 (16.4)	88.0-167.0
QardioArm	128.3 (17.2)	87.0-178.0	131.9 (17.4)	100.0-178.0	126.1 (16.8)	87.0-168.0
Baseline DBP^c						
Omron	74.2 (10.0)	49.0-98.0	73.5 (11.7)	57.0-98.0	74.6 (8.9)	49.0-97.0
QardioArm	75.8 (10.8)	49.0-103.0	75.4 (12.3)	54.0-103.0	75.9 (9.9)	49.0-103.0

^aBMI: body mass index.

^bSBP: systolic blood pressure.

^cDBP: diastolic blood pressure.

Table 2. Intrasession and intersession reliability for the QardioArm in sessions 1 and 2.

Variable	Mean (SD)	Range	ICC (95% CI)	P value	SEM
Session 1					
Systolic pressure (mm Hg)	126.5 (16.1)	87.0-179.0	0.89 (0.84-0.92)		5.35
Diastolic pressure (mm Hg)	74.8 (10.3)	46.7-100.3	0.91 (0.87-0.93)		3.15
Heart rate (bpm)	71.4 (10.4)	53.3-100.7	0.92 (0.87-0.94)		3.00
Session 2					
Systolic pressure (mm Hg)	124.9 (15.8)	89.7-171.7	0.91 (0.86-0.95)		4.67
Diastolic pressure (mm Hg)	73.9 (9.6)	51.7-95.7	0.87 (0.82-0.90)		3.52
Heart rate (bpm)	70.1 (11.0)	44.3-96.0	0.95 (0.93-0.96)		2.53
Intersession					
Systolic pressure (mm Hg)	125.7 (15.3)	87.0-179.0	0.91 (0.87-0.94)	.09	4.73
Diastolic pressure (mm Hg)	74.3 (9.4)	46.7-100.3	(0.83-0.92)	.17	3.36
Heart rate (bpm)	70.7 (9.8)	44.3-100.7	0.80 (0.70-0.86)	.14	4.82

Table 3. shows the validity results for the QardioArm, with the Omron M3 as the criterion. The QardioArm passed both sessions of the ESH validation process for SBP, DBP, and HR.

	Category					Result	Mean difference \pm SD ^a
	5 mm Hg/ 3 bpm ^b	10 mm Hg/ 5 bpm ^b	15 mm Hg/ 8 bpm ^b	2/3 within 5 mm Hg/3 bpm ^c	0/3 within 5 mm Hg/3 bpm ^c		
	Session 1						
Required							
Two of ^d	219	261	288	N/A ^e	N/A	N/A	N/A
All of ^f	195	243	279	N/A	N/A	N/A	N/A
Observed							
SBP1 ^{g,h}	242	286	298	N/A	N/A	Pass	3.43 \pm 3.13
DBP1 ⁱ	277	295	299	N/A	N/A	Pass	2.43 \pm 2.35
HR1 ^j	265	287	297	N/A	N/A	Pass	1.60 \pm 1.92
SBP2 ^k	256	289	300	N/A	N/A	Pass	3.29 \pm 2.74
DBP2	266	295	298	N/A	N/A	Pass	2.79 \pm 2.86
HR2	272	287	295	N/A	N/A	Pass	1.61 \pm 1.99
Session 2							
Required	N/A	N/A	N/A	≥ 72 ^l	≤ 9 ^m	N/A	N/A
Observed							
SBP1	N/A	N/A	N/A	87	0	Pass	N/A
DBP1	N/A	N/A	N/A	95	0	Pass	N/A
HR1	N/A	N/A	N/A	90	0	Pass	N/A
SBP2	N/A	N/A	N/A	94	0	Pass	N/A
DBP2	N/A	N/A	N/A	95	2	Pass	N/A
HR2	N/A	N/A	N/A	93	0	Pass	N/A

^aSD: standard deviation.

^bFrequencies of paired measurements (of 300) within particular ranges.

^cFrequencies of participants (of 100) with measurements meeting certain criteria.

^d“Two of” means that two of the three conditions given in the same row must be met.

^eN/A: not applicable.

^f“All of” means that all three requirements given in the row must be met.

^gSBP: systolic blood pressure.

^hSession 1.

ⁱDBP: diastolic blood pressure.

^jHR: heart rate.

^kSession 2.

^lAt least two of the three pairs of differences for at least 72 participants must fall in the 5 mmHg category.

^mThe three pairs of differences of no more than 9 participants may fall outside the 5 mmHg category.

Table 4. Comparison of Qardioarm and Omron devices in mean estimates and correlations of individual means between devices.

Variable	Omron, mean (SD) ^a	QardioArm, mean (SD)	t-test <i>P</i> value	<i>r</i>	<i>P</i> value
Intrasession 1					
Systolic pressure (mm Hg)	127.34 (16.02)	126.47 (16.06)	.70	.983	<.001
Diastolic pressure (mm Hg)	73.66 (9.82)	74.78 (10.29)	.43	.984	<.001
Heart rate (bpm)	71.31 (10.29)	71.36 (10.42)	.97	.987	<.001
Intrasession 2					
Systolic pressure (mm Hg)	125.65 (16.02)	124.96 (15.84)	.76	.984	<.001
Diastolic pressure (mm Hg)	72.23 (9.08)	73.90 (9.61)	.21	.966	<.001
Heart rate (bpm)	70.12 (10.65)	70.05 (10.99)	.96	.987	<.001
Intersession					
Systolic pressure (mm Hg)	126.50 (15.47)	125.71 (15.30)	.72	.991	<.001
Diastolic pressure (mm Hg)	72.95 (8.90)	74.34 (9.43)	.29	.982	<.001
Heart rate (bpm)	70.72 (9.68)	70.70 (9.76)	.99	.993	<.001

^aSD: standard deviation.

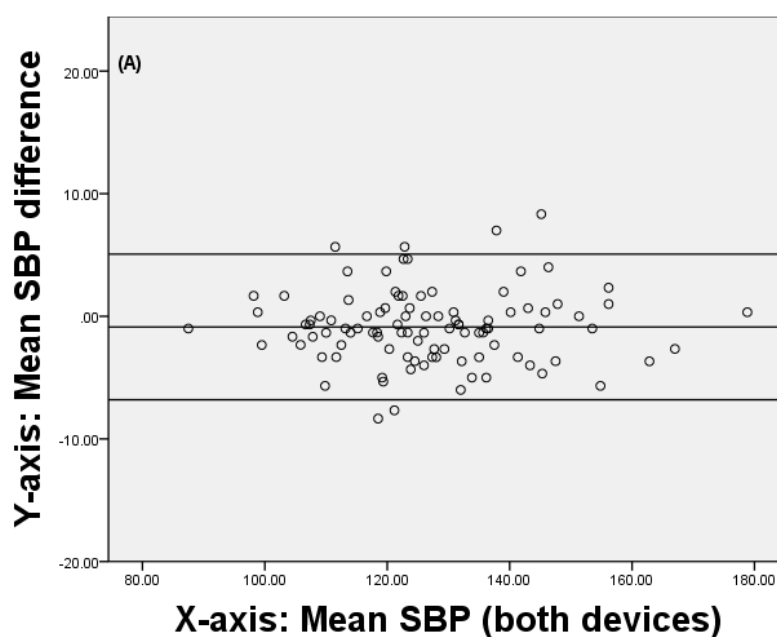
Figure 3. Bland-Altman plot comparing QardioArm and Omron devices for systolic blood pressure (SBP), for individual participants in session 1.

Figure 4. Bland-Altman plot comparing QardioArm and Omron devices for diastolic blood pressure (DBP) for individual participants in session 1.

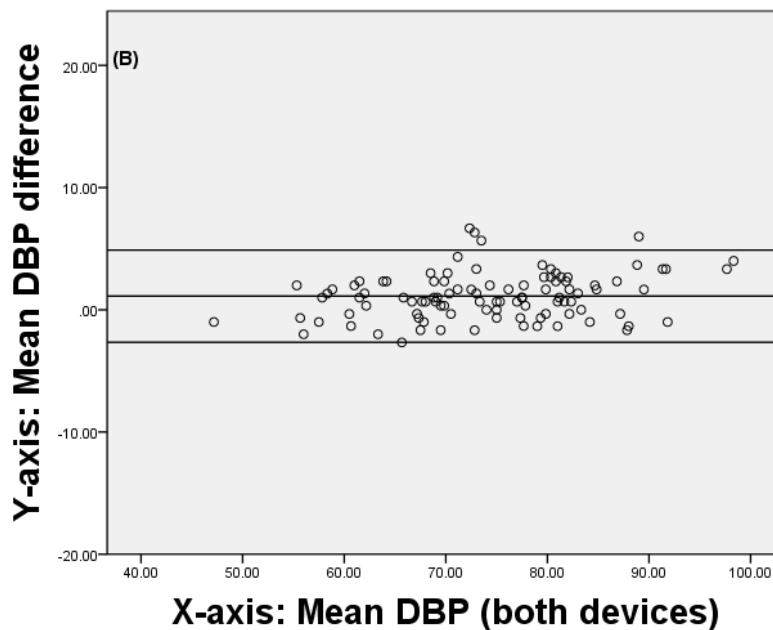
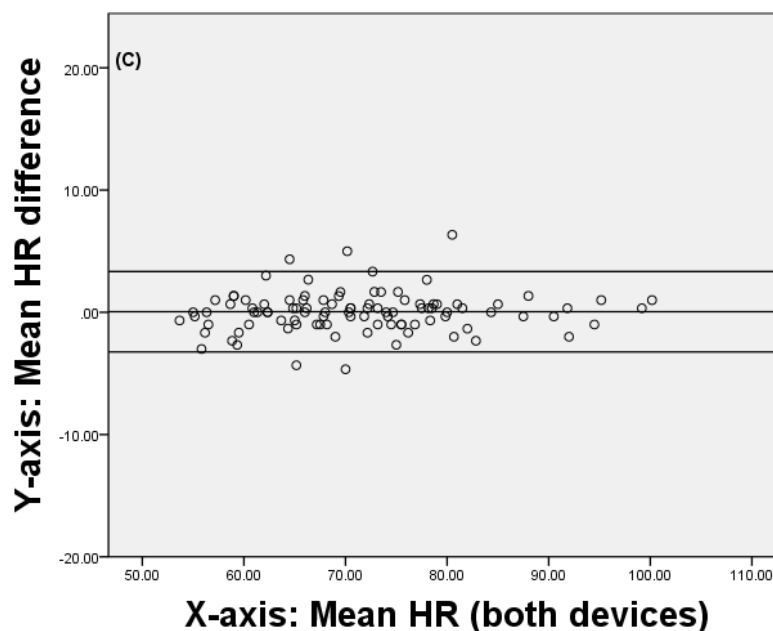


Figure 5. Bland-Altman plot comparing QardioArm and Omron devices for heart rate (HR) for individual participants in session 1.



Discussion

The QardioArm is recommended by dabl Educational Trust, which is an organization that provides an interpreted one-page BP report for the medical team and patient [43], but there are not any validation studies on the QardioArm published in a peer-reviewed journal. Recently, a study compared QardioArm with three other mobile phone-compatible BP measuring devices using a handheld aneroid sphygmomanometer as the reference device [44], but the study did not follow the ESH International Protocol.

We evaluated the reliability and validity of the QardioArm device for self-measured BP with 100 participants in two

measurement sessions. The QardioArm displayed very consistent readings both within and across sessions. The QardioArm measurements corresponded closely to those from the previously validated criterion device, the Omron M3. The QardioArm easily passed all validation standards set by the ESH International Protocol. Therefore, the QardioArm can be recommended for clinical use in individuals with similar characteristics to those who participated in this study, such as adults aged 48 to 56 years with a BMI between 25 and 29, not pregnant, and without cardiac arrhythmia, vascular problems, or arteriovenous fistulas in the arm.

There are several limitations of the ESH International Protocol and, thus, our study. The ESH International Protocol uses the

same validation requirements (eg, ≤ 5 mm Hg difference indicating accuracy) for both SBP and DBP, even though the magnitude of diastolic values is usually half that of systolic measurements.

Also, HR as a parameter is not considered in any version of the ESH International Protocol despite the fact that automatic sphygmomanometers produce measurements of HR as well as BP. We have not found any studies of HR validation attempts in the literature that follow the ESH International Protocol [37,45-49]. Therefore, ours may be the first study to validate this parameter with the criteria of the ESH protocol for BP. We set the requirements for HR validation to be roughly proportional to the magnitude of the measurements, and they may even be more demanding than the BP requirements of the ESH International Protocol.

Moreover, the recommendations made in the ESH International Protocol regarding the populations to which validation results can be applied may not be followed faithfully in clinical practice. The ESH International Protocol imposes certain gender requirements and limits validation studies to individuals older than 25 years who have BPs and arm circumferences within specific ranges. Because these subgroups represent only a portion of the large heterogeneous population with BP abnormalities, extrapolation of ESH validation results to other specific populations could be considered unsafe. Additional

validation studies are needed if the product is to be used in other subpopulations, such as pregnant women, obese individuals, children, or individuals with particular conditions, such as arrhythmia.

The ESH International Protocol also does not indicate the number of validation studies needed to confirm the accuracy of the device. According to experts, at least two validation studies should be performed in different centers and in different populations [37]. The protocol of the Association for the Advancement of Medical Instrumentation recommends more than one study, but does not specify the number of studies or devices [32]. Because the QardioArm device has not been validated previously, we are unable to compare our findings with those of other authors. When compared with the Omron M3, the QardioArm tends to give very slightly and nonsignificantly lower SBP and very slightly and nonsignificantly higher DBP readings. We recommend that the QardioArm be further validated with different study designs and study sites and with different types of populations.

There is a high concordance between the measurements made with QardioArm, both intrasession and intersession. The QardioArm mobile app has validity and there is a direct linear correlation between QardioArm measurements and the previously validated Omron M3 measurements, so it can be used without the risk of major measurement error.

Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index

BP: blood pressure
DBP: diastolic blood pressure
ESH: European Society of Hypertension
HR: heart rate
ICC: intraclass correlation coefficient
SBP: systolic blood pressure
SEM: standard error of measurement

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Review

Mobile Phone Apps for Quality of Life and Well-Being Assessment in Breast and Prostate Cancer Patients: Systematic Review

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Abstract

Background: Mobile phone health apps are increasingly gaining attention in oncological care as potential tools for supporting cancer patients. Although the number of publications and health apps focusing on cancer is increasing, there are still few specifically designed for the most prevalent cancers diagnosed: breast and prostate cancers. There is a need to review the effect of these apps on breast and prostate cancer patients' quality of life (QoL) and well-being.

Objective: The purposes of this study were to review the scientific literature on mobile phone apps targeting breast or prostate cancer patients and involving QoL and well-being (anxiety and depression symptoms) and analyze the clinical and technological characteristics, strengths, and weaknesses of these apps, as well as patients' user experience with them.

Methods: We conducted a systematic review of peer-reviewed literature from The Cochrane Library, Excerpta Medica Database, PsycINFO, PubMed, Scopus, and MEDLINE to identify studies involving apps focused on breast and/or prostate cancer patients and QoL and/or well-being published between January 1, 2000, and July 12, 2017. Only trial studies which met the inclusion criteria were selected. The systematic review was completed with a critical analysis of the apps previously identified in the health literature research that were available from the official app stores.

Results: The systematic review of the literature yielded 3862 articles. After removal of duplicates, 3229 remained and were evaluated on the basis of title and abstract. Of these, 3211 were discarded as not meeting the inclusion criteria, and 18 records were selected for full text screening. Finally, 5 citations were included in this review, with a total of 644 patients, mean age 52.16 years. Four studies targeted breast cancer patients and 1 focused on prostate cancer patients. Four studies referred to apps that assessed QoL. Only 1 among the 5 analyzed apps was available from the official app store. In 3 studies, an app-related intervention was carried out, and 2 of them reported an improvement on QoL. The lengths of the app-related interventions varied from 4 to 12 weeks. Because 2 of the studies only tracked use of the app, no effect on QoL or well-being was found.

Conclusions: Despite the existence of hundreds of studies involving cancer-focused mobile phone apps, there is a lack of rigorous trials regarding the QoL and/or well-being assessment in breast and/or prostate cancer patients. A strong and collective effort should be made by all health care providers to determine those cancer-focused apps that effectively represent useful, accurate, and reliable tools for cancer patients' disease management.

Trial Registration: PROSPERO CRD42017073069; https://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42017073069 (Archived by WebCite at <http://www.webcitation.org/6v38C1b9T>)

KEYWORDS

cancer; mHealth; app; mobile phone; quality of life; well-being

Introduction

The number of new cancer cases diagnosed every year worldwide is rapidly rising from 14.1 million in 2012 to well over 20 million predicted by 2030 [1]. Of those, breast and prostate cancers are the most prevalent diagnosed in women and men, respectively [1]. It should be noted that around 30% to 40% of these cancer patients suffer from psychological distress (anxiety and depression symptoms commonly reported) as has been mentioned previously by a meta-analysis comprising 94 studies and 14,078 cancer patients [2]. This emotional distress has been associated with poorer quality of life (QoL) [3]. Well-being, QoL, and treatment satisfaction in breast and prostate cancer patients could be monitored by ubiquitous technologies such as mobile phone health apps, which can provide useful data to reflect on therapy work [4] and thereby improve patients' well-being.

Mobile phone health apps have the potential to revolutionize psychological science because they can collect behavioral data [5] and behavioral information with great ecological validity [6], facilitating high-frequency assessments and more objective data collection [7]. These apps can also potentially empower patients, promoting behavior changes, facilitating self-monitoring of symptoms [8], improving their educational level [9], and allowing patients the feeling of being in contact with their health care team [10].

Apps are widely used by professionals and patients, and attention to them in health care environments is increasing daily [9]. However, there are some important concerns about their use. Because of the large number of health care apps available, patients could get overwhelmed, encountering difficulties in finding the right app or features [11]. Poorly validated information, often created by nonexperts [12], and a lack of updated data [13] have also been mentioned as concerning issues related to health apps. Limited evidence involving these apps in studies [14] and little or no quality control or regulations to guarantee the apps as user-friendly, accurate, or efficacious tools [15] have also been reported.

In several systematic reviews on mobile phone health apps, authors urge different strategies that will result in higher quality evidence for app effectiveness and contents [8,13,16-20]. This would allow us to distinguish apps that subscribe to evidence-based protocols from those that do not [21]. The health care team should have a leading role not only in the review and verification of app contents but also in determining the most reliable ones and in selecting the patients best suited to using them [13]. Therefore, health care providers and organizations should standardize the identification, evaluation, and selection of these mobile health (mHealth) apps to maximize their utility and safety [15].

Attending to patients' point of view about using mHealth apps, authors have commonly used survey studies to determine the

user experience. In general, cancer patients positively value the use of Internet-based technologies for health care management and feel comfortable using them [22]. Breast cancer patients usually use this technology to seek general information, search for therapies or scientific data, and exchange information with other patients [23]. Authors have also pointed out the importance of including customizable functionalities in mobile phone apps in order to manage care-related information so that these features can be easily modified depending on changes in the user's needs [24]. Other people affected by cancer, such as prostate cancer patients, have shown interest in using apps, indicating apps should be easy to use, tailored to the individual, and include social support [25]. A recent survey of 375 cancer patients reported that about half of the patients (182/375, 48.5%) were willing to send data via an app supporting their oncological treatment and follow-up [4]. Moreover, around two-thirds (125/182, 68.7%) agreed to use these regularly sent data as an ideal complement to the standard follow-up. The most mentioned characteristics that should be included in a cancer-focused app were pseudonymizing, data protection, and feedback from a physician based on the patients' input [4].

Although mHealth apps could be useful tools for cancer patients [26], there are only a few apps focused on oncological care that support patients during treatment and aftercare [4]. The purposes of this study were to (1) identify evidence-based mobile phone health apps focused on QoL and well-being (anxiety and depression symptoms) in breast and/or prostate cancer patients, (2) recognize their clinical and technological characteristics, (3) categorize their clinical and technological strengths and weaknesses, and (4) determine patients' user experience (satisfaction level and comments regarding the apps used).

Methods

Overview

We developed a systematic search strategy to detect all relevant studies involving the use of mobile phone apps for QoL and/or well-being (anxiety and depression symptoms) in breast and/or prostate cancer on July 12, 2017. Once we determined these studies, we searched the identified apps on the online market to describe them. The systematic research protocol is registered at PROSPERO [CRD42017073069].

Reviewing the Scientific Literature

Selection Criteria

Articles were considered potentially relevant if they were trials or peer-reviewed studies published between January 1, 2000, and July 12, 2017, including a smartphone app focused on QoL and/or well-being (anxiety and depression symptoms) used by breast and/or prostate cancer patients.

We considered a smartphone "a mobile phone with Internet connectivity and the ability to download and run third-party software apps available from a commercial marketplace" [27].

We excluded articles that did not involve a mobile phone app (eg, a Web-based or iPad app), medical studies, systematic reviews and meta-analyses, abstracts or congress papers, qualitative studies, study protocols, and studies not including QoL or well-being assessment. We applied no language restrictions.

The search strategy followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines [28]. We searched for trials in The Cochrane Library, Excerpta Medica Database (EMBASE), PsycINFO (via ProQuest), PubMed, Scopus, and MEDLINE (via OvidSP) on July 12, 2017. We extracted trials with the keywords “breast cancer + app,” “breast cancer + mHealth,” “breast cancer + mobile application,” “prostate cancer + app,” “prostate cancer + mHealth,” and “prostate cancer + mobile application” published between January 1, 2000, and July 12, 2017. Two of the authors of this study (ER and EG) independently reviewed the titles and abstracts of the total search yield to identify eligible articles. The full text of the article was retrieved if any reviewer considered a citation potentially relevant. In case of disagreement, a third reviewer (FG) selected the reference finally included, based on inclusion and exclusion criteria. Search results were stored using Endnote version X8 (Clarivate Analytics). Duplications of studies were removed.

Data Extraction

Two of the authors of this study (ER and EG) independently reviewed the full text of the articles meeting the eligibility criteria. The interrater agreement (kappa value) was calculated with SPSS version 22 (IBM Corp). The following data were extracted from the selected papers: (1) general patient and study characteristics (year of publication, country of study, language, author affiliations, number of participants, mean age, and cancer type targeted), (2) clinical characteristics (QoL assessment, other variables measured, functionalities, type of validated questionnaire involved and timing for assessment, treatment offered, main clinical results, quality of the study, randomized controlled trial [RCT] design, social media inclusion, theoretical framework based, and quality of the journal), (3) clinical strengths and weaknesses, and (4) patients' user experience (satisfaction level and comments regarding the apps used). Disagreements were rare and were easily resolved by consensus.

Two of the authors (ORR and ED) independently reviewed the full text of selected articles and extracted the following information: (1) technological characteristics (app name, platform, availability in markets, price, number of downloads, rating, patients targeted, and main features), (2) technological strengths and weaknesses, and (3) patients' user experience (ratings, health certification obtained, and number of user comments). Disagreements were resolved by a third reviewer (FG). The quality of the included studies was assessed in terms of their design. Nonrandomized, observational, descriptive, and

qualitative studies were considered low to medium quality. Quasi-randomized and interventional studies and studies with strongest design were considered of moderate to high quality.

Reviewing the Apps on the Market

In addition to the systematic review, 3 of the authors (ORR, ED, and CSB) downloaded the apps identified in the studies from the online store. They collected the following information: (1) technological characteristics, (2) technological strengths and weaknesses, and (3) patients' user experience (satisfaction level and comments regarding the app used). An English language restriction was applied for the mobile phone apps downloaded.

Results

General Characteristics

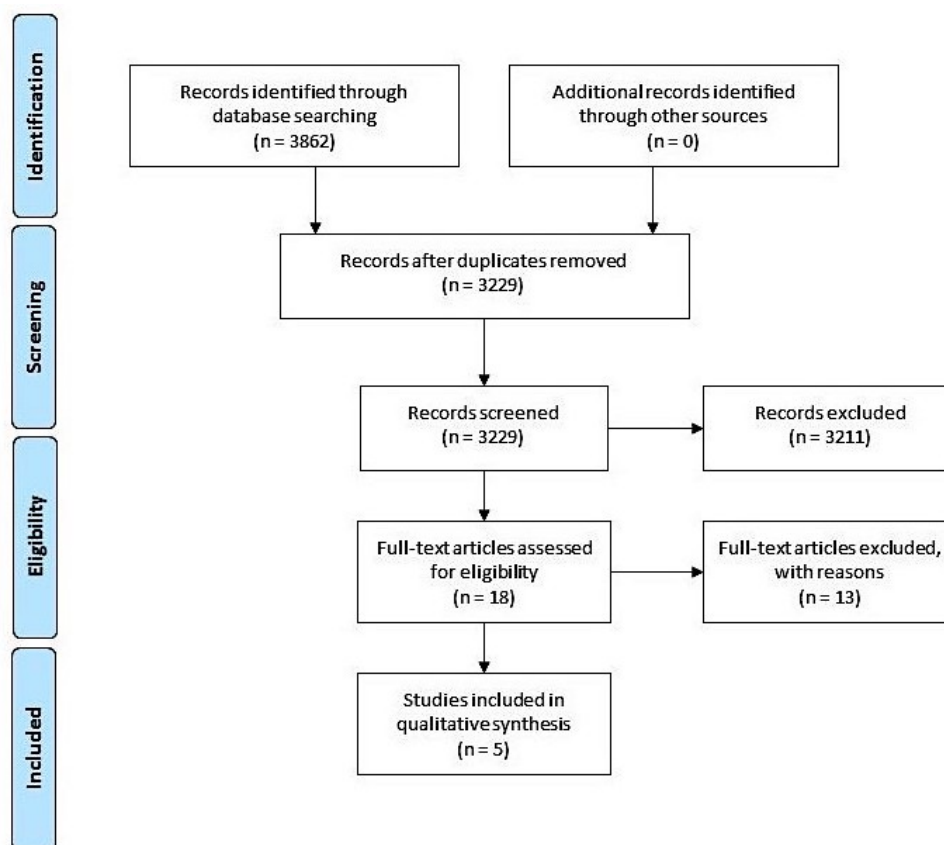
The search of the electronic databases retrieved 3862 citations. After removal of duplicates, 3229 remained and were evaluated on the basis of title and abstract. Of these, 3211 were discarded because they clearly did not meet the inclusion criteria. Based on titles and abstracts, 18 records were selected for full text screening; 13 out of these 18 [29-41] being discarded for various reasons (see [Multimedia Appendix 1](#)). A total of 5 publications [42-46] were finally included. An interrater agreement of kappa=.561 was found, reaching a moderate agreement according to Landis and Koch [47]. All chosen studies were deemed to be of sufficient quality to contribute equally to the thematic synthesis. A PRISMA flowchart is shown in [Figure 1](#) [28].

The 5 studies included a total of 644 patients, mean age 52.16 years (sample sizes and mean ages listed in [Table 1](#)). Of these, 3 studies were conducted in Korea [42,44,46], 1 in the United States [43], and 1 in Sweden [45]. All main authors affiliations were university departments [42-46]. The majority of the studies targeted breast cancer patients [42-44,46]; only 1 focused on prostate cancer patients [45]. Other general characteristics of the studies included are summarized in [Table 1](#).

Clinical and Technological Characteristics

Regarding the clinical approach, 4 of the 5 included studies referred to apps that assessed QoL [43-46]. Among the other variables measured were depression status (mood, anxiety, and sleep satisfaction) [42]; daily food intake, daily exercise, daily body weight, weight efficacy, anthropometrics, and physical activity [43]; sleep disturbance [44]; sense of coherence, bladder and bowel function, fatigue, pain, anxiety, distress, sleep, and flushing [45]; physical activity [43,46]; and user satisfaction [46].

All studies allowed patients to collect patient-reported outcome measures [42-46], and 3 included a related-intervention app [43,45,46].

Figure 1. Systematic review of the literature flowchart.**Table 1.** General characteristics of included studies (n=5).

Study	Publication year	Country/language	Participant number	Mean age	Cancer type
Kim et al [42]	2016	Korea/Korean	78	44.35	Breast
McCarroll et al [43]	2015	United States/English	50	58.4	Breast
Min et al [44]	2014	Korea/Korean	30	45	Breast
Sundberg et al [45]	2017	Sweden/Swedish	130	69	Prostate
Uhm et al [46]	2017	Korea/Korean	356	50.3	Breast

The included studies measured QoL through different questionnaires such as the Functional Assessment of Cancer Therapy–General (FACT-G) [48], a generic core questionnaire that comprises 27 items divided into 4 domains (physical, functional, emotional, and social well-being) [49]; the EuroQol 5 Dimensional Questionnaire (EQ-5D-3L) [50], a generic health outcome instrument comprising 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) [49]; the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core (EORTC QLQ-C30) [51], a 30-item generic cancer questionnaire that consists of 5 function scales (physical, role, emotional, cognitive, and social), a global health scale, 3 multi-item symptom scales (fatigue, nausea/vomiting, and pain), and 6 single item scales (dyspnea, sleep, appetite, constipation, diarrhea, and financial difficulties due to disease) [49]; and the EORTC complementary modules on prostate cancer, QLQ-PR25 [52], and breast cancer, QLQ-BR23 [53]. One study did not assess QoL symptoms [42], focusing only on well-being assessment through the Patient Health Questionnaire (PHQ-9)

[54], which measures both the presence and the severity of 9 depression symptoms and is able to yield a diagnosis [55]. Only one of the included studies reported the theoretical framework on which the app relied. Further details on other clinical variables assessed by the included studies are reported in Table 2.

Concerning the main clinical results, the adherence to the self-reporting measures was associated with higher accuracy of depression screening [42]. Moreover, the compliance with the daily self-reporting rates was not affected by depression symptoms or health-related quality of life (HRQoL) status reported by the patients [44]. Of the 3 studies that included intervention [43,45,46], only 2 reported a QoL improvement [45,46]. The real-time assessment and management of symptoms through Interaktor [45] produced significantly less burden in emotional functioning, insomnia, and urinary-related symptoms at T2 (after end of treatment, which ranged from 5 to 8 weeks) and at T3 (3 months after end of treatment) compared with the control group. Likewise, the 12-week regimen of aerobic and resistance exercise through Smart After Care [46] produced a

significant improvement in physical function, physical activity, and QoL at baseline and 12 weeks. The 4-week comprehensive lifestyle program focusing on nutrition quality, physical activity, and improving eating displayed by LoseIt! [43] did not affect QoL.

With regard to the quality of the studies, 3 were considered of low-to-medium level [42,43,44], and 2 a medium-to-high level of quality [45,46].

The study design involved 2 prospective, nonrandomized multicenter controlled trials [45,46], 1 with control group [45], but no RCT designs were included. None of the 5 studies involved social media features, and only 1 study [43] mentioned the theoretical framework, social cognitive theory, on which it was based.

Concerning the publication journals, 4 out of the 5 included studies [42,43,45,46] were published in the last 3 years (2015-2017). Scientific journals are ranked yearly based on impact factor data, and the Journal Citation Reports (JCR) published by Clarivate Analytics are widely used as a quality indicator. The JCR ranks journals into categories based on which

quartile of the impact factor distribution the journal occupies for that category: Q1 represents the top 25% of journals in the distribution, Q2 between the top 50% and top 25% of journals, and Q3 between the top 75% and top 50% of journals. According to the 2017 JCR, 4 studies [42-44,46] were issued in journals ranking Q1 or Q2.

With regard to technological characteristics, all of the 5 studies included provided the names of the mobile phone apps evaluated [42-46]. There were 2 studies involving the same app [42,44] (see Table 3). The majority of the studies included an app targeted at cancer patients [42,44-46]. The main features of the apps were focused on exercise and nutrition logging [43]; collection of patient-reported outcomes [44]; early detection, reporting, and management of symptoms [45]; and exercise by a step counter [46]. More technological characteristics can be seen in Table 3.

App functionalities included the following: (1) customization and personalization features (create a menu plan and calorie tracker [43] to establish an individual profile), (2) motivational features (providing feedback), and (3) social features (developing a community for inspiration).

Table 2. Clinical characteristics of included studies (n=5).

Study	QoL ^a assessment	Functionalities	Validated questionnaire/timing	Treatment offered	Quality of study
Kim et al [42]	No	PRO ^b : daily mental health ratings over a 48-week period	PHQ-9 ^c via app biweekly	No	Low-medium
McCarroll et al [43]	Yes	PRO: daily, real-time, and motivational feedback + intervention	FACT-G ^d , WEL ^e at baseline and at 4-week follow-up	Comprehensive lifestyle program	Low-medium
Min et al [44]	Yes	PRO: daily basis over a 90-day period	BDI ^f , EQ-5D-3L ^g via app on a daily basis for 90 days	No	Low-medium
Sundberg et al [45]	Yes	PRO: daily, real-time assessment of symptoms and concerns during radiotherapy + intervention ^h	EORTC QLQ-C30 ⁱ , EORTC QLQ-PR25 ^j via app daily at any time during radiotherapy and 3 weeks after completion	Management of symptoms	Medium-high
Uhm et al [46]	Yes	PRO + intervention ^h	EORTC QLQ-C30, EORTC QLQ-BR23 ^k at baseline and 12 weeks	12-week regimen of aerobics	Medium-high

^aQoL: quality of life.

^bPRO: patient-reported outcome measures.

^cPHQ-9: Patient Health Questionnaire-9.

^dFACT-G: Functional Assessment of Cancer Therapy-General.

^eWEL: Weight Efficacy Lifestyle questionnaire.

^fBDI: Beck Depression Inventory.

^gEQ-5D-3L: EuroQol 5-Dimension 3-Level survey.

^hSignificant improvement in quality of life.

ⁱEORTC QLQ-C30: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core.

^jEORTC QLQ-PR25: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Prostate.

^kEORTC QLQ-BR23: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Breast Cancer.

Table 3. Technological characteristics of included studies (n=5).

Study	App name	Platform	Available in markets	Price	Downloads	Ratings	Patients Targeted
Kim et al [42]	Pit-a-Pat	Android/iOS	No	Unknown	Unknown	Unknown	Yes
McCarroll et al [43]	LoseIt!	Android/iOS	Yes	free/premium	Android: 5,000,000-10,000,000	Android: 4.4; iOS: 4.0	No
Min et al [44]	Pit-a-Pat	Android/iOS	No	Unknown	Unknown	Unknown	Yes
Sundberg et al [45]	Interaktor	Unknown	No	Unknown	Unknown	Unknown	Yes
Uhm et al [46]	Smart After Care	iOS	No	Unknown	Unknown	Unknown	Yes

Clinical and Technological Strengths and Weaknesses

Regarding the studies' strengths, 2 of them involved the same app called Pit-a-Pat [42,44]. Pit-a-Pat was developed for cancer patients to self-report factors related with the diagnosis itself and the subsequent treatments: (1) sleep-disturbance symptoms, (2) acute symptoms related to cytotoxic chemotherapeutic agents, and (3) medication diary for antihormonal treatment. Kim et al [42] studied the accuracy of a mobile mental health tracker for depression screening, as well as the adherence on screening accuracy. For that purpose, daily patient reports of anxiety symptoms, mood, and sleep satisfaction were collected through a reliable and valid questionnaire (PHQ-9). The app involved user-friendly functionalities in the form of a facial emoticon scale. Min et al [44] studied the patient's self-reported sleep disturbance, HRQoL status, and depression symptoms via the Pit-a-Pat app on a daily basis for 90 days with standardized questionnaires. Push notifications were sent to participants daily at 9 AM and 7 PM.

LoseIt! [43] was a Web- and mobile-based app, not cancer targeted, used for logging food intake and volitional exercise. McCarroll et al [43] aimed to assess a 4-week comprehensive lifestyle program with emphasis on nutrition quality, physical activity, and improving eating self-efficacy delivered using a beta health care provider version of LoseIt! in which the patients could log daily food choices, daily exercise type and duration, and daily body weight over the treatment period. Participants received motivational patient-provider feedback notifications (phone call, email message, and/or a push notification) in response to their individual input in the LoseIt! app.

Interaktor [45] was codesigned by patients and health care personnel as an interactive app for mobile phones and tablets. Interaktor was specifically intended for early detection, reporting, and management of symptoms and concerns during treatment for prostate cancer. Daily reports via the app enable instant support from a nurse in early detection and management of symptoms and concerns in real-time during treatment for prostate cancer. The app features included symptom assessment, a risk assessment model for alerts directly to a nurse, continuous

access to evidence-based self-care advice, and links to relevant websites. The apps sent patients a reminder message if they had not submitted their report. In addition, the system sent 2 alerts (yellow and red) to the patients, depending on their symptom occurrence and frequency. The red meant a higher priority (should contact the nurse within an hour), and the yellow alert indicated that the nurse should be called that day. Sundberg et al [45] included a control and an intervention group in their study, which used the app for daily, real-time assessment and management of symptoms and concerns during radiotherapy treatment. Participants were asked to send reports daily and at any time point when they felt unwell during the radiation treatment (5 to 8 weeks) and the following 3 weeks.

Smart After Care [46] was a newly developed mobile phone exercise app. This app recorded minutes of physical activity weekly and established a weekly goal for minutes of activity beginning in the second week. Every week, the achievement rate was displayed by the app. Also, patients receiving hormonal therapy could watch a video clip of resistance and stretching exercises through the app. This study included standardized QoL questionnaires and a user satisfaction survey in the intervention group. Patients in the study by Uhm et al [46] performed a 12-week regimen of aerobic and resistance exercise through Smart After Care, where the intervention group received a pedometer and Smart After Care to perform 150 or 90 minutes of aerobic exercise.

Among the main weaknesses could be cited the small samples of the studies [42-44] and the lack of RCT protocols and framework-based apps. Moreover, we can report only 1 app for free download on the market [43], which was used with breast cancer patients despite not being cancer-focused.

Patients' User Experience

Only 1 study [46] reported information regarding patient satisfaction level, and only 1 app showed a quality certification [43] and a considerable number of user comments (see Table 4). The mean Likert scale response for overall patient satisfaction with the service was 4.27/5 in the mHealth group [46].

Table 4. Patient satisfaction levels provided by the health literature review and the online store search (n=5).

Study	Patients satisfaction	Ratings (OSR ^a)	Health certification (OSR)	Number of user comments (OSR)
Kim et al [42]	Unknown	Unknown	Unknown	Unknown
McCarroll et al [43]	Unknown	Android: 4.4; iOS: 4.0	Helix's CLIA ^b certified and CAP ^c accredited lab	Android: 61,063; iOS: 374,815
Min et al [44]	Unknown	Unknown	Unknown	Unknown
Sundberg et al [45]	Unknown	Unknown	Unknown	Unknown
Uhm et al [46]	Satisfied with use	Unknown	Unknown	Unknown

^aOSR: Online store research.

^bCLIA: Certified Laboratory Improvement Amendments.

^cCAP: College of American Pathologists.

Discussion

Overview

The use of mobile phone apps for health purposes continues to increase [7], and currently thousands and thousands of health apps are available on the online market. They target different health conditions, including cancer. Health apps represent an opportunity to monitor psychological distress and QoL related to cancer and its associated treatments. Our systematic review shows that the scientific literature referring to apps targeting breast or prostate cancer patients and involving QoL and/or well-being measurements is very modest, as we only could identify 5 studies meeting the inclusion criteria. However, the quality and dates of publication show a current scientific interest in this research topic.

The most recent reviews involving focused cancer apps started the searching methodology by looking for apps on the online stores, followed by searching bibliographic databases of health literature [8,13]. However, we considered it more appropriate to start by determining whether rigorous trials had been published on cancer-focused apps. Hence, we conducted the systematic literature review first, and then we downloaded the apps from the market stores to examine them.

More Evidence-Based Apps Are Needed

Despite the increase in the number of health care apps available [15], only a very few of them discussed in the scientific literature focus on QoL and/or well-being assessment in breast or prostate cancer patient even though breast and prostate cancer are the most prevalent cancers diagnosed [1] and QoL and well-being are frequently assessed to determine the health status of cancer patients [2,3]. There are only 2 studies that reported QoL improvement by using related-treatment health apps [45,46].

Related research on health apps for cancer patients was identified but not included in the review due to the following reasons (see [Multimedia Appendix 1](#)): it did not involve mobile phone apps [30-32,35,37,38], it did not assess QoL or well-being [29,33,34,36,40], or it involved qualitative studies focused on feasibility or patient opinions [39,41].

We selected the QoL measure considering it has a wide range of variables involving other psychological measures (eg, cognitive, emotional, and social abilities) and not only as

performance status and daily functional activities [29], symptom experience [33], or chemotherapy-related symptoms (nausea, vomiting, fatigue, mucositis, hand-foot syndrome, and diarrhea) [34].

We have defined well-being as existing levels of general anxiety and depression symptoms and not only as perceived stress level [36] assessed by the Perceived Stress Scale (PSS) [56], a scale “designed to measure the degree to which situations in one’s life are appraised as stressful” and suggested by its own authors “as an outcome measure of experienced levels of stress” [56], not well-being levels.

In our review, only 1 of the selected papers provided information regarding patient satisfaction level [46], therefore it is not possible to draw conclusions about the patient satisfaction or perceived effectiveness of the current apps.

Most of the apps referred to in the scientific literature targeted breast cancer, as in previous reviews [8,13,16-18], and only 1 study focused on prostate cancer. All of these health apps were developed by university institutions; in contrast with the review of Mobasher et al [18], which reports that a minority of medical professionals were involved in the apps. Our results showed that, a priori, all the studies have been hosted by significant research and educational institutions.

With regard to the technological characteristics, it should be noted that the 3 apps specifically designed for cancer patients [42,44-46] were not available for download on the market. Furthermore, only 1 [43] out of 4 total apps included was available for download at the online store, and despite this app (LoseIt!) not being specifically patient-targeted, it was used by 50 breast cancer patients to manage exercise and nutrition concerns.

Clinical and Technological Strengths and Weaknesses

Regarding the studies’ strengths, the use of related-treatment mobile phone apps has resulted in a significant improvement in cancer patients’ QoL [45,46]. Some features like displaying daily patient reports in real time and providing personalized feedback [43,45] have also been pointed out as a significant advantage of the apps [34]. Moreover, if the assessment involves user-friendly functionalities such as a facial emoticon scale [42], which could be adapted to the small phone screen, this may facilitate user participation, potentially making the data more

useful. Previous studies [31] have reported important usability adaptation, incorporating several design decisions to account for patients with various disabilities (eg, impaired vision), presenting only 1 question at a time to patients. The easy and visual (similar to a stock chart) way of obtaining the information displayed by the app as feedback on the symptoms report form at any time during the study has also been mentioned as a relevant strength [29]. Also, it is notable that when some researchers wished to test a general-population-targeted app with cancer patients, they delivered a cancer-focused health care provider beta version [43] and designed the user interface of the app based on reliable guidelines developed by the National Cancer Institute, like previous authors did [31].

Participants using their own mobile phones have mentioned this as better than being provided with an additional device [44], probably because in the latter case they must deal with 2 mobile phones in their daily life or because they prefer some relative freedom for testing the app, meaning the possibility of using the app at their convenience with no minimum amount of time to be spent using the app, as previous authors have reported [41]. In contrast, other studies have pointed out patient preferences for using a device without phone functionality [57] instead of using their own phones. Users strongly appreciate the use of no personal patient identifiers or other information stored on the devices used [30], as well as pseudonymizing and data protection [4]. Apps that can be used on more than 1 device could provide the patients with more possibilities to test them, such as LoseIt! [43], which offers both website and mobile versions for users, or Interaktor [45], available for mobile phones and tablets. The real-time feedback component and the motivational feedback notification are considered relevant strengths as well. The flexibility in the self-reporting task [45] could probably be a more suitable option in oncological settings than prefixed hours of a day [44] because of the patients' highly variable functional status during the day, largely dependent on the medical treatments.

Among the main weaknesses could be (1) no cancer-focused apps are being used in studies involving cancer patients [36,40,41,43,57], (2) many of these studies have small samples, (3) studies are without rigorous design based on RCTs, (4) studies are not free to the user, (5) no theoretical framework is reported, and (6) there are usability and accessibility issues with cancer patients.

It is important to highlight the relevance of using cancer-focused apps in oncological settings, as cancer patients could be considered vulnerable recipients [4]. People suffering from cancer have to struggle with quick relapses, bad prognoses [4], side effects caused by cancer treatments, and psychological distress [2]. Also, they represent a population interested in doing everything possible to improve their health [4], so they could be interested in using apps that do not constitute reliable and accurate tools for them, which is even worse if the patients have to pay for them. Mobasher et al [18] reported that of the 30 apps reviewed, which functioned as self-assessment tools for breast disease, only 2 (2/30, 7%) had a documented evidence base (the rest relied on empirical data). It is imperative to develop apps and other health information and technology systems specifically targeted to cancer patients.

Although some encouraging results have been reported using apps in cancer patients [34], bigger samples sizes and framework-based and RCT designs are needed in order to obtain stronger research conclusions. Otherwise, serious concerns could arise regarding the lack of validation [12] and quality control [15] of the studies. Furthermore, the identification of rigorous trials involving empirical testing of these mobile phone apps in oncological settings is imperative, as none of the selected studies in this review followed a randomized method and only 1 was based on a previous framework. The use of theories, models, and frameworks for apps will help to identify the mechanisms, approaches, and functionalities that work best.

Cancer patients and survivors could have cognitive deterioration due to treatments. Therefore, usability and accessibility are relevant aspects to be considered in the development process of these apps, especially when they are intended for older people. Apps not designed for cancer patients and survivors could entail difficult challenges for them, resulting in reduced adoption and engagement rates. Equally, the large variety of apps available makes it difficult to establish which of them are the most adequate for breast and prostate cancer patients and what is the best way to use them. Also, patients could become overwhelmed due to the huge number of cancer apps available [11]. Because of this, stronger efforts should be made to consolidate the evidence base, effectiveness, and safety of cancer-focused apps [8].

In line with previous research [8,13,16-18,20,21], we consider a main challenge the task of ensuring that those apps that are planned to be used with cancer patients be effectively cancer-focused, meaning that they should have been originally designed for, tested on, and adapted to the cancer population. Only if this technology is evidence-based and targeted to cancer patients can health care providers guarantee the apps' safety, accuracy, reliability, and high quality and be able to recommend them in oncological care settings.

Patients' Satisfaction With the Health Apps

Regarding patients' satisfaction, it is noteworthy that only 1 app of the 3 reviewed reported a quality certification and showed user comments regarding its use. Moreover, it is relevant that this app was not cancer-focused and was the only one available for download at the online store. Only user-friendly and quality-certified apps should be provided to cancer patients. Thus, these health apps must be available for download at market stores once they are certified as useful tools for cancer patients. It would probably be helpful as well that these apps provide new users with comments about other patient's experiences, in order to obtain a more powerful overview of the main features included in the app.

More evidence on the patient satisfaction level using health apps for QoL and/or well-being assessment in oncological settings is needed. In our review, only 1 study [46] focusing on cancer patients provided information about satisfaction level.

People affected by cancer are usually open to strategies that could have a positive influence on their disease [4]. Probably due to this fact, mobile phone developers and health care teams involved in oncological settings should be especially careful

with the apps that are going to be used and tested by this population and implement patient-centered design approaches. Current RCTs are still being developed that might produce promising data to help reach a high-quality evidence base for apps for cancer patients' use [32,57-59].

Limitations

Our study had certain limitations. Our selection criteria intentionally excluded apps that were not specifically focused on breast or prostate cancer patients. We considered only the assessment of 2 main psychological variables in psycho-oncological care: QoL and well-being (anxiety and depression symptoms). Additional studies could consider other psychological measures such as fatigue or the secondary symptoms produced by the cancer treatments. Although our

data search represents a wide range of peer-reviewed journals, we might have missed studies that were not identified with our search terms or that were not published.

Conclusions

Despite the existence of hundreds of studies involving mobile phone health apps used by cancer patients, there is a lack of rigorous trials regarding QoL and/or well-being assessment in breast and/or prostate cancer patients. More evidence-based apps, which could be tested in future RCT protocols, are still needed. However, promising results are expected to be available from some RCTs that are still running. A strong and collective effort should be made by all health care providers to determine those cancer-focused apps that provide useful and reliable tools for cancer patients' disease management.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Reasons for exclusion of studies.

[PDF File (Adobe PDF File), 26KB - [mhealth_v5i12e187_app1.pdf](#)]

Multimedia Appendix 2

Overview of the systematic review.

[PDF File (Adobe PDF File), 11MB - [mhealth_v5i12e187_app2.pdf](#)]

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Abbreviations

BDI: Beck Depression Inventory

CAP: College of American Pathologists

CLIA: Clinical Laboratory Improvement Amendments

EORTC QLQ-C30: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Core

EORTC QLQ-BR23: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire complementary module for breast cancer patients

EORTC QLQ-PR25: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire complementary module for prostate cancer patients

EQ-5D-3L: EuroQol 5-Dimension questionnaire

FACT-G: Functional Assessment of Cancer Therapy–General

HRQoL: health-related quality of life

mHealth: mobile health

PHQ-9: Patient Health Questionnaire–9

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

PRO: patient-reported outcome measures

PSS: Perceived Stress Scale

QoL: quality of life

RCT: randomized controlled trial

OSR: online store research

WEL: Weight Efficacy Lifestyle questionnaire

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Original Paper

Patients' Acceptance of Smartphone Health Technology for Chronic Disease Management: A Theoretical Model and Empirical Test

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Abstract

Background: Chronic disease patients often face multiple challenges from difficult comorbidities. Smartphone health technology can be used to help them manage their conditions only if they accept and use the technology.

Objective: The aim of this study was to develop and test a theoretical model to predict and explain the factors influencing patients' acceptance of smartphone health technology for chronic disease management.

Methods: Multiple theories and factors that may influence patients' acceptance of smartphone health technology have been reviewed. A hybrid theoretical model was built based on the technology acceptance model, dual-factor model, health belief model, and the factors identified from interviews that might influence patients' acceptance of smartphone health technology for chronic disease management. Data were collected from patient questionnaire surveys and computer log records about 157 hypertensive patients' actual use of a smartphone health app. The partial least square method was used to test the theoretical model.

Results: The model accounted for .412 of the variance in patients' intention to adopt the smartphone health technology. Intention to use accounted for .111 of the variance in actual use and had a significant weak relationship with the latter. Perceived ease of use was affected by patients' smartphone usage experience, relationship with doctor, and self-efficacy. Although without a significant effect on intention to use, perceived ease of use had a significant positive influence on perceived usefulness. Relationship with doctor and perceived health threat had significant positive effects on perceived usefulness, countering the negative influence of resistance to change. Perceived usefulness, perceived health threat, and resistance to change significantly predicted patients' intentions to use the technology. Age and gender had no significant influence on patients' acceptance of smartphone technology. The study also confirmed the positive relationship between intention to use and actual use of smartphone health apps for chronic disease management.

Conclusions: This study developed a theoretical model to predict patients' acceptance of smartphone health technology for chronic disease management. Although resistance to change is a significant barrier to technology acceptance, careful management of doctor-patient relationship, and raising patients' awareness of the negative effect of chronic disease can negate the effect of resistance and encourage acceptance and use of smartphone health technology to support chronic disease management for patients in the community.

KEYWORDS

smartphone; mobile health; patients; hypertension; chronic disease; disease management

Introduction

Background

Due to its large impact on patients' health status and health care expenditure, there is a growing interest worldwide in developing programs to support consumers to self-manage chronic diseases [1]. As the leading preventable risk factor for myocardial infarction, cerebral infarction, and heart failure, hypertension is an ongoing challenge to health care systems [2]. Patients' self-management and self-care at home is essential for managing chronic diseases such as hypertension [3]. The ubiquitous smartphone technology provides a new opportunity for improving patients' self-management of chronic diseases because it can enable frequent and flexible personal interaction with health care providers at the right time and right place [4]. A variety of smartphone health technologies have been reported worldwide to support different aspects of chronic disease management. There was evidence for smartphone technology to help patients improve blood pressure control [5] and medication adherence [6]. Some examples in hypertension management are patient self-recording of blood pressure [5,7], cardiovascular risk assessment [8,9], regular follow-up by doctors [10], health information recommendation [6], and automatic medication reminders [6]. Therefore, we developed a smartphone-based hypertension management app *Blood Pressure Assistant* and started a major project of introducing it to community-dwelling patients for hypertension management. The purpose of the program was to enable patients and their health care providers in a tertiary hospital to exchange information and collaborate in hypertension management.

Despite its potential benefits, mobile health (mHealth) technologies have encountered various challenges in patient acceptance [11]. According to a market report conducted in 27 countries in 2014, only 1.20% (1.6M/133M) of diabetic patients who had a smartphone were estimated to actually use a diabetes app on their smartphone to manage their disease [12]. For the successful introduction into the routine health care delivery system, it is essential to understand the factors impacting patients' acceptance of the smartphone health technology.

Although there have been studies on consumer acceptance of health technology [13,14], the previous studies were focused on other technologies such as electronic medical records [15-18], telemonitoring technology [19], and the Web-based technology [20-22]. To the best of our knowledge, to date, little theoretically based technology acceptance study has been systematically conducted on smartphone technology. To fill this knowledge gap, this study aimed to develop and test a theoretical model to predict and explain patient acceptance of smartphone technology for chronic disease management. The theoretical model is tested in the context of hypertension management.

Prior Research and Hypotheses

We conducted preliminary interviews with 10 patients who were frequent users of the smartphone health app Blood Pressure Assistant to understand why they used it. We identified 3 factors influencing their usage behavior: the need for hypertension control, compliance with their health care providers' advice, and the reluctance to use it. This preliminary knowledge was taken into account in our conceptualization of the research model. The other constructs of the model were drawn from the relevant theories such as technology acceptance model (TAM) [23], TAM2 [24], dual-factor model [25], and health belief model (HBM) [26].

Technology Acceptance Model

Among its wide adoption in all fields of technology acceptance studies, TAM [23] has been used to predict consumer acceptance of health technology [13,20,27,28]. According to TAM, perceived usefulness and perceived ease of use are the 2 major cognitive determinants of information technology usage [13], such as consumer acceptance of smartphone health technology [23]. Perceived usefulness refers to the extent to which users believe that using a particular system would enhance their task performance. Perceived ease of use is the extent to which users believe that using a particular system would be easy [23]. Intention to use refers to the intention or the continual intention to use the technology. Combining TAM with the other models, Sun et al formulated a model to explain consumer acceptance of health technology [20]. Hung and Jen employed TAM to explore students' intention to adopt mobile technology to manage personal health [27]. If patients believe that the alternative smartphone health technology is easy to use and will help with self-management of chronic disease, they will be more likely to adopt the technology. Moreover, if they feel the technology is easy to use, they would be more likely to perceive the technology as useful [29]. These expectations lead us to hypothesize the following:

H1: Perceived usefulness is positively associated with patients' intention to use smartphone health technology.

H2: Perceived ease of use is positively associated with patients' intention to use smartphone health technology.

H3: Perceived ease of use is positively associated with patients' perceived usefulness of smartphone health technology.

Realizing the limitation of TAM in not considering the social factors that very much likely would influence a person's perceptions about the technology, Venkatesh extended TAM to TAM2, which includes social influence (SI) as a key determinant of perceived usefulness and use intention [30]. SI is the degree to which the users perceive that the people who they trust and resort to believe they should use the technology. People are likely to incorporate trusted referents' beliefs into

their own belief structure [31], and therefore, we propose the following:

H4: Social influence is positively associated with perceived usefulness of smartphone health technology.

Moreover, users' prior technology usage experience can shape their belief in the new technology [32]. Positive experience may help them to feel more confident and perceive that they have the capabilities and resources to repeat that same performance [28,32]. Therefore, we propose the following hypotheses:

H5a: The prior mobile app usage experience is positively associated with patients' perceived usefulness of smartphone health technology.

H5b: The prior mobile app usage experience is positively associated with patients' perceived ease of use of smartphone health technology.

Dual-Factor Model

Cenfetelli developed a dual-factor model of information technology usage to compensate the limitation of TAM being solely focused on users' positive (enabling) perceptions but ignoring the negative (inhibiting) ones [25]. The core argument is that potential users' information technology usage considerations are based on a simultaneous examination of both enabling and inhibiting factors. Cenfetelli contends that inhibitors not only influence information technology usage directly but also indirectly via enablers as the mediators [25].

Resistance to change (RTC) refers to people's attempt to maintain their previous behaviors and habits in the face of change required. A study into physicians' resistance toward health information technology finds that resistance to change is the inhibitor that has significant, direct influence on both behavioral intention and perceived usefulness [15]. Another study on older people's acceptance of preventive mobile health services in China only finds the significant influence of resistance to change on perceived usefulness, not behavioral intention [33]. As patients were used to their familiar chronic disease management model, "social inertia" would likely cause them to have negative cognitive and emotional responses to the new smartphone health technology; thus, they may give relatively low evaluation on the technology's usefulness. Thus, we propose the following hypotheses:

H6a: Resistance to change is negatively associated with intention to use smartphone health technology.

H6b: Resistance to change is negatively associated with perceived usefulness of smartphone health technology.

Health Belief Model

In essence, adoption of smartphone health technology is a patient's behavior to promote, protect, or maintain their own health [20]. Therefore, it can also be explained by HBM [26], which suggests that people's beliefs about health problems, perceived benefits of action and barriers to action, and self-efficacy explain engagement or lack of it in health promotion behavior [26]. In this study, perceived health threat refers to patients' awareness and care of hypertensive condition, and its potential consequences. According to the previous

literature, perceived health threat has both direct and indirect influences on consumer's intention to use health information technology through perceived usefulness [13,15]. We thus propose the following hypotheses:

H7a: Perceived health threat is positively associated with patients' intention to use smartphone health technology.

H7b: Perceived health threat is positively associated with perceived usefulness of smartphone health technology.

The perceived benefits of action in HBM are embodied in perceived usefulness in our new model. Barriers to action are modeled as resistance to change. Self-efficacy is the extent of patients' beliefs in their ability to complete various tasks and reach the goal of controlling hypertensive condition. In the social cognitive theory (SCT), self-efficacy refers to users' confidence in their ability to use a technology, and has been modeled as a determinant of perceived ease of use [30]. The definition of self-efficacy in the HBM includes that in SCT in this study context. In view of the logic, we propose the following hypothesis:

H8: Self-efficacy is positively associated with patients' perceived ease of use of smartphone health technology.

Relationship With Doctor

The positive effects of doctor-patient interaction for chronic disease management have long been established [34]. Patient-doctor relationship is an important factor affecting patients' e-health system adoption intention [35]. As found from the preliminary interview, health care providers play a vital role in guiding patients' practices of chronic disease management. Patients who trusted the doctor's expertise were more likely to communicate with the doctor whenever blood pressure arose. Therefore, these patients were more likely to appreciate the technology's usefulness and ease of use for communication and were less likely to have negative resistance to technology. Therefore, we hypothesize the following:

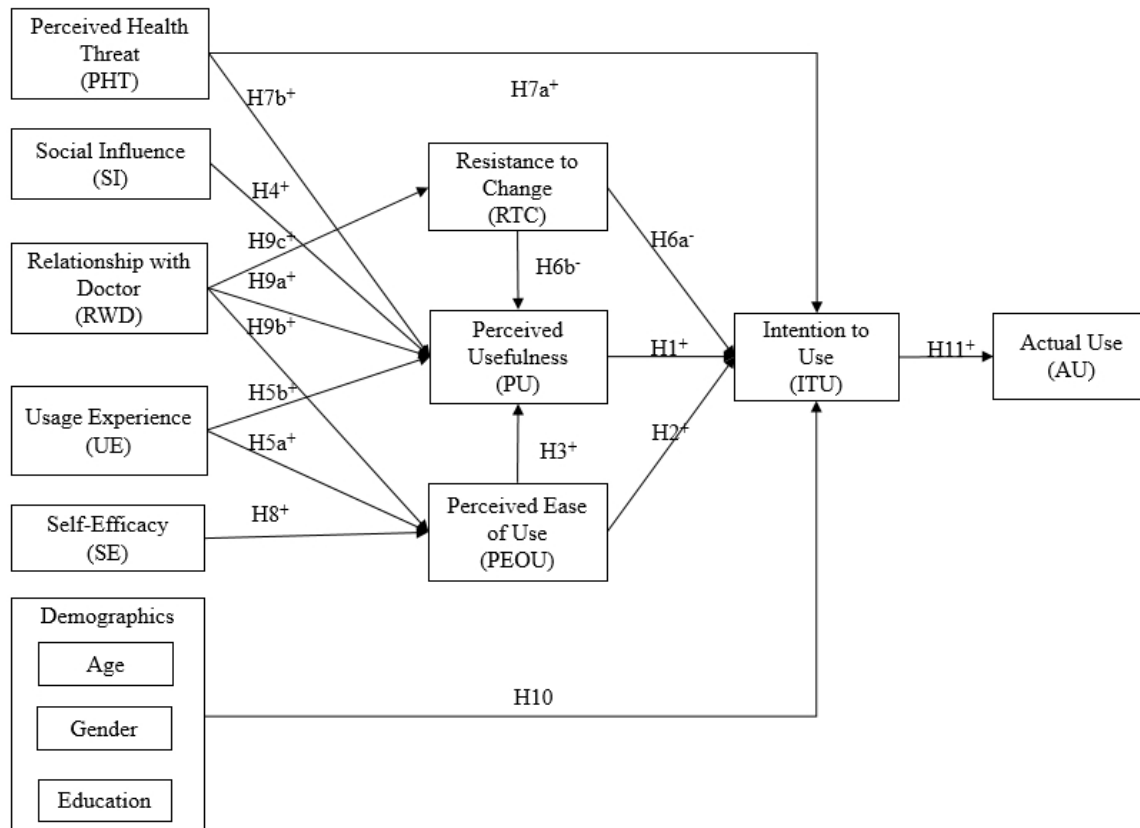
H9a: Relationship with doctor is positively associated with perceived usefulness of the smartphone health technology.

H9b: Relationship with doctor is positively associated with perceived ease of use of the smartphone health technology.

H9c: Relationship with doctor is negatively associated with patients' resistance to change.

Demographic Factors

A systematic review of studies on patient acceptance of consumer-centered health information technologies reveals that the most studied demographic variables on technology acceptance include sex, gender, and education [11]. Gender and age were found to be moderators between perceived usefulness and behavioral intention to use telemedicine service [36]. Age and education level appeared to have influenced consumers' choice of use or nonuse of the e-appointment service [37].

Figure 1. The hypothesized theoretical research model.

Thus, we tested the moderating effects of these 3 variables on intention to use and propose the following hypothesis:

H10a: Age is significantly associated with intention to use.

H10b: Gender is significantly associated with intention to use.

H10c: Education is significantly associated with intention to use.

Actual Use

In this study, we define actual use as the ratio of a patient's actual use of the app to that prescribed in their management plan for a certain period of time. The predictive power of TAM is undermined if actual use is not included in the model [38] because intention is neither behavior nor is it necessarily translated into behavior. Therefore, there is a need to test whether intention is indeed translated into use. We propose the following hypothesis:

H11: Patients' intention to use the smartphone health technology is positively associated with actual use.

The Proposed Theoretical Research Model

On the basis of the above reasoning, we propose that 4 social factors—resistance to change, social influence, perceived health threat, and relationship with doctor—and a technical factor (ie, perceived ease of use), and a personal factor (ie, smartphone usage experience) affect patients' perceived usefulness of smartphone health technology. Three factors, relationship with doctor, usage experience, and self-efficacy, affect patients' perceived ease of use of the technology. Perceived usefulness,

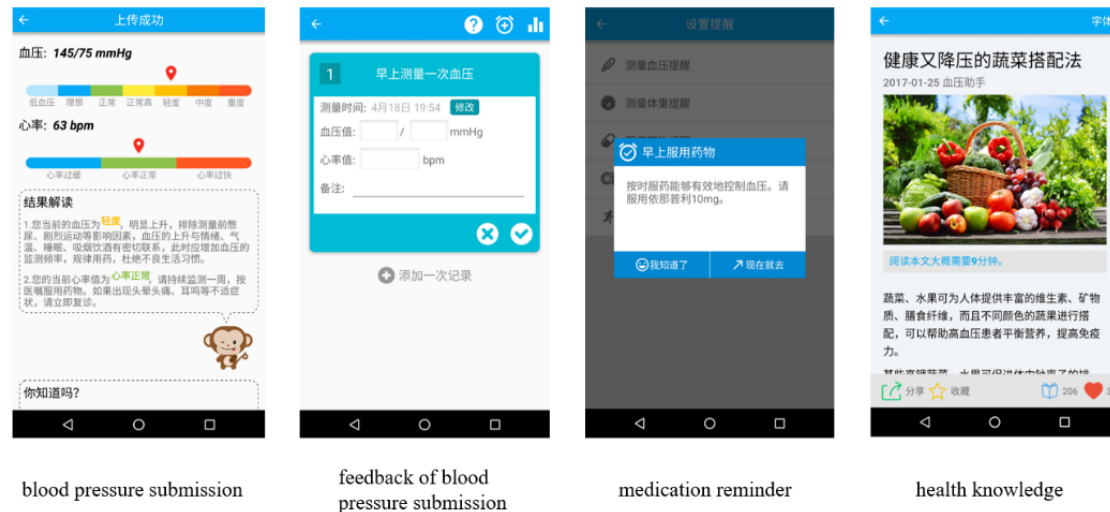
perceived ease of use, perceived health threat, and resistance to change affect patient's intention to use. Three demographic variables, gender, age, and education, mediate the effect of the above variables on intention to use. Ultimately, intention to use affects patients' actual use of smartphone health technology (Figure 1).

Methods

The Hypertension Management Program Enabled by the Smartphone Health Technology

The smartphone health app Blood Pressure Assistant was developed by the Biomedical Informatics Laboratory in Zhejiang University, People's Republic of China. It was designed to enable communication and collaboration between the outpatients and their health care providers in hypertension management. It included a smartphone app for the patients to use, named Blood Pressure Assistant (Figure 2), and a Web-based physician portal for their health care providers to communicate with these patients. The iPhone operating system (iOS) version of the app is downloadable from the Apple Store. Both the iOS and the Android version can be downloaded from a certain website. The physician portal also can be accessed at another certain website (if you want to use this application, please contact the author).

The functions of the smartphone app for patients included a reminder for blood pressure measurement, medication, and exercise; the form to enter and submit blood pressure measurement records; and receiving physician feedback and access to the health information published through the app.

Figure 2. Screenshots of the smartphone-based Blood Pressure Assistant application.

The functions of the physician portal included continuous monitoring of patient health data, data visualization and reminding of abnormal situations, assessing patient health conditions based on the collected data, classification of patients according to their health conditions, and management of regular follow-up.

Study Site

To improve population health, a chronic disease management program had been piloted to develop a model for chronic disease prevention and control in Ningxia Province in China. As the primary health care system was still in the emerging stage of development in the province, the program was run by the 2000-bed General Hospital of Ningxia Medical University, the only tertiary hospital in the province. The initial focus of the program was hypertension management. Therefore, the study population was the hypertensive outpatients in the Department of Cardiovascular Medicine in the hospital.

The health care providers who participated in the hypertension management program included a cardiovascular medicine specialist and a certified health manager. The program started once an outpatient was recruited and the hypertension management plan was developed for the person. A patient was requested to submit the blood pressure data via smartphone regularly according to the care plan. The system would assess whether the data were normal. An alarm would be flagged to the health care providers once any abnormal data were recorded. The health manager would then phone the patient to discuss the person's abnormal health condition, reevaluate, and adjust the self-management plan. The patients could also read the information about chronic disease management published on the smartphone app. The system went live in November 2015.

Recruiting the Study Participants

The health care providers recruited the outpatients into the program. Patients who met the following inclusion criteria were recruited: (1) aged 18 years or over; (2) no other serious complications except hypertension; (3) had a smartphone and sufficient network connectivity at home; (4) able to read and write in Chinese; and (5) resided in Yinchuan city so as to be contactable. After being recruited by the specialist, the health

manager provided face-to-face training to the patients. The content of the training included knowledge about hypertension self-management, and the method to download "Blood Pressure Assistant" and use it, either from Apple Store if the person used an iPhone or from the specific website if the person used an Android phone [39]. Further information about the app can be acquired from the corresponding author. The training session usually lasted for 1 hour.

Conducting Questionnaire Survey

Questionnaire survey was conducted between June and September 2016, 1 month after a patient entered the program. It was conducted either through the telephone survey or the electronic questionnaire survey.

We started conducting telephone interviews to collect questionnaires. A researcher made a phone call to an eligible patient. After informing the person about the survey and seeking the respondent's oral consent, the researcher read and sought the person's answer to each question, and then entered the answer into the electronic questionnaire survey form. After collecting 23 responses, we found this method to be resource-intensive and not efficient. Therefore, we piloted the method of using the mobile phone app to conduct the electronic questionnaire survey. In this method, a patient could fill in the electronic questionnaire survey form that automatically displayed on the smartphone health app interface 1 month after the person was recruited into the program. The information presented included the survey purpose, its voluntary nature, and insurance about anonymity of results in any related research publications. A patient could tick the check box to give consent. Implicit consent was assumed if a patient sent the completed questionnaire survey form back without ticking the check box to express consent.

After collecting 23 copies of electronic questionnaire responses, a *t* test was conducted to identify significant differences in results between the two data collection methods. As no difference was found, the rest of the data were collected via the electronic questionnaire survey.

The researchers extracted the questionnaire responses from the database for data analysis. In addition, data about each

respondent's actual use of the app were obtained from the system log in the database. The person's number of interactions with the smartphone health app was tracked over a 7-day period, including 3 days before and 3 days after the day of response to the questionnaire. At the time of the survey, the system log only tracked the number of times a patient submitted the blood pressure (systolic and diastolic pressure) measurement data. Therefore, the patient's actual use of the smartphone health app was calculated as the ratio of the number of times of submitting blood pressure measurement to the recommended number of times of submission in 7 days in the management plan.

Measurements

A total of 24 questionnaire items were used to measure the 11 constructs in the theoretical model. These items were drawn from the previous validated instruments. A 5-point Likert scale was used for measurement, ranging from 1, strongly disagree, to 5, strongly agree (Table 1). The measurement items were translated into Chinese by 1 researcher, then discussed and

validated by 5 researchers. One researcher back-translated the Chinese version into English.

The questionnaire was piloted on 5 patients to test the content validity. All of the measurement items except 1, "I am able to use Blood Pressure Assistant without much effort," were easy for the patients to understand. We modified the "effort" into "time and energy" to improve readability. The patients' demographic information was also collected, including age, gender, and education.

Data Analysis

The research model was tested by the partial least squares (PLS) path modeling, a well-established statistical method to model the relationship between variables in social sciences, econometrics, marketing, and strategic management [27,41]. PLS modeling is a second-generation multivariate technique used to analyze causal models involving multiple constructs with multiple observed items.

Table 1. The constructs, measurement items, and source references of the measurement items.

Construct	Item code	Measurement items	Source reference ^a
Demographics	—	Age, gender, and education	—
Perceived usefulness (PU)	PU1	Logging or sending blood pressure values would make me cope with hypertension better	[19]
	PU2	Knowing that a doctor checks my blood pressure data gives me confidence in hypertension management	
	PU3	Overall, Blood Pressure Assistant is useful	
Perceived ease of use (PEOU)	PEOU1	Learning how to use the mobile app would be easy for me	[39]
	PEOU2	I would find Blood Pressure Assistant easy to use	
	PEOU3	Blood Pressure Assistant is not cumbersome to use	
Social influence (SI)	SI1	People who are important to me think that I should use Blood Pressure Assistant	[40]
	SI2	People who are important to me use Blood Pressure Assistant	
Usage experience (UE)	UE1	I use smartphone to search health information on the Web	[35]
	UE2	I use mobile apps to help with managing health issues	
Resistance to change (RTC)	RTC1	I do not want the mobile app to change the way I deal with hypertension	[15]
	RTC2	I do not want the mobile health app to change the way I interact with other people	
Perceived health threat (PHT)	PHT1	I am aware of my hypertension condition	Drafted by authors
	PHT2	I am very concerned about hypertension	
	PHT3	I would take effort to manage hypertension	
Self-efficacy (SE)	SE1	I am able to use Blood Pressure Assistant without much time and energy	[20]
	SE2	I get the best value from using Blood Pressure Assistant	
Relationship with doctor (RWD)	RWD1	Doctors are my most trusted source of health information	[35]
	RWD2	When I have a health concern, my first step is to contact a doctor	
Intention to use (ITU)	ITU1	Given the opportunity, I would like to use Blood Pressure Assistant	[39]
	ITU2	I would consider to continuously use Blood Pressure Assistant	
Actual use (AU)	AU	Ratio of the actual number of measurements to the physician's recommended number of measurements in care plan	—

^aThe symbol — denotes that the item has no source reference.

It is most suitable for models with relatively small samples in comparison with the covariance-based structural equation modeling technique [42]. This suits the case of our study. The data analysis was conducted in 2 stages. In stage 1, the reliability and validity of the constructs were evaluated. In stage 2, the structural model was tested.

Ethics Approval

The Ethics Committee of the study hospital claimed that since this study did not involve patient data, there was no need for an ethics audit.

Results

The Demographic Results

There were 279 patients who used the system for more than 1 month. One hundred and fifty-two (54.5% (152/279)) of them completed the questionnaire survey: 30 through telephone and 127 via electronic questionnaire. Giving 18 scale items to be tested, according to the minimum sample requirement of 5:1 subject-to-parameter, 90 questionnaire responses were sufficient for the PLS modeling [43]. Therefore, the sample size of 152 patients is deemed adequate. The general characteristics of the participating patients are shown in Table 2.

Table 2. Demographics of the participating patients.

Characteristics	n (%)
Gender	
Male	106 (69.7)
Female	46 (30.3)
Age in years	
<30	5 (3.2)
<40	15 (9.9)
40-49	55 (36.2)
50-59	57 (37.5)
>60	20 (13.2)
Education	
<Middle school	9 (5.9)
Middle school	12 (7.9)
Vocational and technical education	18 (11.8)
High school	25 (16.4)
Three-year college	34 (22.4)
University	38 (25)
Missing information	16 (10.6)
Users of different types of mobile phone	
iPhone operating system users	20 (13.2)
Android users	132 (86.8)

Measurement Validation

Composite reliability (CR) and indicator reliability were used to assess the reliability of reflective constructs. All the constructs had adequate CR (ranged from 0.822 to 0.935) and indicator reliability (ranged from 0.710 to 0.976), both exceeding the recommended value of 0.70 [33]. Table 3 shows the descriptive statistics of the variables and the reliability coefficients.

The average variance extracted (AVE) of the construct was higher than the threshold of 0.50, confirming the convergent validity. AVE of each latent construct was higher than the construct's highest squared correlation with any other latent construct (Figure 3), indicating the Fornell-Larcker criterion was met and confirming the discriminant validity.

Model Validation

The model was assessed by checking the significance of path coefficients (β) among the independent variables and the latent variables. The demographic variable education was excluded from modeling because of large number of missing values. The variables age and gender were found to not have any significant influence on intention to use. The results of the PLS modeling are shown in Figure 4. In general, the model explained 0.412 of the total variance of intention to use and 0.111 of the variance in actual use.

Table 3. Descriptive statistics of the variables and the reliability coefficients.

