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Review

Mobile Health Solutions for Hypertensive Disorders in Pregnancy: Scoping Literature Review

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Abstract

Background: Hypertensive disorders are the most common complications during pregnancy, occurring in 5% to 11% of pregnancies; gestational hypertension and preeclampsia are the leading causes of perinatal and maternal morbidity and mortality, especially in low- and middle-income countries (LMIC) where maternal and perinatal mortality ratios are still high. Pregnant women with hypertensive disorders could greatly benefit from mobile health (mHealth) solutions as a novel way to identify and control early symptoms, as shown in an increasing number of publications in the field. Such digital health solutions may overcome access limiting factors and the lack of skilled medical professionals and finances commonly presented in resource-poor environments.

Objective: The aim of this study was to conduct a literature review of mHealth solutions used as support in hypertensive disorders during pregnancy, with the objective to identify the most relevant protocols and prototypes that could influence and improve current clinical practice.

Methods: A methodological review following a scoping methodology was conducted. Manuscripts published in research journals reporting technical information of mHealth solutions for hypertensive disorders in pregnancy were included, categorizing articles in different groups: Diagnosis and Monitoring, mHealth Decision Support System, Education, and Health Promotion, and seven research questions were posed to study the manuscripts.

Results: The search in electronic research databases yielded 327 articles. After removing duplicates, 230 articles were selected for screening. Finally, 11 articles met the inclusion criteria, and data were extracted from them. Very positive results in the improvement of maternal health and acceptability of solutions were found, although most of the studies involved a small number of participants, and none were complete clinical studies. Accordingly, none of the reported prototypes were integrated in the different health care systems. Only 4 studies used sensors for physiological measurements, and only 2 used blood pressure sensors despite the importance of this physiological parameter in the control of hypertension. The reported mHealth solutions have great potential to improve clinical practice in areas lacking skilled medical professionals or with a low health care budget, of special relevance in LMIC, although again, no extensive clinical validation has been carried out in these environments.

Conclusions: mHealth solutions hold enormous potential to support hypertensive disorders during pregnancy and improve current clinical practice. Although very positive results have been reported in terms of usability and the improvement of maternal health, rigorous complete clinical trials are still necessary to support integration in health care systems. There is a clear need for simple mHealth solutions specifically developed for resource-poor environments that meet the United Nations Sustainable Development Goal (SDG); of enormous interest in LMIC.

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KEYWORDS

pregnancy; hypertension; pre-eclampsia; blood pressure; telemedicine

Introduction

Background

Hypertensive disorders are the most common complications during pregnancy, occurring in 5% to 11% of pregnancies [1-3]. These incidence rates are showing an increased tendency in some countries [4-9]. There are different types of hypertensive disorders, including gestational hypertension, preeclampsia, chronic hypertension, and preeclampsia superimposed on chronic hypertension [10-12]. Gestational hypertension is the most common cause of hypertension in pregnancy. Preeclampsia is a more severe complication that is often diagnosed after 20 weeks of gestation or within the first 4 to 6 weeks postpartum. It is estimated to affect between 5% and 8% of healthy pregnancies [13]. On the other hand, 10% to 50% of patients with gestational hypertension are diagnosed with preeclampsia 1 to 5 weeks after the diagnosis [14,15].

Gestational hypertension and preeclampsia are the leading causes of perinatal and maternal morbidity and mortality [16-20]. In developed countries, maternal and perinatal mortality ratios are relatively low, but in low- and middle-income countries (LMIC), these ratios are still high. More than 99% of preeclampsia-related maternal deaths occur in LMIC [21]. Nearly one-tenth of all maternal deaths in Asia are associated with hypertensive disorders of pregnancy, whereas one-quarter of maternal deaths in Latin America have been associated with these complications [22]. It is estimated that 9.1% of maternal deaths in Africa are due to hypertensive disorders of pregnancy [23]. Muti et al [24] conducted an analytic cross-sectional study in Zimbabwe and found a pregnancy-induced hypertension prevalence of 19.4%. This ratio was high, and these women were at higher risk of adverse pregnancy outcomes. Tachiwenyika et al [25] also found that pregnancy-induced hypertension was associated with an increased risk of perinatal mortality. Preterm birth complications contribute to a high percentage of under-five mortality causes. As an example, 39% of neonatal deaths are caused by preterm birth complications in Zimbabwe [26]. The Zimbabwe Maternal and Perinatal mortality study of 2007 [27] found pregnancy-induced hypertension to be among the top five causes of maternal mortality and the third highest reason for referral in labor. Placental abruption, disseminated intravascular coagulation, cerebral hemorrhage, and hepatic and renal failure are more likely among pregnant women with gestational hypertension and preeclampsia [11,28]. Preeclampsia is associated with acute kidney function impairments [29,30], a significant number of preterm deliveries, and subsequent neonatal and long-term morbidity [31-33]. Caesarean delivery is more often common among women with a history of preeclampsia than those with an uncomplicated pregnancy history. Bokslag et al [34] found that women with preeclampsia had a shorter gestational age, children with a lower birth weight, and lower placental weight. Moreover, metabolic syndrome is significantly more likely among women with a history of preeclampsia.

Furthermore, gestational hypertension and preeclampsia may also cause long-term effects after pregnancy. Approximately 15% of women with a history of gestational hypertension suffer from chronic hypertension after pregnancy [35]. They are also at increased risk of cardiovascular diseases (CVDs) such as ischemic heart disease and stroke in later life [36-40]. Women experiencing preeclampsia have an increased risk of high blood pressure (BP), cardiovascular complications, kidney disease, diabetes mellitus, thromboembolism, thyroid disease, and impaired memory in later life [36,41-45]. These women have approximately double the risk of cardiovascular events in the 5 to 15 years after pregnancy compared with women who are normotensive during pregnancy [36]. Several studies have demonstrated a greater risk of death from CVD among women who had preeclampsia during pregnancy than those who remained normotensive [36,40,46]. That risk is even greater if the pregnancy ended prematurely [46]. Gestational hypertension and preeclampsia could also affect the offspring's adult health [47]. In addition, children born to women who had preeclampsia during their pregnancy have an increased risk of CVD [42].

The early recognition of signs and symptoms of such hypertensive disorders may prevent some complications [17,48]. In this sense, pregnant women with hypertensive disorders could benefit from mobile health (mHealth) solutions. Information and communication technology (ICT) could be used to support diagnosis and monitoring, management and self-care, communication between patients and maternity care providers, and patient education and empowerment. Many factors such as genetic predisposition, having a previous history of preeclampsia, obesity, excessive weight gain, elevated BP, multifetal gestation, in vitro fecundation, maternal age, and smoking have been associated with gestational hypertension and preeclampsia [49-55], and a number of mHealth solutions are being reported to better control these parameters.

This control of early symptoms is especially interesting in LMIC settings, with delayed identification of women with hypertensive disorders because of their limited health care capability and facilities for testing and managing such patients [56]. In Zanzibar, a mobile phone intervention reduced perinatal mortality [57], as reported in a cluster randomized controlled trial (RCT) with primary health care facilities. Other recent works in LMIC are targeting hypertensive-related problems from a more initial stage [56]. Digital health may overcome access-limiting factors and the lack of skilled medical professionals and finances. Using ICT-based interventions, a large number of patients could be treated at any time and at reduced health care costs, while the quality and efficiency of care are maintained or even increased. Therefore, there is a clear need for simple mHealth solutions specifically developed for resource-poor environments that meet the United Nations Sustainable Development Goals (SDGs) [58], particularly SDG

3: “Ensure healthy lives and promoting well-being for all at all ages, which among its targets are to reduce the maternal and neonatal mortality ratios.”

Objectives

A scoping review of mHealth solutions used as a support in hypertensive disorders during pregnancy has been conducted. The objective of this review was to analyze the current state of knowledge of digital health for hypertensive disorders in pregnancy.

Methods

Research Questions

A methodological review following a scoping methodology as proposed in the studies by Arksey et al and Levac et al [59,60] has been conducted. This literature review aimed to analyze the state-of-the-art and identify research gaps related to how mobile technology could support hypertensive disorders in pregnancy. Table 1 shows the research questions and the corresponding rationale for each one.

Search Strategy

An electronic search of the literature was performed in English across the following databases: MEDLINE, PubMed, CINAHL, Science Direct, and the Cochrane Central Registry of Controlled Trials. A combination of keywords involving medical and ICT-related terms was used. The search string was set through an iterative process to include all relevant keywords identified in previous search results. The final search string is shown in Table 2. Bibliographies and reference lists were also scrutinized to identify any other relevant studies. The literature search was performed on March 3, 2017.

Inclusion Criteria

Textbox 1 shows the inclusion criteria for studies.

Exclusion Criteria

Textbox 2 shows the exclusion criteria for studies.

Study Selection

A literature search was performed by the primary author (OR) according to the search strategy described above. Retrieved titles and abstracts were screened to eliminate duplicates. Then, two authors (OR and AO) reviewed the titles and abstracts and filtered out applying inclusion and exclusion criteria. Discrepancies were solved by consensus. Cohen kappa coefficient was calculated to measure interrater agreement (k=0.84) [61]. Full-text articles in the filtered list were obtained, and two authors (OR and AO) reviewed them, excluding those that did not meet the inclusion criteria or the exclusion criteria. When papers reported data regarding the same digital health solution, only one was included in the final analysis. The included papers were assessed for data extraction.

Table 1. Research questions.

Research question (RQ)	Rationale
RQ 1: Which mobile health (mHealth) solutions have been used in digital interventions involving patients with hypertensive disorders in pregnancy?	To identify different types of mHealth solutions supporting hypertensive disorders in pregnancy.
RQ 2: What are the areas of focus of these mHealth solutions?	To understand how mHealth solutions supported hypertensive disorders in pregnancy (diagnosis, monitoring, decision support, health promotion, or education).
RQ 3: What were the target groups of these mHealth solutions?	To identify potential users of mHealth solutions supporting hypertensive disorders in pregnancy.
RQ 4: What types of interventions or studies were performed?	To determine whether research in the area has been validated through empirical studies and evidence found through clinical trials.
RQ 5: What were the main outcomes?	To discover the benefits and positive outcomes of mHealth solutions supporting hypertensive disorders in pregnancy.
RQ 6: How is the research focused on mHealth solutions to support hypertensive disorders in pregnancy distributed across countries?	To explore the geographic publication trends of information and communication technology (ICT) health to support hypertensive disorders in pregnancy.
RQ 7: How is the research focused on mHealth solutions to support hypertensive disorders in pregnancy distributed over the last 10 years?	To determine how the trends of mHealth solutions to support hypertensive disorders in pregnancy are evolving.

Table 2. Search string.

Scope	String
Health	(Preeclampsia OR eclampsia OR gestational hypertension) AND
Technology	(smartphone OR mobile health OR ehealth OR website OR Internet OR (social AND (net OR media))

Textbox 1. Inclusion criteria.

- Papers published in research journals reporting technical information of a mobile health (mHealth) solution for hypertensive disorders in pregnancy
- Studies reporting the results from an intervention using a digital health solution for the same domain
- Only papers in English or Spanish
- Publications from the period of January 1, 2017 to March 3, 2017
- Papers reporting data regarding digital health solutions intended for both patients and health professionals

Textbox 2. Exclusion criteria.

- Papers published in languages other than Spanish or English
- Studies reporting information on other diseases such as gestational diabetes mellitus and population groups other than pregnant women with hypertensive disorders
- Papers published in research avenues other than research journals

Data Extraction

Three datasets were defined to be extracted from selected papers. As the first dataset, a categorization of mHealth solutions was identified. Initially, three categories were proposed based on those used in digital health reviews performed in other diseases: health promotion, management, and diagnosis. Then, a second category proposal was defined by the consensus of two authors (OR and AO) to identify the most relevant categories related to hypertensive disorders in pregnancy. The resulting categories were as follows: *Diagnosis and Monitoring*, *mHealth Connected Decision Support Systems (DSSs)*, *Education*, *and Health Promotion*. The rest of the authors (RM, PS, MLM, and LB) reviewed the categories defined, and concepts were redefined to clarify them when necessary.

The *Diagnosis and Monitoring* category included all mHealth solutions supporting the diagnosis of hypertensive disorders in pregnancy or monitoring patients' status, including physical or physiological measurements such as BP and the presence of proteinuria. This category was included because there is a recommendation for pregnant women with hypertensive disorders to automatically monitor their BP at home at least twice daily over several days [62]. In addition, measuring weight gain during pregnancy is an important issue that may promote self-care and improve overall engagement with prenatal care [63]. On the other hand, one of the signs that could be used to diagnose preeclampsia or renal disease is proteinuria [62].

Hypertensive disorders in pregnancy must be detected early and appropriately managed to prevent severe complications and potential effects. Predictive personalized models complemented with real-time indicators of the diseases [64] and rapid medical attention should be provided. *mHealth Connected DSSs* are key tools used to improve the quality of health care by enhancing the quality of services and controlling the cost of health care delivery [65]. DSSs can activate alerts when deviation from recommended care is detected or when a new relevant symptom is recognized. Clinician and patient actions may be triggered by these alerts to ensure compliance to clinical care standards and guidelines. There are clinical models with excellent, clinically validated prediction features for many of the most frequent and high-impact diseases in pregnancy [62]. Moreover, there are several sensor technologies that enable the real-time improvement of the predictive capacities of computer models. These existing clinical models and sensor technologies enable the creation of DSSs focused on raising individual awareness and empowering women in the management of their health. They can also be used in the design and development of DSSs supporting health care professionals (HCPs) in the treatment of pregnant women with hypertensive disorders.

The *Education* category was focused on educational computer-based solutions. This category was added because of its relevance for pregnant women with hypertensive disorders. Patients' knowledge about hypertensive disease may improve their health outcomes, leading them to seek earlier appropriate care as soon as they recognize signs and symptoms [66,67]. Many of them have a poor understanding of the disease process [68]. They should be provided with culturally sensitive information at an appropriate reading level. Pregnant women with hypertensive disorders often have significant psychological consequences such as maternal anxiety. Individual levels of anxiety may persist unnecessarily because of the lack of knowledge of the normal pregnant state and the potential complications of pregnancy [69]. In addition, this category was related to *Diagnosis and Monitoring* because of the involvement of the patient in the self-measurement and interpretation of physiological signals, which needs to be carried out following a specific procedure to obtain trusted measurements. This training can be carried out through educational mHealth-based programs.

The final category is *Health Promotion.* Pregnant women with hypertensive disorders may benefit from lifestyle interventions such as exercise, changes in dietary habits, and smoking cessation [70]. Healthy lifestyle recommendations have been included for pregnant women at low or high risk of preeclampsia [62]. Abstention from alcohol, smoking cessation, exercises for the maintenance of fitness, calcium supplementation, and stress reduction, among others, are recommended to prevent preeclampsia and its complications. Some researchers have found a significant reduction of BP with daily intake of chocolate, resulting in a reduced risk of gestational hypertension and preeclampsia [71,72]. Although previous researchers have found a positive influence of physical activity (PA) on pregnant

women and their infants [73-75], there is a lack of clinically validated research aimed to determine the influence of exercise on the risk of hypertensive disorders. However, exercise is included among recommendations for pregnant women with hypertensive disorders because of its positive influence on complications. Healthy lifestyle promotion through ICT may be a powerful and useful tool for pregnant women with hypertensive disorders. In this sense, we included the *Health Promotion* category to classify all ICT health solutions other than DSSs and educational computer-based programs.

The second dataset consisted of technical data on mHealth solutions reported in the selected studies. Data on the type of ICT solution, platform, users, main features, content validation, and communication between patients and HCPs were extracted. The type of ICT solution identified hardware and software used in the studies, including information about affiliation when available. These data were interesting to estimate the cost of the proposed solutions. The information regarding mobile, Web, or medical equipment platforms used in the proposed solution was also gathered. This information was relevant to estimate which solutions could be used in LMIC settings. Potential users of ICT solutions were identified as patients, HCPs, or both. Relevant information about the functionalities and the features implemented was also extracted. Among others, early diagnosis, continuous monitoring, signs and symptoms recognition, and patients' information needs are relevant issues in hypertensive disorders in pregnancy. Users' confidence in the contents included in solutions should be high to effectively empower them. We collected data regarding how authors addressed this confidence in their proposals. In addition, communication between patients and HCPs is an important functionality to be implemented in these solutions. Therefore, we defined a special field to gather information about communication functionality.

Finally, a third dataset was related to interventions reported in the included studies if available. Data regarding the type of interventions, sessions, participants, inclusion criteria, the context in which the interventions were performed, countries in which they were conducted, scales used, measurements collected, and outcomes found were extracted.

Two reviewers (OR and AO) extracted data from the selected papers. Both collected data independently from these selected studies. Differences were discussed, and decisions were made by consensus. The results were then discussed with the medical team (RM, PS, MLM, and LB) to analyze clinical relevance and potential use of mHealth solutions in the health care system.

Results

Included Studies

The search in electronic research databases yielded 327 articles. After removing duplicates, 230 articles were selected for screening. Due to the number of articles, a title review excluded 133 articles. Then, the titles and abstracts of 97 selected articles were obtained; 77 of them were excluded because they did not meet the inclusion criteria. Full-text publications were obtained for the resulting 20 articles; 9 were excluded because of the following reasons: different population group (pregnant women without hypertensive disorders or postpartum women) [76-78], other disorders (gestational diabetes mellitus, GDM) [79,80], and the same mHealth solution [81-84]. Finally, data extraction was performed on the final 11 included articles. A Preferred Reporting Item for Systematic Reviews and Meta-Analyses flow diagram representing the full process described above is shown in Figure 1, and detailed information is presented in Multimedia Appendix 1.