Construct	Items	Mean (SD)	Standardized loading	Composite reliability
Usage Experience (UE)	UE1	3.23 (1.56)	.945	.8948
	UE2	3.07 (1.77)	.835	
Relationship with doctor (RWD)	RWD1	4.59 (0.74)	.870	.8223
	RWD2	4.40 (0.76)	.801	
Perceived health threat (PHT)	PHT1	4.13 (0.87)	.762	.8775
	PHT2	3.29 (2.05)	.863	
	PHT3	4.35 (0.63)	.890	
Perceived ease of use (PEOU)	PEOU1	4.58 (0.79)	.908	.8702
	PEOU2	4.26 (1.13)	.866	
	PEOU3	4.49 (0.84)	.710	
Perceived usefulness (PU)	PU1	4.17 (1.19)	.942	.9413
	PU2	4.68 (0.55)	.944	
Resistance to change (RTC)	RTC1	1.87 (1.25)	.921	.8802
	RTC2	1.66 (1.09)	.852	
Self-efficacy (SE)	SE1	4.33 (1.02)	.889	.9035
	SE2	4.47 (0.62)	.926	
Social influence (SI)	SI1	2.42 (1.98)	.944	.9150
	SI2	1.76 (1.93)	.891	
Intention to use (ITU)	ITU1	4.53 (0.94)	.955	.9350
	ITU2	4.64 (0.56)	.976	
Actual use (AU)	AU1	0.84 (0.13)	1	1

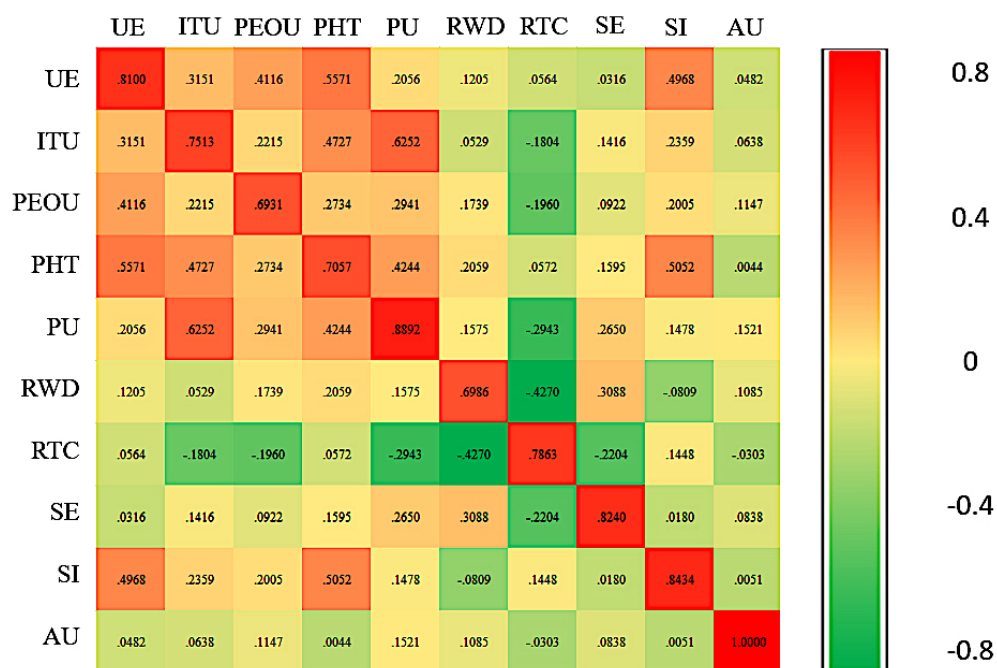
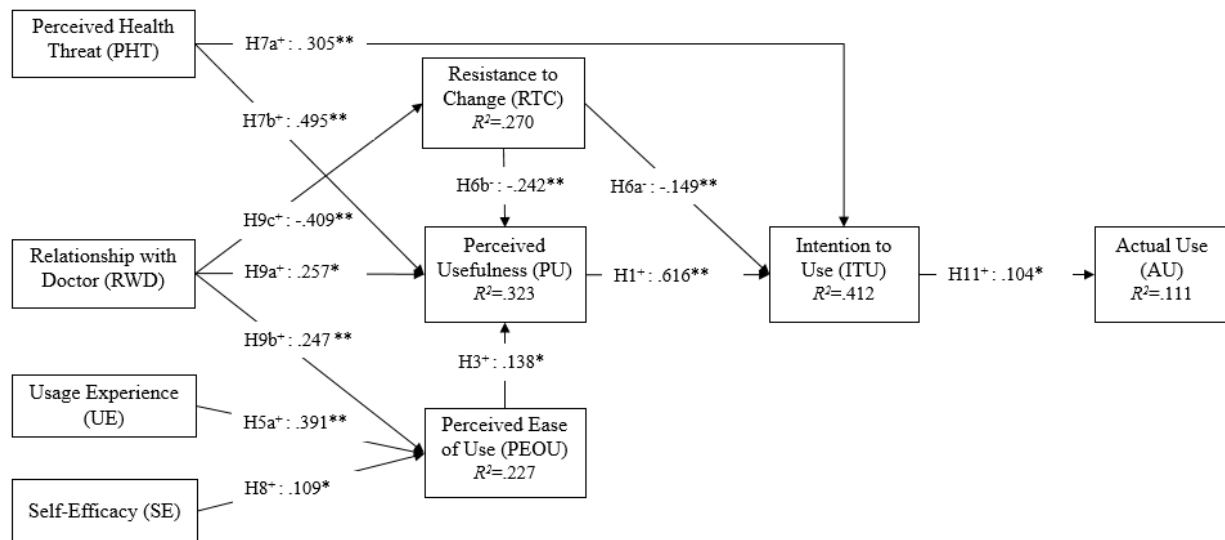
Figure 3. A heat map showing correlations and discriminant validity. The diagonal elements denote the square root of average variance extracted, and all other elements are correlations between the constructs.

Figure 4. The validated theoretical model. * $P < .05$, ** $P < .01$.

With a loading factor of 0.616, perceived usefulness had a major, significant positive effect on intention to use ($\beta=.616$, $t_{151}=6.203$), supporting H1. Perceived ease of use had no significant effect on intention to use but a significant influence on perceived usefulness ($\beta=.138$, $t_{151}=2.335$); thus, H2 was not supported but H3 was. Resistance to change (H6b), perceived health threat (H7b), and relationship with doctor (H9a) had significant associations with perceived usefulness ($\beta=-.242$, $t_{151}=3.058$; $\beta=.495$, $t_{151}=3.180$; and $\beta=.257$, $t_{151}=2.357$, respectively) but not for social influence (H4) and prior technology usage experience (H5b). Therefore, H6b, H7b, and H9a were supported but H4 and H5b were rejected. Relationship with doctor (H9b), prior mobile app usage experience (H5a), and self-efficacy (H8) showed strong positive effects on perceived ease of use ($\beta=.247$, $t_{151}=2.685$; $\beta=.391$, $t_{151}=4.092$; and $\beta=.110$, $t_{151}=1.987$, respectively). Both perceived health threat (H7a) and resistance to change (H6a) had a significant effect on intention to use ($\beta=.305$, $t_{151}=2.718$ and $\beta=-.149$, $t_{151}=2.781$, respectively). Moreover, relationship with doctor was found to have a significant negative effect on resistance to change, thus supporting H9c ($\beta=-.409$, $t_{151}=3.628$). The demographic factors were found to have no significant impact on intention to use, thus the H10 was not supported. Intention to use (H11) was found to have a significant, weak influence on actual usage ($\beta=.104$, $t=1.981$).

Discussion

Principal Findings

This study proposed a hybrid smartphone health TAM for chronic disease management. The model was developed based on an extensive review of the related models and theories, including TAM [23], TAM2 [24], dual-factor model [25], and HBM [26]. The statistical measurements (composite reliability, indicator reliability, and AVE) supported the model's reliability and validity. As the study participants used a specific smartphone health technology Blood Pressure Assistant for communication with their health care providers to manage hypertension, their relationship with doctors was considered an

important antecedent factor in the model. The validity of the model was warranted by the survey participants being actual patients who had 1 month or more experience in using the smartphone health app for hypertension management. Several key findings emerge from this study.

First, as hypothesized, the antecedent variables—including resistance to change, perceived health threat, relationship with doctor, usage experience, and self-efficacy—influenced the patients' acceptance of the smartphone health technology for hypertension management, along with the traditional TAM constructs, perceived usefulness and perceived ease of use. As these factors are considered by HBM to influence patients' engagement in health promotion behavior, therefore, our finding supports the applicability of HBM in explaining patients' behavior in using smartphone health technology for chronic disease management.

Moreover, 0.323 of variance in the perceived usefulness was explained by 3 variables: perceived health threat, relationship with doctor, and resistance to change. First, there were cascading effects starting from perceived health threat, to perceived usefulness, and to behavioral intention. The effect of perceived health threat was also found by Kim et al [13], who suggested that awareness and concern about deteriorating health conditions can motivate people to take action toward disease self-management.

Second, a major contribution of this study is to validate the significant influence of 2 antecedent factors, relationship with doctor and perceived health threat of hypertension, on the 3 intermittent factors for intention to use: the significant positive influences on both perceived usefulness and perceived ease of use, and strong negative influence on resistance to change. This demonstrated the vital role the health care providers play in any intervention that requires patients to self-manage their chronic diseases. In this study, the patients held highly positive evaluation of their relationships with doctors. This was suggested by their agreement with the statements that "doctors are my most trusted source of health information," which scored 4.59 out of 5, and "When I have a health problem, my first step is to contact a doctor," which scored 4.40 out of 5. These

positive feelings were likely to be derived from the full attention and excellent service they received from the health care providers. They received 1-hour personal training from the health manager on hypertension management about how to download and use the smartphone app. If any abnormal blood pressure recording was reported, the health care providers would call the patients to discuss and adjust the hypertension management plan. These positive interactions built up rapport and patients' trust with the health care providers. The trust could enhance the patient's interest in using the smartphone health technology to communicate with the health care providers. Therefore, patients valued the usefulness of the technology.

This high evaluation of the relationship with doctor also led to the highly positive evaluation of the intermediate factors, perceived ease of use, and intention to use. It also strongly impeded resistance to change, with values for both items "I don't want the mobile app to change the way I deal with hypertension" and "I don't want the mobile health app to change the way I interact with other people" laid at the very low level between strongly disagree and disagree.

Third, the study confirmed that resistance to change indeed had a biasing effect on patients' perception of usefulness of the smartphone technology. Its negative direct effect on behavioral intention was in accordance with that found in the middle-aged Chinese people's acceptance of mobile health services, but not in the older people aged 60 years and above [31]. Its indirect negative effect on behavioral intention through the mediation of perceived usefulness was consistent with the previous studies on consumer acceptance of eHealth technology [22]. This reflected a natural tendency for some patients to prefer to continue with the traditional way of hypertension management than switching to use the new smartphone technology.

In accordance with the previous literature [13,28,44], both self-efficacy and smartphone technology usage experience had significant positive influence on the perceived ease of use. A sense of self-efficacy appeared to increase the likelihood for the patients to evaluate the technology to be easy to use. Their previous experience with any smartphone technology also provided them with the confidence with the new health app.

Perceived usefulness and perceived ease of use are 2 significant predictors of intention to use in the previous literature [27,28,31,45]. Consistent with the previous findings about consumer acceptance of eHealth technology [13,20,27,31], perceived usefulness was also found to be the most important predictor on intention to use. Therefore, to encourage hypertensive patients to adopt smartphone health technology to manage hypertension, we need to convince them that the technology is useful for them.

However, different from the previous studies' findings [13,20,27,31,40], perceived ease of use had no significant effect on patients' intention to use smartphone health technology. This difference in finding might be related to the different experiences the study participants had with the targeted technology. For example, Sun et al [20] conducted the study immediately after the participants were introduced to the technology, when they were still in the process of learning and familiarizing themselves with the technology. In this learning process, ease of use might

be an important consideration for acceptance. Our survey was conducted after the patients had 1 month and more experience with the technology. They might be already familiar with it; thus, ease of use was no longer important for them. This was demonstrated by the very positive responses to the following statements: "Learning mobile app would be easy for me," which scored 4.58 out of 5; "I would find Blood Pressure Assistant easy to use," which scored 4.26 out of 5; and "Blood Pressure Assistant is not cumbersome to use," which scored 4.49 out of 5. Another possible reason might be the increased prevalence of smartphone, leading to the general public's increased familiarity with the smartphone apps. Thus, the technology was no longer seen as difficult to learn and use.

Contrary to the suggestion from the previous literature [13,20], social influence had no significant relationship with perceived usefulness. One possible explanation was that as a recently emerging consumer health technology, the smartphone health app was yet to be known by the general public. Therefore, the people who were the close referents to the survey participants had not yet had knowledge or formed their view about the technology. Thus, they did not have much influence on the respondents' mobile health app usage behavior. This observation was supported by the low average score of the responses to the statement "People who are important to me think that I should use Blood Pressure Assistant," which was only between "disagree and neutral" (2.42). The average score of the responses to the item stating "People who are important to me think that I should use Blood Pressure Assistant" was between "strongly disagree" to "disagree" (1.76). Another possibility was that after having hands-on usage experience with the technology for 1 month or more, the respondents' attitudes toward it were no longer influenced by the significant others around. They made judgment based on their own experiences.

Finally, 1 step further from the previous consumer health technology acceptance studies [13,20,27,31,40,44], this study linked the input variables that measured individual beliefs to the actual use of a smartphone health app. It validated that intention to use had significant, weak relationship with actual use, explaining 0.111 of the variance in patients' actual use of the smartphone health technology. This was contrary to Lim et al's finding of a gap between intention and actual use [28]. This provides support to the validity of our tested theoretical model in explaining patient's acceptance of smartphone health app.

Limitations

This study is, understandably, limited by its empirical scope of the study population, their social, economic, and geographic location; the smartphone health app to be used; and the type of chronic disease they suffered from. The results may vary from place to place [40] or from the app in use to the other.

The measurement of constructs can be further developed. For example, relationship with doctor may include multiple aspects, in addition to the 2 items measured in this study. Previous studies found that privacy concern is an important factor influencing patients' acceptance of information technology [46,47]. With portability and small size, use of smartphone app may indeed generate new security and privacy issues such as leakage and tampering of data transmitted over the wireless

network [48], or stolen or lost device. Therefore, there is a need for all the sensor readings to be anonymized before analyzing them to guarantee the privacy of the participants [49]. As our research model did not include privacy concern as a construct, a future research direction is to integrate the privacy concern into the theoretical model.

Another limitation was the means by which the study participants were recruited. As only the patients who already used the smartphone health app Blood Pressure Assistant were recruited into the study, they were the innovative group of patient population who were likely to have a higher level of social economic status to afford to have smartphone than others; therefore, although the finding was valid for this population group, it may not be generalizable to the entire patient population even in our study site.

Only a moderate level of variation in use (0) was explained. The study captured actual use from only 1 dimension, patients' submission of blood pressure recording. It did not capture use of other functions, such as accessing health educational information. Future research can identify other constructs influencing patients' smartphone health technology use. The internal validity of the study was also confined by nonrespondents. Therefore, the future study can fine-tune the measurement of use. It also needs to evaluate the relationship between actual use and outcomes.

Conclusions

The study developed a theoretical model about patients' acceptance of smartphone health technology for chronic disease

management. It found that patients' perceived usefulness of smartphone health technology was positively influenced by their perceived health threat, relationship with doctor, and perceived ease of use, but negatively influenced by resistance to change. Good patient-doctor relationships can alleviate patient resistance to change. Usage experience and self-efficacy positively influenced patients' perceived ease of use. Intention to use was influenced by the enablers of perceived usefulness and perceived health threat, and the inhibitor of resistance to change. Intention to use had a significant, weak relationship with actual use.

Implications for Practice

Although the rapid growth of smartphone technology has opened new opportunities for chronic disease management, the opportunity can only be captured by the patients who accept and use the technology. The findings suggest that 3 antecedent factors, relationship with doctor, perceived health threat, and resistance to change, are important for patients' acceptance and use of smartphone health technology. Therefore, for the successful introduction of smartphone health technology innovation for chronic disease management, efforts need to be focused on improving patient-doctor relationship and providing continuous patient education to raise awareness of the disease's threat to health. These strategies will be effective in overcoming potential resistance to change and encouraging acceptance and use of the new technology.

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Conflicts of Interest

None declared.

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Abbreviations

- AU:** actual use
- AVE:** average variance extracted
- CR:** composite reliability
- HBM:** health belief model
- ITU:** intention to use
- mHealth:** mobile health
- PEOU:** perceived ease of use
- PHT:** perceived health threat
- PLS:** partial least square
- PU:** perceived usefulness
- RTC:** resistance to change
- RWD:** relationship with doctor

SCT: social cognitive theory
SE: self-efficacy
SI: social influence
TAM: technology acceptance model
UE: usage experience

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Original Paper

Web-Based Interventions Supporting Adolescents and Young People With Depressive Symptoms: Systematic Review and Meta-Analysis

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Abstract

Background: Although previous studies on information and communication technology (ICT)-based intervention on mental health among adolescents with depressive symptoms have already been combined in a number of systematic reviews, coherent information is still missing about interventions used, participants' engagement of these interventions, and how these interventions work.

Objective: We conducted a systematic review and meta-analysis of trials to describe the effectiveness of Web-based interventions to support adolescents with depression or depressive symptoms, anxiety, and stress. We also explored the content of the interventions, as there has previously been a lack of coherent understanding of the detailed content of the Web-based interventions for these purposes.

Methods: We included parallel randomized controlled trials targeted at adolescents, or young people in the age range of 10 and 24 years, with symptoms or diagnoses of depression and anxiety. The interventions were from original studies aimed to support mental health among adolescents, and they were delivered via Web-based information and communication technology.

Results: Out of 2087 records identified, 27 papers (22 studies) met the inclusion criteria. On the basis of a narrative analysis of 22 studies, a variety of Web-based interventions were found; the most commonly used intervention was based on cognitive behavioral therapy. Meta-analysis was further conducted with 15 studies (4979 participants). At the end of the intervention, a statistically significant improvement was found in the intervention group (10 studies) regarding depressive symptoms ($P=.02$, median 1.68, 95% CI 3.11-0.25) and after 6 months (3 studies; $P=.01$, median 1.78, 95% CI 3.20-0.37). Anxiety symptoms (8 studies; $P<.001$, median 1.47, 95% CI 2.36-0.59) and moods and feelings (2 studies; $P=.04$, median 5.55, 95% CI 10.88-0.22) improved as well in the Web-based intervention group, but there was no difference in stress scores. However, adolescents in the intervention group left the study early more often, both in short-term studies (11 studies; $P=.007$, median 1.31, 95% CI 1.08-1.58) and mid-term studies (3 studies; $P=.02$, median 1.65, 95% CI 1.09-2.49). We did not find any studies that had assessed the costs of the Web-based interventions.

Conclusions: Despite widely reported promises that information technology use is beneficial to adolescents with depression, the results of our review show only short-term effects on adolescents' mental well-being, whereas long-term effects remain questionable because of the limited number of studies reviewed. Information about the economic benefits of Web-based interventions is still lacking. The quality of the studies, especially biases related to attrition rates and selective reporting, still needs serious attention.

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KEYWORDS

Internet; adolescent; depression; meta-analysis; information and communication technology; intervention; systematic review; treatment as usual

Introduction

Currently, about half of adolescents showing signs of depression get treatment [1]. Identification of potentially effective interventions for adolescents with depression and anxiety is therefore a vital step toward supporting societies in general [2]. Information and communication technology (ICT)-based interventions have the potential to address treatment gaps concerning a variety of mental disorders [3,4]. Over 90% of adolescents use the Internet daily and 56% several times a day [5]. The Internet allows anonymous participation [4], without the fear of stigmatization [6]. Other benefits may include cost-effectiveness [7,8] and high accessibility [3].

Although a wide range of ICT-based interventions has been developed and tested, the impact of these interventions is still controversial in the field of mental health. On the basis of previous reviews, cognitive behavioral therapy (CBT)-based Web-based interventions have been found to impact the appearance of depressive and anxiety symptoms among young people [9-11], whereas online and mobile psychosocial suicide prevention intervention has reduced suicidal ideation, depression, and hopelessness [12]. A relevant study by Reyes-Portillo et al [13] reviews the effectiveness of Web-based treatment and prevention interventions developed for anxiety, depression, and suicide prevention. They found that 10 out of the 25 studies they reviewed reported significant postintervention reductions in symptoms, or improvements in diagnostic ratings. However, the evidence supporting the effectiveness of Internet-based interventions for youth depression and anxiety is still limited. Ye et al [14] performed a meta-analysis on 7 studies related to these types of interventions for young people. They observed a decrease in the severity of anxiety symptoms, but not a statistically significant decrease in depressive symptoms, when the results were compared with a wait list group. Nor were statistical differences found in depressive symptoms when Internet-based treatment was compared with face-to-face treatment in 2 studies. Furthermore, Kauer et al [15] did not find any improvement in the behavior among young people when it came to seeking help from Web-based services (18 studies), and a narrative review by Best et al [16] on the effects of social media technology on adolescent well-being found mixed effects or no effects at all.

Concerns regarding these Web-based intervention studies include methodological flaws such as heterogeneity in the interventions in terms of content, settings, dose, or quality [9,17]. A review by Arnberg et al [18] showed that the quality of evidence was graded as low or very low, and therefore, no conclusions were able to be drawn. Concerns also include insufficient search processes of the literature [10], small sample sizes [13,15], and differences in baseline in study samples [14]. A publication bias toward positive results has also been expressed [10,11,13,18].

Despite promising results of ICT-based interventions for adolescents and young people with depression, the overall picture of the effectiveness of these interventions is still inconclusive. To understand how the intervention works [9], we need to consider in more detail the content and structure of the interventions [19]. Therefore, in this systematic review, we describe the Web-based interventions and explore the impact of these interventions on the reduction of depressive symptoms among adolescents and young people with symptoms or a diagnosis of depression.

Methods

The methods of this systematic review have been based on the preferred reporting items for systematic reviews and meta-analysis (PRISMA) [20]. PRISMA-P for meta-analysis protocols [21] and Cochrane handbook for systematic reviews of interventions [22] were also used in the preparation of our meta-analysis. Where possible, the data extraction was based on the CONSORT-EHEALTH checklist version 1.6.1 [23]. Web-based interventions were described using the template for intervention description and replication (TIDieR) checklist and guide [24].

Eligibility Criteria

The review was limited to assessing the effectiveness of the interventions using a randomized controlled trial (RCT) design to gather only high-quality studies about health care interventions [25]. We included studies targeted at adolescents or young people in the age range of 10 and 24 years [26] who had been diagnosed with depression or had experienced symptoms of depression or anxiety [27]. We focused on interventions that aimed to support mental health among adolescents by preventing, identifying, or decreasing the symptoms of depression or anxiety, or through counseling. The interventions were delivered via ICT, including Web-based technology [28], which could be accessed by computers, tablets, or mobile phones. The review focused on published (or in-press) articles written in peer reviewed journals and published in English. The primary outcome used was depression, and the secondary outcomes used were anxiety, stress, moods and feelings, leaving the study early (attrition rate), and costs.

We excluded dissertations, letters, editorials, literature reviews, book reviews, and book chapters, in addition to studies with designs other than RCT. Study protocols of specific studies were searched for manually and used to verify possible risk of biases. Studies were excluded if the intervention was targeted at adults or persons under 10 or over 25 years old, parents, teachers, or health care staff. If the primary focus of the intervention was something other than depression, such as brain injury, eating disorder, or epilepsy, or if the intervention only included texting, the study was excluded.

Literature Search Strategy

We conducted a comprehensive literature search on September 1, 2015, and an updated search was done on February 10, 2017. Four electronic databases covering published research from the health and social field were investigated: MEDLINE, PsycINFO, CINAHL, and Cochrane. A combination of medical subject headings and text-based search terms [29] for the databases was used. The search was conducted with the help of an information specialist. Due to changes in user interface in databases between the original and updated search, a search for MEDLINE, PsycInfo, and Cochrane was combined via Ovid (in 2017). Electronic databases used, search terms, and number of hits are documented in [Multimedia Appendix 1](#). For additional references, we consulted the references in the included studies. Relevant systematic reviews were identified through electronic searches to avoid overlap between previous studies.

Study Selection

When choosing the selection of studies [22], first, two authors (KA, MA) independently screened all titles of abstracts that were relevant to this systematic review. Second, the abstracts were screened for eligibility. Third, the full papers of the included abstracts were screened for inclusion and exclusion criteria. In cases of discrepancy, the papers were discussed with MV until a consensus was reached. On the basis of the assessment process, the abstracts were included first in the narrative synthesis and later in the meta-analysis (see [Figure 1](#)) based on specific criteria, which are recorded in [Table 1](#).

Data Extraction

We created the data extraction table matrix to collect and describe information, focusing our aims in the synthesis. Data extraction involved describing the included studies and interventions, as well as the excluded studies. For the descriptions of the included studies, the information was collated by authors, year of publication, country of origin, purpose of the study, setting, target group, age, total number of participants randomized, and the number allocated in each study group. Information was combined if the publication (a hit) was based on original data published in more than one paper and the identification was based on the study protocol number. These studies were described in the data extraction tables (matrixes) as one study. The data from 22 included studies (27 hits) for narrative analysis were entered into the specific data extraction grid, where each study was treated as a separate case, and descriptive characteristics of the studies were categorized manually (see [Multimedia Appendix 2](#)).

The interventions were extracted to a matrix table based on the TIDieR checklist and guide [24] (see [Multimedia Appendix 3](#)). The categorization was done under the following themes based

on the thematic analysis of Braun and Clarke [41]: (1) materials and procedures; (2) provider and modes of delivery; (3) location, dose, and length of the program; and (4) tailoring of the intervention, modifications, and fidelity.

Data Analysis

For the meta-analysis, a summary of outcome measures used in 15 studies is described in [Table 2](#). The meta-analysis was undertaken using Review Manager RevMan version 5.3 (Nordic Cochrane Centre, Cochrane Collaboration, 2014) for preparing and maintaining Cochrane reviews [42]. For continuous outcomes, mean differences were compared between groups. When similar scales were used, presuming that there would be only small differences in measurement tools, measurements were combined. This decision was made to answer the overall question of whether there is evidence that Web-based interventions can be an effective intervention among young people with depression or depressive symptoms [22]. Standard deviations were used with the sample sizes to compute the weight given to each study. A random-effects analysis was used instead of a fixed-effect method, as the former allows the outcomes of studies to vary more than the latter does; a random-effects analysis can be seen as a more natural way of explaining outcomes [43].

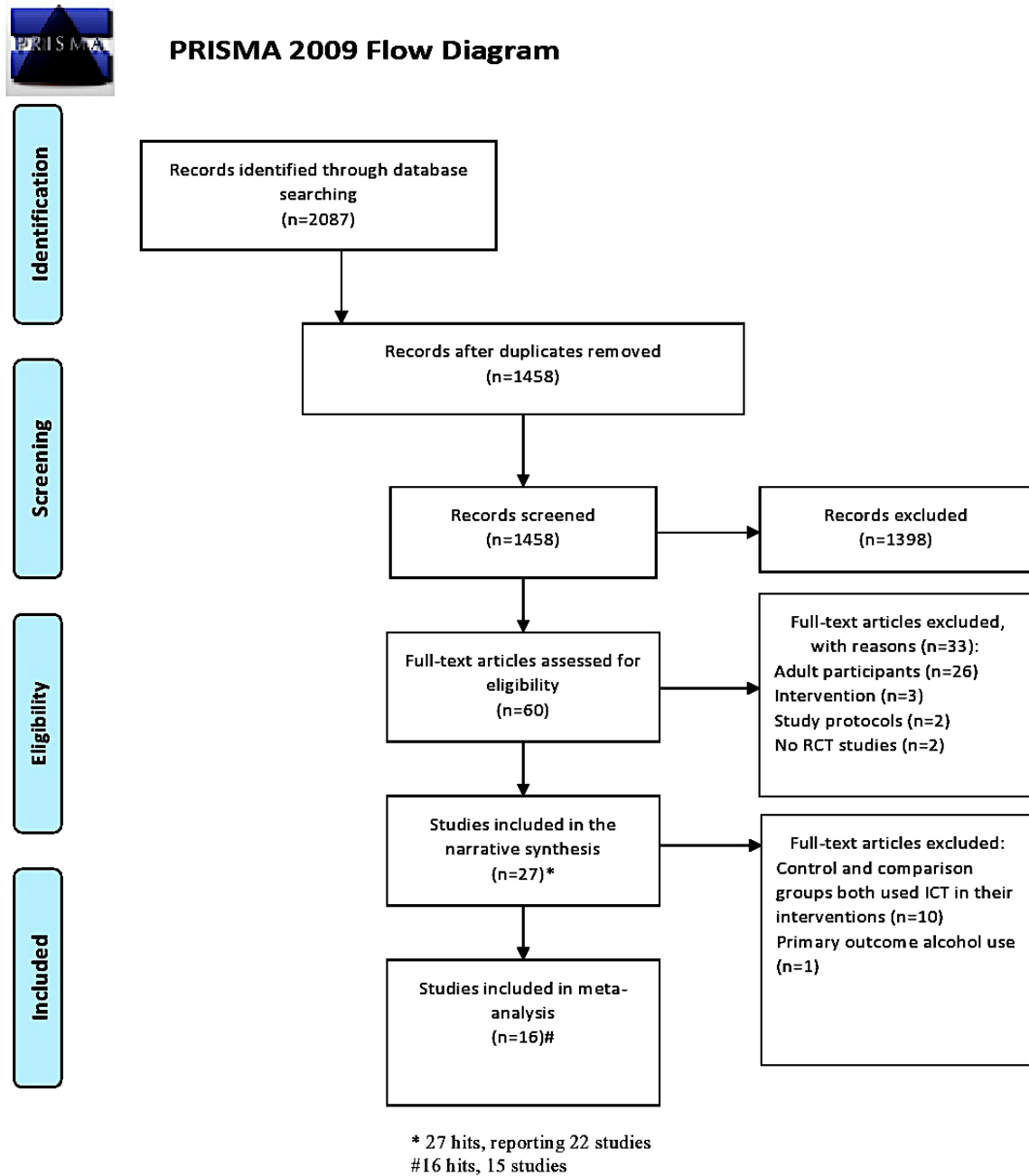
In cases of missing or incomplete data, there was an attempt to contact the authors of the study in question. However, as no replies were received from these attempts, available data was used. Heterogeneity was assessed by calculating the I^2 index. If the estimated I^2 was greater than or equal to 50%, it was interpreted as indicating the presence of high levels of heterogeneity [22].

Assessment of the Studies Included in Meta-Analysis

The quality of the 15 studies included in the meta-analysis was appraised by using a tool measuring risk of bias from Review Manager (RevMan) version 5.3 [60] with the following criteria [22]: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias ([Figure 2](#)). For each study, KA and MV classified the domain as having a low, high, or unclear risk of bias. To minimize the risk of publication bias, bibliographic databases and trial registries were consulted to compare original review plans and outcomes reported. Any discrepancy between the two review authors was resolved through discussion (KA, MV, ML).

A sensitivity analysis was conducted by excluding studies (1) with a sample size that vastly differed from other studies or (2) if one or more of the studies had low-quality issues affecting the study results.

Figure 1. Preferred reporting items for systematic reviews and meta-analysis (PRISMA) flow diagram.



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Table 1. Excluded studies from the meta-analysis and reason for being excluded.

Study	Title
Burckhardt et al 2015 [30]	A Web-based adolescent positive psychology program in schools: a randomized controlled trial ^a
Geisner et al 2015 [31]	Brief Web-based intervention for college students with comorbid risky alcohol use and depressed mood: Does it work and for whom? ^b
Hoek et al 2011 [32]	Randomized controlled trial of primary care physician motivational interviewing versus brief advice to engage adolescents with an Internet-based depression prevention intervention: 6-month outcomes and predictors of improvement ^a
Manicavasagar et al 2014 [33]	Feasibility and effectiveness of a Web-based positive psychology program for youth mental health: randomized controlled trial ^a
Saulsberry et al 2012 [34]	Randomized clinical trial of a primary care Internet-based intervention to prevent adolescent depression: 1 year outcomes ^a
Stasiak et al 2014 [35]	A pilot double blind randomized placebo controlled trial of a prototype computer-based cognitive behavioral therapy program for adolescents with symptoms of depression ^a
Van Voorhees et al 2008 [36]	Integrative Internet-based depression prevention for adolescents: A randomized clinical trial in primary care for vulnerability and protective factors ^a
Van Voorhees et al 2009a [37]	Adolescents dose and rating of an Internet-based depression prevention program: a randomized trial of primary care physician brief advice versus a motivational interview ^a
Van Voorhees et al 2009b [38]	Randomized clinical trial of an Internet-based depression prevention program for adolescents (Project CATCH-IT) in primary care: 12-week outcomes ^a
Whittaker et al 2012 [39]	MEMO—A mobile phone depression prevention intervention for adolescents: development process and post-program findings on acceptability from a randomized controlled trial ^a
Wright et al 2017 [40]	Computerized cognitive behavioral therapy for depression in adolescents: feasibility results and 4-month outcomes of a UK randomized controlled trial

^aIntervention: comparison by ICT versus ICT.

^bTarget population: risky alcohol use.

Table 2. Authors, outcomes, and outcome measures included in the meta-analysis.

Author (year), protocol number	Depression	Anxiety	Stress	Life satisfaction or quality of life	Moods and thoughts	Leaving the study early	Costs
Calear et al 2009 [44] 2013 [45], ISRCTN67189839	Center for Epidemiological Studies Depression Scale (CES-D)	The Revised Children's Manifest Anxiety Scale	Not applicable (N/A) ^a	N/A ^a	N/A ^a	Data available	N/A ^a
Calear et al 2016 [46], Published study protocol not available	CES-D ^b	N/A ^a	N/A ^a	N/A ^a	N/A ^a	Data available	N/A ^a
Costin et al 2009 [47], ISRCTN98406912	Symptoms of depression (CES-D)	N/A ^a	N/A ^a	N/A ^a	N/A ^a	Data available	N/A ^a
Hoek et al 2012 [48], NTR1322	CES-D	Hospital Anxiety and Depression Scale	N/A ^a	Client Satisfaction Questionnaire	N/A ^a	Data available	N/A ^a
Ip et al 2016 [49], Published study protocol not available	Center for Epidemiological Studies Depression Scale-Revised (CESD-R) Depression scale (DASS ^c)	Anxiety scale (DASS)	Stress Scale (DASS)	N/A ^a	N/A ^a	Data available	N/A ^a
Kramer et al 2014 [50], NTR1696	Symptoms of depression (CES-D)	N/A ^a	N/A ^a	N/A ^a	N/A ^a	Data available	N/A ^a
Levin et al 2014 [51], Published study protocol not available	Depression scale (DASS)	Anxiety scale (DASS)	Stress scale (DASS)	N/A ^a	N/A ^a	Data available	N/A ^a
Lillevoll et al 2014 [52], Published study protocol not available	N/A ^a	N/A ^a	N/A ^a	N/A ^a	N/A ^a	Data available	N/A ^a
Merry et al 2012 [53], ACTRN12609000249257	Children's Depression Rating Scale-Revised Reynolds Adolescent Depression Scale-2nd edition (RADS-2)	Spence Children's Anxiety Scale	N/A ^a	Pediatrics Quality of Life and Satisfaction Questionnaire	Mood and Feelings Questionnaire (MFQ) Hopelessness Scale	Data available	N/A ^a
Poppelaars et al 2016 [54], Published study protocol not available	RADS-2	N/A ^a	N/A ^a	N/A ^a	N/A ^a	Data available	N/A ^a
Reid et al 2011 [55], NCT00794222	Depression scale (DASS)	Anxiety scale (DASS)	Stress scale (DASS)	N/A ^a	N/A ^a	Data available	N/A ^a
Rickhi et al 2015 [56], Published study protocol not available	CDRS-R ^b Hamilton Depression Rating Scale ^b	N/A ^a	N/A ^a	N/A ^a	N/A ^a	Data available	N/A ^a
Sethi et al 2010 [57], Published study protocol not available	Depression scale (DASS-21) Kessler Psychological Distress Scale	Anxiety scale (DASS-21)	Stress Scale (DASS-21)	N/A ^a	Automatic Thoughts Questionnaire	Data available	N/A ^a
Smith et al 2015 [58], Published study protocol not available	Children's Response Styles Questionnaire ^b	Screen for Child Anxiety Related Emotional Disorders	N/A ^a	N/A ^a	MFQ	Data available	N/A ^a

Author (year), protocol number	Depression	Anxiety	Stress	Life satisfaction or quality of life	Moods and thoughts	Leaving the study early	Costs
Stallard et al 2011 [59], Published study protocol not available	The Adolescent Well-being Scale ^b	The Spence Children's Anxiety Scale child version ^b	N/A ^a	N/A ^a	The Schema Questionnaire for Children	Data available	N/A ^a

^aN/A signifies missing outcome.

^bUsable data not available.

^cDASS: Depression Anxiety Stress Scales.

Figure 2. Risk of bias of studies included in the meta-analysis.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Calear et al 2009	+	+	+	?	-	-	+
Calear et al 2016	+	+	+	?	-	+	+
Costin et al 2009	+	-	+	+	+	-	+
Hoek et al 2012	+	+	+	+	-	-	+
Ip et al 2016	+	+	+	+	+	+	-
Kramer et al 2014	+	+	+	+	-	-	?
Levin et al 2014	+	?	+	+	-	?	-
Lillevoll et al 2014	+	-	+	+	-	-	?
Merry et al 2012	+	+	+	+	+	+	+
Poppelaars et al 2016	?	+	-	+	+	-	-
Reid et al 2011	?	?	+	+	+	-	+
Rickhi et al 2015	+	-	+	+	+	-	+
Sethi et al 2010	+	?	+	+	+	?	+
Smith et al 2015	+	?	+	?	+	+	+
Stallard et al 2011	+	-	+	+	+	?	?

Results

Results of the Search

We screened 2087 hits of abstracts, which were identified through electronic databases. On the basis of the screening, we removed 1458 duplicates. After assessing their eligibility, 1398 abstracts were excluded, which left us with 60 abstracts. Sixty full papers were then retrieved for potential inclusion in the study, and their eligibility was assessed based on our inclusion and exclusion criteria. We excluded 33 abstracts, which left us with 27 paper hits (22 studies) included in the narrative synthesis. Overall, 16 paper hits (15 studies) were included in the meta-analysis (see [Figure 1](#)).

Characteristics of the Studies

Narrative Analysis

The studies included in the narrative analysis (22 studies, 27 papers) were published from 2008 to 2017. They were conducted in school environments, health care settings, or in community settings in Australia, Canada, China, the Netherlands, New Zealand, Norway, the United Kingdom, or the United States. The number of participants in each study ranged between 20 and 1767. Their ages varied in the age range of 11 and 24 years. The attrition rate of the studies was between 0% (0/38) and 67.3% (385/572) (see [Multimedia Appendix 2](#)).

Meta-Analysis

Fifteen studies (16 hits) included in the meta-analysis were published from 2009 to 2016. The total number of participants was 4979. The attrition rate of the included studies ranged from 0% (0/38) to 61.12% (1080/1767). (see [Multimedia Appendix 2](#)).

Description of the Interventions

In 22 eligible studies (27 articles), a variety of Web-based interventions were used (see [Multimedia Appendix 3](#)). The most common background approach used was CBT. Related to materials and procedures, the interventions were composed of modules, sessions, or lessons, with a variety of themes of background theories. ICT-based interventions used interactive games, online chats, mobile phone apps, and emails. The participants were offered activities to support their progress, such as homework assignments or exercises, skill training, workbooks or guided work, quizzes, and questionnaires. Interventions were provided by various professionals such as teachers, school counselors, research team members, project coordinators, or health care personnel. The programs were delivered on websites through computer software via compact disc read-only memory, mobile phone apps, or emails. They were offered at schools, in health care services, or in community settings. The interventions could include up to 14 modules that lasted from 3 to 10 weeks, typically done once per week. The time spent on the programs ranged from 20 min to 3 hours per week. Regarding the fidelity of the intervention, the participants' completion of the intervention varied between 10% and 94%.

Risk of Bias in the Meta-Analysis

Most studies (12/15) included in the meta-analysis had a low risk of selection bias in random sequence generation. Half of the studies (7/15) had a low risk in allocation concealment, whereas in 4 studies (4/15), the risk was high. The risk involved with blinding participants and personnel (13/15) and outcome assessment (11/15) was low in most studies. More concern was raised regarding attrition bias (6/15 had a high risk) and especially, selective reporting (8/15 had a high risk). Out of 15 included studies, a published trial registration or a protocol was not found for 3 studies ([Figure 2](#)).

Effectiveness of the Interventions on Depressive Symptoms

For the primary outcome, a meta-analysis was performed involving 10 studies [[44,47-51,53-55,57](#)]. We compared Web-based interventions with the control groups of the studies by investigating the short-term effects of the interventions on depressive symptoms. This analysis (postintervention measurement) showed statistically significant improvements in the Web-based intervention groups ($P=.02$, median 1.68, 95% CI 3.11-0.25). However, only 4 of the studies [[36,38,40,54](#)] compared the effects on depressive symptoms regarding mid-term effects (follow-up measurements after 3-5 months). No statistically significant improvements in the Web-based intervention group were found in these comparisons ($P=.08$, median 2.91, 95% CI 6.19-0.36).

We further assessed the long-term effects of the Web-based interventions. Out of 10 studies, we found 3 studies [[44,49,54](#)] that assessed the long-term effects (6 months or longer). As for short-term effects after intervention, statistically significant improvements were found in adolescents' depression scores in the Web-based intervention group ($P=.01$, median 1.78, 95% CI 3.20-0.37).

Substantial heterogeneity was found in the short-term and mid-term effects, but regarding the long-term effects, heterogeneity was only at a moderate level (see [Figure 3](#)).

Web-Based Intervention Group Versus Control Regarding Anxiety Symptoms

Anxiety symptoms were assessed in 8 studies comparing short-term effects of Web-based interventions to control groups [[44,48,49,51,53,55,57,58](#)]. Statistically, significant improvements were found in the Web-based intervention group in the short term ($P=.001$, median 1.47, 95% CI 2.36-0.59). However, for the mid-term assessment (follow-up measurements after 3-5 months), only 2 studies evaluated the effectiveness of a Web-based intervention for anxiety symptoms [[48,53](#)], and no statistically significant improvements in the symptoms were found ($P=.36$, median 1.42, 95% CI 4.45-1.62; see [Figure 4](#)). None of the studies measured the effectiveness at the 6-month mark.

Tests evaluating heterogeneity showed that for short-term and mid-term effects, heterogeneity was on a moderate level (see [Figure 4](#)).

Figure 3. Short-, mid-, and long-term effectiveness of Web-based interventions on depressive symptoms compared with that of a control group.

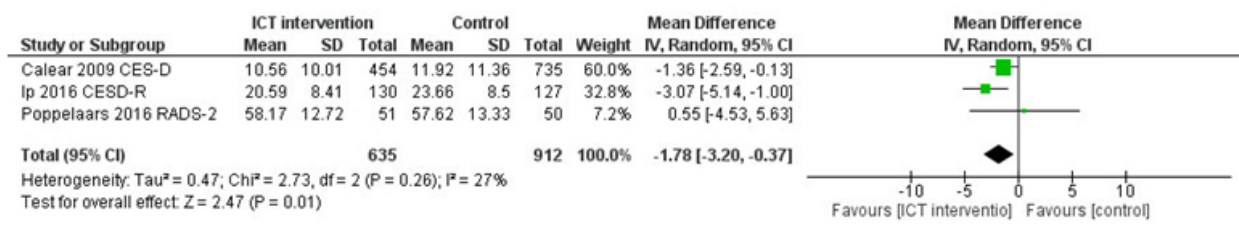
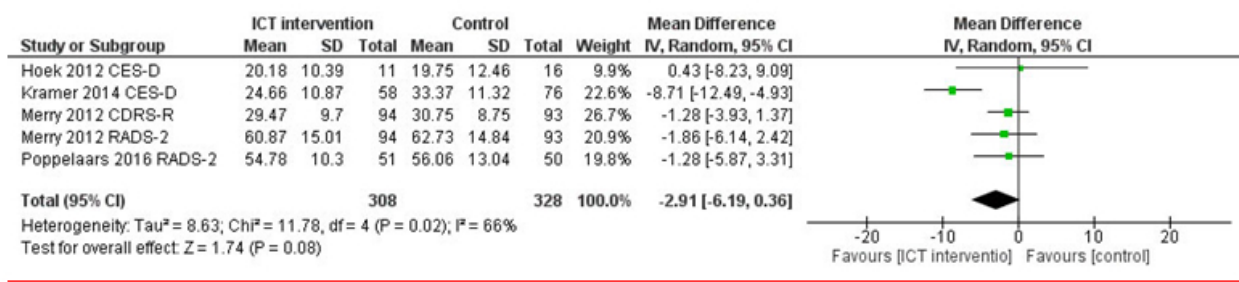
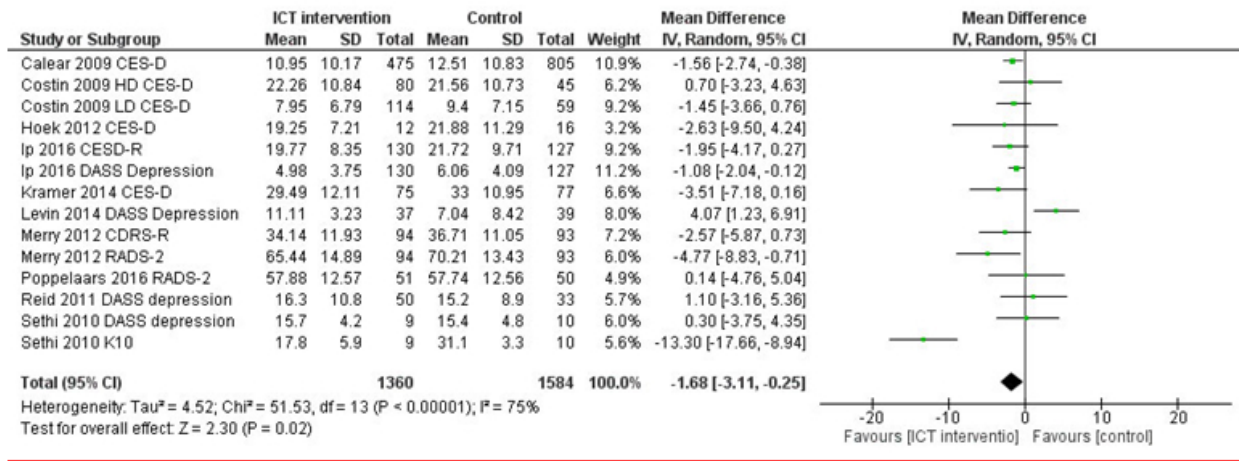


Figure 4. Short-term and mid-term effectiveness of Web-based interventions on anxiety symptoms compared with that of a control group.

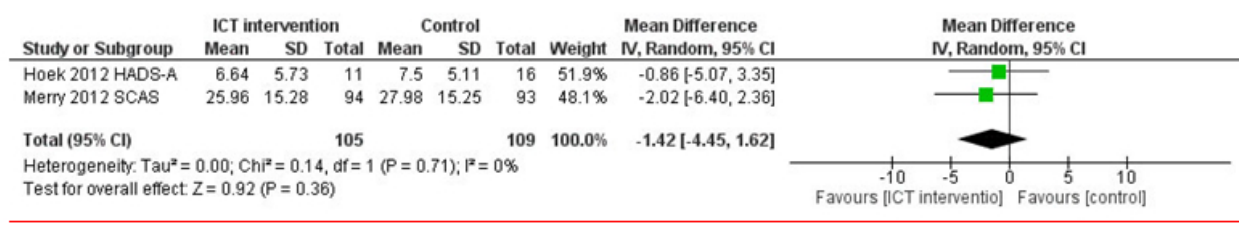
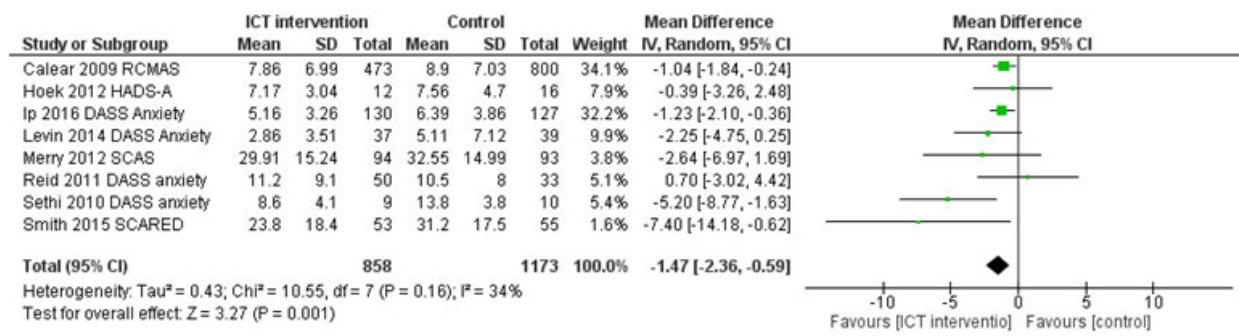
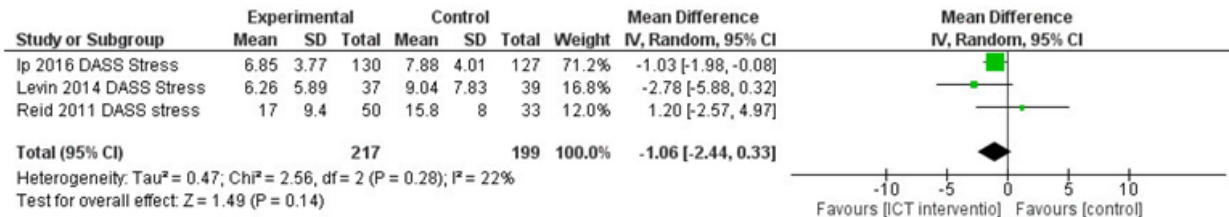


Figure 5. Short-term effectiveness of Web-based interventions on stress symptoms compared with that of a control group.



Web-Based Intervention Group Versus Control Regarding Stress Symptoms

An analysis of stress outcomes was performed (3 studies) [49,51,55] to compare the effectiveness of a Web-based intervention on stress symptoms with that of a control group. The postintervention comparison showed no statistically significant short-term improvements in the intervention group (P=.14, median 1.06, 95% CI 2.44-0.33; see Figure 5).

Heterogeneity tests showed that heterogeneity was on a moderate level in short-term effects (see Figure 5).

Web-Based Intervention Group Versus Control Regarding Moods and Feelings

A meta-analysis was performed on 2 studies [53,58] to compare Web-based interventions with control groups with regard to short-term effects on moods and feelings. These comparisons (postintervention measurement) showed some statistically significant improvements in the Web-based intervention groups

(2 studies; P=.04, median 5.55, 95% CI 10.88-0.22). Heterogeneity tests showed that heterogeneity was at a considerable level in the short-term effects (see Figure 6).

Web-Based Intervention Group Versus Control in Leaving the Study Early (Attrition)

Regarding the secondary outcome, leaving the study early, a meta-analysis was performed on 11 studies [44,47-50,52-55,58,59]. Postintervention measurement comparisons of short-term effects on leaving the study early regarding showed statistically significant results favoring the control group (P=.007, median 1.31, 95% CI 1.08-1.58). In an assessment of the mid-term effects (follow-up measurements after 3-5 months), 3 studies were compared [48,50,53]. Again, a statistically significant result favored the control group, showing that young people left the study earlier in the intervention group (P=.02, median 1.65, 95% CI 1.09-2.49). Heterogeneity tests showed substantial heterogeneity both in short and mid-term effects (Figure 7). An analysis of long-term effects was not possible because of missing data.

Figure 6. Short-term effectiveness of Web-based interventions on moods and feelings compared with that of a control group.

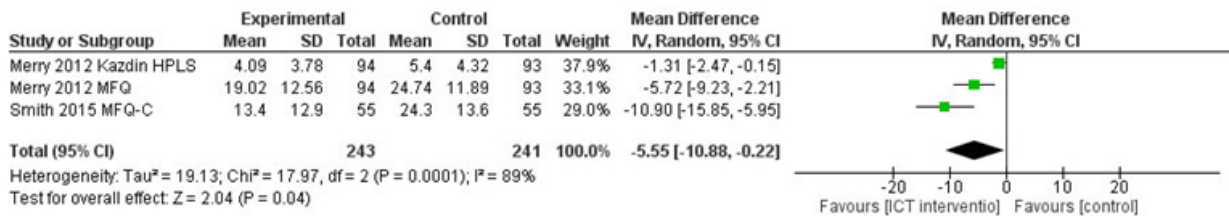
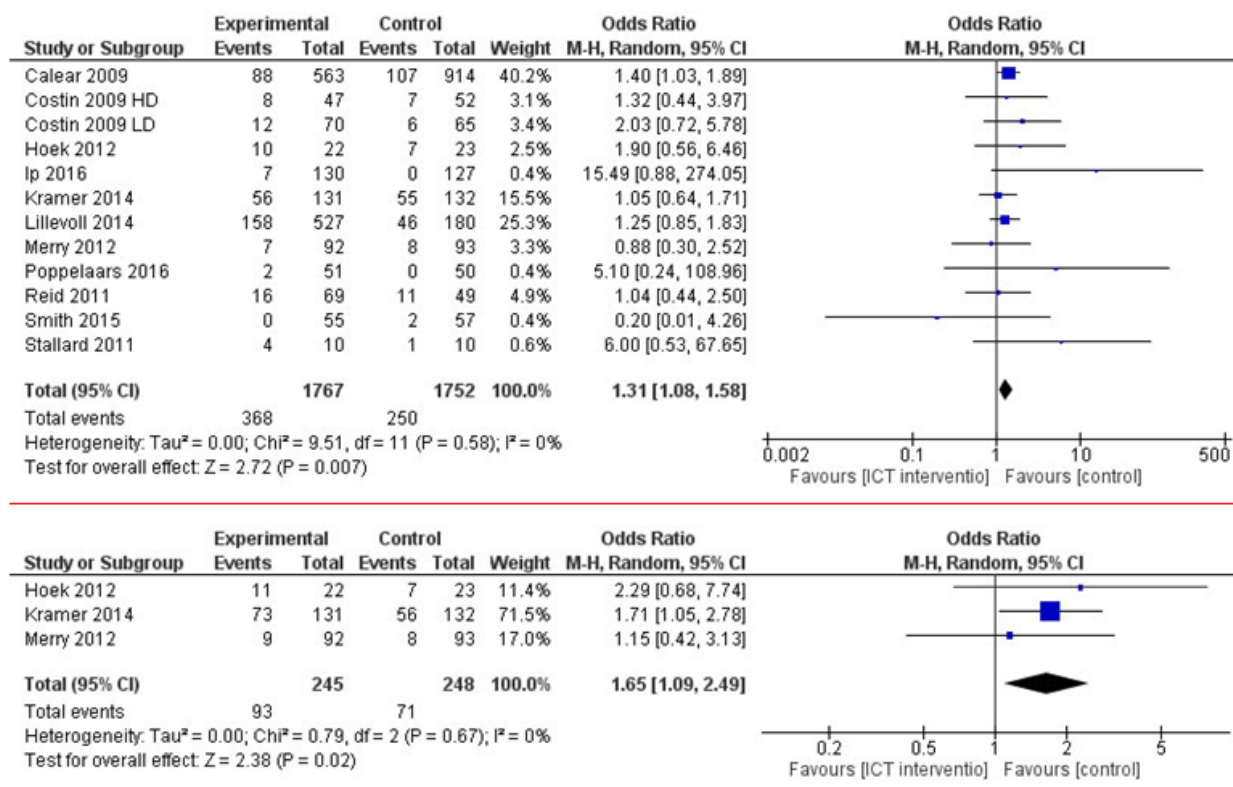


Figure 7. Short- and mid-term effectiveness of Web-based interventions on leaving the study early compared with that of a control group.



Discussion

Principal Findings

Our review showed fluctuations in the results of the effectiveness of the Web-based interventions; there was statistically significant improvement in the short-term and long-term (over 6 months with 2 studies) effects regarding adolescent depression but not in mid-term effects. Furthermore, in scores regarding anxiety and moods and feelings, a statistically significant improvement was found after the intervention but not in follow-up measurements. The fluctuation in the depression scores and a lack of significant findings may be a result of the small number of studies that included follow-up measurements. More studies with longer follow-up periods should therefore be conducted to produce clinically significant evidence on the long-term effectiveness of Web-based interventions.

Comparison With Prior Work

This review is pertinent because the effective interventions for supporting adolescent health are an investment in public health and the future (63). As 92% of adolescents use the Internet daily (5), Web-based interventions could offer solutions to problems in seeking help with depression (1). In line with previous studies related to psychological therapies [61], we assumed that Web-based interventions might have positive effects on stress levels among young people. However, we were unable to fully confirm our hypothesis. Previous studies have found relief in adolescents' stress, if the intervention included psychological therapies with face-to-face contact [62]. Contrary to personal contact, Web-based interventions are often self-directed [9,44,52] or self-guided [33]. We can, therefore, ask whether

the lack of regular human contact produced less-effective results. Indeed, interventions in our study that favored the intervention group included face-to-face guidance, monitoring of engagement, or follow-up telephone calls by teachers and health professionals (eg, [44,46,49]). We also found that participants in the intervention groups left the study early more often, indicating that they may not have been fully engaged in these Web-based interventions [9].

A comparison of costs of stand-alone online interventions and that of personal communication has not been analyzed thoroughly enough. In general, the use of effective interventions for supporting adolescent health has been seen as an investment in the future of public health [63]. The promises of cost savings with the use of information technology could rely on the fact that most adolescents are already frequent Internet users [5], which could save high investment costs. Its features could be translated into health services and offer easy access [1,3], safeguarded anonymity [4], and opportunities to receive help without the fear of stigmatization [6]. However, the Web-based interventions found in our narrative analysis varied greatly, with diverse background approaches, materials and procedures, providers, delivery types, dosages, and lengths of the intervention. Descriptions of interventions have been of poor quality, which has limited the possibility of comparisons, intervention replication, and the usability of study results in practice [24].

Many studies rely on the opportunities of health technologies for better health outcomes and decreased health costs [7,8]. Our review, however, did not reveal any studies assessing the costs of Web-based interventions. This result is noteworthy because huge investments are currently being made in the development of technological solutions for health services. The World Bank

[64] has already screened more than 500 mobile health studies and concluded that evidence regarding the best strategies for effectiveness of the interventions and engaging the users in these interventions is still missing. After our review, the knowledge about the impact of the Web-based interventions remains controversial. Therefore, there is a need for a comprehensive impact evaluation that would show the costs and benefits of Web-based technology in the health sector.

In addition to follow-up periods, larger sample sizes and more rigorous study designs could increase the quality of the research. Specific Web-based interventions instead of *packages of intervention* could also provide a more feasible and accurate conception of the factors impacting the outcomes. Furthermore, more studies are needed in the future to gain a deeper understanding of why adolescents are eager to leave the study and why their engagement in information technology interventions is low.

Limitations

The results of this study should be considered in the light of its limitations. We only included papers from scientific journals that had been written in English, which may have caused relevant studies written in other languages or existing in gray literature to have been left out [65]. Our review is, therefore, biased toward positive results and western countries. Publication bias may have also affected our results. This review may potentially favor results that have been deemed statistically significant. In addition, a number of studies included in the meta-analysis focused on specific outcomes, which may affect the reliability of some results. Moreover, the heterogeneity of

our meta-analysis was high (I^2 ranged between 0% and 89%). Although I^2 is not a measure for absolute heterogeneity, it may refer to the high variation in some outcomes between studies [66]. Another point to consider is that the interventions used were more like “packages of interventions,” which included many different elements. As an outcome, it may be difficult to identify which specific elements influenced the effectiveness of the interventions. Furthermore, based on the sensitivity analysis, problems pertaining to the heterogeneity of interventions were identified. We must consider that participants or severity of depressive symptoms could have varied greatly among the studies included in the meta-analysis, which jeopardizes the results of the review [67]. All these issues should be taken into consideration when interpreting the results.

Conclusions

In conclusion, the principal finding of this review supports the evidence that Web-based interventions are effective in the short term in decreasing depressive and anxiety symptoms and improving moods and feelings among adolescents and young people. The review also indicates that adolescents are not fully engaged in using Web-based interventions. Instead of simply stating that “more studies should be done in this area,” we assert that more critical thinking is needed to understand to whom information technology might be useful, which components or characteristics of interventions make it more effective, and what role human contact in conjunction with information technology may play in engaging and supporting young people with mental health concerns.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Electronic databases, search terms, and number of hits found.

[[PDF File \(Adobe PDF File\), 36KB - mhealth_v5i12e180_app1.pdf](#)]

Multimedia Appendix 2

Characteristics of the studies included in the review.

[[PDF File \(Adobe PDF File\), 374KB - mhealth_v5i12e180_app2.pdf](#)]

Multimedia Appendix 3

Descriptions of interventions in included studies.

[[PDF File \(Adobe PDF File\), 487KB - mhealth_v5i12e180_app3.pdf](#)]

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Abbreviations

CBT: cognitive behavioral therapy

DASS: Depression Anxiety Stress Scales

ICT: information and communication technology

PRISMA: preferred reporting items for systematic reviews and meta-analysis

RCT: randomized controlled trial

TIDieR: template for intervention description and replication

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Original Paper

Using mHealth Technology in a Self-Management Intervention to Promote Physical Activity Among Adults With Chronic Disabling Conditions: Randomized Controlled Trial

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Abstract

Background: Physical activity is considered a comprehensive approach for managing limitations in physical function among adults with chronic disabling conditions. However, adults with chronic disabling conditions often face many barriers to engaging in physical activity. A strategy to promote physical activity among adults with chronic disabling conditions is to encourage the use of mobile health (mHealth) apps.

Objective: The objective of this pilot study was to examine the potential benefits of using commercially available mHealth apps in a self-management intervention among 46 adults with musculoskeletal or neurological conditions.

Methods: Participants were randomized to one of 3 intervention groups: (1) mHealth-based self-management intervention, (2) paper-based self-management intervention, and (3) contact-control intervention. Participants in all 3 groups met in person once and received 3 follow-up phone calls with a trained graduate assistant. Participants in the mHealth-based and paper-based groups received a computer tablet or a paper diary, respectively, to facilitate goal setting, self-monitoring, and action planning. Participants in the contact-control group received information on healthy behaviors without being taught skills to change behaviors. The following outcomes were measured at baseline and at the 7th week: physical activity (Physical Activity and Disability Survey–revised), psychosocial factors (self-efficacy, self-regulation, and social support), and physical function (Patient Report Outcomes Measurement Information System, 6-min walk test, 1-min chair stands, and 1-min arm curls).

Results: Repeated-measures multivariate analysis of variance (MANOVA) indicated significant differences between groups in physical activity levels (Wilks $\lambda=0.71$, $F_{6,76}=2.34$, $P=.04$). Both the mHealth-based and paper-based groups had large effect size increases in planned exercise and leisure-time physical activity compared with the contact-control group (Cohen $d=1.20$ and $d=0.82$, respectively). Repeated-measures MANOVA indicated nonsignificant differences between groups in psychosocial factors (Wilks $\lambda=0.85$, $F_{8,66}=1.10$, $P=.37$). However, both the mHealth-based and paper-based groups had moderate effect size improvements in self-efficacy ($d=0.48$ and $d=0.75$, respectively) and self-regulation ($d=0.59$ and $d=0.43$, respectively) compared with the contact-control group. Repeated-measures MANOVA indicated nonsignificant differences between groups in physical function (Wilks $\lambda=0.94$, $F_{8,66}=0.27$, $P=.97$). There were small and nonsignificant changes between the mHealth-based and paper-based groups with regard to most outcomes. However, the mHealth-based group had moderate effect size increases ($d=0.47$) in planned exercise and leisure-time physical activity compared with the paper-based group.

Conclusions: We found that using commercially available mHealth apps in a self-management intervention shows promise in promoting physical activity among adults with musculoskeletal and neurological conditions. Further research is needed to identify the best ways of using commercially available mobile apps in self-management interventions.

Trial Registration: Clinicaltrials.gov NCT02833311; <https://clinicaltrials.gov/ct2/show/NCT02833311> (Archived by WebCite at <http://www.webcitation.org/6vDVSAw1w>)

KEYWORDS

disabled persons; exercise; self-care; mobile applications; motor activity; behavior; self-efficacy; goals; social support Introduction

Introduction

Background

Promoting engagement in physical activity is an important strategy for reducing the consequences of musculoskeletal and neurological conditions [1]. For example, engaging in physical activity can help mitigate limitations in physical function, which is a hallmark consequence of several musculoskeletal and neurological conditions, such as osteoarthritis, fibromyalgia, systemic lupus erythematosus, stroke, Parkinson disease, and multiple sclerosis [2,3]. Common symptoms of these conditions, such as fatigue, pain, and muscle weakness, can result in physical limitations such as difficulty walking and accomplishing daily chores. Engaging in physical activity can reduce the impact of these common symptoms and help prevent limitations in physical function [2-4]. However, adults with musculoskeletal and neurological conditions are largely sedentary [5,6] because they often encounter barriers that reduce their ability and motivation to engage in physical activity [7-9].

A possible solution for promoting physical activity in adults with musculoskeletal and neurological conditions is delivering self-management interventions [10]. Self-management interventions can encourage the learning of skills (eg, goal setting, communication, and self-regulation) that improve psychosocial factors (eg, self-efficacy and social support) and promote engagement in physical activity [11]. Self-management interventions are effective in a variety of delivery formats, including in-person and remote formats (eg, phone, print, and Internet) [11,12]. Self-management interventions delivered remotely may be as effective as those delivered in person [13,14]. Furthermore, using mobile health applications (mHealth apps) in self-management interventions may help promote physical activity [15]. However, few studies have systematically evaluated whether there are any added benefits of using mHealth apps in self-management interventions among adults with musculoskeletal and neurological conditions.

Incorporating mHealth apps into self-management interventions may have several advantages among adults with musculoskeletal and neurological conditions. [16]. mHealth apps can be used to self-monitor symptoms, set goals, and learn self-management skills. Importantly, mHealth apps may help facilitate the tailoring of self-management interventions and can provide feedback, reminders, and information that can be tailored to encourage physical activity. For example, mHealth apps can provide immediate feedback on physical activity goals and health status via graphs and short messages; remind participants to engage in physical activity; and help tailor content to accommodate preferences for information, aesthetics, and learning style. These functionalities may increase perceived relevance, thereby, making it more likely for participants to think about and act upon recommendations [17]. Studies are needed to confirm whether these potential advantages of using mHealth apps in self-management interventions translate into

better outcomes among adults with musculoskeletal or neurological conditions.

Although there are numerous self-management studies of mHealth apps in healthy populations and in adults with heart disease, cancer, and diabetes, there are far fewer studies among adults with musculoskeletal or neurological conditions [16,18-20]. Furthermore, most self-management research on mHealth apps has focused on developing and testing an app for a single chronic condition [16,21], so generalizability of mHealth apps in promoting healthy behaviors across the population with musculoskeletal and neurological conditions remains unknown. Existing research indicates that mHealth apps may be effective in promoting healthy behaviors in healthy populations and in adults with heart disease, cancer, and diabetes [16,18-20]. However, questions remain about the feasibility and benefits of using mHealth apps in self-management interventions among adults with musculoskeletal or neurological conditions. Studies examining the benefits of using commercially available mHealth apps in self-management interventions may help inform clinical recommendations and prioritize research. Clinicians will be able to make informed decisions about using commercially available mHealth apps to encourage the self-management of symptoms. Furthermore, researchers will be able to make informed decisions about the merits of developing new apps versus refining existing apps for people with disabling conditions.

Objectives

We conducted a randomized controlled pilot study to examine the potential benefits of a self-management intervention that was augmented with mHealth apps used on a computer tablet among 46 adults with musculoskeletal or neurological conditions. Recruitment was focused on including adults who have musculoskeletal or neurological conditions that characteristically result in physical limitations, such as osteoarthritis, fibromyalgia, systemic lupus erythematosus, stroke, Parkinson disease, and multiple sclerosis. Participants were randomized into one of 3 groups: (1) self-management intervention augmented with commercially available mHealth apps used on a computer tablet (ie, mHealth-based group), (2) self-management intervention augmented with paper diary (ie, paper-based group), and (3) information-only intervention (ie, contact-control group). We selected these 3 groups to examine the effects of the self-management interventions while controlling for the number of contacts with the interventionist. Here, we report on the primary outcome—physical activity—and the secondary outcomes related to physical activity—psychosocial factors and physical function. We tested the following hypotheses:

- In comparison with the contact-control group, both the mHealth-based and paper-based groups will yield significant increases in physical activity, with the mHealth-based group yielding a significantly larger increase.

- In comparison with the contact-control group, both the mHealth-based and paper-based groups will yield significant improvement in psychosocial factors (ie, self-efficacy, self-regulation, and social support), with the mHealth-based group yielding a significantly larger increase.
- In comparison with the contact-control group, both the mHealth-based and paper-based groups will yield significant increases in physical function, with the mHealth-based group yielding a significantly larger increase.

Methods

Overview

A randomly allocated, 3-group, single-blinded repeated-measures design was used to generate pilot data to test the hypotheses. Participants ($n=46$) were recruited via community outreach and randomly allocated to one of 3 groups using an allocation ratio of 1:1:1. Participants in all 3 groups were asked to attend 1 in-person session and partake in 3 follow-up phone calls over a 6-week period with a trained research assistant who had a bachelor's degree in health education. Participants in the mHealth-based group and paper-based group were asked to track their progress in meeting self-management goals using a Google Nexus 7 tablet (ASUS, Taiwan) or paper diary, depending on their group assignment. Participants in the contact-control group received information on healthy behaviors. Regardless of the group assignment, all participants received the Google Nexus tablet at the completion of the study. A research assistant blinded to group assignment administered self-report questionnaires and a physical assessment at baseline and at 7th week. The Cleveland Clinic and University Hospitals Institutional Review Board approved this study.

Participants and Procedures

We aimed to recruit 12 to 16 participants in each group, which is consistent with recommendations by Dobkins et al [22] on obtaining stable effect size estimates in pilot studies. Participants were recruited through physician referrals, postings in physician offices, visiting support groups, advertising in e-newsletters, and postings on Facebook and community bulletin boards. The study was advertised as a comparison of different health and wellness programs meant to examine the benefits of using mHealth apps on a computer tablet.

To help ensure adults with disabilities had opportunities to fully participate in the study, we followed universal design principles for research [23]. This included recruiting participants through a variety of media (ie, print and audio), allowing multiple options for responding to recruitment notices (ie, phone and Internet), using large print on recruitment flyers, informed consent, and intervention handouts, and incorporating multiple methods for responding to questionnaires (ie, both audio and visual).

Inclusion criteria were: physician-confirmed diagnosis of a disease of the nerves, muscles, or bones that characteristically results in physical limitations, physician's consent to engage in a physical activity program, age between 18 to 76 years, engagement in 90 min or less of purposeful physical activity

each week, engagement in unhealthy eating habits (ie, <10 on a questionnaire about nutritional habits) [24], score ≤ 17 on mental composite and ≤ 16 on physical composite of the Global Health Questionnaire [25], and access to Internet at home or at a library or a community center. The study criteria for age were changed during the study to include the oldest adults in the study that met all other study criteria. The Global Health Questionnaire [25] was selected from the Patient Reported Outcomes Measurement Information System (PROMIS) [26]. The Global Health Questionnaire generates a mental and physical health status composite score. The 2 composite scores can be compared with those of the general population. We used this measure to help reduce ceiling effects by selecting cutoff scores that would exclude participants who were healthier than the general population in mental and physical health status. Thus, participants in the study may or may not have had a disability, but had a definite diagnosis of a musculoskeletal or neurological condition. For example, a participant could have a diagnosis of multiple sclerosis, but not have a disability or impairment that would limit participation in daily activities and social roles. Exclusion criteria were: report >3 falls per month, comorbid conditions that significantly limit engagement in physical activity (eg, chronic heart failure, myocardial infarction, or uncontrolled diabetes mellitus), severe cognitive deficits (ie, a weighted score of less than 12 on the short version of the Blessed Orientation Memory Concentration test) [27], or report of existing use of mHealth apps or a paper diary to track behaviors.

Randomization and Blinding

Once consent and baseline data were collected, participants were randomly allocated using a numbered series of 48 prefilled envelopes in blocks of 3, using a random number generator. A research assistant not involved in interacting with the participants put the group assignment in an envelope and sealed it. The research assistant who delivered the first in-person session was responsible for opening the randomization envelope. Research assistants who were responsible for administering the questionnaires and physical assessments were blinded to group assignment. It was not feasible to blind research participants to group assignment.

mHealth-Based and Paper-Based Self-Management Interventions

Participants randomized to the mHealth-based group or the paper-based group received the same number of contacts (ie, 1 in-person session plus 3 phone calls) and behavior change techniques. Social cognitive theory inspired both self-management interventions [28,29]. We implemented strategies to enhance self-efficacy (ie, mastery, persuasion, modeling, and appraisal), increase self-regulation subfunctions (ie, setting, monitoring, and achieving goals), and decrease the perceived barriers to the regulation of motivation. We used the behavior change techniques of instruction, goal setting, self-monitoring, action planning, social support, information on the benefits and consequences of behaviors, and barrier management as defined by Michie et al [30]. Participants were taught how to track progress in meeting physical activity goals and overcome barriers to engaging in a physical activity

program. Goal attainment scaling helped participants develop detailed intentions and define success for engaging in a physical activity program. Participants were asked to set goals and develop action plans related to physical activity and nutrition. Details about the nutritional goals and related outcomes are reported elsewhere.

Physical Activity Program

During the in-person session, a personalized physical activity program was developed using an interview guide administered by the research assistant. The first author developed and refined the interview guide in previous studies [31,32]. Participants were asked about their physical activity habits, what they enjoyed and disliked about physical activity, and the barriers encountered to engaging in physical activity. Participants were asked whether they preferred incorporating physical activity into daily routine or setting aside specific times to engage in an exercise program (eg, one 30-min bout or ten 3-min bouts of physical activity). On the basis of participants' responses, recommendations were made either to engage in a physical activity program using a pedometer or to set aside time for a home exercise program. The pedometer-based program consisted of learning strategies to increase step counts throughout the course of the day. The home exercise program consisted of stretching and cardiovascular, strength, and balance training performed using a chair and resistance bands. The program was personalized to the participant's fitness level. Participants were asked to engage in the home exercise program for 30 min, 3 to 5 days a week.

Phone Calls

Participants received 3 follow-up phone calls at a frequency of 1 call placed every other week for 6 weeks after the in-person session. The phone calls were delivered by the same research assistant who delivered the in-person session. During each phone call, adverse events were monitored, questions about engaging in the physical activity program were answered, and education was provided regarding overcoming barriers. The first phone call focused on reinforcing the benefits of engaging in physical activity and setting goals for engaging in physical activity. The second phone call focused on fostering social support for engaging in physical activity. The third phone call focused on managing specific symptoms that were barriers to engaging in the physical activity program. Recommendations were made to continue the physical activity program without changes, modify the types of exercises being performed, or increase the frequency or intensity of exercise. At the end of each phone call, participants were reminded to use the mobile apps or paper diary.

mHealth-Based Self-Management Intervention Group

Participants received a Google Nexus tablet (ASUS, Taiwan) and were shown how to use it during the first in-person session. We decided to provide participants with a tablet rather than a mobile phone because the screen is larger and may be more user-friendly for adults who experience mobility or sensory impairments. Participants learned how to use the following mobile apps downloaded at the Google Play Store: Lose it! (FitNow, Inc, Boston, MA, USA), iPro Habit Tracker Free

(IntelliPro, Atlantis Enclave, India), and Memories: The Diary (Victor Nakonechny, Heidelberg, Germany). We selected these apps because of their popularity, positive reviews, relevance in augmenting self-management interventions, and flexibility in customizing goals and self-monitoring progress, and because they were free to download and use. Participants used the Lose it! app to track physical activity and nutrition behaviors; the iPro Habit Tracker app to track progress in achieving goals; and the Memories app to monitor and describe problematic symptoms. The research assistant asked participants to use the apps at least once a day and review progress in meeting goals at least once a week using the graph or feedback functionalities available with these apps. Participants were shown how to modify settings in each of the apps to accommodate preference about information, aesthetics, goal setting, and self-monitoring. The research assistant asked participants to demonstrate use of each of the apps to ensure proficiency and address potential usability barriers. Any additional questions or difficulties in using the apps were addressed during the phone calls by the same research assistant. No major revisions or updates occurred to the apps during the study.

Paper-Based Self-Management Intervention Group

Participants received a paper diary to track physical activity and nutrition behavior, monitor progress in meeting goals, and describe problematic symptoms. During the in-person session, participants' goals were written in the diary, and they were instructed on how to track their behaviors and monitor their symptoms. The diary had been refined in previous studies to improve efficiency in self-monitoring behavior. Tracking of behaviors involved circling icons or numbers corresponding to participants' goals. They were asked to track their behavior each day, review their journal weekly, and tally the numbers to examine whether they were on track to meet their goals.

Contact-Control Intervention Group

Participants randomized to the contact-control group received the same number of contacts as participants in the mHealth-based and paper-based groups. During the first in-person session, participants received generic education on physical activity and nutrition guidelines for people with disabilities. At each subsequent call, we monitored for adverse events and asked about their overall health and well-being. Phone calls were placed at the same frequency with a similar length of time as phone calls placed in the mHealth-based and paper-based groups. Participants were provided additional information about different forms of physical activity one could engage in and suggestions about making healthy food choices, but goals were not set and skills to change behavior (ie, goal setting, self-monitoring, and barrier management) were not taught. To encourage retention in this group, participants had the option to receive the self-management intervention at the completion of the study.

Treatment Fidelity

We followed guidelines established by Bellg et al [33] for measuring and maintaining treatment fidelity. Manuals of operating procedures were provided to research assistants and incorporated into their training. Standardized training was

provided to research assistants who delivered the intervention and administered the outcome measures. Training included 15 hours of readings and tutorials on understanding how to support self-management of symptoms, encourage behavior change, and conduct clinical trials. Adherence to the intervention protocol was monitored using checklists completed by research assistants and episodic monitoring of the sessions by the first author. Feedback on protocol adherence and ongoing training occurred in follow-up meetings as needed. Fidelity of interventions was further monitored by incorporating process measures, reviewing entries in mHealth apps or paper diary, and using goal attainment scaling (described below).

Measurements

Physical Activity

We used the Physical Activity and Disability Survey–revised (PADS-revised) to comprehensively measure physical activity behavior [34,35]. We selected this survey because it is designed to be relevant across different disabling conditions and can measure the frequency and intensity of different types of physical activity to generate continuous composite scores. Rimmer et al originally developed the PADS. They found the PADS to have significant correlations with absolute peak volume oxygen (VO_2), relative peak VO_2 , maximum workload, and time to exhaustion [36]. In 2 subsequent studies, Kayes et al revised the PADS to facilitate understanding of questions and improve the methods of scoring the scale. PADS-revised comprises 5 subscales: planned exercise/leisure-time physical activity, general physical activity, therapy, employment, and wheelchair use [34,35]. The revised scale has adequate test-retest reliability and distinct subscales. We used the scoring algorithm provided by Kayes et al to calculate the subscales. A higher score indicates a greater amount of physical activity. For the analyses, we used 3 subscales: planned exercise/leisure-time physical activity, general physical activity, and employment physical activity. In our sample, the PADS-revised total composite score at baseline had concurrent validity with self-reported physical function ($r=.54$), the number of chair stands in 1 min ($r=.37$), and the 6-min walk test ($r=.41$).

Self-Efficacy

We used the Exercise Confidence Survey developed by Sallis et al [37]. The survey asks about confidence in sticking to an exercise program and making time for exercise. For example, “How sure are you that you can: stick to your exercise program after a long, tiring day at work; exercise even though you are feeling depressed; and stick to your exercise program when social obligations are very time-consuming?” Cronbach alpha in this study was .92. Thus, the 12 items were averaged to generate a single composite score. A higher score indicates increased confidence to engage in exercise.

Social Support

We used the Social Support and Exercise Survey developed by Sallis et al [38]. The survey asks about the amount of support that family and friends provide for engaging in exercise. For example, “How often family or friends: exercise with me; give encouragement to stick with my exercise; make positive comments about my physical appearance; and take over chores

so I have more time to exercise?” Cronbach alpha for family and friends in this study was .92. Thus, the 13 items for family and friends were averaged to generate a single composite score. A higher score indicated increased social support from family and friends for regular exercise.

Self-Regulation

We used the Goal Setting for Exercise Scale developed by Rovniak et al [39]. Questions pertain to the frequency of setting exercise goals and how goals are monitored and achieved. For example, “I often set exercise goals; I usually set dates for achieving my exercise goals; and if I do not reach an exercise goal, I analyze what went wrong.” Cronbach alpha in this study was .91. Thus, the 10 items were averaged to generate a single composite score. A higher score indicates increased use of self-regulation strategies in setting and achieving exercise goals.

Self-Report Physical Function

We used the PROMIS for self-report physical function [26,40]. PROMIS was developed through an initiative by the National Institutes of Health. Participants completed the computer adaptive test version that assesses physical function or an individual’s ability to carry out activities that requires physical action. It includes questions on lower and upper extremity function. Participants are asked about their abilities to perform a wide range of tasks. A T-score is automatically calculated after the participant completes the questionnaire using the PROMIS Assessment Center website. A higher T-score indicates better physical function compared with the general population. The PROMIS physical function questionnaire has been found to be valid and reliable in adults with neurological and musculoskeletal conditions [26,40].

Performance-Based Physical Function

We administered adapted portions of the Senior Fitness Test [41], which consisted of the 6-min walk test, 1-min chair stands, and 1-min arm curls. A trained research assistant blinded to group assignment administered the assessment. The research assistant provided standardized instructions to each participant and was instructed to be consistent in timing and number of verbal cues delivered during the assessment. Participants were asked to walk as fast as they could or perform as many repetitions as possible, but they could take as many rest breaks as needed during the timed tasks.

Process Measures

Several process measures were incorporated to monitor treatment fidelity and examine the feasibility of conducting a larger clinical trial. Process measures included attrition rate, adverse events, the percentage of phone calls completed following the manual, percentage of entries in the mHealth apps, and percentage of entries in the paper diary. The percentage of mHealth apps and paper diary entries was calculated by dividing the number of actual entries by the total number of days they were supposed to have entries. To further monitor treatment fidelity and help offset biases associated with using a diary to measure the achievement of a goal, we used goal attainment scaling (GAS) following the recommendations of Turner-Stokes et al [42,43].

GAS is a valid strategy for quantifying the achievement of each participant's goal [42,43]. GAS can be used to examine the extent to which each participant's personalized goals are met due to an intervention. Participants in the mHealth-based group and the paper-based group collaborated with the research assistant to set specific, measurable, achievable, relevant, and timed goals. The goal and its attainment were formulated to reflect the participants' motivation and preference for engaging in physical activity and their desire to improve their physical function. Goals consisted of increasing the frequency, duration, or intensity of engaging in exercise or specifying improvements in daily physical activities. For example, common goals pertained to improving balance, increasing walking distances, and engaging in exercise 3 to 5 days per week. Attainment of the goal was quantified on a scale between -2 and +2 in which a response of 0 indicated achieving the goal at the expected level and a response of +2 or -2 indicated achieving the goal much more or much less than the expected level. The participants worked with the research assistant to define each level of attainment at the first visit. At the posttest visit, participants were asked to rate their achievement of the goal on the -2 to +2 scale. An unweighted T-score was then calculated.

Analysis

We first determined whether the data met the assumption to conduct parametric statistical testing. We then conducted an efficacy analysis using a 3 (group: mHealth-based vs paper-based vs control) \times 2 (time: baseline and 7 weeks) multivariate analysis of variance (MANOVA). In total, 3 repeated-measures MANOVAs were conducted to test hypotheses on (1) physical activity levels (ie, planned exercise/leisure-time physical activity, general physical activity, and employment physical activity), (2) psychosocial factors (ie, self-efficacy, self-regulation, and social support), and (3) physical function (ie, PROMIS physical function, 6-min walk test, 1-min chair stands, and 1-min arm curls). If the multivariate test was significant, interactions were examined using post hoc analyses without concern for family wise error. The univariate *F* test was used to examine which dependent variables were significantly different across all 3 groups. Paired and independent samples *t* tests were used to examine whether the dependent variable significantly changed across time and between groups. For variables that were not normally distributed, we also used Wilcoxon signed rank test and Kruskal-Wallis test. The analyses were conducted using IBM SPSS Statistics for Windows, version 24.0 (IBM Corp, Armonk, NY, USA).

We calculated effect sizes as standardized mean differences while adjusting for baseline differences and correlations between

measures, and dividing by the pooled standard deviation [44]. A small effect was considered to be 0.20; a medium effect was considered to be 0.50; a large effect was 0.80 [45]. Independent samples *t* tests were used to compare the mHealth intervention with the paper diary intervention on the GAS and the percentage adherence in self-monitoring physical activity behaviors (ie, process measures).

Results

Demographic characteristics, type and number of chronic conditions, and disability status for each group are presented in Tables 1 and 2. The average age of the sample was 57.8 years. Majority of the research sample comprised females (84%); at least 13% of the sample had a household income \leq US \$25,000 and 17% of the sample was non-white. Participants had an average of 1.5 chronic conditions and 39% of the sample had multiple chronic conditions. The most common conditions were fibromyalgia, multiple sclerosis, osteoarthritis, and Sjögren syndrome. Average time since diagnosis was 13.3 years. Common comorbid conditions included hypothyroidism, diabetes, and high blood pressure. Common symptoms that were described by participants as interfering with engagement in physical activity were fatigue, pain, muscle weakness, and balance problems. On the basis of the screening questionnaire used to determine eligibility (ie, Global Health Questionnaire) [25], the sample was about half to one standard deviation below the general population in terms of global mental and physical health. On the basis of the PROMIS physical function scale at baseline [40], the sample was about one standard deviation below the general population.

Figure 1 illustrates the CONSORT flowchart. All dependent variables had Pearson correlations of $<.6$, indicating that multicollinearity was not a problem. Nonsignificant Box's *M* tests for each of the MANOVAs indicated homogeneity of covariance matrices for the dependent variables across the 3 groups. Most dependent variables for each group were normally distributed based on skewness and kurtosis values and nonsignificant Shapiro-Wilk test of normality. However, the PADs-revised subscale of exercise/leisure-time physical activity was skewed. Thus, we report the results below using both MANOVAs and nonparametric statistics.

The attrition rate for the study was 6.5%. In total, 6 adverse events were possibly related to the study. The adverse events (ie, mHealth-based group=2, paper-based group=3, and contact-control group=1) included mild to moderate musculoskeletal injury resulting from a fall during engagement in physical activity or performance of daily chores.

Table 1. Characteristic of sample (mean and standard deviation).

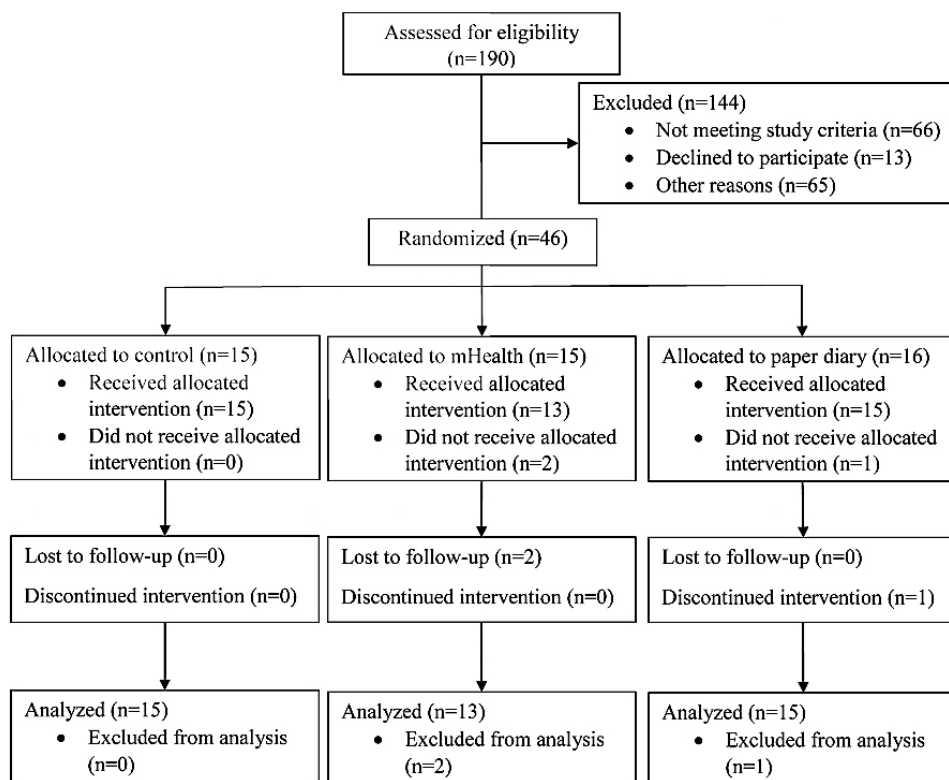
Characteristics	Mean (SD ^a)
Age (years)	57.80 (9.48)
Global mental health scale	13.15 (1.94)
Global physical health scale	12.50 (1.94)
Body mass index	31.69 (8.82)

^aSD: standard deviation.

Table 2. Characteristic of sample (frequency).

Characteristics	Frequency count, n (%)
Gender (female)	39 (85)
Number with multiple chronic conditions	18 (39)
Type of conditions (7 most common)	
Fibromyalgia	17 (37)
Multiple sclerosis	12 (26)
Osteoarthritis	12 (26)
Sjögren syndrome	11 (24)
Parkinson disease	5 (11)
Chronic fatigue syndrome	4 (9)
Systemic lupus erythematosus	3 (7)
Type of comorbid conditions (3 most common)	
High blood pressure	12 (26)
Type II diabetes	5 (11)
Hypothyroidism	5 (11)

Figure 1. Flowchart.



A total of 87% of participants completed all 3 phone calls as intended in the mHealth-based group; 94% completed all 3 phone calls as intended in the paper-based group; and 93% completed all 3 phone calls as intended in the contact-control group. There were no significant differences between the mHealth-based and paper-based groups in terms of GAS. However, participants were significantly ($P=.003$) more likely to keep track of physical activity behaviors using a paper diary

(84.3%) compared with a tablet computer (48.2%). Means, standard deviations, and effect sizes of the outcome measures are presented in Table 3.

Hypothesis 1: In comparison with the contact-control group, both the mHealth-based and paper-based groups will yield significant increases in physical activity, with the mHealth-based group yielding a significantly larger increase.

Table 3. Means, standard deviations, and effect sizes of outcome measures.

Measures	Pretest Mean (SD) ^a	Posttest Mean (SD)	Paper versus control Effect size (Cohen <i>d</i>)	mHealth versus control Effect size (Cohen <i>d</i>)	mHealth versus paper Effect size (Cohen <i>d</i>)
PADs-revised^b: total composite			0.35	0.63	0.16
mHealth ^c	0.36 (0.77)	0.76 (0.92)			
Paper	0.31 (1.01)	0.55 (1.15)			
Control	0.43 (0.68)	0.36 (0.61)			
PADs-revised subscale: exercise/leisure-time physical activity			0.82	1.20	0.47
mHealth	-0.28 (0.98)	0.38 (1.04)			
Paper	-0.09 (0.87)	0.14 (0.65)			
Control	0.08 (0.79)	-0.30 (0.67)			
PADs-revised subscale: general physical activity			-0.25	-0.50	-0.22
mHealth	0.72 (0.91)	0.78 (0.84)			
Paper	0.60 (0.97)	0.89 (1.23)			
Control	0.55 (1.16)	1.12 (1.04)			
PADs-revised subscale: Employment physical activity			0.31	0.43	0.04
mHealth	0.22 (1.06)	0.35 (1.04)			
Paper	0.20 (1.34)	0.28 (1.46)			
Control	0.15 (0.98)	-0.13 (0.50)			
PROMIS^d: physical function			-0.01	-0.08	-0.08
mHealth	39.87 (5.87)	38.44 (7.54)			
Paper	38.89 (3.14)	37.91 (4.52)			
Control	42.44 (5.45)	41.51 (3.96)			
6-min walk test (meters)			-0.06	0.16	0.19
mHealth	303.69 (87.23)	327.46 (68.32)			
Paper	316.32 (117.58)	320.61 (122.02)			
Control	362.32 (91.01)	385.23 (82.26)			
Bicep curls (count, 1 min)			-0.22	-0.29	-0.09
mHealth	23.85 (10.04)	24.23 (11.97)			
Paper	22.40 (8.68)	23.73 (8.86)			
Control	24.13 (8.63)	27.40 (8.77)			
Chair stands (count, 1 min)			0.03	-0.02	-0.04
mHealth	15.00 (6.66)	16.69 (8.38)			
Paper	13.73 (6.64)	15.73 (7.93)			
Control	16.47 (5.13)	18.27 (5.40)			
Exercise confidence survey			0.75	0.48	-0.17
mHealth	3.26 (0.96)	3.25 (0.82)			
Paper	3.29 (0.91)	3.42 (0.76)			
Control	3.33 (0.45)	2.97 (0.55)			
Goal setting for exercise scale (self-regulation)			0.43	0.59	0.13
mHealth	1.98 (0.83)	2.71 (0.96)			
Paper	2.57 (0.96)	3.17 (0.98)			
Control	1.99 (0.93)	2.19 (0.79)			

Measures	Pretest	Posttest	Paper versus control	mHealth versus control	mHealth versus paper
	Mean (SD) ^a	Mean (SD)	Effect size (Cohen <i>d</i>)	Effect size (Cohen <i>d</i>)	Effect size (Cohen <i>d</i>)
Social support and exercise survey			0.38	0.44	0.01
mHealth	1.58 (0.34)	1.79 (0.56)			
Paper	1.85 (0.63)	2.05 (0.75)			
Control	2.13 (0.80)	2.03 (0.83)			

^aSD: standard deviation.

^bPADs-revised: Physical Activity and Disability Survey-revised.

^cmHealth: mobile health.

^dPROMIS: Patient Report Outcomes Measurement Information System.

The MANOVA to test hypothesis #1 indicated that the condition by time interaction was significant (Wilks $\lambda=.71$, $F_{6,76}=2.34$, $P=.04$). The univariate F test indicated that planned exercise/leisure-time physical activity was significantly different across the 3 groups ($F_{2,40}=5.02$, $P=.01$), which was consistent with the Kruskal–Wallis Test ($\chi^2_2=6.4$, $P=.04$). Both parametric and nonparametric tests indicated that the mHealth-based group had a significant and large increase in the planned exercise/leisure-time physical activity subscale of the PADS-revised ($t_{12}=-3.03$, $P=.01$; $Z=-2.49$, $P=.01$) over time, whereas the control group had a small and nonsignificant change in the planned exercise/leisure-time physical activity subscale of the PADS-revised ($t_{14}=1.38$, $P=.19$; $Z=-1.16$, $P=.25$) over time. The paper-based group also had a nonsignificant change in the planned exercise/leisure-time physical activity ($t_{14}=-1.27$, $P=.23$; $Z=-.94$, $P=.35$) over time. There were nonsignificant differences between the mHealth-based and paper-based groups in promoting physical activity. However, the mHealth-based group had a moderate effect size ($d=0.47$) in planned exercise and leisure-time physical activity compared with the paper-based group.

Hypothesis 2: In comparison with the contact-control group, both the mHealth-based and paper-based groups will yield significant improvement in psychosocial factors (ie, self-efficacy, self-regulation, and social support), with the mHealth-based group yielding a significantly larger increase.

The repeated-measures MANOVA to test hypothesis #2 indicated that the condition by time interaction was not significant (Wilks $\lambda=.85$, $F_{6,76}=1.10$, $P=.37$). However, both the mHealth-based and paper-based groups had moderate effect sizes in self-efficacy ($d=0.48$ and $d=0.75$; respectively) and self-regulation ($d=0.59$ and $d=0.43$, respectively) compared with the contact-control group. Both the mHealth-based and paper-based groups had small effect sizes in social support compared with the contact-control group. There was a small and nonsignificant difference in psychosocial factors between the mHealth-based and paper-based groups.

Hypothesis 3: In comparison with the contact-control group, both the mHealth-based and paper-based groups will yield significant increases in physical function, with the mHealth-based group yielding a significantly larger increase.

The repeated-measures MANOVA to test hypothesis #3 indicated that the condition by time interaction was not significant (Wilks $\lambda=.94$, $F_{8,66}=0.27$, $P=.97$). All 3 groups had small within- and between-subject effects in influencing physical function. The negative effect sizes indicate that the control group had smaller declines in both self-report and performance-based physical function compared with the mHealth-based and paper-based groups.

Discussion

Findings of this study indicate that self-management interventions consisting of one in-person visit and 3 phone calls may be efficacious in promoting physical activity among adults with different musculoskeletal and neurological conditions. We found few differences between the mHealth-based and paper-based self-management interventions. Thus, further research is needed to determine the best ways to use mHealth apps in self-management interventions. Hypothesis #1 was partially supported by the results, while hypotheses #2 and #3 were not supported by the results. In regard to hypothesis #1 for physical activity levels, we found that both the mHealth-based and paper-based groups had moderate to large effect size increases in exercise and leisure-time physical activity compared with the control group. In addition, the mHealth-based group had a small to moderate effect size increases in planned exercise and leisure-time physical activity compared with the paper-based group. In regard to hypothesis #2 for psychosocial factors, we found that there were no significant differences between the 3 groups, but both the mHealth-based and paper-based groups had small to moderate effect size improvements in psychosocial factors compared with the contact-control group. In regard to hypothesis #3 for physical function, we found that there were no significant differences between the 3 groups, and there were small and nonsignificant declines in physical function.

Physical Activity

The composite score of PADs-revised indicated that participants in the mHealth-based and paper-based groups increased their engagement in physical activity, whereas participants in the contact-control group decreased their engagement in physical activity. However, participants in the contact-control group reported increased engagement in the general physical activity subscale of the PADs-revised, which helps explain the negative

effect sizes for general physical activity levels among participants in the mHealth-based and paper-based groups. It will be important that future clinical trials measure different types of physical activities to determine whether participants are increasing their overall physical activity levels or substituting one type of physical activity with another type of physical activity.

Several randomized controlled trials of physical activity interventions have shown that research participants in control groups change their physical activity habits. Waters et al [46] found in a systematic literature review that screening to exclude physically active participants and include participants with chronic conditions was related to meaningful control group improvements in physical activity. Changes in physical activity habits among participants in the control intervention group may also be due to the completion of questionnaires on physical activity, information on the benefits of physical activity, and the eagerness of participants to make changes in their physical activity levels (ie, selection bias). Thus, future clinical trials of physical activity interventions in adults with musculoskeletal and neurological conditions will need to ensure sample sizes are of a sufficient size to overcome the possibility that participants in the control groups may increase physical activity levels.

Participants were significantly more likely to track physical activity behaviors using the paper diary compared with the mHealth app. However, using the paper diary did not result in significant increases in physical activity or better health outcomes. In fact, effect sizes indicate that participants in the mHealth-based group had moderate increases in exercise and leisure-time physical activity compared with the paper-based group. These results may indicate that the benefits of augmenting mHealth apps in a self-management intervention may not entirely be due to the functionalities of tracking physical activity behaviors and receiving feedback. As described in the introduction, augmenting mHealth apps in self-management interventions may also facilitate the tailoring of information that may help promote behavior change. Providing participants with the tablet at the beginning of the intervention may also have fostered a stronger sense of commitment to the study, which facilitated engagement in physical activity. Given the cost associated with mHealth technology, there is a need to conduct future qualitative and quantitative research to identify the best ways of augmenting mHealth apps in self-management interventions.

Psychosocial Factors

To understand why there may be benefits of augmenting mHealth apps in self-management interventions consisting of in-person visits and phone calls, additional measures may need to be incorporated beyond the common psychosocial factors that were measured in this study (ie, self-efficacy, self-regulation, and social support). There were small and nonsignificant differences between the mHealth-based and paper-based groups on psychosocial factors. Thus, this result provides limited insight into why there may have been differences between the mHealth-based and paper-based groups in terms of promoting planned exercise and leisure-time physical

activity. Nonetheless, these psychosocial factors may provide insight on how both the mHealth-based and paper-based self-management interventions could be improved in future studies. For example, both the mHealth-based and paper-based self-management interventions had a small effect on social support, which means there may be opportunities to incorporate additional behavior change strategies to promote physical activity. Incorporating social networking functionality of mHealth apps into a self-management intervention may be a strategy to promote social support for engaging in physical activity.

Physical Function

Participants in the mHealth-based and paper-based groups did not have improvements in physical function. Several factors may explain this finding. First, it may be that 6 weeks is simply too short a time span to detect benefits of promoting physical activity. Second, we failed to recruit participants with more severe limitations in physical function, which may have contributed to ceiling effects. Third, adults with different musculoskeletal and neurological conditions engaging in different types of physical activity programs created heterogeneity in responses, which may have led to small average changes. Inclusion of adults with different conditions and accommodating preferences for engaging in physical activity programs is more consistent with patient-centered clinical care [47]. Thus, future studies with a larger sample size and long-term follow-up are needed to examine heterogeneity in responses to different types of physical activity programs that are prescribed to participants with different musculoskeletal and neurological conditions.

Relevance to Existing Research

Most literature reviews of mHealth apps to promote healthy behaviors generally conclude that there is a need for more rigorous research using randomized controlled trial designs [16,18-20,48-53]. Researchers who have restricted reviews to a particular type of chronic condition have generally identified promising studies on the usability of mobile apps, but there is little evidence on the apps' effectiveness to promote healthy behaviors [48-50,54,55]. Researchers who have conducted reviews with a broader focus across populations with disabling conditions indicate that mHealth apps have small to moderate effect sizes in terms of promoting healthy behaviors [16,51,52,56]. Difference in effect sizes may depend upon the type of control group used in the clinical trial and the heterogeneity in the functional capacity of participants. Our results are consistent with these meta-analyses and help advance existing research by demonstrating the feasibility of conducting clinical trials of mHealth technology across a population of adults with different disabling conditions who are inexperienced in using mobile devices to track behaviors.

Our study is one of the first studies to compare mHealth apps with paper diaries in promoting physical activity among adults with disabling conditions. There has been some research on weight loss in the general population comparing mHealth apps with paper diaries [57-60]. These studies have found that mHealth apps can result in better tracking and health behavior outcomes compared with a paper diary. A possible explanation

for these inconsistencies with our results is that we had fewer interactions with our participants using the mHealth apps. For example, Tuner-McGrievy et al [57] sent podcasts twice a week to participants and asked participants to report their frequency of tracking physical activity weekly. They found that participants randomized to the mHealth group showed improved tracking of physical activity behavior compared with participants that did not use the app. Thus, having frequent interactions with participants may help to remind and motivate participants to track their behaviors using mHealth apps. Research is needed to identify the fewest number of interactions needed to motivate consistent use of mHealth apps.

There is a growing research literature on using mHealth apps on a mobile phone to promote physical activity in the general population. Several studies have shown that real-time tracking with a mobile phone and providing personalized feedback can promote physical activity in adults with cardiovascular risk factors [61-63]. Lobelo et al outlined a model to integrate mobile phones and wearables into health care settings [64]. We decided to use a tablet instead of a mobile phone because we thought that the larger screen size would reduce usability barriers. However, the disadvantage of using a tablet is that it may be impractical to use real-time tracking features to monitor physical activity levels. Thus, both the feasibility and accuracy of using a mobile phone to promote and monitor physical activity levels in adults with disabling conditions need to be explored in future research studies.

Limitations

A limitation of our study was that the full potential of mHealth apps was not utilized; features such as social networking, tailored text messages, motion sensors, and global positioning systems were not used. Some of these functionalities may cost extra if used in commercially available apps or may not be relevant to adults with disabling conditions, and may increase the risk to patient privacy. Thus, several researchers have developed their own mobile apps, with moderate success in promoting self-management behaviors and improving health outcomes [21,65-70]. A potential limitation to this approach is expansion of mHealth apps without the creation of knowledge about the best ways to use mHealth apps in self-management interventions. Circumventing this potential limitation will

require collaborations between clinicians, computer scientists, and researchers who conduct comparative effectiveness research to identify the best ways to use mHealth apps in self-management interventions [71].

Other limitations to this study include the small sample size, increased risk of type I error, lack of generalizability, and self-report bias. The small sample size may have resulted in overestimation of effect sizes and lowered probability of reproducing the results. Because this was considered a pilot study, we conducted post hoc analyses without controlling for family-wise error, which increased the likelihood of making a type I error. Results of this study may not be generalizable to adults with more severe physical limitations or adults who are unable to walk. Use of self-report measures of physical activity may have resulted in participants exaggerating engagement in physical activity at the posttest and may have further exaggerated effect sizes. Future studies should measure physical activity levels using an accelerometer. Furthermore, there is a need to examine the validity and reliability of Goal Setting for Exercise Scale, Social Support and Exercise Survey, and Exercise Confidence Survey across a population segment with different musculoskeletal or neurological conditions. In this paper, we did not report on nutritional outcomes or a qualitative process evaluation (eg, participants' subjective experience in the interventions). We intend to publish these results in the future.

Conclusions

Comparing mHealth-based to paper-based self-management interventions may provide insight into the added value of using mHealth apps in self-management interventions, as well as the ways in which mHealth apps can be improved. We found that both the mHealth-based and paper-based self-management interventions consisting of one in-person visit plus 3 phone calls may be efficacious in promoting physical activity. However, the mHealth-based self-management intervention was not significantly different from the paper-based self-management intervention. There is a need to conduct further research using a larger sample size, incorporating objective measures of physical activity, and having a long-term follow-up period in order to validate the results of this study and address its limitations.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.1).

[[PDF File \(Adobe PDF File\), 676KB - mhealth_v5i12e185_app1.pdf](#)]

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Abbreviations

GAS: goal attainment scaling

MANOVA: multivariate analysis of variance

PADS-revised: Physical Activity and Disability Survey–revised

PROMIS: Patient Reported Outcomes Measurement Information System

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Original Paper

The Impact of a Mobile Diabetes Health Intervention on Diabetes Distress and Depression Among Adults: Secondary Analysis of a Cluster Randomized Controlled Trial

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Abstract

Background: Diabetes is a complex, demanding disease that requires the constant attention of patients. The burden of self-management, including different medication regimens, routine self-care activities, and provider visits, has an impact on patients' emotional well-being. Diabetes distress and depression are two important components of emotional well-being that may negatively affect diabetes outcomes.

Objective: The aim was to determine the impact of the 1-year Mobile Diabetes Intervention Study cluster randomized clinical trial on emotional well-being measured by diabetes distress and depression among adults with type 2 diabetes (T2D).

Methods: A total of 163 adults with not-well-managed T2D were enrolled from community primary care practices. Primary care practices were cluster randomized into either a usual care control group or intervention group. Intervention participants were given a mobile phone with coaching software including a Web portal to communicate with providers. A priori established secondary outcomes included distress measured by the Diabetes Distress Scale (DDS), with subscales measuring emotional burden, interpersonal distress, physician-related distress, and regimen-related distress, as well as depression measured by the Patient Health Questionnaire (PHQ-9). Linear mixed models were used to calculate the effect of the intervention on diabetes distress levels over time, both overall and separately by sex, and to determine if the intervention affected distress or depression. The impact of total DDS on changes in HbA_{1c} was also studied.

Results: There were no significant treatment group effects for DDS total (baseline: $P=.07$; differences over time: $P=.38$) or for depression ($P=.06$ over time). Significant declines in total DDS were observed over the 12-month intervention period ($P=.01$). Regimen-related distress significantly decreased for all study participants ($P<.001$), but no significant change over time was observed for emotional burden ($P=.83$), interpersonal distress ($P=.64$), or physician-related distress ($P=.73$). Women in both the usual care and intervention groups were more likely to have higher overall DDS, emotional burden, physician-related distress, and regimen-related distress, but not interpersonal distress. Women also reported higher baseline depression compared to men ($P=.006$). Overall, depression decreased over the treatment period ($P=.007$), but remained unaffected by group assignment ($P=.06$) or by sex ($P=.97$). Diabetes distress had no effect on the change in HbA_{1c} ($P=.91$) over the treatment period.

Conclusions: Although we found no definitive overall or sex-specific effect of the intervention on diabetes distress or depression, this study makes an important contribution to the understanding of mobile health interventions and the impact on emotional health. Our study verified previous work that although diabetes distress and depression are highly correlated, these measures are

not evaluating the same construct. Design of future mobile technology provides an opportunity to personalize, contextualize, and intervene in the emotional well-being of persons with diabetes.

Trial Registration: Clinicaltrials.gov NCT01107015; <https://clinicaltrials.gov/ct2/show/NCT01107015> (Archived by WebCite at <http://www.webcitation.org/6vVgRCLAF>)

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KEYWORDS

diabetes distress; mobile health; depression; diabetes; Diabetes Distress Scale; Patient Health Questionnaire; women; emotional well-being

Introduction

Diabetes affects an estimated 30.3 million people in the United States [1]. Diabetes prevalence continues to increase across all age, minority, and income groups [2,3]. It is projected that one in three US adults will be diagnosed with diabetes by 2050 [4]. Type 2 diabetes (T2D) comprises 90% of diabetes and is caused by modifiable lifestyle factors, genetics, and aging. As a result of long exposure to the physiological consequences of T2D—unmanaged blood glucose, blood pressure, and cholesterol—individuals may experience complications. These complications may affect individuals' physical and emotional well-being, making diabetes a challenging and demanding disease to manage.

Previous studies have shown that the first line of defense to delay or manage diabetes complications is through self-management practices [5,6]. In addition to multiple daily self-care activities, patients experience multiple medication regimens, high out-of-pocket health expenses, complication-specific treatments, and interactions with five or more health providers that can add up to as much as two hours each day spent managing their diabetes [7,8]. When considered together, the burden of these chronic disease factors may have a long-term impact on psychological functioning or emotional well-being [9]. Two components of emotional well-being include diabetes distress and depression. Diabetes distress is conceptually different from diabetes-related depression, and evaluation and treatment of diabetes distress has clinical utility because moderate to high distress is related to poor diabetes outcomes [10].

Diabetes Distress

Diabetes distress includes emotional responses to the diabetes diagnosis, risk of complications, self-management demands, unresponsive providers, and/or indifferent interpersonal relationships [11,12]. Feeling that family, friends, and even health care providers do not fully understand the everyday struggles of living with the chronic disease may further create an isolating experience for patients with diabetes. Complex and perhaps confusing daily diabetes self-management regimens may be overwhelming. Diabetes distress does not affect both sexes equally. In previous studies, women reportedly had a greater relative risk of experiencing diabetes distress [13,14], as well as higher odds of becoming distressed over an extended treatment period compared to men [15].

One of the most frequently used measures of diabetes distress is the Diabetes Distress Scale (DDS). This 17-item self-report

questionnaire is used to gauge physician-related distress as well as problems related to diabetes self-management, self-care, and metabolic outcomes [16]. To establish clinical meaningfulness, the DDS total and its subscales were studied in relation to diabetes-specific clinical (glycated hemoglobin A_{1c} [HbA_{1c}]) and behavioral (self-efficacy, diet, physical activity) variables. High DDS and increases in distress are associated with poorer outcomes: high HbA_{1c}, low self-efficacy, and not choosing healthy foods [17].

Diabetes Distress Scale and Depression

Within the United States, the high prevalence of depressive symptoms among patients with diabetes—between 18% and 35%—has been well-documented [18,19]. Depression with diabetes is associated with suboptimal disease management, inadequate glycemic control, higher functional impairment [20,21], and risk of diabetes complications [22-24]. Although there are similarities, diabetes distress is not indicative of depression—research shows that diabetes distress is related to, but distinct from, major depressive disorder [24,25]. This may explain why treatment of depression in patients with diabetes may have little effect on diabetes management [24].

Creating technological interventions to improve diabetes outcomes is not new, yet as mobile device use increases, these interventions are becoming even more widespread [26]. Several studies that incorporate digital health interventions have reported overall success in reducing depressive symptoms [27] and improving diabetes outcomes such as HbA_{1c} [28-31], self-management, and self-efficacy [31]. However, few studies have evaluated the intervention effects on DDS total or DDS subscale variables and depression. The REDEEM study compared three interventions with varying degrees of computer-assisted self-management to reduce diabetes distress and improve self-management with non-clinically depressed adults with T2D. Across all intervention conditions, REDEEM investigators observed significant reductions in DDS, emotional burden, and regimen-related distress. Self-management behaviors also improved, such as healthy eating and medication adherence, but not HbA_{1c} [32].

Diabetes and its complications affect a substantial number of Americans, and there is lack of evidence on intervention strategies that meet their emotional needs [32,33]. As technology advances, interventions may reach new audiences and promote better diabetes outcomes if presented in the convenience of a mobile platform. The primary aim of this secondary analysis was to determine the impact of a one-year mobile diabetes intervention on diabetes distress and depression among adults

with T2D. We also aimed to examine the effect of diabetes distress on HbA_{1c}.

Methods

Participants and Procedures

Details of the Mobile Diabetes Intervention Study (MDIS) have previously been reported [34-36]. Secondary analyses pertaining to emotional health reported here were established a priori in the protocol.

Eligibility criteria for this cluster randomized controlled trial (RCT) included physician diagnosis of diabetes within the 6 months prior to enrollment, HbA_{1c} level of 7.5% or higher within the previous 3 months, English speaking, and age between 18 and 64 years. Patients were deemed ineligible for participation if they were beneficiaries of Medicare or Medicaid, were uninsured, used an insulin pump, were pregnant, had actively abused alcohol or drugs within the past year, were being treated for psychosis or schizophrenia, suffered from severe, uncorrected hearing or vision impairment, or if they did not have an email address and access to the Internet [34,35]. At the time of consent, patients knew their assignments to control or intervention.

The study was conducted in primary care settings within four Maryland areas. Each patient was randomized at the physician-practice level (cluster) to either the control group (group 1: control-usual care), or one of three intervention groups: coach only, coach primary care provider (PCP) portal, and coach PCP portal with decision support. The coach-only and coach-PCP portal groups were prespecified as ancillary to the study design of the clinical trial and were not included in this analysis. Therefore, N=114 for this analysis.

Intervention

The aim of this analysis was to determine whether a mobile phone Web-based portal intervention and messaging communication intervention had an effect on diabetes-related distress and depression. The control-usual care patients received care as usual provided by their primary care physicians. Participants in the intervention group, coach PCP portal with decision support, had access to a mobile coaching system, which collected and analyzed glucose trends over a 1-year period. The physicians of patients in this group had full access to patient data via Web portals and were given summarized reports with patient treatment recommendations every 3 months. All patients received a One Touch Ultra 2™ (LifeScan, Milpitas, CA, USA) glucose meter and blood glucose testing supplies for a year. Physicians of patients in the control group were instructed to provide care as usual.

Patients in the coach PCP portal with decision support group received a multitier coaching system aimed at gaining control over the disease. Patients received one of two mobile phone models, a 1-year unlimited data and service plan and coaching software on their mobile phones to communicate their diabetes-specific information. For example, patients could enter their blood glucose levels, carbohydrates consumed, diabetes medications taken, and any comments about their diabetes

self-care, all recorded in real time in a Web-based logbook. Participants received automated self-management messages specifically tailored to the values they entered, longitudinal data trends, and their physicians' individualized medication instructions. Patients could also receive communications from their study certified diabetes educator or endocrinologist by communicating through secure messages on a patient-specific Web portal. Messages included automatic information responding to patient-reported values (ie, blood glucose) and reminders to use educational materials on the patient Web portal directed at diabetes self-management behaviors. Messages and interactions with diabetes educators included managing daily regimens, worries about complications, and anxiety about poor disease management, but did not target specific concepts in the DDS or DDS subscales.

Study Oversight

The Institutional Review Board of the University of Maryland, Baltimore, MD, approved this study. After study enrollment was closed, errors in consent form completion were found on audit. To assure that we obtained the appropriate signatures, the Institutional Review Board asked us to repeat our consent procedures, which we did for 163 patient participants and all 39 physician participants. Patients excluded due to not receiving re-consent did not significantly differ ($P>.10$) at baseline from included patients in age, gender, or baseline HbA_{1c}. A Data and Safety Monitoring Board was appointed to review the study procedures and adverse events.

Measures

Demographic characteristics including sex, age, and race were patient self-reported and confirmed through medical chart review. Education and smoking status were self-reported by patients during study interviews. Trained staff blinded to group assignment used the Bayer DCA 2000 to measure HbA_{1c}. If HbA_{1c} levels were not obtained within 14 days of the conclusion of the 12-month study, reminders were sent to both physicians and patients to complete the test. Measures of systolic blood pressure, diastolic blood pressure, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides, total cholesterol, and medications have previously been reported [35,36]. Study data for primary and secondary outcomes were collected by research staff separately from data transmitted through the mobile device.

Diabetes distress and depression were measured by the 17-item DDS and the nine-item Patient Health Questionnaire (PHQ-9). The DDS asks respondents to rate the degree to which diabetes situations caused distress or bothered the person during the previous month [25]. Four subscales have been identified as distinct areas of potential diabetes distress: emotional burden assesses the extent patients with diabetes feel overwhelmed by their disease, physician-related distress addresses the availability and open communication with health care providers, interpersonal distress assesses feelings pertaining to the support of family and friends, and regimen-related distress evaluates patients' preparedness to adhere to meal plans, monitoring blood glucose levels, and taking medications [17]. The DDS, including the four subscales, was measured at baseline and at the end of

the intervention (12 months). Internal consistency has been assessed by the alpha coefficient (0.93 for the total scale and 0.88 to 0.90 for the four subscales) [17]. The DDS asks individuals to rate each item on a Likert-like scale from 1 (not a problem) to 6 (a very serious problem) [25]. The total DDS score is based on averaging responses across items; therefore, the total DDS ranges from 1 to 6 [25]. For this analysis, we summarized total DDS scores in three categories: little or no diabetes distress (DDS <2.0), moderate diabetes distress (DDS=2.0-2.9), and high diabetes distress (DDS ≥3), which were previously documented to have clinical meaning [37]. The DDS subscale measures, emotional burden, physician-related distress, regimen-related distress, and interpersonal distress were also analyzed. To score the subscales, the sum of patient responses for the subscale items were divided by the number of items in that subscale. Emotional burden included five items (1, 3, 8, 11, and 14), physician-related distress included four items (2, 4, 9, and 15), regimen-related distress included five items (5, 6, 10, 12, and 16), and interpersonal distress included three items (7, 13, and 17).

Depression was assessed by the PHQ-9 at baseline and at 12-month study end. The PHQ-9, tested in primary care, has demonstrated clinical relevance to *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition) depression criteria and is used as a research diagnosis of depression. The PHQ-9 scores range from 0 to 27, with scores indicating minimal depression (0-4), mild depression (5-9), moderate depression (10-14), moderately severe depression (15-19), and severe depression (≥20) [38].

Statistical Analysis

The main comparison for this analysis stated a priori was between the control group and the intervention group (coach PCP portal with decision support). Means and standard deviations for continuous variables, and frequencies and proportions for categorical variables were analyzed. Means of total DDS scores and the four subscales (emotional burden, physician-related distress, regimen-related distress, and interpersonal distress) were calculated by treatment group and sex. Linear mixed models were used to examine the effects of the intervention over time both overall and separately by sex on levels of diabetes distress while accounting for practice level (cluster) randomization. Linear mixed models were also used to determine whether the mobile health intervention impacted changes in total DDS, DDS subscale measures, and depression, and whether the effects differed by sex. Correlations for DDS, DDS subscales, and PHQ-9 were computed to examine if diabetes distress and depression were measuring the same construct in this population. SAS version 9.2 (SAS Institute Inc, Cary, NC, USA) was used to perform all statistical analyses. A $P < .05$ was considered statistically significant.

Results

Baseline characteristics of study patients are shown in Table 1. Mean age was 52.6 (SD 8.2) years and the duration of diabetes

diagnosis was mean 8.5 (SD 6.1) years. In all, 56.1% (64/114) were white and 71.9% (82/114) had at least some college education. Of the 114 participants, 37 (32.5%) had mild diabetes distress and 44 (38.6%) had moderate diabetes distress at baseline (Table 1).

Significant declines in total DDS scores were observed over the 12-month intervention period ($P = .01$) (Table 2). However, group assignment did not significantly affect total DDS scores ($P = .79$) (Table 2 and Figure 1). Furthermore, differences in total DDS score changes between the usual care and coach PCP portal with decision support groups were not significant ($P = .38$) (Table 2).

Diabetes Distress Scale Subscales

Regimen-related distress showed the highest mean of all subscales at baseline (mean 3.3, SD 1.3), corresponding to high diabetes distress (Table 2). Among all study participants, regimen-related distress significantly changed over the 12-month treatment period ($P < .001$) (Table 2 and Figure 2). Emotional burden ($P = .83$), physician-related distress ($P = .73$), and interpersonal distress ($P = .64$) did not significantly change over 12 months. The DDS subscales did not significantly differ at baseline and changes in subscale scores over time did not significantly differ (Table 2).

Diabetes Distress Scale and Sex

Baseline DDS total scores were significantly different between males and females, regardless of group assignment ($P = .002$). Sex differences at baseline were observed for all but one DDS subscale scores including emotional burden ($P = .04$), regimen-related distress ($P = .01$), physician-related distress ($P = .009$), but not interpersonal distress ($P = .08$). However, the effect of the intervention on total diabetes distress and the subscale scores did not significantly differ by sex (Table 3). Males had lower total DDS, emotional burden, regimen-related distress, and physician-related distress than females.

At baseline, women had higher depression than men did ($P = .006$). There was no significant change over time by sex ($P = .97$). Linear mixed models determined that PHQ-9 scores significantly declined over the 12-month study period ($P = .007$), but did not significantly differ by treatment group ($P = .06$). Correlational analyses found that higher baseline diabetes distress (DSS total) was significantly associated with higher depression ($r = .57$, $P < .001$). Subscale correlations with PHQ-9 were moderate: emotional burden ($r = .53$, $P < .001$), interpersonal distress ($r = .46$, $P < .001$), regimen-related distress ($r = .44$, $P < .001$), and physician-related distress ($r = .21$, $P = .009$).

We previously reported that HbA_{1c} levels of study participants significantly decreased over the 12-month treatment period [34]. In this analysis, linear mixed models determined that baseline DDS scores were not significantly associated with baseline HbA_{1c} ($P = .45$) nor were changes in DDS associated with HbA_{1c} change over time ($P = .91$).

Table 1. Baseline characteristics of patients and primary and secondary outcomes.

Baseline characteristics	Both groups (n=114)	Control-usual care		Coach PCP ^a portal with decision support			
		All (n=56)	Male (n=28)	Female (n=28)	All (n=58)	Male (n=30)	Female (n=28)
HbA_{1c}^b (%), mean (SD)^c	9.6 (2.0)	9.2 (1.7)	9.2 (1.7)	9.1 (1.7)	9.9 (2.1)	9.8 (2.3)	10.1 (2.0)
7.5%-8.9%, n (%)	61 (53.5)	35 (62.5)	17 (60.7)	18 (64.3)	26 (44.8)	15 (50.0)	11 (39.3)
≥9%, n (%)	53 (46.5)	21 (37.5)	11 (39.3)	10 (35.7)	32 (55.2)	15 (50.0)	17 (60.7)
Age (years), mean (SD)	52.6 (8.2)	53.2 (8.4)	51.9 (8.4)	54.6 (8.2)	51.9 (8.1)	54.3 (6.7)	49.4 (8.7)
Race, n (%)							
Nonwhite	50 (43.9)	30 (53.6)	14 (50.0)	16 (57.1)	20 (34.5)	7 (23.3)	13 (46.4)
White	64 (56.1)	26 (46.4)	14 (50.0)	12 (42.9)	38 (65.5)	23 (76.7)	15 (53.6)
Duration of diabetes							
Diagnosis (years), mean (SD)	8.5 (6.1)	9.0 (7.0)	7.3 (4.4)	10.7 (8.6)	8.1 (5.3)	7.5 (4.9)	8.7 (5.7)
Smoking status, n (%)							
Current smoker	19 (16.7)	11 (19.6)	5 (17.9)	6 (21.4)	8 (13.8)	5 (16.1)	3 (9.7)
Not current smoker	95 (83.3)	45 (80.4)	23 (82.1)	22 (78.6)	50 (86.2)	26 (83.9)	28 (90.3)
Education, n (%)							
High school/trade school or less	32 (28.1)	14 (25.0)	5 (17.9)	9 (32.1)	18 (31.0)	12 (40.0)	6 (21.4)
Some college or associates	41 (36.0)	20 (35.7)	10 (35.7)	10 (35.7)	21 (36.2)	8 (26.7)	13 (46.4)
Bachelors degree or higher	41 (36.0)	22 (39.3)	13 (46.4)	9 (32.1)	19 (32.8)	10 (33.3)	9 (32.1)
Body mass index (kg/m ²), mean (SD)	35.3 (6.8)	34.3 (6.3)	33.8 (6.3)	34.8 (6.4)	36.2 (7.1)	33.2 (4.5)	39.4 (8.0)
Comorbidities, n (%)							
Hypertension	69 (60.5)	29 (51.8)	14 (50.0)	15 (53.6)	40 (69.0)	21 (70.0)	19 (67.9)
Hypercholesterolemia	66 (57.9)	34 (60.7)	17 (60.7)	17 (60.7)	32 (55.2)	20 (66.7)	12 (42.9)
Coronary artery disease	10 (8.8)	5 (8.9)	4 (14.3)	1 (3.6)	5 (8.6)	3 (10.0)	2 (7.1)
Microvascular complications (any)	14 (12.3)	8 (14.3)	4 (14.3)	4 (14.3)	6 (10.3)	3 (10.0)	3 (10.7)
Depression (PHQ-9^d)							
Score (0-27), mean (SD)	5.1 (5.5)	4.7 (5.6)	3.2 (4.2)	6.2 (6.5)	5.5 (5.4)	4.8 (5.4)	6.3 (5.5)
Minimal to mild (0-9), n (%)	90 (78.9)	45 (80.4)	26 (92.9)	19 (67.9)	45 (77.6)	25 (83.3)	20 (71.4)
Moderate to severe (10-27), n (%)	24 (21.1)	11 (19.6)	2 (7.1)	9 (32.1)	13 (22.4)	5 (16.7)	8 (28.6)
Diabetes Distress Scale, n (%)							
Little or no distress (DDS <2.0)	37 (32.5)	20 (35.7)	11 (39.3)	9 (32.1)	17 (29.3)	13 (43.3)	4 (14.3)
Moderate distress (DDS=2.0-2.9)	44 (38.6)	21 (37.5)	10 (35.7)	11 (39.3)	23 (39.7)	13 (43.3)	10 (35.7)
High distress (DDS ≥3)	33 (28.9)	15 (26.8)	7 (25.0)	8 (28.6)	18 (31.0)	4 (13.3)	14 (50.0)

^aPCP: primary care provider.^bHbA_{1c}: glycated hemoglobin A_{1c}.^cSD: standard deviation.^dPHQ-9: Patient Health Questionnaire.

Table 2. Diabetes Distress Scale (DDS)^a and subscale scores.

Study measures	Both groups (n=114)			Usual care (n=56)		Coach PCP ^b portal with decision support (n=58)		<i>P</i> ^{c,d}
	n	Mean (SD) ^e	<i>P</i> ^f	n	Mean (SD)	n	Mean (SD)	
DDS								
Baseline	114	2.5 (0.9)		56	2.4 (0.9)	58	2.6 (0.9)	.79 ^c
12 month	103	2.3 (0.8)		46	2.3 (0.9)	57	2.3 (0.8)	
Change	103	-0.2 (0.8)	.01	46	-0.1	57	-0.3	.37 ^d
Emotional burden								
Baseline	114	2.6 (1.3)		56	2.6 (1.3)	58	2.6 (1.3)	.75 ^c
12 month	104	2.6 (1.3)		46	2.6 (1.3)	58	2.5 (1.2)	
Change	104	0 (1.2)	.83	46	0.1	58	-0.1	.48 ^d
Interpersonal distress								
Baseline	114	2.1 (1.3)		56	1.9 (1.1)	58	2.3 (1.4)	.24 ^c
12 month	103	2.0 (1.2)		46	1.8 (1.1)	57	2.2 (1.2)	
Change	103	0 (1.2)	.64	46	0.1	57	-0.1	.65 ^d
Physician-related distress								
Baseline	114	1.7 (1.0)		56	1.8 (1.0)	58	1.6 (0.9)	.86 ^c
12 month	104	1.7 (1.0)		46	1.7 (1.0)	58	1.7 (1.0)	
Change	104	0 (1.0)	.73	46	-0.2	58	0.1	.12 ^d
Regimen-related distress								
Baseline	114	3.3 (1.3)		56	3.1 (1.3)	58	3.5 (1.2)	.65 ^c
12 month	104	2.7 (1.1)		46	2.7 (1.1)	58	2.7 (1.0)	
Change	104	-0.6 (1.4)	<.001	46	-0.4	58	-0.8	.16 ^d

^aThe three categories of DDS scores are little or no diabetes distress (DDS <2.0), moderate diabetes distress (DDS=2.0-2.9), and high diabetes distress (DDS ≥3) [36].

^bPCP: primary care provider.

^cGroup effect on diabetes distress, regardless of gender.

^dGroup by time effect on diabetes distress, regardless of gender.

^eSD: standard deviation.

^fTime effect on diabetes distress scores in all groups.

Figure 1. Mean and standard deviation for the change in total Diabetes Distress Scale scores from baseline to 12 months for control (n=46-56) and intervention (n=57-58) groups. Whiskers represent standard deviation.

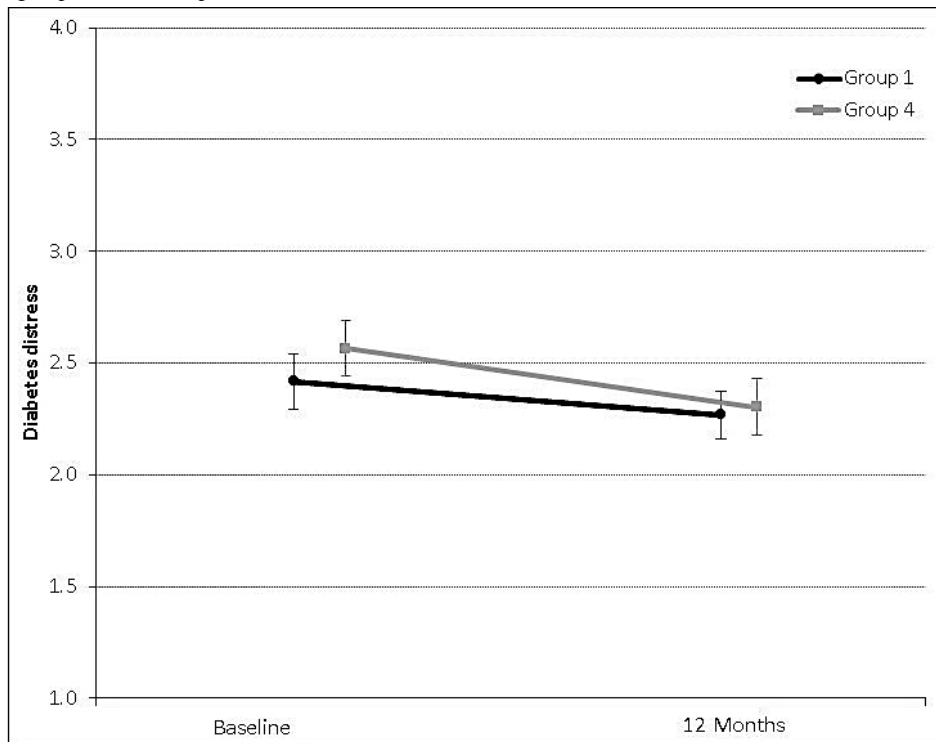


Figure 2. Mean and standard deviation for the change in Diabetes Distress Scale subscale scores from baseline to 12 months for control (n=46-56) and intervention (n=57-58) groups. Whiskers represent standard deviation.

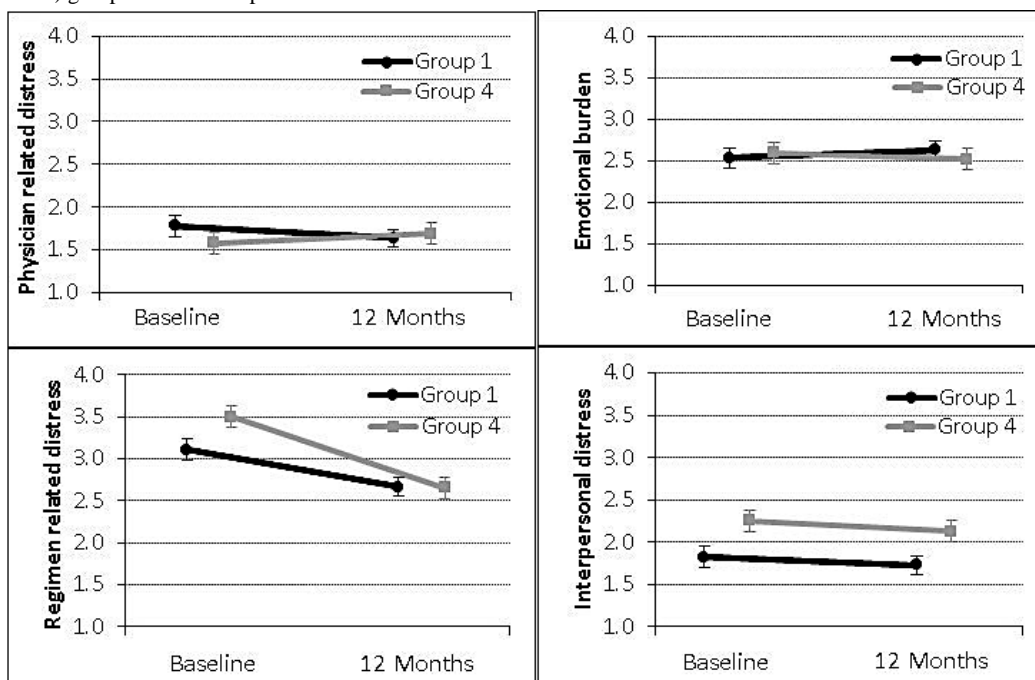


Table 3. Diabetes Distress Scale (DDS)^a and subscale scores by sex.

Study measures	Both groups (n=114)			Usual care				Coach PCP ^b portal with decision support				<i>P</i> ^c
	n	Mean (SD) ^d	<i>P</i> ^e	Male (n=28)		Female (n=28)		Male (n=30)		Female (n=28)		
				n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	
DDS												
Baseline	114	2.5 (0.9)		28	2.4 (1.0)	28	2.5 (0.9)	30	2.2 (0.7)	28	3.0 (0.9)	
12 month	103	2.3 (0.8)		23	2.2 (0.8)	23	2.4 (0.9)	29	2.0 (0.7)	28	2.6 (0.7)	
Change	103	-0.2 (0.8)	.01	23	-0.1 (0.8)	23	-0.1 (0.7)	29	-0.1 (0.7)	28	-0.4 (0.8)	.23
Emotional burden												
Baseline	114	2.6 (1.3)		28	2.3 (1.2)	28	2.8 (1.4)	30	2.3 (1.2)	28	3.0 (1.4)	
12 month	104	2.6 (1.3)		23	2.4 (1.0)	23	2.9 (1.6)	30	2.4 (1.2)	28	2.7 (1.3)	
Change	104	0 (1.2)	.83	23	0.1 (1.0)	23	0.2 (1.3)	30	0.1 (1.1)	28	-0.2 (1.3)	.41
Interpersonal distress												
Baseline	114	2.1 (1.3)		28	2.0 (1.0)	28	1.8 (1.1)	30	1.8 (0.9)	28	2.8 (1.6)	
12 month	103	2.0 (1.2)		23	1.7 (0.9)	23	1.9 (1.3)	29	1.9 (1.0)	28	2.5 (1.4)	
Change	103	0 (1.2)	.64	23	0.0 (0.8)	23	0.2 (1.3)	29	0.0 (1.0)	28	-0.3 (1.6)	.18
Physician-related distress												
Baseline	114	1.7 (1.0)		28	1.8 (1.1)	28	1.8 (1.0)	30	1.2 (0.4)	28	2.0 (1.1)	
12 month	104	1.7 (1.0)		23	1.7 (0.9)	23	1.6 (1.1)	30	1.3 (0.6)	28	2.1 (1.1)	
Change	104	0 (1.0)	.73	23	-0.2 (0.8)	23	-0.2 (0.9)	30	0.1 (0.6)	28	0.2 (1.4)	.77
Regimen-related distress												
Baseline	114	3.3 (1.3)		28	3.1 (1.3)	28	3.1 (1.3)	30	2.9 (1.1)	28	4.0 (1.1)	
12 month	104	2.7 (1.1)		23	2.6 (1.1)	23	2.7 (1.0)	30	2.3 (0.9)	28	3.0 (1.0)	
Change	104	-0.6 (1.4)	<.001	23	-0.4 (1.6)	23	-0.3 (1.1)	30	-0.6 (1.3)	28	-1.0 (1.5)	.38

^aThe three categories of DDS scores are little or no diabetes distress (DDS <2.0), moderate diabetes distress (DDS=2.0-2.9), and high diabetes distress (DDS ≥3) [36].

^bPCP: primary care provider.

^cTreatment by gender effect on diabetes distress.

^dSD: standard deviation.

^eTime effect on diabetes distress scores in all groups.

Discussion

Principal Results

In the MDIS, we hypothesized that the intervention would reduce diabetes distress, since self-management of diabetes during periods between health care provider visits can be challenging for patients. Lack of interactive communication with health care providers may leave patients unmotivated to maintain their diabetes regimen. Unlike the REDEEM study [32], we found no overall effect of the intervention on diabetes distress or depression, nor did we find treatment differences by sex. We also observed that DDS total had no significant impact on the change in HbA_{1c} over time. These findings may be due to study participants who at baseline had overall mean low-moderate diabetes distress and overall mean low-moderate distress conditions (ie, emotional burden interpersonal distress, physician-related distress, and regimen-related distress). Another explanation may be that for individual participants who had

moderate to high levels of distress, participating in the intervention added to their disease burden [7,8,39]. Despite these null results, we found that regimen-related distress, total DDS, and depression significantly decreased over the treatment period. Women were significantly more depressed and had higher baseline DDS total scores, emotional burden, regimen-related distress, and physician-related distress scores compared to men.

In a behavioral RCT, Hessler et al [40] also tested an intervention to reduce diabetes distress, but included participants with at least a moderate level of regimen-related distress. Cross-sectional, prospective model analyses within the study identified significant time-varying findings that suggested decreases in regimen-related distress were associated with improved medication adherence, physical activity, and HbA_{1c} over time [40]. The authors suggest that linkages found among regimen-related distress and glycemic control may be explained

by biological (hormonal), behavioral (nonadherence), and affective (burden of diabetes management) factors.

Spring et al [41] showed that the effect of mobile feedback on a targeted behavior (eating more fruits and vegetables) had a reciprocal effect on an untargeted behavior (physical activity). In the MDIS, we did not target the intervention on a single behavior to reduce distress. It may be that the impact of change in one diabetes distress subscale on another over time is complex, reciprocal, and iterative. Therefore, it may be important for future mobile diabetes studies to assess multiple causal pathways of emotional well-being with differences evaluated among various patient populations [42].

The Diabetes Attitudes, Wishes and Needs (DAWN2) study was groundbreaking in addressing psychosocial issues [43] including diabetes distress, the value of team care, inclusion of family members [44], and importance of behavioral needs of patients [45]. Despite the evidence for effectiveness of diabetes self-management [46,47], DAWN2 reported low participation rates for patients and family groups, with participants reporting education and psychosocial support are seldom available [45]. Advances in mobile technology that enable us to track individual behavior linked to clinical measures within contextual factors (disease severity, comorbidities, age, resources, and distress factors) afford us the opportunity to engage patients and personalize education or emotional needs to address diabetes distress [48].

Multiple causal pathways may also explain the impact of diabetes distress on changes in depression over time. Our study verified previous work [32] that although diabetes distress (as measured by DDS) and depression are highly correlated, these measures are not evaluating the same construct ($r=.57$). Despite patients having less-than-well-managed diabetes at baseline in the MDIS, participants were not substantially depressed. Therefore, it was difficult to measure improvement in depression over time. Participants in our study were diagnosed with diabetes for a mean 8.5 (SD 6.1) years and may have developed coping strategies as suggested by Fisher et al [32]. Also in the MDIS, patients knew study group assignment at baseline; self-selection may have influenced their initial level of distress. One option for future mobile health studies would be to consider collecting mobile data on trait-like variables (mindful eating, positive affect, feeling empowered) [49-51] shown to influence distress, disease management, and health outcomes (HbA_{1c}) [50]. Also, concealing treatment assignments at baseline evaluation could lead to more sensitive comparisons.

In this analysis, we also explored the role of patient sex on diabetes distress. Diabetes distress was higher among women than men at baseline, but there was no difference by sex over the treatment period. Women also experienced higher levels of regimen-related distress, physician distress, and emotional burden, but no difference from men in interpersonal distress. Previous studies of similar community populations with T2D and diabetes distress have not found differences by sex [37].

To our knowledge, this is the first cluster RCT to report a mobile health evaluation of emotional well-being and diabetes clinical outcomes. This study has several strengths, including a population with T2D treated by PCPs in which 90% of diabetes care is provided, use of validated measures of diabetes distress and depression, and a 12-month intervention study of an important clinical measure of diabetes (HbA_{1c}).

Limitations

Although this analysis had many strengths, there are limitations that should be considered when interpreting our findings. The study was not powered for this secondary analysis, and the small sample size within groups may have obscured true moderate-sized differences. The exclusion of participants who had Medicare or Medicaid limited our sample size; of those diagnosed with diabetes, 97.6% and 89.9% of individuals with these payer types have type 2 diabetes, respectively [52]. Also, we did not measure participant engagement in the intervention during the 12-month period. If patients did not enter their glucose levels, medication use, or other diabetes-specific information into their mobile devices regularly, they would receive fewer automated self-management messages and thus potentially have missed the opportunity to reduce feelings of distress or depression. Specific participant demographics, such as race, age, health literacy, or proximity of diagnosis to study treatment, may influence the utilization of a mobile health intervention [53,54]. Although participants in our study had low levels of diabetes distress and depression at baseline, it may be that the technology design, including messaging content, should address potential disease burden which impacts emotional health.

Conclusion

Although we found no definitive overall or sex-specific effect of the intervention on diabetes distress or depression, this study does make an important contribution to the understanding of mobile health interventions and the impact on emotional health. Design of future mobile technology provides an opportunity to personalize, contextualize, and intervene in the emotional well-being of persons with diabetes.

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Authors' Contributions

CCQ was principal investigator for these studies. CCQ, MDS, MLT, and ALG-B were responsible for the design, data analyses, writing, and review of the manuscript. EAB was responsible for the data analyses and manuscript review. SHB and KKS contributed to the writing and review of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

- DDS:** Diabetes Distress Scale
HbA_{1c}: glycated hemoglobin A_{1c}
MDIS: Mobile Diabetes Intervention Study
PCP: primary care provider
PHQ-9: Patient Health Questionnaire-9 item
RCT: randomized controlled trial
T2D: type 2 diabetes

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Original Paper

A Smartphone App to Reduce Sugar-Sweetened Beverage Consumption Among Young Adults in Australian Remote Indigenous Communities: Design, Formative Evaluation and User-Testing

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Abstract

Background: The disproportionate burden of noncommunicable disease among Indigenous Australians living in remote Indigenous communities (RICs) is a complex and persistent problem. Smartphones are increasingly being used by young Indigenous adults and therefore represent a promising method to engage them in programs seeking to improve nutritional intake.

Objective: This study aimed to consult RIC members to inform the content of a smartphone app that can be used to monitor and reduce sugar-sweetened beverage intake in RICs.

Methods: The study was conducted in two phases. The formative phase involved a simulated grocery selection activity with think aloud (“think aloud shop”), a semistructured interview, a questionnaire outlining current smartphone and app use, and a paper prototyping activity. A preliminary end-user testing phase involved a think aloud prototype test and a semistructured interview regarding user satisfaction. Convenience sampling was used to recruit 20 18- to 35-year-old smartphone users for each phase from two RICs in the Northern Territory, Australia. Thematic analysis of transcribed audio recordings was used to identify determinants of food choice from the think aloud shop; themes related to the Theory of Planned Behavior (TPB) from the eating behaviors interview; and usability, comprehension, and satisfaction with the app from the preliminary end-user testing.

Results: Smartphone use in RICs is currently different to that found in urban environments; in particular, extremely low use of Facebook, restricted variety of phone types, and limited Internet access. Findings regarding promoting app engagement indicate that utilizing an opt-in approach to social features such as leader boards and team challenges is essential. The inclusion of games was also shown to be important for satisfaction, as were the use of audio features, contextually embedded dissemination, and streamlined app design for comprehension in this target group.

Conclusions: This research provides critical insights and concrete recommendations for the development of lifestyle improvement apps targeted toward disadvantaged young adults in nonurban settings, specifically RICs. It serves as a framework for future app development projects using a consultative user-centered design approach, supporting calls for the increased use of this strategy in app development.

KEYWORDS

behavior; diet; health promotion; Indigenous; Telemedicine; mobile applications; public health

Introduction

Effective strategies are needed to facilitate long-term weight control and improve health in Indigenous Australians living in remote communities, particularly in the young adult population who are still forming lifelong habits and often shaping those of their children. Smartphone apps are rapidly emerging as a tool to assist delivery and uptake of behavior change programs [1,2], with emerging evidence of modest efficacy in improving health-related behaviors in adolescent and young adult populations [3,4]. Smartphones and apps are increasingly being used by young Indigenous adults and therefore represent a promising method to engage them in programs seeking to improve nutritional intake [5]. The research reported in this paper intended to develop and test with Indigenous young adults living in remote communities the acceptability of an app designed with the aim of improving attitudes, self-efficacy, and intention to reduce sugar-sweetened beverage (SSB) intake.

Indigenous Australians, especially those who live in remote Indigenous communities (RICs), experience substantially worse health outcomes compared with other Australians [6]. Sixty-six percent of all Indigenous Australians (and 55% of those aged between 18 and 24 years) are overweight or obese [7]. This contributes to a disproportionately large burden of noncommunicable disease in this population, with 8.6% of Indigenous Australians living with diabetes; 3.9% with heart, stroke, and vascular diseases; and 1.8% with kidney disease [7]. Late adolescence and early adulthood (18-24 years) are important life stages for targeting interventions to prevent obesity and cardiometabolic disease in remote Indigenous Australians [8]. Additionally, as this age bracket is synonymous with preconception and parenthood for many young Indigenous adults, improving dietary intake at this point can benefit multiple generations [9].

Indigenous Australians living in RICs typically consume a nutritionally very poor diet that underpins the high rates of overweight and obesity. A key contributor to poor diet quality is the alarmingly high intake of SSBs; SSBs account for 10% of calories and 25% of food expenditure in RICs, with relatively higher intakes reported for young adults [10]. Several meta-analyses have shown that consumption of SSBs is independently associated with excess calorie intake, weight gain, and an increased risk of type 2 diabetes and cardiovascular disease [11,12]. Identifying effective strategies to reduce SSB intake, therefore, has the potential to make a substantial impact on dietary intake and weight status in this young adult population.

Apps and social media are rapidly evolving as tools to deliver targeted nutrition interventions at an individual level, as they can provide critical information and motivation for behavior change [1,13-15]. Access and use of smartphone technology, particularly by young adults, is rapidly growing with mobile

network coverage now available in many RICs [5]. These technologies provide a cost-effective way to increase user interaction, provide peer-to-peer support, and widen access to health interventions [16] with the potential to modify behaviors [5]. Recent reviews of the evidence for the use of apps in improving health-related behaviors in adolescents have demonstrated modest improvements [3,4], suggesting apps to be a promising mode of delivery of health intervention for this typically difficult-to-reach population group. Systematic reviews of studies that have used apps to deliver diet and/or exercise interventions for weight loss have also found consistent evidence that digital technology-based/assisted interventions provide a weight loss advantage [17,18]. Although there are a multitude of apps targeting nutrition improvement available in the marketplace, many do not incorporate behavioral theory, and fewer still specifically target SSB consumption or disadvantaged populations [13,14].

The purpose of this study was to consult RIC members to inform the development of a smartphone app that can be used to monitor and reduce SSB intake in RICs. The aims of this research are threefold: to provide critical information for the future development of an app targeting SSB consumption in RICs; to afford insight into eating behaviors and smartphone use in the young adult RIC population which can be applied in many nutrition improvement and app development projects with disadvantaged, nonurban groups; and finally to contribute learnings about the application of best practice app development processes in an RIC context which can be broadly applied to disadvantaged and nonurban target populations internationally.

Methods

Preliminary Work

Prior to conducting this study, a scoping review [2] was performed to identify best practice methods for app development and end-user testing. The scoping review identified numerous app features that were successfully used to promote app engagement in adolescents, young adults and disadvantaged communities that were applicable to this study. Additionally, it highlighted key technical design elements important to consider during app development, such as app functionality without Internet connection. The research protocols for this study were subsequently designed based on the scoping review recommendations that were tailored to enable their application in the unique RIC setting.

This study was approved by the “Human Research Ethics Committee of Northern Territory Department of Health and Menzies School of Research” (HREC 20162659). All participants provided written, informed consent before participation.

Study Design

The study was conducted in 2 phases. The structure is outlined below, and the methodological details of each component are further elaborated in the “data collection methods” section.

Phase 1: Formative Research

The formative research phase aimed to inform preliminary app features, content, and structure. It included the following 3 components: (1) a simulated grocery-selection activity with think aloud (henceforth “think aloud” shop); (2) a semistructured interview regarding eating behaviors; and (3) a questionnaire outlining current smartphone and app use and paper prototyping activity.

Phase 2: Preliminary End-User Testing

An early pilot app was developed using information from both the initial scoping review [2] and preliminary analyses of the data collected in phase 1 (please see images supplied in [Multimedia Appendix 1](#)). Features and content of the early pilot app relate to the constructs of the Theory of Planned Behavior (TPB): attitudes, subjective norms, and perceived behavioral control [19,20]. The app contained a log-in screen for the user to enter individual information that could be used to estimate energy balance and associated weight changes. Screens for selecting and tracking regularly consumed drinks and progress screens presenting information about the sugar and energy consumed in the past month from drinks were included in an effort to impact control beliefs, and therefore, positively influence users’ perceived behavioral control over SSB consumption [19]. Team challenges aimed at supporting nutrition improvement were incorporated to influence normative beliefs, and therefore, adjust subjective norms around the consumption of SSBs [19]. Finally, a quiz-style game was included with the aim of positively influencing attitudes toward SSB consumption, and therefore, behavioral beliefs and intention to change [19,20]. The preliminary end-user testing phase aimed to trial the functionality and acceptability of the developed early pilot app. It included the following 2 components: (1) think aloud prototype test and (2) user satisfaction semistructured interview.

Setting

The study was conducted in 2 RICs in the Northern Territory, Australia. The communities were purposively selected to represent diversity in culture, geographic location (coastal vs inland), and remoteness (339 and 890 km from the capital of the Northern Territory, Darwin). Community authority or cultural safety groups within communities were approached and provided with information on the project to ensure community support and advice on the study process. Following approval from the relevant community authority or cultural safety group, project information was provided to key community leaders, services, and groups. Data collection for the formative research phase took place between September and November 2016, with end-user testing in December 2016.

Recruitment and Sampling

Purposive sampling was used to recruit 10 participants from each community for each research phase, with researchers

positioning themselves and study materials at prominent locations in the community, including the community store and recreational areas. Participants who completed phase 1 were invited to also complete phase 2; however, new participants were recruited for phase 2 when existing participants were unable to be followed up. Eligible participants were Aboriginal and/or Torres Strait Islander adults aged between 18 and 35 years who were active smartphone users (ie, use a messaging/chat system at least 3 times per week and/or other phone features) and who had planned to reside in the community until December 2016. Sampling aimed to recruit a balance of genders and participants of a variety of ages, languages, and family groups.

Data Collection and Analysis Methods

Formative Research

The formative research phase involved the following 3 components: a think aloud shop, a semistructured interview exploring food behaviors, and a brief questionnaire examining smartphone use with a paper prototyping activity [21]. Two researchers collected data (LJ and BC), 1 researcher from each gender to work with participants of the same gender to ensure cultural norms were respected. The 3 parts of the formative research were carried out sequentially with each participant in 1 session, and sessions ranged from 20 to 60 min in length. A local interpreter was available to assist when required. Participants chose the location for each session and sessions were completed individually, in pairs, or in groups at the participants’ discretion. Additionally, during the interviews, many participants were accompanied by children, partners, or friends. All sessions were audio-recorded, transcribed verbatim by 1 researcher (LJ), de-identified, and imported into NVivo 11 (QSR International, Doncaster) for analysis. Analysis varied by study component.

Think Aloud Shop

The think aloud shop activity was included to collect data related to the determinants of food choice for young adults living in RICs. These data were collected to identify key nutrition features and content for the app. Think aloud methods are increasingly used in nutrition research to gain insight into food decision-making processes [22–24]. These methods are based on the foundational work of Ericsson and Simon [25] and involve participants completing a task while verbally narrating their thoughts to elicit the sequence and information involved in processing the task. In nutrition research, the original method from Ericsson and Simon is typically adapted to suit the research aims and setting, the setting often being an accompanied shop [26]. While an accompanied shop scenario was considered ideal by the research team, this was logistically unachievable in the RIC setting for a number of reasons that are elaborated in the Discussion. As such, participants were asked to shop using a paper supermarket catalogue while thinking aloud. The catalogue used for the think aloud task extensively advertised SSB in prime positioning, as well as other healthier alternatives such as bottled water. A modified version of the think aloud training described by Barnett et al [22] was used to familiarize participants with the method [27,28]. Standardized prompts such as “what are you thinking?” were used to remind

participants to think aloud when they had fallen silent [22]. The think aloud task was completed when participants stated they were finished. Thematic analysis of the think aloud shop transcripts focused on identifying reasons for food choice. Two researchers (LJ and BC) separately coded the transcripts and developed a list of themes related to food choice emerging from the data. The separate lists were then merged and definitions for each theme were agreed upon and defined in a codebook. Using this codebook, 2 researchers (LJ and ET) then recoded all transcripts, ensuring analyst triangulation [29]. A high level of agreement in coding was achieved, and disagreements were discussed until a consensus decision was reached.

Semistructured Interview

The semistructured interview ([Multimedia Appendix 2](#)) aimed to collect data related to eating behavior and food attitudes. These data were collected to determine approaches to app design to best support behavior change in this population group. The interview schedule was designed using the constructs of the TPB [19,20]. The questions explored social identity associated with food, self-efficacy, knowledge, and intention to make dietary changes, and supports and barriers to previous attempts to changing eating behavior. Analysis of the interview transcripts was carried out by 2 researchers (LJ and ET). The transcripts were segmented into sections based on question, and the responses to each question summarized. Most participants provided yes/no responses and also elaborated with further explanation. Summaries of the responses for each question were synthesized and grouped according to the constructs of the TPB for presentation.

Smartphone Use Questionnaire and Paper Prototyping Activity

A questionnaire examining current smartphone and app use elicited key data to inform foundational app functionality ([Multimedia Appendix 3](#)). Questions were developed by research team members with experience working in RICs to specifically target known phone behaviors unique to the RIC setting. The questionnaire was administered verbally to ensure adequate understanding of all questions. The paper prototyping method has been used in previous app development scenarios [30] to involve target users in the development of app features and styling. This method involves the researcher using trigger materials (eg, images showing features and capabilities of health-related apps) to encourage participants to build an app prototype. In some cases, due to constraints related to location, environmental factors, and the presence of young children, it was necessary to modify the paper prototyping activity. In these instances, the activity was altered to instead present participants with different trigger materials (see examples in [Figure 1](#)) and ask for their preferences with reasoning. As the paper prototyping activity was conducted similarly to a structured interview, transcripts were analyzed by question, and responses to both the paper prototyping activity and questionnaire were aggregated and summarized numerically by 1 researcher (LJ).

Qualitative data from the paper prototyping activity has been added where appropriate.

End-User Testing

End-user testing involved the following 2 components: usability testing of the early pilot app using the think aloud method [25], followed by a brief interview regarding comprehension and satisfaction.

Think Aloud Usability Testing

Think aloud is a common approach to assess software usability [31,32] and app prototype testing [21]. Think aloud sessions were conducted with 10 participants from each community as Nielsen [31] showed that there are diminishing returns for each think aloud test conducted beyond 7 participants in the context of software usability testing, and this is consistent with other studies [33,34]. Participants were familiarized with the think aloud method using the same procedure as in the phase 1 think aloud shop. Participants were then asked to download the app and carry out a series of tasks using the app while thinking aloud. This involved each participant working through each screen of the app (eg, “log-in screen” and “games screen”) and being prompted to think aloud while doing so. Sessions were audio-recorded and researchers noted actions and issues with usability, comprehension, and satisfaction. The protocol identified that, if necessary, participants would be asked to elaborate on these issues in a short interview after all tasks were complete, not while thinking aloud, to preserve an uninterrupted stream of information processing [25].