Description of the Included Solutions

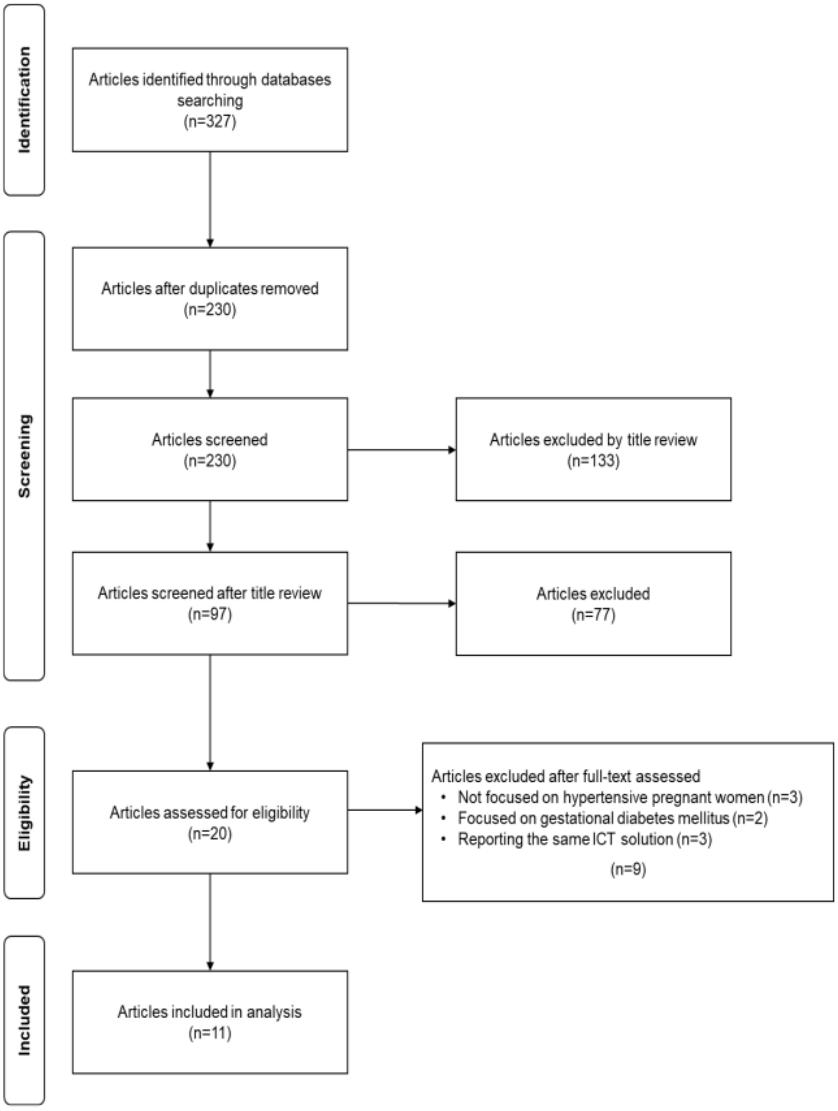
Walker et al [69] proposed an educational website to empower women with high-risk pregnancy. In the website, the information related to the placental complications of pregnancy was provided. Researchers defined an education strategy based on this website and studied its impact on the maternal knowledge of the placental complications of pregnancy and on the maternal anxiety of women with high-risk pregnancy. The intervention significantly improved the patient knowledge and significantly reduced the maternal anxiety.

Peleg et al [84] established a ubiquitous, user-friendly, and patient-centered mobile DSS for both patients with chronic conditions and for their care providers. The system was based on clinical guidelines and monitored continuously the patients' heath state using mobile sensors and self-reporting of symptoms. Patients' preferences and psychosocial and demographic context was considered by the system to empower the patients and increase their compliance. In addition, a semantic data integration into a personal health record was implemented based on a generic architecture supporting interoperability of different devices and electronic health records. The feasibility of the system and some of the potential benefits of the evidence-based distributed patient-guidance system were tested with a first prototype.

Berlage et al [85] created the GerOSS platform aimed at generating a deeper insight into the relevant risk factors to improve the diagnosis and the treatment of severe complications during pregnancy and delivery. The GerOSS platform contained a database with information that was collected through an Internet-based system. This information included the reporting and the documentation of rare obstetric events. The data were analyzed by experts, and the results and insights were presented and disseminated. The GerOSS platform was primarily conceived as a system for the improvement of quality in the management of care.

Wagner et al [86] developed ValidAid, a context-aware system for determining the patient adherence levels to clinical recommendations when using current BP self-measurement methods and equipment. The ValidAid prototype consisted of several technical components: an adherence model, physical context sensors, health care devices, and an app. The ValidAid app implemented the adherence model; provided a user interface for the test facilitator, data processing, and communication facilities; and implemented an audio context classification.

Figure 1. Flow diagram for the inclusion of the studies reporting information and communication (ICT) solutions for hypertensive disorders in pregnancy.



Huberty et al [87] used Fitbit devices to describe the trajectory of PA and sedentary behavior and whether they differ among weight status in pregnant women self-identified as inactive. A total of 80 inactive pregnant women participated in this study. Different patterns were discovered, providing a first insight into the study of the influence of these parameters in pregnant women.

Jeon et al [88] evaluated 4 mobile apps that provide tailored nursing recommendations for the metabolic syndrome management (obesity, GDM, hypertension, and hyperlipidemia). Six lifestyle management and five disease-specific knowledge domains were extracted. However, the work was presented without detailed information on the design of the different apps, and the results focused only on usability measurements.

Jonas et al [89] developed a smartphone app based on the Congo Red Dot test; a simple modality to assess the presence of misfolded proteins in urine, as a diagnostic and prognostic tool for preeclampsia. Its purpose was to guide nonspecialized personnel through seven easy steps. A high agreement between manual and automated processing was calculated, but no complete clinical validation was carried out.

Marko et al [90] conducted a prospective observational study to determine the feasibility of monitoring patients remotely in prenatal care using a mobile phone app and connected digital devices. Eight women with low-risk pregnancy in the first trimester were recruited; each receiving a mobile phone app with a connected digital weight scale and BP cuff for at-home data collection for the duration of pregnancy. At-home data were assessed for abnormal values of BP or weight to generate clinical alerts to the patient and provider. As a measurement of the feasibility of the system, the engagement with the app, accuracy of remote data, efficacy of alert system, and patient satisfaction were analyzed. Automatic clinical alerts identified two episodes of abnormal weight gain with no false triggers, and patients demonstrated a high satisfaction with the system.

Torres et al [91] conducted a lifestyle intervention for Hispanic pregnant women based on two components: nutrition and PA. The nutrition component consisted of recommendations for total calories, food quantity, and improving carbohydrate and fat quality. The PA focused on limiting sedentary behavior and promoting regular movement. The intervention was delivered through individual and group sessions and phone calls. The published results focused only on identifying barriers to

delivering this lifestyle intervention, and the complete clinical results were postponed for future publications.

Lange et al [92] conducted a study aimed to evaluate the readability, content, and quality of patient education materials addressing preeclampsia. Websites of US obstetrics and gynecology residency programs were searched for patient education materials. Readability, content, and quality were assessed, with a one-sample *t* test to evaluate the mean readability level compared with the recommended 6th grade reading level. As a result of this study, it was concluded that the mean readability was above the recommended 6th grade reading level. However, the content, readability, and actionability of preeclampsia patient education materials should be improved.

Fernández Arana [93] performed a review focused on the study of SMS text messages (short message service, SMS) as a health promotion tool in pregnant women. The objective of this study was to analyze the results of documented experiences in health promotion among pregnant women, through the use of SMS text messages to mobile phones in the stages of pregnancy and puerperium, presenting its future use as one more complement of telemedicine. The potential benefits of this technology, because of the characteristics of universality, mobility, instant access, and direct communication offered by these devices, was pointed out.

Research Question 1: Which Mobile Health Solutions Have Been Used in Digital Interventions Involving Patients With Hypertensive Disorders in Pregnancy?

The different technological solutions used were grouped into websites (n=5) [69,85-87], mobile apps (n=6) [84,86-90], and others (n=1) [91]. When analyzing mobile apps, 2 were Android apps [86,88] and the other 2 iOS apps [89,90].

Only 4 studies used sensors for physiological measurements [86,87,90,91]. We found a wide range of sensors (digital weight scales, BP cuffs, context sensors, pedometers and movement sensors, or phone oximeters).

Despite the evident use of BP sensors in the study of hypertensive disorders, only 2 studies [86,90], both included in the *Diagnosis and Monitoring* category, used them.

Research Question 2: What Are the Areas of Focus of These Mobile Health Solutions?

Two articles proposed ICT solutions that matched in two different categories [86,88]. Most of the ICT solutions proposed in selected papers were classified as *Diagnosis and Monitoring* (5/11 [85,86,88-90]).

The *Education* [69,92] and *DSS* [84,86] categories were identified in 2 of 11 included ICT solutions. Finally, the *Health Promotion* [87,88,91,93] category was proposed in 4 of the 11 included studies.

Research Question 3: What Were the Target Groups of These Mobile Health Solutions?

Most of the analyzed ICT solutions were exclusively intended to be used by patients (7/11). These solutions were classified into the *Education*, *Health Promotion*, and *Diagnosis and Monitoring* categories. In three cases, solutions were intended for both patients and HCPs. All the DSSs were designed to be used by HCPs. Solutions developed exclusively for HCPs were included into the *Diagnosis and Monitoring* category.

Research Question 4: What Types of Interventions or Studies Were Performed?

Regarding the type of study, we found observational studies (n=4) [69,86,88,90], qualitative research (n=1) [84], RCTs (n=2) [87,91], review papers (n=1) [93], or others (n=3) [85,89,92]. Most involved a small number of participants. Figure 2 shows the distribution of the different types of interventions by categories. Observational interventions were conducted in all categories. On the other hand, RCTs were only performed in the *Health Promotion* category. Torres et al [91] performed an RCT to evaluate a lifestyle modification intervention for overweight and obese pregnant women. Huberty et al [87] conducted an RCT to analyze sedentary behavior over the course of pregnancy in inactive women.

Research Question 5: What Were the Main Outcomes?

In general, patients using mHealth solutions felt satisfied with their prenatal care. They also felt more connected with their providers and more knowledgeable about their pregnancy. Reduced maternal anxiety was also found in relation to this enhanced knowledge. The usability of some of these solutions was assessed, resulting in medium-high scores.

On the other hand, HCPs were also satisfied with the initial prototypes reported in most cases. However, clinical evidence to include these solutions in the health care systems of many countries would require more complete RCTs, as many studies involved a small number of patients.

Research Question 6: How Is the Research Focused on Mobile Health Solutions to Support Hypertensive Disorders in Pregnancy Distributed Across Countries?

Most of the studies reviewed were conducted in European or North American countries, as shown in Figure 3. Only 2 studies were reported in other countries (Puerto Rico and Korea).

Research Question 7: How Is the Research Focused on Information Communication Technology Solution to Support Hypertensive Disorders in Pregnancy Distributed Over the Last 10 Years?

All articles included in this review were published recently (within the last 5 years). Most (9/11) were published in the last 2 years, indicating the current research interest in this topic.

Figure 2. Types of interventions by categories. DSS: decision support system; RCT: randomized controlled trial.

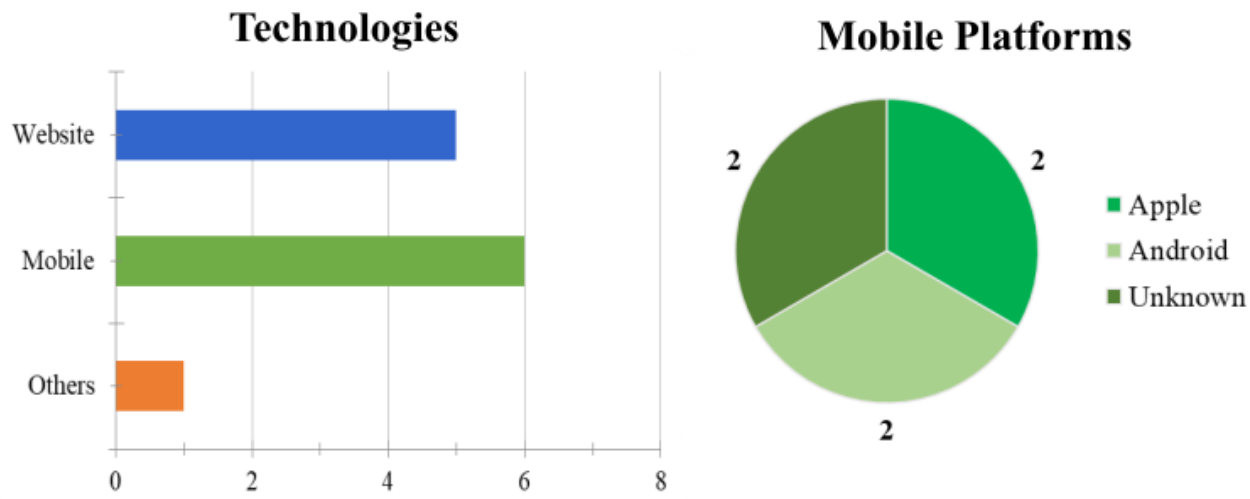
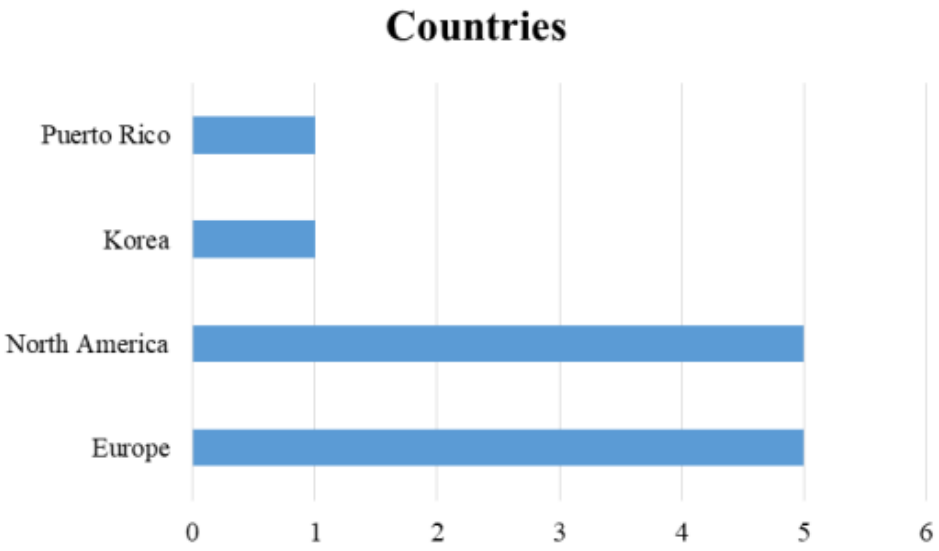


Figure 3. Countries of the studies analyzed.



Discussion

Benefits of mHealth Solutions

Pregnant women with hypertensive disorders can greatly benefit from mHealth solutions as a novel way to identify and control early symptoms, as shown in the increasing number of publications in the field. Very different benefits from the use of these mHealth solutions are found in the different studied categories described below.

Diagnosis and Monitoring

The early detection and prevention of hypertensive complications during pregnancy are crucial. Sensors that enable measurements of relevant factors related to hypertension must be used to detect changes in women's status and to manage them appropriately. Most of the analyzed works report the use of apps and commercial sensors for hypertension. A wide variety of commercial sensors are used. Despite the evident use of BP sensors in the study of hypertensive disorders, only 2 studies used commercial devices to monitor BP. Monitoring factors such as BP is crucial for pregnant women with hypertensive disorders to early detect and appropriately manage new symptoms and to avoid severe complications. In this sense, communication between hypertensive pregnant women and their HCPs is essential. However, only 2 papers proposed solutions, including communication features to alert physicians when a new symptom arises and manage it appropriately. This suggests that the overall process of BP monitoring can still be improved in clinical practice.

On the other hand, no use of new sensors for BP is found. Although BP is being measured from a long time, there is no precise wearable medical device that can monitor with precision

BP in a continuous way. As aforementioned, simple, accurate, and low-cost new devices may be used in resource-poor environments.

Another relevant issue is that no real integration with health care systems is reported in any of the papers. Most of the studies and prototypes have been tested with a small number of participants, partly because of this lack of integration with health care systems, and therefore, larger RCTs would be necessary to find clinical evidence for these new mHealth solutions.

Decision Support Systems and Mobile Health

DSSs are valuable tools supporting HCPs in the treatment of pregnant women with hypertensive disorders. Furthermore, DSSs could raise individual awareness and empower women in the management of their health. Although there are technologies that enable the development of DSSs, only two DSSs were found in the literature. Both were intended to be used by HCPs. No DSSs for pregnant women with hypertensive disorders have been proposed in the literature; therefore, there is a lack of evidence regarding the impact of using them on the patient's quality of life (QoL) during pregnancy.

Education

Patient knowledge about hypertensive disease is a relevant factor to improve health outcomes. Although there is evidence of the positive effect of educational computer-based programs in pregnant women with hypertensive disorders, we found only 2 papers focused on patient education. In addition, both educational interventions were performed using Web technologies.

Ecological momentary interventions can be conducted using mobile technologies, and educational programs could benefit from mHealth solutions. However, there is a lack of evidence of the impact of mobile educational programs on pregnant women with hypertensive diseases.

Health Promotion

Healthy lifestyle recommendations have been included for the management of pregnant women with hypertensive disorders. In this sense, they may benefit from lifestyle interventions. Computer-based lifestyle interventions have been tested in a wide range of domains, resulting in a significant positive impact. However, only 1 paper proposing a lifestyle modification intervention for pregnant women with hypertensive disorders was found in the literature review.

On the other hand, despite the potential influence of sleep on QoL and on the risk of hypertensive disorders, no digital interventions for the management of sleep disorders have been proposed. The impact of such interventions on the QoL and their effectiveness on reducing risk of complications should be studied.

Types of Interventions and Outcomes

Most of the included studies are focused on observational and qualitative research. The most advanced apps analyzed describe only the usability of the tool. No significant clinical study on the use of mobile apps in the control of hypertension has been reported. Only 2 RCTs are analyzed, focused on health promotion, although no medical evidence on the improvement of hypertension is reported. Therefore, there is a clear need to conduct digital interventions using the proposed solutions to clinically validate them and evaluate their outcomes. This is found to be a necessary step to support the integration of reported prototypes and protocols in health care systems and therefore improve current clinical practice.

The potential reduction of costs in the health care system would be another important outcome. However, almost all the solutions found are prototypes, and authors did not include any economic information. A complete cost analysis for each solution would be interesting, including costs related to the development, the required adaptations (translation, cultural adaptation, etc), or other required resources such as the Internet connection.

Low- and Middle-Income Countries

Digital health is especially interesting in LMIC settings, with the delayed identification of women with hypertensive disorders because of their limited health care capability and facilities for testing and managing such patients. Using ICT-based interventions, a large number of patients could be treated at any time and place, reducing health care costs, while the quality and efficiency of care are maintained or even increased. In this sense, smartphones are becoming an interesting option because of their increasing penetration in many LMICs, their small size and weight, their communication capabilities (3G or Wi-Fi connections), their integrated sensors, and their reduced costs. Although most of the analyzed solutions were based on mobile technologies, only 2 were Android apps, which may meet the requirements for resource-poor environments of LMIC. This is very important to meet the United Nations SDG [58], particularly SDG 3: "Ensure healthy lives and promoting well-being for all at all ages, which among its targets are to reduce the maternal and neonatal mortality ratios."

Although a mobile app can be a good tool to avoid or treat hypertension disorders in LMIC, with a limited health care budget, most of the studies have been conducted in European or North American countries. Furthermore, many of the apps (n=2) have been developed for Apple systems, which are of limited use in these countries.

Limitations

This scoping review analyzed journal articles from five databases, but additional results may be obtained by taking into consideration conference proceedings and gray literature and by using other databases.

The results are especially interesting for LMIC, and although no more information has been found in the analyzed databases, further unpublished information and recent clinical experiences in these countries may be found.

Conclusions

Hypertensive disorders are the most common complications during pregnancy, with gestational hypertension and preeclampsia being the leading causes of perinatal and maternal morbidity and mortality. Pregnant women with hypertensive disorders could greatly benefit from electronic health and mHealth solutions, which are useful tools for the early

recognition of signs and symptoms of these hypertensive disorders and may prevent important complications.

However, there is still room for improvement in several areas such as the remote monitoring methods of BP of utmost importance in the management of gestational hypertension. Furthermore, at the moment, no real integration with health care systems is reported in the reviewed papers. Most of the reported mHealth prototypes have been tested with a small number of participants, and therefore, larger clinical trials would be necessary for these new mHealth solutions to be supported for integration in health care systems.