Interview

User satisfaction was then assessed using a structured, audio-recorded interview with the end-user participants ([Multimedia Appendix 4](#)). This interview involved verbal administration of a modified version of the System Usability Scale (SUS) [35] as it has been shown to be a robust tool across many user interfaces [36] and used in other app development projects [30,37]. In addition to SUS, questions were adapted from the Computer System Usability Questionnaire [38]. Modifications to these standard questionnaires were necessary to ensure comprehension for participants in the RIC setting. Modifications included exchanging technical words, and those that experts suggested would not be comprehended, with words that would be understood (eg, “this system” was replaced with “the app” and “well-integrated” was replaced with “worked well together”). The researcher assessed comprehension when administering the instrument and further rephrased questions to ensure comprehension as necessary.

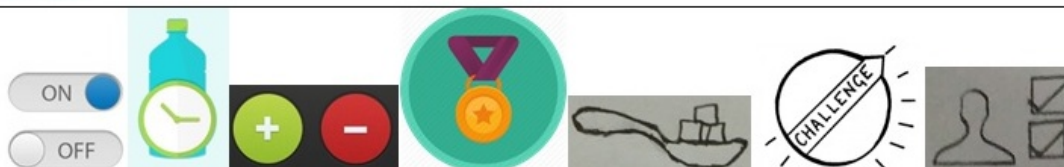
Analysis of the think aloud usability testing and user satisfaction interview transcripts focused on the themes of usability, comprehension, and satisfaction, and was carried out by 1 researcher (ET). In addition to the transcripts, the researchers’ notes on these themes from testing sessions were also included in the analysis. Data were organized according to app screen and synthesized under the main themes for presentation here.

Figure 1. Example trigger materials for paper prototyping activity.

Drink images



Icons



Screens



Results

Participant Details

Ten participants from each of the 2 communities completed the formative research phase; 4 also completed the end-user testing phase, as did 16 new participants. Participant characteristics are provided in Table 1.

The following sections report the findings for each of the 2 research phases, organized by study component.

Formative Research

The formative research phase collected data related to drivers of food choice, eating behavior, attitudes toward dietary change, and smartphone use to inform app content and functionality.

Think Aloud Shop

Eight major determinants of food choice were identified through the think aloud shop activity. Taste was the most frequently vocalized reason for food choice, with 17 participants (85%) referring to positive taste attributes (sweet, salty, crunchy) on 50 occasions throughout the sessions. Family was another key driver, with children’s preferences frequently motivating choice. Health also appeared to be front of mind for 15 participants (75%); however, sometimes health was considered but not acted on; for example, “It’s got nice flavor, I know it’s got too much salt and fat, I know that, I just get ’em when we are hungry.” For younger participants (18-25 years), the ability to share or use food during social activity was an important consideration and often motivated choice. Nine (45%) participants made food choices driven by price during the shop, with foods either considered to be cheap or of good value.

Table 1. Participant characteristics.

Characteristics	Formative research (n=20) n (%)	End-user testing (n=20) n (%)
Gender		
Female	10 (50)	11 (55)
Age in years		
18-20	6 (30)	0 (0)
21-25	5 (25)	5 (25)
26-30	5 (25)	7 (35)
30-35	4 (20)	8 (40)
Family situation		
Children present	7 (35)	5 (25)
Partner present	1 (5)	4 (20)
Partner and children present	1 (5)	5 (25)
Friends/family present	10 (50)	1 (5)
Alone	1 (5)	5 (25)

Convenience was another factor considered by 6 participants (30%), and this related to either the ease and speed of meal preparation, or alternatively that the food was useful for taking on bush trips (eg, conveniently packaged and heat tolerant). The final major factors motivating food choices were familiarity with a product and repeatedly purchasing it as part of a regular shop and the longevity of a product in the sense that it could last until the next shop or pay.

Semistructured Interview

Control Beliefs and Perceived Behavioral Control

When discussing making changes to their eating habits, 10 of 19 participants (53%) would like to involve family and friends. Furthermore, 9 of 19 participants (47%) preferred to make changes alone; however, with 1 participant demonstrating her reasoning using the example of smoking:

Cause some families are smokers too and instead of encouraging you to stop smoking, they'll keep on smoking beside you and making you want to smoke, cause that's what happening to me now.

Most participants (16/20, 80%) identified that there are drinks that they would find difficult to give up, soft drinks (defined here as carbonated drinks, either unsweetened, sweetened, or artificially sweetened) being the main type of drink mentioned (14/20, 70%). However, others considered changing their drinking habits to be easy, particularly when they had a strong motivation:

Participant: I quit [cola soft drink brand] 2 weeks ago... Cause I just had too...I'm always thinking about the other two [her children].

Researcher: What did you change to?

Participant: [diet cola soft drink]

Researcher: Was that an easy change or hard change?

Participant: Easy.

One participant mentioned that flyers and reminders around the community would help her stay on track with dietary changes.

Behavioral Beliefs and Attitudes

Many (11/20, 55%) participants did not believe that what they eat affects their body and mind, and these same participants also did not worry about their dietary habits. Seven of these same participants also did not find anything about food and drink interesting or worth learning more about:

I know about the drinks because I went to the factory. I went when I was, we went with school trip. I know about drinks how many sugar they got and how many thing they got [sic]. I know about that.

The other 9 of the 20 participants (45%) did, however, believe that dietary habits impacted health, reporting worrying about food choices:

Sometimes I worry to eat good foods...we might get sick like from the other foods.

This group did find information about food and drink interesting and wanted more specific information related to recipes, cooking, and food composition:

I would, yeah, be happy to learn more especially when comes down to recipes and mixing and yeah that sort of stuff. Pretty much basic but there is more to it.

Other responses indicated a need for more resources related to food choice:

Yeah, to you know when you go out maybe or when you're at the shop or somewhere and you need something that you need, and you know with the sheet and show you what you can eat.

Normative Beliefs and Subjective Norms

When discussing foods that made participants feel strong and proud, most described bush foods (“bush tucker”), fishing, and hunting for animals such as barramundi, turtle, bush turkey, and kangaroo with family and friends. In contrast to these foods, some participants discussed drinking sugary drinks:

I'm normally addicted to um [cola soft drink brand]...I drink [cola soft drink brand] whenever I'm out.

Water and fruit was also frequently mentioned. In terms of learning about healthy eating, most participants (7/12, 58%) reported being taught the most from their family, whereas others specifically mentioned the health service (2/12, 17%), their friends (1/12, 8%), the store (1/12, 8%), and their work (1/12, 8%).

Behavioral Intention

Participants were evenly split regarding whether they would like to change their eating behaviors in any way (yes, n=7; no, n=7). However, it was clear that “change” was a difficult concept for these participants. Translators highlighted that it was hard to explain to participants, and 1 participant verbalized the difficulty when answering the question:

That's a hard one. But if I were to change someone, hang on, how do I put it? Sorry what's the question again?

Despite this, most participants described having attempted dietary change before (12/20, 60%), typically motivated by health, as shown in the quote below:

I want to go back 'cause I'm overweight. That's what I want to do...Make myself lighter, cause when I was light I was alright, I can do everything, you know, do anything. But at the moment I'm stuck with my fatness and I need to lose it all

Smartphone Use Questionnaire and Paper Prototyping Activity

The details of smartphone and app use can be found in [Table 2](#). Generally, the brand of phone was determined by factors outside the participant's control, such as it being the only brand available at the store at that time, or it was a gift. Participants most commonly used their smartphones for SMS text messaging (short message service, SMS) or calls (19/20, 95%) and games (16/20, 80%), with less common uses being to watch movies (8/20, 40%), do banking (5/20, 25%), access Centrelink (5/20, 25%), play music (4/20, 20%), and access email or social media (3/20, 15%). More than half of the participants (11/20, 55%) did not loan their phone to others, whereas 7/20 (35%) did loan their phone to family, typically their children, and 2 of 20 (10%) allowed others to use their phone for calls. The majority of participants used multiple languages when texting ([Table 2](#)), such as Rembarranga, Kriol, Warlpiri, and Guringji. Only a few participants owned other information technology (IT) devices: 3 of 20 (15%) owned iPads and 2 of 20 (10%) owned laptops. Some participants referred to owning tablets or laptops that

were no longer functional. Games, YouTube, and banking apps were the most common apps used, and additional details of app use can be found in [Table 2](#).

During the paper prototyping activity, participants suggested ideas for a health app for their community, with the most common ideas being an app on how to be strong, healthy, and fit (4/20, 20%), an app to provide information on good/bad foods (4/20, 20%), a food/health games app (3/20, 15%), a quiz app (2/20, 10%), and an app with cooking ideas/recipes (2/20, 10%). A number of participants elaborated as follows:

A health app, maybe in [local language] too, with a quiz game you know in [local language]. Talk about...just a little guessing game how much you reckon in [cola soft drink brand] an all that, 'cause asking them is trying to get an idea of that person in answering back.

So, if it's going to be health wise, it's just something to do with fitness, like marathon running or footy game or something, something to do with sports with fitness.

Specific app features that participants wanted within an app included games (3/11, 27%), audio/music (3/11, 27%), videos (2/11, 18%), and e-stories (2/11, 18%). One participant preferred Aboriginal art and the colors of the Aboriginal flag (red, yellow, and black) to be featured.

The following sections describe findings relevant to specific app screens. As this activity was participant-led as much as possible, not all participants contributed to all sections.

Log-In and Profile Screen

Only 1/20 participant indicated they were happy to sign in via Facebook, with most other participants not holding a Facebook account. Although 9 participants had no objection to include their height and weight in their app profile, many did not know their anthropometric measurements and therefore suggested these figures would have been guessed. Three participants wanted to keep their height and weight information private. Four participants liked the idea of inspirational images and suggested these could include sport, food, or personal photos.

Drink Selection and Recording Drinks Screen

Six participants said they would like to use an app to record their drinks. A number of participants elaborated on this question: 1 participant would like to record their drinks for a week, another 1 day at a time, 1 participant suggested this would be easy, and another mentioned it would be difficult to remember to do but would be useful if you remembered. Two participants would be happy to share their drink history; however, 1 participant was asked if they would still want to share even if they had consumed “bad” drinks and they responded, “no...some...I will share with my closest friends.” Most participants (4, 57%) preferred drinks to be displayed as a picture of a bottle with words. Participants preferred grouped icons to a scroll-through function for selecting drinks.

Table 2. Characteristics of smartphone and app use.

Characteristics	Participants (n=20) n (%)
Characteristics of smartphone use	
Brand of smartphone	
Telstra (Android OS ^a)	8 (40)
Samsung (Android OS)	5 (25)
iPhone (iOS)	3 (15)
Huawei (Android OS)	4 (20)
Length of current phone ownership	
<1 month	3 (15)
2-5 months	5 (25)
6-12 months	1 (5)
1-2 years	3 (15)
2-3 years	6 (30) ^b
“long time”	2 (10)
Frequency of carrying phone	
Always	14 (70)
Sometimes	6 (30)
Daily usage of smartphone	
<once per day	2 (10)
>once per day	17 (85)
No response	1 (5)
Languages used when texting	
Mix of local language and English	9 (45)
Mostly English, some local language	6 (30)
Only English	3 (15)
Pidgin English	2 (10)
Internet use^c	
Mobile data	7 (35)
Wi-Fi	5 (25)
Both	4 (20)
No Internet use	4 (20)
Characteristics of app use	
Facebook account ownership	
Yes	9 (45)
Facebook app use	
Yes	1 (11)
No	4 (44)
Undetermined	4 (44)
No	11 (55)
Previous use of social media or apps to assist in dietary change	
Yes	0 (0)

Characteristics	Participants (n=20) n (%)
No	20 (100)
Apps used by participants^d	
Games	16 (80)
YouTube	7 (35)
Banking	5 (25)
AFL ^e	4 (20)
Music	4 (20)
Centrelink ^f	3 (15)
Maps	3 (15)
Email	3 (15)
Snapchat	2 (10)
Gumtree ^g	2 (10)

^aOS: operating system.

^bTwo participants had recently lost their phones and were planning to purchase a new one, but had owned the phone for 2 to 3 years before losing it.

^cOne interpreter corrected participants when they mentioned they used Wi-Fi; it seemed that participants were unclear about the difference between mobile data and Wi-Fi. Only 1 participant clearly described using both.

^dThe researchers observed that with some participants it was unclear if the apps mentioned were indeed apps or accessed via an Internet browser; for example, YouTube and email.

^eAFL: Australian Football League.

^fCentrelink is a department of the Australian Government Department of Human Services that administrates welfare and social support payments.

^gGumtree is an Web-based platform for selling used goods.

Accurately recording drinks consumed was highlighted as a problem as the researcher identified that 3 participants were sharing bottled drinks with family members during the activity. This was discussed with 1 participant as shown in the following quotes:

Participant: Well if it was a little can I would maybe give them about that bit...Just a few sips and if it was bottle sometime I would only have half or just store it up for myself.

Researcher: Would that make it hard if you were recoding your drinks, do you think that would make it hard sharing and just drinking half?

Participant: I reckon yeah. Yep

Researcher: Do you think, how can we get around that in the app?

Participant: Oh that's a hard one now, maybe if there was a sip included, or how many sip you reckon; one, two sips. Or if it's like scull [ie, drinking a lot very quickly], then scull.

Feedback/Progress Screen

Participants suggested to have their progress displayed in body weight gain (kilograms) prevented, money saved, and volume

of sugar intake prevented. Most participants (10/16, 63%) preferred sugar to be displayed as teaspoons, rather than bags (3/16, 19%), cups (1/16, 6%), sugar cubes (1/16, 6%), or as a percentage of volume/energy (3/16, 19%). Three participants thought a leader board was a good idea, with 1 noting this could be based on water consumption.

Challenges Screen

Both participants who were asked said they would like to complete a challenge and notify their friends and family. They both preferred to select from a list of challenges rather than develop a challenge themselves, participate "sometimes...yeah when I feel like it," and suggested prizes could be real money (AU \$50-100). One participant suggested some motivational messages that would be provided by the app, which were as follows:

To keep going like with what we're doing, like to change.

Say to me to be strong and keep going.

Give my kids change a bit [suggest to me to implement changes with my children], like for me as well.

From the 3 components of the formative research phase combined, a list of commonly selected beverage choices was compiled and is presented in [Table 3](#).

Table 3. Common beverage choices in the remote Indigenous communities studied, ordered by frequency of mention.

Beverages	Formative research component in which the beverage was identified		
	Think aloud shop	Eating behaviors interview	Paper prototyping activity
Soft drinks			
Cola (Coke, Pepsi)	Identified	Identified	Identified
Lemonade (Sprite)	Identified	Identified	Identified
Lemon soft drink (Lift, Solo)	Identified		
Diet cola (Diet Coke, Coke Zero, Pepsi max)	Identified	Identified	Identified
Orange soft drink (Fanta, Sunkist)	Identified		
Passionfruit soft drink (Pasito, Passiona)	Identified	Identified	
Raspberry soft drink	Identified		
Citrus soft drink (Mountain Dew, 7-Up)			Identified
Diet lemonade	Identified		
Flavored mineral water (Deep Spring)			Identified
Diet creaming soda soft drink	Identified		
Ginger beer			Identified
Diet lemon soft drink	Identified		
Soda water	Identified		
Other drinks			
Water	Identified	Identified	
Tea	Identified	Identified	
Coffee	Identified	Identified	Identified
Fruit drink	Identified	Identified	Identified
Orange juice	Identified	Identified	Identified
Cordial	Identified		
Sports drinks (Powerade)		Identified	
Apple juice	Identified		Identified
Milk/Up and Go		Identified	Identified

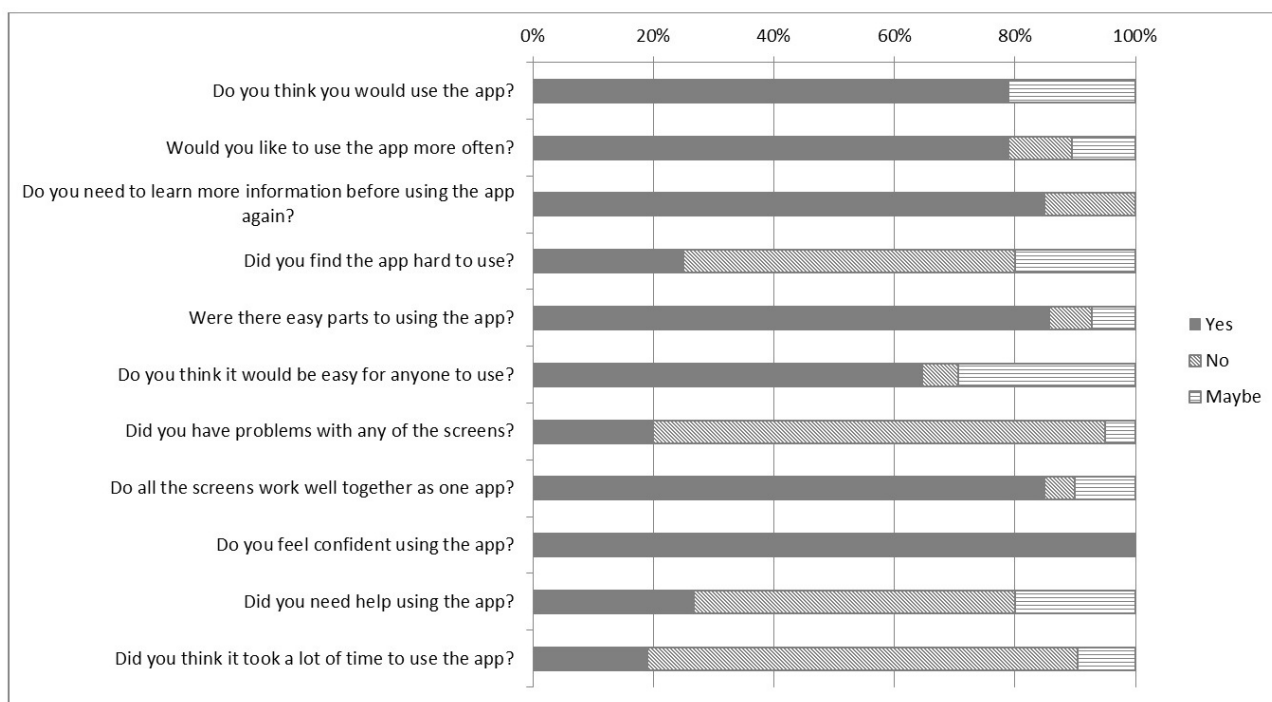
End-User Testing

The usability and participant comprehension and satisfaction with the early pilot app were assessed in the end-user testing phase. Briefly, screens included general log-in and profile screens, screens for recording SSB intake (drinks selection and recording screens), screens demonstrating progress/feedback related to SSB consumption, a screen enabling users to complete challenges related to reducing SSB consumption, and games ([Multimedia Appendix 1](#)). Here, we report findings from the think aloud testing most translatable to other development projects, and the responses to the user satisfaction interview are graphically presented in [Figure 2](#).

Think Aloud Usability Testing

Overall the app was considered usable, albeit slow, given that it was an early prototype. Besides the issues arising from participant unfamiliarity with apps in general (eg, difficulty using scroll functions and navigating using a ribbon menu),

many participants struggled to grasp the concept of the app. However, once it was explained it was well received and many participants commented that it would be of great benefit to their community, especially for people with type 2 diabetes and children. Generally, there was an app component that every participant enjoyed, whether it was the quiz, challenges, or simply entering information about consumed drinks. Most participants reported their satisfaction would be increased with additional use of sound within the app, including talking voices providing information, explanations, and stories; music; and notification sounds such as “bing.” One participant noted that more role modeling through the use of images with people choosing different drinks would be motivational. A number of male participants suggested that enhancing links to sport and bush tucker would increase interest. Additionally, many participants reported it would be more useful if the app scope was extended to include food. Finally, many participants referred to wanting to include family in some way within the app, especially their children.

Figure 2. Responses to end-user testing interview questions.

The following sections describe findings relevant to specific app components that may be transferrable to other app development projects.

Log-In and Profile Screen

It was confirmed that using a Facebook log-in was not feasible as again there were a low number of Facebook users in the sample. In addition, self-reported anthropometric information (for body weight change and energy balance feature estimates) was unlikely to be accurate. Most participants found profile setup difficult due to the use of scroll functions. Some participants reported that having to go in and out of settings to change profile information, including regular drinks, made the app confusing and frustrating to use. Notifications were also not well understood as a concept, but once explained participants commonly set their ideal notification receipt time as midmorning and were pleased with the customizability of this feature.

Drink Selection and Recording Drinks Screen

Again, many participants struggled with the concept of selecting “regular” drinks and then adding daily consumption in a later screen (see [Multimedia Appendix 1](#), screens 3, 4, and 5). They appeared to think they had to have consumed a particular drink that day to add it, rather than simply selecting usual drinks consumed over an extended period. Many suggested the addition of hot drinks, such as tea with sugar, was needed to make app use worthwhile. Generally, most participants found it easy to differentiate (intentionally nonbranded) drink types based on shape (can, small, or big bottle) and color (see [Multimedia Appendix 1](#), screen 3), but many suggested including logos would further assist recognition.

Feedback/Progress Screen

Progress reported as teaspoons of sugar was well received; however energy (presented as “kJ”) was not understood as a concept, and some participants wanted to see total drinks

consumed in bottles/liters. Presenting progress in monthly increments did not seem to be useful, with shorter time periods preferred, such as daily or weekly. It was again confirmed that many participants would have liked to see progress reported as change in body weight, although it was unclear whether they wanted this projected based on energy within drinks, or if they wanted to track their actual body weight. Some suggested a talking voice to explain their progress would assist comprehension. Finally, some participants wanted suggestions of better choices at the shop based on their entries.

Challenges Screen

The challenges were initially not well understood as a concept, but once explained participants were eager to try them. They thought presenting images with the challenges was fun and enhanced comprehension. As with the progress screen, many wanted more explanation as to why these challenges would help, preferably verbally. Participants were seeking a greater response from the app upon reporting completion of a challenge; again noises, flashing, ticks, and visual messages such as “good work.”

Games

Overall, the quiz feature was well comprehended, worked well and had high reported satisfaction. Some participants wanted feedback on their guesses to be clearer, including noises as well as visuals such as a tick or cross. A minority did not interpret the subtle color change of the correct answer as feedback ([Multimedia Appendix 1](#), images 7 and 8). Many participants reported that including more games such as the quiz would increase their interest and frequency of use of the app.

Discussion

Principal Findings

This study used a consultative user-centered approach to identify key considerations for app design that can be used to inform app development for disadvantaged and nonurban populations, specifically young adults living in RICs. A number of important insights regarding app functionality have been illuminated, as have considerations for features and content to ensure user engagement and comprehension in disadvantaged, nonurban populations. Additionally, important learnings related to carrying out best practice app development research have been highlighted through the process of conducting this research. These findings are discussed in the context of prior work in the following sections, and [Textbox 1](#) outlines concrete recommendations arising from the research that are translatable to a wide range of app development projects.

Comparison With Prior Work

The findings support previous work emphasizing that a user-centered design process is critical to developing a functional app [39-41]. This is starkly demonstrated here, where despite high rates of Facebook update in the Australian population, only 1 participant reported the willingness to use a Facebook log-in to access the app in the formative testing, and no participants had a functioning Facebook account to log-in with during the prototype testing. Use of Facebook log-ins is routine in app development, thought to minimize user burden. However in this setting exclusive use of a Facebook log-in would have excluded most of the target user group. Similarly, it was found that the types of phones used by participants were determined by those available in the RIC store; thus, initial groundwork to establish what these are is essential for optimizing apps for these target users. Additionally, the choice to develop a mobile app was reinforced as few participants had either access to other IT devices or consistent Internet

availability for Web browser-based interventions that require constant Internet connection, unlike a mobile app. Therefore, despite the increased use of smartphone technology in RICs [5], it was established that characteristics of smartphone use are currently different in a number of small but critical ways when compared with urban, young adult populations. These findings, therefore, highlight that thorough formative research is vital for app development projects in other disadvantaged, nonurban populations.

Strategies for fostering engagement with both apps and dietary change in a disadvantaged, nonurban population were also identified. The participants in this study were evenly divided in their desire to involve family and friends in any potential dietary change.

Previous literature has shown that competition, team, and social interaction were useful for motivating app engagement across a variety of population groups [30,37,42-46]; however, research with young adult populations emphasizes this must be voluntary [46-49]. Therefore, providing users with the *option* to include others through an opt-in approach to sharing and leader boards, and making both personal and group challenges available, is critical to ensure those users who do not find social support within the app as necessary for change are not alienated from the app. It also appeared from the formative semistructured interview responses that a large number of participants were not aware of the need to, or not motivated to, change their SSB consumption behaviors. While the behavioral theory used in designing the study, and therefore, the pilot app was TPB, these data emerging from the formative work are usefully explored using the Transtheoretical Model of health behavior change [50]. It appears that half the participants were in a “precontemplative” stage of change, whereas the remaining participants were at other stages along the behavior change pathway, potentially making them more open to, and therefore engaged with, app content.

Textbox 1. Recommendations for app development projects targeting disadvantaged and nonurban populations arising from this study.

<p>Project development recommendations</p> <ul style="list-style-type: none"> • Prioritize the conduct of comprehensive formative research in project planning • Work in development teams that include members with in-depth local knowledge • Utilize mixed data collection methods (quantitative and qualitative) and triangulate methods where possible • Consider the potential for the availability of technology and patterns of use to differ greatly in the target group compared with urban populations, and therefore, include this in formative data collection <p>App development recommendations</p> <ul style="list-style-type: none"> • Include nonwritten communication strategies extensively throughout the app to aid comprehension (eg, audio of talking, inclusion of audio cues such as “beeps” and “dings”) • Include colorful, animated feedback throughout the app to foster engagement • Include local jargon where possible (eg, in this case, “sip” and “skull”) • Include games and tailor these to the target population through language, color, sound, and content • Include only tangible health language (eg, spoons of sugar, not calories) • Ensure social aspects of the app are opt-in • Ensure the app is disseminated in a supportive context (eg, through a health provider)

This suggests that it would be useful to use the Transtheoretical Model alongside TPB to structure app content and features to cater for users at all stages of the behavior change cycle, particularly features that draw participants in, despite a lack of intention to change target behaviors. One option to engage this group of users is the inclusion of games with an inherent educational element, with games commonly being used in apps targeted toward low socioeconomic status and adolescent populations to enhance engagement [2,51,52]. During all stages of this research, it was demonstrated that even simple quiz games were enjoyed, consistent with findings from others [53-55], and in this, participant group games were the second most common reason for phone use. Thus, the inclusion of games in any app targeted within RICs or similar disadvantaged, nonurban populations appears to be essential, especially for initiating and maintaining engagement of users in a precontemplative stage of change. Other app content such as feedback and progress information will be more useful to users in “determination,” “action,” and “maintenance” stages of change.

A key advantage of a user-centered design approach is to tailor apps to specific target populations to enhance not only engagement but also comprehension [2,40]. The findings suggest audio features, sounds, and voice-delivered explanations would augment comprehension across all app screens in this user group. It was also evident in the prototype testing that participants struggled to grasp the overall concept of the app before it was explicitly described. This may be explained by the fact that the participants were presented the pilot app somewhat out of context; for example, it was not suggested by a friend or health worker as might be the case in a real-world scenario. This suggests that dissemination of future apps needs to be contextually embedded, with many potential avenues available. Apps could be presented and explained to users at clinic visits [56], through sporting team coaches or schools [57], or as part of larger interventions [58]. Another design consideration related to comprehension was the need to streamline the app as much as possible. This is consistent with previous literature suggesting that complex setup and log-ins inhibit use [46,48,49,59]. As the need for streamlining potentially presents a competing priority to the aforementioned need for customizability, piloting of apps with target users will be essential to achieve a successful balance.

A number of unique challenges impact everyday life in RICs and provide context for these findings. Many RICs are serviced by a single food store that sells a limited range of packaged, fresh, and takeaway foods [60]. These stores often have restricted opening hours, closing at late notice for important community events. Similarly, idiosyncratic behaviors related to smartphone use result from the nearest location to buy and service IT devices often being hundreds of kilometers away.

The social dynamics of RICs too are not comparable with the urban environments in which many apps are developed and tested, as many communities are composed of only a few hundred people [61], with many related. Finally, many Indigenous Australians enter parenthood earlier than nonIndigenous Australians [61,62], dramatically altering the outlook, priorities, and eating behaviors of this young adult group compared with their nonIndigenous counterparts. As such, the value of this research extends beyond this project alone to others who are exploring eating behaviors and smartphone use in disadvantaged, nonurban settings, and the user-centered development approach employed in this work is a major strength of the research.

Limitations

These unique qualities of RICs, however, impacted how best-practice app development methods could be implemented, generating limits to the generalizability and comparability of the research findings but strengths regarding validity and authenticity of the data. Given that for most participants English was a third, fourth, or fifth language, with much of the terminology used in the context of app development simply untranslatable, the modification of the end-user testing methods enabled participant comprehension, and therefore, the collection of useful and insightful data; however, responses cannot be scaled and compared with similar projects. Similarly, the limited opening hours of the 1 community store, combined with the small population resulting in participant discomfort with thinking aloud in the store, meant modification of the think aloud shop activity was required. While this prevents nuanced environmental impacts of the store environment from being included in the drivers of food choice, it ensured the data collection was completed at the participant’s convenience, comfort, and in relative privacy, thus enhancing data quality overall. In addition, a major strength of the project was the triangulation of methods and combination of qualitative and quantitative methods and analysis [29]. For example, without all 3 of the components in the formative research phase, the comprehensive list of SSBs consumed in RICs (Table 3) could not have been generated. This provides an important lesson for future research. Therefore, the detailed methods and research tools provided in this report may serve as a roadmap for future user-centered app development projects.

Conclusions

This research provides critical insights for the development of apps targeted toward young adults in disadvantaged populations and nonurban settings. It also serves as a framework for future app development projects using a consultative user-centered design approach and supports calls for the increased use of this strategy in projects developing apps for health behavior change.

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Authors' Contributions

ET, LJ, TPW, RS, CM, and JB contributed to the design of the study; ET and LJ developed and TPW and JB contributed to the development of data collection tools; JH developed and JB, RS, TPW, and CM contributed to the development of the early pilot app; LJ and BC collected all data; ET, LJ, and BC contributed to the data analyses; ET, LJ, TPW, and JB contributed to interpretation of results; and ET drafted the final manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshots of the app.

[[PDF File \(Adobe PDF File\), 836KB - mhealth_v5i12e192_app1.pdf](#)]

Multimedia Appendix 2

Interview guide—eating behavior and food attitudes.

[[PDF File \(Adobe PDF File\), 21KB - mhealth_v5i12e192_app2.pdf](#)]

Multimedia Appendix 3

Smartphone and app-use questionnaire.

[[PDF File \(Adobe PDF File\), 19KB - mhealth_v5i12e192_app3.pdf](#)]

Multimedia Appendix 4

Structured phone interview schedule for stage 2 app testing.

[[PDF File \(Adobe PDF File\), 57KB - mhealth_v5i12e192_app4.pdf](#)]

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Abbreviations

IT: information technology

RIC: remote Indigenous community

SSB: sugar-sweetened beverage

SUS: System Usability Scale

TPB: theory of planned behavior

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Original Paper

Factors Influencing Engagement and Behavioral Determinants of Infant Feeding in an mHealth Program: Qualitative Evaluation of the Growing Healthy Program

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Abstract

Background: Infant feeding practices, including breastfeeding and optimal formula feeding practices, can play a role in the prevention of childhood obesity. The ubiquity of smartphone ownership among women of childbearing age provides important opportunities for the delivery of low-cost, broad reach parenting interventions delivered by mobile phone (mHealth or mobile health interventions). Little is known about how parents engage with mHealth programs targeting infant feeding and how such programs might influence infant feeding practices.

Objective: The objectives of this study were to explore participant views on (1) factors influencing engagement with the Growing healthy program, an mHealth program targeting healthy infant feeding practices from birth to 9 months of age, and (2) the ways in which the program influenced behavioral determinants of capability, opportunity, and motivation for breastfeeding and optimal formula feeding behaviors.

Methods: Semistructured, telephone interviews were conducted with a purposeful sample (n=24) of mothers participating in the Growing healthy program. Interviews explored participants' views about engagement with the program and its features, and the ways the program influenced determinants of infant feeding behaviors related to breastfeeding and optimal formula feeding. The interview schedule was informed by the Capability, Opportunity, Motivation, and Behavior (COM-B) model.

Results: Participants reported that engagement fluctuated depending on need and the degree to which the program was perceived to fit with existing parenting beliefs and values. Participants identified that the credibility of the program source, the user friendly interface, and tailoring of content and push notifications to baby's age and key transition points promoted engagement, whereas technical glitches were reported to reduce engagement. Participants discussed that the program increased confidence in feeding decisions. For breastfeeding mothers, this was achieved by helping them to overcome doubts about breast milk supply, whereas mothers using formula reported feeling more confident to feed to hunger and satiety cues rather than encouraging infants to finish the bottle. Participants discussed that the program provided around-the-clock, readily accessible, nonjudgmental information and support on infant feeding and helped to reinforce information received by health professionals or encouraged them to seek additional help if needed. Participants reflected that their plans for feeding were typically made before joining the program,

limiting the potential for the program to influence this aspect of motivation. Rather, the program provided emotional reassurance to continue with current feeding plans.

Conclusions: Our findings suggest that engagement with the program was influenced by an interplay between the program features and needs of the user. Participants reported that the program enhanced confidence in feeding decisions by providing a 24/7 accessible, expert, nonjudgmental support for infant feeding that complemented health professional advice. It is likely that interventions need to commence during pregnancy to maximize the impact on breastfeeding intentions and plans.

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KEYWORDS

mobile health; parents; personal satisfaction; behavior; infant; obesity; prevention and control

Introduction

Child Obesity Prevention and Infant Feeding

Childhood overweight and obesity remains a substantial public health challenge in Australia and internationally, with important health and economic consequences [1]. Children are becoming overweight at a young age, with 22.8% of children aged 2 to 4 years *already overweight or obese* [2]. Infants who grow rapidly during infancy are at increased risk of subsequent obesity in both childhood and adulthood [3,4]. Infant feeding practices, including whether an infant is breastfed (and for how long) [5] and how formula is used (including the protein content of the formula, how much is offered, how it is prepared, feeding on a schedule, and putting infants to bed with a bottle), are all associated with rapid weight gain in infancy [5-9]. Australian data from a 2010 national survey indicated that approximately 10% of Australian infants were exclusively formula fed from birth, 40% had at least some formula by 1 month of age, and only 15% were exclusively breastfed until 6 months of age [10]. Similar proportions are reported in the United States where national rates of exclusive breastfeeding at 6 months are 22% [11]. This clearly highlights the need for interventions to promote longer breastfeeding duration and exclusivity, but given the high rates of formula use, strategies are also required to promote optimal formula feeding practices to prevent rapid weight gain and early onset of obesity.

mHealth and Infant Feeding

Mobile health (mHealth) interventions present an appealing new avenue to support parents with infant feeding. Smartphone ownership is increasing worldwide [12], with Australia having the highest rate (93%) of access to smartphones [12]. Furthermore, women of childbearing age (18-49 years) spend, on average, around 21 hours a week on their smartphone [13]. Well-designed smartphone apps can provide “around-the-clock” high-quality information as well as personalized and tailored support at low cost and are easily scalable to maximize reach [14]. A key gap identified in our previous qualitative work with mothers [15] was the lack of reliable and practical advice at the exact time of need (eg, breastfeeding support in the middle of the night), highlighting the value of mHealth approaches in the context of infant feeding. Although studies [16-20] suggest that the majority of mothers (ranging from 51 to 97% across studies) use the Internet for information on infant feeding and care, less information is available on the use of apps in the postpartum period. A recent study [21] among low-income women reported

that apps were commonly used during pregnancy but not in the postpartum period because of limited availability of high-quality apps, creating a postpartum app gap. In line with this, our own research [22] found that 78% of apps on infant feeding available in Australia were of poor quality because of deficits in navigability, design, readability, breadth of coverage, and author credibility.

Efficacy and User Engagement With mHealth Interventions

Early research on the efficacy of mHealth interventions in changing health behavior is promising [23-25]; however, there is a paucity of research on the efficacy of such interventions in influencing infant feeding behaviors. A recently published review of mHealth interventions found that only 6 of 23 studies used behavior change theory to inform the development of the app [26]. Given that it is well accepted that interventions underpinned by behavior change theory are more likely to be effective [27-29], this represents an important gap in the mHealth literature.

The same review [26] reported that some features improved the effectiveness of health-related apps. These included if apps were time efficient, easy to use, provided real-time feedback, were individualized, provided detailed information, and included health professional involvement [26]. This suggests that factors influencing user engagement can have a direct bearing on how effective mHealth interventions will be [26]. Engagement is influenced by the attributes of the user, the system, and user-system interaction [30]. Specifically, in mHealth interventions, the mode of delivery (eg, use of push notification and games), content (eg, behavioral targets and use of behavior change techniques), and quality (such as credibility, functionality, aesthetics, and subjective experience) have been shown to influence engagement [31]. Evidence also suggests that interventions designed to address the unique preferences of the participants will have a greater impact on program engagement and subsequent outcomes [32]. The mHealth design and delivery characteristics important in the parent infant feeding domain are poorly understood.

The Growing Healthy Program

We have recently developed the Growing healthy program, an mHealth intervention for parents of young infants, which encourages healthy infant feeding practices across the first 9 months of life, with a focus on socioeconomically disadvantaged parents. Details about the program and its development have been published elsewhere [33]. Briefly, the program consisted

of an app and website, providing parents with a “one-stop shop” for evidence-based advice and strategies that are consistent with national guidelines on infant feeding in the 9 months after birth. The features of the mode of delivery included information (videos, written content, and links), automated messages (3 personalized push notifications or short message service text messages per week, tailored to the infants’ age and feeding mode: breast, formula, or mixed feeding, and a weekly email summarizing the messages), and communication functions (Facebook, sharing content with others). Personalized messages direct users to tailored information (eg, breastfeeding mothers were directed to breastfeeding content), but participants were not restricted from accessing other information (eg, on formula feeding).

The development of the program was guided by the Behavior Change Wheel framework, a well-recognized approach to developing behavioral interventions that takes into account the context in which behaviors occur [34]. To understand infant feeding behaviors, extensive formative work including 2 systematic reviews [35,36] and qualitative interviews with both health practitioners [37] and socioeconomically disadvantaged parents [15] were used to identify the selection of the target behaviors, key determinants of these behaviors in context, and appropriate intervention delivery mode. Determinants of infant feeding behaviors were explored within the domains of capability (eg, skills, knowledge, and confidence), opportunity (eg, access to information or equipment or social and cultural norms), and motivation (eg, habits, emotions, plans, or goals) as outlined in the Capability, Opportunity, Motivation, and Behavior (COM-B) model [34]. Behavior change techniques were mapped to the determinants underlying each behavior using Michie’s taxonomy [38] and were selected if they were feasible to be used in the mHealth format. The design of the app was also informed by best practice principles in mobile health app design [39] with the purpose of addressing key gaps in existing infant feeding apps.

Study Aims

This qualitative study aimed to explore participant views on (1) factors influencing engagement with the Growing healthy program and (2) the ways in which the program influenced behavioral determinants of capability, opportunity, and motivation for breastfeeding and optimal formula feeding behaviors. The findings from this study will provide important new insights to guide the development of future mHealth interventions targeting infant feeding to maximize behavior change and effectiveness.

Methods

The Growing Healthy Feasibility Study

A feasibility study of the Growing healthy program has been conducted to examine the acceptability and preliminary effectiveness using a quasi-experimental design, with an mHealth intervention group and a concurrent nonrandomized comparison group [33]. Participants were recruited to the Growing healthy program in the following 3 ways: via their primary care providers in socioeconomically disadvantaged

communities in 2 Australian states, face-to-face by researchers, and through advertising on the Web [40]. Eligibility criteria for participation in the program included the following: pregnant (30+ weeks’ gestation) or parent/main carer of an infant aged under 3 months, smartphone ownership, English literacy, aged 18 years or older, and resident in Australia. Further details of the recruitment process and outcomes have been described elsewhere [40].

Study Participants

For this qualitative substudy, Growing healthy participants (n=301) were purposefully selected from those expressing interest in participating in an interview about their experiences of using the program when their infants were between 6 and 9 months old. From those who expressed interest (n=67), participants were purposefully sampled to recruit mothers with a range of feeding modes, including breastfeeding, formula feeding, and mixed feeding (combining both breastfeeding and formula feeding) and those who were university or nonuniversity educated. Purposefully selected individuals (n=39) were invited by email to participate. Nonresponders were sent a reminder email 1 week following the initial invitation, and if they were unresponsive, participants were called 1 week later to confirm their interest and to schedule an interview. A total of 24 individuals agreed to take part, the remaining 15 were uncontactable. Data saturation was reached (as determined by no new information emerging) after conducting interviews with all who agreed to participate. Verbal consent to participate was given at the initiation of the interview and a Aus \$30 supermarket voucher was provided as compensation for the time taken to complete the interview.

Data Collection

The interview schedule consisted of semistructured questions tailored to mothers’ feeding mode and the mode of delivery of the Growing healthy program (ie, whether the participant was an app- or website user, used push notifications or text messages, and read the Growing healthy emails). The questions were structured to address the 2 aims of the study (Table 1). First, questions were asked about their engagement with the program and its features. The second part of the interview sought to explore in what ways the program influenced behavioral determinants of capability, opportunity, and motivation for breastfeeding and optimal formula feeding behaviors. Interviews were conducted by 1 author (EL) until saturation was reached (ie, until no new information emerged). Interviews were recorded with participants’ permission and transcribed verbatim by a professional transcription service.

Data Analysis

Transcriptions were de-identified and cross-checked with the audio file for accuracy. Thematic analysis was performed using the methods of Braun and Clarke [41]. This method starts with the familiarization of the data by reading the interviews, generating initial codes based on the data. In this study, coding was also informed by factors known to influence engagement with mHealth, including mode of delivery, quality, and content as well as the COM-B model for behavioral determinants [34].

Table 1. Outline of interview questions.

Domain	Examples of interview questions/prompts
Engagement	<p><i>To start with can you tell me if you used:</i></p> <p>The app? If YES, did you receive any push notifications or messages from the app? Did you read any of these? Did you click on any of the push notifications? How did you mainly use the app?</p> <p>The website? Did you receive weekly email with links to the website? Did you ever click on these links?</p> <p><i>I wonder if you could tell me a little bit about your experience of using the Growing healthy app/website?</i></p> <p>What did you think of the app/website?</p> <p>When did you use the app/website?</p> <p><i>Let's look at the home page of the app/website together (as a memory prompt for the questions below)</i></p> <p>Were there any particular sections that you looked at more than others? Why was that?</p> <p>What have been the most helpful sections of the app? Can you tell me about a time when you used it and how it helped?</p> <p>Were there any sections of the app which you didn't find helpful? Can you tell me more about that?</p>
Behavioral determinants	<p><i>I would now like to ask you about formula feeding/breastfeeding/mixed feeding and the formula feeding/breastfeeding/mixed feeding section of the app (get them to open it if possible)</i></p> <p>How helpful was this section of the app/website? Prompts: what did you like? Dislike?</p>
Behavior	In what ways (if any) do you think it changed how you fed your baby?
Capability	What new things (if any) did you learn from the app/website about formula feeding/breastfeeding/mixed feeding?
Motivation	Did it change the way you felt about formula feeding/breastfeeding/mixed feeding?
Opportunity	How well supported overall did you feel in breastfeeding/formula feeding/mixed feeding your baby? To what extent (if any) did the Growing healthy program (app/website/push notification) influence how well supported you felt in breastfeeding/formula feeding/mixed feeding?
Opportunity	<p>Did you seek any additional advice or information on formula/breastfeeding/mixed feeding outside of that received on the app/website? What prompted you to seek this advice or information? How did this section of the app (website or the notifications you received) fit with the advice or information you received from elsewhere? How did you deal with any conflicting advice?</p> <p>Do you have any further comments or anything to add about the Growing healthy program and your experience of feeding your baby?</p>

An initial coding manual was devised based on a review of 5 interviews and subsequently revised several times during the coding process, adding new codes as needed until no new codes were identified. Three researchers (EL, CGR, and RL) were involved in developing the coding manual based on reading transcripts individually and meeting to discuss the manual. Upon finalizing the coding manual, all interviews were coded by EL with a subset coded by RL. Minor inconsistencies were identified and were resolved through discussion. The researchers then looked for key themes within the data, and upon reviewing these themes, condensed them where appropriate. Finally, themes were defined and appropriately named. Coding, storing, and sorting of de-identified transcripts was undertaken using QSR NVivo software version 11.

Ethics and Study Approvals

Ethics approval was provided by Deakin University 2014-093 and University of Technology Sydney 2014000123.

Results

Participants

Participant characteristics are shown in [Table 2](#). Of the 24 participants, 13 were breastfeeding, 9 were formula feeding,

and 2 were mixed feeding. Half of the sample were university educated (which is representative of the total sample of participants for the feasibility study) and the infants were aged between 25 and 36 weeks at the time of interview. There was no significant difference in sociodemographic characteristics between those who agreed to participate and those who were uncontactable ([Table 2](#)). Interviews were conducted over 6 weeks from January to March 2016. The mean duration of the interview was 17 min (range: 13-35 min).

Participant Views on Factors Influencing Engagement With the Program

Participants in this study reported high engagement with the Growing healthy program. Participants used the program to browse content, to actively search for a particular topic to address an immediate need, or were prompted to use the program from a push notification or text message or email. Most participants indicated that they used the app more than the website because it was more conveniently accessed on their smartphone. Engagement with the program was influenced by a range of factors, including user needs and program features ([Table 3](#)).

Table 2. Participant and infant characteristics.

Characteristics	n=24
Participant characteristics	
Mean age in years (range)	31 (24-38)
Education	
University	12
Non-university	12
Country of birth	
Australia	22
United States	1
Indonesia	1
Infant characteristics	
Mean age in weeks (range)	31 (25-36)
Gender	
Male	15
Feeding methods (in addition to solids)	
Breastfeeding	13
Formula feeding	9
Mixed feeding (formula and breastfeeding)	2

Table 3. Factors influencing engagement with the program: themes and illustrative quotes.

Theme	Illustrative quotes
User needs	
Baby age and transition points	<i>Yeah at the beginning I didn't know what I was doing, but now I think I've got the hang of it. [Participant #23]</i>
First-time mother	<i>...well as a first time mum, I didn't have any clue because I've never been around babies and I'm like "Is this normal?" [Participant #5, first-time parent]</i> <i>I guess I felt I knew it all by now, with my third [baby] but yeah. Would have gotten a lot of tips if it were my first baby. [Participant #24, 3 children]</i>
Vulnerable parents	<i>...it just really helped me because not really knowing what to do or where to turn to and things like that. It helped me to go on. Like for example the talk to other mums (section) was like "Okay, I'll join in with my local maternal child health nurse mums group" and make sure I keep going to that. [Participant #6]</i>
Congruence with parenting philosophy and beliefs	<i>...I found it quite good because it goes along with the guidelines of the WHO like the World Health Organization which is what I go by personally. So yeah, I quite liked it. [Participant #14]</i> <i>I guess it's less that I wasn't interested and more that I found a lot of the topics didn't really mesh well with my sort of parenting style or my parenting philosophy kind of thing. [Participant #6]</i>
Program features	
User friendly and easy to navigate	<i>I think it's really well organized. Like it's really user friendly with all the topics and you can go in and it's really easy to find what you're looking for... [Participant #10]</i>
Credible facilitator	<i>I found that reading the Growing healthy app I had the confidence that the information was Australian and that it was best practice and that it was put out by a university that has—a couple of universities that have some kind of I guess credence and reliability. So I know that what I was reading wasn't necessarily just the opinion of some whacko. [Participant #8]</i>
Push notifications, email, and text messaging prompt	<i>It's like they (the push notifications) were reading my mind, quite often they popped up at the right time when I was actually thinking I wonder what's going on with X,Y or Z, and that's when it usually pops up. [Participant #11]</i> <i>I turned off push notifications for a lot of my apps because I was just getting so many. [Participant #17]</i>
Technical issues	<i>One of the things that did deter me a bit was that the app would just randomly close down. [Participant #9]</i>

User Needs

Engagement with the program fluctuated depending on the mothers' needs (eg, when she was in need of more support on a particular topic) and on their infant's stage of development. In particular, participants reported that their engagement was highest when their baby was very young and they were establishing routines (eg, breastfeeding, sleeping) and during times of transition (eg, introducing a bottle, formula, or solids and going back to work). First-time mothers reported using the program as a learning tool, whereas mothers with older children discussed using the program less frequently, typically to reinforce what they had learned with their older child or children. A number of vulnerable parents (those with postnatal anxiety, depression, feeding problems, or those who reported finding the transition to motherhood difficult) reported referring to the app for tips, resources, and reassurance. Participants reported that for their engagement with the program to be high, the content needed to be consistent with their own parenting beliefs and values. For example, if the content was consistent with their extant beliefs about appropriate ways for infants to sleep and feed, they were more likely to engage with the program. In contrast, if the content did not align with their preexisting parenting beliefs and values, they were less likely to engage with the program.

Program Features

Most participants thought the app was clear, contained sufficient information, was user friendly, and was easy to navigate. Many participants perceived the quality of the program to be high because 2 credible universities designed it. This encouraged feelings of trust and confidence in the information, which participants felt was important in promoting greater app use. The receipt of push notifications, text messages (for Web users), and emails was important in prompting engagement for some participants, particularly when the messages aligned with participants' experiences and needs. Others reported difficulty with knowing how to retrieve push notifications (even if they were perceived to be relevant) or switching off push notifications because of the large number received from multiple apps. Other technical glitches, including the failure of the app to work at times, were reported to reduce engagement.

Participant Views on How the Program Influenced Capability, Opportunity, and Motivation

The key themes arising from participant interviews on how the Growing healthy program influenced capability, opportunity, and motivation for breastfeeding and optimal formula feeding practices are outlined in [Table 4](#) and described below.

Capability

Many mothers interviewed reported that the Growing healthy program increased their confidence in feeding decisions.

Confidence was increased by the reassurance provided by the program that mothers were engaging in feeding behaviors that were healthy for their infant and they were doing the "right thing." This was evident for the majority of participants interviewed, regardless of their feeding mode (breast, mixed, and formula). Breastfeeding mothers reported that the program helped confirm they were breastfeeding their baby correctly. These mothers also noted that the program provided them with the confidence to continue breastfeeding, particularly when they doubted their milk supply. Formula and mixed feeding mothers discussed that the app increased their confidence to demand feed following their infants' hunger and satiety cues rather than encouraging infants to finish the bottle. Confidence was also increased because of the credibility of the information source coming from university experts.

Opportunity

Participants discussed that the program provided access to understandable, credible information while also providing social support. Participants particularly commented upon the value of the support provided by the app at times of need such as when they were questioning their milk supply and during times when it was not possible to seek advice from others (eg, in the middle of the night). Participants who were formula feeding or mixed feeding also indicated that the program provided support without fear of judgment of their decision to use formula. These women reported feeling reluctant to discuss formula use with health professionals because of fear of being judged. Some participants noted that the information in the program reinforced advice provided by others in their social and health networks (eg, Midwives, Maternal and Child Health Nurses, and General Practitioners) particularly with regard to breastfeeding. Mothers who were exclusively breastfeeding at the time of the interview were more likely than formula or mixed feeders in this sample to talk about having sought additional help for infant feeding from a range of sources. That is, the program encouraged them to seek additional help if needed, thus potentially increasing both the advice and support they received (opportunity) as well as their skills, knowledge, and confidence in breastfeeding (capability).

Motivation

Motivation in the form of plans was rarely mentioned as having been influenced by the Growing healthy program. For example, mothers appeared to have set plans for if and how long an infant would be breastfed and desires to introduce formula, and these were reportedly formed before joining the program. Nonetheless, mothers reported that the program influenced their motivation to continue with their current behaviors by providing reassurance that they were doing the "right thing" for their baby, both nutritionally and for nonfeeding-related behaviors, such as sleeping.

Table 4. Participant views on how the Growing healthy program influenced behavioral determinants (ie, capability, opportunity, and motivation): themes and illustrative quotes.

Theme	Illustrative quotes
Capability	
Reassurance—doing the “right thing”	<i>So the app said about demand feeding and letting them stop when they're full, etc, which I found really useful because of course when you're looking in the bottle and they're not drinking it all you start thinking no, why aren't they drinking. [Participant #20, mixed feeding mother]</i>
Confidence to keep going	<i>I guess it gave me the confidence to continue even when I was struggling, having issues and starting to doubt myself and doubt that I had enough milk supply. I guess it was just the information that I needed to keep me going. [Participant #11, breastfeeding mother]</i>
Credibility of provider-enhanced confidence	<i>I think it gave me more confidence in the decisions I made because I felt like the decisions I made were supported by good information and a reputable distributor of information. [Participant #8, formula feeding mother]</i>
Opportunity	
24/7 access to clear, credible information and support	<i>...you could go into that app any hour of the day even if it's 3 am in the morning and you're breastfeeding and you want to check something and you got your phone there but none of those primary support people are around because they're asleep. [Participant #17, breastfeeding mother]</i>
Support without fear of judgment	<i>I would never go to my nurse or like any of those things to tell that I was going to stop breastfeeding or anything like that because you tend to get a lecture but it's nice to have I suppose an information source that's not very anti formula for a change. That's yeah—most sources are anti formula. [Participant #4, mixed feeding mother]</i>
Reinforced information from other health and social networks	<i>It was just good information; clear, concise. Similar to some of the other material that I'd been referred to by my maternal health nurse...It was good that at least they were both consistent in the information that they were presenting. [Participant #15, breastfeeding mother].</i>
Encouraged seeking of health professional support	<i>...reading the app actually directed me to the Australian Breastfeeding Association and a lactation consultant. So that kind of, the app is the one that I recommend that I see them. [Participant #14, breastfeeding mother]</i>
Motivation	
Feeding plans/intentions already formed before app use	<i>I don't think the Growing healthy app really played any part in it. Like I think I started formula feeding before that [having the App], like in that first week. [Participant #12, formula feeding mother]</i>
Motivation to continue with current behaviors by providing reassurance	<i>I was stressed that she wasn't getting enough milk and reading through that it said so long as she had so many wet nappies and things like that, and she actually had all of the things, like she was fine and I was just overthinking it and stressing it...so then it actually relieved my anxiety of thinking she wasn't getting enough milk and I was going to give up breastfeeding. [Participant #11, breastfeeding mother]</i>

Discussion

Principal Findings

To our knowledge, this is the first study to explore participant views on factors influencing engagement with an mHealth intervention targeting infant feeding and the ways in which the program reportedly influenced key behavioral determinants of breastfeeding and formula feeding practices. The findings suggest that engagement is influenced by an interplay between the needs of the users, congruence between the program and existing parenting beliefs, and the program features. Participants reported that the program enhanced confidence in feeding decisions by providing an “around-the-clock,” credible, nonjudgmental support for infant feeding that reinforced and complemented information received from social networks and health professionals. Participants reflected that motivation in terms of feeding plans and intentions were rarely influenced by the program because these were generally formed before using the program; rather, the program provided emotional reassurance to continue with current feeding plans.

Participants' use of an mHealth program is critical if participants are to be exposed to the behavior change strategies underpinning the program's effectiveness. Poor or limited engagement reduces the intervention “dose” received and limits the program's effectiveness even if the behavior change strategies are sound. Our findings highlight the importance of understanding the unique needs of the intended users and how this might influence the mHealth design and delivery characteristics that are likely to be effective with those particular users. This fits with existing literature on user-centered design principles for developing mHealth programs [42].

Our finding that participants reported engagement with the program fluctuated according to need fits well with our quantitative analysis of predictors of actual app use based on analysis of app analytics [43]. In this analysis, first-time parents and those who registered when their infant was younger indeed had significantly higher levels of program use. These qualitative findings suggest that this was because of the higher learning needs of users at this time and their desire for quality information and support. This is in line with other effective

face-to-face intervention programs targeting early-life obesity risk that have largely targeted first-time parents with young infants [44-46]. Understanding key infant feeding and developmental transition points (such as the introduction of solids) that may act as “sticky hooks” to engage parents in program content was also identified as important in this study. To achieve this, the program’s push notifications were specifically tailored to the infant’s age and stage of development and feeding method and pretested with parents to ensure the content and tone resonated with our target group [33]. Finally, understanding how the content may fit with predominant parenting beliefs and philosophies was identified as an important consideration. For example, our formative work suggested that some parents support reference to infant feeding guidelines in the program content, whereas others believed that guidelines were “too prescriptive” and approaches should be tailored to each individual baby [15]. Understanding the genesis of beliefs and philosophies around infant feeding could potentially inform the tailoring of content. Clearly, getting the tone and balance of content “right” for the target group is important in maintaining engagement.

In line with previous research [26,30,47], our findings highlight the importance of mHealth design and delivery features in influencing engagement. For parents in our study, app mode of delivery was preferred over the website because of ease of access on their smartphone and the use of a combination of push notifications/text messages and emails was important for prompting program use. Again, this concurs with our quantitative analysis in which those using the app and receiving email notifications had higher levels of program use compared with those using the app alone [43]. This suggests that multiple points of contact with parents may promote better engagement. Consistent with previous research [48], the importance of having a credible content provider was a strong reoccurring theme in our findings and this was seen to enhance engagement with the program. This is not surprising given that although parents are increasingly relying on informal sources of support for infant feeding such as the Internet, family, and friends, they often report receiving conflicting information [49] and like the opportunity to cross-check with evidence-based recommendations. As expected, some technical glitches in the delivery of the program, including the temporary disabling of the app by new operating system updates, reportedly reduced engagement. This highlights the importance of extensive testing of the program across a range of devices before program launch and the need for ongoing app maintenance to accommodate operating system and other updates that might impact app functionality. For mHealth researchers, this will involve allowing time and budget for extensive beta testing and app maintenance during mHealth trials.

Participants reported that the program increased their confidence in feeding decisions by providing reassurance from a credible and trustworthy source, highlighting the interplay between program features and behavior change. Breastfeeding mothers reported that the program increased their confidence in their milk supply, which is critical given that a perceived lack of milk supply is the most common reason given for giving up breastfeeding in the literature [50]. Formula and mixed feeding

mothers reported that the program gave them confidence to trust their infant’s hunger and fullness cues and not to pressure infants to finish all of the formula in the bottle. Given that responsive feeding in infants decreases the likelihood of rapid weight gain in infancy [5], this is an encouraging finding.

Our findings highlight the value of the Growing healthy program in providing an accessible “24/7” source of nonjudgmental support for infant feeding, potentially increasing participants opportunity for achieving optimal infant feeding practices. In particular, some mothers who mixed or formula fed felt that society provided little advice or support regarding how to use formula well. Consistent with our previous qualitative work [15], participants reported they often felt unsupported by health professionals in their decision to formula feed, with some viewing practitioners as “antiformula.” This is consistent with recent studies reporting that advice and guidance on formula feeding from health professionals is deficient and that parents typically rely on informal sources of support such as family, friends, and the Internet [51-53] to learn how to prepare and feed formula. Participants reported that the Growing healthy program helped to fill the void by providing a credible noncommercial source of information on formula feeding, and parents were receptive to messages about best practice formula feeding. The program also provided support when traditional sources of support such as health professionals were unavailable (eg, in the middle of the night) or difficult to access (eg, long wait times for a lactation consultant). Given that a trigger for behavior change can be situational and momentary [54] (eg, the urge to introduce formula to promote sleep in the middle of the night), having access to support at the exact time of need highlights one of the key advantages of mHealth programs over traditional face-to-face behavior change programs. Finally, participants reported that the program reinforced the advice received from health professionals and/or improved access to health professional support (particularly for breastfeeding), underscoring the potential value of mHealth programs in complementing health professional-delivered interventions to promote behavior change.

Our findings suggest that the program was less able to influence motivation in terms of infant feeding plans and intentions as these were reportedly formed before joining the program. It is likely that the timing of program delivery was an important limitation here. The average age of infants at the time of enrollment was 7 weeks, and around one-third of mothers had introduced formula at this time, limiting the ability of the program to influence plans around breastfeeding duration. Evidence suggests that plans about whether a mother will breastfeed and for how long are made antenatally, highlighting the importance of commencing the program before birth to influence goals, plans, and ultimately motivation for breastfeeding. Despite this, our findings suggest that mothers who were breastfeeding were motivated to continue because of the reassurance provided about their milk supply. Mixed feeding and formula feeding mothers were also motivated to practice responsive feeding by the reassurance that they were doing the “right thing.” This highlights the importance of reassurance as a motivator for continuation of desired infant feeding practices.

Strengths and Limitations

This study has a number of strengths and limitations. The use of qualitative methods is a strength in enabling an in-depth exploration of factors influencing engagement with the program, how the program influenced behavioral determinants, and the interplay between engagement and behavior change. However, social desirability bias is a potential issue, as some participants may have been eager to please researchers with positive accounts of the program and its effect and possible overreporting of desirable infant feeding practices. Nevertheless, this risk was minimized by having no contact between researchers and participants during the feasibility study and encouragement to provide their honest feedback to help improve the program. Furthermore, it is possible that those who volunteered to be interviewed were more engaged with and had more positive views about the program than those who declined or were unable to be contacted. However, there was no difference in the sociodemographic characteristics between those who

participated and those who were uncontactable, suggesting no systematic bias.

Conclusions

Our findings suggest that to maximize parental engagement, an mHealth program targeting infant feeding should come from an expert and credible source; be tailored to specific needs of the target group (eg, first-time mother, attitudes to parenting); use a combination of engagement strategies such as emails, push notifications, and text messages; and undergo extensive testing and ongoing maintenance to ensure high levels of functionality. Participants reported that the program enhanced confidence in breastfeeding and optimal formula feeding behaviors by providing a “24/7” accessible, expert, nonjudgmental support for infant feeding that complemented health professional advice. To improve the impact of the program on motivation and plans for breastfeeding, the program needs to commence antenatally and include behavior change strategies that specifically target motivation and intentions.

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Authors' Contributions

RL, CG, and EL conceived the qualitative study. EL conducted the interviews with parents and analyzed the data with the support of CG and RL. EL wrote the first draft of the manuscript and subsequent revisions of the manuscript were undertaken by RL, with the support and input from all authors. All authors approved the final manuscript for publication.

Conflicts of Interest

None declared.

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Abbreviations

COM-B: Capability, Opportunity and Motivation, and Behavior.

mHealth: mobile health.

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Original Paper

Insights From Google Play Store User Reviews for the Development of Weight Loss Apps: Mixed-Method Analysis

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Abstract

Background: Significant weight loss takes several months to achieve, and behavioral support can enhance weight loss success. Weight loss apps could provide ongoing support and deliver innovative interventions, but to do so, developers must ensure user satisfaction.

Objective: The aim of this study was to conduct a review of Google Play Store apps to explore what users like and dislike about weight loss and weight-tracking apps and to examine qualitative feedback through analysis of user reviews.

Methods: The Google Play Store was searched and screened for weight loss apps using the search terms *weight loss* and *weight track**, resulting in 179 mobile apps. A content analysis was conducted based on the Oxford Food and Activity Behaviors taxonomy. Correlational analyses were used to assess the association between complexity of mobile health (mHealth) apps and popularity indicators. The sample was then screened for popular apps that primarily focus on weight-tracking. For the resulting subset of 15 weight-tracking apps, 569 user reviews were sampled from the Google Play Store. Framework and thematic analysis of user reviews was conducted to assess which features users valued and how design influenced users' responses.

Results: The complexity (number of components) of weight loss apps was significantly positively correlated with the rating ($r=.25$; $P=.001$), number of reviews ($r=.28$; $P<.001$), and number of downloads ($r=.48$; $P<.001$) of the app. In contrast, in the qualitative analysis of weight-tracking apps, users expressed preference for simplicity and ease of use. In addition, we found that positive reinforcement through detailed feedback fostered users' motivation for further weight loss. Smooth functioning and reliable data storage emerged as critical prerequisites for long-term app usage.

Conclusions: Users of weight-tracking apps valued simplicity, whereas users of comprehensive weight loss apps appreciated availability of more features, indicating that complexity demands are specific to different target populations. The provision of feedback on progress can motivate users to continue their weight loss attempts. Users value seamless functioning and reliable data storage.

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KEYWORDS

weight loss; mobile applications; telemedicine; consumer behavior

Introduction

Mobile apps addressing health and fitness issues have emerged in large numbers over the last couple of years. In 2016, 231,000

mobile health (mHealth) apps were available on the Android and Apple app stores, of which nearly 100,000 had been added since 2015 [1]. The total number of worldwide downloads was estimated at 3.2 billion by the end of 2016 [1]. It is predicted

that by 2020, over 2.5 billion people will have downloaded at least one health and fitness app onto their phone [1]. Many of these mHealth apps claim to provide weight loss support.

Given the wide reach of mHealth apps, researchers have started to explore their quality. In several app reviews, researchers have criticized the limited extent to which mHealth app features are grounded in evidence [2-7]. For instance, Pagoto and colleagues compiled 20 behavior change strategies from effective weight loss treatments and assessed how many of them were implemented by weight loss apps. They found that fewer than 20% of the strategies were used on average [8]. It is argued that the paucity of established behavioral techniques incorporated in the apps may limit their effectiveness in supporting users to change their behavior [9].

However, even the most evidence-based app is unlikely to be successful if it does not attract and retain users, as repeated and long-term interaction with an intervention is often critical for its effectiveness [10-12]. This is especially the case for self-monitoring interventions, where frequent self-monitoring is associated with greater weight loss [13-15]. Moreover, research shows that the popularity of an app is not necessarily associated with the extent of its evidence base [6]. Bardus and colleagues found that the popular mHealth apps on the app market were the ones that had good functionality and an appealing appearance, even though they were only of moderate quality content-wise [16]. Hence, for a health app to be engaging and effective, attention has to be paid to its presentation and design, not just its content. User retention is particularly challenging as the app store is a constantly changing market [17], meaning that users can easily switch apps. In fact, three-quarters of all downloaded health apps are used less than eleven times [18].

This paper explores which aspects of mHealth apps affect user satisfaction to provide guidance on how to keep users engaged. User reviews on app stores offer an opportunity to gain such insights from a large pool of people. Reviews often contain complaints, suggestions of change, and innovative ideas [19,20] and can therefore help identify the key aspects that affect user satisfaction. To the best of our knowledge, no academic analysis of user reviews on weight loss apps has yet been conducted. We aim to assess satisfaction with common features, explore user suggestions, and generate guidance for further weight loss app development. We focus on weight-tracking apps specifically, as the effectiveness of their main functionality, that is, self-monitoring, is dependent on the appeal and engagingness of the intervention [13-15]. Analyzing user reviews to improve likability and usability can therefore especially help improve the effectiveness of the respective apps. Moreover, self-monitoring is particularly likely to benefit from the technological advantages of smartphones, as they allow for instantaneous feedback, are easy and quick to use, are mobile and hence accessible most of the day, and their usage in social contexts is more acceptable than the usage of their nondigital alternatives [21-23]. Self-monitoring apps therefore provide an interesting example to study and advance developers' capabilities in making use of the unique technological

possibilities that mHealth apps provide to create appealing interventions.

Methods

Study Design

In a first step, weight loss apps were sampled from the Google Play Store. The components of these apps were coded to attain an overview of the most common weight loss app features. In a second step, the sample was screened for weight-tracking apps, which underwent a second and more detailed component coding. Finally, reviews were sampled from the weight-tracking apps and qualitatively analyzed according to users' liking and disliking of components.

Sampling Strategy—Weight Loss Apps

In March 2017, an electronic search on the Google Play Store was conducted using two search terms: *weight loss* and *weight track**. The search was performed using an incognito browser in Google Chrome that was not connected to a Google account. Each search resulted in the display of 249 mobile apps. Due to the conceptual closeness of the search terms, the results partly overlapped.

For each results list, we sampled apps until no conceptually new apps were found. If saturation was not reached after the first 100 apps in the search results, more apps were considered from the list in batches of ten. This method resulted in the screening of 120 apps for the term *weight loss* and 110 apps for the term *weight track**.

Where the same app was available in both a free and a paid version, we treated them as two separate apps. Properties of the mobile apps, such as app and developer name, app category, rating, number of reviews, number of downloads, version of the app, cost of the app, availability of in-app purchases, as well as the search term used and the position in each search results list were noted. The sampling process was conducted over 2 days, 1 day per search term.

First Screening and Component Coding—Weight Loss Apps

Each mobile app was screened for the following three criteria: (1) whether it was targeted at people who want to lose or monitor their weight; (2) whether it had stand-alone functionality, meaning that it is usable without a membership subscription or ownership of specific devices; and (3) whether it was available in the English language. This screening resulted in the exclusion of 25 apps. Two more mobile apps were initially recorded but could no longer be found on the Google Play Store at the time of the screening process.

Details concerning the remaining 179 apps can be found in [Multimedia Appendix 1](#). The mobile apps were manually coded by components using information available from the app description pages on the Google Play Store. We used an adapted version of the Oxford Food and Activity Behaviors (OxFAB) taxonomy ([Table 1](#)) that consists of 23 domains and can be used to classify self-help interventions for weight loss [24,25].

Table 1. Summary and definitions of components in the Oxford Food and Activity Behaviors (OxFAB) adaptation. The first column lists the adapted OxFAB components, the second column contains a definition for each adapted component and the third column contains the original OxFAB domains.

Adapted version	Definition	OxFAB domains ^a
Goal setting	Setting of a specific target, either behavioral or outcome-related; for example, weight loss goal	Goal setting
Feedback on goal progress	Feedback on the progress towards this target, quantifiable; for example, amount of weight left to lose to reach target	Non-existent
Impulse management	Components specifically designed to help users cope with impulses to eat or binge; for example, distraction	Impulse management: Acceptance Impulse management: Awareness of motives Impulse management: Distraction
Motivation	Components increasing motivation of users; for example, motivational quotes	Motivation
Planning content and scheduling of diet and activity	Components that provide support in planning and scheduling weight loss-related activities; for example, diet plans, physical activity challenges	Planning content Scheduling of diet and activity
Behavioral strategies		
Physical activity	Advice on behavioral strategies related to physical activity that can help with weight loss; for example, raising knees higher during walking	Regulation: Allowances Regulation: Restrictions Regulation: Rule setting
Dieting	Advice on behavioral strategies related to diet that can help with weight loss; for example, restricting portion sizes	Restraint Stimulus control Energy compensation
Information		
Physical activity	Information on the benefit of a specific physical activity; for example, which muscle groups are trained with an exercise	Non-existent
Dieting	Information on the nutritional value of foods; for example, amount of calories in a banana	Non-existent
Prescriptive help		
Physical activity workout	Instructions for physical activity; for example, a workout	Non-existent
Menus	Instructions related to food; for example, recipes, shopping lists	Non-existent
Calorie calculator	Component that calculates the daily energy expenditure or maximum amount of daily calories allowed	Non-existent
Reframing	App reframes weight loss as, for example, a change in lifestyle	Reframing
Reward	Reward for reaching a specific outcome, usually a gamification element; for example, winning badges, unlocking new components	Reward
Self-monitoring		
Weight tracking	Component that logs weight measurements over time	Self-monitoring
Body fat tracking	Component that logs body fat measurements over time	Self-monitoring
Body measurements tracking	Component that logs body measurements over time	Self-monitoring
Physical activity tracking	Component that logs physical activity over time	Self-monitoring
Diet tracking	Component that logs diet over time	Self-monitoring
Body fat calculator	Component that calculates body fat percentage	Self-monitoring
BMI calculator	Component that calculates BMI	Self-monitoring
Reminder setting	Component that allows to set a reminder; for example, reminds to enter weight measurement	Non-existent

Adapted version	Definition	OxFAB domains ^a
Support		
Buddying	Social community component which allows users to link up with each other to pursue goals together; for example, compete with each other in a weight loss challenge	Support: Buddying
Motivational	Social media linkage which allows users to share their progress with their friends and family	Support: Motivational
Professional	Offers provision of direct support from a health professional; for example, possibility to chat to a dietician	Support: Professional
Weight management aids	Components that offer other weight management aids; for example, hypnosis, advice on weight loss body wraps	Weight management aids
Self-experimentation	App encourages users to try out different weight loss strategies; for example, experiment with different diets	Self-experimentation

^aOxFAB domains “Imitation (modeling)” and “Information seeking” were deleted from the adapted version.

In many cases, the mobile apps offered in-app purchases that enabled access to premium features. For this component coding, all premium features that were mentioned on the app description pages were considered.

The component coding was performed by two coders for 10.1% (18/179) of the mobile apps. Prevalence-adjusted and bias-adjusted kappa (PABAK) scores assessing the agreement between the coders showed fair to good results (mean PABAK=0.91). Disagreements between the coders were mostly based on differences in the conceptual understanding of the domain definitions. The definitions were subsequently clarified, which resulted in a slightly higher PABAK score (0.94). One coder performed the rest of the component coding.

Second Screening and Component Coding—Weight-Tracking Apps

For the review analysis, the weight loss app sample was screened for weight-tracking apps. To be eligible, these apps (1) had to be primarily focused on weight-tracking (ie, have no other main function such as a detailed diet tracker or exercise instructor but could have additional minor features such as a body mass index [BMI] calculator and counter of glasses of water consumed), (2) had to have a user rating above 3 stars, and (3) had to have at least 1000 reviews. Of the 179 mobile apps that were coded by component, 15 met these criteria. We conducted another, more fine-grained coding of the components for the weight-tracking apps. Each app was downloaded from the Google Play Store to an HTC A9 smartphone (Android 7.0) and manually rated according to the existence of several features ([Multimedia Appendix 2](#)). No paid versions of the apps were purchased. Premium features were coded according to their mentioning in the app description pages on the Google Play Store or in the app itself.

Review Sampling—Weight-Tracking Apps

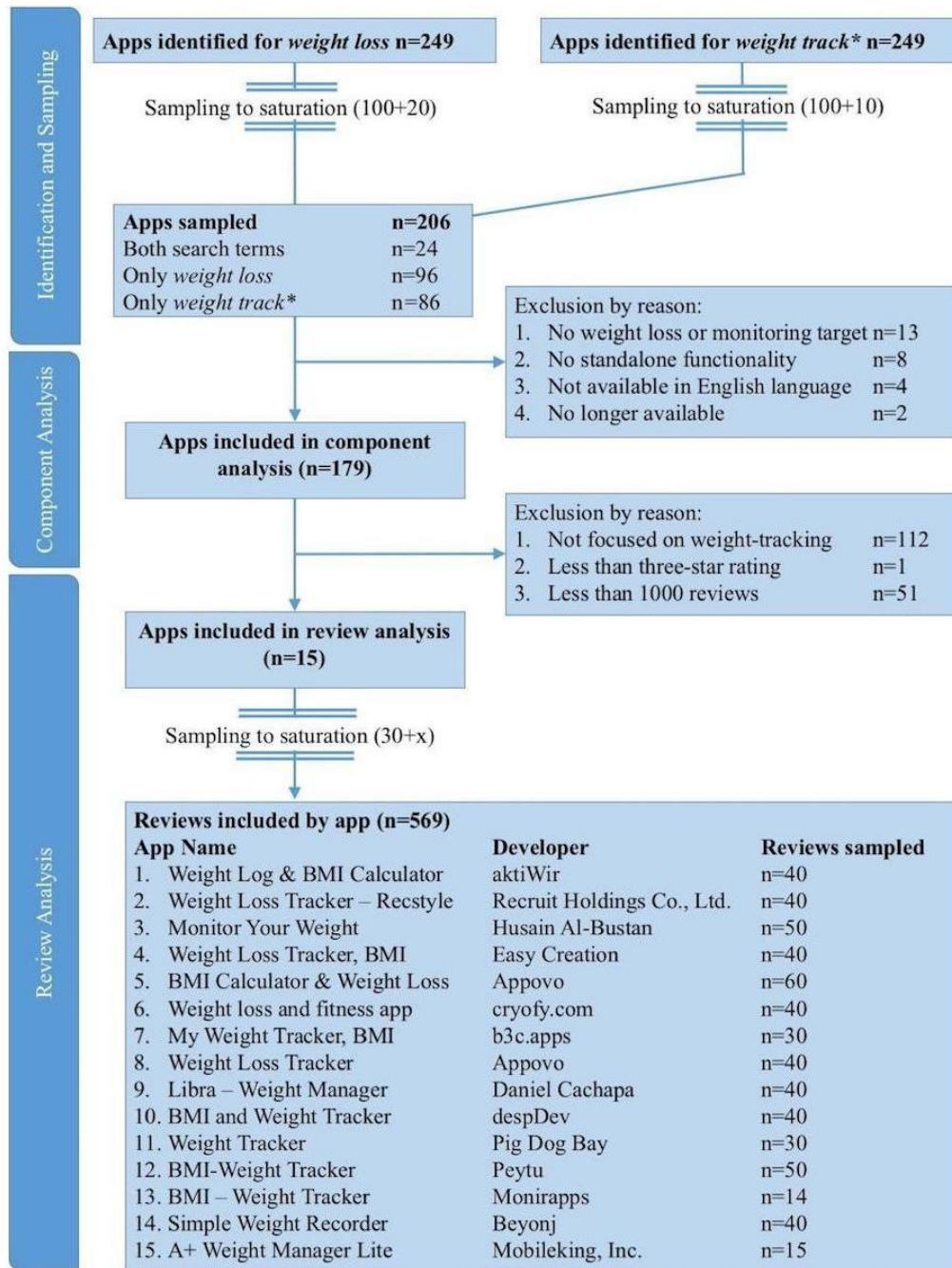
In a next step, user reviews were sampled from the 15 mobile apps. Only reviews written in the English language were considered. A sampling to saturation strategy was employed, whereby we extracted the first 30 reviews displayed for each app when the reviews were sorted by helpfulness. If saturation was not reached after 30 reviews (ie, new aspects were still raised by the users in the last ten reviews), we continued extracting text from further reviews in batches of ten until no new information was gathered. For two of the 15 apps, less than 30 reviews included text, and thus, all available reviews with text were included in the analysis. [Figure 1](#) displays the screening and sampling process for both the component coding and the review analysis.

Data Analysis

Data was analyzed using a mixed-methods approach. Using data from the first component coding, Pearson correlations assessed the relationship between complexity of the app and popularity indicators (rating, number of reviews, and number of downloads). These calculations were performed using the Statistical Package for the Social Sciences (SPSS) version 24 (IBM Corp).

The reviews of weight-tracking apps were imported to and analyzed in NVivo (QSR International) using a framework and thematic analysis. With the framework analysis, our aim was to evaluate the popularity of the components present in weight-tracking apps. To this end, we set up a node structure, including main components from the second component coding. In the thematic analysis, further nodes, which were not covered by the framework analysis, were added according to emerging themes. Coding was performed by two independent coders for the first three apps, reaching high interrater reliability ($\kappa=.83$). The node structure was then collapsed, and the rest of the mobile apps were coded and analyzed by one researcher.

Figure 1. Screening and sampling procedure for this review.



Results

Component Analysis Weight Loss Apps

Descriptive Analysis

In the first component analysis, we applied the adapted version of the OxFAB domains to 179 weight loss and weight management apps from Google Play Store. The apps covered on average 5.15 domains (standard deviation [SD] 3.33). More than half of the mobile apps had weight-tracking and goal setting functionalities. Other frequent domains were the BMI calculator and feedback concerning the progress toward a set goal (Table 2). Considering only the five tracking domains (ie, weight, body

fat, body measurements, diet, and exercise), we found that the apps covered 1.21 domains on average (SD 1.29). Approximately one-third (n=62) of the apps focused on one tracking function only, another third incorporated two or more tracking components (n=52), and the last third did not have a tracking function at all (n=65).

Correlational Analysis

Using Pearson correlations, we found that the count of components was strongly positively correlated with rating ($r=.25$; $P=.001$), number of reviews ($r=.28$; $P<.001$), and number of downloads ($r=.48$; $P<.001$). Hence, the mobile apps that incorporated more components (ie, that were more complex) were more popular in our sample (see Table 3).

Table 2. Frequency with which the adapted Oxford Food and Activity Behaviors (OxFAB) components were coded in weight loss apps.

Component	Frequency (%)
1. Self-monitoring: weight-tracking	106 (59.2)
2. Goal setting	99 (55.3)
3. Self-monitoring: body mass index calculator	86 (48.0)
4. Feedback on goal progress	77 (43.0)
5. Planning content and scheduling of diet and activity	48 (26.8)
6. Prescriptive help: menus	48 (26.8)
7. Information: diet	44 (24.6)
8. Prescriptive help: physical activity	43 (24.0)
9. Calorie calculator	43 (24.0)
10. Reminder setting	37 (20.7)
11. Self-monitoring: physical activity tracking	35 (19.6)
12. Motivation	31 (17.3)
13. Self-monitoring: body measurements tracking	27 (15.1)
14. Behavioral strategies: diet	27 (15.1)
15. Self-monitoring: diet tracking	26 (14.5)
16. Self-monitoring: body fat calculator	26 (14.5)
17. Support: motivational	25 (14.0)
18. Self-monitoring: body fat tracking	23 (12.8)
19. Behavioral strategies: physical activity	19 (10.6)
20. Information: physical activity	16 (8.9)
21. Reward	14 (7.8)
22. Weight management aids	7 (3.9)
23. Support: buddying	6 (3.4)
24. Support: professional	3 (1.7)
25. Impulse management	3 (1.7)
26. Reframing	2 (1.1)
27. Self-experimentation	1 (0.6)

Table 3. Pearson correlations assessing the association of the complexity of weight loss apps with the three popularity indicators: rating, number of reviews, and number of downloads.

Popularity indicators and complexity	Rating	Reviews	Downloads	Count components
Rating				
Coefficient	1			
<i>P</i>				
N	170			
Reviews				
Coefficient	.14	1		
<i>P</i>	.08			
N	169	178		
Downloads				
Coefficient	.19	.33	1	
<i>P</i>	.01	<.001		
N	170	178	179	
Count components				
Coefficient	.25	.28	.48	1
<i>P</i>	.001	<.001	<.001	
N	170	178	179	179

Review Analysis Weight-Tracking Apps

Descriptive Analysis

After conducting the second screening, 15 mobile apps remained in the sample (Table 4). The apps' ratings ranged from 3.6 to 4.6 (mean=4.21) on a scale from 1 (low) to 5 (high satisfaction). The number of reviews lay between 1196 and 121,871 (mean=22084.27), and the number of downloads ranged accordingly from 100,000-500,000 to 10,000,000-50,000,000. From these 15 mobile apps, 569 reviews were sampled for qualitative analysis.

Framework Analysis

In the framework analysis, we assessed the frequency and valence of comments addressing specific components of an app. The first most positively commented on group of components was related to weight-tracking and (graphical) feedback (components 1-6 in Table 5). The second most positively commented on group of components was related to reliable data storage (components 7-10 in Table 5).

Detailed (Graphical) Feedback

Users frequently highlighted the importance of receiving graphical and nongraphical feedback on their weight loss journey. They appreciated seeing graphs of their weight over time, especially when additional visual cues such as a trend line were given. Comments included:

I like how it graphs out your weight loss to show your progress. It's very motivating to see how far you have come from where you started.

The trend line is a neat feature to forecast when I'll reach my goal weight.

Some mobile apps had a component that predicted the date by which the user would reach his or her goal. This function was remarked positively by several users:

I like the way it predicts the date for you to reach your goal and the timeline showing your percentage of progress. The graphs are great too! Very motivating.

Generally, users stated that the feedback provided them with motivation to keep going. Where weight loss success was lacking, users appreciated neutral feedback:

I love the cheering when you lose a bit of weight. That's very sweet and makes you feel good. even when you are going through a bad spell it seems non-judgy.

Reliable Storage of Data

Users emphasized the importance of reliable storage of their data that was often collected over a long period of time. When the data was lost through a malfunctioning update or a glitch, it caused frustration in the user:

New update deleted all my data. Horrible. What's the point of making an account if your data doesn't get stored? I'm so mad!

Back up doesn't work! I'd been backing up my data weekly to my SD card. Just got my new phone yesterday, went to import database and it says "database empty"—3 years of data lost! Fantastic!

Table 4. Basic information about the 15 weight-tracking apps.

App name	Developer	Rating	Reviews	Version	Downloads
Weight Loss Tracker, BMI	Easy Creation	4.6	1457	1.2.11	50,000-100,000
Weight Log & BMI Calculator	aktiWir	4.5	31,455	1.44	1,000,000-5,000,000
Weight Loss Tracker-RecStyle	Recruit Holdings Co., Ltd.	4.4	17,067	3.1.8	1,000,000-5,000,000
Monitor Your Weight	Husain Al-Bustan	4.4	91,617	4.9.2	5,000,000-10,000,000
Libra-Weight Manager	Daniel Cachapa	4.4	19,623	3.3.3	1,000,000-5,000,000
BMI and Weight Tracker	despDev	4.4	16,559	3.4.4	1,000,000-5,000,000
BMI-Weight Tracker	Peytu	4.4	3007	1.97	100,000-500,000
My Weight Tracker, BMI	b3c.apps	4.2	5276	3.4	500,000-1,000,000
Weight Tracker	Pig Dog Bay	4.2	1196	1.18.05	100,000-500,000
Simple Weight Recorder	Beyonj	4.2	3551	-	1000000-5000000
Weight Loss Tracker	Appovo	4.1	1537	1.0.9.8	100,000-500,000
BMI Calculator & Weight Loss	Appovo	4.0	121,871	4.2.4	10,000,000-50,000,000
BMI-Weight Tracker	Monirapps	4.0	1560	3.3	100,000-500,000
Weight loss and fitness app	cryofy.com	3.8	13,464	1.3.6	1,000,000-5,000,000
A+ Weight Manager Lite	Mobileking, Inc.	3.6	2024	1.6	500,000-1,000,000

Table 5. The top 10 most positively commented on components. Improvement comments refer to comments where users suggested or demanded the improvement of a specific aspect of the app.

Component	Frequency of positive comments	Frequency of improvement comments
1. Weight-tracking	70	4
2. Graph feedback	51	22
3. Target line graph	48	0
4. Feedback goal	35	1
5. Prediction target date	34	0
6. Trend line graph	27	2
7. Google Drive	25	3
8. Sync Google Fit	22	12
9. Backup cloud server	19	1
10. Import data	18	9

Table 6. The most prominent themes identified through thematic coding.

Themes and nodes	N ^a
Simplicity or ease of use	
Easy to use	133
Simple	73
Right amount of complexity	14
Smooth functioning	
Technical issues	66
Smooth working	26
Long-term app usage	
Long-term use	54

^aN: the frequency of comments addressing the respective node.

Following the loss of data, many users stated that they would discontinue their usage of the app and switch to a different one:

Lost all of my tracking history upon update. Even update on 11/16/16 did not correct the issue. All tracking ID just gone. Time to uninstall.

I was using this track [sic] my weight loss over a year. Updated and lost everything. Going to try a different app now.

Users appreciated mobile apps that allowed them to protect their weight data with a password:

...love that can back up data and put password on it. A pin code for privacy on the app would be great.

Thematic Coding

In addition to the comments that directly addressed specific components of the app, we also conducted inductive thematic coding of user comments. The three most frequently identified themes were simplicity and ease of use, smooth functioning, and long-term app usage (Table 6).

Simplicity and Ease of Use

Users of weight-tracking apps expressed a preference for simple apps, equipped with only a few key features. These key features were mostly weight logging and graphing. Elaborate additional components were perceived to add unnecessary complexity to the app:

Just what I needed and nothing more to clutter the screen. I was looking for an app to log my weight and graph it. This got it right.

I love this app because it is simple and just does exactly what I want instead of a bunch of extra stuff that I'm not going to use and is just going to be in the way.

Reviewers commonly expressed a preference for app designs that were intuitive and easy to use, allowing for efficient app usage:

I can log data in seconds without navigating through needless steps.

Smooth Functioning and Technical Issues

The smooth running of the app emerged as a main criterion for user satisfaction and was critical to user retention:

Been using for a few years, it runs smooth and does what it says it will, which is tough to find sometimes.

Most reports of technical issues reflected problems with an update of the app, suggesting developers were not always able to meet the needs and demands of their users when releasing a new version:

As seems to be the norm these days, every time a good app is "updated" it gets ruined. Updated on 11/11 and visibility is terrible and takes ages to display main screen.

Nov update has ruined this app. Won't use anymore. ...lost all my data after upgrade, behaves really odd, locks up! used to love it...

Long-Term Usage

In 54 of the 569 reviews, people commented on their intention to use a weight-tracking app on a long-term basis:

Been using it for years and always been reliable.

Has been my Go-To weight tracking app for several years now, can't fault it :)

Once users found the app that best fits their needs, they were willing to remain loyal to the app and even downloaded it onto new devices:

Every time I change my phone, this app is a must to be downloaded.

Additional Themes

There were several other less prominent themes. Users appreciated it when developers acted mindfully with memory space. Either keeping the size of the app to a minimum or storing the app onto the secure digital card automatically received positive attention by the users:

Does exactly what you need without it being a bloated app that gobbles up much needed memory.

As someone who gets annoyed with my tiny phone memory filling up, the fact that this not only can be stored on a SD card but actually automatically saves to it is brilliant.

Similarly, users appreciated the mindful deployment of advertisements. Inappropriate advertising (such as for a fast food chain) or impairment of app functionality through advertisements were criticized:

What's up with the Duncan donut add every time I open.

Too many ads. Covers the page so you can't enter stats.

Inaccuracy of in-app calculators (such as BMI and body fat) was perceived as frustrating. Users criticized the inaccuracy harshly and expressed disbelief:

I'm severely [sic] underweight and on and off I've been hospitalized for it so when I calculated my weight and height I was very shocked to see that apparently I'm overweight and my 139 pound friend is obese class I.

Providing options to customize the appearance of the app and its functionality was well perceived. Users liked personalizing aspects such as background color, font style, or the amount of measurements to be tracked:

I wish you could customize the widget colors, font size, etc.

...love it if I could personalise the colours in the app.

Finally, we found that when users were satisfied with an app, they stated their willingness to spend money on premium features or blocking of advertisements:

Happily paid the few \$ for the pro version after trying the free one for a couple months.

...but I haaaaate the update that has now put ads in the app. I totally understand the developer needing to make money, but I'd rather pay for a premium version to get rid of the ads.

Discussion

Principal Findings

Our results provide insights into the preferences of app users. In correlational analyses, including all weight loss apps, we found that more complex apps had higher ratings, more reviews, and more downloads, suggesting higher popularity. In our review analysis of weight-tracking apps, we found that components related to feedback on the weight loss journey were of high importance. Receiving positive feedback and visualizing weight loss success provided the user with positive reinforcement and thus increased motivation. Furthermore, users emphasized the importance of reliable data storage as they intended to use the app on a long-term basis. Users appreciated mobile apps that were specialized, with few additional components unrelated to weight-tracking and that were intuitive and easy to use. Users emphasized that the smooth functioning of the app is of immense importance. When technical issues arose, users appeared likely to discontinue using the app.

What Weight Loss Apps Offer

In our component analysis of general weight loss apps, we found that more than half had components related to weight-tracking and goal setting. Another 43.0% (77/179) of the apps provided users with feedback on their goal progress. This finding resembles previous content analyses of weight loss apps. For instance, Bardus and colleagues assessed behavior change techniques (BCTs) of weight management apps in 2015 and found that the most prominent ones were based on self-monitoring, goal setting, and feedback [16]. Similarly, Pagoto's review found that goal setting and self-monitoring were the most prominent behavioral strategies in their sample of weight loss apps in 2012 [8]. This suggests that the content of weight loss apps is quite stable, as the same components remain prominent over time. Importantly, these three component types are well-studied BCTs that are known for their effectiveness in fostering a healthier lifestyle [26].

Fewer than 20% of the 179 weight loss apps in our sample offered social support features. Social support can contribute to weight loss success, as has been shown in randomized studies comparing individual- with group-based approaches [27,28]. It is therefore surprising that only few apps made use of the technological opportunities to connect users with other weight loss seekers around the world. The lack of social support components has already been criticized by Breton and colleagues in 2011 after they had conducted an app market review of weight control apps [2]. However, the implementation of social support features in mobile apps is costly to build and maintain. It is therefore conceivable that only the most economically valuable (ie, popular) mobile apps such as *Lose It!* or *MyFitnessPal*, are able to offer these features.

What Users Find Important

In line with our results of the content analysis of weight loss app components, the most positively commented on components in the review analysis were also related to self-monitoring and feedback on goal progress. Our finding that users perceived feedback on and visualization of their weight loss progress as useful and motivating is consistent with the findings of other studies [29,30]. Burke and colleagues showed that self-monitoring with feedback helps participants achieve more weight loss than self-monitoring alone [23]. They suggest that feedback provides guidance and accountability to the user, regardless of the valence of this feedback. Although users in our sample did not state they felt accountable to their device, they did state that the feedback kept them on track with their weight loss goal. Users liked to receive as many details about their progress as possible to gain the most reward out of a satisfactory outcome. In a qualitative study by Dennison and colleagues, participants expressed their concern that they might find corrective feedback and lack of success particularly daunting and deterring in weight loss apps [30]. The results of this review do not support these concerns; lack of success was mostly responded to with neutral feedback, and users did not feel negatively judged for their lack of progress.

Beyond the weight management components, users expected high levels of technical reliability and secure data storage. This is critical because users often intend to use a weight-tracking app on a long-term basis, meaning that these apps often cover years of data. This data is often of emotional value, as it provides motivation to the user and visualizes previous successes and hard work. Losing data that has been collected for several years is perceived as immensely frustrating and can lead to a loss of trust in the app.

In addition, reliable data storage is also important from a user retention perspective: there are many weight-tracking apps available on the app store market, so initially users can easily switch from one to another, and they often try out several at a time [30]. Switching barriers are only created once a user starts collecting data in one app over a considerable amount of time, as this data is usually not transferable between mobile apps. A loss of data eradicates this additional value of the app, making it easier for users to switch to another app.

Reviewers highlighted the importance of an intuitive and simple app design, which is consistent with findings in the literature [29]. A qualitative study by Dennison and colleagues showed that users do not have a lot of patience in dealing with mobile apps and quickly discard them when usage is perceived as complicated [30]. Hence, a simple and straight-forward design is critical.

With regards to simplicity, we found conflicting results for the weight loss compared with the weight-tracking apps. Whereas the correlational analysis showed that complex weight loss apps are more popular than simple ones, the review analysis of weight-tracking apps indicated that users prefer simple and basic apps. One possible explanation for the finding that more complex weight loss apps had higher popularity ratings could be that these complex apps met the needs of more users. People seeking to download a weight loss app for the first time might

settle for a more general and comprehensive app than a specific one in order to be able to test several strategies for weight loss. Once they have found the right features for them, they might download an app that is more specific to their needs. This could explain our finding that for weight-tracking apps, less complexity and fewer components were preferred by the users. Further research is needed to examine this.

A substantial amount of reviews contained complaints about the malfunctioning aspects of a given app. Most of these complaints were related to dissatisfaction with an update of the app. The topics of the reviews ranged from the emergence of technical issues and the lack of a previously existing feature to disliking of a new user interface design. This suggests that updated versions were premature and not sufficiently tested on users before they were made available to the public. Similarly, in a study analyzing complaints in user reviews from the top 20 apps on the iOS app store, Khalid and colleagues also found that a substantial number of comments originated from issues with an update [31]. They concluded that developers should engage in more rigorous testing and work more closely with users before introducing new versions of an app. They warned that user frustration with an update can lead to bad ratings of an otherwise good app. On the other hand, we found that updates can also lead to positive outcomes. In our review, there were several cases in which reviewers commented on positive changes to issues they complained about or edited their negative ratings to more positive ones when problems were resolved. Similarly, a recent analysis showed that nearly 50% of user suggestions are implemented in app updates and that this consideration of user opinions is rewarded with higher app ratings [32]. Hence, involving users in the development of an app is highly recommended.

Another approach to enhancing user satisfaction can be to allow for personalization of the app. In our review, users appreciated the opportunity to adapt the app to their needs and likes, for instance, by allowing for the choice of a theme or design. Similarly, Dennison and colleagues found in their study that users liked to be able to make personalized settings such as deciding when to receive reminders to weigh [30]. Generally, allowing for personalization enables the developer to cater more needs and preferences and therefore attract more users.

Strengths and Limitations

A major strength of this app market review is that we analyzed the voices of a large and diverse sample of people. The content of app reviews is influenced by the needs and expectations of the user, as well as the context of usage and can therefore vary considerably. Asking only a small group of people, such as Dennison and colleagues' focus group, can restrict the variety and representativeness of the data. With our large sample, we were able to see patterns and analyze which concerns are shared by most users and which ones are more specific. This allows us to make more reliable conclusions about what users like and dislike in mHealth apps. Importantly, to the best of our knowledge, we are the first to use this method of qualitatively analyzing user reviews of weight loss apps. We found this process to be very fruitful for gaining insights into user experience and opinion.

One limitation of our review is that not all of the recommendations we conclude from our results will be generalizable to other kinds of apps. That is, it is conceivable that the most important aspects that users are concerned about differ between app categories. For instance, the importance of feedback on a goal is most probably specific to self-monitoring apps and will not be of imminent importance for, for example, gaming apps. However, concerns about reliable data storage, ease of use, and app updates most probably pertain to other app categories.

It is also possible that people who write user reviews on the app store are not necessarily representative of the broader population of app users. Nevertheless, our approach to reviewing user experience allowed us to capture feedback from a large number of users and hence, provided us with a more diverse sample than would have been achieved through commonly used methods such as qualitative interviews or focus groups.

Another limitation of this review is that we only considered mobile apps from the Google Play Store. This decision was due to a lack of similar indexing methods and technological issues with the download of user reviews from the iOS store. However, a recent analysis of the mHealth marketplace has concluded that 75% of today's health and fitness app developers produce mobile apps for both the Android and iOS market [1]. The two markets therefore overlap substantially, and it is questionable whether we would have found any meaningful differences between the two stores. By searching the app store directly rather than through a search engine, our results are limited by the fact that the Google Play Store only displays 249 mobile apps per search term. Our approach was guided by the intention to analyze those mobile apps that users of the Google Play Store can find. However, several more apps would have been found when using a search engine.

Finally, our results are limited in that this review focused on popularity but not on the effectiveness of discussed mobile apps. However, reviews assessing the evidence-base and potential effectiveness of mHealth apps can be found elsewhere in the literature, where the occurrence of BCTs has been used to evaluate their quality [5]. Moreover, when comparing our results with the literature, we find that effectiveness and popularity partly overlap, as well-accepted and effective BCTs such as self-monitoring and feedback [13,33] are particularly liked by users.

Conclusions

This review extends the literature by highlighting which facets of weight loss apps are especially important to users and should be considered when developing an app. In particular, findings from this review suggest several aspects of app design that developers of self-monitoring apps should consider. First, developers should focus on providing appropriate feedback on goal progress, as users appeared to respond favorably to detailed feedback on weight loss success and appreciated it when mobile apps remained neutral when success was lacking. Second, we recommend that developers make sure that data is stored reliably to enable people to use the app on a long-term basis. Third, developers should keep in mind who the chosen target audience is. A simple and basic app version may be sufficient when

speaking to a specifically targeted audience. However, more comprehensive weight loss apps may attract more people, as they speak to anyone who is generally looking into weight loss support. Fourth, we recommend that developers incorporate users' opinion in all design and development stages to ensure that the app fulfils users' expectations. Furthermore, it is important to perform rigorous testing on an app before making

it available to the public, as smooth functioning is critical to user satisfaction and long-term usage. Overall, we believe that our novel methodology and large sample size strengthen our conclusions. We recommend that future app market reviews assess user experience in addition to the evaluation of app components.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Details of all 179 weight loss apps.

[[XLSX File \(Microsoft Excel File\), 18KB - mhealth_v5i12e203_app1.xlsx](#)]

Multimedia Appendix 2

Features of the second component coding.

[[XLSX File \(Microsoft Excel File\), 31KB - mhealth_v5i12e203_app2.xlsx](#)]

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Abbreviations

BCT: behavior change technique
BMI: body mass index
mHealth: mobile health
OxFAB: Oxford Food and Activity Behaviors
PABAK: prevalence-adjusted and bias-adjusted kappa
SD: standard deviation

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Original Paper

Developing mHealth Messages to Promote Postmenstrual Regulation Contraceptive Use in Bangladesh: Participatory Interview Study

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Abstract

Background: Abortions are restricted in Bangladesh, but menstrual regulation is an approved alternative, defined as a procedure of regulating the menstrual cycle when menstruation is absent for a short duration. Use of contraception after menstrual regulation can reduce subsequent unintended pregnancy, but in Bangladesh, the contraceptive method mix is dominated by short-term methods, which have higher discontinuation and failure rates. Mobile phones are a channel via which menstrual regulation clients could be offered contraceptive support after leaving the clinic.

Objective: This study aimed to support the development of a mobile phone intervention to support postmenstrual regulation family planning use in Bangladesh. It explored what family planning information women want to receive after having a menstrual regulation procedure, whether they would like to receive this information via their mobile phone, and if so, what their preferences are for the way in which it is delivered.

Methods: We conducted participatory interviews with 24 menstrual regulation clients in Dhaka and Sylhet divisions in Bangladesh. Women were recruited from facilities in urban and peri-urban areas, which included public sector clinics supported by Ipas, an international nongovernmental organization (NGO), and NGO clinics run by Marie Stopes. Main themes covered in the interviews were factors affecting the use of contraception, what information and support women want after their menstrual regulation procedure, how respondents would prefer to receive information about contraception, and other key issues for mobile health (mHealth) interventions, such as language and privacy. As part of the in-depth interviews, women were shown and played 6 different messages about contraception on the research assistant's phone, which they were given to operate, and were then asked to give feedback.

Results: Women were open to both receiving messages about family planning methods on their mobile phones and talking to a counselor about family planning methods over the phone after their menstrual regulation. Women most commonly wanted information about the contraceptive method they were currently using and wanted this information to be tailored to their particular needs. Women preferred voice messages to text and liked the interactive voice message format. When asked to repeat and identify the main points of the messages, women demonstrated good understanding of the content. Women did not seem too concerned with privacy or with others reading the messages and welcomed including their husbands in speaking to a counselor.

Conclusions: This study found that menstrual regulation clients are very interested in receiving information on their phones to support family planning use and wanted more information about the method of contraception they were using. Participatory voicemail was the preferred modality.

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KEYWORDS

abortion; reproductive health services; contraception; family planning; mHealth; Bangladesh

Introduction

Background

Rapid expansion in mobile phone ownership has led to the development of numerous mobile health (mHealth) interventions targeting a wide range of health issues in both developed and developing countries [1,2]. This relatively new field of public health has the advantage of being able to reach large audiences with targeted, personalized information at low cost, including individuals who may not have easy access to health services. In 2015, there were 82 phone subscriptions for every 100 inhabitants in Bangladesh [3], and by 2012, two-thirds of rural women of reproductive age reported that their household owned at least one functional mobile phone [4]. mHealth has been used successfully in Bangladesh to facilitate identification and treatment of malaria [5], provide timely care for obstetric emergencies [6], improve vaccination rates [7], and enable glycemic control among patients with type 2 diabetes [8].

Abortions are legal only to save a woman's life in Bangladesh, but menstrual regulation is an approved procedure, defined as regulating the menstrual cycle when menstruation is absent for a short duration [9] up to 12 weeks after their last period [10]. Menstrual regulation services use manual vacuum aspiration (MVA) or the combination regimen of mifepristone and misoprostol to establish nonpregnancy, and pregnancy is not confirmed before the procedure or administration of medications. Menstrual regulation procedures are common in Bangladesh and occur at a rate of 37 per 1000 women of reproductive age [11].

Provision of family planning services to menstrual regulation clients offers an important opportunity to increase uptake of effective contraception and reduce the need for repeated menstrual regulation services, as this population often wishes to delay or limit future pregnancies. A global systematic review found that the existing evidence on the effectiveness of postabortion family planning counseling and services in low-income countries to address the problem of unsafe abortion is inconclusive; studies showed increases in contraceptive uptake, but none provided evidence on its effectiveness on maternal morbidity and mortality [12]. In Bangladesh, menstrual regulation guidelines recommend the provision of family planning services, yet in one study fewer than half of facilities offered contraceptive methods to postmenstrual regulation clients, and fewer than half of these ultimately received a method [13]. Where there is postmenstrual regulation counseling, it is generally conducted by either designated counselors or family planning staff; providers typically offer a range of family planning methods: oral contraceptive pills, injectables, and intrauterine contraceptive device (IUCD). Implants are offered

in some locations, and condoms are sometimes suggested to clients who do not wish to take other family planning methods (personal communication with Bangladeshi family planning expert). Quality of care, including the quality of counseling and availability of family planning methods, varies widely [14]. These inequalities in postmenstrual regulation family planning services have been shown to impact contraceptive use: nearly all women who received the highest quality of care were using a modern method of contraceptive 3 months post procedure, whereas rates for those who received the lowest quality care were significantly lower [14]. The type of contraception women use also has implications for how successfully they can prevent unintended pregnancy. Use of short-term methods of contraception is common in Bangladesh [15]; however, short-term methods (condoms, pills and injectable) are less effective at preventing pregnancy than long-acting methods (implant, IUCD and sterilisation) and have higher rates of discontinuation [15].

Regardless of quality of care and counseling, some women may not want to make a decision about family planning on the day of the procedure [16]. mHealth offers an opportunity to reach women with information about family planning after they have left the clinic; however, evidence for the effectiveness of mobile phones in increasing contraceptive use is limited and mixed [17]. A recent Cochrane review found just 5 high-quality studies, and only 1 of these focused on postabortion populations; a randomized controlled trial (RCT) of mobile phone voice messages to support postabortion contraception in Cambodia found an increase in long-acting contraceptive use at 12 months among the intervention group [17,18].

Studies investigating the feasibility of mHealth interventions in Bangladesh found a number of barriers, including inadequate understanding of how mobile phones work [19] and the fact that most mobile phones lack the capacity to show and type in Bengali script [20,21]. An evaluation of an mHealth intervention to support contraceptive knowledge in Kenya found similar concerns; lack of English literacy is seen as a possible reason for the skewed demographic profile of intervention users [22].

Recent work in Bangladesh on the adoption of mHealth based on the extended technology acceptance model [23] found that perceived ease of use, perceived usefulness of the intervention, and subjective norms all had significant positive impact on the intention to adopt mHealth services, although personal innovativeness (the desire to be among those first to adopt a new technology) in information technology was not significant. Formative research and tailoring of interventions to specific settings and groups are important to ensure adoption but are often omitted; a systematic review of 44 papers on mHealth behavior change communication interventions found that less

than half of the reviewed interventions described targeting or tailoring the content [2].

Objective

This study aimed to inform the development of a mobile phone intervention to support postmenstrual regulation family planning use and decision making by exploring what family planning information women in Bangladesh want to receive after having an menstrual regulation procedure, whether they would like to receive this information via their mobile phone, and if so, what their preferences are for the way in which it is delivered. This formative research has been used to design an intervention, which is being evaluated by an RCT, and results are forthcoming.

Methods

In-Depth Interviews

Between March and June 2015, we conducted 24 participatory in-depth interviews with menstrual regulation clients from 7 facilities located in Dhaka and Sylhet divisions in Bangladesh. Facilities were selected from urban and peri-urban areas with varying socioeconomic surroundings, with the aim of accessing the views of women living in those particular areas. The facilities included public sector clinics supported by Ipas, an international nongovernmental organization (NGO), and NGO clinics run by Marie Stopes. We planned to conduct 32 interviews across 8 facilities, but one relatively rural facility was dropped because it was inaccessible during the data collection period because of political violence. To maintain our timeline, 24 women sampled from 7 facilities were interviewed.

A convenience sample of women was recruited from the selected facilities. Women were eligible to participate if they were aged between 18 and 49 years, had received menstrual regulation services using MVA or medication from the facility, had not received general anesthesia for their procedure, and had a personal mobile telephone with short message service (SMS) capability. The menstrual regulation provider introduced clients to the research assistant after the completion of their menstrual regulation procedure and postprocedure counseling. The research assistant told the client about the study, determined whether she was eligible to complete the interview, administered informed consent, and conducted the interview. Research assistants were nonclinic staff, which gave women the opportunity to speak more freely about their experiences at the clinic. A total of 4 female research assistants received 3 days of training, which included familiarization with the study topics, objectives, and interview guide and role-play practice sessions with feedback. The importance of informed consent was stressed.

The research assistants gave women the option to complete the interview the same day or within 2 days of their procedure; women could complete the interview at the clinic or could agree to a different location with the research assistant. All women gave written informed consent before the interview was conducted.

Development and Content of the In-Depth Interviews

We developed the in-depth interview guide in English, and then translated it into Bengali. We pilot-tested the interview guide through peer testing and further adapted it during the interviewer training. The main themes covered in the interviews were factors affecting the use of contraception, what information/support women want after their menstrual regulation procedure, how respondents prefer to receive information about contraception, and other key issues for mHealth interventions, such as language and privacy.

As part of the in-depth interviews, women were shown and played 6 different messages about contraception on the research assistant's phone, which they were given to operate (see [Multimedia Appendix 1](#) for interactive voice message format), and were then asked to give feedback on these. The interactive voice message did not connect to a call center, but included this as an option to illustrate to participants how the system could work. The messages shared in the interviews were adapted from a series of messages developed and validated by FHI 360, a nonprofit organization based in the United States that aims aimed to support contraceptive use using mobile phones [22,24].

After hearing and seeing the messages, respondents discussed what type of modality they preferred (SMS or voice messages, interactive or one-way messages), what they thought of different styles and genres (eg, reminders, factual information, or personal stories), and what kind of information they would want to receive.

Of the 6 messages that were shared in the interview, 2 were brief reminder messages, one about oral contraceptive pills and the other about injections; 2 were factual messages about the effectiveness and side effects of the IUCD, respectively; and 2 messages were stories about women's experience of using contraceptives, one about using pills and the other on the IUCD (see [Textbox 1](#)). To test different modalities, the IUCD message was sent as a text SMS, a voice message, and as part of an interactive voice message with additional options to select at the end of the message. The SMS message was written in phonetic Bengali in English letters, as most phones do not have the capability to type or show Bengali script. For the one-way voice message, an automated message played after the phone was picked up. The interactive voice message worked in the same way but, at the end of the message, the caller could choose from a number of options by pressing a number on the keypad.

We tape-recorded interviews and then transcribed and translated them into English. We used qualitative thematic analysis; we created codes based on themes both from the interview guide and from concepts that emerged from the data. We created the codebook and final themes in an iterative process. We presented initial results at a workshop in Dhaka, and we included comments from the authors and workshop participants in additional analysis and synthesis. All coding was done using nVivo 10 (QSR International Pty Ltd, London, UK).

We received ethical approval from the Bangladesh Medical Research Council, the Population Council Institutional Review Board, and the Marie Stopes International Independent Ethical Review Committee.

Textbox 1. Content of messages shared in the in-depth interviews.

<p>Messages 1 and 2: Pill and injection use (Reminder)</p> <ul style="list-style-type: none"> Remember to take your pill. Your dose is due next week. You can return to the clinic to get your next dose. <p>Message 3: IUCD effectiveness (Factual)</p> <ul style="list-style-type: none"> IUCD is a small device placed inside the womb. Highly effective for 5 to 12 years. May increase monthly bleeding and cramps at first. When removed, can become pregnant with no delay. No infertility or birth defects; does not move around in body. <p>Message 4: IUCD side effects (Factual)</p> <ul style="list-style-type: none"> IUCD has few side effects. Monthly bleeding may be irregular, heavy, and longer during the first 3 to 6 months. May have painful cramps. Wounding of the uterus is rare. Some women don't have side effects. <p>Message 5: Pill use (Story)</p> <ul style="list-style-type: none"> I called my sister Sumi and she told me she used oral contraceptive pills (daily pills) for 2 years after she married Mahmud. She stopped to start a family. Now Sumi and Mahmud have 2 beautiful children. Sumi said that lately Mahmud is worried about the cost of raising 2 kids, so she is using daily pills again and now they don't worry about unplanned pregnancy. Sumi uses the alarm on her mobile as a reminder to take her pill every night before bed. Mahmud makes sure Sumi has new pill packs when she needs them. What a great guy—I wonder if my husband would do that for me? <p>Message 6: IUCD use (Story)</p> <ul style="list-style-type: none"> After Samreen got married to Rifat, she knew she didn't want to get pregnant for a few years, but she wanted to use a method that she didn't have to think about. Her sister-in-law Maliha used an IUCD for 2 years before she had her first son Shehan. She recommended that Samreen get one, too. Samreen was a bit nervous about having it fitted, but she's happy she did. She doesn't have to worry about getting pregnant, and she doesn't have to remember to do anything either.
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Results

In total, 24 in-depth interviews were completed with women aged between 18 and 34 years, with an average age of 25 years. All women were married, were ethnically Bengali, and had undergone MVA procedures. Sample characteristics (Table 1) show that we possibly oversampled urban women and those with higher levels of education.

Overall Response to the Idea of Receiving Family Planning Messages

Women were overwhelmingly open to both receiving messages about family planning methods on their mobile phones and talking to a counselor about family planning methods over the phone after their menstrual regulation. Women generally felt that a female counselor would be better, but many reported that they would not have a problem speaking to a male counselor.

Women were asked whether they would prefer free messages or whether they would be willing to pay for them, and although they generally felt that a free service would be preferable, many said they were willing to pay if necessary. It seemed reasonable to pay for information you needed, and it was also suggested that people would pay more attention to the messages if they had to pay for them:

It is better to have calls free of cost. But if they demand money for this call, I am ready to pay it. [Participant 8]

Bengali people don't pay much attention towards free things. They pay much more attention towards paid benefits. [Participant 4]

What Information Do Women Want?

When women were asked what information about family planning they would like to receive after their menstrual regulation, the most common responses were to have content about the contraceptive methods they had selected after their menstrual regulation procedure as well as overall advice on family planning methods. Many women were interested in receiving more information about what methods would "suit" them, suggesting interest in information tailored to them and their situation:

I would also like to know about the method that will suit my body. [Participant 9]

When asked what kind of messages they would want after a menstrual regulation procedure, women wanted to know specifically about what family planning methods they could use at this time. Women also had menstrual regulation related questions about returning to work, how long to refrain from intercourse, what medication they should be taking, and their future fertility.

Table 1. Sample characteristics.

Participant	Age	Currently employed	Highest education	Children	Division	Urban/rural
1	20	No	Primary	1-2	Sylhet	Peri-urban
2	26	Garment sector	Secondary	1-2	Dhaka	Urban
3	30	No	Primary incomplete	1-2	Dhaka	Urban
4	28	Community Clinic	College	1-2	Dhaka	Urban
5	34	Health worker	Primary	3 or more	Dhaka	Urban
6	18	No	Primary	N/A ^a	Sylhet	Peri-urban
7	30	No	None	3 or more	Sylhet	Peri-urban
8	23	Herbal company	Primary incomplete	1-2	Dhaka	Urban
9	25	No	Secondary	1-2	Sylhet	Peri-urban
10	22	No	College	1-2	Dhaka	Urban
11	26	No	College	1-2	Dhaka	Urban
12	25	Garment sector	Primary	1-2	Dhaka	Urban
13	22	No	Primary	1-2	Dhaka	Urban
14	20	No	College	1-2	Dhaka	Urban
15	21	No	Primary	None	Dhaka	Peri-urban
16	21	No	College	None	Dhaka	Peri-urban
17	25	No	Secondary	1-2	Dhaka	Urban
18	25	No	Secondary	1-2	Dhaka	Urban
19	32	Nurse	Secondary	1-2	Dhaka	Urban
20	30	No	Secondary	None	Dhaka	Urban
21	24	Domestic worker	Primary	1-2	Dhaka	Urban
22	24	No	Primary	1-2	Dhaka	Peri-urban
23	34	No	None	3 or more	Sylhet	Peri-urban
24	22	No	Secondary	1-2	Sylhet	Peri-urban

^aN/A: data not available.

Women spoke repeatedly about only wanting information that was relevant to them; they were not interested in hearing about alternative family planning methods. Participant 21, who is currently using condoms, said the following with respect to Message 3 (IUCD effectiveness):

Interviewer: Do you think that this is valuable message?

Respondent: Since I don't use it, not to me.

Interviewer: Why?

Respondent: Like I said, it's not important to me. I don't use it, it probably is important to other people, but not to me. [Participant 21]

Conversely, women also seemed to value new information and stated that knowledge about family planning methods was very important to them. Participant 19, currently not using an IUCD, said the following about Message 4 (IUCD side effects):

Interviewer: Was this message helpful?

Respondent: Yes.

Interviewer: How?

Respondent: Because I got to know new information, and I will let other people know about it as well.

Interviewer: How does the message meet your needs?

Respondent: It gave me a lot of new information. [Participant 19]

Technology and Language

Women generally preferred voice messages to SMS; the consensus was that reading SMS messages could be difficult or impossible for some women:

Those who are illiterate they will not be able to read. So, SMS is not convenient to them. For them voice mail is easy to understand. [Participant 7]

They overwhelmingly said they preferred Bengali script and found the English hard to read and thought others would too:

If it had been in Bengali, the message would have been clearer to me. [Participant 1, via SMS]

Women generally liked the interactive voice message and found this easy to understand. They also liked the different options

this modality gave them and the fact that they could go straight to the information they wanted to hear:

I like the fact that I can press a button and get to know what I want to know; I don't have to go through unnecessary information to get what I want to know. [Participant 17]

Only one woman found any difficulty using the interactive voice message option:

Since I don't have education it's tough for me. [Participant 3]

Women were however aware of the transitory nature of voice message—that it could not be accessed in their own time or recalled in the same way an SMS could. They liked the fact that the SMS came to their phones without actions on their part, even if the phone was switched off, and that they could read and reread in their own time, which they could not do with a voice message:

...if this message comes in my mobile just like an SMS, I can even read or see it later on, after finishing my job. [Participant 14]

Something women mentioned throughout the interview, often unbidden and in response to different questions, was that they wanted a “fixed number” to call; they wanted somewhere they could ask their own questions in their own time:

Interviewer: Are you interested in subscribing for the number of the call center via SMS? Why?

Respondent: Yes, because if I need to know something else other than what they are providing in the voicemail service, I could ask. [Participant 16]

Overall, women preferred messages that included voice message options because it would be accessible to women who are illiterate and may not be able to read SMS.

Message Style

Overwhelmingly, women had no problem understanding the content of the messages. When relaying the meaning of messages, women differed in the sections they highlighted, possibly reflecting those aspects that they found most interesting or had concerns about, as examples of the responses to Message 3 (IUCD effectiveness) show:

For people who use the IUCD, if removed they will get pregnant. That is the basic message here. [Participant 11]

What I understood from this message is that it remains in the same place in the uterus where it is placed. [Participant 23]

...yes, it speaks about the validity of the IUCD for 5-12 years. [Participant 10]

There were some instances, particularly concerning the IUCD, where women reported content that wasn't included in the message, possibly reflecting prior knowledge, misconceptions, or concerns. When asked what they knew about the IUCD, women often cited concerns and worries before any factual aspects of the message, such as participant 5 speaking about Message 4 (IUCD side effects):

The main substance of the message is that many people are afraid of it while the others are not. [Participant 5]

One woman referred to the fact that the IUCD is not popular and pointed out that stating side effects may make other women even more afraid (Message 4: IUCD side effects):

IUCD has some problems. If the message points out on the pain that may be felt during the implantation of it, many people will get afraid of it. Therefore, many people may ignore this message. [Participant 9]

Women appeared to be somewhat torn between short, factual messages and longer story messages. They reacted strongly and emotionally to the messages portraying stories about families but at the same time reporting that these messages were too long and not informative enough.

Story messages were overall more emotion than content driven, and this is what women remarked on after hearing the messages. They also reported emotionally driven understanding that was different from the actual content of the message:

Now the husband had fear. But when it was given to her, he became worry free. [Participant 2, responding to Message 6]

Family members are angry about her taking the pills. [Participant 13, responding to Message 5]

Women however also found the story messages too long and not factual enough:

You need to mention about the topic of the message first. You need to make people understand about what you want to convey with this message. Only then they will read it. [Participant 17, responding to Message 5]

Things can be removed and shortened. Most people don't have the time to listen to such a big message. [Participant 18, responding to Message 6]

Reminder messages (Messages 1 and 2: Pill and injection use) about short-term methods were well received and understood. Women said the reminder messages would be very useful to them, as it would remind them if they forgot to take the pill when they were busy with work and would remind women of the date of their next contraceptive injection, which they felt could be difficult to remember for rural women.

...reminding you is the biggest help that it does. In family planning mistakes only happen when you forget. [Participant 18]

Women also wanted specifics in their reminders, to add specific time and date. In this case, to Message 2 (reminder about injection):

The later part of the message is okay “To take your next dose please report to the clinic.” But the first part needs the addition of date. If you can add the date, it would be more suitable. Other than that, if you don't include the date, you can include the day of the week, which can work wonders too. I only say

this because women from villages don't remember dates well. If you mention the day of the week it would be great, for example "You need to take your injection dose by Thursday of the next week. To take your next dose please report to the clinic." [Participant 4]

Privacy

Women were asked about privacy and whether it would be a problem if anyone saw or heard the messages. They generally reported that privacy would not be an issue. When asked specifically about which people should not see the message, in-laws and children were most commonly mentioned by participants who explained that this could cause embarrassment and shame:

Suppose, there are many senior father-in-laws or children. It becomes a matter of shame if they listen to it. [Participant 8]

Women often responded to questions about privacy with answers welcoming sharing the message, so that others, including family members, could learn from it:

It is important because it is informing people who don't know about it. In my case, I didn't know about it much, so I got to know as well, and it is also reminding me of things I have learned in the past and forgot. When all of it will come to me, I will be able to explain it to other people. [Participant 19]

Husband's Involvement

Women were asked whether they thought their husbands would want to talk to counselors over the phone. They felt their husbands would be interested to know more about family planning methods, that they could learn from the counselor, and that this would make them more helpful and supportive.

Women reacted very strongly to Message 5, the story message about the husband helping out with pills. They were very keen for their husbands to listen to and learn from this and to become more involved. The story's protagonist's relationship with her husband was by far the most remarked upon aspect of this message, and women expressed desire for this message to change their own husband's behavior.

I felt a little envious about the message. The couple is so happy, if my husband changes when he gets to see the message then it would be so good. [Participant 19]

Participants reported that men were also very involved in decision making for family planning methods; most commonly women explained that there were discussions between the couple regarding what methods to choose, but the final decision maker was more likely to be the husband.

I know my husband is very conscious and whatever he will decide, will also be my decision. [Participant 1]

Women said their husbands would generally be supportive of them receiving messages on their phone, but some said that they would need their husband's permission to receive them, or at least to inform him beforehand.

Yes, I am interested, but I need his permission.
[Participant 2]

If my husband knows about the matter beforehand then there is no problem. If my husband finds out that I have chosen to follow a method without his concern, then it will result in marital dispute. If he is in a good mood, he probably will say "you could've let me know at least." [Participant 4]

Discussion

Principal Findings

In this exploratory study, we asked women questions about their interest in contraceptive mHealth services and about their views on sample mHealth message content and modalities. Women strongly welcomed the idea of receiving messages about family planning on their mobile phones after their menstrual regulation and wanted the option of being able to talk to a call center counselor. Women reported that the type of information included in the sample messages would be helpful to them; in particular, they wanted information about the method of contraception they were using, as well as guidance on which methods they could use after the menstrual regulation and which were best suited to them.

Women liked the interactive content as it gave them control over the information they received, that is, they can select the additional information or services that are relevant to them. Reminders were seen as particularly useful for those women using short-term methods, as they knew that forgetting to use the method would have an impact on its effectiveness. In 2013, a pilot study tested the feasibility of using a simple, one-way SMS to send contraceptive reminders to menstrual regulation clients in Bangladesh, of which 93% (51/55) of women reported that the SMS helped them use their method correctly [25].

New information on family planning was seen as something valuable that could benefit not just the recipient but also other women in her family and networks. Their husbands' involvement in family planning decision making and use also appeared very important to women; women wanted to share the message content with their husbands and were interested in their husbands talking to counselors. Women also reacted very strongly to a positive example of a man helping his wife to use the contraceptive pill. As many women report that men make the final decision for family planning methods [26], it is important to consider how best to support women who want to engage more with their husbands on this topic.

mHealth interventions have been gaining popularity and one of the reasons for this is their potential for broad reach; yet, although disparities in mobile phone ownership are decreasing [27], they still exist. Poorer or less educated women have less access to mobile phones than urban women [15,28], and ownership is still higher among men than women (61.76% (1213/1964) versus 34.38% (1015/2952) [21].

Voice messages were favored over SMS, and most women found interactive voicemail easy to use. Women in our study suggested that rural and less educated women may have difficulty reading SMS messages, which is consistent with

findings that literacy is lower among rural women and those in the lowest socioeconomic quintile [15]. Women found the Bengali words in English letters difficult to read and would have preferred Bengali script. Most phones in Bangladesh are not smartphones and lack the capability to support Bengali script. This may at least, in part, explain why among rural mobile phone users in Bangladesh only 49.87% (1111/2228) know that SMS messages can be received and sent, and only 36.62% (816/2228) read SMS messages [21]. Similar difficulties have been reported in Cambodia where pictures or audio messages were suggested as alternatives to SMS [29].

The findings from this exploratory study will be used to inform an mHealth intervention for postmenstrual regulation family planning in Bangladesh and may be used for development of similar interventions in the future. Including the target population in the development of mHealth messages can help to ensure that their views, preferences, and needs are taken into account. Voice messages may be preferential in terms of effort expectancy and ease of use for the women; however, information shared in an automated call has to be received at when it is delivered, rather than when the individual is ready as is the case with SMS or pull-type interventions such as call centers. The desire to have a number to call for information was expressed in similar studies in Bangladesh [25,30]. Women receiving mobile phone messages about reproductive health could be given the option of connecting to the call center.

Although women felt it would be better if the services were provided free of charge, many reported willingness to pay a fee if necessary. Women participating in feasibility research for Aponjon, a mobile phone intervention for expectant and new mothers, also reported not wanting to pay for mobile phone messages; however, the program used an income-based fee scale and found that those charged were willing to pay [30].

Social norms are known to be strong influencers of contraceptive behaviors. Women reported that confidentiality and privacy would not be a problem for them, and many reported that they wanted to share the messages, and information they contained, with other women so they could learn from them too. Women mentioned some people around them who they felt should not see the messages, meaning privacy could be a concern in some situations. Additionally, although women here did not seem very worried about privacy, other studies have found that women's perception changed over the course of actually receiving the text messages, for example women in South Africa were more concerned about privacy after receiving the SMS intervention than they had been before [31].

Limitations

This study aimed to inform the development of an intervention targeted at postmenstrual regulation family planning, and relevance to other interventions, contexts, or populations is likely to be limited. We made efforts to recruit participants from a range of socioeconomic backgrounds by recruiting women from clinics in both urban and peri-urban areas of Dhaka and Sylhet, but we did not recruit women from a more rural clinic as planned because of political violence at the time of data

collection. Half of the participants in the sample were educated to secondary level or higher; it is likely that women in our sample have higher education and income levels, as well as more experience and greater fluency with technology than their counterparts in more rural areas of Bangladesh.

A further limitation is the use of convenience sampling, which is inherently biased as it is a nonprobability sampling technique. The views shared by respondents in this sample may not be representative of all women who are accessing menstrual regulation services and own mobile phones.

All participants in our sample had had an MVA procedure. Medical menstrual regulation clients may have differing needs in terms of follow-up information, at least in the short term. For example, they may be more focused on the menstrual regulation procedure than on family planning because their procedure is not yet complete. Bias could have been introduced during the sampling; providers may have been more inclined to ask certain women to participate, possibly those they felt were more approachable or who had been satisfied with their menstrual regulation procedure, who may in turn have been more likely to want to participate. Clients who were not feeling well after the menstrual regulation or were in a hurry may also have been missed.

A further limitation of the methodology is that women were asked to give their views on a hypothetical intervention: the example messages were shared during the interview at a time when the woman was somewhere quiet and had time to listen carefully without interruption. Responses to the content and length of messages and to questions about privacy may differ in a real-life intervention when the timing of messages delivery may not be so convenient.

Conclusions

Overall, this study showed that this sample of Bangladeshi menstrual regulation clients were very interested in receiving information on their phones to support family planning use after their procedure, providing a solid foundation for the planned intervention. Women were most interested in learning more about the method of contraception they took after their menstrual regulation procedure and how to recover after their menstrual regulation procedures.

Interactive voicemail was the preferred modality and would give women in our study the option to select the information most useful to them. This approach could satisfy both those who are keen to hear information about a range of methods and those who only want content about the method they are currently using. An interactive system could also include an option to be connected directly to a call center counselor. Drawbacks of voice messages are that they are harder to share and cannot be played when it is most convenient; interactive SMS could be offered as an alternative or in addition to voice messages for literate clients. Sharing information on a sensitive topic such as family planning by mobile phone has privacy implications, and this is an area that should be closely monitored when delivering interventions on this topic.

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Author SN is currently an independent consultant, but at the time of the study, he was employed at and affiliated with Marie Stopes Bangladesh.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Interactive voice message format.

[[JPG File, 100KB - mhealth_v5i12e174_app1.jpg](#)]

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Abbreviations

- IUCD:** intrauterine contraceptive device
- mHealth:** mobile health
- MVA:** manual vacuum aspiration
- NGO:** nongovernmental organization
- RCT:** randomized controlled trial
- SMS:** short message service

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Original Paper

How Do Infant Feeding Apps in China Measure Up? A Content Quality Assessment

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Abstract

Background: Globally, with the popularization of mobile phones, the number of health-related mobile phone apps has skyrocketed to 259,000 in 2016. In the digital era, people are accessing health information through their fingertips. In China, there are several apps that claim to provide infant feeding and nutrition guidance. However, the quality of information in those apps has not been extensively assessed.

Objective: We aimed to assess the quality of Chinese infant feeding apps using comprehensive quality assessment criteria and to explore Chinese mothers' perceptions on apps' quality and usability.

Methods: We searched for free-to-download Chinese infant feeding apps in the iTunes and Android App Stores. We conducted a comprehensive assessment of the accountability, scientific basis, accuracy of information relevant to infant feeding, advertising policy, and functionality and carried out a preliminary screening of infant formula advertisements in the apps. In addition, we also conducted exploratory qualitative research through semistructured interviews with Chinese mothers in Shanghai to elicit their views about the quality of apps.

Results: A total of 4925 apps were screened, and 26 apps that met the selection criteria were evaluated. All 26 apps were developed by commercial entities, and the majority of them were rated poorly. The highest total score was 62.2 (out of approximately 100) and the lowest was 16.7. In the four quality domains assessed, none of them fulfilled all the accountability criteria. Three out of 26 apps provided information covering the three practices from the World Health Organization's infant feeding recommendations. Only one app described its advertising policy in its terms of usage. The most common app functionality was a built-in social forum (19/26). Provision of a website link was the least common functionality (2/26). A total of 20 out of 26 apps promoted infant formula banner advertisements on their homepages. In addition, 12 apps included both e-commerce stores and featured infant formula advertisements. In total, 21 mothers were interviewed face-to-face. Mothers highly valued immediate access to parenting information and multifunctionality provided by apps. However, concerns regarding incredible information and commercial activities in apps, as well as the desire for information and support offered by health care professionals were expressed.

Conclusions: The findings provide valuable information on Chinese infant feeding apps. The results are concerning, particularly with the relative absence of scientific basis and credibility and the large number of commercial advertisements that are displayed. Apps do seem to be able to provide an opportunity for mothers to access health information and support; it is time for tighter controls on content and advertisements. Ongoing app research and development should focus on implementation of a standard framework, which would drive the development of high-quality apps to support healthy infant feeding through cooperation among academics, health professionals, app users, app developers, and government bodies.

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KEYWORDS

apps; mobile phone; Chinese

Introduction

Globally, with the development of new information and communication technologies, mobile phones have reached further than any other communication tool in terms of access [1]. The World Health Organization (WHO) [2] defines mobile health (mHealth) as the use of mobile and wireless technologies to support the achievement of health objectives. The number of health-related mobile phone apps has skyrocketed, reaching 259,000 worldwide in 2016 [3]. In the digital era, people are accessing health information through their fingertips, with health literacy skills improved in all age groups [4]. For example, pregnant women are often disappointed with the quality of their prenatal care and so turn to the Internet and apps to fill the gap [5]. A study in Shanghai, China, found that approximately 40% of 657 surveyed pregnant women chose the Internet as their main source of information on breastfeeding [6]. The number of monthly active users for the most popular parenting app (Babytree) in China reached 8.89 million in 2016 [7]. For new mothers, immediate access to informational resources has been appreciated [8] and also recognized as an essential component of successful maternal role transition [9].

In China, on average, only 28% of infants are exclusively breastfed for 6 months, and the rate of early initiation of breastfeeding, within 1 hour of birth, was only 41% for 2008-2012 [10]. A recent study has shown that of 1350 Chinese infants and young children, aged between 6 and 35 months, only 40% consumed dark green leafy vegetables [11]. Poor food consumption patterns and eating habits in infancy can have an adverse effect on later life, such as a number of chronic health conditions, including being overweight or obese, or having high blood pressure or diabetes [12]. China is now the largest market for infant formula, valued at US \$17,783 million, and it is projected to be more than double in value by 2019 [13].

Promoting healthy infant feeding practices is critical for improving nutrition, health, and development of children [14]. The widespread use of apps and the growth in demand for parenting information online, particularly infant feeding information, position apps as a potentially ideal tool to deliver breastfeeding and healthy infant feeding knowledge. However, a content assessment of 46 infant feeding English-language apps from United States, Australia, and United Kingdom revealed poor quality [15]. Notably, studies assessing health-related apps were concentrated in English-speaking countries, whereas countries where apps were downloaded in large numbers such as China, Brazil, and Mexico were relatively neglected [16].

Given the continually increasing number of infant feeding apps and users in China and the lack of existing research to provide detailed app evaluation, exploring the quality of these apps and understanding mothers' thoughts on them are both essential, particularly in a commercial context of apps being increasingly used for promoting and selling breast milk substitutes [17]. The primary purpose of this study was to perform the quality

assessment of free-to-download infant feeding apps available, followed by preliminary qualitative data to accompany with. To take a complete picture of Chinese infant feeding apps, we conducted evaluation on accountability, scientific basis, advertising policy, and functionality of apps; carried out a preliminary screening of infant formula advertisements and e-commerce services within the apps; and collected some preliminary qualitative data on mothers' opinions on downloaded apps through interview.

Methods**App Quality Study****App Selection**

Parenting apps have been categorized into four catalogues according to their primary feature: *informational* apps are primarily aimed at providing accurate and updated information related to parenting, such as infant feeding, education, and entertainment; *social networking* apps are designed mainly as social platforms to share motherhood experience or images of their infants; *record* apps are used as infants' growth diary; and *e-commerce* apps are designed as e-stores to sell maternal and baby products [18]. In this study, infant feeding apps are defined as *informational apps* that are primarily aimed at providing information related to infant feeding including breastfeeding and complementary food feeding.

In April 2016, apps were searched from the 360 Mobile Assistant (the premier store for distributing Android mobile phone apps in China) and the Chinese iTunes App Store. Search terms (in Chinese) included infant feeding, baby feeding, breastfeeding, mother + baby, and solid food. Inclusion criteria of apps were as follows: (1) intended for the promotion of healthy infant feeding practices, (2) having stand-alone functionality (ie, not requiring subscription to another program to operate), (3) in simplified Chinese characters or simplified Chinese characters available, (4) updated since 2015, (5) only *informational apps*, (6) targeted at parents of infants and young children, and (7) developed in mainland of China. Exclusion criteria for apps were as follows: not free; in videos, electronic books, audio files, news, and blog forms; designed mainly for social networking and e-commerce or designed as a daily tracker or calculator; and not accessible because of broken or dead links. Each app underwent initial screening based on the description page in iTunes and 360 Mobile Assistant, which consisted of a brief description of the app, user ratings, customer reviewers, and associated screenshot images. Apps that fulfilled the inclusion criteria were downloaded onto an iPhone 6 (for iTunes App Store) and onto a Samsung Galaxy 7 (for 360 Mobile Assistant).

Evaluation Scale

On the basis of previous studies and tools used to evaluate the quality of online health information [16,19,20] such as Silberg scale [21], Health On the Net Foundation code (HONcode) principles [22], *Journal of the American Medical Association*

benchmarks [21], and DISCERN rating instrument [23], we developed a quality assessment tool (Table 1), including criteria in four domains (accountability, scientific basis, advertising policy, and functionality). Accountability was rated on Silberg's standards [21]. The 9-point Silberg scale is the most commonly used criterion for evaluating information quality [24]. This includes authorship (ie, the author's credentials and affiliations), attribution (ie, provision of information sources and references), disclosure (ie, ownership or sponsorship disclosure), and currency (ie, whether the app had been modified in the previous month or last modification date is specified).

Scientific basis domain examined the accuracy of information related to infant feeding regarding the level of adherence to the three main practices from the WHO's infant feeding

recommendations [25]: early initiation of breastfeeding within 1 hour of birth, exclusive breastfeeding for the first 6 months of life, and introduction of nutritionally adequate and safe complementary (solid) foods at 6 months together with continued breastfeeding up to 2 years of age or beyond. Each of the three practices was coded as 0 indicating "incorrect information," 1 indicating "no information provided," and 2 indicating "correct information."

The advertising policy domain was included to determine whether any advertising policy was stated and adopted by the app developer. Advertising policy was assessed against the HONcode, one of the most well-known and widely used quality labels [26]. Each item was coded as 0 indicating "not described the policy" or 1 indicating "described the policy."

Table 1. Quality assessment evaluation criteria.

Evaluation criteria	Maximum score (points)
Accountability	9
Authors credited	1
Author's affiliations	1
Author's credentials	1
Information sources	1
References given	1
App ownership disclosed	1
Sponsorship disclosed	1
App modified in the previous month	1
Creation or last modification date specified	1
Scientific basis	6
Early initiation of breastfeeding within 1 hour of birth attribution	2
Exclusive breastfeeding for the first 6 months of life	2
Introduction of nutritionally adequate and safe complementary (solid) foods at 6 months together with continued breastfeeding up to 2 years of age or beyond	2
Advertising policy	4
Any description on advertising policy that the app developer adopted	1
Any description on which advertisements are accepted	1
Any statement that advertisement has to be clearly separated and distinguished from the editorial content	1
Any statement that promotional information has to be clearly separated and distinguished from the editorial content	1
Functionality	8
Calendar	1
Baby weight or length record	1
Graph mensuration of infant growth	1
Social forum	1
Internet website links	1
Reminders to log breastfeeding or bottle feeding	1
Internal keywords search	1
Personalized context-based notification and alert	1

Textbox 1. Interview guide.

Mothers who use an infant feeding app:

- Current breastfeeding and child feeding situation (exclusively breastfeeding, breastfeeding, and complementary feeding)
- Usage of infant feeding app; the reasons to use the app
- Criteria used for choosing infant feeding app
- Attitude toward breastfeeding and infant feeding information in the app
- Preferred content/function in used infant feeding app
- Any influence on mothers' understanding of breastfeeding and appropriate infant feeding (information/advertisement)
- Mothers' expectation/issues related to baby feeding, which could be solved by technology (new app function or app function improvement)

Mothers who do not use an infant feeding app:

- Current breastfeeding and child feeding situation (exclusively breastfeeding, breastfeeding, and complementary feeding)
- The main source of breastfeeding and infant feeding information
- The reason why they do not use an infant feeding app

The functionality domain appraised eight app functionality compiled from common functionality criteria used in previous app studies [27,28], such as including a built-in online social forum where women can go to seek infant feeding information and support [29]. We examined the homepage of each app for any commercial banner advertisement and then recorded whether any of these advertisements were for infant formula. Additionally, we screened any e-commerce service in each app and noted any infant formula advertisement.

Evaluation Procedure

All apps were downloaded and then coded for each criterion of the four domains, namely, accountability (9 points), scientific basis (6 points), advertising policy (4 points), and functionality (8 points). Each evaluation domain was awarded 25 points equally and 100 points in total for all four domains; each app was then given a weighted score out of 100 points for its fulfillment of the different features of the quality evaluation criteria ([Multimedia Appendix 1](#)). One assessor (JZ) conducted all the app quality evaluations using this tool, and the results were verified by the second assessor (ML). Statistical analyses were conducted using SPSS Statistics for Windows, version 22.0 (IBM Corp).

Interviews

For this exploratory research, we conducted face-to-face interviews to elicit information about mothers' current use of infant feeding apps and whether these apps had any influence on their understanding of breastfeeding and appropriate infant feeding. In addition, we explored mothers' current practices and the main obstacles that they faced when using these apps. Ethics approval was obtained from the Human Research Ethics Committee of the University of Sydney, Australia (2016/300).

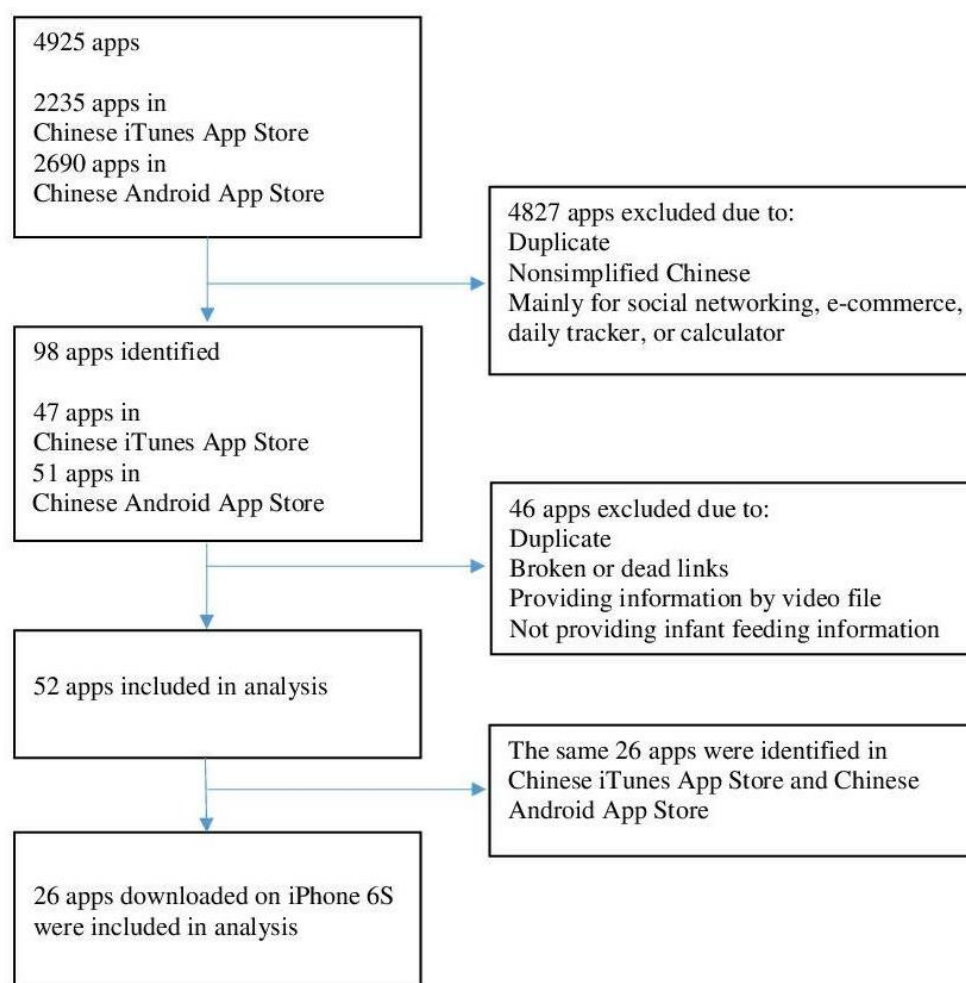
Semistructured interviews were conducted using an interview guide ([Textbox 1](#)) and held with 21 mothers over 14 days in

May 2016 in Jiading District Maternal and Child Health Hospital, Shanghai, China. At the waiting area of the child health clinic, women who had given birth in the past year, were over 18 years of age, and competent in Mandarin were invited to take part in the interviews. Interviews were conducted in Mandarin and audiotaped with permission from the women. Interviews lasted for approximately 20 to 30 min each. The four app evaluation domains formed the basis of the interview guide. In addition, questions related to app usability were included. All interviews were transcribed verbatim in full in Chinese and then translated into English. Common concerns and experiences among interviewees in relation to the four app evaluation domains were identified.

Results

App Selection

The initial search from 360 Mobile Assistant Android App Store (n=2690) and iTunes App Store (n=2235) resulted in a total of 4925 apps ([Figure 1](#)). After initial screening based on the inclusion criteria, we deleted duplicate apps (n=152), nonsimplified Chinese apps (n=168), social networking apps (n=829), and e-commerce apps (n=1757) or apps designed for daily record or entertainment (n=1921), and then 98 apps were identified and downloaded to an iPhone 6S and a Samsung Galaxy for initial screening. Apps with the same content under different name, broken or dead links, or apps providing information only by video file were deleted (9 apps from iPhone and 13 apps from Samsung). Following these deletions, we found that the same 26 apps were downloaded in both iPhone and Samsung separately, thus we only used the 26 apps in the iPhone 6S for data abstraction. Furthermore, the final sample included in the quality assessment comprised 26 apps.

Figure 1. Flow diagram for selection of Chinese infant feeding apps.

Apps Quality Assessment

Sample Characteristics

Of the 26 apps analyzed, all were developed by a commercial entity. Each app was evaluated using the quality assessment tool. Each app's name in both Chinese Pinyin and English translation, relative ranking, and its original and weighted quality scores for each domain are presented in [Multimedia Appendix 1](#). Overall, mean score (weighted) for the 26 apps was 40.4 (standard deviation [SD] 10.9). *Murumamashouce* ("Mothers' Handbook of Breastfeeding") received the highest total score of 62.2, followed by *Yuxueyuan* ("Garden of Parenting Knowledge") with a score of 61.9. The lowest scored app was *Baobaochengzhangrili* ("Calendar of Baby's Growth") with a score of 16.7.

Accountability

Of the 26 apps, none fulfilled all the accountability criteria. The mean score for accountability was 3.9 out of 9 (SD 1.4). More than half of the apps were modified within the last month and clearly stated the modification date (16/26, 62%). Approximately 81% (21/26) of the apps only disclosed the app ownership, whereas only 16% (4/25) disclosed app sponsorships. Only one app, *Jiadingmama* ("Adding"), credited the app authors and their affiliations. None of the apps reported authors' credentials

(educational background, professional affiliations, certifications, and past writings).

Scientific Basis

The mean score for this domain was 3.4 out of 6 (SD 1.4). Only 3 out of 26 apps provided infant feeding information covering all three practices from WHO's infant feeding recommendations. Less than half of apps (11/26) provided information on early initiation, whereas the other apps either did not mention early initiation at all or did not include specific timing for initiation. More than one-third of apps (10/26) advised 6 months' exclusive breastfeeding, and a similar number (9/26) recommended exclusive breastfeeding for the first 4 months. In addition, 7 apps did not specify the time period of exclusive breastfeeding or when solid food introduction should begin. Less than a quarter of apps (6/26) mentioned that the introduction of complementary foods should be at 6 months, together with continued breastfeeding up to 2 years or beyond.

Advertising Policy

The mean score for the advertising policy category was 0.9 out of 4 (SD 1.0). Only one app described the advertising policy in its terms of usage; none of the apps identified the advertisement policy accepted or adopted in the app. Approximately 60% (15/26) of the apps did not have a policy clearly separating

advertisements from the editorial content. An equal number of apps (15/26) did not have a policy to separate and distinguish commercial promotional information from the editorial content.

Functionality

The most popular app functionality was a built-in social forum (19/26), followed by a calendar (16/26). Provision of a website link was the least common functionality (2/26); none of them provided the authoritative infant feeding information website links, such as UNICEF China and WHO China. The app with the most inclusion of functionality was Babytree, which included 7 out of 8 measured items within the functionality domain, whereas *Mengbao* ("Cute Baby"), *Youbaobaola* ("There is a Baby"), and *Baobaochengzhangrili* ("Calendar of Baby's Growth") only contained one functionality each.

Banner Advertisements and E-Commerce Feature

On their homepages, 85% (22/26) apps displayed commercial banner advertisements related to maternal and baby products, such as food and clothing. Four-fifths of these apps (20/22) promoted infant formula advertisements. A total of 12 out of 26 apps included e-commerce, which is an e-store with products directly available for sale. All 12 apps that included e-commerce stores also had infant formula advertisements.

Preliminary Interview Findings

In total, 21 mothers were interviewed. The mean age of mothers was 31 years (range 25-42 years), and their educational status was predominantly junior college or university level. All respondents were married and currently not working. In the sample, all women owned a mobile phone; the majority of them had used at least one infant feeding information app assessed (16/21); all used infant feeding apps were free to download and were reviewed in app quality study. In addition, 5 mothers did not use infant feeding apps, as they felt that searching questions through the Internet search engine, such as Baidu (a Chinese search engine), is easier than using the app:

I don't use app, Baidu is very easy to search answers.
[Mother 5, age 29 years]

Overall, there was a common interest in using apps for accessing infant feeding knowledge. All the mothers (16/21) who use infant feeding apps felt confident using them and had a positive response for using the apps. In addition, mothers noted that they would have no difficulty navigating the apps on their own; they thought it was easy to use infant feeding apps, and nobody mentioned the need for technical support:

These two apps [I am using] both were recommended by a friend, very easy to use. [Mother 18, age 30 years]

Accountability

In China, the child-raising environment is changing. Unsatisfied with merely providing enough food, which was the major concern of previous generations, mothers now are longing for modern and accurate parenting information:

My mum's experiences may not be wrong, but they were already outdated. [Mother 2, age 27 years]

More than half of the mothers (12/21) revealed that they paid special attention to the source of information and messages to ensure they received the best infant feeding advice. However, some mothers (9/21) were aware of the fact that many apps are developed or supported by commercial companies. A few mothers (5/21) complained about the difficulty of assessing the credibility of information in the apps, as one mother said:

After all, these apps are developed by commercial companies, not a medical institution. [Mother 16, age 30 years]

Scientific Basis

In addition, some women (5/21) were confused about the information in used apps:

Hm, the parenting information is somehow not reliable, like "4 months" and "6 months to start feeding solid food" both were found in the app.
[Mother 1, age 28 years]

Mothers (10/21) stated that they could not completely trust the accuracy of apps. This is consistent with the quality assessment that very few apps provided information based on scientific basis. However, because of very limited access to health care providers, which was mothers' most trustworthy source of infant feeding information, one common precautionary measure most mothers took was to combine information from multiple sources, including apps, elders, peers, the Internet, and books. If there was any conflicting information, they would try to make a decision for themselves:

Usually I listen to the suggestions of elders, also communicate with peers and other mothers, and consult with the sellers of maternal products shops, then I conclude those suggestions. [Mother 17, age 26 years]

Functionality

Mothers (10/21) valued apps that are multifunctional. Features such as reminders and keyword searches were very helpful, which was consistent with apps that scored reasonably in the functionality evaluation. Most of the mothers (13/21) stated that they would use the app frequently because of the helpful functionality, such as reminders, and the social networking features. In addition, the interviews showed that the social forum was an important source of infant feeding information and support. The forum also provided opportunities to help mothers in unusual situations to connect with others with similar experiences, such as when babies are highly allergic or feeding twins. For example, one mother said:

I not only used during pregnancy but also after the baby was born. Because I had twins, quite unusual, I followed closely the women in a similar situation in the discussion room. [Mother 21, age 29 years]

However, several mothers (7/21) expressed that information was overwhelming and jumbled in the social forum, and many discussion topics were related to family issues, such as the relationship between a mother-in-law and a daughter-in-law.

Notably, mothers (8/21) described how they used the app to “look stuff up” by internal keyword search functionality, which could provide convenience and immediacy of accessing information right at the time when needed. Some mothers stated that personalized notification was very useful, such as:

...the notification is very helpful, it was set out according to my baby's height and weight, and is very prompt.

However, there should be a balance, as too many functions in turn could result in poor usability, which was supported by some users' opinions:

...those apps are too fancy to use. [Mother 1, age 27 years]

Advertising Policy

Many mothers (8/21) also expressed concern about the commercial advertisements of infant products and the apps. However, some mothers (5/21) noted that they felt powerless over the commercial advertising on account of the fact that the apps were provided by commercial entities. Compared with these types of apps, apps that were supported by government were viewed as more trustworthy:

If it is an official app from government, it can be trusted. [Mother 3, age 29 years]

Discussion

Principal Findings

In this study, we found a high level of interest and utilization of infant feeding apps, showing the high potential for implementing mHealth in China. The content quality assessment showed that the total score of most apps was low, below 50 points over the four domains. Few apps scored well for measures of accountability, although most of the apps scored full points on currency. This implied that the apps were updated and modified within the month. The quantitative data were supported by interview findings that mothers had a strong willingness for immediacy of information, but many were skeptical about the credibility of content sources. The apps reviewed in this study do not serve as a new tool to support mothers seeking health knowledge, but rather as a new media technology to disseminate formula advertisements and potentially misleading health information.

The content of analyzed apps had low-level adherence to WHO's breastfeeding and infant feeding recommendations. Additionally, apps largely did not connect users to professional resource links outside of the app. Considering the current large number of app users and strong demand for infant feeding knowledge in China, this should be recognized as a missed opportunity for the promotion of healthy infant feeding practices, particularly exclusive breastfeeding. One reason for the poor scores of scientific basis may be that health professionals and institutions are not involved in app development. All the evaluated apps were developed by commercial companies without academic and government agencies' input. The development of the apps, therefore, is most likely to be driven by commercial motivation rather than provision of health promotion information. Even

though we had deleted all the e-commerce apps (1757/4925, 35.68%) from the initial screening in app stores, we found that almost half (12/26) of the included apps offered e-commerce feature, so parents could still make purchases of products directly through these informational apps. In these e-stores, advertisements of formula often have a clear definition of different stages of the formula, such as “newborn” and “3 to 6 months.” It was reported that in-app advertising has been another source of income among mHealth app publishers [30]. We found that commercial banner advertisements including infant formula were embedded in the homepages of 22 out of 26 apps. Although the Chinese Regulations of the Code were released in 1995 [31], China does not have an operative system to ensure full implementation of the Code [32]. Concern has already been expressed that Internet may be a new source of noncompliance with the Code with respect to infant formula [33]. Given the ubiquity of Internet advertising, the Chinese Government launched Interim Measures for the Administration of Internet Advertising on September 1, 2016, including new regulations on online infant and toddler formula advertising [34], which are expected to be put into practice. As the regulation was launched after this study, we do not have any data relevant to its practical utility in this study.