In LMIC, mHealth solutions may overcome access-limiting factors and the lack of skilled medical professionals and low health care budget. Using ICT-based interventions, a large number of patients could be treated at any time and place, reducing health care costs, while the quality and efficiency of care are maintained or even increased. Therefore, there is a clear need for simple mHealth solutions specifically developed for resource-poor environments that meet the United Nations SDG [58], particularly SDG 3: “Ensure healthy lives and promoting well-being for all at all ages, which among its targets are to reduce the maternal and neonatal mortality ratios.” A complete clinical trial on the use of mHealth solutions for the diagnosis and monitoring, medical treatment, or prevention of hypertensive disorders and their effects in pregnant women would also be necessary in these countries to improve current clinical practice and demonstrate such improvement.

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Authors' Contributions

ORR led the scoping review, contributed to all phases of the analysis, and wrote the main body of the manuscript. AO contributed to the identification, screening, eligibility phases, quantitative analysis, and supported the manuscript writing. RM, PS, and MLM contributed to the definition of the datasets to be collected and the revision of the manuscript from a professional point of view. LMB contributed to the data analysis and the revision of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Summary of data collected.

[PDF File (Adobe PDF File), 49KB - mhealth_v6i5e130_app1.pdf]

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Abbreviations

BP: blood pressure
CVD: cardiovascular disease
DSS: decision support system
HCP: health care professional
ICT: information and communication technology
LMIC: low- and middle-income countries
mHealth: mobile health
PA: physical activity
RCT: randomized controlled trial
SDG: Sustainable Development Goal
SMS: short message service
QoL: quality of life

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Original Paper

Nontraditional Electrocardiogram and Algorithms for Inconspicuous In-Home Monitoring: Comparative Study

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Abstract

Background: Wearable and connected in-home medical devices are typically utilized in uncontrolled environments and often measure physiologic signals at suboptimal locations. Motion artifacts and reduced signal-to-noise ratio, compared with clinical grade equipment, results in a highly variable signal quality that can change significantly from moment to moment. The use of signal quality classification algorithms and robust feature delineation algorithms designed to achieve high accuracy on poor quality physiologic signals can prove beneficial in addressing concerns associated with measurement accuracy, confidence, and clinical validity.

Objective: The objective of this study was to demonstrate the successful extraction of clinical grade measures using a custom signal quality classification algorithm for the rejection of poor-quality regions and a robust QRS delineation algorithm from a nonstandard electrocardiogram (ECG) integrated into a toilet seat; a device plagued by many of the same challenges as wearable technologies and other Internet of Things–based medical devices.

Methods: The present algorithms were validated using a study of 25 normative subjects and 29 heart failure (HF) subjects. Measurements captured from a toilet seat-based buttocks electrocardiogram were compared with a simultaneously captured 12-lead clinical grade ECG. The ECG lead with the highest morphological correlation to buttocks electrocardiogram was used to determine the accuracy of the heart rate (HR), heart rate variability (HRV), which used the standard deviation of the normal-to-normal (SDNN) intervals between sinus beats, QRS duration, and the corrected QT interval (QT_c). These algorithms were benchmarked using the MIT-BIH Arrhythmia Database (MITDB) and European ST-T Database (EDB), which are standardized databases commonly used to test QRS detection algorithms.

Results: Clinical grade accuracy was achieved for all buttocks electrocardiogram measures compared with standard Lead II. For the normative cohort, the mean was −0.0 (SD 0.3) bpm (N=141 recordings) for HR accuracy and −1.0 (SD 3.4) ms for HRV (N=135). The QRS duration and the QT_c interval had an accuracy of −0.5 (SD 6.6) ms (N=85) and 14.5 (SD 11.1) ms (N=85), respectively. In the HF cohort, the accuracy for HR, HRV, QRS duration, and QT_c interval was 0.0 (SD 0.3) bpm (N=109), −6.6 (SD 13.2) ms (N=99), 2.9 (SD 11.5) ms (N=59), and 11.2 (SD 19.1) ms (N=58), respectively. When tested on MITDB and EDB, the algorithms presented herein had an overall sensitivity and positive predictive value of over 99.82% (N=900,059 total beats), which is comparable to best in-class algorithms tuned specifically for use with these databases.

Conclusions: The present algorithmic approach to data analysis of noisy physiologic data was successfully demonstrated using a toilet seat-based ECG remote monitoring system. This approach to the analysis of physiologic data captured from wearable and connected devices has future potential to enable new types of monitoring devices, providing new insights through daily, inconspicuous in-home monitoring.

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KEYWORDS

algorithms; delineation; ECG; EDB; electrocardiogram; Internet of Things; IoT; MITDB; signal quality; wearable

Introduction

Background

Wearable and internet-connected medical devices have the potential to fill a gap in patient monitoring, providing insights into disease progression and cardiovascular health between office visits, as well as enabling prevention-focused personalized care. The sluggish adoption of such technology within health care can be attributed to a lack of clinical value due to the large volume of difficult-to-interpret data and poor confidence in measurement accuracy [1,2]. This is due to use in uncontrolled environments and limited signal quality, resulting in noisy and highly variable signals that change from moment to moment. As a result, many wearable and connected devices do not meet the requirements for medical use and instead target self-management of fitness and well-being.

The literature approaches this problem by directly addressing noise in physiologic signals, through signal enhancement and noise removal techniques. A common approach to reproducing a clean signal (eg, photoplethysmogram) is to utilize information from other simultaneously gathered signals such as accelerometer data, impedance measurements, and/or multiple electrocardiogram (ECG) channels [3-5]. Additional statistical approaches utilize a priori information about the signal to de-noise signals for more accurate analysis [6-9]. Although these approaches can be beneficial, the assumptions made about the physiologic waveforms during this process have the potential to create false measurements, especially for those with cardiovascular disease who often have abnormal morphologies and rhythm [10].

An alternative approach to managing noise-corrupted physiologic signals is to reject regions that are insufficient for analysis, rather than forcing them through analysis. By automatically rejecting poor quality regions of physiologic signals, only regions where the subsequent algorithms can accurately determine specific measures are analyzed, increasing confidence. There are only a few examples in the literature that take this approach to rejecting poor-quality regions, where the focus is on hospital-grade medical equipment with the goal of reducing false alarms and increasing the confidence of automated results [11,12], or where results are only presented for healthy subjects [13,14]. Since these algorithms have been designed for hospital-grade equipment used in a controlled environment or on normative subjects, they have limited applicability to wearables or in-home devices that typically contain greater variability in signal quality.

This study expands upon the literature by implementing a robust signal quality classification algorithm for the rejection of poor-quality regions designed specifically to work with a highly accurate delineation algorithm designed for noisy signals. The effectiveness of these algorithms is demonstrated using a nonstandard, dry electrode–based ECG integrated into a toilet seat for inconspicuous in-home monitoring. The objective of this work was to demonstrate successful utilization of this approach to physiologic analysis through a study of both normative and HF subjects.

Motivation for In-Home Electrocardiogram Monitoring of Heart Failure

Heart failure (HF) occurs when the heart muscle is weakened and unable to maintain the blood flow required to meet the body's needs. Approximately 6.5 million Americans have HF, with 960,000 new cases per year [15]. HF costs the United States an estimated US $30.7 billion each year and is expected to increase to 127% to reach $69.7 billion by 2030 [15]. With approximately 80% of the total cost associated with HF due to hospitalization [16], there is an opportunity to reduce the cost of HF by lowering hospitalization rates through remote patient monitoring. The literature shows that hospital readmissions of HF patients can be reduced by the remote monitoring of a single-lead ECG [17-19]. Although a single lead has limited diagnostic capabilities, it can be useful for monitoring of disease progression, specifically through tracking arrhythmias, heart rate (HR), heart rate variability (HRV), QRS duration, and corrected QT interval (QT_c).

Changes in both HR and HRV can be used to predict cardiovascular events. For individuals with or without coronary artery disease, resting HR is a predictor of mortality, independent of other risk factors [20,21]. Low HRV is associated with a 32% to 45% increased risk of a first cardiovascular event for patients with no previous history of cardiovascular disease [22]. It is also associated with chronic HF, diabetes, and alcoholic cardiomyopathy [23].

An increase in QRS duration can be used in the diagnosis of disease state and as a predictor of sudden death [24]. For example, a QRS width of greater than 120 ms suggests that cardiac dyssynchrony may be present [25]. In addition, QRS duration may have secondary value in predicting the prognosis of patients with HF [24]. In one study, implantable cardiac defibrillator patients with HF who had a wide underlying QRS complex showed more than double the rate of cardiac mortality than those with a narrow QRS complex [26]. The degree of QRS prolongation is correlated with an increase in severity of left ventricular systolic dysfunction, left ventricular dilation, and mitral regurgitation [27]. Left ventricular function worsens as the QRS duration increases [26-29], making it an important parameter to monitor over time.

A prolonged QT_c interval is a strong, independent predictor of adverse outcomes in patients with HF, because it is related to ventricular polarization and repolarization [30]. Many drugs prescribed to cardiovascular patients change the PR interval and the QRS duration. However, they can also prolong the QT interval, which can be very dangerous. A drug-induced prolongation of the QT interval is associated with Torsades de Pointes (a polymorphic ventricular tachycardia), which may cause sudden cardiac death (unexpected cardiovascular collapse without warning) [31,32].

The Opportunities and Challenges of In-Home Electrocardiogram Monitoring

Currently, ECG monitoring is performed in a hospital or doctor's office, or for a short duration (typically from 1 to 7 days) at a patient's home using a Holter monitor [33,34]. Daily monitoring has the potential to avoid issues with the episodic nature of hospital or doctor visits and to provide insights beyond short-term Holter monitoring. Visits to the hospital or doctor occur neither at a consistent time of day nor with the subject at a consistent physiologic state, making it difficult for physicians to see trends in the measured parameters across time. In addition, white coat syndrome can significantly affect measurement results.

Although the 12-lead ECG cannot be replaced with a single-lead ECG for diagnostic purposes, there is an opportunity to fill a gap in patient monitoring with daily single-lead ECG measurements. If data can be gathered reliably, physicians can begin using each of these parameters (HR, HRV, QRS duration, and QT interval) to monitor disease progression over time. This would allow trends to be picked up that would otherwise be missed, enabling an alert-based system for facilitating early intervention. The many challenges of in-home physiological monitoring that are not present in a hospital environment or doctor's office need to be addressed for the data to be gathered reliably. In the home, a trained expert is not on hand to make any real-time changes that would ensure correct electrode placement and signal integrity. In addition, patient compliance is often low, resulting in inconsistent data collection that impedes accurate trend analysis. The fully integrated toilet seat form factor and the algorithms presented herein have the potential to address many of these challenges.

A Toilet Seat–Based Electrocardiogram Addresses Challenges in Patient Compliance for In-Home Monitoring

A toilet seat–based cardiovascular monitoring system can be integrated into a subject's natural daily routine with no change in habit, enabling measurements to be taken at one or more times each day. Furthermore, issues with subject preparation and subject error are greatly reduced, since skin contact is automatic and has sufficient pressure to create a repeatable electrode interface at a consistent location for each subject. Although a toilet seat–based buttocks electrocardiogram (bECG) is intermittent in nature, ensured compliance will enable long-term daily tend monitoring of parameters that do not require continuous monitoring, such as the QRS duration and QT_c interval.

Challenges Associated With a Toilet Seat–Based Electrocardiogram

Standard gel-based ECG electrodes cannot be used in a toilet seat-based device, necessitating the use of dry electrodes. Both the measurement location and the use of dry electrodes increase the noise present in the captured signal and reduce the amplitude of the ECG signal. Despite these challenges, the literature shows that it is possible to capture an ECG from a toilet seat [35-40]. Only the work presented in by Baek et al [38] has quantitatively compared the ECG from a toilet seat to a gold-standard ECG measure, where capacitive electrodes on the seat and wet electrodes placed adjacent on the thigh were compared with a standard limb lead ECG. The results of this study showed that manual R-peak delineation resulted in less than a 2-ms error in location and that the estimated HR was within 0.003 bpm for a single test subject. To date, no study has quantitatively compared the bECG HRV, QRS duration, QT_c interval, and waveform morphology with a clinical 12-lead ECG.

Unique algorithms have been developed to address the challenges associated with capturing and analyzing the bECG. The broad objective of this work was to demonstrate the feasibility of the present algorithms and bECG-based system for accurately monitoring key cardiovascular parameters in both a healthy population and an HF population, as a precursor to long-term trend-based intervention studies. The human subject data used herein were obtained at the Rochester Institute of Technology and the University of Rochester Medical Center. Studies were performed under informed consent and used protocols approved by each institution's Institutional Review Board for Protection of Human Subjects. These controlled studies compare the capabilities of the bECG to a clinical grade 12-lead ECG, quantitatively comparing the accuracy of extracted R-peaks, HR, HRV, waveform morphology, QRS duration, and QT_c interval for algorithm validation.

Methods

A Toilet Seat–Based Buttocks Electrocardiogram

The bECG is integrated into an elongated toilet seat, with dry electrodes on the surface and electronic instrumentation inside of the seat (Figure 1). It contains three electrodes, consisting of a differential electrode pair and grounded right leg reference, each with a diameter of 28 mm. Stainless-steel electrodes are chosen for their noncorrosive and nonirritant properties. The differential electrode pair is placed on the seat such that skin contact is made in proximity to the subject's gluteal fold when seated. A grounded right leg electrode is placed approximately 12 cm below the differential electrode pair on the right side of the toilet seat from the vantage point of a seated subject (Figure 1). Each electrode is securely integrated into the surface of the toilet seat with epoxy, to ensure repeatability across recordings.

The active front-end instrumentation is integrated inside of the seat and connected to each of the differential stainless-steel electrodes with welded wires. This results in a maximum distance of 10 mm between the electrode and the front-end instrumentation. The active electrodes contain electrostatic discharge protection and a high-pass filter with a −3 dB cutoff frequency of 0.16 Hz that removes any direct current voltage bias present on the body. This ensures that the signal is within the valid input voltage range.

For the normative subject study, the instrumentation is powered by a 3.3 V boost converter, which in turn is powered by a 3.7 V (nominal voltage) rechargeable lithium polymer battery. The output from each active electrode is differentially amplified using the ECG instrumentation (ECG100C) within a BIOPAC MP150 system (BIOPAC Systems, Inc, Goleta, CA, USA), which is also used to gather a 12-lead gold standard ECG. All

signals are then acquired with a sample rate of 1000 Hz using a National Instruments cRIO-9075 CompactRIO Data Acquisition System (National Instruments Corp., Austin, TX, USA), which is controlled by a laptop. The toilet seat with integrated electrodes and active ECG front-end instrumentation is secured to an elongated toilet mounted to the floor. A schematic overview of the system is shown in Figure 1. All devices that are not battery-powered are plugged into a medical-grade isolation transformer (ILC-1400MED4) to ensure electrical safety (TSi Power Corp., Antigo, WI, USA).

For the in-hospital HF subject study, all instrumentation and data acquisition circuitry are integrated into the toilet seat (Figure 1). The instrumentation is powered by a 3 V linear regulator that is powered by a 3.3 V boost converter, which in turn is powered by a 3 V primary lithium battery. The AD8232 (Analog Devices, Inc, Norwood, MA, USA) is used to differentially amplify the bECG in the cardiac monitor configuration application circuit [41]. The integrated ADC in the MSP430FR5969 (Texas Instruments, Inc, Dallas, TX, USA) is used to acquire the bECG signal, which is sent through a universal serial bus to a laptop computer. The 12-lead ECG is acquired using the BIOPAC. A pulsatile transistor-transistor logic signal sent from the MSP430FR5969 and captured with the BIOPAC data channels enable both systems to be synchronized automatically, with a timing offset error no greater than ±1 ms. All devices that are not battery-powered are plugged into a medical-grade isolation transformer (ILC-1400MED4) to ensure electrical safety (TSi Power Corp., Antigo, WI, USA).

Normative Subject Testing

Normative subject testing was performed on 26 healthy subjects who had no history of heart disease. One subject was rejected from inclusion in the normative study due to a prolonged QRS duration and abnormal ECG morphology in the 12-lead ECG, as determined by a Board-Certified cardiologist. Of the remaining 25 subjects, there were a total of 13 male and 12 female subjects in the age group of 20 to 50 years, with a mean age of 26.7 years. For the at-rest measurements, five 150-s (2.5-min) recordings were captured with each subject sitting on the toilet seat at rest. Between recordings, each subject was instructed to stand up to introduce positioning differences that would normally be associated with multiple uses of a toilet in the home, potentially changing signal quality and waveform characteristics. Next, to induce stress, each subject was instructed to raise his or her HR to 75% of their maximum predicted HR (220 – age) on a Schwinn 230 recumbent bicycle and then quickly transition back to the toilet seat upon reaching the desired HR. For the poststress measurement, a final 150-s (2.5-min) recording was then taken for each subject. A simultaneous, standard, 12-lead ECG with gel electrodes was acquired using the ECG100C ECG amplifier and MP150 system from BIOPAC.

Heart Failure Subject Testing

Testing was performed on 29 subjects diagnosed with HF in a hospital setting; there were a total of 21 male and 8 female subjects in the age group of 22 to 83 years, with a mean age of 55.4 years and a body mass index of 29.9 (SD 7.7) kg/m^2. At the time of testing, all the subjects were inpatients due to HF. Seven 150-s (2.5-min) recordings were captured with each subject sitting on the toilet seat at rest. Between recordings, each subject was instructed to stand up to introduce positioning differences that would normally be associated with multiple uses of a toilet in the home, potentially changing signal quality and waveform characteristics. Measurements were only gathered at rest from the HF subjects. A simultaneous, standard, 12-lead ECG with gel electrodes was acquired using the ECG100C ECG amplifier and MP150 system from BIOPAC.

Figure 1. Stainless-steel electrodes are integrated into the seat and are connected directly to the integrated ECG analog front-end. The output of each front-end is low-impedance, allowing for a low-noise connection to the differential ECG amplifier inside of the BIOPAC MP150 system (left). The resulting full-scale ECG signal is acquired on a NI CompactRIO DAQ. For the HF subject study, all instrumentation and data acquisition circuitry are integrated into the toilet seat (right). DAQ: data acquisition system; ECG: electrocardiogram; bECG: buttocks ECG; NI: National Instruments; HF: heart failure.