Another interesting finding is that most reviewed apps (19/26) offered social forum space covering various topics related to mothers and infants. Mothers could not only get information from the social forum but could also build relationships and find support that was not easily offered in a face-to-face setting, particularly in the isolated period after childbirth. However, these social forums are not typically monitored or guided by professionals; we know little about far-reaching health consequences of these forums. Our quantitative finding indicated that the majority of apps had a social forum allowing their registered users to discuss and communicate freely in this space, except for illegal content. This is obviously an essential feature of the current Chinese infant feeding apps. Most interviewed mothers reported that social forum was an irreplaceable source of infant feeding information and support they need. Our finding is supported by other studies that more and more women are seeking peer support and parenting information online, particularly for breastfeeding [35-37]. However, a large amount of information featured on these discussion boards was based on mothers' experience including infant medical issues, breastfeeding struggles, and the onset of solid food consumption. This information could sometimes be misleading, as they often come from informal sources without scientific basis. In addition, the social forum has limited ability to support health information seeking. One study about social support communication via top online breastfeeding forums in English found that approximately 80% of requests in the discussion board were for information support, but only approximately 60% of them received a message as a result of offering support [29]. From our qualitative study, many mothers said that health workers were the most trusted information source but the least accessed. Therefore, mothers sought reassurance from social forum in apps and other nonprofessional sources, such as their mother-in-law, nanny, or friend. Although mothers appreciated infant feeding information that apps could provide, their views on the information that they got in apps revealed their greater desire

to access information and support of health care professionals or government. Indeed, various available but unreliable infant feeding information sources that mothers relied on may help mothers take their own decisions relevant to infant feeding, but it may not be the best choice.

Future Research

A more in-depth qualitative study is needed to understand how women use feeding apps and how an ideal app could be developed to suit their needs. On the basis of current interviews, participants will be asked to talk aloud while using a parenting app, detailing what type of information they are looking for, where they think they can find it, and what are their reactions to overwhelming information provided through the app, family member, and peer. In-depth, face-to-face and group interviews with probing questions about the app experiences could provide better understanding beyond the four domains. Such a study could inform the development of mHealth interventions in infant health promotion in China. In addition, we plan to conduct a content analysis of breast milk substitute advertising in popular Chinese maternal and baby apps.

Limitations

This study has several limitations. The study evaluated 26 infant feeding information apps available to the public that satisfied

the inclusion criteria. Hence, it is possible that other existing apps could be missed. There is no published comprehensive content quality assessment tool to study health-related apps; therefore, the scope and some of the criteria used in the analysis may impact the variability and comprehensiveness in the scoring.

Conclusions

This study adds to the understanding of Chinese infant feeding apps in the context of health promotion and online support through mHealth, as well as preparatory investigation of infant formula advertisements on these apps. The result of content analysis and evaluation is not promising, particularly with the relative absence of scientific basis and credibility and the large number of commercial advertisements that are displayed. Apps do seem to be able to provide an opportunity for mothers to access health information and support, but there is a plea for tighter controls on content and advertisements. In the future, ongoing app research and development should focus on implementation of a standard framework, which would drive the development of high-quality apps to support breastfeeding and healthy infant feeding through cooperation among academicians, health professionals, app users (particularly mothers), app developers, civil society, and government bodies.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Relative ranking and scoring of each evaluated app.

[\[PDF File \(Adobe PDF File\), 80KB - mhealth_v5i12e186_app1.pdf\]](#)

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Abbreviations

mHealth: mobile health

HONcode: Health On the Net Foundation code

SD: standard deviation

WHO: World Health Organization

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Review

Chinese Cardiovascular Disease Mobile Apps' Information Types, Information Quality, and Interactive Functions for Self-Management: Systematic Review

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Abstract

Background: China has a large population with cardiovascular disease (CVD) that requires extensive self-management. Mobile health (mHealth) apps may be a useful tool for CVD self-management. Little is currently known about the types and quality of health information provided in Chinese CVD mobile apps and whether app functions are conducive to promoting CVD self-management.

Objective: We undertook a systematic review to evaluate the types and quality of health information provided in Chinese CVD mobile apps and interactive app functions for promoting CVD self-management.

Methods: Mobile apps targeting end users in China with CVD conditions were selected in February 2017 through a multi-stage process. Three frameworks were used to evaluate the selected apps: (1) types of health information offered were assessed using our Health Information Wants framework, which encompasses 7 types of information; (2) quality of information provided in the apps was assessed using the 11 guidelines recommended by the National Library of Medicine of the National Institutes of Health; and (3) types of interactive app functions for CVD self-management were assessed using a 15-item framework adapted from the literature, including our own prior work.

Results: Of 578 apps identified, 82 were eligible for final review. Among these, information about self-care (67/82, 82%) and information specifically regarding CVD (63/82, 77%) were the most common types of information provided, while information about health care providers (22/82, 27%) and laboratory tests (5/82, 6%) were least common. The most common indicators of information quality were the revealing of apps' providers (82/82, 100%) and purpose (82/82, 100%), while the least common quality indicators were the revealing of how apps' information was selected (1/82, 1%) and app sponsorship (0/82, 0%). The most common interactive functions for CVD self-management were those that enabled user interaction with the app provider (57/82, 70%) and with health care providers (36/82, 44%), while the least common interactive functions were those that enabled lifestyle management (13/82, 16%) and psychological health management (6/82, 7%). None of the apps covered all 7 types of health information, all 11 indicators of information quality, or all 15 interactive functions for CVD self-management.

Conclusions: Chinese CVD apps are insufficient in providing comprehensive health information, high-quality information, and interactive functions to facilitate CVD self-management. End users should exercise caution when using existing apps. Health care professionals and app developers should collaborate to better understand end users' preferences and follow evidence-based guidelines to develop mHealth apps conducive to CVD self-management.

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KEYWORDS

mobile health; mHealth; cardiovascular disease; CVD; patient preferences; information quality; self-management; mobile applications; mobile apps; China

Introduction

Cardiovascular disease (CVD) is a leading cause of morbidity and mortality in China, accounting for 45% of all deaths in rural areas and 42% in urban areas [1]. Currently, approximately 290 million people in China live with CVD [2]. Meanwhile, there is a severe shortage of doctors in China, where the doctor-patient ratio is 1.4 doctors per 1000 patients [3]. Mobile health (mHealth) apps therefore hold promise for delivering health information and services to Chinese patients, especially for chronic conditions like CVD, which require extensive self-management [4]. Self-management is key to person-centered care [5], but its support requires an understanding of individual preferences for different types of health information and decision-making autonomy [6]. The Health Information Wants (HIW) framework suggests 7 types of information that patients typically desire in health care contexts: (1) information about the specific health condition, (2) treatment, (3) laboratory tests, (4) self-care, (5) complementary and alternative medicine (CAM), (6) psychosocial aspects, and (7) health care providers (HCPs) [6-8]. Empirical research using the HIW framework has shown that diabetes-related mobile apps for Mainland Chinese users offer inadequate information [9]. However, little is currently known about whether Chinese CVD mobile apps might offer a broad range of high-quality information and functions that can facilitate effective CVD self-management.

The self-management of chronic conditions requires the ability “to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition” [10]. Self-management is inherent to person-centered care that promotes a “balanced consideration of the values, needs, expectations, preferences, capacities, and health and well-being of all the constituents and stakeholders of the health care system” [5]. Effective self-management and person-centered care require full accommodation of people’s needs and preferences for different types and amounts of information and other care services [11,12], a degree of autonomy in health-related decision-making [13,14], and support from their formal (eg, health care professionals) and informal caregivers (eg, family members) [15,16].

Although mHealth apps have the potential to promote effective self-management and person-centered care [17,18], existing apps tend to provide limited types of information [9], lack information quality assurance [19-21], and offer inadequate functionalities [22]. These limitations may have negative impacts on mHealth app users. Information quality is important to users of electronic health (eHealth) and mHealth products or services [23,24]. However, the quality of online health information is often unregulated and problematic [25], especially in the context of mHealth apps [23,24]. The situation is even worse in developing countries, including China [26-28]. One study, for example, has found that the quality of Chinese

mHealth apps is poor, especially due to limited coverage of medication topics [29]. Another study found that Chinese mHealth apps tend to lack information accountability and have limited coverage of relevant topics [30]. Empirical evidence also suggests that concerns about privacy and information quality could hinder Chinese people’s mHealth app usage [31].

Nevertheless, mobile apps’ interactive functions have the potential to assist users in their health care activities and improve user satisfaction [32-34]. A randomized controlled trial undertaken in Sweden, for example, found that an interactive health app was more effective than a noninteractive tool for improving medication adherence, lifestyle changes, and quality of life [35]. However, little is currently known about the types of interactive functions in Chinese CVD apps and whether they might meet existing guidelines for promoting CVD self-management; even studies that have focused on Chinese CVD-related apps have not considered these characteristics [21,30].

In the present study, we assessed (1) the types of health information that Chinese CVD apps offer, (2) the quality of information available in the apps, and (3) the apps’ interactive functions for promoting CVD self-management.

Methods

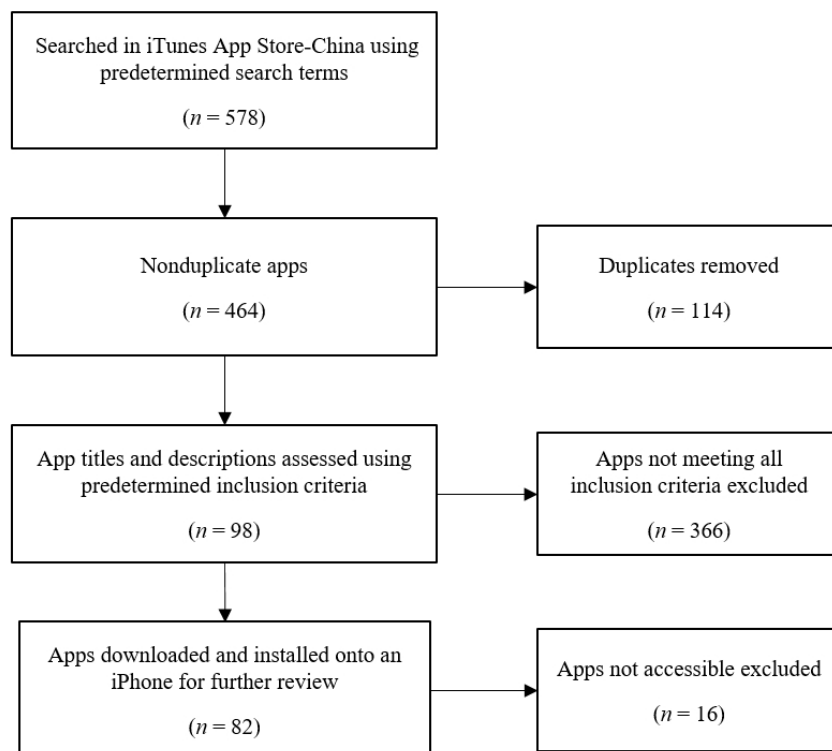
We selected the mobile apps for this study in multiple steps. First, in February 2017, we conducted searches on the Chinese website for the iTunes App Store, using predetermined search terms consistent with New York State Department of Health definitions of CVD [36] and based on our research team’s knowledge of the terms that Chinese people typically use when describing CVD-related conditions (one of our research team members, a surgeon, specializes in CVD-related conditions and has practiced in China for over 20 years). The use of lay people’s search terms enabled us to obtain the types of apps that people in China would typically find in their own searches (see [Textbox 1](#)).

The initial search yielded 578 results. After we removed duplicates, 464 apps remained. Next, we reviewed the titles and descriptions of the remaining apps in iTunes and included those that: (1) targeted Mainland China; (2) had full text in simplified Chinese characters (used in Mainland China); (3) targeted end users/patients/the general public; and (4) covered at least one CVD condition. Apps that did not meet all four of these criteria were excluded. A total of 98 apps remained in the review.

Finally, we downloaded (or attempted to download) each of the 98 apps to an iPhone for further examination. During this step, we found that 16 of the apps were not accessible or downloadable, so they too were excluded. The final sample consisted of 82 apps that could be downloaded and installed for further examination (see [Figure 1](#)).

Textbox 1. Chinese search terms used.

心脏病 (heart diseases)
 心脑血管 (cardiovascular diseases)
 中风 (stroke)
 卒中 (stroke)
 冠心病 (coronary artery disease)
 高血压 (high blood pressure)
 偏瘫 (paralysis)

Figure 1. App selection process.

After downloading and installing the 82 apps onto an iPhone to simulate Chinese end users' experiences, we used the HIW framework, the National Library of Medicine's (NLM's) guidelines, and our own self-management framework to systematically evaluate the apps' (1) information types, (2) information quality, and (3) interactive functions for self-management, respectively. One researcher (a trained graduate research assistant) first coded five apps using these frameworks. The coding results were verified by another researcher (a faculty member experienced with this type of research). Differences between these two researchers were resolved through discussions. The research assistant then completed the coding for all apps in the final sample, with the faculty member randomly verifying 10% of the results; differences were again resolved through discussions. The research assistant then revised relevant coding based on the discussions.

The Health Information Wants Framework for Evaluating the Types of Information

We adapted the HIW framework [37] to assess the types of health information provided in the apps. As stated in the introduction, this framework covers 7 types of health information commonly wanted by patients in health care encounters; based on the descriptions for each type and subtype from our earlier studies [9,37], we adapted items to apply to CVD specifically, when necessary (eg, *information about the type of diabetes* was changed to *information about the type of CVD*). The presence of each type of health information was recorded as 1, and each absence was recorded as 0 (scoring range: 0-7). The higher the score, the more types of information identified in the apps.

The National Library of Medicine Framework for Evaluating Quality of Information

Based on the NLM guidelines [38], we developed operational definitions to determine the quality of the apps' information. This framework includes 11 indicators of information quality;

the presence of each indicator was recorded as 1, and each absence was recorded as 0 (scoring range: 0-11). The higher the score, the higher the app's information quality (Table 1).

The Self-Management Framework for Evaluating Interactive App Functions

A major advantage of mobile apps is that they enable user input (eg, recording of physical activities) and interaction with others (eg, HCPs, families, and peers) that are key to effective self-management. Current app evaluation frameworks tend to focus on limited interactive functions. For instance, the Mobile Apps Review Scale [39] narrowly defines interactivity within the parameters of user input, feedback, and prompts, with no consideration of other important interactive functions (eg, virtual rewards, online-offline integration, family involvement). Hale et al [40] developed an evaluation framework to assess the congruency between apps' intervention strategies and user needs. However, their framework was designed to assess apps' topics (eg, healthy eating) and intervention strategies (eg, self-monitoring); it did not offer a systematic way to evaluate the scope of interactive app functions (the authors mention only briefly that self-monitoring, social support, modelling/vicarious learning, and stimulus control are highly interactive strategies that an app can adopt) [40].

Based on the literature on strategies for effective self-management of chronic conditions [4,6,7,9,10,41-43] as well as the aforementioned frameworks for evaluating mobile apps [39,40], we developed our 15-item Self-Management Framework for Evaluating Interactive App Functions (SFEIAF) to specifically assess interactive functions that are necessary for effective CVD self-management in CVD apps. We did not, however, include *providing information* as an app function in our SFEIAF, even though providing relevant information to ensure patient education is essential for effective self-management. This decision was based on two reasons: (1) the function of providing patient education information is already fully covered in our HIW framework, which focuses specifically on a broad range of health information; and (2) the typical approach to providing patient education information is top-down, such that information flows from the app developer to the user with no input from the user. In contrast, our SFEIAF emphasizes user input in information provision that is essential to effective self-management. The presence of each function in the SFEIAF was recorded as 1, and each absence was recorded as 0 (scoring range: 0-15). The higher the score, the more the interactive functions in an app (Table 2).

Table 1. National Library of Medicine guidelines for information quality and our operational definitions.

NLM guideline	Operational definitions
Providing information on who is in charge of the app	Provides information that could help users understand who is in charge of the app (eg, information about the app provider's name). Such information is typically found via the <i>About Us</i> button in the app and/or on the app's iTunes page.
Providing information about why the app is being provided	Provides information that could help users understand the app's purpose, intended users, and functionalities. Such information is typically found on the app's iTunes page and/or via the <i>About Us</i> button in the app (eg, indicating that the app is developed for CVD ^a patients, or to provide CVD-related information, or to provide one-on-one consultation with a CVD physician).
Providing the app provider's physical address	Provides information about the physical address of app developer or administrator.
Providing information on the source of the app's information	Provides information that could help users understand where the information used by the app came from (eg, an article or book with author names, or, for Web-based information, the website from which the information was retrieved).
Providing information on how the app's content was selected	Provides a logical explanation for how the app's information was selected (eg, information selected from peer-reviewed journals).
Having expert review of the information	Provides information to make clear that information presented in the app has been reviewed by qualified health care professionals.
Financial disclosure	Provides information on where the money to support an app comes from (eg, government agencies, non-profit organizations, drug companies). This information could help users understand whether the app's providers have financial motives that users should be aware of (eg, the sale of CVD drugs).
Content is up-to-date	The original NLM ^b guidelines did not specify what timeframe would be considered <i>up-to-date</i> ; in our study, we operationalized this indicator as app content updated in the past 3 months.
Does not have advertisements	Whether or not an app contains advertisements. Note: if a drug or treatment option mentioned in an app was a part of scientific results (eg, if reported in a research article) then it was <i>not</i> considered an advertisement.
Does not use unbelievable or emotional claims	Whether or not an app makes claims that are too good to be true, or are based on emotions instead of scientific facts (eg, "Lose 30 pounds in 2 weeks!").
Does not ask for personal information	Whether or not users must submit personal information (eg, name, phone number, email address) in order to use certain app functions.

^aCVD: cardiovascular disease.

^bNLM: National Library of Medicine.

Table 2. Interactive app functions in the Self-Management Framework for Evaluating Interactive App Functions and their operational definitions.

Interactive app function	Our operational definition
Monitoring of physical or health indicators	Functions that allow users to record and monitor their health or physical indicators (eg, body mass index, blood pressure)
Exercise and physical activity management	Functions that enable users to record and monitor their exercise and physical activities (eg, interactive pedometers)
Lifestyle management	Functions that enable users to record and monitor aspects of their lifestyles relevant to the prevention of, or coping with, CVD ^a (eg, monitoring of alcohol drinking)
Medication management	Functions that enable users to manage their medication (eg, when to take what medicine as prescribed)
Interaction with health care providers	Functions that enable the user to interact with HCPs ^b (eg, consultation via the app)
Condition management or prevention	Functions (other than medication management) that enable user input or interaction to control or prevent CVD (eg, hypertension self-detector)
Psychological health management	Functions that enable users to understand or manage their psychological health (eg, self-evaluation of psychological health)
Peer interaction	Functions that enable users to interact with other users with similar health conditions (eg, in-app peer support groups)
Family involvement	Functions that enable users to include family in their CVD self-management
Virtual rewards/gamification	Functions that provide motivational or gamification functions to encourage user commitment to their CVD self-management (eg, virtual rewards to encourage medication adherence)
Personal health records management	Functions that enable user input of their health-related data (eg, electronic health profiles)
Individualized care management	Functions that enable tailoring of prompts based on user input (eg, care recommendations tailored to users' specific health conditions)
Multiple platform care management	Functions that enable users to connect their CVD care concerns across multiple platforms (eg, short message reminders sent from the app to other apps or electronic services such as email)
Online-offline integration	Functions that enable users to connect and integrate their online and offline self-management activities (eg, connecting the app with a blood glucose device to manage one's blood sugar level)
Interaction with the app provider	Functions that enable users to communicate with, and receive feedback from, the app provider. Depending on the questions that users ask, this type of interaction could involve technical support (eg, questions about how to use the app) or medical issues (eg, CVD-specific questions).

^aCVD: cardiovascular disease.

^bHCPs: health care providers.

Results

Types of Information

Ten of the 82 (10/82, 12%) apps in our final sample received scores of zero, because they offered none of the 7 types of information in the HIW framework; 15 (15/82, 18%) received scores of 1-2 (ie, they offered 1 or 2 types of information); 27 (27/82, 33%) offered 3 or 4 types; and 30 (30/82, 37%) offered 5 or 6 types of information. No app offered all 7 types of information. Self-care was the most commonly offered type of information (67/82, 82%), followed by information about the specific health condition (63/82, 77%) and treatment (55/82, 67%); information about laboratory tests (5/82, 6%) was the least common (Table 3).

Quality of Information

Nineteen (19/82, 23%) of the apps received scores of 2-3 (ie, they met 2 or 3 NLM guidelines for information quality). Sixty-two (62/82, 75%) met 4-6 guidelines, and only one app

(1/82, 1%) met 8; no app met more than that. The most commonly-met NLM guidelines were those that addressed providing information about the apps' developers (82/82, 100%) and purpose (82/82, 100%). The least commonly-met guideline was that which addressed disclosing the app's source of financial support; none of the apps did this (Table 4).

Interactive App Functions for Self-Management

Nine (9/82, 11%) apps scored zero on the interactive app functions for self-management (ie, they offered none of the 15 interactive functions for CVD self-management specified in the SFEIAF). Twenty-nine apps (29/82, 35%) scored 1-3, offering 1-3 functions; 21 (21/82, 26%) offered 4-6, 12 (12/82, 15%) offered 7-9; 7 (7/82, 9%) offered 10-12; and only 4 (4/82, 5%) offered 13 functions. No app offered more than 13 functions. The most commonly offered interactive function was interaction with the app provider (57/82, 70%), and the least commonly offered was psychological health management (6/82, 7%; Table 5).

Table 3. Types of health information covered by Chinese CVD apps.

Type of health information	n (%)
Self-care	67 (82)
Health-condition specific	63 (77)
Treatment	55 (67)
Complementary and alternative medicine	34 (42)
Psychosocial aspects	29 (35)
Health care providers	22 (27)
Laboratory tests	5 (6)

Table 4. National Library of Medicine's information quality indicators covered by the apps.

Information quality indicator	n (%)
Provided information on who is in charge of the app	82 (100)
Provided information about why the app is being provided	82 (100)
Does not use unrealizable, emotional, or sensational language	67 (82)
Does not have advertisements	46 (56)
App content is up-to-date	35 (43)
Does not ask for personal information	30 (37)
Provided information on the source of the app's information	5 (6)
Provided the app provider's physical address	3 (4)
Expert review of the information selected in the app	3 (4)
Provided information on how the app's content was selected	1 (1)
Financial support disclosure	0 (0)

Table 5. Interactive app functions for self-management.

Interactive app function	n (%)
Interaction with the app provider	57 (70)
Interaction with health care providers	36 (44)
Online-offline integration	34 (42)
Multiple platform care management	33 (40)
Monitoring of physical or health indicator	28 (34)
Personal health records management	28 (34)
Condition management or prevention	27 (33)
Individualized care management	26 (32)
Family involvement ^a	20 (24)
Peer interaction	19 (23)
Virtual rewards/gamification	19 (23)
Medication management	18 (22)
Exercise and physical activity management	15 (18)
Lifestyle management	13 (16)
Psychological health management	6 (7)

^aFamily involvement included app features that enabled user-designated family members to access user information in the app and allowed app developers to directly send family members information (eg, general health education information related to users' health conditions, reminders of important things for users to do, and emergency alerts).

Table 6. App purposes.

Category	Definition	n (%) ^a
Health education	App has a function that aims to provide information and resources that could inform people about CVD ^b conditions	44 (64)
Self-management	App has a function that aims to help users' own monitoring and management of their health	36 (52)
CVD risk evaluation	App has a function that aims to provide a calculator for users to assess their odds of developing one or more CVD conditions	13 (19)
Interaction with health care providers	App has a function that aims to facilitate user-health care provider communications, including making appointments and having face-to-face or virtual one-on-one medical consultations	35 (51)
Interaction with peers	App has a function that aims to allow users to communicate and bond with other users with similar health conditions	9 (13)
Family involvement	App has a function that aims to involve users' family members in the care management process	12 (17)
Selling products and services	App has a function that aims to sell products (eg, medications) and services (eg, housekeeping services) to users	7 (10)

^aWe coded an app into multiple categories if it had multiple purposes, so the total percentage exceeds 100% (27 of the apps, or 39%, were coded as having a single purpose; the remaining 42 apps each had multiple purposes).

^bCVD: cardiovascular disease.

Follow-Up Analysis Results

In September 2017, following reviewers' feedback, we performed follow-up analyses on app purposes. The definitions and results are reported in Table 6. At this point, 13 of the 82 original apps were no longer available; thus, these analyses were based on a sample of 69 apps.

In October 2017, we further examined the types of providers in charge of the apps in our final sample. Of the 69 apps that we had examined in the previous month, only 59 were still available. Of these, 48 (48/59, 81%) were developed by for-profit companies (46 by information technology/software companies; 2 by pharmaceutical companies), and 11 (11/59, 19%) were developed by individuals with no clear connection to any organization. No app in this sample was developed by government agencies or nonprofit organizations. We also analyzed the type of CVD on which the apps focused: 20 (20/59, 34%) of the apps focused on general heart health monitoring/management; 17 (17/59, 29%) on hypertension; 9 (9/59, 15%) on stroke; 6 (6/59, 10%) on diabetes; 6 (6/59, 10%) on coronary heart disease; and 1 (1/59, 2%) on heart failure.

Discussion

Self-management is key to person-centered care, which acknowledges the importance of respecting people's health care preferences for types and amounts of health information and social interactions (eg, family involvement in care) in their own health or disease management [9-11,13]. Effective self-management requires the building of a safe and shared care environment that can meet people's information wants, their desires to make their own decisions, and their desires for high-quality health care and social interactions [14-16,25].

mHealth apps have the potential to assist self-management of many health conditions [17,18]. However, to ensure that mobile apps can adequately meet the wide range of users' information wants [9,12], needs for high-quality information and care access

[19,20], and self-management decision-making, evidence-based insights are needed to bridge current knowledge gaps [14,16,22]. Such insights could guide research and practice in China. In the Chinese health app market, the number of technology and health app users is growing exponentially [44,45], yet the quality of Chinese mHealth apps appears to be inferior to that of those in developed countries [27-29], and research on the current development of Chinese CVD apps has so far been limited [29,30].

In this study, we have systematically assessed (1) the types of health information that Chinese CVD apps offer, (2) the quality of health information available in the apps, and (3) the apps' interactive functions for promoting self-management. The results show that none of the reviewed apps offered all 7 types of information specified in the HIW framework, met all 11 NLM guidelines for information quality, or provided all 15 of the SFEIAF's interactive functions for promoting CVD self-management. Given that CVD self-management requires a variety of information [46], a lack of comprehensive information may hinder CVD self-management. For example, of all apps that were reviewed, only 5 offered information about laboratory tests, yet such information is crucial for patients [47].

None of the apps revealed sources of financial support or sponsorship, and very few revealed information about the selection of the apps' content, app providers' physical addresses, or the sources of the apps' content. Over 60% of the apps asked for users' personal information without a clear indication of how such information would be stored or used. Privacy concerns might affect app usage [48], so Chinese health app developers should integrate privacy protection measures into their future app designs. Overall, Chinese CVD apps fail to provide sufficient information for users to evaluate apps' information quality.

Nine of the CVD apps offered none of the 15 interactive functions for self-management. This finding is troublesome, because a major advantage of mHealth apps is their ability to

facilitate user input in managing their own health care [49,50]. This finding for Chinese apps, along with similar findings reported in studies of English-language mHealth apps [51,52], suggests that the same challenge exists across national/cultural boundaries. No app in our study offered more than 13 interactive functions for CVD self-management. Furthermore, although psychological health is closely associated with CVD conditions [53], only 7% (6/82) of the apps offered interactive functions that might facilitate self-management of psychological health. Given that individuals with CVD conditions or concerns may have to deal with comorbid psychological stress or other mental discomfort [54,55], it is important that this feature is addressed in future app design as well.

Facilitating family involvement is important in chronic disease self-management [56], especially in Chinese society, where the patient's family traditionally plays a major role [57]. In China, family involvement is often considered integral to, and indispensable for, individuals' health care [58,59]. A lack of functionality for family involvement might disconnect app users' online self-management from the offline family-centered management of their condition. However, only 24% of the apps in our study had functions that enabled family involvement. Future app development should strive to include functions for family involvement, and should investigate and compare the efficacy of different interactive functions for family involvement to provide more guidance for app development (some interactive functions might work better for some users and their families, whereas others might find other functions more useful).

Limitations and Future Directions

This was a cross-sectional study. Although this study is novel in that it provides, to our knowledge, the first systematic

evaluation of Chinese CVD apps' information types, information quality, and interactive functions, it does so for a snapshot of apps available when the search was performed. Future research could examine issues at multiple time points to reveal the evolution of app development. This study only examined apps developed for iOS users in Mainland China (due to limited resources, we focused only on iOS apps available in Apple's App Store); thus, the findings should not be generalized without caution. However, the overall findings of this study do resemble those reported in a Western context and across mobile platforms [25], suggesting that such problems may be common across different cultural/national and mobile platform contexts. Future research can apply the frameworks used in this study to examine apps in other national contexts to provide more systematic comparisons across the globe. It would also be desirable to secure research funding for researchers to purchase other types of mobile devices (eg, Android) to study mobile apps running on platforms other than iOS (it is certainly not ideal to rely completely on personal devices for data collection, as we did in this study).

Conclusions

Chinese CVD apps currently provide a limited range of high-quality information and lack sufficient interactive functions conducive to effective CVD self-management. Although family involvement in health care is expected in Chinese society, functionality for family involvement has not been adequately integrated into Chinese CVD apps. This study's findings call for the development of more evidence-based, user-centered mHealth apps, with further systematic examination and monitoring of the apps' abilities to provide a broad range of high-quality information and more interactive app functions to facilitate self-management of CVD.

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Conflicts of Interest

None declared.

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Abbreviations

CAM: complementary and alternative medicine

CVD: cardiovascular disease

eHealth: electronic health

HCP: health care provider

HIW: Health Information Wants

mHealth: mobile health

NLM: National Library of Medicine

SFEIAF: Self-Management Framework for Evaluating Interactive App Functions

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Original Paper

Mobile Health Intervention to Increase Oral Cancer Therapy Adherence in Patients With Chronic Myeloid Leukemia (The REMIND System): Clinical Feasibility and Acceptability Assessment

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Abstract

Background: Optimal dosing of oral tyrosine kinase inhibitor therapy is critical to treatment success and survival of patients with chronic myeloid leukemia (CML). Drug intolerance secondary to toxicities and nonadherence are significant factors in treatment failure.

Objective: The objective of this study was to develop and pilot-test the clinical feasibility and acceptability of a mobile health system (REMIND) to increase oral drug adherence and patient symptom self-management among people with CML (chronic phase).

Methods: A multifaceted intervention was iteratively developed using the intervention development framework by Schofield and Chambers, consisting of defining the patient problem and iteratively refining the intervention. The clinical feasibility and acceptability were examined via patient and intervention nurse interviews, which were audiotaped, transcribed, and deductively content analyzed.

Results: The intervention comprised 2 synergistically operating elements: (1) daily medication reminders and routine assessment of side effects with evidence-based self-care advice delivered in real time and (2) question prompt list (QPL) questions and routinely collected individual patient adherence and side effect profile data used to shape nurses' consultations, which employed motivational interviewing to support adoption of self-management behaviors. A total of 4 consultations and daily alerts and advice were delivered over 10 weeks. In total, 58% (10/17) of patients and 2 nurses participated in the pilot study. Patients reported several benefits of the intervention: help in establishing medication routines, resolution of symptom uncertainty, increased awareness of self-care, and informed decision making. Nurses also endorsed the intervention: it assisted in establishing pill-taking routines and patients developing effective solutions to adherence challenges.

Conclusions: The REMIND system with nurse support was usable and acceptable to both patients and nurses. It has the potential to improve adherence and side-effect management and should be further evaluated.

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KEYWORDS

mobile phone; neoplasms; Internet; medication adherence

Introduction

Chronic myeloid leukemia (CML) is an uncommon clonal bone marrow stem cell disorder. The disease has a triphasic natural history—commencing in chronic phase, unless well controlled, progressing to accelerated phase, and ultimately to blastic phase with over 90% of patients being diagnosed in the chronic phase [1]. Oral tyrosine kinase inhibitor (TKI) therapy is the standard of care for patients with chronic-phase CML. Imatinib, nilotinib, and dasatinib, currently first-line oral TKI therapies, are highly successful in improving progression-free and overall survival [2-4]. However, optimal adherence to TKIs is critical to treatment success and survival, with continuous, daily dosing required for an indefinite period, often lifelong [4,5], unless complete deep molecular response has been achieved when a treatment-free period can be tested [6,7].

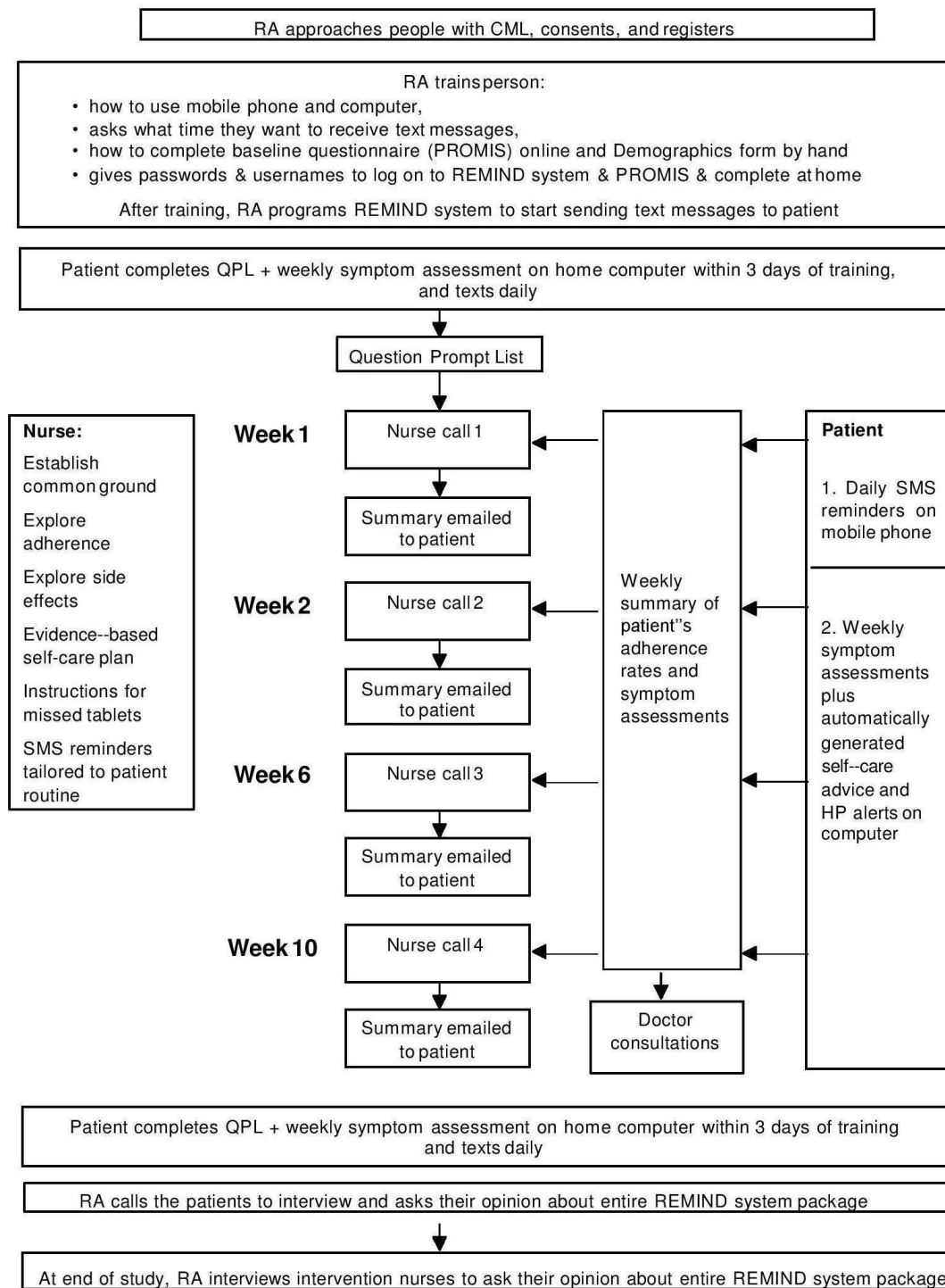
TKIs are associated with numerous potential toxicities, including myelosuppression, nausea, diarrhea, fatigue, and soft-tissue edema, especially in the face and lower legs [8-11]. Given these toxicities, it is not surprising that medication adherence is problematic; a recent review found that one-third to one-quarter of patients with CML have poor TKI adherence [12]. This is serious as treatment response is compromised for patients with less than 90% adherence [13,14]. Greater frequency of adverse events and higher levels of patient-reported symptoms predict lower levels of medication adherence [15,16]. Conversely, good knowledge of disease and treatment and confidence in medication self-management are linked to improved adherence [15,17], whereas forgetfulness is the most common reason for unintentional nonadherence [18]. These factors are potentially modifiable by educational and behavioral interventions. There is an urgent need to improve patient medication adherence among patients with CML [4,19,20].

Mobile health (mHealth), defined as employing mobile devices to support medical practice and public health, may improve TKI adherence using cellular phone apps and text messages.

Internationally, phone text interventions have been tested to prompt oral drug adherence in a number of chronic conditions, including human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) [21-27], diabetes mellitus [28-31], asthma [32], and tuberculosis [33,34]. Studies reported short- [21,23,24,28,29,32] and long-term [26,29] improvements in adherence, with patients generally perceiving text reminders as beneficial [21,22,27,33,34]. Reviews of phone text reminder interventions have demonstrated efficacy in enhancing patients' compliance to drug therapy [35-39]; however, only one study of cancer patients was identified, which was targeted at adolescents and young adults and phone text messages were not utilized [40]. A secondary in-depth analysis found no published trials that investigated a medication adherence intervention that integrates nurse-led phone consultations with mHealth systems in oncology [41].

Oncology nurses are central to providing education and coaching in patient self-management of drug toxicities and medication adherence [16,42,43]. Patient and clinician acceptability of nurse-led mHealth interventions aimed at improving postchemotherapy symptom management has been demonstrated in solid tumors [44,45]. We conceived a multifaceted intervention package consisting of 2 integrated elements delivered over 10 weeks: (1) the REMIND mHealth system comprising daily medication reminder texts and individualized self-care advice based on self-reported side effects delivered in real time and (2) nurse telephone consultations to promote adherence to imatinib (Gleevec) and coach patients in toxicity self-management (Figure 1). Briefly, after the patient was trained in using the REMIND system, he or she completed a Web-based symptom survey and question prompt list (QPL), which was used to guide the first nurse telephone consultation. Daily, the patient was asked to respond to a text reminder message for each dose based on his or her individual regimen. Once a week, a text message was sent to patients to remind them to complete an online symptom survey. For moderate to severe symptoms, self-care information was sent to the patient in real time.

Figure 1. Flowchart of the nurse-mediated telehealth (including REMIND system) intervention package (CML, chronic myeloid leukaemia; HP, health professional; QPL, question prompt list; RA, research assistant; SMS, short message service).



Adherence and symptom profiles were available for clinician review and used to guide 3 more nurse telephone consultation. The aim of this paper is to describe the development of this intervention and its clinical feasibility and acceptability. The study is reported in accordance with the CONSORT eHealth checklist (V1.6.1) [46].

Methods

Phase 1: Development of the Intervention

The framework for the development of effective, clinically feasible, and sustainable interventions by Schofield and Chambers was used to guide intervention development [47]. This intervention framework represents an expansion of the Medical Research Council (MRC) framework for complex interventions development [48]. The MRC framework provides

broad recommendations for intervention development, such as establishing the theoretical and evidence base and testing procedures. The intervention development framework by Schofield and Chambers specifies 7 features: (1) targeting cancer type and stage, (2) tailoring to unique individual needs, (3) promoting self-management, (4) efficient intervention delivery, (5) ensuring evidence-based and theoretical grounding, (6) specifying protocol training and adherence, and (7) confirming stakeholder acceptability.

The features of the framework by Schofield and Chambers [47] used to guide intervention development are described below.

Targeting

To understand the problem, a prior qualitative study by this team with 16 patients with CML prescribed a TKI and 10 health professionals was conducted to examine the nature, extent, and reasons for medication nonadherence [49]. Findings revealed that nonadherence was reported on at least one occasion among 75% of patients sampled with reasons for unintentional nonadherence including forgetfulness or misunderstanding medical instructions. Intentional nonadherence was related to side effects and insufficient health care support. Health professionals also experienced difficulty in accurately evaluating the medication adherence of their patients. These findings, in addition to those of others [17], indicate that intervention goals should be to increase depth of knowledge of disease, treatment regimen, and toxicities; increase confidence in self-management of side effects; and prompt TKI self-administration according to medical advice in relation to timing, dose, and frequency.

Tailoring

For the REMIND system, the timing of daily text-based medication reminders could be set to suit individual preferences. The evidence-based self-care advice was electronically delivered in real time, corresponding to the individual's responses to weekly self-assessment of side effects. The structure and content of the nurse consultations were directed by a QPL administered electronically to the patient just before the first nurse consultation.

Promoting Self-Management

Successful self-management requires the ability to self-assess problems; marshal information, skills, or resources to problem-solve; set goals; and implement the planned solution. Key to this is self-efficacy, which is defined as a person's beliefs in his or her ability to succeed in a given task. Although the REMIND system (medication reminders texts, side-effect assessment, and self-care advice) facilitated self-assessment of side effects and provided information and resources, coaching in self-management and behavior change was accomplished by the nurse-led phone consultations using motivational interviewing, which is a client-centered method that allows patients to explore and resolve their own ambivalence about adopting a new behavior, such as medication adherence, and to evoke self-motivation as opposed to traditional didactic health advice provision [50].

Efficiency

The combined delivery methods of this intervention were used to increase the efficiency of the intervention. Blending nurse phone consultations with the REMIND system increased the dose of the intervention, permitting the nurses to focus their expertise on coaching. Exclusive use of communication technologies for intervention delivery was intended to increase access to those living in rural communities or those who were too ill or had less time to attend face-to-face consultations.

Evidence and Theory

Both intervention content and delivery mechanism should be based on theory and available evidence. The list of relevant drug toxicities was generated using Monthly Index of Medical Specialties and expert clinician advice (JFS). Authors (PS and SA) updated their systematic review of self-care strategies for chemotherapy side effects [51] with additional literature searches to develop self-care recommendations for imatinib side effects in conjunction with an expert clinician (JFS). A consumer with CML (AD) iterative reviewed all content along with the multidisciplinary study team. Motivational interviewing, the central technique used the nurse delivery of content, arose from self-determination theory [52], which is a framework of intrinsic and extrinsic motives that facilitate or forestall behavior change. Motivational interviewing by telephone is significantly associated with improving medication adherence [53].

Protocolization

Interventions that layer digital technologies with targeted clinician contact rely on adequate training and supervision to ensure uniform delivery of content across intervention clinicians. Standardized manuals were developed specifying (1) the intervention content, including the resource manual describing the disease, treatments, side effects, and evidence-based, self-management advice; and (2) the training and supervision protocols. Protocolization of standardized content and training ensures a comprehensive knowledge base and attainment of core skills required by the intervention nurses and consistent, standardized, and reproducible delivery of the intervention content.

Stakeholder Acceptability

Using a codesign process involving the end users (clinicians and patients) throughout the development process optimizes stakeholder acceptability [54,55]. Our stakeholder qualitative research [49] directed the intervention goals and structure to ensure relevance. A clinical nurse specialist was engaged to write the nurse intervention manuals, detailing the content of each intervention session. A resource manual to support the provision of evidence-based advice was developed from booklets, fact sheets, and websites which were sourced from reputable peak cancer and other health bodies, in particular, the Leukaemia Foundation of Australia. The intervention development working party consisting of a consumer, hematologists, hematology nurse specialists, clinical psychologists, behavioral scientists, and an oncology pharmacist reviewed iterative revisions of intervention and resource manuals.

Phase 2: Pilot Testing

Setting

This study was conducted in a comprehensive cancer hospital in Melbourne, Australia.

Design

A qualitative research design was used to examine the clinical feasibility and acceptability of the intervention package to patients and nurses.

Participants

Participants were patients who received the intervention and nurses who delivered the intervention. Inclusion criteria for patients were as follows: age >18 years, proficiency in English, a confirmed diagnosis of chronic-phase CML with no signs of progression, and >3 months of continuous treatment with imatinib (Glivec) with no evidence of drug resistance. On the basis of feedback from the first 3 patients in this pilot testing phase, this last criterion was changed to treatment with imatinib and no evidence of drug resistance. Exclusion criteria were cognitive or psychological difficulties as assessed by the patient's treatment team and being too unwell. In total, 2 clinical nurse consultants with postgraduate qualifications in cancer nursing and extensive experience in hematological oncology were trained to deliver the intervention.

Nurse Training

The nurses were trained to deliver the structured telephone consultations and use the REMIND system in a 1-day workshop, facilitated by a clinical communication expert (PS). The workshop comprised an overview of the project and intervention manual and training in (1) identifying and responding to emotional cues on the phone, (2) exploring concerns about medication adherence and providing evidence-based self-care advice, and (3) coaching patients using motivational interviewing techniques. Didactic instruction was complemented by 2 role-play sessions with a simulated patient and facilitator feedback: 1 in the workshop and 1 in a subsequent phone consultation, which was audiorecorded for self-appraisal and facilitator feedback.

Procedure

Potentially eligible participants were identified by clinician referral or pharmacy records of imatinib dispensing and examined for eligibility as per the eligibility criteria by the research assistant. After confirming eligibility and suitability with the treating clinician, patients were approached either face-to-face at outpatient clinic visits or over the telephone. An appointment was made with interested participants to review and sign the consent form, complete a baseline questionnaire, and be trained to use the REMIND system. All patients then received the intervention over 10 weeks and at the end of the intervention, completed a follow-up questionnaire. The patient-reported outcomes in both questionnaires covered quality of life [56], psychological morbidity [57], and self-management [58].

Patient and Intervention Nurse Interviews

Following completion of the intervention, consenting patients and intervention nurses participated in a semi-structured telephone interview of 20 to 40 min. Separate interview schedules were developed for patients and health professionals. Both interview schedules covered perceptions of the intervention package, including content, timing, and perceived utility of each component of the REMIND system and the nurse consultations, perceived impact of the intervention on adherence and self-management, overall satisfaction with intervention, and recommended changes. All interviews were audiorecorded and transcribed verbatim.

A content analysis was undertaken to identify themes [59]; 2 investigators (APS and JW) analyzed intervention patient data and 2 investigators (PS and JW) analyzed nurse data separately. The process involved iterative movement between transcripts, rereading to establish familiarity with content and reflection of ideas. Similar content was collated and summarized to form themes with codes assigned by each analyst. Following analysis completion, all data analysts met to discuss results of their respective data. Disagreements between coders were identified and discussed until agreement was reached. Coding themes were then agreed upon, and the data from each group were coded into these themes. Themes were then collapsed or divided through consultation and discussion. As the interviews covered similar topics, perspectives of the 2 groups were aggregated. Survey outcomes were not analyzed due to sample size.

Results

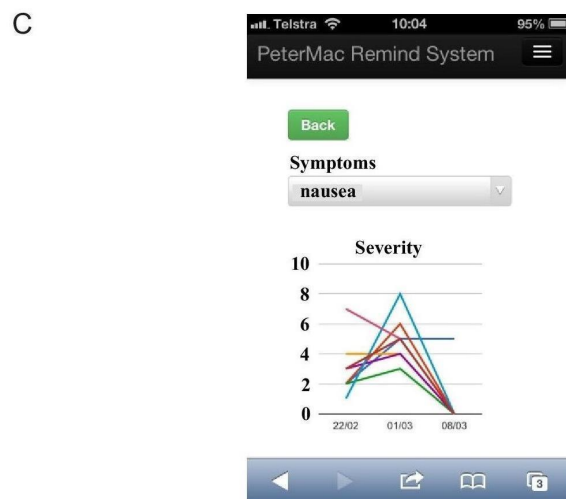
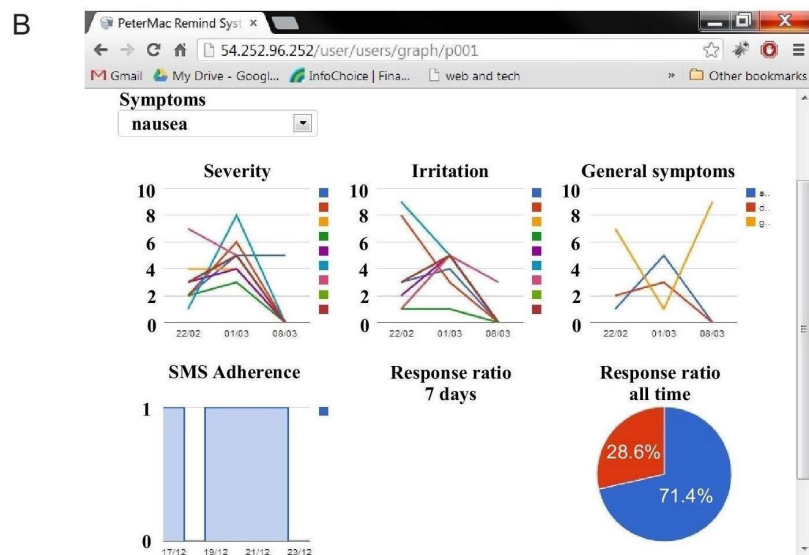
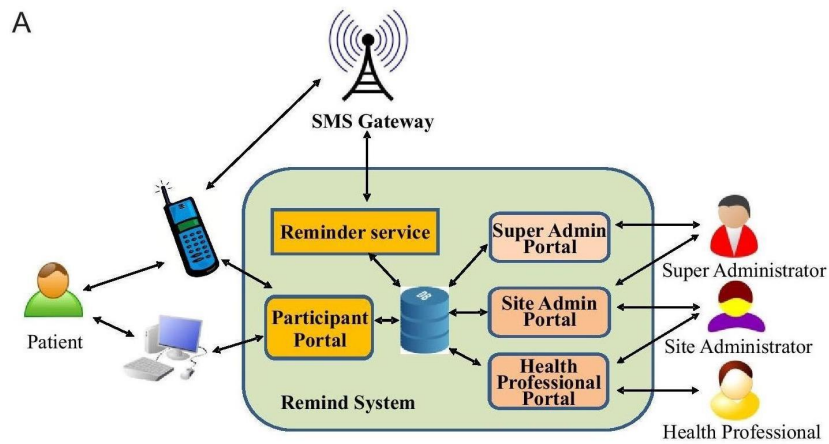
Phase 1: Development of the Intervention

The REMIND System

The REMIND system was a hosted Web application, deployed on the Amazon Web Services cloud platform as an EC2 instance, with multiple Web- and text-based interfaces provided for a variety of users and a range of services that control text messages sent to a third-party short message service (SMS) text messaging Gateway (Figure 2). It comprises the following:

1. A database of all user information, including patient and health professionals' log-in information; patient phone numbers and preferred notification time for medication reminders; and a log of all responses to daily reminders and answers to weekly survey questions
2. A Web-based application that allows patients and health professionals to view, and for health professionals to edit information regarding users, and patients to edit responses to reminders and symptom survey answers. The pages displayed by this application are designed for both laptop/desktop and mobile phone screens.
3. An automatic nightly service that pulls responses from the SMS Gateway, updates the database, creates SMS messages for the next day from information in the user database, and then forwards these messages to the SMS Gateway to be queued to be sent out at the preferred notification times. This program is sensitive to time zone and daylight saving and automatically adjusts the send-time of messages according to the local time of the patient's location.

Figure 2. REMIND system representation. (A) Architecture of the REMIND system showing context of interaction with different types of users (patients, health care professionals, and administrators) and external SMS Gateway service. The patient receives reminders on his or her cellular phone, sent from the SMS Gateway, and can interact with the weekly symptoms survey via a browser on a standard computer or a smartphone. (B) Screenshot of patient dashboard, showing graphs (from left to right) of scores (for severity and irritation) for symptom (in this case, nausea) over time, bar chart indicating daily adherence (measured by response), and pie chart showing overall adherence rate. (C) Screenshot of specific symptoms—severity graph for nausea—as displayed on the cellular smartphone interface.



Daily or twice-daily cellular phone reminder message were sent via the REMIND system to each patient for each dose based on patients' individual dosing regimen. Patients were asked to reply with a *Yes* message once the dose was taken or *No* if not taken. Adherence, patient compliance with imatinib, was considered to be a response of *Yes* received via a phone message from patients. If no reply was received within a designated time period (2 hours), this was interpreted as *No*.

Once a week, patients completed a side-effect assessment online via the REMIND system using a *smart* cellular phone or computer. For each of 11 potential side effects/symptoms patients may experience when taking imatinib, they reported severity and extent of bother on a scale of 1-10 for each side effect present. Automatically generated self-care advice was customized to the symptoms reported and sent to the patients in real time.

If 10% of scheduled doses in a week were missed or if side-effect severity was ≥ 4 , this was included on a *daily digest*, which was forwarded to the nurse assigned to that patient via email. The nurse could decide to contact the patient outside of the scheduled consultations to discuss self-management strategies or address medication adherence barrier(s).

Phone-Based Nurse Consultation Sessions (4 Sessions in Weeks 1, 2, 6, and 10)

In the week before the first nurse consultation, the patient reported medication adherence daily, completed the weekly medication side-effect assessment, and selected questions from the CML-specific QPL. QPLs are structured list of commonly

asked questions customized to disease type and have been found to improve clinician-patient communication and increase the amount of desired information received by patients [60]. The nurse accessed the REMIND system to view the patient's responses to shape content of the first nurse consultation session. It covered the following: (1) building rapport; (2) addressing questions noted on the QPL; (3) establishing *common ground* by assessing patients' understanding of their diagnosis, current symptom experience, and medication regimen; (4) discussing the patient's medication adherence and explored adherence barriers; (5) coaching to address barriers; (6) discussing medication side effects; (7) coaching in evidence-based self-care strategies targeting each reported side effect; and (8) summarizing the consultation and assessing patient understanding. The subsequent consultations used the REMIND system's patient-reported information to cover (4) to (8).

Phase 2: Pilot Testing

A total of 10 out of 17 patients agreed to participate, with a response rate of 58% (Figure 3). Of the participants, 9 completed all components of the intervention and 1 participant ceased before week 10 due to travel. Another participant was lost to follow-up. In total, 9 patients and 2 nurses completed interviews.

Participant demographics are described in Table 1. Median age of patient participants was 54 years, ranging from 35 to 72 years; the majority of participants, that is, 6 out of 9, were male (67%). The 9 patients who participated in the pilot testing had received imatinib therapy for a median of 4 years before the start of the study, with a range from 15 days to 12 years.

Figure 3. CONSORT flowchart of participants completing each intervention component and data collection point (RA refers to research assistant).

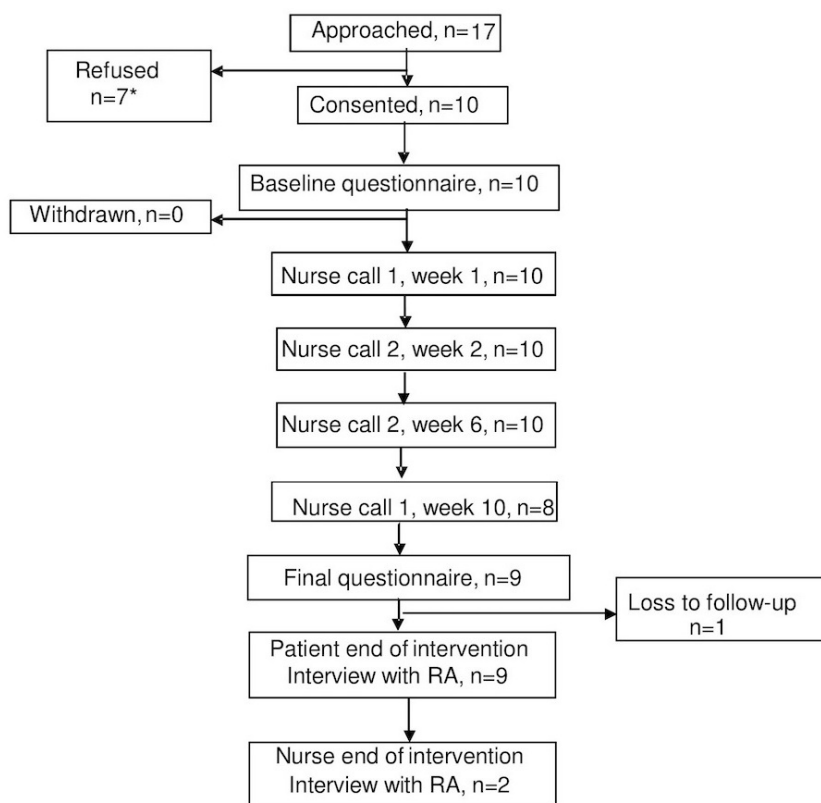


Table 1. Participant demographics.

Characteristics	Patients (N=9)
Age (years)	
Median (interquartile range)	54 (44.5-60.0)
Range	35-72
Sex, n (%)	
Male	6 (67)
Female	3 (33)
Country of birth, n (%)	
Australia	7 (78)
China	1 (11)
England	1 (11)
English as first language, n (%)	
Yes	8 (89)
No	1 (11)
Education (highest level completed), n (%)	
Secondary/high school	3 (33)
Trade/Technical and Further Education	1 (11)
Bachelor's degree	3 (33)
Postgrad diploma/masters/PhD	2 (22)
Time since diagnosis	
Median (interquartile range in years)	4 (1-13)
Range	1 month-17 years
Imatinib treatment duration ^a	
Median (interquartile range in months)	48 (16-123)
Range	15 days-12 years
Employment status, n (%)	
Full time	4 (44)
Part time	2 (22)
Home duties	1 (11)
Retired	2 (22)
Residence	
Metropolitan	4 (44)
Rural	5 (56)

^aDuration on imatinib at the start of REMIND study: Patient 2 (9 years), Patient 3 (5 years), Patient 4 (4 years), Patient 5 (2.5 years), Patient 6 (11.5 years), Patient 7 (1 year), Patient 8 (1.6 years), Patient 9 (12 years), Patient 10 (2 weeks).

The system administrator as detected by the REMIND system monitored adherence (Table 2). The SMSs were sent on time (<1 hour) to patients on 671 out of 684 (98.0%) occasions, with a range of 0-7% participants experiencing SMS failure and a range of 0-22% participants not replying to SMS messages at all, over the total study period. In total, 2 patients reported that

up to 40% of messages were not received by them by the appointed time due to problems with slow networks, particularly in rural areas.

A number of common themes were identified across the nurses and patients.

Table 2. System administrator details of SMS (short message service) texts sent and answered by patients.

Patient	Total days	SMS failure, n (%)	Patient failure to answer SMS when sent, n (%)	
			In 2 hours of SMS	Not at all
2	74	5 (7)	5 (7)	5 (7)
3	79	1 (1)	3 (4)	3 (4)
4	62	0 (0)	4 (7)	3 (5)
5	69	0 (0)	14 (20)	10 (15)
6	120	0 (0)	8 (7)	6 (5)
7	79	0 (0)	4 (5)	4 (5)
8	80	1 (1)	32 (41)	17 (22)
9	57	0 (0)	2 (4)	0 (0)
10	75	4 (5)	8 (11)	8 (11)

Accountability and Routine

Patients and nurses reported that they found the intervention acceptable and helpful for improving adherence through enabling patient accountability. A newly diagnosed patient stated:

...it definitely helped reinforce habit when I was at the start of getting on, getting this medication into routine. [PT10]

Longer-term patients with changed circumstances also benefited:

I've had overseas visitors for the last 2 weeks so I'm out of my usual routine...I'm sure I would have missed some of my drug taking...had I not had the reminders. [PT6]

A nurse spoke about the intervention for modifying adherence behavior:

...we discussed the barriers that she had to taking her tablet regularly. And then over time she softened and realized that she could develop strategies to overcome the problems... [N2]

Alleviating Psychological and Symptom Distress

Patients spoke about the benefits for alleviating psychological and symptom distress. The intervention was reported to be particularly useful for easing uncertainty about symptoms/side effects. One of the participants said:

It was good...if someone (nurse) noticed a change in symptoms I might not have picked up on it, and they were able to discuss it with me and find out why it might have happened. [PT3]

Patients felt reassured by the intervention:

...the good part...was the personal touch...it's just that really nice reminder that there's someone out there that's half looking out for you. [PT5]

Access to expert advice was also valued.

You do talk about things with your partner but you don't go down some of the tracks that you probably

would with a nurse...they prompt information out of you from their knowledge. [PT5]

Supporting Self-Efficacy

The intervention was identified as useful for uptake of self-management strategies and encouraging informed decision making. One patient commented:

Because I've been doing this, it makes me think about other things like diet. [PT2]

Another patient explained self-care options and informed choice:

...we did discuss that I could take Imodium (diarrhoea medication) or something like that if I wanted to but...I didn't want to take any more tablets...where I can't get to a toilet and if I did need, like a wedding, I'd take Imodium to make sure that I didn't have any accidents. [PT3]

Functionality of Intervention

Overall, patients found the REMIND system highly usable. Although a patient (PT6) described the process as "pretty straightforward," another mentioned:

I suppose the only bit I found a bit off-putting the most was the questions around depression and anxiety. [PT10]

Patients routinely had access to a cellular phone; however, one patient admitted that they:

...struggled with that [the 2 hour window to respond]. [PT 7]

Most patients found the system reliable and received the messages at the appointed time, but there were exceptions:

There were maybe three times that the computer system either didn't send a text or it was an hour or 2 late... [PT3]

A rural patient had ongoing problems as he had an unreliable telephone network, and reported as many as 40% of the text messages delayed by 30-45 min [PT10]. The 2 participating nurses differed in their opinion about the REMIND system: one found it easy but the other needed time to become familiar with it. Both nurses found the initial QPL useful, comprehensive,

and helpful in shaping the consultation content and facilitating rapport. The resource and intervention manuals supplied to the nurses were endorsed as comprehensive and very helpful, particularly the session checklist. Reorganization of the manual was suggested:

...I find these manuals just a bit fiddly to work around so that's why I've got like post it notes everywhere...it'd be good if there was tabs or something... [N1]

Training in motivational interviewing was perceived as beneficial:

I gained skills in the motivational interviewing techniques which I continue to use. [N2]

Both nurses felt that the timing and number of interview sessions were appropriate with no recommendations for alterations. Both suggested that daily digest (or summary) of patient adherence and symptom responses should be emailed less frequently than daily because it was “too much.”

Overall, 3 patients fell below 90% reported adherence levels. The protocol stated patients with adherence below 90% should have been contacted outside to the scheduled calls. However, both nurses expressed that they were in a quandary when patients did not SMS Yes, but relied on their experience and decided not to make extra contact. One of the nurses commented:

My personal experiences on the phone calls has been that patients report that they are adhering to their medications even if they're not responding to their SMS, so it's kind of a bit tricky...I guess it's a guide as to whether they're taking their tablet but it's not definitive... [N1]

Optimal Intervention Target Group

In terms of timing, most patients thought the intervention would be most beneficial at the start of therapy or, even at diagnosis:

...if they're just starting out on Glivec I reckon it would be invaluable. [PT2]

The newly diagnosed participant (PT10) commented that it was “good timing” for him. Nurses agreed suggesting:

...A lot of people said it would have been helpful when they were first diagnosed. [N1]

However, they also suggested that the intervention has broad applicability:

Not only in patients with CML but...there's a whole lot of new oral medications on the market now for a whole variety of cancers and conditions. [N1]

Discussion

Principal Findings: Intervention Development

The framework by Schofield and Chambers was successfully applied to the development process. Preliminary qualitative research [49] served to delineate the patient problem and aligned the intervention goals with patients' needs. Relevant evidence and theoretical perspectives were investigated through literature

reviews and combined with reputable patient education material to create appropriate evidence-based content and resources for the intervention. The automated features of the REMIND system permitted flexibility in intervention content and responsiveness to individualized concerns. Combining automated reminders, side-effect assessments, and self-care advice with personalized coaching fostered self-management. The *dose* of the intervention was maximized by using resource-intensive nursing expertise efficiently by basing the content of consultations on automated reminders and symptom assessments. While the standardized material supports reproducibility, the codesign processes promote acceptability. These approaches are consistent with the current literature that recognizes improved knowledge of disease course, medication, and management of side effects paired with expert clinician support as integral to improving medication adherence in patients with CML [15].

Principal Findings: Acceptability and Clinical Feasibility of Intervention

Pilot testing demonstrated that this intervention was able to be implemented and integrated into the clinical management of 10 patients with CML. It was highly acceptable to both patients and nurses. Most patients indicated that receiving and responding to the text reminders prompted medication adherence due to accountability. Nurses felt many long-term patients already had well-established routines. Although most patients agreed, those who changed their routine, for example, dining out, found the text reminder was useful to them. Nevertheless, both patients and nurses believed that this intervention would be most useful for patients at commencement of drug therapy. Patients found discussing their medication side effects with the nurse and receiving expert advice regarding self-management highly beneficial. Other benefits included increasing awareness of self-care, encouraging informed decision making and feeling reassured.

The usability of the intervention was high: most patients expressed ease with text reminders and the weekly symptoms survey. A small proportion of patients did experience difficulty either receiving or responding to the text within 2 hours either because they were not used to carrying a cellular phone or slow Internet speed. However, as the adoption of cellular phones/devices continues to rise and Internet speed and geographic coverage improve [61], this barrier is likely to diminish in future.

The nurses endorsed all facets of the system, including the administration website, QPL, resource and intervention manuals, session checklists, symptom surveys, automatically generated advice, and nurse phone consultations. They suggested improving the layout of the intervention manual and less frequently emailed daily digest (or summary) of patient adherence and symptom responses. One departure from the intervention protocol was nurses not calling patients when patients were less than 90% adherent. It is recommended that the application of the protocol is routinely monitored and departures are addressed through ongoing supervision and training. In particular, the importance of contacting patients who are less than 90% adherent immediately, not waiting until the next scheduled consultation, should be emphasized.

Supervision could include role playing these scenarios to increase the skills to deal with issue.

Limitations

The limitations of this study include a relatively small sample of nurses and patients used to pilot test this intervention. Given the sample size, it is unlikely that saturation was reached. As CML is a relatively rare disease, it proved difficult and time-consuming to achieve this modest sample size. Furthermore, most patients had been diagnosed years before the study, hence possibly had higher levels of medication adherence than those newly diagnosed. Future trials may need to explore a different cancer type to test the impact of this intervention upon oral medication adherence. As high-cost oral therapeutics in oncology continue to become more prevalent, it will be critical to ensure that adherence is high to deliver the anticipated survival outcomes to ensure that the health care expenditure is justified [4].

Comparison With Prior Work

Despite phone text reminder interventions for patients' with HIV [37], cardiac disease [35], and other chronic conditions [38] demonstrating improvements to medication adherence, not all studies included nurse or counselor supportive care in the intervention. In our study, an innovative medication intervention was developed and tested, which combined 2 features: (1) daily medication reminders and routine assessment of side effects with evidence-based self-care advice delivered in real time; and (2) QPL questions and routinely collected individual patient adherence and side-effect profile data used to shape nurses' consultations, which employed motivational interviewing to support adoption of self-management behaviors.

A secondary analysis [41] identified 2 randomized controlled trials of phone text reminder adherence interventions combined with counseling sessions, 1 study in patients with HIV [62,63] and the other in patients with diabetes, which has since been retracted. Qualitative findings indicated beneficial experiences where patients with HIV emphasized emotional and mental support from health care providers in addition to medical care [63]. A similar finding has been described in patients with tuberculosis who reported feeling cared for and thankful that health professionals were available to answer their questions while reminders instilled a sense of responsibility and personal accountability for their treatment [33]. Comparably, patients receiving phone symptom monitoring and nurse support while undergoing chemotherapy for cancer have reported feeling reassured [45]. Although previous studies have recognized text

reminders prompt adherence in the home environment as well as on vacation [21,34], some patients believed reminders may be more useful earlier in diagnosis before habits being formed [34]. Many of these sentiments were also expressed by patients in our study.

Patients in our study reported technological difficulties and an absence of cellular phones, whereas additional reasons for not responding have been reported in the literature. These include problems with cellular phones, out-of-phone credit, the phone being switched off, the phone's battery running out, and losing the cellular phone [25,33,63]. It will be difficult for health services to overcome these types of practical problems and they may have to be accepted as a limitation of this type of intervention.

Conclusions

This paper contributes to the evolving knowledge base of how to develop an evidence-based, acceptable, and potentially effective complex intervention. We have provided examples of strategies that may assist researchers and clinicians in developing or trying out a new psychoeducational intervention. These strategies can enhance intervention methodological rigor for testing in a randomized controlled trial through standardized intervention content and training; and implementation considerations such as improved clinical acceptability through the codesign process. To our knowledge, this is the first cancer medication adherence intervention that integrates a mHealth platform with tailored phone consultations based on patient-provided questions, adherence rates, and side-effect profiles provided by nurses trained in motivational interviewing. The intervention was clinically feasible. Patients and nurses endorsed this intervention as acceptable and useful particularly for a newly diagnosed patient. The next step will be to conduct an appropriately powered randomized controlled trial targeting a wider range of cancer diagnoses that are currently managed by oral therapeutics to ensure adequate recruitment and assess broader applicability. This future research will focus on patients at diagnosis and assess adherence with an electronic pill monitoring device to examine short- and long-term adherence. In addition, because chronic illnesses are more prevalent among older citizens, many people will have 2 or more comorbidities requiring self-management with oral medications. Future iterations of the REMIND platform should cater for multiple medications for multiple comorbidities. Health care resource utilization and sustainability of the intervention should also be considered by integrating an economic evaluation into the randomized controlled trial.

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Authors' Contributions

PS, JFS, PB, LC, AU, SA, SB, and SK designed and lead the research program. AD provided patient feedback on the intervention design and research procedures. AP-S, JW, LR, CV, BO, and KO carried out the research program. PS, JFS, PB, SA, SB, AU, AD, CV, SK, and BO developed the content of the intervention. AP-S, JW, and PS analyzed the data. LC and KO designed and built the Web-based platform. All authors contributed to the writing and/or critical revision of the paper.

Conflicts of Interest

Janssen employs PS as an ad hoc consultant on medication adherence.

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Abbreviations

AIDS: acquired immunodeficiency syndrome

CML: chronic myeloid leukemia

HIV: human immunodeficiency virus

mHealth: mobile health

MRC: Medical Research Council

QPL: question prompt list

TKI: tyrosine kinase inhibitor

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Viewpoint

Medication Adherence and Technology-Based Interventions for Adolescents With Chronic Health Conditions: A Few Key Considerations

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Abstract

The number of children and adolescents with chronic health conditions (CHCs) has doubled over the past two decades. Medication adherence is a key component of disease management within these groups. Low adherence to prescribed medications is a known problem in adolescents with CHCs and is related to health outcomes, including quality of life, disease complications, and mortality. Adolescence is a critical time to create routines and health behaviors that optimize disease self-management and transition to adult care. The mounting interest in the development and use of mobile health tools provides novel opportunities to connect patients, particularly adolescents, with their providers outside of the clinic and to improve health outcomes. There is growing evidence to support the efficacy of technology-based approaches, in particular text-messaging and mobile apps, to improve adherence behavior in adolescents, although cost-effectiveness and long-term health benefits remain unclear. In this short viewpoint article, we review some important considerations for promoting medication adherence in adolescents with CHCs using technology-based approaches.

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KEYWORDS

adolescents; adherence; compliance; technology interventions; mobile apps; text messaging

The number of children and adolescents with chronic health conditions (CHCs) continues to increase and has doubled over the past two decades, which represents an important public health concern [1]. Pediatric patients with CHCs, particularly adolescents, face challenges when trying to manage their illnesses and optimize their self-management skills. Adolescents with CHCs form a special subpopulation of pediatric patients (12-17 years old) learning how to self-manage medical decisions in preparation for an inevitable transition to adult care. Although the number of adolescents with CHCs is increasing, the number of validated self-reported scales for medication adherence that have been developed and tested specifically for adolescents is limited. Assessment of adolescent patients using parental proxy

reports is not ideal. The use of tools designed for (and validated in) adults may be problematic, given the unique physiological, developmental, psychosocial, and education/vocational considerations of adolescence.

Adolescence is a critical time to create routines and health behaviors that optimize disease self-management and preparation for a seamless transition to adult care. The involvement of adolescents with CHCs in their own care can be demanding for both families and health care professionals, although it is an important investment given the short-term and long-term gains [2]. Medication adherence is a key component of disease management and low adherence to prescribed

medications is a known problem in adolescents with CHCs, which is related to health outcomes, including quality of life, disease complications, and mortality [3]. Moreover, medication nonadherence has been associated with more frequent utilization of health services as well as higher health care expenses across pediatric CHCs [4]. Nevertheless, approaches to increase adherence to prescribed medications among adolescents with CHCs that are efficacious, practical, and cost-effective are lacking.

Taking daily medication(s) is a daunting task for many adolescents with CHCs, regardless of the prescribed regimen. Despite differences in disease-specific monitoring and treatment requirements among adolescents with CHCs, recent data suggest that barriers are similar across conditions [5]. Hanghoj and Boisen systematically reviewed data on perceived barriers from 2501 adolescents who had at least one of 14 chronic illnesses [5]. In order of frequency, the common barriers to medication adherence included: (1) aspects of physical well-being, such as side effects (including changes in physical appearance), reduction in symptoms/feeling well, and pill taste or swallowing problems; (2) forgetting to take medications, in part due to competing activities or changes in schedule; (3) desire to be normal and forget, ignore, or be free of their disease; and (4) lack of support from peers, parents, and health professionals. Therefore, the challenges that adolescents with CHCs need to overcome to optimize their medication adherence may be multi-faceted, but amenable to common adherence-enhancing interventions [5].

Clinics need information on evidence-based approaches to be able to implement these initiatives in the practice environment. Patient-centered and stakeholder-informed interventions developed with and for adolescents with CHCs are essential to improve adherence and enhance uptake, as well as engagement with interventions over time (particularly technology-based approaches). Access to personal technology, in particular smartphones, is becoming ubiquitous [6-8]. The mounting interest in the development and use of mobile health tools provides novel opportunities to connect patients with their providers outside of the clinic to improve health outcomes. Adolescents have adopted communication technology at a relatively fast pace, regardless of their socioeconomic status. A recent report indicates that most adolescents have widespread access to personal technology tools, including smartphones (73%), tablets (58%), desktop computers (87%), and/or laptop computers (81%) [6]. These findings suggest that technology-based interventions may present a unique

opportunity to improve medication adherence and enhance self-management skills in adolescents across CHCs.

The use of personal and widely available technology-based approaches (in particular text-messaging, mobile apps, and mobile social media) to improve adherence behavior and other health outcomes in adolescents has shown overall acceptability and feasibility, with modest evidence for efficacy [9-12]. Nevertheless, the long-term health benefits, cost-effectiveness, and sustainability of patient engagement through technology-based approaches remain unclear [13,14]. Additionally, text messaging delivery methods often lack innovative features targeted to adolescents. Furthermore, methods to quantify patient fatigue, which is assumed to occur among adults with frequent text messaging, and the sustainability of patient engagement may apply differently to adolescents, representing a challenge for researchers. Therefore, while the evidence to date is encouraging and promising, further study of technology-based interventions for adolescent self-management and medication adherence, with rigorous study designs and across a wide range of CHCs, are needed. Moreover, further research is needed to explore adolescents' insights into the role and the design of technology-based interventions in identifying facilitators or preferred strategies to improve medication adherence. The consistent use of reporting guidelines for technology-based interventions is also critical to support the evidence generated, and conclusions that can be drawn, from adherence intervention studies [15].

While research efforts continue to produce better evidence for these technologies to promote health outcomes among adolescents with CHCs, we encourage medical providers to begin a conversation with leadership within their provider group or hospital about the incorporation of mobile technology into the practice environment, and to ask patients about their use of mobile technology and apps to promote self-care.

In conclusion, the number of adolescents with chronic illnesses continues to increase. Medication nonadherence is a challenge in adolescents across chronic conditions. Adolescents are frequent users of technology and engaging adolescents with chronic illnesses in their self-management could be invaluable for improving long-term outcomes. The use of technology-based interventions to improve medication adherence has shown promising results, and seeking adolescents' perspectives could enhance uptake and long-term engagement, and minimize patient fatigue. Following guidelines for reporting results of technology-based interventions, and validating adolescent-specific adherence assessment instruments, would enhance further comparative research across studies.

Conflicts of Interest

None declared.

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Abbreviations

CHC: chronic health condition

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Original Paper

Health App Use Among US Mobile Phone Users: Analysis of Trends by Chronic Disease Status

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Abstract

Background: Mobile apps hold promise for serving as a lifestyle intervention in public health to promote wellness and attenuate chronic conditions, yet little is known about how individuals with chronic illness use or perceive mobile apps.

Objective: The objective of this study was to explore behaviors and perceptions about mobile phone-based apps for health among individuals with chronic conditions.

Methods: Data were collected from a national cross-sectional survey of 1604 mobile phone users in the United States that assessed mHealth use, beliefs, and preferences. This study examined health app use, reason for download, and perceived efficacy by chronic condition.