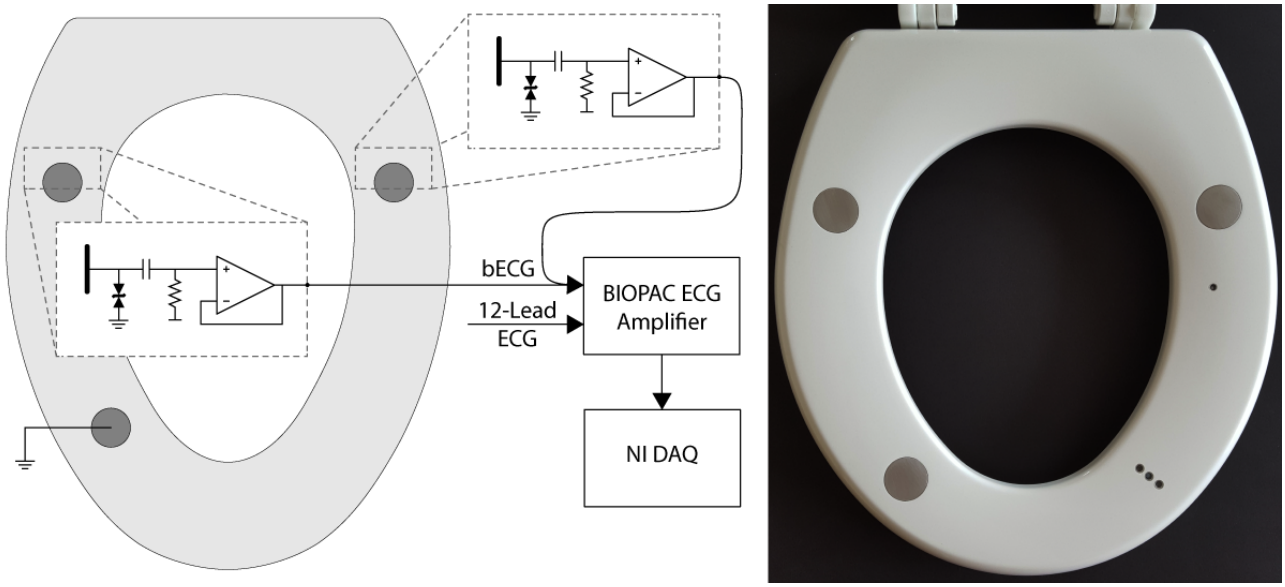
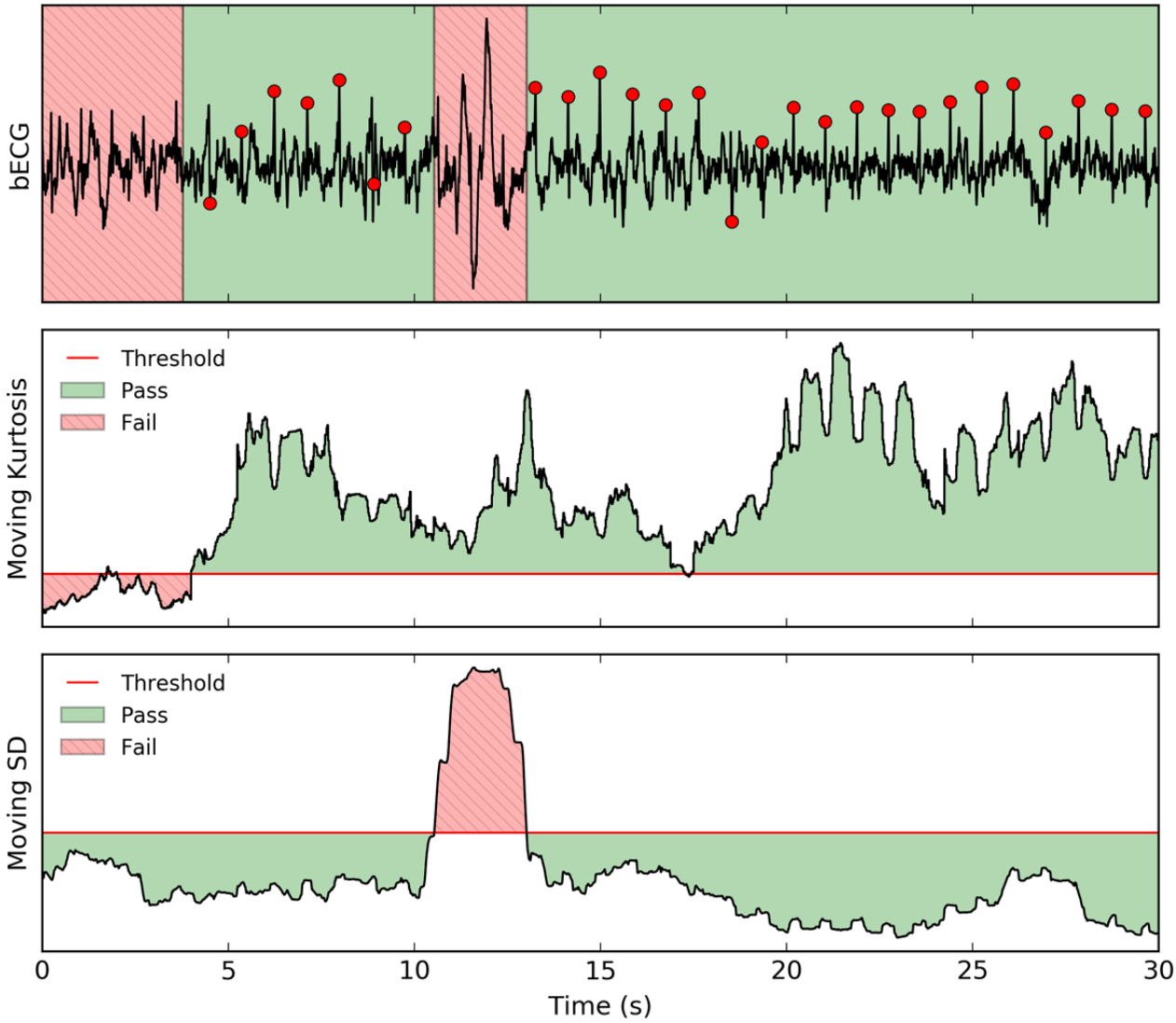


Figure 2. Signal quality is calculated from the bandpass filtered (1-45 Hz) and notch filtered (60 Hz) bECG (top) using a moving kurtosis (middle) and moving SD (bottom). The first signal quality index (moving kurtosis) rejects regions with in-band noise that have a kurtosis below a threshold of 3.6. The second signal quality index (moving SD) rejects noisy spikes that have a moving SD greater than 1.25 times the overall SD. R-peak delineations are shown as red circles to indicate where each beat is located within regions that have passed the signal quality test. bECG: buttocks electrocardiogram.



Automated Signal Quality Classification

Rejecting regions of poor signal quality is necessary for the accurate analysis of the dry electrode bECG because it is more prone to noise and motion artifacts than traditional wet electrode ECG systems. Custom algorithms were developed to automatically assess signal quality and reject noisy waveform segments using two signal quality indices (SQIs): one based on the kurtosis and the second based on the SD for spike detection.

The kurtosis is a statistical measure that is commonly used to determine ECG signal quality [42-44]. It is defined as the fourth moment about the mean (μ_4), divided by the SD to the fourth power (σ^4), as shown in equation 1. The kurtosis is a statistical measure of the *tailedness* of a distribution, where a normal distribution has a kurtosis of 3. When the kurtosis is lower than 3, the distribution under test has longer tails than a normal distribution. Typically, the kurtosis is calculated across a large window of at least 10 s and is used to locate large motion artifacts or excessive baseline wander [42]. A clean, sinus rhythm ECG with no motion artifacts or baseline wander has a kurtosis of greater than 5 [45].

Here, to identify waveform segments that contain excessive in-band noise, the moving kurtosis is calculated across a 2-s window on a bandpass-filtered ECG with a bandwidth of 5 to 15 Hz (second-order Butterworth filter), chosen to isolate the QRS complex. By using a smaller 2-s window, the kurtosis measure is no longer dominated by episodic large motion artifact or baseline wander. A kurtosis threshold of 3.6 was empirically chosen for this work based on the normative subject data. An example of the resulting kurtosis value compared with the threshold of 3.6 for a typical waveform is shown in Figure 2.

Large-amplitude spikes due to motion artifacts are detected using a second-stage SQI. Spikes are identified as an increase in the moving SD within a 2-s window. In this new approach, a threshold of 1.5 times the SD of the entire signal was empirically determined to provide robust rejection of noisy

spikes. Figure 2 shows an example of the resulting SQI and threshold.

R-Peak Delineation Using a Modified Version of the Pan–Tompkins Algorithm

ECG R-peaks are delineated on a beat-by-beat basis using a modified version of the well-known Pan–Tompkins (PT) algorithm [46]. The raw ECG signal is processed to isolate the QRS complex in both the frequency domain and the temporal domain. A first-order Butterworth bandpass filter with a bandwidth of 5 to 15 Hz is used on the input ECG waveform. This is the same filter that was used in the signal quality algorithm. A five-point derivative of the filtered ECG is taken and the resulting waveform is then squared, as described in the original PT algorithm [46]. The squared signal is low-pass filtered using a third-order Butterworth filter with a −3 dB cutoff frequency of 8 Hz, such that the resulting waveform will have smooth, individual peaks for each QRS complex. The cutoff frequency of 8 Hz was chosen to match the duration of a prolonged QRS complex, which is 120 ms [25,27]. Two thresholds are calculated from the resulting signal using a 5-s moving average (chosen to include multiple beats regardless of the HR), where the upper threshold is 1.25 times the moving average and the lower threshold is 0.3 times the moving average. Example waveforms from various stages of the modified PT algorithm are shown in (Figure 3), including both thresholds.

Each peak in the processed signal is located from largest-to-smallest amplitude with a minimum duration of 200 ms between peaks, corresponding with the cardiac refractory period [46]. Peaks that have an amplitude greater than the larger threshold are delineated. The median beat interval is calculated using all beats within 20 s of the current interval under test, to allow for natural variations in HR over time. If any of the resulting beat intervals are greater than 1.5 times the median beat interval, the lower threshold is used to locate missing peaks.

This algorithm differs from the original PT algorithm in Pan et al [46], which was designed to use integer arithmetic for real-time functionality on an 8-bit embedded system. Specifically, the present algorithm uses alternate filtering approaches and a different mechanism for calculating the dual thresholds. A Butterworth filter with a bandwidth that better isolates the constituent frequencies of the QRS complex is used, and a third-order low-pass filter is used in place of moving window integration. The modified PT thresholds are continuously updated to incorporate magnitude information from the peak, baseline noise, motion artifacts, and other ECG features to dynamically adjust to extreme changes in signal quality typical of dry electrodes.

Locating the exact peak of the R-wave is necessary when ensemble averaging to avoid feature smearing. Both the PT algorithm and the modified PT algorithm do not always locate the exact peak of the R-wave because the exact location is smoothed out by the processing stages, as shown in Figure 3. The R-peak location is refined by locating the two largest peaks in the squared derivative of the filtered ECG signal, within 150 ms of the original delineated point. These two peaks bound the search window for the R-peak, which is defined as the first zero-crossing of the first derivative of the filtered ECG signal.

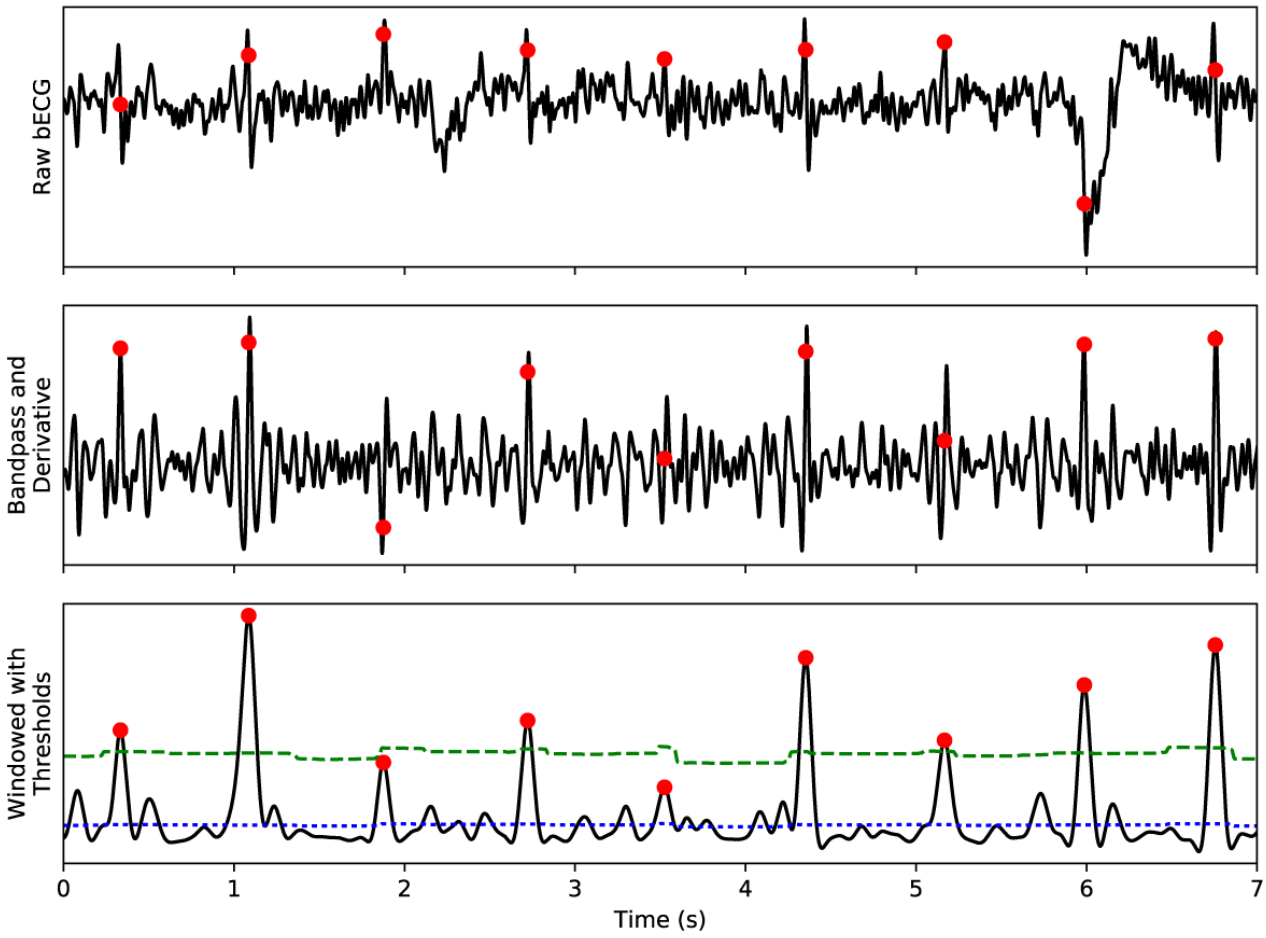
The modified PT algorithm with signal quality-based classification is verified using the annotated MIT-BIH Arrhythmia Database (MITDB) and European ST-T Database (EDB) as a gold-standard [47,48]. The purpose of using both databases is to enable a direct comparison between the present algorithm and other published QRS delineation algorithms and to demonstrate that the algorithm performs well on a standard ECG. The MITDB contains 48 records that are each 30 min in duration, and the EDB contains 90 records that are each 120 min in duration, provided by PhysioNet [49]. The signals from the MITDB and EDB have not been resampled because the modified PT algorithm does not require the ECG to be a specific sample rate. The beat-by-beat (bxb) function in the WaveForm DataBase application [49] was used to determine the sensitivity (Se) and positive predictive value (PPV) of the algorithm compared with the gold-standard annotations using a standard acceptance window (eg, match window) of 150 ms. The aforementioned signal quality algorithm was used to indicate periods of shutdown (regions of poor signal quality), where the classification results are tallied separately. The beats that would be missed during the shutdown period are excluded when calculating the number of false negatives (FN). In addition, the original PT algorithm has been implemented as described in Pan et al [46] and tested on both standard databases and the bECG dataset to facilitate a direct comparison with the modified PT algorithm.

Ensemble Averaging

Ensemble averaging is a technique used in ECG signal processing to reduce noise and improve feature prominence within the cardiac cycle. Features such as the T-wave may not be visible on a beat-by-beat basis, but ensemble averaging allows these features to become clear and easily located. This study uses standard ensemble averaging techniques [50,51], in which each beat is stacked relative to the R-peak and then averaged sample-by-sample as shown in Figure 4. Only sections of the ECG that pass the signal quality index algorithm and two additional ensemble average beat rejection criteria are included when generating the ensemble average. The first additional criterion for rejection is based on the beat interval; only beats within ±10% of the median HR are included. The second criterion is that the root mean square (RMS) of the beat under test must be between 75% and 200% of the median RMS of every delineated beat.

This process is required for accurate delineation of the Q-wave onset, S-wave end, and T-wave end when analyzing an ECG captured using dry ECG electrodes. Despite the benefit of using ensemble averaging, this process removes beat-to-beat variations such as T-wave alternans. This type of analysis, including arrhythmia analysis, must be performed separately before ensemble averaging.

Figure 3. The modified PT algorithm processes the raw ECG signal (top) to isolate QRS complexes for delineation using a bandpass filter and derivative (middle). Dual thresholds (dashed and dotted lines) are calculated using a moving window average and are continually updated (bottom), rather than updating only when a delineated feature is found. The resultant delineations, shown as red circles, are often shifted from the R-peak location, necessitating a subsequent refinement stage. ECG: electrocardiogram; PT: Pan–Tompkins.



Q-Wave, S-Wave, and T-Wave Delineation

Once the ensemble averaged beat is generated, the Q-wave onset, S-wave end, and T-wave end become clearly visible, allowing manual delineation of each feature. A trained expert manually located each of these three features using a custom graphical interface. Manual delineations were only used to calculate the QRS duration and QT interval for each recording. Delineations were spot-checked by 2 additional independently trained experts to ensure features were delineated correctly. Recordings where features are not clearly visible are marked as insufficient quality and are not included in the QRS or QT analysis by the trained expert. The bECG channel is delineated first so that the trained expert is not biased by prior knowledge of the gold-standard lead. After the bECG is completely delineated, the gold-standard lead undergoes the same delineation process.

The QRS duration is calculated as the time between the Q-wave onset and S-wave end. The Q-wave onset is defined as the return to baseline before the Q-wave. If no Q-wave is visible, it is defined as the initial deviation of the QRS complex from baseline. The S-wave end is defined as the point of inflection after the S-wave before the T-wave or before the return to baseline. If no S-wave is visible, the final return of the QRS complex to baseline is used. For the purposes of this work, the T-wave end is defined as the return to baseline after the maximum point of the downslope of the T-wave (or upslope, in the case of an inverted T-wave). The corresponding uncorrected QT interval is defined as the interval between the Q-wave onset and the T-wave end.

Correlation Analysis to Select a Gold-Standard Electrocardiogram Lead

To determine the accuracy of the bECG QT_c interval and QRS duration, a standard ECG lead is required as a gold-standard. Each of the 12 standard leads is a projection of the heart dipole and is unique in shape. As the heart dipole changes magnitude and orientation during the cardiac cycle, ECG features measured on each differential pair have different timing, amplitude, and orientation. Differences in projection affect the extracted cardiovascular intervals (eg, bias in the QT_c interval) and the clinical interpretation of any given ECG lead [52]. The bECG is a nonstandard lead, so correlation analysis was used to determine which of the 12 standard leads most closely matched the bECG morphology. Analysis was performed on the ensemble averaged beats of each lead from each normative recording. To minimize errors that are introduced by timing differences in the R-peak locations, R-peaks from a single channel were used

across all 12 leads and the bECG. This ensured a consistent reference point when ensemble averaging. The R-peaks from chest lead V1 were selected as a reference for all other leads, because this lead contained the fewest motion artifacts.