Results: Among participants, having between 1 and 5 apps was reported by 38.9% (314/807) of respondents without a condition and by 6.6% (24/364) of respondents with hypertension. Use of health apps was reported 2 times or more per day by 21.3% (172/807) of respondents without a condition, 2.7% (10/364) with hypertension, 13.1% (26/198) with obesity, 12.3% (20/163) with diabetes, 12.0% (32/267) with depression, and 16.6% (53/319) with high cholesterol. Results of the logistic regression did not indicate a significant difference in health app download between individuals with and without chronic conditions ($P > .05$). Compared with individuals with poor health, health app download was more likely among those with self-reported *very good health* (odds ratio [OR] 3.80, 95% CI 2.38-6.09, $P < .001$) and *excellent health* (OR 4.77, 95% CI 2.70-8.42, $P < .001$). Similarly, compared with individuals who report *never or rarely* engaging in physical activity, health app download was more likely among those who report exercise 1 day per week (OR 2.47, 95% CI 1.6-3.83, $P < .001$), 2 days per week (OR 4.77, 95% CI 3.27-6.94, $P < .001$), 3 to 4 days per week (OR 5.00, 95% CI 3.52-7.10, $P < .001$), and 5 to 7 days per week (OR 4.64, 95% CI 3.11-6.92, $P < .001$). All logistic regression results controlled for age, sex, and race or ethnicity.

Conclusions: Results from this study suggest that individuals with poor self-reported health and low rates of physical activity, arguably those who stand to benefit most from health apps, were least likely to report download and use these health tools.

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KEYWORDS

smartphone; telemedicine; chronic disease

Introduction

Health conditions, such as hypertension and obesity, are associated with lower quality of life and increased health care costs [1]. Individuals with chronic conditions are often burdened by complex treatment regimens [2-4], and poor adherence to treatment in chronically ill populations is common [3]. Evidence suggests that chronic illness is exacerbated by modifiable health and lifestyle factors such as sedentary behavior and unhealthy dietary habits [5-8]. Mobile technologies have been tailored to chronically ill populations [9,10], but little work has examined current preferences, attitudes, and use of mobile health in these groups.

These behavioral factors pose a significant challenge for effective chronic disease management. For instance, medication nonadherence is prevalent in populations with chronic conditions and is associated with increased risk for hospitalization and mortality [8]. Other modifiable factors, such as poor stress management, have also been linked to increased mortality risk in patients with chronic conditions [7]. Unfortunately, poor adherence to disease management increases risk for additional chronic diagnoses and is associated with higher health care costs. Specifically, per person health care costs increase from US \$211 in patients with a single chronic disease to US \$13,000 in patients with two or more chronic conditions [4]. Identifying methods for optimal disease management and health promotion among chronic disease populations is critical, and mobile health technologies may aid in these efforts.

Overall, mobile technology is increasingly prolific across the populations. Approximately two-thirds of adults in the United States own a mobile phone [10]. Mobile phones feature robust capacities such as Bluetooth, location sensing, and software apps [11]. These technologies can help users perform a variety of tasks such as tracking exercise and providing reminders to take a medication or to go for a walk [12,13]. A vast number of health-related apps are available to consumers; over 100,000 apps are currently available for assisting users in achieving diverse objectives, from quitting smoking to taking more steps [13]. A number of apps have been designed specifically for populations with chronic conditions. A review study found over 3500 apps designed for chronic conditions, with a majority of available apps tailored to assist patients with diabetes or depression [14].

Health apps are a promising future direction for chronic disease treatment and care [11,15,16]. For instance, mobile technologies have capabilities to nudge modifiable actions, such as medication adherence or making healthy lifestyle choices, and thus offer promise for assisting with treatment and care among individuals with chronic conditions [17,18]. The Centers for Disease Control and Prevention Healthy People 2020 goals include a call for technology to improve population health and disease management [19]. Despite the potential for health apps in management or treatment of chronic conditions, we know little about current health app use among individuals with these conditions. Research to date has examined the use and effects of health apps [20] as well as beliefs about health apps among healthy populations [21,22]. We know little, however, about

the beliefs individuals with chronic conditions hold regarding health apps, making this study novel in its approach.

The aim of this study was to examine beliefs related to perceived efficacy of health apps and current health app behaviors among individuals with and without chronic conditions in a national sample of mobile phone users. We utilized data collected in a previous study [20] among mobile phone and mobile health use broadly to answer this question. Results of this study on behaviors regarding health apps among individuals with and without chronic conditions outline a direction for future research and design on apps for chronic disease patients that are tailored to their unique behavior patterns among individuals with particular chronic conditions.

Methods

Sample and Procedures

This study utilizes data from a national cross-sectional sample of mobile phone users in the United States [20]. Data were collected in 2015 from a sample of 1604 adult respondents. Owning a mobile phone was an inclusion criterion for this study. To provide a national sample efficiently, Toluna, a survey management company, was contracted to deliver the survey. Toluna identified participants by emailing their existing panel of participants and then employing quota sampling to gather data from groups who are traditionally underrepresented in technology-related surveys. Sampling quotas set before data collection were as follows: 50% male and 50% female; 50% with high school or higher level of education; 60% earning less than US \$50,000 and 40% earning more than US \$50,000; and 30% white, 30% Latino or Hispanic, 30% black, and 10% Asian.

Items on health apps were developed for this study following standard item design techniques [23]. First, research assistants conducted Web-based queries to identify health app uses using search terms such as *uses* and *capabilities*. This generated a long list of potential health app uses and functions for these apps among users. Next, we met and devised a list of health apps they encountered in their social networks, or in their research or experience interacting with patients. Then, we organized responses thematically and deleted redundant inputs. The final list of items for this study, such as reasons for downloading or perceived efficacy of health apps, was identified and incorporated in this study.

The survey was pilot-tested with a sample of nonresearch team members using cognitive interviewing techniques to ensure the survey was clear and the items were easy to understand. Before taking the online questionnaire, participants provided their consent to participate in the study. The survey took on average 9 min to complete. This study was approved by the New York University School of Medicine Institutional Review Board (IRB #14-02046). As this research included surveys with human subjects, participants' consent for participation was obtained before any data capture activities. A copy of the consent form may be provided upon request. Data are retained by the corresponding author. Any individuals interested in obtaining a copy of the dataset will be addressed promptly.

Measures

The survey consisted of 36 questions, assessing demographics (age, gender, race, income, and education), health (chronic condition diagnoses, self-rated health, and physical activity), reasons for downloading and not downloading health apps, frequency of using health apps, and perceived efficacy of health apps.

Participants were first asked “Have you ever downloaded an ‘app’ to track anything relating to your health?” Participants who reported health app download were prompted with several follow-up questions about reasons for download (eg, “To track what I eat” and “Help with weight loss”). Overall use of health app use was measured by asking participants how frequently they use health apps, both frequency of each session (response options ranged from “less than once a month” to “2 or more times per day”) and duration of each session (response options ranged from “1-10 minutes” to “more than 30 minutes”). Participants who reported using a health app were asked to report perceived efficacy of health apps (on a scale from “made my health worse” to “very much improved my health”). Chronic condition diagnoses were collected via self-report. Chronic illnesses were selected if prevalence was at least 5% in this sample (eg, hypertension, obesity, diabetes, depression, and high blood cholesterol). Chronic conditions comprising less than 5% on the sample included cancer (n=64, 4%), chronic obstructive pulmonary disease (n=62, 4%), heart attack (n=51, 3%), stroke (n=51, 3%), substance abuse (n=45, 3%), ulcers (n=38, 3%), liver disease (n=17, 1%), and human immunodeficiency virus (n=10, 1%).

Statistical Methods

Differences in response between the conditions (no chronic condition, hypertension, obesity, diabetes, depression, and high blood cholesterol) were examined by demographic factors (age, race, education, sex, self-rated health, and physical activity). As discussed, chronic illnesses were selected if prevalence was at least 5% in the sample (eg, hypertension, obesity, diabetes, depression, and high blood cholesterol).

Differences in responses to frequency of health app use, perceived app efficacy, and reasons for download were also examined by condition. Finally, logistic regression was performed utilizing the generalized linear model technique. Health app download was examined with chronic condition, self-reported health, and physical activity. In the case of health conditions, a variable was created that was coded to indicate condition (eg, no condition, hypertension, obesity, diabetes, depression, and high cholesterol) to allow for analyses between conditions. Consistent with previous literature [24], age, sex,

and race or ethnicity were included in the models as covariates. We analyzed the data using SPSS version 22 (Armonk, New York).

Results

Sample Characteristics

A total of 7189 people visited the survey page, 6871 (95.61%) agreed to participate in the survey, 2089 (29.04%) completed the survey, and 485 (6.75%) were randomly removed because of overfilling of sociodemographic quotas. Table 1 displays demographic characteristics of the sample. Overall, 49.56% (795/1604) of the study sample was female, with a mean age of 40.1 (SD 15.8) years. Among the participants, 35.47% (569/1604) were white. Among participants, 37.59% (603/1604) reported *very good* to general health and 13.52% (217/1604) reported *excellent*. Regarding physical activity, the majority of individuals reported being active *3-4 days per week* (35.09%, 563/1604).

Of the 1604 individuals in the study, the most prevalent chronic conditions included hypertension (n=364, 22.69%), obesity (n=198, 12.34%), diabetes (n=163, 10.16%), depression (n=267, 16.64%), and high cholesterol (n=319, 19.89%).

Mobile Health App Use, Frequency, and Perceived Efficacy by Chronic Condition

Table 2 displays differences by condition for number of health apps and frequency of use. Regarding the number of apps, *1-5 apps* was reported by 38.9% (314/807) of individuals with no conditions, 6.6% (24/364) with hypertension, 15.0% (34/163) with diabetes, 7.6% (16/198) with obesity, 25.8% (69/267) with depression, and 27.6% (88/319) with high cholesterol. In addition, reason for health app download varied significantly for *help me watch/improve what I eat* ($P=.00$), *weight loss* ($P=.01$), *track a health measure* ($P=.04$), and *help me relax* ($P=.01$) by chronic condition.

Examining Mobile Health App Characteristics by Chronic Condition

Among individuals with no chronic conditions, 66.0% (533/807) reported health app download. Of the individuals with one chronic condition, 53.4% (189/352) reported health app download, whereas just less than half (47.0%, 211/449) of individuals with a chronic condition reported health app download. Significant differences in app download were found by condition ($\chi^2=44.3$, $P=.003$) and examined using logistic regression models. See Table 3.

Table 1. Demographic characteristics of mobile phone users in the United States by chronic condition (N=1604).

Variable	No condition (n=807)	Hypertension (n=364)	Obesity (n=198)	Diabetes (n=163)	Depression (n=267)	High cholesterol (n=319)	P value
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Age ^a	33.8 (12.8)	40.1 (15.8)	33.8 (16.5)	41.4 (16.5)	50.6 (16.1)	38.6 (15.9)	<.001
Sex							<.001
Male	399 (49.4)	193 (53.0)	71 (35.8)	84 (51.5)	91 (34.1)	203 (63.6)	
Female	408 (50.6)	170 (46.7)	125 (63.1)	79 (48.5)	176 (65.9)	116 (36.4)	
Education							<.001
Less than 12th grade	43 (5.3)	17 (4.7)	9 (4.5)	7 (4.3)	20 (7.5)	12 (3.8)	
High school or General Equivalency Degree	388 (48.1)	142 (39.0)	73 (36.8)	61 (37.4)	120 (44.9)	115 (36.1)	
Some college	176 (21.8)	110 (30.2)	66 (33.3)	41 (25.2)	75 (28.1)	91 (28.5)	
Bachelor's degree	148 (18.3)	61 (16.7)	35 (17.6)	40 (24.5)	38 (14.2)	66 (20.7)	
Graduate degree	52 (6.4)	34 (9.3)	15 (7.6)	14 (8.6)	14 (5.2)	35 (11.0)	
Race or ethnicity							<.001
African American/black	219 (27.1)	111 (30.5)	58 (29.3)	43 (26.4)	61 (22.8)	54 (16.9)	
Asian	70 (8.7)	15 (4.12)	10 (5.1)	10 (6.1)	9 (3.3)	15 (4.7)	
White	199 (24.6)	175 (48.1)	77 (38.9)	65 (39.8)	125 (46.8)	173 (54.2)	
Native American	6 (0.7)	2 (0.5)	2 (1.0)	1 (0.6)	4 (1.5)	3 (0.94)	
Latino/Hispanic	279 (34.6)	56 (15.4)	48 (24.2)	44 (26.9)	62 (23.2)	65 (20.4)	
Other	34 (4.2)	5 (1.4)	3 (1.5)	0 (0.0)	6 (2.3)	9 (2.8)	
Self-reported health							<.001
Poor	9 (1.1)	5 (1.4)	1 (0.5)	7 (4.3)	21 (7.8)	5 (1.6)	
Fair	44 (5.5)	17 (4.7)	7 (3.5)	46 (28.2)	79 (29.6)	17 (5.3)	
Average	254 (31.5)	26 (7.1)	20 (10.1)	80 (49.1)	118 (44.2)	26 (8.2)	
Very good	417 (51.7)	24 (6.6)	23 (11.6)	33 (20.3)	73 (27.3)	24 (7.5)	
Excellent	155 (19.2)	7 (1.9)	6 (3.0)	17 (10.4)	28 (10.5)	7 (2.19)	
Physical activity							<.001
Never	115 (14.3)	21 (5.8)	14 (7.1)	5 (3.1)	38 (14.2)	70 (21.9)	
1 day	86 (10.6)	7 (1.9)	10 (5.1)	1 (0.)	26 (9.74)	38 (11.9)	
2 days	198 (24.5)	17 (4.7)	22 (11.1)	13 (7.9)	40 (15.0)	58 (18.1)	
3-4 days	340 (42.1)	28 (7.7)	25 (12.6)	24 (14.7)	48 (18.0)	98 (30.7)	
5-7 days	140 (17.3)	14 (3.8)	8 (4.0)	14 (8.6)	31 (11.6)	55 (17.2)	

^aRepresents mean and standard deviation.

Table 2. Responses to health app use, frequency, and perceived efficacy by chronic condition (N=1604).

Variable	No condition n (%)	Hypertension n (%)	Obesity n (%)	Diabetes n (%)	Depression n (%)	High cholesterol n (%)	P value
Number of health apps							<.001
1-5 apps	314 (38.9)	24 (6.6)	34 (17.2)	16 (9.8)	69 (25.8)	88 (27.6)	
6-10 apps	55(6.8)	2(0.5)	12 (6.1)	2 (1.0)	15 (5.6)	18 (5.6)	
11-15 apps	52 (6.4)	2 (0.5)	1 (0.5)	2 (1.2)	6 (2.2)	4 (1.3)	
16-20 apps	77 (9.5)	4 (1.1)	1 (0.5)	2 (1.2)	4 (1.5)	5 (1.6)	
Frequency of health app use							.001
Less than once a month	32 (4.0)	0 (0.0)	3 (1.5)	0 (0.0)	15 (5.6)	9 (2.8)	
A few times a month	34 (4.2)	6 (1.60)	4 (2.0)	0 (0.0)	8 (3.0)	16 (5.0)	
A few times each week	119 (14.70)	7 (1.9)	10 (5.1)	5 (3.1)	21 (7.9)	33 (10.3)	
About 1 time each day	211 (26.1)	10 (2.7)	11 (5.6)	5 (3.1)	28 (10.5)	34 (10.7)	
2 or more times a day	172 (21.3)	10 (2.7)	26 (13.1)	20 (12.3)	32 (12.0)	53 (16.6)	
Duration of health app use							.17
1-10 min	312 (38.7)	78 (21.4)	52 (26.3)	33 (20.2)	77 (28.8)	66 (20.7)	
11-30 min	339 (42.0)	50 (13.7)	47 (23.7)	32 (19.6)	48 (18.0)	55 (17.2)	
More than 30 min	72 (8.9)	27 (7.4)	20 (10.1)	20 (12.3)	25 (9.4)	24 (7.5)	
Perceived efficacy of health apps							.13
Made my health worse	20 (2.5)	2 (0.5)	2 (1.0)	2 (1.2)	1 (0.4)	3 (0.9)	
Did not help at all	51 (6.3)	15 (4.1)	15 (7.6)	14 (8.6)	9 (3.4)	6 (1.9)	
Just a little improved	164 (20.3)	47 (12.9)	43 (21.7)	43 (26.4)	25 (9.4)	21 (6.6)	
Somewhat	237 (29.4)	47 (12.9)	38 (19.2)	45 (27.6)	43 (16.1)	24 (7.5)	
Very much improved	215 (26.6)	44(12.1)	47 (23.7)	46 (28.2)	41 (15.4)	31 (9.7)	
Reason for health app download							
Track activity or exercise I get	370 (45.8)	97 (26.6)	77 (38.9)	53 (32.5)	82 (30.7)	92 (28.8)	.06
Help me watch/improve what I eat	335 (41.5)	85 (23.4)	76 (38.4)	52 (31.9)	90 (33.7)	72 (22.6)	.00
Weight loss	333 (41.3)	77 (21.2)	80 (40.4)	49 (30.1)	86 (32.2)	66 (20.7)	.01
Track a health measure	189 (23.4)	60 (16.5)	38 (19.2)	42 (25.8)	50 (18.7)	54 (16.9)	.04
Help me relax	143 (17.7)	3 (0.8)	8 (4.0)	6 (3.7)	17 (6.4)	33 (10.3)	.01

Table 3. Health app download, self-reported health, and physical activity by chronic condition (N=1604).

Variable	Unadjusted models		Adjusted models ^a	
	Odds ratio (95% CI)	P value	Odds ratio (95% CI)	P value
Chronic conditions				
No chronic condition	Reference		Reference	
Hypertension	0.34 (0.21-0.53)	<.001	0.74 (0.45-1.22)	.24
Obesity	1.18 (0.72-1.94)	.51	1.63 (0.96-2.77)	.07
Diabetes	0.61 (0.36-1.04)	.07	1.24 (0.69-2.24)	.47
Depression	0.72 (0.52-1.00)	.05	0.91 (0.64-1.28)	.58
High cholesterol	0.46 (0.35-0.59)	<.001	1.00 (0.73-1.37)	.99
Self-reported health				
Poor health	Reference		Reference	
Fair health	1.07 (0.69-1.66)	.76	1.30 (0.82-2.07)	.27
Good health	1.29 (0.86-1.94)	.23	1.55 (1.00-2.40)	.05
Very good health	3.28 (2.12-5.06)	.000	3.80 (2.38-6.09)	.000
Excellent health	5.36 (3.14-9.14)	.000	4.77 (2.70-8.42)	.000
Physical activity				
Never	Reference		Reference	
1 day per week	3.08 (2.05-4.64)	.000	2.47 (1.60-3.83)	.000
2 days per week	5.38 (3.78-7.66)	.000	4.77 (3.27-6.94)	.000
3-4 days per week	6.15 (4.43-8.54)	.000	5.00 (3.52-7.10)	.000
5-7 days per week	5.13 (3.53-7.45)	.000	4.64 (3.11-6.92)	.000

^aModel adjusted for age, sex, race or ethnicity.

In unadjusted models, individuals who were less likely to report health app download included those with hypertension ($P<.001$), depression ($P<.05$), and high cholesterol ($P<.001$). No chronic conditions were significant predictors of health app download after adjusting for covariates (age, sex, and race or ethnicity). However, *very good* ($P<.001$) and *excellent* ($P<.001$) self-reported health were strong predictors of health app download in adjusted models and in models adjusting for covariates. These findings were consistent in adjusted models. Similarly, individuals reporting 1 day or more of physical activity were significantly more likely to report health app download compared with those who reported *never* for physical activity ($P<.001$).

Discussion

Principal Findings

Health apps and other mobile technologies hold promise as tools for health promotion among healthy individuals as well as those with chronic illness [13]. Over 3000 apps exist that are targeted to chronically ill populations [18]. Although the majority of research has examined effects of apps tailored to assist individuals with chronic illness [14], little attention has been paid to health app use between individuals with poor general health and/or chronic illness. Our study recruited a sample of mobile phone users throughout the United States, as well as a large proportion of minority participants to compare beliefs and

attitudes, as well as use of health apps, between individuals with no chronic illness and those with specific diagnoses.

Previous research has examined motivation to download health apps among healthy populations, including college students and adults. In the study conducted by Kwon and colleagues, mobile health app use was associated with perceived efficacy of apps [21]. In two studies examining health app use among healthy adults, one found that health app use was associated with perceived usefulness of apps [22], and another study found that high perceived cost was a deterrent to health app download but health app use was overall quite high among the population [20]. The published literature on health app use and download has thus largely emphasized trends, use, and beliefs about health apps among general, and largely healthy, populations, with little attention to health app use between individuals with poor health and chronic illness.

Our study provides a meaningful contribution to the literature, in examining beliefs about health apps among those with good health indicators as well as poor health indicators. Our study found that approximately one-third of individuals across each chronic illness agreed that health apps have the ability to dramatically improve health. Although it is promising that one-third of people with chronic conditions report belief in health app efficacy, it remains that only a minority of at-risk populations would be likely to use health apps to improve their conditions and that most either do not know they exist or believe

that apps could be helpful. Interest in and use of these apps will likely remain low and that motivating download of these resources among high-risk populations remains a critical challenge for the field.

Among research on health apps with chronically ill populations, another area of emphasis has been designing apps tailored to chronically ill patients. For instance, research has developed apps for assisting with specific disease management functions, such as improving medication adherence [16,18], and also for promoting healthy lifestyle choices among these populations [18]. According to our findings, although slight variations between conditions were identified, the most common reasons for health app download among individuals with chronic illness had to do with healthy lifestyle behaviors, such as tracking exercise, improving nutrition, and assisting with weight loss. The nuance in responses between conditions could in part be explained by different treatments for each condition. For instance, just over one-third of individuals with obesity reported most use of health apps for exercise tracking, as this is consistent with treatment for their condition, yet depression management would not necessarily require regular tracking; thus, less than one-third reported use of health apps for this function. However, hypertension and cholesterol are conditions that are largely dependent on exercise and nutrition but fewer reported use of health apps for these functions, suggesting differences in characteristics of the apps they are using or less adherence in modifying these behaviors. It is interesting to note that these were also the most common uses of health apps among populations without chronic illness.

Our results meaningfully extend the literature on health apps in several ways. Interestingly, our results found no significant difference in likelihood of health app download between individuals with and without chronic illness. That is, individuals with health apps were not more likely to have chronic health conditions than those without health apps. This could be due to the fact that use of health apps reported by participants in this study was actually quite high among those with and without chronic illness. In addition, individuals with chronic illness represented less than half of our sample. Nevertheless, we found individuals with *very good* and *excellent* self-reported health to be more likely to report health app download than individuals with *poor* self-reported health. We also found individuals with any report of regular physical activity (from *1 day per week* to *5-7 days per week*) to be more likely to report health app download than individuals without physical activity habits.

Our study extends the literature and our understanding of health app use and beliefs about these tools by comparing responses from individuals with markers of good health and those with markers of poor general health. Taken together, our findings suggest preliminary evidence that individuals who are using health apps may be those already engaging in healthy lifestyle behaviors. There may be an opportunity to better market health apps toward chronically ill populations, or design tailored apps specifically for these groups.

Limitations

Despite strengths, this study was not without limitations. The primary limitation is the cross-sectional survey. In addition, our

sample was skewed toward younger populations, and a more generalized sample across age would likely have yielded different results as patterns of use and preference are likely to be different in older populations. One example of sampling bias is the low prevalence of participants with a history of cancer (<5%), whereas the lifetime risk of developing cancer is about 40% for men and women. Sampling a more diverse or broad sample may have achieved different findings. It should also be noted that individuals without chronic illness represented a large portion of the sample (n=807). Additionally, the study surveyed a general population rather than those known to be medically ill. Hospital- or clinic-based populations that regularly receive health care may differ in their behaviors and current uses of health apps. Furthermore, the groups of comorbidity were heterogeneous, presenting a limitation in the ability of the findings identified here to apply to all individuals with comorbidity. Opinions of health app use could change over time, and although we used a validated instrument to assess chronic medical conditions, it nevertheless relied on self-reported data. Furthermore, the potential uses of mobile health and medical apps are nuanced and varied in nature. It would be challenging to capture the numerous and varied uses and types of apps. The results of this study are limited and may not capture all potential uses of apps or types of apps for health or disease management. It should be noted that the authors measured health app *download* and app use *frequency* in the survey. The authors chose the terminology *download* to align closely with the actual behavior being conducted (downloading a health app) and then assessed frequency to understand how often respondents engage with health apps.

Future Research

Our study extends the literature and our understanding of health app use and beliefs about these tools by comparing responses from individuals with markers of good health and those with markers of poor general health. Our findings illuminate not only behavioral patterns of healthy individuals but also those of individuals with poor general health indicators (eg, low self-rated health). We also found lower download among individuals who may need these interventions the most. The results of this study suggest high use of health apps among individuals with high self-rated health and physical activity.

The study illuminates future research on public health interventions to promote mobile health uptake among individuals with chronic conditions. Future interventions may consider how best to tailor health apps toward individuals with specific conditions and the needs of those conditions (eg, weight management among individuals with obesity) or identify ways to better communicate health apps and their benefits to those with chronic illness. More trials and well-designed studies can help provide data regarding efficacy of specific health apps to change the cost-value perception among both patients with chronic conditions and health care providers. Furthermore, designing targeted interventions may be a strategy for easing the burden of complex treatment regimens and promoting health in populations with chronic conditions.

Conclusions

Mobile technology is increasingly low cost and well suited for population health. Although there is interest in applying mobile technology to health and particularly to disease management, little attention has been paid to current use in populations with chronic health conditions. Our study found no difference in health app use between healthy and chronically ill populations, but we did find self-reported health and physical activity to be

the strongest predictors of health app use. Our study also found approximately one-third of individuals with chronic illness reported beliefs that health apps have potential to improve health, suggesting these tools could be better marketed toward individuals with chronic illness. Results have direct application for health communication and intervention to promote population health and assist individuals with chronic disease management.

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Authors' Contributions

RR analyzed data and drafted the Introduction, Methods, and Discussion. RJ analyzed data and drafted the manuscript. PK developed the analysis plan and collected the data. GJL drafted the Conclusions. DD developed the analysis plan and collected the data. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

OR: odds ratio

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Original Paper

Connected Health Devices for Health Care in French General Medicine Practice: Cross-Sectional Study

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Abstract

Background: The integration of Connected Health Devices (CHDs) is growing within mobile health (mHealth) and telemedicine, encouraged by institutions and industries. The idea is to improve lifestyle habits and health behaviors as a preventive goal in an aging population with fewer physicians available. However, their ill-defined place in health care does not promote their use in current medical practice.

Objective: The primary objective of this study was to quantify CHDs' use rate by general practitioners (GPs). A secondary objective was to evaluate their benefits and limitations in usual care.

Methods: A cross-sectional study through an Internet-based survey was addressed to French GPs via regional medical unions and continuous education agencies, supplemented with an informative website, from March 2015 to July 2015. Surveys where either the form was insufficiently filled or the main question was left unanswered were excluded from the study.

Results: A total of 1084 answers were analyzed, of which 19.46% (211/1084, 95% CI 17.1-21.8) GPs used CHDs, and 10.15% (110/1084, 95% CI 8.5-12.1) prescribed a CHD. CHD users statistically prescribed more CHDs (7.38% [80/1084] in the user group vs 2.86% [31/1084] in nonusers; $P < .001$) and were more likely to use them in the future. Major interests in their utilization were in patient monitoring for 84.96% (921/1084) and patient education for 75.83% (822/1084), especially for diabetes (89.67%, 972/1084) and hypertension (84.13%, 912/1084). Generated data had to be managed securely by the patient primarily for 85.79% (930/1084) of the GPs. CHDs had to not constrain GPs outside clinical consultation, nor restrain their time for 75.83% (822/1084). Additional actors in patient care were not desired for 79.98% (867/1084) of the GPs. Questions about data management issues and technical difficulties were raised.

Conclusions: CHDs are little used by French GPs and even less prescribed to their patients, as only a few GPs use these tools. Their benefits as tools of patient empowerment, although expected, remain to be demonstrated in real-life setups.

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KEYWORDS

general practice; physician-patient relations; monitoring, ambulatory; wireless technology; medical informatics; telemedicine

Introduction

Mobile health (mHealth) is the medical and public health practice supported by mobile devices such as smartphones, patient monitoring devices, personal digital assistants, and other wireless devices (World Health Organization, WHO) [1]. Two major categories of mHealth tools are now being developed: mobile phone apps and connected health devices (CHDs). CHDs are objects generating physiologic information synchronized via a wireless network (Wi-Fi or Bluetooth) to a mobile phone, tablet, manufacturer's website, and so on. They make it possible to get rid of pen and paper and to access processed information—from numbered data to graphic reports, or to alarms of exceeded threshold. They communicate with other computer systems to obtain or provide additional information: these are called *intelligent* objects. They may be objects intended for medical use or often objects for managing health and well-being.

By the end of 2016, major app stores listed more than 259,000 mHealth apps and reached 3.2 billion downloads [2]. Economic impact of CHDs and connected fitness was about 190 billion US dollars worldwide and is expected to double by 2020 [3].

Technological advancements in CHDs have allowed the development of the self-quantification of a wide range of aspects of a person's life, such as quality of sleep, physical activity, blood pressure, or mental state, as well as the blooming of trending behaviors such as the quantified self. According to the WHO, "up to 80% of cardiovascular diseases (...) and more than a third of cancers could be avoided by eliminating risk factors such as (...) sedentary behaviors" [4], and those could account for 40% of premature deaths in the United States [5].

Treatment adherence in chronic diseases is a key element as, "increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments" [6]. Surveys reported real expectations of health professionals, patients, and industrials about CHDs [7]. Some studies showed an improved [8], longer-lasting [9], hypertension control achieved through remote monitoring. A 2015 meta-analysis of randomized controlled trials evaluating remote monitoring in heart failure showed a significant reduction in mortality (odds ratio [OR]=0.52, 95% CI 0.37-0.72 compared with usual care) and hospital admissions (OR=0.70, 95% CI 0.51-0.96) [10].

Overall, 69% of US adults keep track of at least one health indicator such as weight, diet, exercise routine, or a symptom, with 21% using a technology-based tracker [11]. Of these, 46% of adults using trackers said that it had changed their overall approach to maintaining their health. For PEW Internet Research Center and according to a study published in *Health Care*, about two-thirds of Americans were monitoring at least one health indicator, 20% of them with a form of technology; however, only half of the general population was sharing these data with their physicians (via email or a screen) [11,12].

General practitioners (GPs) are gatekeepers to accessing care in many health care systems, and so are the GPs in France. They might be an interesting medium to develop CHDs' use, and they could use CHDs to engage and maintain patients' behaviors into healthier ones. Little is known about how they integrate CHDs in their toolbox as nonpharmacological interventions. The primary objective of this study was to quantify the current use of CHDs by GPs in France. The secondary objectives were to assess the place of CHDs in patient care in general practice and to identify barriers to their use, according to GPs.

Methods**Design**

We conducted a cross-sectional survey using Google forms and emails to GPs ([Multimedia Appendix 3](#)). The questionnaire was developed by the authors LEA and FC based on PubMed bibliographic research and data retrieved from European health and economic organizations' documents. The questionnaire consisted of 25 questions divided into four sections. Section 1 collected data about personal and professional use of CHDs. Section 2 focused on GPs' patients' use of CHDs. Section 3 elicited information on their benefits, the barriers to their use, and how to optimize their integration into their daily practice. Section 4 collected demographic data related to the practice and GPs.

A link to a website purposely developed to inform or remind GPs about the different CHDs available worldwide was included in that email ([Multimedia Appendix 2](#)). For the purposes of the study, CHDs were classified by the authors as connected medical devices (ie, glucometers, oximeters, sphygmomanometers, pill boxes, thermometers, and peakflow meters), as health-related connected devices in general or "mainstream" CHDs (ie, weight trackers, activity and sleep trackers, breath-analyzers, smoking cessation tools, diet monitors, oral hygiene and prevention of low back pain trackers, trackers for infants and seniors, and tools for pregnancy and quality of air monitoring), and as other specialized connected devices (urine "scanners," specialized epilepsy clothing, and so on).

The survey remained available on the Web from March 10, 2015 to July 10, 2015. Responses were collected automatically on an Excel (Microsoft) type spreadsheet. Multiple submissions from a single submitter were resolved using Internet protocol addresses and time stamps from submission.

The review board from the department of General Practice of University of Montpellier gave their approval before submitting the survey to the different organisms.

Population

This work focused on GPs in France. To reach the GPs, the 26 Regional Health Practitioners Unions (Union Régionale des Professionnels de Santé, URPS) of France were contacted by phone starting March 10, 2015 to collect their email addresses, then by email to present the study and survey for distribution

to all GPs registered to them. They were contacted again by email on May 2015 to dispatch the email once more to improve the survey's distribution. A total of 26 URPS were initially contacted: 11 URPS refused to participate, 15 emailed the questionnaire to the GPs registered on their mailing list, and 9 dispatched the email again on May 2015.

The survey was also spread through the GPs' "UG-Zapping" newsletter and the continuous medical education association "FMC-Action". The link to the survey was published in the monthly newsletter "UG-Zapping" on April 6, 2015 and was distributed by email to the 35,000 GPs members of "FMC-Action" in early June 2015.

Exclusion criteria were lack of response to the question meeting the primary objective of the study, or answering less than 80% of the survey.

Statistical Analysis

The number of subjects needed to achieve statistical significance with a risk of 5%, based on bibliographic databases, was 384.

An initial descriptive analysis on the included population was performed.

We named the group currently using the CHD "CHD+" and the nonuser group "CHD-".

Qualitative variables were expressed by their effectives and their percentage (number, %). Comparison of qualitative variables was executed through the chi-square test for parametric tests, or Fisher exact test when the conditions for applying chi-square were not observed, and performed on Microsoft Excel and BiostaTGV software. The significance threshold was set at 5%.

Results

Population Characteristics

A total of 1086 GPs from all over France responded. Of the 1086 GPs who answered the questionnaire, 1084 were included in the analysis, as two of the responders met the exclusion criteria.

Demographics of GPs who responded to the survey are shown in [Table 1](#).

Personal and Professional Use of Connected Health Devices

Of the 1084 GPs included, 211 were using a CHD at the time of the study ("CHD+"; ie, 19.46%; 95% CI 17.1-21.8) versus 873 GPs who were not using a CHD ("CHD-"; ie, 80.54%; 95% CI 78.2-82.9).

Among the CHD+, 105 were using a connected device for general health or "mainstream" (ie, 49.8%, 105/211; 95% CI 7.9-11.4), 70 a connected medical device (ie, 33.2%, 70/211; 95% CI 5-7.9), and 36 used both (ie, 17%, 36/211; 95% CI 2.3-4.4). CHDs most used by GPs were connected glucometers in first place (29.9%, 63/211 of users), activity trackers (18.5%, 39/211 of users), and connected sphygmomanometers (17.5%,

37/211); 51.7% (109/211) of users did not answer the previous question.

A total of 111 GPs had prescribed CHDs to their patients (10.15%, 110/1084; 95% CI 8.4-12.0) versus 971 who had not (ie, 89.57%, 971/1084; 95% CI 87.8-91.4). Physicians using connected devices significantly prescribed CHDs more than those who were not (7.38%, 80/1084 in the "CHD+" group vs 2.86%, 31/1084 in the group "CHD-"; $P < .001$). There was no statistical difference between prescription of "mainstream" CHDs and those for medical purposes (respectively 4.43%, 48/1084 vs 3.97%, 43/1084; $P = .549$).

In the near future, physicians-CHD users thought "very likely" (28.9%, 61/211 of them) or "certain" (32.7%, 69/211 of them) to use such objects in 2020 ([Figure 1](#)). On the contrary, GPs non-CHD users thought that the likelihood of using such items in the future was "unlikely" (31.9%, 278/873 of them) or "moderate" (33.9%, 296/873 of them).

Patients' Use of CHDs

A total of 428 GPs (39.48%, 428/1084) were aware of their patients using CHDs; 11.72% (127/1084) of GPs received their patients' CHDs' data (vs 88.28%, 957/1084 who did not receive them). They received it either through email, secured messaging, a secured website, or through "other" means.

Patients often shared general health information (in whatever mode) with their GP: 855 (78.87%) of the responding physicians were receiving numbered health data from their patients, with no difference between the two groups ($P = .93$). They received these data primarily on paper records (n=816, 95.4%).

Additionally, 652 (60.2% of responders) were interested in automating these health data, especially in the "CHD+" group (80.1% [169/211] in the group "CHD+" vs 55.3% [483/873] in the group "CHD-"; $P < .001$). There was a link between the interest in data automation and the fact that physicians were already receiving numbered data from their patients: GPs whose patients shared numbered health data (in whatever mode) were more interested in data automation (50.00%, 542/1084 vs 10.33%, 112/1084; $P < .001$).

Benefits of CHDs in Patients' Care

GPs generally recognized a usefulness to CHDs for their patients. They felt they could provide assistance in some chronic diseases ([Table 2](#)).

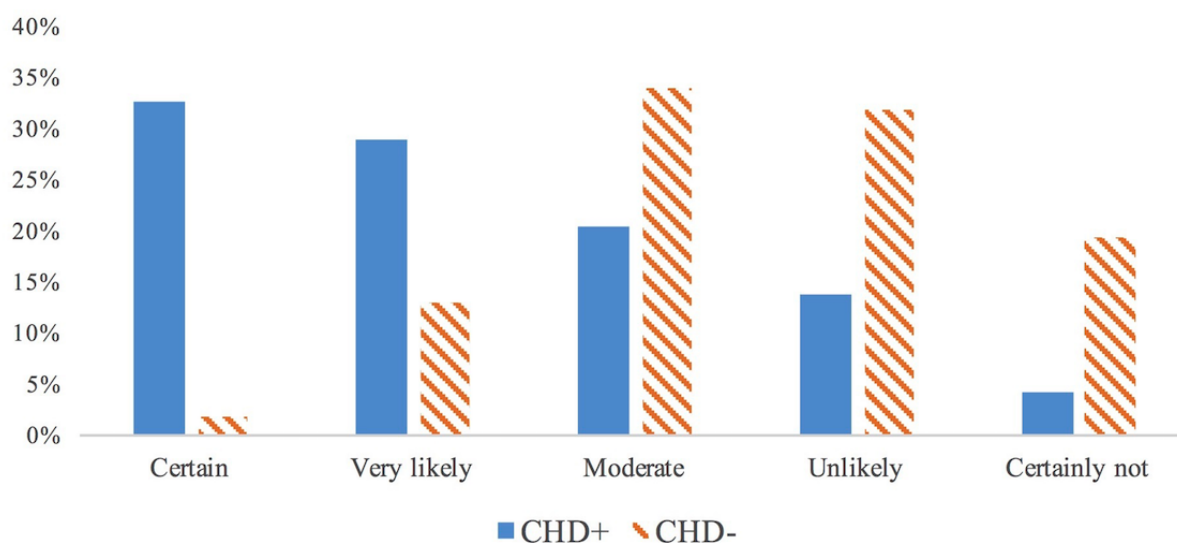
They could also be an aid in the GPs' patient' management: follow-up, health education, and therapeutic education; however, 3.2% of the responding doctors thought they had no use ([Table 2](#)).

Now or in the near future, these tools could enable early intervention, prevent crisis management of a pathology, and avoid disease progression and complications (for 62.55%, 678/1084). For the CHD+ group, they also could help reduce hospital admission or readmission, health care costs, and improve quality of life ([Table 3](#)).

Table 1. Comparison of general practitioners' demographics (N=1084); some general practitioners chose not to answer some questions; hence, data can be missing, and totals are not all 100%.

Group	CHD ^a + (N=211) n (%)	CHD- (N=873) n (%)	P value	Total (N=1084) n (%)
Sex				
Female	67 (31.8)	381 (43.6)	.002	448 (41.33)
Male	139 (65.9)	479 (54.9)		618 (57.01)
Age (years)				
Less than 35	23 (10.9)	122 (14.0)	.61	145 (13.38)
36-50	72 (34.)	282 (32.3)		354 (32.66)
51-65	104 (49.)	426 (48.8)		530 (48.89)
More than 65	12 (5.7)	41 (4.7)		52 (4.80)
Smartphone, tablet, or smartphone and tablet use				
Yes	205 (97.2)	702 (80.4)	<.001	907 (83.67)
No	5 (2.4)	170 (19.5)		175 (16.14)
Smartphone and tablet model type				
iPhone	132 (62.6)	365 (41.8)	.18	497 (45.85)
Android mobile phone	68 (32.2)	263 (30.1)		331 (30.54)
Windows mobile phone	3 (1.4)	27 (3.1)		30 (2.77)
Blackberry	5 (2.4)	5 (0.6)		10 (0.92)
iPad	107 (50.7)	269 (30.8)		376 (34.69)
Android tablet	37 (17.5)	82 (9.4)		119 (10.98)
Windows tablet	9 (4.3)	18 (2.1)		27 (2.49)
Type of practice				
Private practice	181 (85.8)	743 (85.1)	.29	924 (85.24)
Employee	8 (3.8)	18 (2.1)		26 (2.40)
Substitute	7 (3.3)	46 (5.3)		53 (4.89)
Mixed	10 (4.7)	33 (3.8)		43 (3.97)
Teaching position (professor, clinical assistant, or lecturer)				
Yes	49 (23.2)	146 (16.7)	.03	195 (17.99)
No	162 (76.8)	721 (82.6)		883 (81.46)

^aCHDs: connected health devices.

Figure 1. Probability of CHD (connected health device) use in 5 years (n=1084).**Table 2.** Pathologies in which connected health devices (CHDs) could be useful according to general practitioners (GPs; N=1084).

Total size (%)	Yes, n (%)	95% CI	No, n (%)	Unknown, n (%)
In pathologies (N=1084)				
Hypertension	912 (84.13)	82-86.3	101 (9.32)	71 (6.55)
Diabetes	972 (89.67)	87.9-91.5	58 (5.35)	54 (4.98)
Obesity	494 (45.57)	42.6-48.5	354 (32.66)	236 (21.77)
Chronic obstructive pulmonary disease	528 (48.71)	45.7-51.7	292 (26.94)	264 (24.35)
Asthma	642 (59.23)	56.3-62.2	221 (20.39)	221 (20.39)
Sleep apnea	643 (59.32)	56.4-62.2	230 (21.22)	211 (19.47)
Elderly falls	461 (42.53)	39.6-45.5	300 (27.68)	323 (29.80)
Health (as defined by the WHO ^a)	284 (26.20)	23.6-28.8	350 (32.29)	450 (41.51)
In situations (N=1084)				
Aid to follow-up	921 (84.96)	82.8-87.1	87 (8.03)	76 (7.01)
Aid adapting treatment	849 (78.32)	75.9-80.8	135 (12.45)	100 (9.23)
Access to recorded data	832 (76.75)	74.2-79.3	153 (14.11)	99 (9.13)
Health education	822 (75.83)	73.3-78.4	119 (10.98)	143 (13.19)
Treatment education	817 (75.37)	72.8-77.9	113 (10.42)	154 (14.20)
Patient empowerment	702 (64.76)	61.9-67.6	139 (12.83)	243 (22.42)
Help addressing to a specialist	451 (41.61)	38.7-44.5	442 (40.77)	191 (17.62)
No use	35 (3.23)	2.2-4.3	437 (40.31)	612 (56.46)
Help achieving a diagnosis	455 (42.0)	39-44.9	405 (37.36)	224 (20.66)
Help prescribing additional tests	481 (44.4)	41.4-47.3	396 (36.53)	207 (19.10)
No use	35 (3.23)	2.2-4.3	437 (40.31)	612 (56.46)

^aWHO: World Health Organization.

Table 3. Current or future usefulness of connected health devices (CHD) according to general practitioners (GPs; N=1084).

Total size (%)	CHD ^a + (N=211) n (%)	CHD- (N=873) n (%)	P value	Total (N=1084) n (%)
Enable an early intervention				
Yes	168 (79.6)	584 (66.9)	.002	752 (69.37)
No	23 (10.9)	151 (17.3)		174 (16.05)
Unknown	20 (9.5)	138 (15.8)		158 (14.58)
Enable crises prevention				
Yes	149 (70.6)	490 (56.1)	<.001	639 (58.95)
No	35 (16.6)	194 (22.2)		229 (21.13)
Unknown	27 (12.8)	189 (21.6)		216 (19.93)
Avoid disease progression and complications				
Yes	151 (71.6)	527 (60.4)	.01	678 (62.55)
No	32 (15.2)	189 (21.6)		221 (20.39)
Unknown	28 (13.3)	157 (18.0)		185 (17.07)
Reduction of medical interventions				
Yes	81 (38.4)	233 (26.7)	<.001	314 (28.97)
No	101 (47.9)	458 (52.5)		559 (51.57)
Unknown	29 (13.7)	182 (20.8)		211 (19.47)
Reduction of hospital admission				
Yes	106 (50.2)	291 (33.3)	<.001	397 (36.62)
No	67 (31.8)	378 (43.3)		445 (41.05)
Unknown	38 (18.0)	204 (23.4)		242 (22.32)
Reduction of hospital readmission				
Yes	108 (51.2)	299 (34.2)	<.001	407 (37.55)
No	61 (28.9)	347 (39.7)		408 (37.63)
Unknown	42 (19.9)	227 (26.0)		269 (24.82)
Quality of life improvement				
Yes	133 (63.0)	378 (43.3)	<.001	511 (47.14)
No	34 (16.1)	227 (26.0)		261 (24.08)
Unknown	44 (20.9)	268 (30.7)		312 (28.78)
Reduction of health costs				
Yes	105 (49.8)	294 (33.7)	<.001	399 (36.81)
No	45 (21.3)	275 (31.5)		319 (29.43)
Unknown	61 (28.9)	304 (34.8)		365 (33.67)
Reduction of mortality				
Yes	83 (39.3)	233 (26.7)	.002	316 (29.15)
No	60 (28.4)	279 (32.0)		339 (31.27)
Unknown	68 (32.2)	361 (41.4)		429 (39.58)

^aCHDs: connected health devices.

Table 4. Recipients of connected health devices (CHD)—generated data according to general practitioners (GPs; N=1084).

Total size, n (%)	Yes, n (%)	95% CI	No, n (%)	Unknown, n (%)
Patient	930 (85.79)	83.7-87.9	83 (7.66)	71 (6.55)
General practitioner	796 (73.43)	70.8-76.1	159 (14.67)	129 (11.90)
Specialist from the field of the data	699 (64.48)	61.6-67.3	211 (19.47)	174 (16.05)
Patient's nurse	651 (60.06)	57.1-63	278 (25.65)	155 (14.30)
Patient's private supplementary insurance	16 (1.48)	0.8-2.2	974 (89.85)	94 (8.67)
Patient's state insurance	24 (2.21)	1.3-3.1	962 (88.75)	98 (9.04)
Private company	43 (3.97)	2.8-5.1	918 (84.69)	123 (11.35)
Patient's pharmacist	174 (16.05)	13.9-18.2	715 (65.96)	195 (17.99)
Health network	414 (38.19)	35.3-41.1	475 (43.82)	195 (17.99)
Other physical or moral people	514 (47.41)	44.4-50.4	369 (34.04)	201 (18.54)
Patient's helper	20 (1.85)	1-2.6	350 (32.29)	714 (65.87)

Barriers to the Use of CHDs in Patients' Care

Main barriers were the data generated themselves and how they could generate anxiety for the patients. They might be generated in excessive quantities, lead to problems in their analysis, be too time-consuming to be used during or outside clinical consultation, or to learn how they work ([Multimedia Appendix 1](#)). Regarding data security, GPs were divided: for 482 (44.46%, 482/1084) of the responders, the lack of data security was a hindrance to their use, against 441 (40.68%, 441/1084) who considered that this did not preclude using them ($P=.07$).

GPs would agree to receiving these data in the form of a graphic synthesis (78.32%, 849/1084) but would not agree to receiving them in the form of raw data (68.54%, 743/1084). They were divided on the fact of receiving these data in the form of automatic alerts (48.06%, 521/1084 would accept vs 38.56%, 418/1084 who would not) or interpreted by another health professional (32.47%, 352/1084 would accept vs 44.28%, 480/1084 who would not, and 23.25% (252/1084) were undecided); 7.56% (82/1084) would rather not receive any data from these devices, especially in the nonuser group (2.8%, 6/211 in the group “CHD+” vs 8.7%, 76/873 in the group “CHD-”; $P=.04$).

They also were worried how these CHDs and generated data would affect patient-doctor communication. A total of 539 (49.72%, 539/1084) were worried of legal responsibility of data; 42.25% (458/1084) considered that they should not be constrained by a delay of response to the alert. The appropriate time to respond to the automatic alert would be in the half-day (16.61%, 180/1084) or in the day (17.99%, 195/1084). They considered that the appropriate time for data interpretation per day should not exceed 10 minutes (53.04%, 575/1084). About a third of them, however, considered that the interpretation of these data should not hold any of their daily time (31.09%, 337/1084), especially for CHD nonusers (33.9%, 296/873 in the group “CHD-” vs 19.4%, 41/211 in the group “CHD+”; $P<.001$).

Mostly, this automatic alert should take the form of an email (32.93%, 357/1084), with no difference between groups ($P=.12$).

Regarding data management, the data generated should mainly be received by the patient himself (85.80%, 930/1084; [Table 4](#)).

Technical problems such as the lack of interoperability between devices themselves and with medical software were also raised, especially for the “CHD+” group ($P=.001$).

GPs were also concerned by the costs induced by their use for the physicians (no compensation for their use) and for the patients (lack of reimbursement of CHDs and the high cost of these devices; [Multimedia Appendix 1](#)).

Other obstacles to their use were identified in the “CHD-” group: absence of recommendation by scientific societies (53.0%, 463/873 of them, $P=.03$) and time GPs must invest in learning how to use them (56.9%, 497/873 of them, $P<.001$).

Discussion

Principal Findings

Only 19.47% (211/1084) of the interviewed French GPs were using CHDs and 10.15% (110/1084) prescribing them to their patients.

The users already are in an innovative environment. They have a teaching position, which fosters exchanges with younger students who are widely exposed to Web technologies [13]. They have adopted mHealth tools such as smartphones or tablets [14]. Thus, they were more keen on believing that the CHDs would be a part of their 2020's toolbox, and they even prescribed more CHDs than nonusers. These results indicate that CHDs are compelling and that CHDs' path to success in health will probably amplify with the labor market entry of “millennial” medical students.

For the moment, most used CHDs are in fact well-known medical devices—such as glucometers and sphygmomanometers—upgraded to be connected to a wireless device. As for the popularity of physical activity trackers, it is probably related to the widespread notion of a WHO recommendation to take 10,000 steps a day recorded by a pedometer [15].

Although their use is widespread, GPs are falling behind [16]: 39.5% of GPs were aware of their patients using CHDs, which was twice the GP's use rate. This suggests that GPs are not initiators of the CHD spread. These results are not surprising as these technologies were made to empower patients and are patient-centered.

However, there are wide possibilities to integrate CHDs in medical practice. For example, almost 80% (867/1084) of GPs declared that they received numbered health data from their patients, almost systematically on paper. Interest for data automation was particularly strong among the GPs who already shared automated data with their patients. CHDs might be used to monitor chronic diseases [17] and prevent crisis management of a pathology or its complications. CHD users went further into believing that these tools could help reduce hospital admission, readmission, and health care costs, as well as improve quality of life. Those beliefs are in line with the goals of these objects' industrial design, as well as those of Public Health, facing an aging population with chronic diseases in the context of a reduced number of physicians and budgetary constraints [18]. The European Commission believes that "mHealth could (...) promote the transition to a preventive approach while increasing the efficiency of the system" and that "remote monitoring using mobile health solutions could decrease by about 15% the cost of healthcare" [7].

Still, if current clinical research studies highlighted improvements in morbidity, mortality, and results in chronic diseases [8,10,19] with the use of connected objects, they have not yet shown such results just by themselves. Each and every time, CHDs were teamed with the intervention of partners to the patients, such as a trained nurse or the intervention of new health actors such as specialized companies. A 2013 study found no benefit on mortality in heart failure with remote monitoring through a human to machine interface [20]. A meta-analysis about educative telemonitoring of decompensated heart failure showed an insufficient or a low level of evidence in hospital readmissions and mortality up to a 6-month follow-up [21]. Improvement to one's health could be not only linked to the use of connected devices but to the debriefing of their, even irregular, results [22].

GPs identified the following barriers to CHD use: CHDs themselves and their impact on GPs, on their patients, and on doctor-patient relationship.

Concerns expressed by CHD users were mainly focused on technical aspects such as interoperability issues with the software already used by GPs. Implementation of new technologies with their technical challenges create a risk of a digital divide already widely noticed [23,24]. This echoes the delays and technical difficulties known in France with the deployment of the electronic medical records. CHD reliability was also questioned—as devices and as software—particularly by CHD users. Few connected objects are in fact approved by regulatory authorities. Until 2014, the Food and Drug Administration (FDA) had only approved iHealth's balance and oximeter, Withings' and Qardio's sphygmomanometers, AliveCor's EKG, and Propeller Health's spirometer [25]. The FDA has decided to intervene only when their use was

considered a risk for the patients. European regulatory authorities have, for their part, not yet issued specific recommendations. Both users, and in particular nonusers, agreed that CHDs may create new time constraints to GPs because of the time needed to learning and teaching patients how to use them and analyze data.

How the data generated by CHDs was integrated to the patient-doctor communication was a concern expressed par GPs, mainly by nonusers. They agreed that it should take the form of an email alert. But there were neither agreements on the appropriate response time to the alerts nor on how these data should be treated: whether automated via automatic alerts or interpreted by another health professional. They only agreed on the fact that they did not want these data to be raw but synthetic as they feared excessive data generation and how time-consuming they might be. It must be recalled that, in France, GPs are still on fee for service. To this date, there are no fees scheduled for CHD management by GPs, and French telemedicine's fee has just been published at the Official Gazette [26]. Similarly, the cost of CHDs for the patients is questioned by GPs, as in France, efficient medical devices and drugs may be reimbursed by health insurance.

The issue of data security was also raised but, surprisingly, did not worry the population of GPs studied as much as one would expect. Data security should be taken more seriously. The rapid market flow of connected devices still provides them with security vulnerabilities accessible to malware that can be used for larger cyberattacks [27].

Finally, GPs feared that the data generated might cause anxiety or depression [8]. There are also risks of higher performance research [28] and risks of overmedicalization of general population with the spread of devices quantifying various corporeal data as they might become "an integral part of a pervasive, ubiquitous future, of a patient-centered care system" [23]. In addition, there's a patient safety issue with data self-management by patients themselves "when one can use the results from a device or mobile health application to take himself a decision that might jeopardize his health, or when the information received from the application incorrectly indicates that the person is in good health" [7].

Still, for GPs surveyed, it was the patients that should receive the data generated by the connected objects in priority. Studies emphasized the importance of patients' education and self-management on their illness to improve adherence and outcomes [29]. This is also the wish of regulators: "one of the main objectives is to enable people to become, through information and communication technologies (ICT), co-managers of their health and well-being" [7]. It was probably to assist them at best that GPs defined themselves and the patient's nurse as corecipient of the data generated by CHD.

Strengths and Limitations

Sociodemographic data of GPs in our study were comparable with those of the French health ministry in January 2015 [30]: mean age of 53 years, 55% male, 58% liberal, and 84% equipped with smartphones and/or tablets. Their equipment rate was also similar to other studies administered online to GPs [31]. Lack

of links of interest or funding for the study using this type of free distribution, coupled with the anonymity of responses, allowed us to receive honest answers, close to the reality of current medical practice. Emails enabled us to reach a large sample size to improve the power of our study with a more than adequate number of responses but also a diverse sample including GPs working in both urban and rural areas.

However, the way our questionnaire was delivered (many dispatchers and a newsletter) made it hard to calculate a response rate (which would be lower than 3%) in a population knowingly lacking availability even to address issues concerning them [32]. Our nonrandomized study was also exposed to the known selection bias of email surveys: those most interested and those most worried about the subject studied answer more frequently, raising the question about the representativeness of the participating GPs. In addition, our subject was perhaps a bit long to respond to (about 10 minutes), and only the completed questionnaires were saved, probably adding an information and a recall bias. Moreover, GPs may hold little interest in connected objects in their professional practice: the URPS from the Provence Alpes Côte d'Azur region, for example, judged unnecessary to distribute the questionnaire to GPs, as "connected health devices did not match the current practice of medicine."

This refusal might also be explained by their wish to limit the emailed solicitations of the GPs.

Perspectives

Expectations are high about CHDs for patients, caregivers, and health authorities in particular to prevent and manage chronic diseases, with a broad road ahead of them. mHealth, as electronic health and, in general, nonpharmacological interventions need new ways to be explored and validated to be taken seriously by scientific communities [33]. So far, CHDs' scientific evaluation meets a reality constraint because of their rapid obsolescence.

Ultimately, for the GPs, CHDs are mostly tools of accountability and patients' empowerment. They are complementary to the practice of the medical art, which must remain primarily humanist and based on the customized clinical doctor-patient relationship. In the short to medium term, their challenge is to become part of the physician's toolbox to prevent and manage diseases. As well as being effective and then covered by health insurance, they need to be usable tools created in a "plug and care or cure" philosophy. In a more ambitious step, CHDs might also release themselves from the usual constraints of the doctor-patient relationship and attain their autonomy in health, but integrative and comprehensive CHDs are not marketed yet.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Obstacles to connected health devices' (CHDs) use according to general practitioners (GPs; N=1084).

[PDF File (Adobe PDF File), 263KB - [mhealth_v5i12e193_app1.pdf](#)]

Multimedia Appendix 2

Screenshots of the website.

[PDF File (Adobe PDF File), 368KB - [mhealth_v5i12e193_app2.pdf](#)]

Multimedia Appendix 3

Questionnaire.

[PDF File (Adobe PDF File), 413KB - [mhealth_v5i12e193_app3.pdf](#)]

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Abbreviations

- CHDs:** connected health devices
- GPs:** general practitioners
- mHealth:** mobile health
- OR:** odds ratio
- URPS:** Regional Health Practitioners Unions
- WHO:** World Health Organization

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Original Paper

The Swedish Web Version of the Quality of Recovery Scale Adapted for Use in a Mobile App: Prospective Psychometric Evaluation Study

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Abstract

Background: The 40-item Quality of Recovery (QoR-40) questionnaire is well validated for measuring self-assessed postoperative recovery. The Swedish version of the 40-item Quality of Recovery (QoR-40) has been developed into a Web-based questionnaire, the Swedish Web version of the Quality of Recovery (SwQoR) questionnaire, adapted for use in a mobile app, Recovery Assessment by Phone Points, or RAPP.

Objective: The aim of this study was to test the validity, reliability, responsiveness, and clinical acceptability and feasibility of SwQoR.

Methods: We conducted a prospective psychometric evaluation study including 494 patients aged ≥ 18 years undergoing day surgery at 4 different day-surgery departments in Sweden. SwQoR was completed daily on postoperative days 1 to 14.

Results: All a priori hypotheses were confirmed, supporting convergent validity. There was excellent internal consistency (Cronbach alpha range .91-.93), split-half reliability (coefficient range .87-.93), and stability ($ri=.99$, 95% CI .96-.99; $P<.001$). Cohen d effect size was 1.00, with a standardized response mean of 1.2 and a percentage change from baseline of 59.1%. An exploratory factor analysis found 5 components explaining 57.8% of the total variance. We noted a floor effect only on postoperative day 14; we found no ceiling effect.

Conclusions: SwQoR is valid, has excellent reliability and high responsiveness, and is clinically feasible for the systematic follow-up of patients' postoperative recovery.

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KEYWORDS

psychometric evaluation; postoperative recovery; Web version; evaluation studies; mobile application; Quality of Recovery scale

Introduction

Day surgery (ie, minor surgery) is an expanding, well-established practice internationally. Surgical and anesthetic advances, in day surgery in particular, have drastically reduced mortality and major morbidity frequencies [1]. Before discharge, patients admitted for day surgery are monitored postoperatively for only a few hours; they must then assume primary responsibility for managing their own recovery [2,3]. There are

numerous postdischarge symptoms, such as pain, drowsiness, fatigue and tiredness, postoperative nausea and vomiting, sleep disturbance, and sore throat [4-7]. Although such symptoms are rarely life threatening, they may be unpleasant and disturbing, extending the recovery time and delaying resumption of normal activity [2,8]. The introduction of patient-centered care has made recovery a multidimensional construct, and recovery assessment tools address physical (nociceptive), functional

(activities of daily living), cognitive, and psychological (emotive, satisfaction) outcomes [8].

The 40-item Quality of Recovery (QoR-40) questionnaire is well validated for measuring self-assessed postoperative recovery [9,10]. This questionnaire had been previously tested in a population of Swedish day-surgery patients [11]. A meta-analysis that included the Idvall et al study demonstrated the QoR-40's high validity, reliability, responsiveness, and clinical utility in a broad range of patient populations [7]. However, all the included studies relied on paper-based assessments during postoperative recovery. Instead of paper-based postoperative follow-up, the use of mobile phones could be ideal, as many people of all ages and across socioeconomic and geographic boundaries own these ubiquitous devices. The Swedish version of QoR-40 has therefore been further developed into a Web-based instrument, the Swedish Web version of the Quality of Recovery (SwQoR) questionnaire, and adapted for use in the Recovery Assessment by Phone Points (RAPP) mobile app [12-14] equivalent to the paper version of the SwQoR [14].

SwQoR is a multi-item questionnaire including 24 negatively worded items rated on 11-point visual analog scales (VASs) ranging from 0, "none of the time," to 10, "all of the time" [15]. That all items are negatively worded differs from the QoR-40, which includes both positive and negative items. In an earlier study by our research group [14], patients reported that, as they respond to the items one by one, they would find it easier if all of the items were either positively or negatively worded. As patients undergoing surgery are used to rating their postoperative pain using a VAS or numeric rating scale, and most of the items (n=17) were negatively worded, all positive items (n=7) were reformulated into negatively worded items [13,15]. To facilitate responding to each item, a dot on the VAS line is programmed to return to a score of 5 each time a new item appears on the screen, clarifying that a new item is to be responded to [12]. Each item appears separately on the screen and the dot must be moved to indicate a response. The item disappears from the screen immediately after a response is given, and each item must be responded to before the patient can submit the daily assessment [15]. The global score for SwQoR ranges from 0 to 240, with good postoperative recovery indicated by a score of 0 to 31 and poor postoperative recovery indicated by a score of 32 or more (ie, more discomfort) on postoperative day 7 [16].

The aim of this study was to undertake a psychometric evaluation of SwQoR in a day-surgery population.

Methods

This psychometric evaluation study is a part of a multicenter, 2-group, parallel, single-blind randomized controlled trial with the primary aim to estimate the cost effectiveness of using, versus not using, RAPP for follow-up on recovery after day surgery (trial registration NCT02492191 [15]). The study was conducted from October 2015 to July 2016 at 4 day-surgery departments in Sweden. Here we present data only on participants who were randomly allocated into the intervention group. Study implementation upheld the ethical standards of

the Declaration of Helsinki (6th revision) and was approved by the Uppsala/Örebro Regional Ethics Committee (2015/262).

Sample and Procedure

Patients were told of the study and invited to enroll on the day of surgery. Written information about the study was also sent out in advance, together with information about the planned surgery. Oral information was provided preoperatively on the day of surgery, and all participants gave oral and written consent. The research nurse responsible for participant recruitment at the day-surgery department ensured that all participants eligible for study participation were invited to enroll. Inclusion criteria were undergoing day surgery, over 17 years of age, access to a mobile phone, and able to understand written and spoken Swedish. Exclusion criteria were visual impairment, memory impairment, substance abuse, or undergoing a surgical abortion.

Preoperatively, the research nurse installed RAPP, including SwQoR, on each participant's own mobile phone. The participants were individually briefed and allowed to test the app by inputting sample responses. The research nurse explained in detail the RAPP functionalities, such as how to move between items, input responses, and use the navigation keys. The participants completed SwQoR daily for 14 days using RAPP and received a daily reminder via the app.

Preoperatively, we measured overall health using the paper-based EuroQol visual analog scale (EQ VAS), comprising a vertically graduated scale ranging from 0, "worst imaginable health state," to 100, "best imaginable health state" [17].

We gathered participants' demographic and pre- and postoperative data from their patient records, which included age, sex, American Society of Anesthesiologists (ASA) physical status classification, type of anesthesia, and duration of postoperative stay calculated from when the patient entered the postanesthesia care unit (PACU) to the time of discharge.

Psychometric Evaluation

The psychometric evaluation was guided by the Consensus-Based Standards for the Selection of Health Measurement Instruments [18] and previous psychometric evaluations of the QoR-40 [9,10,19] and QoR-15 questionnaires [20,21].

Acceptability and Feasibility

We assessed *acceptability* and *feasibility*, which measure clinical user friendliness, in terms of (1) participant recruitment rate, days 1 to 14; and (2) successful response rate, days 1 to 14.

Floor or Ceiling Effects

We deemed floor or ceiling effects to be present if over 15% of participants reported, respectively, the highest or lowest postoperative SwQoR score on days 1 to 14 [22].

Validity

We assessed *validity*, which evaluates the accuracy, in terms of *construct validity* and *discriminant validity*.

Construct validity is the extent to which questionnaire scores are consistent with hypotheses, assuming that the questionnaire

validly measures the construct addressed. We assumed a correlation coefficient of $.3 < r < .7$ to indicate moderate correlation. To analyze construct validity, we conducted a priori hypothesis testing, hypothesizing that SwQoR on day 14 would correlate negatively with EQ VAS on day 14 postoperatively: that is, high scores of SwQoR (ie, poor quality of recovery) correlate with low quality of life. We expected lower correlations (ie, $\rho < .3$) due to day surgery between SwQoR on day 1 postoperatively and duration of surgery, duration of PACU stay, and age. In addition, we expected higher scores of SwQoR (ie, poor quality of recovery) in female versus male patients and in general anesthesia versus regional anesthesia.

Discriminant validity, tested on days 1 to 7 and 14, suggested that patients with low overall health as defined by an EQ VAS score of < 76 mm preoperatively (guided by the mean value of 75 in this study) would have higher scores on SwQoR (ie, poor postoperative recovery).

Reliability

We assessed *reliability*, which evaluates the consistency of results, in terms of the following 4 measures.

Internal consistency was measured as the average correlation between the SwQoR items on days 1 to 14, indicated by Cronbach alpha, as well as between the items captured by the factors emerging in the exploratory factor analysis (EFA).

Split-half reliability was measured by the correlation between randomly split segments of SwQoR on days 1 to 14.

Exploratory factor analysis identified the underlying relationships between the 24 items on day 1.

Test-retest reliability was assessed by having a subset of patients ($n=17$, mean age 48.8 years, 8 male and 9 female patients, 9 ASA I and 8 ASA II) complete SwQoR twice on one of postoperative days 1 to 7 within a time frame of 2 to 30 minutes (mean 6 minutes); we then assessed the correlation between the repeated questionnaire results.

Responsiveness

We assessed *responsiveness*, which evaluates SwQoR's sensitivity and ability to detect clinically important changes, in terms of the following 3 measures.

Cohen d effect size was calculated as the average changes in scores from days 1 to 7, 1 to 14, and 7 to 14, divided by the pooled standard deviation of all measurements: 0.2 to 0.5 indicates a small effect, 0.5 to 0.8 indicates a moderate effect, 0.8 to 1.2 indicates a large effect, 1.2 to 2.0 indicates a very large effect, and > 2.0 indicates a huge effect [23].

Standardized response mean (SRM) was calculated as the mean change in scores divided by the standard deviation of this change, with values of 0.20, 0.50, and 0.80 or greater being considered small, moderate, and large effect sizes, respectively [24].

Mean changes over time and percentage changes from baseline from days 1 to 7, 1 to 14, and 7 to 14 were calculated.

Statistical Analysis

We present data as mean (SD), numbers, percentages, ranges, or 95% CI for the sake of clarity. Although the questionnaire is considered to be an ordinal scale, the data were skewed and we performed nonparametric tests. All percentages are rounded up to the nearest integer. We measured associations using Spearman rank correlation coefficients (ρ). We assessed internal consistency with Cronbach alpha. To detect differences between sex and type of anesthesia, we performed Mann-Whitney *U* tests. We assessed test-retest reliability with the intraclass correlation coefficient (*ri*). We used IBM SPSS version 24 (IBM Corporation) for Windows for the statistical analyses. We rejected the null hypothesis if the 2-tailed $P < .05$.

Results

Acceptability and Feasibility

In the main study, 1796 patients were eligible for inclusion. Of these, 433 did not meet the inclusion criteria and 336 declined to participate, resulting in 1027 day-surgery patients who were included for random allocation. Of the 513 patients randomly allocated to the intervention group, we excluded 19 due to canceled operations ($n=15$), refusal to participate ($n=3$), and technical issues ($n=1$). Thus, 494 patients were covered in this study dataset. Table 1 presents patients' demographic variables and perioperative factors.

The response rate was 86.8% ($n=429$) on postoperative day 1, then 69.0% ($n=341$) on day 7, and 57.5% ($n=284$) on day 14. The global SwQoR score decreased from 49.3 (SD 34.2) on day 1 to 19.5 (SD 25.0) on day 14 (Table 2). There were no missing items because each item had to be responded to before submitting the daily assessment.

Floor or Ceiling Effects

The distributions of SwQoR global scores on days 1, 7, and 14 were skewed to the left and ranged from 0 to 191, from 0 to 178, and from 0 to 133, respectively. We found a floor effect on day 14, when 45 (15.8%) participants reported SwQoR global scores of 0. No ceiling effects were present (Table 2).

Validity

Construct validity analysis indicated a moderate and negative correlation between the SwQoR and EQ VAS results on postoperative day 14 ($\rho = -.53$, $P < .001$). As hypothesized, the construct validity results indicated rather low correlations between SwQoR and PACU stay ($\rho = .28$, $P < .001$), duration of surgery ($\rho = .17$, $P < .001$), and age ($\rho = .20$, $P < .001$). Women reported significantly higher mean SwQoR scores (ie, poorer recovery) than men (mean 53.2, SD 35.7 vs 46.3, SD 33.8; $P = .04$). These differences were also significant between general (mean 52.7, SD 35.5) and regional anesthesia (mean 39.3, SD 27.1; $P = .02$). All hypotheses were therefore confirmed.

We determined *discriminant validity* by comparing patients with good versus poor overall health, as defined by EQ VAS scores of ≥ 75 or < 75 mm, respectively. The lower SwQoR scores on day 1 of those patients with good overall health indicated significantly better recovery (mean 44.3, SD 32.4 vs

59.4, SD 35.5 for patients with poor health), for a mean difference of 15.1 (95% CI 8.1-22.0; $P < .001$).

Table 1. Participants' demographic variables, and surgical and anesthetic factors (n=494).

Variables	Data
Sex n (%)	
Male	220 (44.5)
Female	274 (55.5)
Age (years)	
Mean (SD ^a)	45 (15)
Median (range)	46 (18-81)
ASA^b classification, n (%)	
I	242 (49.0)
II	147 (29.8)
III	11 (2.2)
Missing information	84 (17.0)
Type of anesthesia, n (%)	
General anesthesia	362 (73.3)
Regional or local anesthesia	107 (21.7)
Missing information	25 (5.1)
Type of airway management, n (%)	
Endotracheal tube	77 (15.6)
Laryngeal mask airway	267 (54.1)
Mask ventilation	6 (1.2)
Spontaneous breathing	119 (24.1)
Missing information	25 (5.1)
Type of surgery, n (%)	
Orthopedic	160 (32.4)
General	126 (25.5)
Hand	116 (23.5)
Ear, nose, and throat	52 (10.5)
Gynecological	26 (5.3)
Eye	5 (1.0)
Urological	3 (0.6)
Dental	2 (0.4)
Duration of surgery (minutes), mean (SD)	40 (29.6)
PACU ^c stay (minutes), mean (SD)	151 (63.0)

^aSD: standard deviation.

^bASA: American Society of Anesthesiologists.

^cPACU: postanesthesia care unit.

Table 2. SwQoR^a response rate, mean and range, floor effect, Cronbach alpha, and split-half coefficient on days 1-14 (n=494).

Postoperative day	Response rate, n (%)	SwQoR			Cronbach alpha	Split-half coefficient
		Mean (SD) ^b	Range	Floor effect ^c , n (%)		
1	429 (86.8)	49.3 (34.2)	0-191	3 (0.7)	.91	.87
2	405 (82.0)	42.3 (34.2)	0-201	6 (1.5)	.92	.88
3	393 (82.7)	35.2 (32.3)	0-179	12 (3.1)	.93	.91
4	380 (80.2)	34.5 (32.5)	0-177	11 (2.9)	.93	.91
5	363 (73.5)	29.7 (30.8)	0-169	13 (3.6)	.93	.91
6	356 (72.1)	26.7 (27.2)	0-155	17 (4.8)	.93	.90
7	341 (69.0)	29.4 (30.4)	0-178	15 (4.4)	.93	.91
8	336 (68.0)	26.6 (29.7)	0-172	21 (6.3)	.93	.88
9	325 (66.0)	24.5 (27.9)	0-174	26 (8.0)	.92	.93
10	310 (62.8)	22.1 (25.8)	0-133	25 (8.1)	.92	.88
11	305 (61.7)	22.7 (26.8)	0-140	25 (8.2)	.92	.89
12	304 (61.5)	21.3 (26.6)	0-128	32 (10.5)	.93	.89
13	320 (64.8)	18.8 (25.0)	0-131	46 (14.4)	.93	.87
14	284 (57.5)	17.5 (22.5)	0-133	45 (15.8)	.92	.91

^aSwQoR: Swedish Web version of the Quality of Recovery.

^bSD: standard deviation.

^cParticipants scoring 0.

These differences were also significant on day 7 (mean 23.7, SD 24.8 vs 40.3, SD 36.6; mean difference 16.6, 95% CI 10.1-23.2; $P < .001$), and on day 14 (13.1, SD 16.6 vs 27.1, SD 29.1; mean difference 14.0, 95% CI 8.6-20.6; $P < .001$).

Reliability

Internal consistency, indicated by Cronbach alpha, ranged from .91 to .93, while the split-half coefficient ranged from .87 to .93 (Table 2). Test-retest reliability was indicated by an intraclass correlation coefficient of $ri = .99$ (95% CI .96-.99; $P < .001$).

For EFA, in assessing sampling adequacy, the Kaiser-Meyer-Olkin test result exceeded .70, with a value of .91, and Bartlett test of sphericity indicated a significant result

($\chi^2_{276} = 4393$, $P < .001$). These measures allowed us to legitimately perform EFA. The EFA gave a 5-factor solution and no forcing was necessary. The eigenvalue of the factor explaining most of the observed variance was 8.1. The EFA of the 24 items found factor loadings of .34 to .81, with 5 components identified as explaining 57.8% of the total variance. Cronbach alpha ranged from .74 to .88 for 4 of the factors and was .43 for 1 factor (Table 3).

Responsiveness

We found Cohen d effect sizes of 0.62 and 1.00 and SRMs of 0.82 and 1.20 between days 1 and 7 and between days 1 and 14, respectively. The mean change from baseline was -29.15 (range -25.98 to 32.32) between days 1 and 14 (Table 4).

Table 3. Item mean scores and factor loadings of SwQoR^a day 1, by exploratory factor analysis and Cronbach alpha.

Item	Item score, mean (SD ^b)	Component				
		1	2	3	4	5
Cronbach alpha		.88	.75	.75	.74	.43
Sleeping difficulties	3.04 (3.02)	.62				
Not having a general feeling of well-being	3.10 (2.08)	.78				
Not feeling in control of my situation	2.49 (2.90)	.59				
Having difficulty feeling relaxed or comfortable	3.07 (2.86)	.80				
Depressed	1.71 (2.35)	.66				
Anxious	2.00 (2.40)	.62				
Difficulties concentrating	2.09 (2.58)	.55				
Fever	0.56 (1.40)		.50			
Voice not sounding the same as usual	1.44 (2.56)		.67			
Sore throat	1.62 (2.61)		.79			
Sore mouth	0.77 (1.87)		.79			
Having trouble breathing	0.68 (1.69)		.67			
Having difficulty taking care of my personal hygiene	2.54 (2.75)			.62		
Having difficulty returning to work or usual home activities	6.28 (3.40)			.58		
Nausea, vomiting, or both	1.59 (2.52)			.64		
Dizziness	2.03 (2.64)			.71		
Headache	1.68 (2.49)			.52		
Muscle pain	2.94 (2.69)				.43	
Pain in the surgical wound	5.02 (3.09)				.57	
Reddened surgical wound	1.66 (2.52)				.77	
Swollen surgical wound	2.58 (3.11)				.81	
Trouble urinating	0.83 (1.84)					.55
Diarrhea	0.35 (1.12)					.66
Feeling constipated	1.01 (2.15)					.34

^aSwQoR: Swedish Web version of the Quality of Recovery.

^bSD: standard deviation.

Table 4. Cohen *d* effect size, mean change, and standardized response mean, days 1-7, 1-14, and 7-14.

Measure	Days 1-7	Days 1-14	Days 7-14
Cohen <i>d</i>	0.62	1.00	0.35
Mean changes (95% CI)	-21.2 (-18.38 to 24.06)	-29.15 (-25.98 to 32.32)	-8.15 (-6.25 to 10.06)
Mean percentage change from baseline (%)	43.0	59.1	27.8
Standardized response mean	0.82	1.20	0.66

Discussion

Principal Findings

The aim of this study was to undertake a psychometric evaluation of SwQoR, which comprised only negatively worded items and was completed using a mobile phone app by a population of persons undergoing day surgery. SwQoR retained the high validity, reliability, responsiveness, and clinical user

friendliness of the paper-based instrument. Supporting the validity of SwQoR, all construct validity hypotheses were confirmed [22]. Reliability and responsiveness both exceeded recommended levels. Content validity has previously been demonstrated [14].