Pearson correlation coefficient, which is a measure of the linear correlation between two variables, was used to determine how closely each standard lead was to the bECG. This measure is calculated by dividing the covariance of the two variables by the product of their SD. Resulting values are between −1 and +1 (where *−1* represents a perfect negative linear relationship and *+1* represents a perfect positive linear relationship). Tukey boxplots were generated across the normative subject dataset, with whiskers 1.5 times the interquartile range to show the range of correlations between each lead. A paired Student *t*-test was used to determine if there was a statistically significant difference in the correlation results for each of the standard leads.

Beat Classification Analysis

The efficacy of the bECG was evaluated by comparing clinically relevant parameters to those extracted from the highest correlated limb lead, as determined in the Methods section. Beat classification is used to determine how consistently and accurately beats can be located on the bECG. The bECG signal quality must be sufficient for robust determination of beats; otherwise, it cannot be used for further analysis. Six recordings from each normative subject were used in these analyses: five at rest, and one post stress.

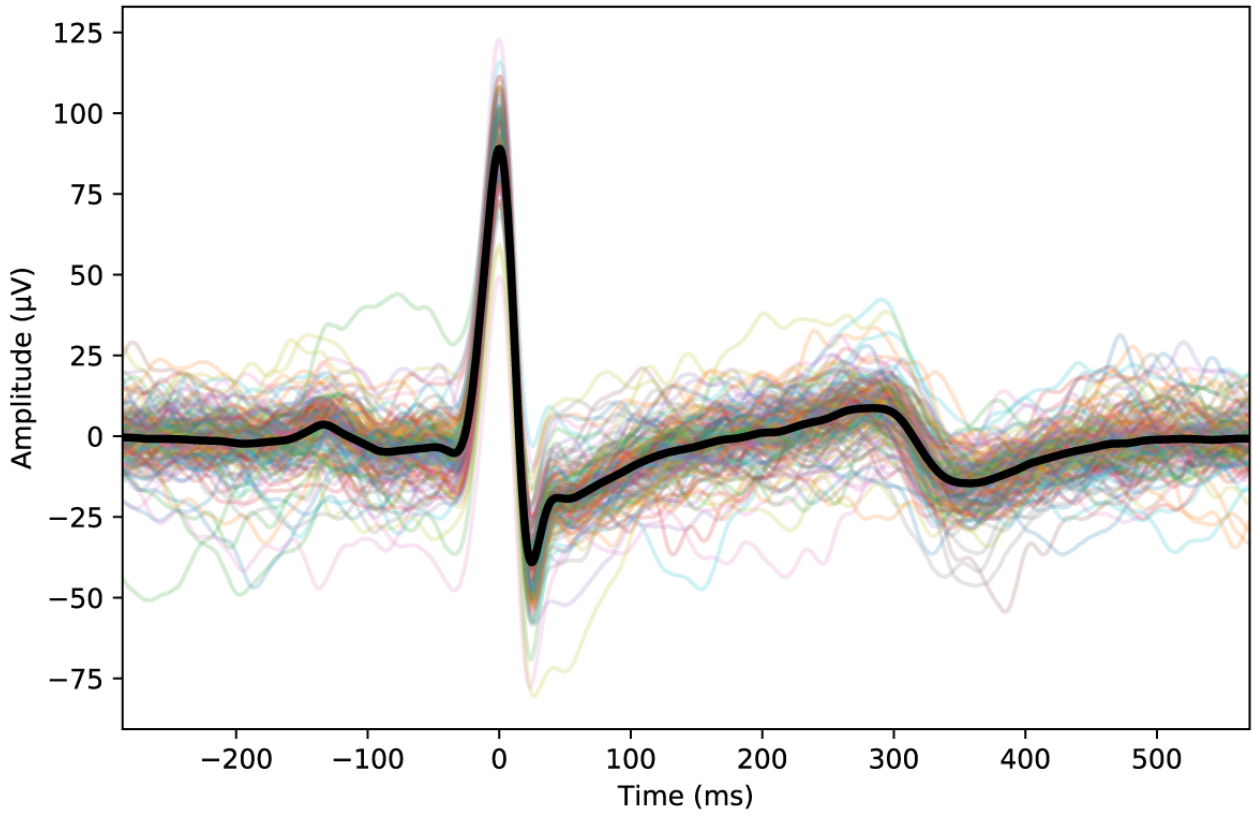
The Se and PPV (also known as precision) were then calculated for the bECG waveform using the corresponding beat delineations from the gold-standard ECG channel. Feature locations identified within an acceptance interval on either side of the gold standard were considered true positives (TPs), while reported time indices that are not within this acceptance interval were considered false positives (FPs). If a corresponding feature was not found within the acceptance interval of the gold-standard feature, it was considered a missed beat, or an FN.

The interval used when analyzing standard databases is 150 ms, based upon the bxb function provided by PhysioNet [49]. For normative analysis a more stringent acceptance interval of 100 ms was chosen, as it is half the myocardium refractory period of 200 ms [46]. This ensures that multiple beats will not be present for a single gold standard beat within the acceptance window.

The Se, representing the percentage of correctly delineated beats, is calculated using equation 2:

The PPV, representing the probability of a detected time index being a true positive, is calculated using equation 3:

Figure 4. Ensemble averaging aligns multiple beats based on the R-wave peak location to calculate an average beat. Individual beats that passed all the rejection criteria are shown as thin light-colored lines, and the resulting ensemble averaged beat is shown as a thick dark line.



Cardiac Intervals Analysis

For each recording the HR, HRV, QRS duration, and QT_c interval measured from the bECG were compared with the gold-standard lead that had the highest correlation with the bECG. The HR for a specific recording was calculated by taking the median RR interval (interval between consecutive R-peaks) after rejecting RR intervals that were more than 60% out of tolerance with respect to the initial median RR interval. Multiple methods can be used to calculate HRV. In this study, the SD of the RR intervals (SDNN) was used. For HR and HRV a minimum of 15 and 60 beats per recordings were required for analysis, respectively; if fewer beats were present, the recording was rejected and not included in the results.

QT_c and QRS intervals were extracted from the manually delineated feature timing on the ensemble averaged waveform for both the bECG and the gold-standard ECG lead. The minimum number of beats required for generating the ensemble averaged waveform for QT and QRS analysis was 60 beats. If fewer beats were present, the recording was rejected and not included in the analysis. Results were compared using Bland–Altman plots. Correcting the QT interval for different HRs is necessary when looking for trends or comparing across recordings. The QT_c interval is calculated using Bazett's formula [53], which is as follows in equation 4:

Results

The Buttocks Electrocardiogram Is Closely Correlated With Standard Electrocardiogram Limb Lead II

Correlation results between the bECG and each of the standard 12-leads are shown in (Figure 5), where the leads are shown in the order of highest to lowest median correlation. The bECG had the highest correlation with Lead II, − aVR, and aVF, with median correlations of .904, .899, and .893, respectively. The correlations for aVR, V1, aVL, and V2 have been inverted to facilitate visual comparison for high negative correlation. While the R-peaks from V1 were used as reference points for the ensemble averaging in the correlation analysis, there is no bias toward V1 since ensemble averaging is a linear process and every ensemble averaged beat from each of the 12 leads used the same reference points. Because each of the 12 leads was time-synchronized, a paired Student *t*-test was used to test whether differences in calculated lead correlations were statistically significant (Figure 5). Although there was no statistically significant difference between Lead II and −aVR (P=.41), Lead II was chosen as the gold-standard for the bECG since −aVR is an augmented lead calculated from Lead II.

Successful Validation on Standard Databases

The algorithms presented herein have been tested on the MITDB and the EDB to evaluate their accuracy against established standards. Both the MITDB and EDB are standard databases that contain hand-annotated gold-standard references. These databases are commonly used to verify beat delineation algorithms. The Se, PPV, and accepted signal quality percentages for the MITDB and EDB are shown in (Table 1). The algorithms presented herein have a cumulative Se of 99.83% and PPV of 99.82% across both databases, while the original PT algorithm has a cumulative Se of 99.72% and PPV of 95.93%. The slight differences in classification results for the original PT algorithm compared with the published results, which were only provided for the MITDB (Se=99.75% and PPV=99.54%) [46], can be attributed to minor difference due to incomplete implementation details in the original work. The modified PT results are comparable with best-in-class algorithms that typically have an Se and PPV over 99.5%, with very few over 99.8% [54]. The cumulative statistics were generated by calculating the total number of TP, FN, and FP across both the MITDB and the EDB.

Buttocks Electrocardiogram Delineations Robustly Correlate to Gold-Standard Lead II

One fundamental difference between the standard clinical ECG and the bECG is the signal amplitude. Both the electrode location relative to the heart dipole and the type of electrode can reduce signal amplitude. Example bECG waveforms that have been preprocessed with a bandpass filter (1-45 Hz) and notch filter (60 Hz) for visualization are shown in Figure 6, illustrating best, average, and poor signal quality compared with a time-synchronized Lead II. Each of these waveforms has passed the SQI test and was considered to have sufficient quality for analysis. Effective signal quality utilization, as well as the use of robust algorithms, are absolute requirements in this application, because the bECG is acquired using dry electrodes and is much more prone to noise and motion artifacts than a typical wet electrode ECG. This is of additional importance for HF subjects, where ECG amplitude is often low compared with normative subjects due to myocardial necrosis. Despite these challenges the bECG captures rhythm and critical waveform features in the HF population, as shown in Figure 7.

Across 54 normative and HF subjects with a total of 882.5 min of data, 60.1% (530.4 min) of the bECG signal passed the signal quality algorithm with an overall Se and PPV of 96.4% and 97.6%, respectively, compared with Lead II. Detailed results for the normative and HF subject groups are shown in Table 2. The modified PT algorithm presented herein provided significant improvements in both Se and PPV as compared with the original PT algorithm for the bECG dataset.

The signal quality across subjects and population groups were very polarized, with 16 out of the 25 normative subjects having over 85% of the bECG waveforms pass the signal quality test, compared with 3 of the subjects having less than 40% of the bECG waveforms pass the signal quality test. The polarization of signal quality within the normative subjects is caused by a combination of low body weight (each of the three subjects weighed less than 61.4 kg) and a high impedance electrode/skin interface, which varies on a subject-by-subject basis.

Figure 5. Box plots across normative recordings (N=140) show the correlation between the bECG and the standard ECG leads. Leads aVR, V1, aVL, and V2 have been inverted to facilitate visual comparison. Leads are organized from left to right by highest to lowest correlation. The top 3 correlated leads were Lead II, aVR, and aVF with median correlations of .904, .899, and .893, respectively. Statistical significance was tested using a paired Student t-test (*P<.05, **P<.01, and ***P<.001). bECG: buttocks electrocardiogram, ECG: electrocardiogram.

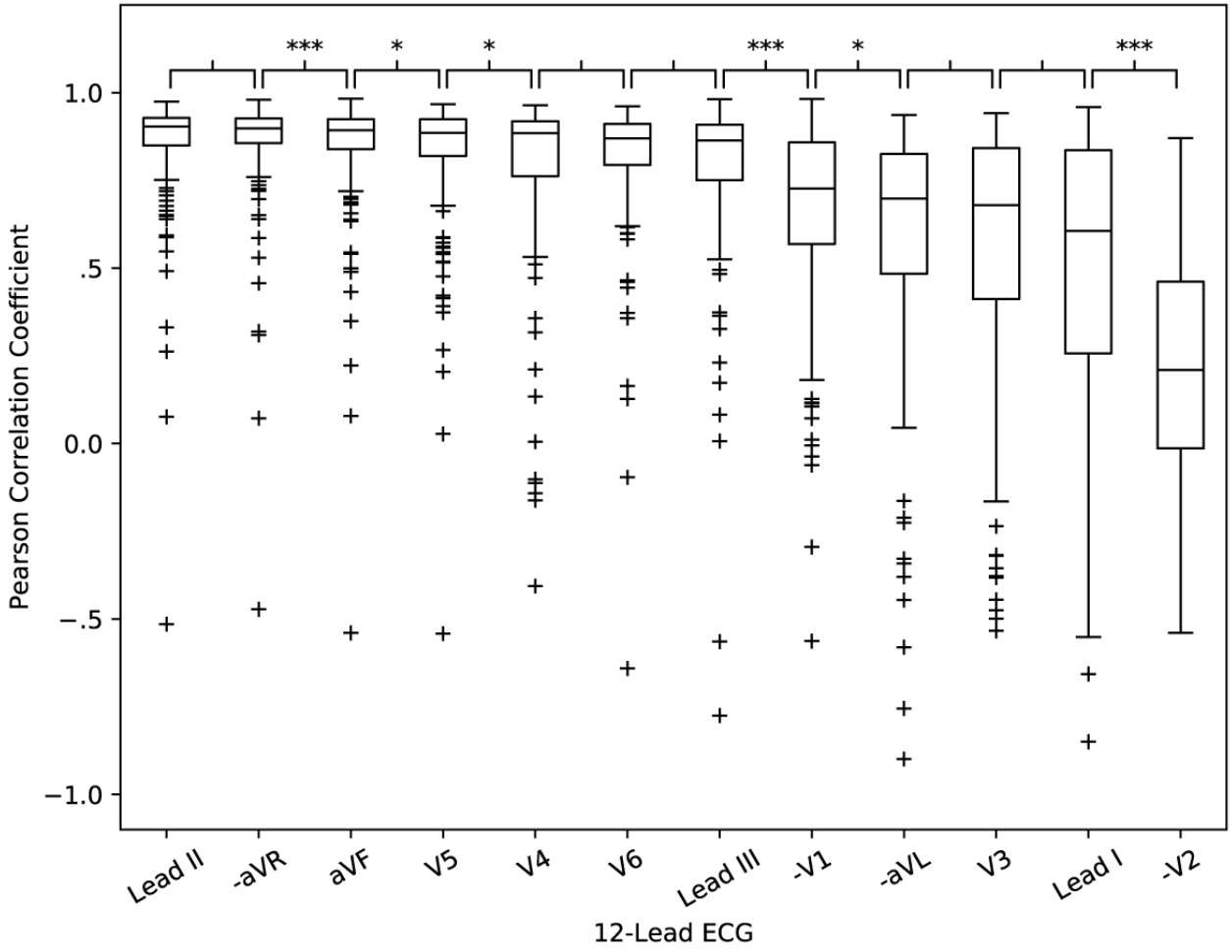


Table 1. QRS classification using the original and modified Pan–Tompkins algorithm on standard databases.

Database	Total beats	Original PT[a]		Modified PT		
		Se[b] (%)	PPV[c] (%)	Se (%)	PPV (%)	SQI[d] pass (%)
MITDB[e]	109,494	99.73	99.33	99.58	99.95	98.07
EDB[f]	790,565	99.71	95.48	99.87	99.80	96.55
Cumulative	900,059	99.72	95.93	99.83	99.82	96.73

[a]PT: Pan–Tompkins.

[b]Se: sensitivity.

[c]PPV: positive predictive value.

[d]SQI: signal quality index.

[e]MITDB: MIT-BIH database.

[f]EDB: European ST-T database.

Figure 6. The signal quality of the bECG can vary across subjects and measurements because it is captured using active, dry electrodes. Three examples of signal quality are shown for the bECG (top) compared with a time synchronized Lead II ECG (bottom). The best signal quality example (a) shows the best signal quality achieved from the bECG study. The average example quality (b) shows the typical signal quality of the bECG. The poor example (c) shows a very noisy waveform that passed the signal quality check before analysis. bECG: buttocks electrocardiogram; ECG: electrocardiogram.

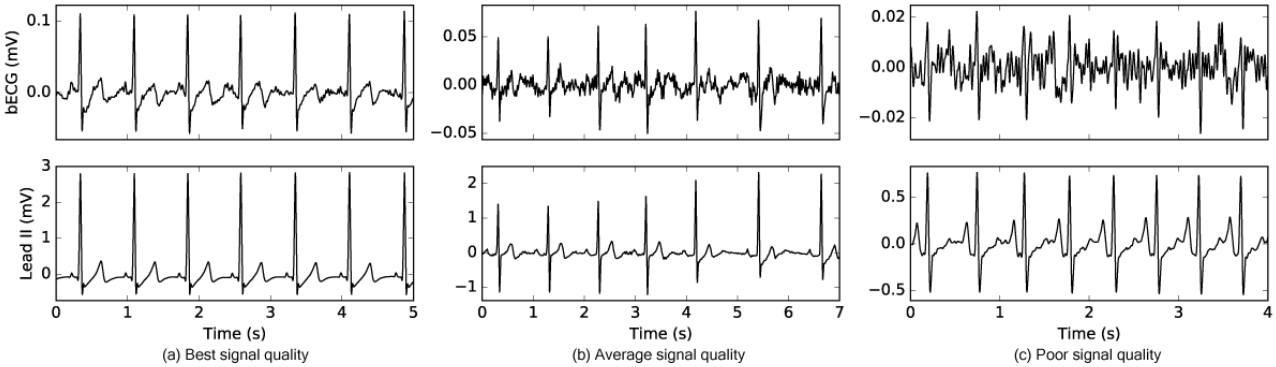


Figure 7. An example waveform from a heart failure subject during a period of arrhythmia, demonstrates that the bECG has sufficient quality to perform single-lead based rhythm analysis for those with disease states. bECG: buttocks electrocardiogram.

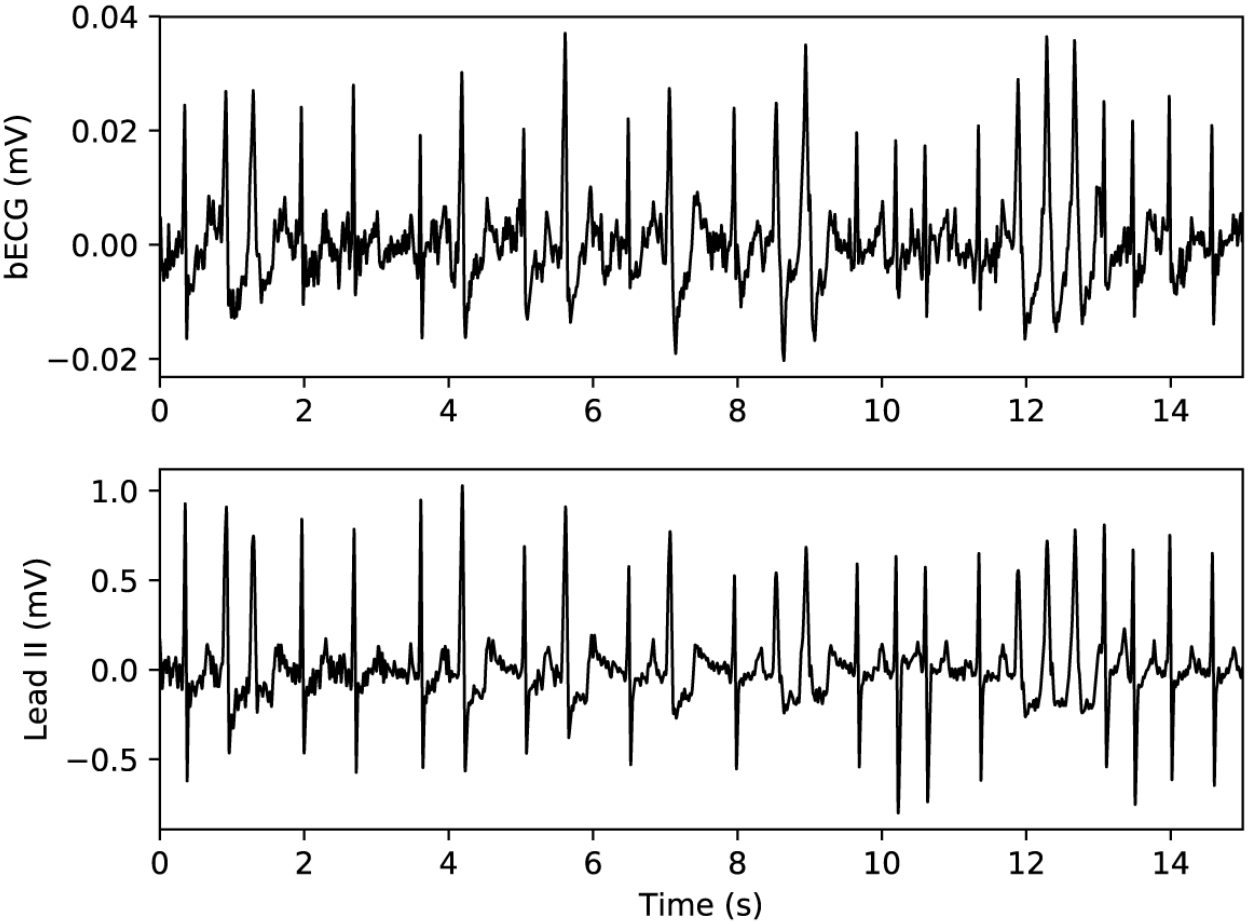


Table 2. Buttocks electrocardiogram beat classification results comparing the original and modified Pan–Tompkins algorithm.