The response rate on day 1 was 86.8%, compared with 56% in Kleif et al [21] and 95% in Stark et al [20], in both of which the follow-up used the paper-based QoR questionnaire (the patients

in Stark et al's study were also required to be available for in-person or telephone follow-up). Our results suggest that using an app with a Web-based questionnaire results in higher response rates. Our response rate decreased over time, with the lowest rate of 57.5% observed on day 14. In an earlier study by the same research group, patients were asked how many postoperative days they thought it would be useful to complete the instrument using the app, after using RAPP daily for 7 days postoperatively. On average, the patients considered 9 days acceptable for reporting, via an app, postoperative recovery after day surgery [14]. On day 9 in our study, the response rate was 66%, and we found no floor or ceiling effects. Only on day 14 did we find a floor effect, of 15.8%, slightly above the 15% considered to represent a floor effect [22]. However, the dwindling response rate probably reflects study response fatigue. On the other hand, there were no missing items because each item had to be responded to before submitting the daily assessment. We suggest a follow-up time of at least 10 days, but this should be further investigated.

Construct validity was strongly indicated, and SwQoR could distinguish known determinants of postoperative recovery. As stated by Terwee et al [22], construct validity is assessed by testing predefined hypotheses—for instance, concerning expected correlations between measures and expected differences in scores between “known” groups or within groups or subgroups of at least 50 participants. Without specific hypotheses, the risk of bias is high because retrospectively it is tempting to think up alternative explanations for low correlations rather than concluding that the questionnaire may not be valid [22]. Our study used well-known groups and, as hypothesized, due to the minor nature of the surgery, low correlations were found between SwQoR and duration of surgery, duration of PACU stay, type of anesthesia, and age. Stronger correlations have been reported previously for patients undergoing major surgery [10,19-21]. SwQoR discriminated between the sexes in postoperative recovery, noting poorer postoperative recovery in women than in men. Sex differences in postoperative recovery have been reported in earlier studies from Australia [10,20,25], Denmark [21], and Iran [19], although no sex differences were found in a study from Iceland [6].

We assessed discriminant validity by comparing patients with good versus poor overall health, as defined by EQ VAS scores of ≥ 75 or < 75 mm, respectively. SwQoR clearly differentiated between patient groups, and SwQoR scores increased significantly among those with poor overall health. Discriminant validity was therefore confirmed at all 3 time points.

Overall, the test-retest reliability was excellent ($ri=.99$). We conducted a test-retest with a subset of patients ($n=17$) completing SwQoR twice on one of postoperative days 1 to 7 within a time frame of 2 to 30 minutes (mean 6 minutes). Our test-retest design could be a limitation in that the time frame is narrow, perhaps leading to recall bias. However, the narrow time frame ensured that the patient's clinical condition had not changed. Earlier studies analyzing test-retest reliability in the postoperative recovery period suggest a 30-minute gap between the tests [14,20,21,26].

Regarding the SwQoR factor structure, the EFA obtained a 5-factor solution, of which 4 factors had good internal consistency [22] with an alpha range of .74 to .88. One factor, comprising 3 items, had an alpha of only .43, indicating poor correlation between the constituent items, meaning that the items could not justifiably be summarized [22]. However, all 3 items seemed to measure the same phenomena—that is, difficulties in elimination or constipation, diarrhea, and trouble urinating. The original QoR-40 items were summarized and reported across the following 5 dimensions: *emotional state*, *physical comfort*, *psychological support*, *physical independence*, and *pain* [9,10]. However, as SwQoR concentrates on individual items, not dimensions, we believe that when following up their patients, day-surgery departments should attend to specific items in evaluating and improving anesthetic and postoperative care. For example, in evaluating intravenous versus inhalation anesthesia and related postoperative differences in nausea and vomiting, follow-up and evaluation should consider “nausea, vomiting or both” values, not quality of recovery according to the *physical comfort* dimension [14]. The EFA results should therefore be treated only as a guide to organizing the items.

We assessed internal consistency using Cronbach alpha and split-half reliability; both these coefficients were high, and published recommendations for Cronbach alpha (ie, .70-.95) were satisfied [22]. However, Cronbach alpha is sensitive to the number of items, increasing with an increasing number of items [22]. These results were similar to those obtained using QoR-40 [7,10,11,19,21], QoR-15 [20], and SwQoR [14].

We measured the responsiveness of SwQoR using Cohen d effect size, SRM [22], and percentage change from baseline. For both the Cohen d effect size and SRM measures, 0.20, 0.50, and ≥ 0.80 are considered small, moderate, and large effect sizes, respectively [24], permitting the relative size of a change, here in global SwQoR, to be assessed. SwQoR had an effect size of 1.00 and an SRM of 1.20 between days 1 and 14. These values are equivalent to those obtained with the Swedish version of QoR [11], measuring the change in SRM between days 1 and 14 in day-surgery patients, and with QoR-40 [10,21] and QoR-15 [20], measuring the change between preoperative values and values on day 1 in patients having minor or major surgery. Our findings indicate that SwQoR has a strong ability to detect clinically important changes following minor surgery—that is, day surgery. It is an eminently suitable patient-centered, Web-based outcome measure for clinical practice and clinical trials. Responsiveness is the most important psychometric index for evaluative instruments [22]—that is, those intended to detect clinically important changes over time.

Implications

Bowyer and Royse [8] stated that, in the future, recovery assessment would be multidimensional, be patient focused, and occur in real time at multiple clinically relevant postoperative time points. Real-time or concurrent recovery monitoring, as well as synchronous data collection, analysis, and reporting, are beneficial in any complex time-dependent system, as they minimize the delay in implementing corrective interventions to address any errors or deviations from expected norms. SwQoR can meet this need for real-time measurements. In 2008,

Valderas et al recommended that future research should emphasize technological improvement, as well as the organizational and theoretical systems needed to create a care structure having patient-related outcomes as a fundamental element [27]. In our main study, 18.82% (n=338) of those assessed for eligibility (n=1796) did not have mobile phones or did not bring them to the day-surgery department [16,28], threatening the external validity. Even though 19% is low, we believe that this percentage will only decrease in the future, and adopting modern information technology to follow up patients' postoperative recovery will be essential.

Limitations

This study has some limitations. The study was conducted in Sweden and included only Swedish-speaking patients, so the

results may not apply in other settings. We did not measure preoperative SwQoR scores, and we recruited only day-surgery patients. Furthermore, we determined neither content validity nor minimal clinically important differences for SwQoR. However, both content and cross-cultural validity, as well as agreement between positively worded and negatively worded items, have previously been evaluated [12-14].

Conclusions

To our knowledge, this study is the first to evaluate a Web-based quality of recovery questionnaire, SwQoR, using an app installed in patients' mobile phones. The SwQoR instrument is valid, highly reliable, highly responsive, and clinically feasible for use in systematically following up postoperative patient recovery.

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Authors' Contributions

UN, KD, and MJ developed the sampling strategy for the psychometric testing. KD and MJ cleaned the dataset and developed the sample for analysis. UN conducted all the psychometric analyses and wrote the first draft of the manuscript. KD and MJ wrote the manuscript and approved the final version of the paper.

Conflicts of Interest

UN and Örebro University Enterprise AB hold shares in RAPP-AB.

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Abbreviations

- ASA:** American Society of Anesthesiologists
- EFA:** exploratory factor analysis
- EQ VAS:** EuroQol visual analog scale
- PACU:** postanesthesia care unit
- QoR:** Quality of Recovery
- RAPP:** Recovery Assessment by Phone Points
- SRM:** standardized response mean
- SwQoR:** Swedish Web version of the Quality of Recovery

VAS: visual analog scale

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Viewpoint

Methods for Evaluating the Content, Usability, and Efficacy of Commercial Mobile Health Apps

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Abstract

Commercial mobile apps for health behavior change are flourishing in the marketplace, but little evidence exists to support their use. This paper summarizes methods for evaluating the content, usability, and efficacy of commercially available health apps. Content analyses can be used to compare app features with clinical guidelines, evidence-based protocols, and behavior change techniques. Usability testing can establish how well an app functions and serves its intended purpose for a target population. Observational studies can explore the association between use and clinical and behavioral outcomes. Finally, efficacy testing can establish whether a commercial app impacts an outcome of interest via a variety of study designs, including randomized trials, multiphase optimization studies, and N-of-1 studies. Evidence in all these forms would increase adoption of commercial apps in clinical practice, inform the development of the next generation of apps, and ultimately increase the impact of commercial apps.

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KEYWORDS

mHealth; mobile health; mobile applications; telemedicine/methods ; treatment efficacy; behavioral medicine; chronic disease

Introduction

Mobile health (mHealth), or the use of mobile technology to improve health, is a rapidly expanding field [1]. As of 2015, more than 165,000 mHealth apps were available on the Apple

iTunes and Android app stores, and 34% of mobile phone owners had at least one health app on their mobile device [2-4]. Although health apps have drawn great public interest and use, little is known about the usability and efficacy of the majority of commercially available apps [5,6].

Much mHealth research focuses on the development and testing of new apps in academic settings [7]. However, the pace of traditional academic research is slow and less nimble relative to commercial app development, and this may result in huge lags in dissemination into commercial markets or settings where the general public has access to them [8], assuming the researcher takes steps to disseminate into commercial markets at all. Producing an app for public use requires content, programming, design expertise, the ability to continually host and update the app, and the resources to provide both customer service and technical support [8-10]. Apps generally take 7 to 12 months to fully develop and launch and cost on average US \$270,000 [10]. This does not include the added expense to maintain the app postdevelopment or the costs to publish the app to multiple platforms (eg, Apple and Android). Because many researchers will not have access to these resources, leveraging existing commercial apps in research may be an efficient and cost-effective alternative. The greater the scientific workforce dedicated to gathering evidence for health apps, the more quickly this field can evolve into one that is well grounded in evidence.

Health care providers also have great interest in determining the evidentiary basis of commercial apps. In fact, the American Psychiatric Association [11] and others [12] have developed guidelines for clinicians in selecting commercial apps to recommend to patients. A bedrock of these guidelines is that clinicians examine the evidence to make these decisions. With little evidence available for commercial apps, clinicians risk recommending a tool that does not work or worse one that causes harm. Although methods for systematically developing and establishing the effectiveness of apps in academic research laboratories have been described [13], little guidance is available on ways to develop an evidence base for commercial apps.

A recent systematic review provides a helpful starting point to describe methods that have been used in studies evaluating the quality of commercial health apps [14]. They report that among studies analyzing the quality of downloaded app content, methods used included rating apps relative to predefined criteria, rating apps relative to evidence-based criteria, and usability testing of functions [14]. Other studies analyzed content descriptions of apps using methods such as adapted website assessment tools, user ratings and reviews, and degree of involvement of experts in app development [14]. This review not only provides a useful overview of methods used in published studies but also points to the need for further work in developing and describing methods including those that have not yet been applied in research on commercial apps. We build on this work by detailing a wide variety of methods and study designs that can be used to evaluate commercial health apps.

The purpose of this paper is to present the full scope of methods for generating evidence for commercial health apps. Methods

for evaluating commercial health apps reviewed include content analysis, usability testing, observational studies, and efficacy testing. Illustrative examples are used when possible to demonstrate the application of methods described; examples were identified using the results of PubMed searches with related terms (eg, mobile apps, content analysis, usability testing, observational study, and randomized controlled trial [RCT]). This review will also shed light on decisions regarding which methods match specific research question and the degree of time and resources involved in the various study designs. The identification of high-quality commercial apps is essential for research, clinical practice, and to inform the development of the next generation of commercial apps.

Content Analysis

Content analysis is a research methodology that involves coding and interpreting qualitative, usually text-based material [15]. Commercial apps include multiple features, health information, and advice, all of which can be subject to content analysis. The first step in conducting a content analysis is to access the app content for review. In previous studies, the content that was analyzed came from either directly downloading the app and exploring its features or from the information provided in the app store (eg, app description and list of features) [14]. Although content analysis can simply involve describing the content included, another approach is to select a comparator against which the app content would be assessed. Three common comparators used in the scientific literature include clinical guidelines, evidence-based protocols, and behavior change techniques (see Table 1) [16-18]. Other possible comparators might include theoretical constructs or even other well-validated apps.

Accessing Content

Content analyses of descriptions in the app store [19] or of content in the downloaded app [14] address different questions. Evaluating the app descriptions gives insight into the content that influences a user's decision to download an app. A drawback is that app descriptions are not necessarily exhaustive sources of app content and may not exhaustively describe all features or content included in the app [19]. Coding the content of the downloaded app, on the other hand, will give insight into the actual content of the app. The drawback of this approach is that it may require some expense as many apps must be purchased. It also necessitates greater time investment as some apps require a period of use to experience all features. Content may also vary user by user as apps begin to employ artificial intelligence to personalize the content. Therefore, time, resources, and the research question must be considered when selecting an approach to accessing content for evaluation. Researchers should clearly articulate the limitations to the approach selected.

Table 1. Examples of evaluations of commercial mobile health apps.

Method and types of evaluation	Example studies	Study aim	Findings
Content analysis			
Clinical guidelines	Diabetes self-management [19]	Apps (N=227) evaluated for use of 7 self-management behavioral practices recommended by the American Association of Diabetes Educators	No apps promoted all 7 practices; 22.9% (52/227) included at least four of the practices, and 14.5% (33/227) did not include any practices
	Smoking cessation [20]	Apps (N=225) evaluated for use of the 5As clinical practice guidelines	51.1% of apps (115/225) implemented “ask,” 47.1% (106/225) “advise,” 8.0% (18/225) “assess,” 96.0% (216/225) “assist,” and 11.1% (25/225) “arrange follow-up”
	Pediatric obesity prevention and treatment [21]	Apps (N=57) examined for inclusion of 8 strategies and 7 behavioral targets recommended by the Expert Committee for Pediatric Obesity Prevention	61% (35/57) apps did not incorporate any evidence-based behavioral strategies; of the remaining 39% (22/57) apps, the mean number of strategies used was 3.6 (standard deviation [SD ^b] 2.7) out of the possible 15
Evidence-based treatment strategies	Weight loss [22]	Apps (N=30) evaluated for inclusion of 20 evidence-based weight loss strategies used in the Diabetes Prevention Program	Apps included 19% (3.8/20) of the strategies
	Depression [23]	Apps (N=117) evaluated for incorporated cognitive behavioral therapy and behavioral activation treatment strategies	10.3% (12/117) of apps were coded as delivering any elements of cognitive behavioral therapy or behavioral activation
Behavior change techniques	Physical activity [24]	Apps (N=64) reviewed for use of behavior change techniques	On average, apps included 22% (5/23) of the behavior change techniques (range 2-8)
	Physical activity [25]	Descriptions (N=167) for top-ranked apps evaluated for use of behavior change techniques	On average, App descriptions included 16% (4.2/26) of the behavior change techniques (range 1-13)
Usability testing			
Laboratory studies	Multiple health outcomes (depression, diabetes, caregiving) [26]	Usability of apps (N=11) evaluated among diverse participants (N=26) through completion of a series of app-related tasks	42.7% (79/185) of tasks completed without assistance; participants were interested in using technology, but lacked confidence navigating the apps and were frustrated by design features
	Diabetes self-management [27]	Usability of apps (N=42) evaluated by two experts based on ease of use, user interface design, customizability, data entry and retrieval, integration of data into charts/graphs, data sharing	10% (4/42) of apps had a composite usability score above 20 (scale 1-30)
	Pain management [28]	Usability of apps (N=2) evaluated by patients with chronic pain (N=41) through recall of two pain memories; assessed for ease of use and time to enter pain data	Entry for the app Pain Scale was 89% faster than entry for the app Manage My Pain; Manage My Pain incorporated more attractive fonts and colors
Field testing	Heart disease [29]	Usability of an app, Heartkeeper, evaluated through user feedback (N=26) on a survey that solicited feedback from existing users of the app in the field based on ease of use, performance, appearance, and perceived app security	Responses indicated that users were satisfied with the app
User ratings	General patient-centered health [30]	User ratings for apps (N=234) evaluated for presence of 12 features; analyzed whether these features explained variation in user ratings of the app	Plans, ability to export user’s app data, general usability, and app cost associated with higher user ratings; presence of a tracking feature associated with low user ratings

Method and types of evaluation	Example studies		
	Health topic	Study aim	Findings
Observational studies			
N/A ^a	Mental health [31]	Evaluated data from users (N=152,747) of the stress reduction app Happify to explore whether greater usage predicted higher well-being	Greater app use predicted more positive emotion among app users
	Weight loss [32]	Examined cross-sectional associations between weight loss and components of weight loss app Lose It! use among app users (N=972,687)	People who used the app most often were more likely to achieve weight loss success of losing 5% of their starting weight (73% success) than those users who only used the app occasionally (5% success)
	Physical activity [33-35]	Three studies examined the associations between use of Pokémon Go and physical activity (two through survey and one through ongoing use of a physical activity device); an outcome external to the app	Use of the app was associated with short-term increases in physical activity
Efficacy testing			
Randomized controlled trials	Weight loss [36]	Tested the effect of a weight loss app versus two traditional diet counseling methods (pen and paper and memo function on phone) on self-monitoring and weight loss among adults during an 8-week trial (N=57)	No between-group difference for weight loss; app condition participants kept more consistent diet records than pen and paper participants but not more than phone memo participants
	Weight loss [37]	Tested the effects of using MyFitnessPal weight loss app plus usual care versus usual care alone, for effects on weight loss and blood pressure over 6 months with N=212 primary care patients	No between-group differences found for weight loss or reduction in blood pressure differed between groups; app users set a calorie goal more often than the usual care group
	Smoking cessation [38]	Compared the efficacy of two smoking cessation apps over 8 weeks: a commercial app (QuitGuide) versus a researcher-developed app that incorporated Acceptance and Commitment Therapy	Researcher-created app was more effective than QuitGuide for quit rates (13% vs 8%) and participants engaged with it more than QuitGuide (opened app 37.2 times vs 15.2 times)

^aN/A: not applicable.

^bSD: standard deviation.

Selecting a Comparator

Clinical Guidelines

Some content analysis studies have compared app content with clinical guidelines put forth by professional organizations (eg, Expert Committee for Pediatric Obesity Prevention) [39,19-21]. This approach can identify apps that are most comprehensive in their incorporation of clinical guidelines and identify gaps in the content of other apps. It can also lend credibility to commercial apps that score highly among researchers, clinicians, and patients [19]. Studies comparing the content of commercial health apps with clinical guidelines have found that guidelines are sparsely used (see Table 1) [19-21]. For example, 227 diabetes self-management apps were evaluated against seven self-management behavioral practices recommended by the American Association of Diabetes Educators [40]. Results revealed that no apps promoted all seven, 22.9% (52/227) included at least four, and 14.5% (33/227) of apps did not include any of the behavioral practices [19]. However, as the researchers suggest, it is unlikely that all users will need or want every aspect included in clinical guidelines; for example, some

patients may want to track their medications, whereas other patients may not be on medication [19]. Although commercial apps may not incorporate all components of clinical guidelines, they can still be useful tools to deliver some key components of the guidelines. Understanding which components of the guidelines are included can help users and providers select the app that best matches their needs. One challenge for app developers is that clinical guidelines change as the science evolves, and some changes are heavily debated among scientists and practitioners (eg, American Heart Association dietary fats recommendations) [41], which can be confusing for developers and users. Staying abreast of changing guidelines would be necessary to insure that information provided is current.

Evidence-Based Protocols

Another comparator for commercial app content analysis is an evidence-based protocol. An evidence-based protocol is a structured collection of behavioral strategies that when implemented together and as recommended have produced significant effects on behavior or a health condition in randomized trials (eg, Diabetes Prevention Program Lifestyle Intervention) [42]. A comparison of apps with evidence-based

protocols can provide useful information about the strategies being deployed. To date, studies comparing the content of commercial health apps with evidence-based protocols have consistently found low rates of strategies included (See [Table 1](#)) [22,23]. For example, one study evaluated 30 weight loss mobile apps for inclusion of the 20 evidence-based weight loss strategies used in the Diabetes Prevention Program lifestyle intervention protocol (eg, weight loss goal, portion control, problem solving, and stress reduction) [22]. Overall, the apps included only 19% (3.8/20) of the strategies, but nearly all apps (93%) included setting a weight loss goal [22]. These findings suggest that although commercial apps do not generally appear to be providing a comprehensive set of behavioral strategies, they may assist the user with specific behavioral strategies.

Behavior Change Techniques

Another approach to analyze the content of apps has been to identify and classify the behavior change techniques used in the apps. A taxonomy of behavior change techniques was developed through a systematic process where health behavior theories and meta-analyses of interventions were reviewed to generate a list of discrete evidence-based techniques (eg, prompt barrier identification, model or demonstrate the behavior, and plan social support) [17]. The goal of the taxonomy is to provide a list of behavior change techniques in their smallest reducible size and to improve the specification, replication, and implementation of behavioral interventions [16-18]. Numerous validation studies have shown that researchers can use the taxonomy to reliably classify behavior change techniques [17,43]. Furthermore, research has shown that certain behavior change techniques are associated with more favorable outcomes [17,44,45]; therefore, evaluating apps for inclusion of these behavior change techniques could aid in identifying appropriate apps for specific behavior change goals. Two studies have evaluated the content of commercial physical activity apps to describe their utilization of behavior change techniques [24,25]. One study found that, on average, physical activity apps incorporated 5 of the 23 behavior change techniques (22% of total) [24]; another one found that app descriptions mentioned, on average, 4.2 of the 26 behavior change techniques (16% of total) [25]. As more behavior change techniques are implemented in commercial apps, behavioral providers may be able to give tailored recommendations of apps to match patients' specific behavioral challenges.

Challenges to Content Analysis

Content analyzing commercial apps can be challenging for four main reasons. The first challenge is the variability in the way apps implement clinical guidelines, evidence-based strategies, and behavior change techniques. For example, an app might implement goal setting by allowing a user to set a behavioral goal. Goal setting implemented during behavioral counseling would not only involve the individual selecting a goal but would also provide assistance with selecting realistic and measurable goals and guidance on adjusting the goal over time based on the individual's performance. In this case, the app developers would have to make a judgment call as to whether goal setting in the app reached the fidelity threshold for goal setting as originally intended. When evaluating the content of apps,

researchers are encouraged to specifically describe the threshold for each behavioral strategy. Continuous rating scales could also be used instead of simple yes or no" indicators of the presence of a strategy to more fully capture the extent to which the strategy was implemented.

A second challenge to content analysis is that methods presented here rely on subjective ratings of app content and app features. A recent study demonstrated the difficulty of conducting consistent assessments of app content between reviewers, as evidenced by low interrater reliability scores [46]. Researchers are cautioned to use tools that involve little reviewer discretion (ie, assessed on a factual basis) to reliably evaluate app content and features across individuals [46].

A third challenge to content analysis is that apps are frequently updated which may result in continuously changing features, loss of features, and new features. The app version number and download and review dates should be disclosed in content analysis reports. Given how often companies release app updates, content analysis reviews can quickly become obsolete and may need to be performed quickly and frequently.

A final challenge to content analysis is that some apps release features only after a period of use or with an additional cost [22]. The period of use may be based on time spent or accomplishment of specific goals. These features might be missed if coding is only done in a single use episode or without purchasing the extra features. Therefore, proper recording of the duration of use and presence of additional paid features in apps is recommended.

Usability Testing

Usability or user testing refers to how well an app functions and whether or not it serves its intended purpose. Typically, usability is measured across dimensions such as user ratings of app flexibility, operability, understandability, learnability, efficiency, satisfaction, attractiveness, consistency, and error rates [47-51]. Usability testing specific to a target population can be particularly helpful for researchers or clinicians whose work focuses on those populations [47]. The International Organization for Standardization (ISO) is a leader in developing industry standards and evidence-based guidelines for the development of a range of services and products, including technologies [52]. Two recent International Standards (ISO 9241 and ISO 25062) provide guidelines for conducting and reporting on usability testing of mobile apps [53]. These standards frame usability testing and results in terms of the feedback from users, as opposed to past standards that defined usability based on the software product itself [53]. Developers may approach the process of usability evaluation through methods such as experts-based evaluation (ie, experts describe the problems that users might encounter), observation (ie, watching users interact with the app), surveys (ie, to collect user feedback), and experimental evaluation (ie, evaluation of a product through interaction with app by experts or users to collect feedback on usability issues) [47,53]. Evaluation of commercial app usability can include laboratory testing, field-based evaluations, and reviewing ratings and narrative user reviews from app marketplaces ([Table 1](#)).

Laboratory-Based Testing

Usability testing can be conducted in a laboratory where users are asked to carry out specific tasks with an app in a controlled setting with extensive observation [51]. Laboratory-based testing can be helpful, especially when usability needs to be assessed in a specific population who may have different characteristics than the users targeted by the company (see Table 1 for examples) [26-28]. Usability metrics, such as comprehensibility and ease of use, can be collected over a short period of time with a small number of people. In a single visit, laboratory-based usability testing can provide rich data by allowing user behavior to be audio- or video-recorded. Investigating the way that members of the target population click through and understand various screens and features may uncover usability issues [47]. For example, a researcher might be interested in identifying a commercial exercise app that has high usability in older cancer survivors. Results from laboratory-based testing can be used to inform the instructions and training given to the target population or additional technology needed to support use of the app. For example, investigators might be able to design workarounds for app deficiencies (eg, use mobile phone settings for color changes and font size to make app more readable) to boost their usability in future research. One limitation of usability testing is that it may not represent how users will interact with the app in the real world [28,51]; therefore, more extensive field testing may be necessary.

Field Testing

Field testing or mobile in the wild testing allows observation of how people use the app in their real lives [51] to better understand real-world usage of the app [54,55]. Testing apps in the field can test usability of an app for a specific target population or help determine which of the several apps is best for a target population. Few studies have used field-based methods to evaluate the usability of commercial health apps (Table 1) [29]. One study evaluated the app Heartkeeper by incorporating a button into the app where users could click and complete a quality of experience survey to rate content quality, security, ease of use, availability, performance, appearance, and learning of the app [29]. Responses indicated that users were satisfied with the app [29]. Another method to collect field usability data is through app tracking software. Software can be installed on mobile phones to monitor the number of active app users, how long users spend in the app, what they click on, and so on. Researchers should consider utilizing these programs and reporting on app use data to supplement other field testing results. Despite the rich data field tests can provide, capturing app use in a dynamic environment makes direct observation difficult [21]. Furthermore, findings may only be relevant to the sample of users selected and samples tend to be small [26]. Additional evidence for app usability in a variety of populations is critical to provide further insight into which apps might be best suited for whom.

User Feedback: Ratings and Reviews

User feedback on the app marketplace is a source of usability data that reflects the experiences of people who presumably downloaded and used the app. These data can demonstrate app popularity via total number of ratings, as well as quality via

average rating (typically as a number of stars out of 5) and narrative reviews. Although mean rating provides an overall estimate of quality or desirability, the distribution of ratings may be important to understanding the mean rating. For example, an average rating of 3 stars could either suggest that most ratings hovered around 3 stars, or could be reflective of highly polarized ratings (ie, mostly 1-star and 5-star ratings). Low ratings may indicate a specific issue with the app or contradictory opinions of the app overall. Ratings may change over time because of updates (eg, bug patches and function improvements) and users changing their past ratings over the course of app use (as allowed by some app stores). However, recent research suggests that caution should be taken when interpreting these ratings as they are correlated with unexpected factors such as time to last update, app vocabulary, and the app description [56]. Narrative reviews can provide qualitative data about the positive and negative aspects of usability, user interface, and match between intended use and functionality. Reviews may also include users' perceptions of efficacy (eg, "this app is great!! I lost 10lbs using it!!"). Because not all users provide reviews, reviews may oversample highly positive and negative experiences rather than the "average" experience. Content analysis [57], sentiment classification, and natural language processing may be useful for examining user-narrative reviews. One limitation is that app creators can write reviews themselves or otherwise incentivize users to give favorable ratings, affecting interpretability of these data [14].

Observational Studies

Observational studies can be used to assess app use, satisfaction, and the predictive value of app use on behavioral and clinical outcomes. Observational studies can be conducted via large databases of users or case series of a small number of users to assess outcomes tracked by the app (Table 1) [31-35]. Although observational studies cannot establish causality (ie, efficacy of the app on an outcome), they can be used to explore associations between app use and outcomes. For example, an observational study of users of popular weight loss apps might examine whether length of use is associated with greater weight loss. Observational studies can also provide information about duration of use in real-world settings for specific types of users [58]. For example, ecological momentary assessment can be utilized to gather data numerous times throughout a day [59] to provide information about use patterns across people or intraindividual use patterns. A limitation of observational studies is the potential for selection bias, especially when examining prolonged use of the app and the inability to draw causal conclusions about observed behavior changes. Additionally, app users are not likely representative of patient populations (eg, MyFitnessPal users likely have different characteristics than primary care patients with obesity). Furthermore, information regarding the characteristics of users may be limited, making it difficult to ever know whom the data represent. For this reason, it would be important to clearly describe the limitations of the data in manuscripts and other public reports. Given the massive amount of data companies have on the use of their apps, observational studies present an enormous opportunity for academic-industry collaboration. Academics

could partner with companies who are interested in having their outcome (eg, weight loss and physical activity) and process data (eg, self-monitoring patterns) analyzed. Alternatively, companies are increasingly hiring behavioral and data scientists to explore their data, providing a novel industry career path for academics looking to use their skills to inform commercial products.

Efficacy Testing

Efficacy testing is a critical step in establishing whether use of a commercial app results in meaningful change in behavior and clinical outcomes. The gold standard approach to efficacy testing is the RCT [60]. However, given the time and expense required to perform RCTs, alternative study designs like N-of-1 and case series can be considered as initial steps to justify the progression to RCT.

Randomized Controlled Trials

Evidence from RCTs (Table 1) is considered the gold standard in the context of clinical guidelines [61], which is ultimately the gateway to becoming a part of standard practice. A major decision point in RCTs is the appropriate control or comparison group with each option addressing a unique question. Usual care control groups address whether a commercial app improves upon usual care [37]. On the other hand, one might be interested in testing whether an app-delivered behavioral strategy improves upon the same behavioral strategy when delivered via a traditional modality (eg, dietary self-monitoring via app vs paper diaries) [36], in which case a noninferiority trial using the traditional condition as comparator is appropriate. If the research question is whether an app improves upon a standard practice, a comparison could be made between standard practice with and without the app [37]. Comparative effectiveness studies including both equivalence and noninferiority designs might compare two apps or an app with another treatment approach. For example, one RCT tested whether a new investigator-generated smoking cessation app utilizing a novel behavior change model was more effective than a commercially available app [38].

Challenges

RCTs are time and resource intensive, which means their use must be reserved for apps in which other previously discussed forms of evidence support the investment. Another challenge to RCTs with commercial apps is that frequent app updates make it difficult to ensure that all participants receive identical intervention. Treatment fidelity and receipt should be tracked so that such deviations can be documented and controlled for in analytic models. Finally, researchers have no control over the features in a commercial app, making it difficult to test whether the “success” of an app-delivered intervention is attributable to the total package of the app or because of specific app components.

Alternative Study Designs

Optimization Strategies

To address research questions about the efficacy of individual app features, researchers may consider utilizing an optimization design, such as the one described in the multiphase optimization

strategy (MOST) framework [62,63]. The MOST framework is an iterative research design that allows investigators to select and evaluate individual components, rather than the treatment as a whole, to optimize the effect of individual components on behavior change. Specific study designs within this framework include factorial designs and sequential multiple assignment randomized trials [62]. Furthermore, parallels have been drawn between the use of optimization designs, such as MOST, for behavioral trials and the process used for software development, which is described as an “agile science” process for behavioral research [64]. The agile science process calls for researchers to target and test specific components of new products (eg, apps) for rapid testing of and adaptation to the smallest meaningful unit possible, allowing for more efficient iteration and dissemination [64]. The MOST framework has yet to be applied to testing the efficacy of commercial apps, and one challenge is in randomizing participants to only using parts of an app when they have access to the entire app. This work might ideally be performed during the design phase of the app in the context of an academic-industry partnership. Studies could leverage a MOST design to test different combinations of commercial apps that each provide a unique behavioral strategy; however, efforts would need to be taken to prevent contamination as commercial apps are publicly available.

N-of-1 Studies

A fairly quick way to build efficacy data for a commercial health app is via N-of-1 designs. This methodology, also known as “single-case,” involves the repeated measurement of an individual over time and is a practical method for understanding within-person behavior change after presenting an intervention (ie, AB design) or after presenting the intervention and then removing it (ie, ABA design). Similar to the process recommended by researchers to rapidly iterate mobile app development in the laboratory [8], N-of-1 trials could be used to test the preliminary efficacy of established commercial apps using methods analogous to personalized medicine (ie, iterative crossover designs) [65]. For example, those interested in testing whether exposure to theory-based content of a healthy eating app influences the dietary choices of individual participants might use a series of ABA N-of-1 designs to describe intraindividual variation in behavior before and after exposure to that feature. Furthermore, ongoing work in dynamic statistical modeling provides guidance for analyzing the data from N-of-1 trials [66], including techniques to increase the generalizability of estimates [67]. Although no published studies have used N-of-1 designs for testing commercial apps, a recent systematic review examined the evidence for using N-of-1 studies for other health behavior interventions, describing the current state of evidence supporting N-of-1 studies, and methodological considerations for designing and executing N-of-1 studies [68]. The review also offers insights about the potential for technology to help collect large amounts of individual data from participants both unobtrusively and longitudinally [68]. N-of-1 designs do have important limitations, including lack of generalizability, limited consensus on appropriate analytic techniques, and failure to address long-term maintenance of behavior change. Additionally, use of N-of-1 designs for testing mobile apps include the potential to overestimate effects because of the so

called “digital placebo” effect, which is the ability of expectations of the benefit of using a digital tool such as an app to lead to clinical improvement [69]. The digital placebo effect could partially explain consumers’ reports of benefits from apps that are largely devoid of evidence-based strategies and unlikely to provide substantive benefit [69]. Researchers employing an N-of-1 design are cautioned to account for these limitations in their study designs.

Discussion

In this paper, we described a host of methods that can be used to systematically evaluate commercial apps as a way to stimulate a science of commercial health apps. Greater evidence for commercial apps could increase their adoption in clinical practice and impact on behavioral and clinical outcomes. Commercial apps are typically developed with a high level of expertise in design and function and many are well marketed and have enormous user bases. Scientists who do not have the resources to develop their own apps can instead employ less resource-intensive research on commercial health apps. Industry professionals and investors would benefit from data on the content, usability, and efficacy of the commercial apps to inform their decisions on future products and investments.

Future Research

Additional areas of exploration in researching commercial apps may include evaluation of the technical functions of the app, developer transparency, and policies regarding user data privacy and security (eg, transparency about how developer will use app data) [70]. In terms of technical performance of the app, research could evaluate features such as validation of information inputs (eg, app verifies that the information a user inputs is plausible or flags the entry and asks for a correction) and information security precautions (eg, whether user’s medical data are susceptible to interception) [70]. In terms of developer transparency, researchers could use app metadata to extract manufacturer information, contact information, and product information. For example, do manufacturers include professional expertise in the target health area, such as endocrinologist for a diabetes self-management app? These data would also allow researchers to evaluate relationships between app quality, user ratings, and developer transparency [56,71]. Another important dimension of transparency is extent of user information required to run the app and whether permissions requested are necessary. A recent review investigated the declarations of manifest files and app source code to determine whether the permissions requested were related to the information needed to run the app [72]. Results suggested that requested permissions often

surpassed what the app needed, which means these apps could pose an unnecessary threat to user privacy and safety [72]. In terms of evaluation of the privacy and security of commercial apps, researchers can track whether users retain the rights to their own data, whether data are adequately protected during transmission and storage, and developer transparency (eg, published contact information if users have questions) [73]. A growing interdisciplinary dialogue is emerging about the ethical considerations of using health technologies, including proper precautions that should be taken to ensure user privacy and safety [73,74].

Limitations

This review has some limitations. First, we did not conduct a systematic review of app evaluation studies, but rather present a focused summary of methodologies commonly used in studies testing traditional interventions with details on how they can be applied to commercial apps, with illustrative examples where possible. In general, another limitation of this review is that commercial products may be updated, completely changed, or discontinued while a research study is in progress, making findings obsolete before they are even published. Apps that were developed by established companies, have been in the marketplace for a while without major changes, and have large and devoted user bases may be less likely to change drastically over the course of a research study. Research on a commercial app that contains features that are common to many other commercial apps will have relevance to those other apps even if the target app no longer exists. However, the rapid pace of technology means researchers should avoid delays in data analysis and publication for this work. Historically, traditional interventions have evolved relatively slowly, which allowed lags in the research process. Such lags cannot be afforded for this work. To speed the process, researchers should be sure to establish a firm project timeline, select collaborators who are willing to commit to the project timeline, and target journals with fast review turnaround times and brief report article types.

Conclusion

Research on commercial mHealth apps can take many forms depending on the research question as well as the time and resources required to complete it. No single methodology is best as each provides a different type of evidence and involves a unique set of advantages and limitations. Research on commercial mobile apps complements research exploring the development and testing of novel apps in academic laboratories. Both have a place in the literature and together will propel the mHealth space forward and strengthen the degree to which its foundation is empirical evidence.

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Conflicts of Interest

GGB declares that he has equity in Scale Down, which develops digital health technologies, and he declares that he also has equity in Coeus Health, which develops technologies for digital health. SLP declares that she is a scientific advisor for Fitbit.

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Abbreviations

ISO: International Organization for Standardization

mHealth: mobile health

MOST: multiphase optimization strategy

RCT: randomized controlled trial

SD: standard deviation

N/A: not applicable

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Original Paper

Predictors of Playing Augmented Reality Mobile Games While Walking Based on the Theory of Planned Behavior: Web-Based Survey

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Abstract

Background: There has been a sharp increase in the number of pedestrians injured while using a mobile phone, but little research has been conducted to explain how and why people use mobile devices while walking. Therefore, we conducted a survey study to explicate the motivations of mobile phone use while walking

Objective: The purpose of this study was to identify the critical predictors of behavioral intention to play a popular mobile game, *Pokemon Go*, while walking, based on the theory of planned behavior (TPB). In addition to the three components of TPB, automaticity, immersion, and enjoyment were added to the model. This study is a theory-based investigation that explores the underlying mechanisms of mobile phone use while walking focusing on a mobile game behavior.

Methods: Participants were recruited from a university (study 1; N=262) and Amazon Mechanical Turk (MTurk) (study 2; N=197) in the United States. Participants completed a Web-based questionnaire, which included measures of attitude, subjective norms, perceived behavioral control (PBC), automaticity, immersion, and enjoyment. Participants also answered questions regarding demographic items.

Results: Hierarchical regression analyses were conducted to examine hypotheses. The model we tested explained about 41% (study 1) and 63% (study 2) of people's intention to play *Pokemon Go* while walking. The following 3 TPB variables were significant predictors of intention to play *Pokemon Go* while walking in study 1 and study 2: attitude ($P<.001$), subjective norms ($P<.001$), and PBC ($P=.007$ in study 1; $P<.001$ in study 2). Automaticity tendency ($P<.001$), immersion ($P=.02$), and enjoyment ($P=.04$) were significant predictors in study 1, whereas enjoyment was the only significant predictor in study 2 ($P=.01$).

Conclusions: Findings from this study demonstrated the utility of TPB in predicting a new behavioral domain—mobile use while walking. To sum up, younger users who are habitual, impulsive, and less immersed players are more likely to intend to play a mobile game while walking.

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KEYWORDS

mobile phone; pedestrians; safety on the street; psychological models; predictive value of tests; intention; age factors; attitude; social norms; self-efficacy; habits; immersion; self-report

Introduction

The Ubiquity of Mobile Devices

Despite the efficiency and convenience of communication technology, the increased use of mobile media technology produces alarming safety issues in society, such as mobile phone use while driving [1] and walking [2,3]. Although researchers have been paying a great deal of attention to the perils of mobile phone use while driving [1], concerns about using a mobile phone while walking have only recently been raised. Researchers have examined the effects of mobile phone usage on cognitive and gait performance [4-6]. Their findings indicated that people who used mobile phones while walking were cognitively distracted and did not pay enough attention to their surroundings, such as traffic signals or oncoming automobiles. Pedestrians who use their mobile phones while walking cannot maintain their balance, which may cause an increase in unsafe behaviors, injuries, or even death.

Despite the prevalence and popularity of mobile device use in everyday life across all age groups, there has been little interest in exploring and understanding what motivates people to use mobile devices, such as a mobile phone, while walking. This study attempts to fill in this gap in prior literature in the psychology of mobile device use. The findings from this study will provide a better understanding of people's mobile device use in everyday life, which may help health communication researchers and practitioners to create interventions targeting risky behaviors related to mobile device use. The next section provides a short review of mobile phone use literature and the theory of planned behavior (TPB) literature.

Prior Work on Perils of Mobile Phone Use While Walking

There is extensive research examining the effects of mobile phone use on distracted driving [1,7]. Recently, attention has shifted to the dangers of texting while walking [2,6,8]. Similar to the harmful impact of texting while driving for drivers, the dual task of texting while walking visually and cognitively distracts pedestrians from the road [4]. Several studies examined the effect of mobile phone use while walking on pedestrians' gait performance. For example, Lamberg and Muratori [9] found that people who used a mobile phone while walking demonstrated a reduced walking speed and greater lateral deviation from a straight path than people who did not use a mobile phone while walking. Furthermore, people texting while walking showed greater interference effects from mobile phone use than those talking on the phone while walking. These findings imply that a dual task such as texting or playing games on a phone while walking would be a factor that threatens pedestrians' safety by increasing cognitive demand or limiting availability of visual information. These findings also raise concerns about pedestrian safety due to mobile phone use while walking in general. Furthermore, researchers have shown a

significant association between mobile phone use while walking and the risk of collisions, falls, and traffic accidents [2,10].

The pedestrian safety issue, playing augmented reality mobile games such as *Pokemon Go* while walking [11,12], has been recently highlighted by media. *Pokemon Go* has been downloaded more than 550 million times and continues to be downloaded worldwide [13], and Wagner-Greene et al indicated that playing *Pokemon Go* could lead to unsafe walking without paying attention to surroundings [12]. Although some research found a positive effect of playing *Pokemon Go* on the amount of daily physical activity [12,14], the findings from recent research are contradictory at best. For example, Howe et al found that the increase in the average daily steps was significant only in the first week, eventually decreasing over the following 5 weeks [15]. There was no significant difference in the average daily steps between *Pokemon Go* players and nonplayers 6 weeks after beginning the game.

Although the potential health benefits of playing *Pokemon Go* are controversial, the negative aspects of playing *Pokemon Go* while walking are potentially life threatening. Health experts reported increased user injuries because of *Pokemon Go* and warn against the risks associated with playing augmented reality games while walking [10,16]. To prevent the potentially severe consequences due to unsafe mobile use practices including augmented reality gaming while walking, it is necessary to identify significant factors associated with mobile use while walking to inform people of the potential risks.

Theoretical Background: The Theory of Planned Behavior

This study uses TPB to find salient predictors of people's intentions to play a mobile game, in particular *Pokemon Go*, while walking. TPB has been applied to understand distracted driving among people, specifically understanding the factors that lead people to use mobile phones while driving [1,7]. TPB posits that an individual is willing to choose to perform or not to perform a certain behavior through rational considerations [17]. The theory of reasoned action (TRA) [18] and TPB [17] assume that individuals systematically use and evaluate available information about outcomes associated with behaviors before engaging in the behaviors. In addition, those volitional behaviors can be best predicted from a person's willingness or behavioral intention, which is defined as "a measure of the likelihood that a person will engage in a given behavior" [19].

According to TRA, a person's behavioral intention can be predicted from one's attitude toward the performance of the behavior and subjective norms. Within the TRA framework, attitude toward a behavior is defined as the extent to which a person evaluates a certain behavior favorably or unfavorably, and subjective norms refer to a person's perceived social pressure from important others (eg, family members or close friends) about whether one should carry out the behavior or not [17]. Both attitude and subjective norms contain a belief and

evaluative component. Later, TPB added a component, perceived behavioral control (PBC), to predict a person's behavioral intention. PBC refers to the degree of control that individuals perceive themselves to have over performance of a behavior, which has a direct impact on a behavior. TPB has been widely applied to various research topics including health-related behaviors [20-22], binge drinking [23], recycling [24], organ donation [25,26], and distracted driving [1,7,27] to predict and explain human behavior. Findings from previous studies indicated that TPB has a predictive and explanatory power [20].

Thus, this study hypothesizes that positive attitudes toward mobile game play (H1), greater perceived subjective norms (H2), and a higher level of PBC (H3) would lead to a strong intention to play mobile games while walking through cognitive evaluation:

H1: As people have more positive attitudes toward playing *Pokemon Go* while walking, they would more likely intend to play *Pokemon Go* while walking.

H2: As people perceive greater social pressure on playing *Pokemon Go* while walking, they would more likely intend to play *Pokemon Go* while walking.

H3: As people have a greater degree of PBC over playing *Pokemon Go* while walking, they would more likely intend to play *Pokemon Go* while walking.

Although previous findings have shown the effectiveness of TPB to predict and explain human behavior in many different contexts, researchers argue for the necessity to improve the predictive and explanatory power of the theory with the inclusion of relevant factors such as affective states (ie, anticipated regret), moral norms, or personal norms [28-30]. This study attempts to add relevant components to TPB considering the characteristics of the mobile game behavior in question.

Additional Predictors in Mobile Communication

One of the most common criticisms on TPB has been that it only focused on the conscious, reasoned behavioral motivations [31]. TPB recognizes cases in which individuals sometimes less consciously use and evaluate available information before engaging in behaviors (ie, automaticity) [32]. People may not need to assess their beliefs and relevant information with great consciousness to decide whether they perform a behavior once they have performed it many times. They could retrieve their stored attitudes and intentions from memory and make decisions without much cognitive effort. Bayer et al argue that people rely on automatic (less conscious) or immersive (more conscious) behavioral orientations when they engage in communication activities using mobile devices [33]. Using mobile devices is a behavior that is performed in a less conscious manner (ie, with a high level of automaticity) or in a high conscious manner (ie, with a high level of immersion), depending on the context or personality (ie, trait self-regulation or trait mindfulness) [33]. For example, people sometimes use mobile devices for calling, texting, surfing the Web, or playing mobile games with minimal consciousness (eg, automaticity, habits, and impulses), whereas they use mobile devices for the

same behaviors with conscious effort other times (eg, flow, immersion, presence, and absorption). That is to say, mobile communication involves both less conscious (ie, automaticity) and more conscious (ie, immersion) processes based on the levels of media users' perceived behavioral consciousness.

Bayer et al empirically tested the distinct roles of automaticity and immersion in mobile communication [33]. In their study, automaticity refers to a behavioral process in mobile device use including the following four behavioral dimensions: lack of attention, lack of awareness, lack of intention, and lack of control. Immersion refers to a behavioral process in mobile device use with maximal behavioral attention and awareness. Immersive process also includes a lack of temporal and spatial awareness because of the great concentration on the media activities. The interactive nature of mobile communication such as texting or playing augmented reality games is associated with an immersive behavioral process such that users actively attend to their mobile-mediated interactions and construct a virtual social space while navigating the physical environment. Along the spectrum, automaticity lies on the less conscious end, whereas immersion lies on the more conscious end.

On the basis of the spectrum, Bayer et al (study 1) explored whether automaticity and immersion independently or simultaneously influence mobile use behaviors such as texting (ie, texting frequency and affective benefits of texting) [33]. They found that only automatic behavioral orientation (ie, less conscious use of texting) was positively associated with texting frequency, whereas both automatic and immersive behavioral orientations were positively related to perceived affective benefit of texting (called affective temptation). In other words, automatic behavioral orientations and immersive behavioral orientations would cowork when people feel that mobile use activity produces positive affect. Although automaticity and immersion are located on the opposite side of a conceptual continuum, both Bayer et al and other researchers have found that human behavior emerges from a combination of the unconscious and conscious processes [33,34].

Given that previous research found both automaticity and immersion as significant predictors of mobile use behavior, this research adds these two different behavioral tendencies to TPB, automaticity and immersion in mobile communication. Previous research recommends to simultaneously incorporate two mobile use related-behavioral orientations [33]. Thus, this study hypothesizes that greater automatic behavioral orientation (H4) and greater immersive behavioral orientation (H5) toward mobile game play would lead to a strong intention to play mobile games while walking:

H4: As people have greater automaticity of playing *Pokemon Go* while walking, they would more likely intend to play *Pokemon Go* while walking.

H5: As people have greater immersion in playing *Pokemon Go* while walking, they would more likely intend to play *Pokemon Go* while walking.

Another factor relevant to playing a mobile game while walking, in general, is an individual's feeling of enjoyment [35]. Such an intrinsic motivation encourages people to persist in performing a behavior [36]. Prior literature found that enjoyment

was a significant predictor of intention to play Web-based games [35,37]. Thus, this study assesses the effect of an individual's enjoyment on their decision to play a mobile game while walking.

H6: As people experience greater enjoyment of playing *Pokemon Go* while walking, they would more likely intend to play *Pokemon Go* while walking.

This paper addresses this emerging health issue related to mobile communication by testing 2 samples. Study 1 used a sample of young college students aged 18 to 34 years. Study 2 addressed the lack of diversity of the sample in study 1 by recruiting a sample of people aged 18 to 65 years from Amazon Mechanical Turk (MTurk). The following section details the methodology for this study.

Methods

Participants and Procedure

This study used a convenience sample and Web-based survey to ask participants to report their intention of playing *Pokemon Go* while walking, automaticity tendency, immersion tendency, enjoyment, and 3 TPB components, including attitude, subjective norms, and PBC. It took about 15 minutes to complete the Web-based survey. This study was approved by an Institutional Review Board and pretested by researchers.

Study 1

Participants were recruited online from a nonprobability sample (ie, the general communication pool) at a large southern university in the United States from November 2016 to April 2017. Participants were required to be mobile phone users to participate in the complete survey of the psychological processes. In recognition of their participation, they received extra course credit.

Study 2

As student convenience samples have limited generalizability, the Web-based sample from MTurk was utilized to provide a more diverse sample for this study [38-40]. This is particularly relevant because prior research has related mobile device use to age and life phase [33,41]. Participants were recruited from MTurk in the United States in March 2017. Only US workers could participate in the study to minimize the effect of different cultural background on the outcome variable. Participants were required to be mobile phone users to participate in the complete survey. Participants received US \$ 0.75 in recognition of their participation.

Measurement

The same measures were used in both study 1 and study 2. Each measure was checked for inter-item correlations, item contribution to scale reliability, and internal consistency. All measures were 7-point scales except for the automaticity and immersion, which used a 5-point scale anchored by 1 (*not at all*) and 5 (*completely*). All measures are available in [Multimedia Appendix 1](#).

Attitude

Participants' attitude toward playing *Pokemon Go* while walking was assessed with a 7-point semantic differential scale adopted from a previous study [42]. Participants were asked to respond to the statement "For me, playing *Pokemon Go* while walking would be..." The following items were included: beneficial/harmful, foolish/wise, unpleasant/pleasant, enjoyable/unenjoyable, bad/good, favorable/unfavorable, and positive/negative.

Subjective Norms

To measure the extent to which participants perceived behavioral expectation from their important people, seven items were used [1,43]. An example item is "Those people who are important to me would want me to play *Pokemon Go* while walking." (1=strongly disagree, 7=strongly agree).

Perceived Behavioral Control

The extent to which participants perceived that they had control over playing *Pokemon Go* while walking was assessed using three items with a 7-point Likert-type scale adopted from a previous study [44]. An example item includes "How much personal control do you feel you have over playing *Pokemon Go* while walking?" (1=not at all, 7=very much so). To improve the reliability, an item that did not contribute to scale reliability was removed from the scale.

Automaticity

Automaticity was defined as a behavioral orientation that occurs without conscious awareness. Four items were used to measure the extent of participants' automatic behavioral orientations toward playing *Pokemon Go* while walking. The items were adapted from a previous study [33]. Automaticity includes the following four dimensions: lack of behavioral attention, lack of behavioral awareness, lack of behavioral intention, and lack of behavioral control. An example item is "When I play *Pokemon Go*, I do it without thinking."

Immersion

Immersion was defined as a behavioral orientation that occurs in a conscious manner. Four items were used to measure the extent of participants' immersive behavioral orientations toward playing *Pokemon Go* while walking. Immersion includes the following four dimensions: maximal behavioral attention, maximal behavioral awareness, lack of spatial awareness, and lack of temporal awareness [33]. The items were adapted from a previous study [33]. An example item includes "When I play *Pokemon Go*, my eyes are fixed on doing it."

Enjoyment

To assess individuals' feeling of enjoyment while playing *Pokemon Go* while walking, four items were adopted from a previous study [35]. One of the examples includes "Playing *Pokemon Go* is enjoyable." (1=strongly disagree, 7=strongly agree).

Intention to Play *Pokemon Go* While Walking

To measure behavioral intention to play *Pokemon Go* while walking, this study used three items adopted from previous research [1]. An example item is, "I plan to play *Pokemon Go*

while walking.” (1=strongly disagree, 7=strongly agree). Tables 1 and 2 present descriptive statistics of the measures, including means, standard deviations (SDs), and Cronbach alphas for study 1 and study 2.

Table 1. Means, standard deviations, and Cronbach alphas for study 1 variables.

Study 1 variables	Mean (SD)	Cronbach alpha
Intention	3.90 (1.32)	.98
Attitude	3.91 (1.32)	.96
Subjective norms	3.86 (1.04)	.82
PBC ^a (after deleting #3)	6.12 (1.01)	.71
Automaticity	2.09 (0.96)	.87
Immersion	2.37 (0.99)	.93
Enjoyment	4.84 (1.23)	.92

^aPBC: perceived behavioral control.

Table 2. Means, standard deviations, and Cronbach alphas for study 2 variables.

Study 2 variables	Mean (SD)	Cronbach alpha
Intention	4.28 (1.98)	.97
Attitude	4.68 (1.43)	.97
Subjective norms	4.36 (1.42)	.91
PBC ^a (after deleting #3)	6.18 (1.08)	.77
Automaticity	2.54 (1.10)	.89
Immersion	2.92 (1.05)	.91
Enjoyment	5.36 (1.33)	.91

^aPBC: perceived behavioral control.

Finally, questions regarding demographic information, including age, gender, ethnicity, and mobile phone addiction, were measured.

Analytic Plan

To test the study hypotheses, hierarchical regression analysis was employed. Before conducting hierarchical regression analyses, the categorical variable was dummy coded. For gender, male was coded as 0 and female was coded as 1. Other continuous variables, except the dependent variable, were mean

centered to avoid potential multicollinearity [45]. Two demographic variables, age and gender, were included as covariates in the analyses based on the findings from prior literature [33,41,46]. For each analysis performed, the first block of the regression analyses contained the study covariates. The second block of the regression analyses contained the three TPB predictors, followed by additional predictors, automaticity, immersion, and enjoyment, in the third block. Tables 3 and 4 reported the zero-order correlation matrix of continuous variables for study 1 and study 2.

Table 3. Correlation matrix of variables in study 1 (N=262), shown as Pearson correlation coefficient r (P value).

Study 1 variables	1	2	3	4	5	6	7	8	9
1 Intention	— ^a								
2 Attitude	.53 (.001)	—							
3 Subjective norms	.50 (.001)	.57 (.001)	—						
4 Perceived behavioral control	-.11 (.08)	.09 (.14)	.05 (.41)	—					
5 Automaticity	.25 (.001)	.06 (.38)	.13 (.03)	-.15 (.02)	—				
6 Immersion	.13 (.03)	.13 (.04)	.14 (.02)	-.10 (.10)	.60 (.001)	—			
7 Enjoyment	.37 (.001)	.42 (.001)	.38 (.001)	-.02 (.79)	.14 (.03)	.22 (.001)	—		
8 Age	-.10 (.10)	.01 (.84)	.05 (.43)	-.02 (.79)	-.07 (.23)	-.01 (.94)	-.08 (.20)	—	
9 Gender	.01 (.91)	-.08 (.23)	.01 (.85)	-.03 (.62)	-.12 (.049)	-.09 (.17)	.12 (.05)	-.04 (.54)	—

^a— signifies the correlation of 1.

Table 4. Correlation matrix of variables in study 2 (N=179), shown as Pearson correlation coefficient r (P value).

Study 2 variables	1	2	3	4	5	6	7	8	9
1 Intention	— ^a								
2 Attitude	.73 (.001)	—							
3 Subjective norms	.65 (.001)	.64 (.001)	—						
4 Perceived behavioral control	-.05 (.52)	.11 (.14)	.17 (.02)	—					
5 Automaticity	.27 (.001)	.18 (.02)	.24 (.001)	-.32 (.001)	—				
6 Immersion	.41 (.001)	.36 (.001)	.32 (.001)	-.05 (.49)	.63 (.001)	—			
7 Enjoyment	.51 (.001)	.56 (.001)	.42 (.001)	.24 (.001)	.19 (.01)	.43 (.001)	—		
8 Age	-.08 (.27)	-.09 (.23)	-.15 (.049)	.09 (.21)	-.15 (.04)	-.05 (.52)	.02 (.74)	—	
9 Gender	-.20 (.008)	-.12 (.12)	-.13 (.09)	.12 (.12)	-.32 (.001)	-.29 (.001)	-.03 (.68)	.08 (.26)	—

^a— signifies the correlation of 1.

Results

Sample Characteristics

Study 1

A total of 417 participants participated in a Web-based survey. After removing individuals who played other mobile games that were not *Pokemon Go* (n=148) and individuals who missed reporting main predictors (n=7), a total of 262 participants who completed the Web-based survey were used to test hypotheses. The age of participants ranged from 18 to 34 years. The mean age of the participants was 20.32 (SD 1.86) years. Most participants were white (47.7%, 125/262), but the sample included people who reported as Asian/Asian American (28.6%, 75/262), Hispanic/Hispanic American (18.3%, 48/262), African American (2.3%, 6/262), and other (3.1%, 8/262). The others included participants who answered biracial (n=2), Middle Eastern (n=1), and mixed (n=2). The study sample included more females (63.7%, 167/262).

Study 2

A total of 264 participants participated in a Web-based survey. After removing individuals who played other mobile games that were not *Pokemon Go* (n=58) and individuals who missed reporting main predictors (n=27), a total of 179 participants who completed the Web-based survey were used to test hypotheses. The age of participants ranged from 18 to 65 years. The mean age of the participants was 30.61 (SD 9.04) years. Most participants were white (70.4%, 126/179), but the sample included people who reported as Hispanic American (10.1%, 18/179), Asian (8.9%, 16/179), African American (6.1%, 11/179), Native American (1.7%, 3/179), and other (2.8%, 5/179). Regarding participants' highest education level, 90.5% (162/179) of participants had completed some college or a 2-year degree or higher. Finally, regarding income level, 30.7% (55/179) of the participants had an income of US \$25,000 to US \$49,999, followed by US \$50,000 to US \$74,999 (24.6%, 44/179), over US \$100,000 (16.2%, 29/179), less than US \$25,000 (15.6%, 28/179), and US \$75,000 to US \$94,999 (12.8%, 23/179). The study sample included more males (56.9%, 102/179).

Hypothesis Tests

Study 1

The results show that the overall model, including all the predictors, was significant, $F_{8,253}=23.95$, $P<.001$, adjusted $R^2=.41$. In the first block, none of the covariates was a significant predictor of intention to play *Pokemon Go* while walking. However, age was a significant predictor in the second and third block. Older people were less likely to intend to play *Pokemon Go* while walking. To test the hypotheses 1 to 3, when the three main components of TPB were entered into the second block of the regression analysis, all three predictors were significant. As people had more positive attitudes (beta=.40, $P<.001$, semipartial correlation [sr]=.32) and perceived stronger social pressure from people around them (beta=.29, $P<.001$, $sr=.23$), they were more likely to play *Pokemon Go* while walking. Thus, the data were consistent with H1 and H2. Although PBC was a significant predictor of intention, the relationship was in the direction opposite to that hypothesized relationship. As people with lower levels of perceived control (beta=-.16, $P=.002$, $sr=-.15$), they were more likely to intend to play *Pokemon Go* while walking. Thus, the data were not consistent with H3.

Hypotheses 4 to 6 predicted that automaticity, immersion, and enjoyment would be significant predictors of intention to play *Pokemon Go* while walking, which would improve the predictive power of the model. When these additional three variables were entered into the third block, the regression coefficients of the three main components of TPB were readjusted, taking into account the three additional predictors entered in the third block. All three TPB components remained significant even after including the additional three variables. The additional three variables were significant, which increased the explained variances in intention by 4.4%. As people who perceived greater automatic behavioral orientation (beta=.24, $P<.001$, $sr=.19$) and felt greater enjoyment (beta=.11, $P=.04$, $sr=.10$), they were more likely to intend to play *Pokemon Go* while walking. Thus, the data were consistent with H4 and H6. That is, the results indicated that as people played *Pokemon Go* while walking in a less conscious manner and felt greater enjoyment, they were more likely to play *Pokemon Go* while walking. Although

perceived immersive behavioral orientation was a significant predictor of intention, the relationship was in the direction opposite to that hypothesized relationship. As people perceived less immersive behavioral orientation ($\beta = -0.14$, $P = .02$, $sr = -.11$), they were more likely to intend to play *Pokemon Go* while walking. Thus, the data were not consistent with H5. [Table 5](#) reported regression analysis results for study 1.

Study 2

The overall model, including all the predictors, was significant, $F_{8,170} = 38.76$, $P = .001$, adjusted $R^2 = .63$. In the first block, gender was a significant predictor of intention to play *Pokemon Go* while walking ($\beta = -.19$, $P = .01$, $sr = -.19$). Women were less likely to intend to play *Pokemon Go* while walking. However, none of the covariate was a significant predictor in the second and third block. When the three main components of TPB were entered into the second block of the regression analysis, attitude ($\beta = .53$, $P < .001$, $sr = .41$) and subjective norms ($\beta = .33$,

$P < .001$, $sr = .25$) were statistically significant. PBC was a negative predictor of behavioral intention toward playing *Pokemon Go* while walking ($\beta = -.16$, $P = .001$, $sr = -.15$). The results showed that the more positive attitudes, stronger subjective norms, and less perceived behavior control over playing *Pokemon Go* while walking individuals had, the more strongly they intended to play *Pokemon Go* while walking. Thus, the data were consistent with H1 and H2, but inconsistent with H3.

The same procedure that was used in study 1 was conducted to test the Hypotheses 4 to 6. All three TPB components remained significant even after including the additional three variables (see [Table 6](#)). Enjoyment ($\beta = .15$, $P = .01$, $sr = .12$) was the only significant predictor of intention to play *Pokemon Go* while walking. An additional 2.2% of the variances in the behavioral intention was explained. Thus, it was concluded that the data were consistent with H6 but inconsistent with H4 and H5. The regression analysis results for study 2 are presented in [Table 6](#).

Table 5. Regression results for intention to play a mobile game while walking in study 1 (N=262).

Predictors	B ^a	Standard error (SE)	Beta	t (df=260)	P value	sr ^b
First block^c						
Age	-.10	.06	-.10	-1.66	.10	-.10
Gender	.01	.23	.003	0.05	.96	.003
Second block^d						
Attitude	.54	.08	.40	6.59	<.001	.32
Subjective norms	.49	.10	.29	4.76	<.001	.23
PBC ^e	-.27	.09	-.16	-3.15	.002	-.15
Third block^f						
Attitude	.51	.08	.38	6.13	<.001	.29
Subjective norms	.41	.10	.24	4.06	<.001	.19
PBC ^c	-.23	.09	-.13	-2.74	.007	-.13
Automaticity	.44	.11	.24	3.92	<.001	.19
Immersion	-.25	.11	-.14	-2.31	.02	-.11
Enjoyment	.16	.08	.11	2.04	.04	.10

^aB: unstandardized coefficients.

^bsr: semipartial correlation.

^c $F_{2,259} = 1.39$, $P = .25$, adjusted $R^2 = .003$.

^d $F_{\text{change}3,256} = 52.31$, $P < .001$, $R^2_{\text{change}} = .38$.

^ePBC: perceived behavioral control.

^f $F_{\text{change}3,253} = 6.57$, $P < .001$, $R^2_{\text{change}} = .044$.

Table 6. Regression results for intention to play a mobile game while walking in study 2 (N=197).

Predictors	<i>B</i> ^a	Standard error (SE)	Beta	<i>t</i>	<i>P</i>	<i>sr</i> ^b
First block ^c						
Age	-.02	.02	-.07	-0.91	.36	-.07
Gender	-.76	.30	-.19	-2.59	.01	-.19
Second block ^d						
Attitude	.73	.08	.53	8.73	<.001	.41
Subjective norms	.46	.09	.33	5.28	<.001	.25
PBC ^e	-.29	.09	-.16	-3.29	.001	-.15
Third block ^f						
Attitude	.60	.09	.44	6.56	<.001	.30
Subjective norms	.44	.09	.32	5.06	<.001	.23
PBC	-.35	.10	-.19	-3.63	<.001	-.17
Automaticity	-.06	.12	-.04	-0.54	.59	-.03
Immersion	.14	.12	.08	1.13	.26	.05
Enjoyment	.23	.09	.15	2.55	.01	.12

^a*B*: unstandardized coefficients.

^b*sr*: semipartial correlation.

^c $F_{2,176}=3.99$, $P=.02$, adjusted $R^2=.033$.

^d $F_{\text{change}3,173}=88.95$, $P<.001$, $R^2_{\text{change}}=.58$.

^ePBC: perceived behavioral control.

^f $F_{\text{change}3,170}=3.54$, $P=.02$, $R^2_{\text{change}}=.02$.

Discussion

Principal Findings

The three TPB variables (attitudes, subjective norms, and PBC) were significant predictors of intention to play *Pokemon Go* while walking in both studies. Although attitudes and subjective norms were the positive predictors of intention to play the mobile game, PBC had negative impact on intention (ie, the less they feel in control, the more they play the mobile game while walking). Automaticity tendency, immersion, and enjoyment were significant predictors in study 1, whereas enjoyment was the only significant predictor in study 2.

Compared with the long tradition of research on people's perception, attitudes, and behaviors affected by newspaper, magazines, radio, television, and the Internet, we have relatively little understanding of the psychological and behavioral impact of mobile media. There has been a drastic increase in pedestrian injuries while using mobile phone, but little research has been conducted to explain individuals' motivations to use mobile devices while walking. This research identifies the predictors of intention to play a popular mobile game, *Pokemon Go*, while walking, by combining two theoretical approaches: TPB in health communication and recent findings related to behavioral orientations regarding mobile devices use in the field of media effect. This study addresses a very timely issue by recruiting the users who play *Pokemon Go*, one of the most popular augmented reality games that brought up significant concerns

about safety issues both for pedestrians and drivers. Findings from this study contribute to expanding the scope of TPB to an emerging area in health communication—mobile device use and pedestrian safety, in particular playing a mobile game while walking.

Overall, the model we tested explained 41% of people's intention to play a mobile game while walking in study 1 and 63% of people's intention to play a mobile game while walking in study 2, with attitude toward playing a mobile game while walking emerging as the strongest predictor, followed by subjective norms. Both in study 1 and study 2, the three TPB components significantly predicted one's intention to play a mobile game while walking. The three TPB components explained 37.6% in study 1 and 58% in study 2 of behavioral intention to play a mobile game in this study. The results indicated that attitude and subjective norms were positive significant predictors of intention to play a mobile game while walking, whereas PBC was a negative significant predictor of intention to play a mobile game while walking. The more they thought that playing the mobile game while walking was positive and beneficial, the greater their intention to play was; the more they believed that others would like them to play the mobile game while walking, the greater their intention to play was. However, the less they felt that they had control over playing it while walking, the greater their intention to play was.

The results demonstrated the utility of TPB in the context of mobile-related health behavior. TPB has been applied to many health-related behaviors including behaviors that cause public

safety issues such as distracted driving [1,7,27]. Only few attempts have been made to apply the theory to mobile media usage [3,47], and this study is one of the very few studies that examined predictors of playing a mobile game while walking. Theoretically, our results demonstrated that attitudes, normative beliefs, and perceived control beliefs are the three main predictors to explain this new behavior. The accessibility and mobility of new media technology is new, but the underlying psychological motivations that drive individuals' mobile media use while walking share commonality with other behavioral decision-making. TPB assumes that volitional behaviors will be best predicted from behavioral intention [19]. Playing a mobile game is a volitional behavior as people often engage in the behavior voluntarily and without coercion. Future research should examine the association between intention to play a mobile game and actual behavior to confirm the primary assumption of TPB. Overall, findings from this study demonstrate the predictive and explanatory power of TPB in a new context that has a significant implication for public safety—mobile game play while walking.

Especially, the significant effect of normative beliefs is thought-provoking in that previous studies pointed out that mundane tasks such as road crossing were less likely to be influenced by normative beliefs [47,48]. Perhaps, playing mobile games while walking is still considered to be uncommon, and individuals adhere to social norms (ie, perceived prevalence and approval) to evaluate the behavior. In addition, the popularity of *Pokemon Go* and recent media coverage on its safety issues (eg, news covering people who got injured while distracted by the game) may have enhanced the effects of social norms related to this particular game. For campaign message designers, findings from this study suggest that campaign messages should incorporate normative information to influence people's mobile-related behaviors, including mobile game play while walking.

Contrary to the hypothesis 3, there was a negative association between individuals' PBC and behavioral intention to play the game. In fact, previous research pointed out that a lesser degree of PBC leads to greater behavioral intention [49] when a behavior in question is socially undesirable. In other words, individuals often perform an undesirable behavior because they find it irresistible. Results from this study suggest that playing a mobile game while walking could be regarded as an undesirable as well as an addictive behavior. Players are aware of the fact that playing while walking may cause potential health threats to themselves as well as others, but they feel little control over this habitual behavior.

Further supporting this point, the feeling of enjoyment was a positive significant predictor of intention to play a mobile game in both study 1 and study 2. People who felt greater enjoyment were more likely to intend to play the game while walking than those who felt less enjoyment. This finding is consistent with prior literature on the effect of enjoyment on intention to play a Web-based game [35]. Wu and Liu found that enjoyment had a direct effect as well as an indirect effect via attitude on intention to play a Web-based game [35].

This study also found that automaticity and immersion were significant predictors of playing the mobile game in study 1. The automaticity and immersion factors increased by 4.4% of the amount of explained variances in intention to play a mobile game in addition to enjoyment factor in study 1. As college students played the mobile game more habitually and impulsively, they were more likely to play it while walking. This implies that people who have a tendency to play mobile game without intending to do so are more susceptible to perform such behaviors, which is consistent with prior literature's findings on habitual mobile media use [33]. In contrast, immersion was a negative predictor of intention to play, suggesting that immersive players are less likely to play a mobile game while walking. Given that immersive users tend to play the mobile game with greater attention and often feel completely absorbed in playing the mobile game, they might be more reluctant to play it in a distracted setting. Although texting frequency was predicted only by automaticity, not immersion in a prior study [33], this study found that mobile game play while walking was negatively associated with immersion, perhaps because playing a mobile game requires a significant amount of time and attentional resource to be fully absorbed.

Our correlation results reported in Tables 3 and 4 provide further information to understand these ostensibly contradictory tendencies: automaticity and immersion. Although PBC was negatively correlated with automaticity, its correlation with immersion was not significant in both studies. Individuals who feel greater control over playing a mobile game while walking are less likely to play it impulsively and habitually. Instead, they could realize that they start playing a mobile game while walking, and probably stop themselves from doing it. However, this does not necessarily mean that they are less immersed while playing a mobile game. Regardless of their perceived control over the behavior, users can feel absorbed in playing a mobile game while walking.

In fact, it has to be noted that individuals' levels of automaticity and immersion were significantly, and positively, correlated with each other in both studies. Bayer et al also found that these two tendencies are highly correlated in texting behavior—individuals who habitually text also do so with more immersion [33]. Our results replicated this finding and suggest that individuals who play a mobile game while walking do so at both high and low levels of attention. In other words, for the most respondents in our sample, they start playing a mobile game without meaning to do it, but at the same time, they get lost in the moment while they are playing it while walking.

Yet, these behavioral tendencies were not significant predictors of the intention of playing a mobile game while walking in study 2. In study 2, enjoyment was the only additional predictor of intention to play apart from the three components of TPB. It should be noted that there were differences in terms of sample characteristics between study 1 and study 2. The participants in study 1 were recruited from a university, whereas study 2 participants were recruited through MTurk, the crowdsourcing website that is known to be more representative of the US population. In addition, a post-hoc analysis using an analysis of variance (ANOVA) revealed that there was a significant difference in the degree of mobile phone addiction between

study 1 (mean 5.07 [SD 0.99]) and study 2 (mean 4.74 [SD 1.26]). Participants in study 1 reported greater levels of mobile phone addiction ($F_{1,439}=9.27, P=.002$) than those in study 2. In short, study 1 participants were in general younger, more homogeneous in their education, and more addicted to mobile phone use.

For these college students, their intention to play a mobile game can be significantly explained by their behavioral tendencies, because playing a mobile game is more than mere enjoyment to them. For addicted users, their habitual and impulsive tendency of playing a mobile game while walking would be an additional motivational factor that leads to greater intention to play. In addition, younger users' attention is more likely hijacked by immersive media such as video games [50], and the degree of immersion that they experience from the media may have greater impact on how much they want to be engaged in the media use. In contrast, for older users who are less addicted to their mobile phones, whether they enjoy playing the mobile game is a more important predictor, regardless of their behavioral tendencies.

This finding suggests that playing a mobile game such as *Pokemon Go* has an addictive component, especially for college students. Individuals who are more likely to play a mobile game while walking also pay less attention and think less while playing the game, habitually performing the behavior. Video game addiction and its detrimental effects on well-being [51,52] are well known, but mobile game addiction has been only recently highlighted by researchers [53]. An augmented reality game such as *Pokemon Go* may provide even stronger senses of presence and flow [54] because of its capability of seamlessly blending the virtual world into the real world, leading to more habitual and addictive game play. Health campaigns targeting mobile users should point out the possibility of addiction and incorporate it into their prevention messages regarding playing a mobile game while walking.

In addition, there was a considerable difference in the amount of explained variances in intention: study 1 explained 41%, whereas study 2 explained 63% of variance in their intention to play. Our model focused on attitudes, subjective norms, and PBC as main predictors, which did not address individuals' digital media use patterns in general, including the level of addiction discussed above. College students in study 1 may have already developed their own digital media preference and could have been more experienced in mobile game play, whereas older users in study 2 may have been less influenced by these factors. Future research may benefit from identifying more media use variables for predicting college students' mobile game play while walking.

Practical Implications

The studies' findings have implications for health promotion practice and policy. First, health practitioners and designers should incorporate normative information in their campaign

messages to amend people's false beliefs and optimistic biases, and thus change such habitual and addictive behaviors in a desirable way. Second, inattention is one of prevalent causal factors of road incidents [10]. When playing mobile-based augmented reality exergames such as *Pokemon Go* while walking, running, or cycling, pedestrians would focus more on their screens and thus be less aware of their surroundings. Therefore, augmented reality functions and technologies should incorporate realistic features to increase the spatial and temporal awareness to avoid potential risks and motivate physical activity [55].

Limitations

This study investigated playing a mobile game as the only target behavior. However, it seems significant to examine other mobile usage behaviors (eg, social media use such as Snapchat, listening to music, or taking pictures or videos while walking), given that they may trigger different types of safety issues from playing a mobile game. In addition, it is still unclear how different predictors of TPB would be applied to a different set of mobile behaviors. For instance, subjective norms were not a significant predictor for crossing streets while listening to music or texting [47], whereas findings from this study indicated that normative influence was associated with playing a mobile game while walking in our model. Thus, future studies ought to investigate different psychological factors associated with different scenarios of distracted walking or pedestrian safety issues.

By showing the significant effect of individuals' consciousness tendency on behavioral intention to play mobile games while walking, this study suggests the need for future studies on habitual or addictive mobile media use. Individuals who habitually use mobile media while walking, without meaning to do it, might be more likely to experience serious health threats such as accidents. Therefore, future studies ought to investigate some predictors of the unconscious media use, including personality and situational factors, and further analyze how these factors are associated with mobile game play in unsafe settings.

Our sample size was not big, limiting the generalizability of our results. After selecting only those who played *Pokemon Go*, we had 262 respondents for study 1 and 179 respondents for study 2 who completed the survey. In addition, respondents' actual behavior or experience of being injured by distracted walking was not addressed in this study. Future studies should test the effect of predictors of TPB on individuals' actual mobile use behavior while walking, as well as the effect of personal experiences. Given the cross-sectional design of this study, causal claims could not be made. On the basis of TPB, it was assumed that three predictors precede people's intention to play a mobile game while walking. However, it is also likely that the temporal order of these two variables could be reversed. In future research, a longitudinal design or experimental method should be employed to explore the causal relationship between three TPB predictors and intention.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Survey questionnaire.

[[PDF File \(Adobe PDF File\), 41KB - mhealth_v5i12e191_app1.pdf](#)]

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Abbreviations

ANOVA: analysis of variance
MTurk: Amazon Mechanical Turk
PBC: perceived behavioral control
SD: standard deviation
SE: standard error
TRA: theory of reasoned action
TPB: theory of planned behavior

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Corrigenda and Addenda

Addendum of: Fall Detection in Individuals With Lower Limb Amputations Using Mobile Phones: Machine Learning Enhances Robustness for Real-World Applications

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fall detection; lower limb amputation; mobile phones; machine learning

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