Study Cohort	Total beats	Modified PT[a]			Original PT	
		SQI[b] pass (%)	Se[c] (%)	PPV[d] (%)	Se (%)	PPV (%)
Normative	30,075	79.6	98.2	98.1	86.1	77.7
HF[e]	41,820	45.4	94.2	96.6	62.2	59.6
Cumulative	71,895	60.1	96.4	96.7	72.2	67.4

[a]PT: Pan–Tompkins.

[b]SQI: signal quality index.

[c]Se: sensitivity.

[d]PPV: positive predictive value.

[e]HF: heart failure.

In addition, HF subject bECG signal quality was generally lower than that of the normative subjects (45.4% compared with 79.6%). The abnormal morphologies of the HF subjects' bECG is a contributing factor to the lower percentage of sufficient quality regions. In addition, beats that result in an abnormal rhythm are not included when generating the ensemble average, resulting in a higher percentage of rejected regions for the HF subjects compared with normative.

Despite the challenges of using dry electrodes on a toilet seat, the percentage of acceptable waveforms, as well as the corresponding Se and PPV, are more than sufficient for accurate estimation of physiologic parameters. Instrumentation improvements focused on increasing the signal-to-noise ratio when using dry electrodes are expected to significantly increase the percent of waveforms that pass the signal quality algorithm.

Cardiac Intervals Are Accurately Extracted From the Buttocks Electrocardiogram

HR and HRV are calculated per recording for the bECG and Lead II ECG waveforms for all subjects at rest and post stress. A total of 250 recordings passed SQI and were analyzed for HR and 234 for HRV; results are shown as Bland-Altman plots in Figure 8. The automated delineation algorithms resulted in an excellent agreement between the bECG and the gold-standard HR, with virtually no bias and only six outliers having an error greater than 1 bpm. The SDDN HRV was clustered very close to the zero-error line, but with positive bias induced by a small number of significant outliers dominated by the HF population, shown in Figure 8. Although the results are excellent for a dry electrode system with no skin preparation, additional enhancements to the automated SQI algorithm may provide opportunities to further improve results for those with cardiovascular disease.

The results comparing the bECG QRS duration and QT_c interval to Lead II are presented as Bland-Altman plots in Figure 9. A smaller number of recordings are included in the QRS duration and QT_c interval analysis compared with the HR and HRV analysis. This is due to the more stringent requirements imposed by the two additional beat rejection criteria when ensemble averaging and due to the rejection of recordings that did not have sufficiently clear features for delineation by the trained expert.

The Bland-Altman plot in Figure 9 shows a near zero bias in the QRS measures and 1.96 times SD of 17.8 ms. The Bland-Altman plot in Figure 9 shows a −13.2 ms bias in the QT_c interval, with an error of 29.3 ms (1.96 times the SD). The accuracy of the seated bECG measures of QRS duration and QT_c interval are within the limits of the expected accuracy of manual determination with a caliper, which has an error between 20 and 40 ms [52] and four standard automated approaches that have a 1.96 times SD error of over 35.5 ms [54,55]. Correlation analysis between the normative and HF subject groups showed statistically significant differences for bECG QRS duration ($P<.001$) and QT_c interval ($P<.001$) using the Student *t*-test. Algorithm refinement will provide an opportunity to remove outliers that have a significant impact on the overall SD, however, the present results compare well with the existing standards for measurement.

Figure 8. Heart rate (left) and heart rate variability (right) extracted from the bECG signal for normative rest (red x), normative post-stress (blue o), and heart failure (green +) are closely aligned with those extracted from the gold standard Lead II ECG. The dashed line shows the mean error. The dotted lines show 1.96 times the SD, corresponding to a 95% limits of agreement. bECG: buttocks electrocardiogram; ECG: electrocardiogram.

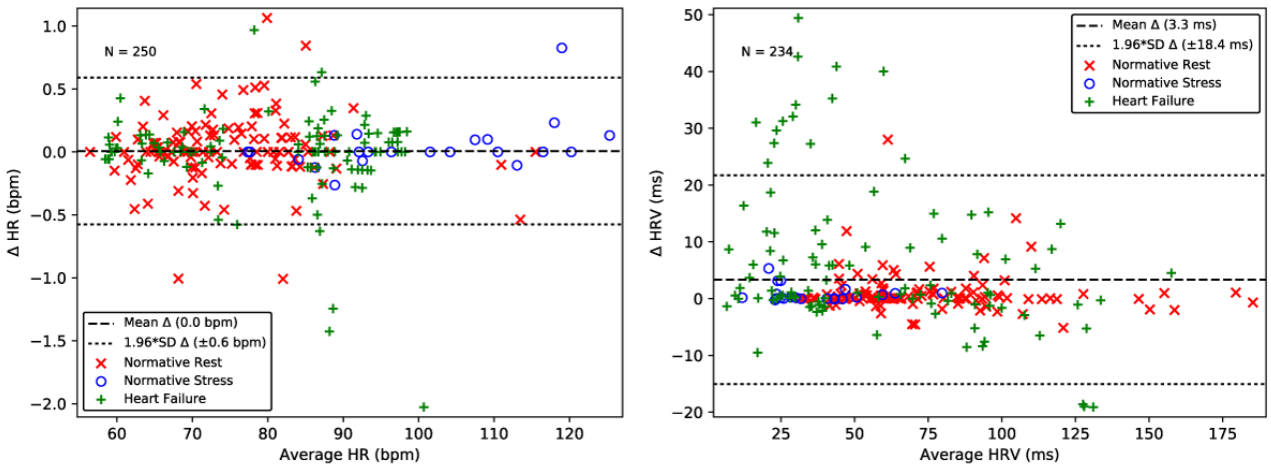
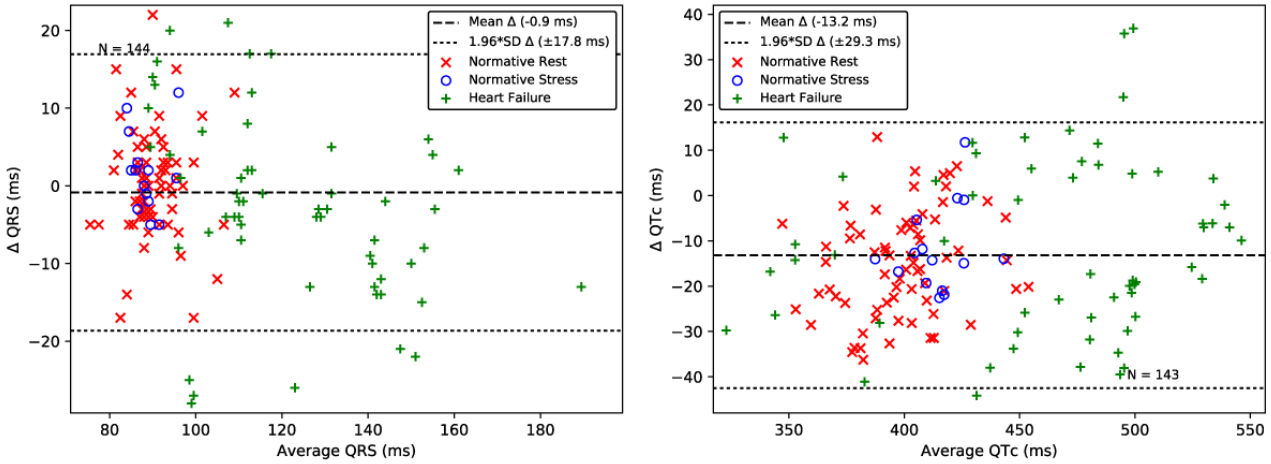


Figure 9. QRS duration (left) and QTc interval (right) extracted from the bECG signal for normative rest (red x), normative poststress (blue o), and heart failure (green +) are closely aligned with those extracted from the gold-standard Lead II ECG. The dashed line shows the mean error. The dotted lines show 1.96 times the SD, corresponding to a 95% limits of agreement. bECG: buttocks electrocardiogram; ECG: electrocardiogram; QTc: corrected QT.



Discussion

Principal Findings

This study demonstrates that a dry electrode, toilet seat–based ECG provides robust determination of HR, HRV, QRS duration, and QT_c interval as compared with a standard Lead II ECG captured using traditional wet electrodes (Table 3). Results showed that the bECG was most closely correlated with standard Lead II, showing clinical relevance and demonstrating confidence in the fully integrated toilet seat measures. The success of the toilet seat–based ECG is attributed to the advanced signal processing algorithms presented herein, which have been custom designed for noisy, dry electrode ECG signals.

Standard algorithms designed for clinical grade devices expect a certain level of signal quality and would either perform poorly or reject too large of a percentage of recorded data for wearable and connected devices. To ensure that a high percentage of the waveform is not rejected, the signal quality rejection algorithm in this study was designed to reject only regions where the subsequent delineation algorithm will perform poorly. While providing robust results for the system it was designed for (ie, a nonstandard dry electrode ECG), these algorithms also excel at analyzing hospital-grade ECG signals without any modification, as demonstrated using the MITDB and EDB standard databases. The resulting Se and PPV are comparable with best-in-class algorithms that have been designed specifically for use with these databases, with exceptional accuracy on EDB, a much more challenging dataset for delineation algorithms.

Limitations and Future Work

One limitation of this study is that data were recorded from subjects in either a lab or a clinical setting. While subjects were instructed to sit as they would at home during actual use, data captured in the home may result in additional motion artifacts and increase variability in signal quality. However, our results and the success of the signal quality algorithm suggest that in-home data can be successfully analyzed, even if a large percent of the signal does not have sufficient signal quality.

Table 3. Principal cardiac interval results of the buttocks electrocardiogram compared with Lead II for the normative and heart failure cohorts.

Study Cohort	HR[a] (SD), in bpm	HRV[b] (SD), in ms	QRS[c], (SD), in ms	QT_c[d] (SD), in ms
Normative	−0.0 (0.3)	−1.0 (3.4)	−0.5 (6.6)	14.5 (11.1)
Heart failure	0.0 (0.3)	−6.6 (13.2)	2.9 (11.5)	11.2 (19.1)
Cumulative	0.0 (0.3)	−3.4 (9.4)	0.9 (9.1)	13.2 (15.0)

[a]HR: heart rate.

[b]HRV: heart rate variability.

[c]QRS: QRS duration.

[d]QT_c: correct QT interval.

Similarly, this study did not investigate strain during use, which has the potential to modulate physiologic state in a similar fashion as the Valsalva maneuver. Future studies will investigate both the robustness of ECG measures during strain as well as the potential to detect cardiovascular shifts during strain that may have clinical value. Finally, the algorithms presented herein were only tested on ECG signals. To demonstrate broader applicability, future work will investigate the ability of the proposed approach to improve the performance of measurements captured with other signals such as the photoplethysmogram, which is commonly used in commercially available wearable technologies.

Despite these limitations, the results from this study lay the foundation for future studies on the clinical impact of the toilet seat measures, by having successfully demonstrated the accurate extraction of key cardiac intervals and parameters from the bECG as compared with a clinical gold-standard on both normative and HF populations. Since confidence in the form factor and measurements have been achieved, an in-home observation study and a subsequent intervention-based study can be executed. The initial in-home observational study will utilize daily HR, HRV, QT, and QRS measurements to create an alert-based system for HF patients. In the subsequent intervention study, cardiologists will be given the option to change medications or request a visit to the clinic based on automated alerts generated from seat data. This study will quantitatively determine how decision-making is affected through the enhanced monitoring capabilities of the seat, as well as how outcome events are impacted, such as hospitalization and the quantity of unnecessary procedures.

Broad Impact

In addition to directly enabling the fully integrated toilet seat, the present algorithms have applicability to wearable and internet-connected in-home medical devices that generate a large amount of data and are used in an uncontrolled environment, where optimal sensor placement and consistent signal integrity cannot be guaranteed. The algorithms from this study are not computationally complex and have the potential to be executed by the on-board processors present in many wearable devices with minor modifications. By combining signal quality classification, accurate delineation, and robust ensemble averaging, new applications can be realized, such as cuffless blood pressure and noninvasive cardiac output monitoring. Utilizing this approach, additional sensors and measurements can be integrated into wearable and connected devices, creating novel comprehensive remote cardiovascular monitoring systems. Such devices have the potential to fill a gap in patient monitoring by capturing trend data that has been previously unattainable, through daily measurements and ensured compliance requiring no change in habit. This will enable new approaches and capabilities in the diagnosis and treatment of cardiovascular disease, including those with HF and hypertension. Through the successful development, deployment, and integration with clinical practice, wearable and connected medical devices that monitor clinically relevant measures can facilitate the transition from a reactive- to proactive-based approach to health care.

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Conflicts of Interest

None declared.

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Abbreviations

bECG: buttocks electrocardiogram
ECG: electrocardiogram
EDB: European ST-T database
FN: false negative
FP: false positive
HF: heart failure
HR: heart rate
HRV: heart rate variability
MIT-BIH: Massachusetts Institute of Technology - Beth Israel Hospital
MITDB: MIT-BIH database
PPV: positive predictive value
PT: Pan–Tompkins
QTc: corrected QT interval
RMS: root mean square
Se: sensitivity
SQI: signal quality index
TP: true positive

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Original Paper

Users' Perspectives on mHealth Self-Management of Bipolar Disorder: Qualitative Focus Group Study

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Abstract

Background: Recent research indicates that current mHealth apps for bipolar disorders (BDs) show crucial shortcomings. They lack important functionality, are of inconsistent quality, and are insufficiently evidence-based. mHealth apps need to be better adapted to the needs of users. The perspectives of adult service users with BD regarding mHealth apps have not been well investigated.

Objective: The objective of this study was to examine the needs and expectations of adults with BD regarding mHealth apps.

Methods: Two focus group sessions were organized in which patients' views on self-management and design and functionality of an mHealth app for BD were assessed. During session 1, four focus groups were organized to identify users' needs regarding support for self-management. Session 2 contained three cocreation focus groups. Through this method, the desired functionality and design were explored.

Results: Participants indicated that they were in need of support in various ways. Not only support in psychoeducation, including daily routine, sleep pattern, maintaining social contacts, maintaining a healthy lifestyle, and avoidance of stimuli, was considered important for them but also gaining insight into their illness was found to be crucial.

Conclusions: According to the participants, their illness-related information is a key factor in gaining insight into their mood pattern. Participants wanted a functional design that would increase daily use and prevent overstimulation. The results of this study should be taken into account when developing new mHealth apps.

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KEYWORDS

bipolar disorder; self-management; mHealth; focus groups

Introduction

Bipolar disorder (BD) is characterized by severe episodic disruption of mood. Medication alone is insufficient in reducing its impact [1]. Acquiring insight and monitoring of the illness are important for an optimal quality of life [2]. A crucial aspect is self-management [3]. Barlow et al [3] describe self-management as the individual's capacity to cope with symptoms, treatment, potential physical and psychosocial

effects, and lifestyle changes that are inextricably linked to living with a chronic illness. Thanks to effective self-management, patients can engage in suitable cognitive and emotional response, as well as handle the challenges related to their mental health to maintain a good quality of life [3].

The use of mobile computing and mobile communication technologies is growing rapidly in health care [4,5]. mHealth has great potential in the transformation of health care to improve its quality and efficiency [6]. It also has the ability to reduce costs in health care and improve its accessibility [7]. Mobile apps are a way to inform patients about their treatment process. As such, mHealth has the potential to empower patients. They can learn to manage their health more actively and independently through self-management [8,9]. mHealth apps, because of their usability, functionality, and proximity, are ideally suited to optimize the self-management of chronic diseases [9]. However, few mHealth apps for BD are evidence-based, most of them need to be better tailored to the needs and perspectives of people with BD [10,11], and user involvement remains a challenge [12,13]. Although intrinsic motivation of patients to learn is crucial for self-management and adherence [14], the current mHealth market has failed to develop an app that is both scientifically relevant and motivating [15].

For the development of evidence-based apps, it is important that developers take the needs of people with BDs into account [10-13], especially regarding the implementation of self-management strategies [5].

The qualitative studies among mHealth and especially user's needs are very limited [16]. It should be noted that literature and research on the needs of people with BD and self-management strategies are lacking [17]. A study by Todd et al [18] focuses qualitatively on the needs of people with BD according to a Web-based self-management intervention. Other recent studies are researching quantitatively the needs of self-management apps [12] and focusing on the individual's needs and opinions concerning existing apps or tools [13]. Therefore, this study is one of the first that aims to examine from scratch and broadly the needs and perspectives of people with BD concerning the development of a self-management app. By adding aspects of context mapping and cocreation, this research explores which elements of design and functionality should be included in a self-management app.

Methods

In this qualitative study, a total number of 16 participants were represented, comprising 9 women and 7 men. These participants took part in the first 4 focus groups in session 1. Of this group of 16 participants, 10 participated a second time in the following 3 focus groups in session 2.

Participants

To be eligible, participants had to report that they received a diagnosis of BD from a health professional, received a treatment for their BD or were undergoing treatment at the time of the study, and were aged at least 18 years. Another inclusion criterion consisted of a positive screening according to the Mood Disorder Questionnaire [19]. Participants were recruited through the Flemish patient network, Ups and Downs, a self-help organization for people suffering from BD. The average age was 42 years (SD 14) and the age range was 21 to 69 years. To investigate the subjective severity of their condition, participants were asked to indicate the severity of their BD on a scale (cf [18]) of 1 to 5, where 1 indicated the least severe, and a score of 5 indicated extreme severity. The average severity score of the participants was 3.5, indicating a moderate self-reported severity of BD. Sample characteristics are outlined in Table 1.

Procedure

Seven focus groups were assembled with users with BD. Four groups took part in session 1, and 3 groups in session 2. In session 1, context mapping was used to gather insights into the users' needs regarding self-management in general and mHealth self-management for BD specifically. Context mapping is a creative, exploratory research method, aimed at bringing out more latent needs and ideas [20].

Session 2 took place 10 weeks after session 1 and used cocreation to assess information about the users' needs concerning the functionality and design of a self-management app. Cocreation is a form of collaboration in which participants are involved in the process of, in this case, designing a self-management app [21,22]. Both focus group sessions were 4 hours in length, including breaks of about 45 min in total. Audio and video data were collected during each session. The focus groups were conducted by trained clinicians under the supervision of the lead researchers. Due to the strong emotional impact of the subject and the intensity of the research methodology, each focus group had no more than 4 participants [23]. Four participants are sufficient for a group discussion and small enough for the moderator to pay attention to the input of each individual [24,25].

Table 1. Sample characteristics.

ID	Gender	Age, in years	Employed	Highest educational degree	Use of digital tools	Participation session 2	Severity score of bipolar disorder from 1 to 5
1	Female	59	No	Primary education	Computer, tablet, smartphone	Yes	3
2	Female	56	No	University education	Computer, mobile phone	Yes	5
3	Female	54	No	Higher education	Computer, smartphone	No	3
4	Female	47	No	Primary education	Computer, tablet, mobile phone	Yes	4
5	Female	37	Yes	Secondary education	Computer, tablet, smartphone	Yes	4
6	Female	24	No	Secondary education	Computer, tablet, smartphone	Yes	4
7	Female	36	No	University education	Computer, tablet, smartphone	No	3
8	Female	37	No	Higher education	Computer, tablet, smartphone	Yes	4
9	Female	21	No	Secondary education	Computer, smartphone	No	3
10	Male	36	No	Secondary education	Computer, tablet, smartphone	No	4
11	Male	28	No	Secondary education	Computer, tablet, smartphone	No	3
12	Male	41	No	Secondary education	Computer, tablet, smartphone	Yes	3
13	Male	53	No	University education	Computer, tablet, smartphone	No	2
14	Male	29	No	Secondary education	Computer, mobile phone	Yes	4
15	Male	69	No	University education	Computer, mobile phone	Yes	4
16	Male	41	Yes	Primary education	Computer, smartphone	Yes	4

Session 1: Context Mapping

In session 1, participants were asked about their experiences and needs regarding the self-management of their BD. Participants were invited to think creatively about the development and use of the app. Several creative exercises were presented to participants (Figure 1). They were first asked to create a mood board in the form of a scrapbook of magazine clippings about (potential) beneficial and harmful self-management strategies. Participants had to structure their scrapbook according to a 4-cell grid:

1. Which strategies do you use and work for you?
2. Which ones do you use but do not work?
3. Which strategies do you not use but in your opinion, might work well?
4. Which ones do you not use and might also not work well?

Structuring the exercise this way allowed us to gather information about positive and negative experiences participants have had with different self-management strategies. Participants were then asked to present their personal scrapbook to their focus group. Meanwhile, the moderator asked questions in case clarification was needed and collected the strategies that the participants found important. The third exercise was a brainstorming session. Participants had to write their preferred self-management strategies on post-it notes, selected from the strategies collected in the scrapbook exercise, and post them on a 2-axis grid. The 2 axes represented how pleasant versus how effective each strategy was considered. Subsequently, each participant indicated his or her 3 most important self-management strategies. These chosen strategies were then clustered allowing 4 main strategies to be chosen by the entire group of participants, the 4 focus groups.

Session 2: Cocreation

Cocreation is a creative, explorative research method. This session was moderated according to various creative techniques. During the first exercise in the cocreation session, questions in the form of scenarios were asked and discussed within the 3 focus groups. These questions were based on the categories of the specific user's needs gathered in session 1. The main categories form session 1 are love and relationships,

psychological support, knowledge about yourself and disorder, rest, and avoidance of stimuli (examples of scenarios: You experience a crisis; how would you explain this to the app? How can the app possibly send a signal to the emergency services, family, or confidant? You want that you get enough sleep; How can the app facilitate this?) Respondents first had time to think about these scenarios individually, after which there was a discussion within the 3 different focus groups. Next, each focus group had to design an advertisement for a self-management app. The following elements were keys: a name, a commercial slogan, their target users, the main self-management strategy, one image, and the suggested price. This exercise allowed participants to think about the app in a different and creative way by making e-prototype of a self-management app; in addition, they needed to think about the essence of such an app. Participants of the focus groups were allowed to add further explanation if they thought it necessary. Thereafter, participants from the various focus groups presented their advertisements with accompanying explanations to the entire group of participants. Finally, each focus group had to design and draw screens for a possible self-management app on post-its. Subsequently, they presented their app to the entire group. During the presentations, questions and comments were posed by the entire group of participants.

Analysis

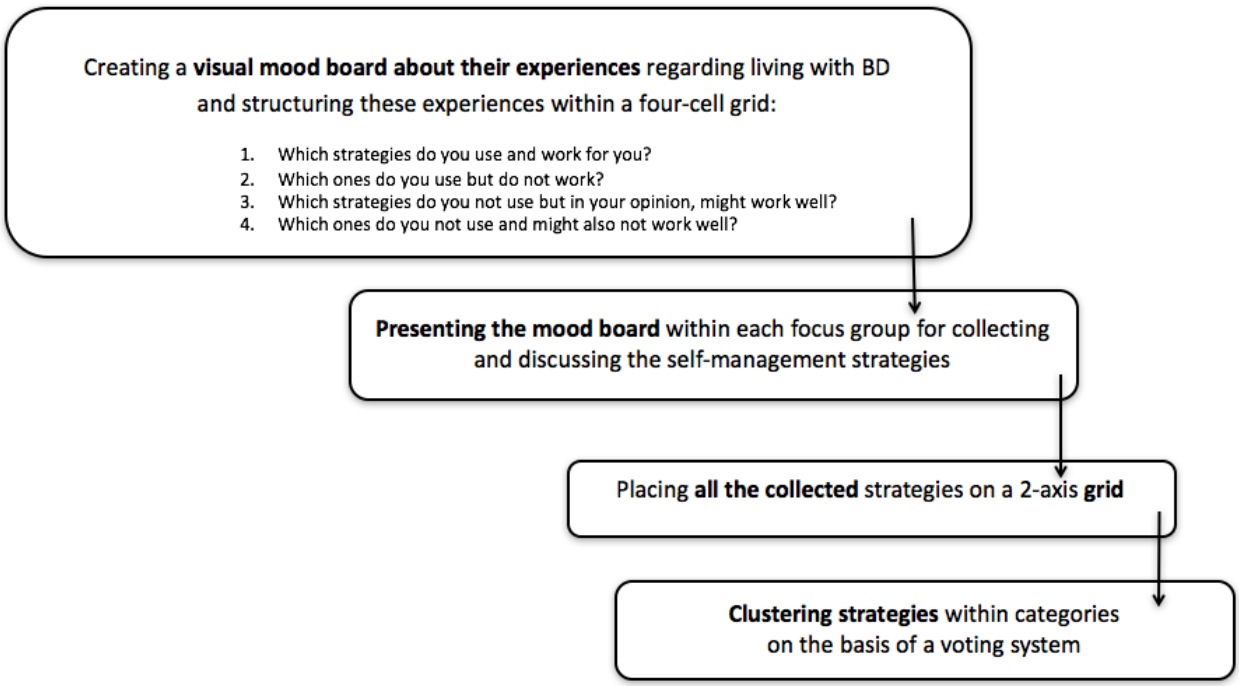
During the focus groups, participants were encouraged to provide personal input. Although this produced very rich data, it presented challenges when attempting to align the needs and expectations of the participants. It was therefore key to look for factors that were important to all participants while still leaving room for individual creativity [26]. The qualitative data were submitted to both deductive and inductive analyses [27]. The analysis had a deductive aspect, as labels were derived from previous research focusing on BD and self-management apps [12,13,18]. Furthermore, the analyses included an inductive aspect, as new themes and labels were generated from the reading and analysis.

Focus groups were audio-recorded and transcribed verbatim. After the transcription, the first author saturated into the data by reading them several times with reference to the research questions. On the basis of the literature and feedback from the focus groups, an analysis scheme was created: the data were divided into fragments, tagged, organized, and categorized according to the open coding method, a technique that increases the chance of obtaining new insights [26]. Labels were assigned to the transcribed focus group data. For this purpose, we used the MAXQDA software (VERBI GmbH) to analyze the focus group data [26]. Labeling is assigning a name or code to similar phrases. A code shows the relationship between the words of the participants and the research questions. To facilitate this process, a labeling scheme was devised in which each core label was listed with associated sublabels [26,28]. The first author primarily completed the analysis, but feedback was derived from the coauthors to deepen the analyses. If coauthors disagreed on assigned labels, we reexamined this labeling to reach consensus. The description of the results is based on this labeling process.

Ethics

The participants gave their oral and written informed consent before the start of each focus group. Ethical approval was granted by the Independent Ethics Committee (Committee for Medical Ethics at the University Hospital Antwerp), after consultation with the Ethical Committee of Emmaüs vzw (record no.: 15/13/128), Belgian registration number: B300201524839.

Figure 1. Flowchart on context mapping. BD: bipolar disorder.



Results

Data from the two sessions were analyzed together because aspects of design and functionality are closely interconnected. From sessions 1 and 2, four key themes were distilled from the data: (1) psychoeducation, (2) avoidance of stimuli, (3) social connection, and (4) personal support.

Theme 1: Psychoeducation

Psychoeducation covered the following topics: insight into personal illness, information, medication, and therapy. These themes were selected by cross-referencing the data from the focus groups with an extensive literature review about the relationship between self-management strategies, triggers, and prodromes.

Insight Into Personal Illness

All participants indicated that their understanding of their BD is extremely important in improving self-management. Participants clearly expressed a need for support to gain insight into their disorder. For example, participants suggested that greater knowledge regarding their disease might aid early detection, which could encourage them to seek help sooner. Participants indicated that keeping a mood diary is useful to get a better understanding of their bipolar condition. Several participants already used a mood diary in a paper version, and some had experience with a digital version. Although most found it to be a very useful tool, they indicated that it was challenging to keep a diary at regular intervals. Participants claimed to be more committed when caregivers urged them to keep a diary. In the absence of such external motivation, most participants stopped keeping a journal even despite their belief that they could gain better control over their condition.

Importantly, participants expressed that one of the most powerful ways to gain insight is through gaining a better understanding of their episodic characteristics. Some indicated that the app could act as a "mirror" of their behavior. This means that they thought it would be a helpful feature of the app and provide knowledge and early warning signs regarding their prodromal behavior. In other words, they would like the app to "show" them their own behavior like a mirror would. One participant stated:

> *Everyone experiences a bipolar disorder differently; their effects are very individual. That's what I notice within my circle of friends with bipolar disorder.* [Participant 6, female, 24 years]

Another participant indicated that she found it challenging to describe how she feels during a mood episode. Describing her daily activities is more tangible and concrete and would allow her to gain more insight into the course of her illness. She said:

> *When I start a manic episode for example, I spend a lot of money. I cannot describe my feelings during such a mood switch, but I can describe my expenses.* [Participant 4, female, 47 years]

In summary, participants stated that support for self-monitoring based on their behavior would be especially helpful for them to manage their mood.

Information

Another theme in psychoeducation is the acquisition of illness-related information. Participants indicated a need for information about medication, available assistance, and the course of their disorder. They felt insufficiently informed about available assistance and were often unaware of where they could find the right information. One participant felt that he was often sent from one care provider to another and could not get suitable support. Another participant indicated that she learned a lot by reading about BD, and this helped her to manage her condition more effectively:

> *[it is] important and really helps me to learn about bipolar disorder and read about stuff.* [Participant 6, female, 24 years]

According to participants, an app could be useful for accessing the correct information when it is needed.

Medication and Therapy

All participants took daily medication. They reported no moral problems to take their medication consistently and regularly. However, daily intake was difficult for some participants because of a lack of structure and daily routine. Participants suggested that it would be useful when the app can send a reminder or daily encouragement.

Therapy via a mobile self-management app was not a prominent topic mentioned during group discussions. Participants felt that face-to-face contact with a psychologist or therapist was very important; however, some indicated that therapy within a mobile self-management app had the potential to provide added value and support (eg, ability to contact social support, therapist, or psychologist quickly and more easily).

Theme 2: Avoidance of Stress

Daily Routine and Good Sleep Hygiene

Participants frequently cited the importance of routine and structure for getting enough rest and sleep. Daily routine and good sleep hygiene" was an aspect whereby they need support. Participants found it challenging to maintain regular sleep and wake times. One participant commented:

> *Sleeping is very effective and useful, sleeping too much is not good either. To structure it, yes a good balance, is not easy.* [Participant 11, male, 28 years]

Good sleep hygiene was viewed as necessary, but many participants experienced challenges in this area.

One participant suggested that a mobile self-management app would be helpful if it could send her a message with a warning if she had lost sleep for a certain number of nights in a row. This would allow her to adjust her activities for the next few days as part of a preventive approach for mood episodes. Participants indicated that structure was important in their daily activities. Although they felt that an agenda could help, there was some ambivalence around this idea. One of the participants said:

> *Schemes and schedules to follow, it would certainly help, but it does not work. That currently interferes most in my daily life.* [Participant 6, female 24 years]

Some participants indicated that the main function of the app should focus on supporting them in maintaining structure in their lives.

Avoidance of Stimuli

A further topic that was extensively discussed in the focus groups relates to the avoidance of stimuli and stress. Participants indicated that the Internet, social media, smartphones, and tablets increase stimulation and are thus very distracting. Consequences included disrupted sleeping patterns, leading to feeling fatigued and having less structure in daily activities. A possible function of an app according to the participants would be to engage them in self-management but at the same time support them in taking time to rest. One participant indicated that if the mobile app could turn off daily between certain hours, it would avoid unnecessary stimulation and distraction:

> *The app switched off between certain hours, just quiet.* [Participant 12, male, 41 years]

Another participant suggested that the mobile app could suggest taking time out to rest. Interestingly, this aspect of avoiding stimuli is closely associated with the functionality of the app itself. Namely, the app itself was seen as a form of stimulus that should be minimized so as not to be invasive. Participants emphasized the importance of having a mobile app that would not distract too much or motivate them to use it continuously. Most participants indicated that pressure and stress had a significant negative impact on their mood; thus, an important self-management strategy should reduce stimulation. One participant stated:

> *I try to avoid business and stress and chaos.* [Participant 5, female, 37 years]

Relaxation

Participants stated that exercise as a relaxation strategy (eg, walking sports) was helpful for their mental state as well as improving self-management overall. Some participants suggested that an app could help to motivate them to perform these activities because they indicated that is difficult to do so regularly. However, personal preferences and individual factors are important to consider. Specifically, certain activities can be helpful for one individual, yet act as a trigger for another. For example, one participant indicated that sport could be a triggering factor for a manic episode. Another respondent indicated that mindfulness, relaxation, and breathing exercises accompanied by music would be calming and motivating for him, whereas others indicated such strategies would not be pleasant or useful for them. Mobile self-management apps need to take these nuances into account, supporting individuals to engage in activities that they not only enjoy but are also helpful for self-management of mood.

Theme 3: Social Connection

Participants reported that both social relationships and contact with peers are important self-management strategies. Contact with others to exchange experiences, information, and tips was discussed as particularly helpful. They stated that maintaining social relationships also has an important supportive function. One participant said:

> *To me, good relations are very important for support. But if it goes wrong in a relationship, that is a trigger, then yes it could go wrong.* [Participant 6, female 24 years]

All participants agreed that an important function of the app would be to encourage them in supporting their social relationships. For example, the app could keep their friends and family informed on their well-being and contact the relevant person easily if the individual was in need of support. One participant considered this as potentially the core task of a self-management app:

> *...I want to let others know when I'm not well, the app would help me.* [Participant 12, male, 41 years]

Here, "ownership" was an important facet of the discussion. Some felt that family or friends should not be informed of their condition without their consent:

> *I would like to have control of the app. I would not like it if 5 people would automatically be notified.* [Participant 8, female, 37 years]

Thus, participants indicated that they should be able to decide when and who would receive information about them through the app.

Theme 4: Personalized Support

Participants highlighted the importance of being able to customize an app, as this reflects the personalized nature of their BD and how they engage in self-management. One participant stated:

> *This works for me, but therefore not for anyone else. It's all very personal.* [Participant 8, female, 37 years]

Being able to add a personal touch to the app would increase engagement and overall self-management efficiency. Participants indicated an important aspect here would be for the app to make suggestions, for example, supporting individuals by offering tailored information and suggestions for the management of their disorder. One of the participants said:

> *The app should be my life-coach.* [Participant 5, female, 37 years]

When asked to design an app, almost all participants indicated the importance of a crisis or emergency button in the app. This can again be personally programmed to either contact professional help, family or friends, or allow quick access to an automatic contingency plan.

Furthermore, participants mentioned that when the app is used in concert with health care workers, they would be more motivated to use the app. Participants found that the app should give tips and information using a positive and encouraging tone:

> *The text of the alert should be an encouring, positive, and interactive one. Not saying "watch out" but positive approach, more along the lines of: "I've noticed that..."* [Participant 8, female, 37 years]

Importantly, participants wanted control over the number of feedbacks generated by the app. This held for the number of tips, warning signals, and reminders that would suggest them to actively input data into the instrument. Therefore, a customizable setting would be preferable. Simple language was preferred, as participants felt that the use of the app would be adversely impacted by needlessly complex language. Visually, participants indicated a preference for the app to be appealing: playful, pleasant to look at, but simple. Finally, entering games or game elements into the app was barely mentioned during the focus groups although past research has shown that game elements can be useful to encourage health behavior [29,30]. Participants indicated that it is still a care-related app that must be taken seriously. On the other hand, small, limited gameplay elements might be applied to motivate them as long as they do not strongly distract them.

Discussion

Principal Findings

Participants highlighted their need for support in adopting various self-management strategies. The following self-management strategies were cited frequently: sleep, rest/relaxation, eating, exercise, self-monitoring, education about BD, relationships with others and finally, and a contingency plan. These results are consistent with previous patient-centered studies on successful self-management strategies in BD [31-33]. Research by Bair et al [34] shows several obstacles with regard to the use of self-management strategies, such as shortage of knowledge about strategies, absence of reliance on social support from family and friends, scarceness of medical communication, lack of time, or other priorities. These obstacles were found in our study as well. Any app should be adaptable to individual's needs, so it can take such obstacles into account when providing support.

Congruent with previous research by Aujoulat et al [2], we found that the development of insight into illness was of great importance to users. Crucially, participants indicated a particular need to increase their understanding of their BD and state of mind by reflecting on their behavior. Prodromal behavior is more tangible than abstract mood values and thus gives users more foothold in early detection of possible episodes and subsequent strategic intervention. Gaining insight into which individual behavior accurately predicts mood destabilization is very important, and any self-management app should certainly support this.

Participants expressed their need for a coaching style to help them gain insight into their mood through their behavior. Rather than a directive instructor, their preference was for an app to act more like a personal coach encouraging better understanding of their unique condition and gently guiding them toward insight and successful self-management—in addition, the way in which the app encourages the users' needs to be tailored to the individual. The question then is, how is this aspect of coaching best integrated into a self-management app? Participants provided a few ideas here. One is that the app itself would be the coach who gives suggestions and acts as an educator. Conversely, coaching could be done in concert with a psychologist or psychiatrist. This corresponds to use in a blended care program. Blended care occurs when a (digital) stand-alone treatment such as internet-based therapy is supported by short face-to-face consultation with care providers such as a psychologist or psychiatrist [35]. This method of coaching could be integrated into the use of the self-management app. According to participants, if the self-management app were supported by professional assistance, it would encourage greater adherence, a finding that is supported in previous literature [36-38].

Participants indicated that the app should provide support for the use of various self-management strategies from which they can make a selection according to their personal needs. According to the participants, this malleability would benefit the sustainable usability of the app. These results are supported by Holmstöm and Roing [39] who state that quality of care increases when the patient is the owner of their own care process. This study shows that users have very differing needs and wants regarding a self-management app. As they indicate, prodromal and episodic symptoms can vary widely between individuals. In addition, strategies that work for one user might not work for another or might even adversely influence their mood state. This holds both for functionality and design elements of an app. Where some functions (eg, relaxation therapy, encouragement in exercise, playing restful music, etc.) are vital for one user, it might put off another to use the app. Although a truly individual app might not be feasible, it is clear that a one-size-fits-all approach is inappropriate. User preferences from this study indicate that those with BD should at least be able to maximally choose which features of the app they want to use and how to use them. These results are congruent with a recent study by Nicholas et al [12], indicating that young adults want a range of self-management strategies supported by different app functions.

Torous and Powell [40] indicate that a distinction can be made between active and passive apps. Active apps require practical cooperation of the patient, whereas passive apps do not. A passive app can have a diagnostic role and monitors symptoms, whereas an active app can provide interventions such as sending reminders regarding health. The results of this study suggest that participants would prefer both elements in a self-management app for BD. They require the choice between several guises of active or passive use (ie, a diagnostic role, reminders, and psychoeducation) on the basis of their personal behavior. Providing this choice might motivate users to engage with the app.

Limitations

This study has a number of limitations. Although participant groups represented men and women of different ages, the generalizability of the study to individuals with BD is limited because of the qualitative nature of the findings. A further limitation of this study is the self-reported diagnosis of BD, rather than a clinical diagnosis.

Our sample was relatively homogeneous in the sense that most participants were recruited through a patient support group. These participants might be more actively engaged in managing their condition than others who are not members of such peer

groups. The aspects of psychoeducation came up regularly during the group discussions. Importantly, acknowledging the mood disorder is crucial for psychoeducation to take effect [41]. We cannot determine how the level of illness awareness influenced the results. However, most of our participants took part in a peer-led support group. Therefore, they might have a higher level of illness awareness.

Most participants rated the severity of their BD as 3 or above on a 5-point scale. Individuals with lower severity ratings were not included in the sample; thus, it is unclear whether the perceived burden of the illness would affect study outcomes.

Finally, the majority of participants were unemployed. This may have resulted in an overestimation of the need for structure, which featured prominently in our results.

Conclusions

There are limited studies exploring the needs of people with BD with respect to mHealth [12,18]. This research adds insight into the needs of people with BD regarding the use of self-management strategies and how these could best be supported by mHealth apps. Study findings aim to bridge the gap between research and development that is currently present in the mHealth market.

Individuals with BD in this study expressed a need for interventions that provide solutions, suggestions, ideas on overcoming barriers, and personalized support. In addition, psychoeducational components including building insight into their condition and behavior were viewed as crucial aids for self-management. Behavioral insights were deemed to be important predictors of mood dysregulation. Furthermore, participants indicated that the app should act as a personalized coach rather than a strict instructor.

Finally, although this study is an important step in the integration of user perspectives in the mHealth design for BD, future work with larger samples with varying characteristics is needed to ensure that mHealth developments take a wide variety of users' needs and preferences into account. This, in turn, will provide users with powerful digital health care tools that empower them in managing their well-being and improve longer term outcomes.

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Conflicts of Interest

The authors HVD (Cronos NV) and JFEO (Curio NV) are employed by a company that also designs and develops apps. Curio NV is currently developing an mhealth self-management application that will be partly based on the data gathered in the current study.

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Abbreviations

BD: bipolar disorder

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Original Paper

Determinants of Intention to Use Mobile Phone Caller Tunes to Promote Voluntary Blood Donation: Cross-Sectional Study

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Abstract

Background: Voluntary blood donation rates are low in sub-Saharan Africa. Sociobehavioral factors such as a belief that donated blood would be used for performing rituals deter people from donating blood. There is a need for culturally appropriate communication interventions to encourage individuals to donate blood. Health care interventions that use mobile phones have increased in developing countries, although many of them focus on SMS text messaging (short message service, SMS). A unique feature of mobile phones that has so far not been used for aiding blood donation is caller tunes. Caller tunes replace the ringing sound heard by a caller to a mobile phone before the called party answers the call. In African countries such as Ghana, instead of the typical ringing sound, a caller may hear a message or song. Despite the popularity of such caller tunes, there is a lack of empirical studies on their potential use for promoting blood donation.

Objective: The aim of this study was to use the technology acceptance model to explore the influence of the factors—perceived ease of use, perceived usefulness, attitude, and free of cost—on intentions of blood or nonblood donors to download blood donation-themed caller tunes to promote blood donation, if available.

Methods: A total of 478 blood donors and 477 nonblood donors were purposively sampled for an interviewer-administered questionnaire survey at blood donation sites in Accra, Ghana. Data were analyzed using descriptive statistics, exploratory factor analysis, and confirmatory factory analysis or structural equation modeling, leading to hypothesis testing to examine factors that determine intention to use caller tunes for blood donation among blood or nonblood donors who use or do not use mobile phone caller tunes.

Results: Perceived usefulness had a significant effect on intention to use caller tunes among blood donors with caller tunes (beta=.293, $P<.001$), blood donors without caller tunes (beta=.165, $P=.02$, nonblood donors with caller tunes (beta=.278, $P<.001$), and nonblood donors without caller tunes (beta=.164, $P=.01$). Attitudes had significant effect on intention to use caller tunes among blood donors without caller tunes (beta=.351, $P<.001$), nonblood donors with caller tunes (beta=.384, $P<.001$), nonblood donors without caller tunes (beta=.539, $P<.001$) but not among blood donors with caller tunes (beta=.056, $P=.44$). The effect of

free-of-cost caller tunes on the intention to use for blood donation was statistically significant (beta=.169, *P*<.001) only in the case of nonblood donors without caller tunes, whereas this path was statistically not significant in other models.

Conclusions: Our results provide empirical evidence for designing caller tunes to promote blood donation in Ghana. The study found that making caller tunes free is particularly relevant for nonblood donors with no caller tunes.

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KEYWORDS

caller tunes; blood donation; sub-Saharan Africa; technology acceptance model; mobile health

Introduction

Background

Lack of adequate blood for transfusions is a major global health challenge in low- and middle-income countries, particularly those in sub-Saharan Africa [1,2]. According to the World Health Organization (WHO), countries need to achieve blood donation rates of at least 1 per 100 population [3]. However, of 67 countries worldwide that fall below this target, 38 are in the WHO Africa region [3]. Lack of adequate blood donation in sub-Saharan Africa has been attributed partly to sociocultural beliefs [4-7]. One such belief is that donated blood would be used for performing rituals [8]. These beliefs could be addressed through use of culturally appropriate communication interventions, including the use of face-to-face communication [9-12], mass media [11-16], and mobile phones [10,11,16,17].

According to a 2015 Pew Research Center report, mobile phone ownership has surged in sub-Saharan Africa, with, for example, Ghana and Kenya, respectively, having 83% and 82% of the population owning mobile phones in 2014, up from the 2002 figure of nearly 10% for both countries [18]. The report shows that across seven African countries surveyed, 80% use mobile phones to send SMS text messages (short message service, SMS), but only 14% and 18% get consumer and health information, respectively, through their mobile phones.

Health care interventions that use mobile phones have increased in developing countries [19], although many of them focus on SMS text messages. The use of mobile phone apps for encouraging voluntary blood donation is increasing in the Western countries, but less so in sub-Saharan Africa [20].

In sub-Saharan Africa, some blood transfusion services have used mobile phone SMS text messages to increase awareness about blood donation [17,21]. Although SMS text messages have an important role to play in health care, they do not reach audiences with limited ability to read or write [22]. Thus, there is a need for culturally appropriate mobile health (mHealth) interventions, including use of voice messages created in languages spoken by the target audience.

Mobile Phone Caller Tunes as New Communication Phenomenon

One popular phenomenon in sub-Saharan Africa is mobile phone caller tunes. A caller tune is the sound a caller to a mobile phone hears before the receiver picks the call [23]. Normally, one hears the “ring, ring, ring” sound. However, in some sub-Saharan African countries, a caller to a mobile phone could hear a song or message in place of the “ring, ring, ring” sound.

Caller tunes operate with a logic reverse to that of ring tones. A ring tone is the sound the called party hears. However, a caller tune, also called ringback tone, is the sound the caller hears [24]. A ring tone is usually available as part of the phone settings. A caller tune, however, is usually determined by the mobile telecommunication operator. The normal “ring, ring ring” sound a caller hears is free. However, mobile phone subscribers who download particular songs or messages as caller tunes may pay a relatively small monthly fee to their mobile phone telecommunication companies [25]. Worldwide, many telecommunication companies have caller tunes. For example, in the United States, T-Mobile has caller tunes. Telecommunication companies such as MTN, Vodafone, and Airtel that operate in Africa and Asia also have caller tunes.

Despite the popularity of such caller tunes, there is lack of empirical studies on its potential use for promoting health or improving health care services.

Context: Blood Donation Recruitment Strategies in Ghana

In Ghana, blood donor recruitment strategies include visiting schools, workplaces, and places of worship such as churches and mosques to collect blood. During school recesses, blood collection teams struggle to get enough voluntary blood donors [26]. Thus, hospitals have to rely on “family” blood donors. Such blood donors may include others who donate blood for money, but present themselves as family members.

There is a need to attract first time voluntary blood donors and retain them as repeat donors because these are the safest donors. The WHO has a target of requiring all countries to get 100% of all donated blood from voluntary, unpaid donors by 2020 [27]. Thus, the National Blood Service Ghana has been exploring opportunities to increase voluntary blood donation. In a qualitative study to explore how journalists, clinicians, and blood donors could team up to promote blood donation in Ghana, the potential of using mobile phones caller tunes was identified [11].

The overall goal that this project will contribute to is to assess the feasibility of using mobile phone caller tunes on blood donation, if created, to increase the number of blood donors and those who go on to donate regularly.

Theoretical Foundation

We selected technology acceptance model (TAM) for this study partly because of its use in assessing user acceptance of novel mobile technologies, particularly in health care [28]. Additionally, our primary reason to use TAM was because it

has been tested widely in information systems research [29], including its extensions to include new variables [30].

Although we could not identify a single study that had used TAM to evaluate intention to adopt caller tunes to promote blood donation, TAM constructs such as perceived ease of use, perceived usefulness, attitudes to technologies, and intention to use technologies is particularly applicable to this study because of their validation in health information system environments [31].

TAM posits that perceived ease of use and perceived usefulness of a mobile technology such as caller tune positively influence the attitudes about the technology, with attitudes positively influencing intention to use the technology [32]. Moreover, both perceived usefulness and intention to use the technology positively influence actual use of the technology (Figure 1). We introduced a factor "free of cost" of downloading caller tunes to the original TAM.

Research Models and Hypotheses

We adapted TAM and used it in the context of mobile phone caller tunes to predict intentions of blood donors and nonblood donors to download caller tunes to promote blood donation. We tested the TAM (as shown in Figure 1) for blood or nonblood donors who use or do not use caller tunes. We focused on these populations because our aim was to explore whether caller tunes could increase the number of blood donors and those who go on to donate regularly.

We introduced "free of cost" of downloading caller tune as a predictor of intention to use caller tunes as seen in Figure 1. The original TAM did not have this variable. However, cost has been operationalized in a prior TAM study as "affordability" or "device perceived as affordable" [33].

Perceived Ease of Use

Perceived ease of use was defined by Davis as "the degree to which a person believes that using a particular system would be free of effort" [32]. We adapted this definition to the context of mobile phone caller tunes to mean the extent to which users feel it is easy to download caller tunes onto a mobile phone. In general, the belief that it is easy to use a particular health information technology has an influence on one's intention to use the technology. Many studies have shown that perceived ease of use significantly predicts attitudes to technology [32,34-37] and perceived usefulness of the technology [38-41]. Thus, we test the following hypotheses:

> Hypothesis 1: perceived ease of use will have a positive effect on perceived usefulness of caller tunes among blood donors with or without caller tunes.
>
> Hypothesis 2: perceived ease of use will have a positive effect on attitudes to caller tunes among nonblood donors with or without caller tunes.

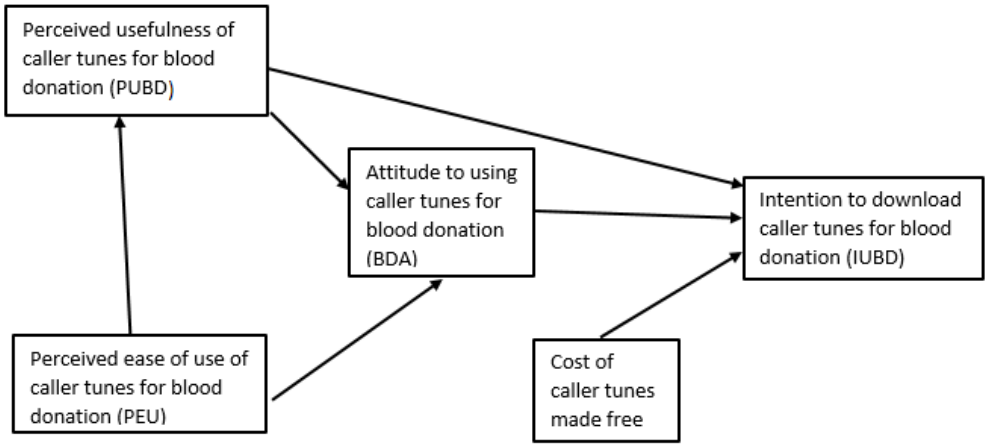
Perceived Usefulness

Defined by Davis as "the degree to which a person believes that using a particular system would enhance his or her job performance" [32], perceived usefulness is known to have positive effect on attitudes. We adapted this definition to indicate the extent to which users believe caller tunes could help encourage callers to mobile phones to become blood donors, and thus, increase voluntary blood donation. The belief that a given technology is useful could make people develop attitudes to using it and increase their intention to use it. For example, studies show significant relationship between perceived usefulness and attitudes to a health information [31,40,41] and intention to use technology [31,33,38,42].

Thus, based on these results, our third and fourth hypotheses are as follows:

> Hypothesis 3: perceived usefulness will have a positive effect on attitudes to caller tunes among blood donors or nonblood donors with or without caller tunes.
>
> Hypothesis 4: perceived usefulness will have positive effects on intention to use caller tunes among blood donors or nonblood donors with or without caller tunes.

Figure 1. Conceptual research model (technology acceptance model).



Attitudes

Attitude was adopted from the theory of reasoned action that posits that intention to perform a given behavior is determined by an individual's overt behavior [43]. Some studies have shown significant relationship between attitudes and behavioral intention [31,40,41]**.** Thus, this study explores the relationship between attitude and behavioral intention in the context of using mobile phone caller tunes for aiding blood donation.

> Hypothesis 5: attitudes toward caller tunes will have positive effects on intention to use caller tunes among blood donors or nonblood donors with or without caller tunes.

Free of Cost

The cost of a technology could determine whether people intend to use it or will actually use it. For example, affordability has been found to influence patients' intention to use point-of-care medical devices for medical testing [33]. Moreover, cost negatively influences the adoption of mHealth services [44]. Thus, we assessed whether blood donation-themed caller tunes that are to be made free to download could influence the intentions of blood donors and nonblood donors to use them to encourage callers to donate blood.

> Hypothesis 6: making caller tunes free to download will have positive effects on intention to download it for promoting blood donation.

Behavioral Intention

Behavioral intention is a construct that describes people's target or goal to use a future product or service [45]. Studies show significant relationship between intention and actual use [46,47]. Because caller tunes on blood donation have not yet been developed, this study does not assess the relationship between intention and actual use of mobile phone caller tunes for promoting blood donation. Currently, mobile phone caller tunes in Ghana include songs of popular artistes and religious messages. The outcome of this feasibility study would inform the design and use of caller tunes to promote blood donation among blood or nonblood donors.

Methods

Survey Development

Two questionnaires, one for blood donors and another for nonblood donors, were adapted from previous studies on TAM conducted outside Ghana (eg, [48-57], see Multimedia Appendix 1). The questionnaires were then pretested among 5 blood donors and 5 nonblood donors at the Korle Bu Blood Bank in Accra, Ghana for ease and understanding of use. The pretest resulted in reduced overall number of questionnaire items because some respondents found it time-consuming in answering questions on use of caller tunes for promoting blood donation, medication adherence, and patient reporting of adverse drug reactions (ADRs). Seven-point Likert scale with answers ranging from "strongly agree" (1) to "strongly disagree" (7) was used to measure perceived ease of use, perceived usefulness, attitudes, behavioral intention, and free of cost as presented in Multimedia Appendix 1.

Data Collection

Blood donors and nonblood donors were recruited for the questionnaire survey at blood donation sites such as schools, churches, hospitals, and workplaces in Accra, Ghana. Purposive sampling [58] was used to recruit blood or nonblood donors because it was practically impossible to have a list of all blood donors or nonblood donors at blood donation sites to be used for random sampling. We were also interested in the perspectives of blood or nonblood donors; hence, the use of purposive sampling.

The inclusion criteria for both blood or nonblood donors were being at least 18 years of age and being able to understand English. In addition, blood donors were selected if they indicated that they have donated blood before, including on the day of the interview. The survey did not identify whether those who indicated that they had donated blood before were unpaid blood donors, paid blood donors, or irregular blood donors such as those who donate blood for family members or friends.

Each prospective blood donor or nonblood donor who understood English was provided with information about the study verbally. Those who consented to the study were interviewed. Trained interviewers read the questionnaires in English to the participants and recorded participants' responses on the paper-based survey questionnaires, which were designed in English (see Multimedia Appendix 2). On average, each interview lasted about 20 min.

The survey questionnaires required participants to answer questions on TAM constructs related to blood donation and intention to use mobile phone caller tunes to promote blood donation, medication adherence, and patient reporting of ADRs as part of a larger project. The focus of this study is on the blood donation component. Data collection occurred from October 2016 to December 2016.

A total of 955 questionnaires were successfully completed for 478 blood donors and 477 nonblood donors out of the 965 who met the inclusion criteria and were approached, representing 99.0% response rate. The 10 agreed to participate but did not complete the questionnaires because they had to leave the blood donation sites. Each respondent received Ghana Cedi equivalent of US $1 as compensation for the time spent in responding to the questionnaires. The study protocol was approved by ethics committees of the Ghana Health Service (GHS-ERC 05/08/16) and Texas A&M University (IRB2016-0655D).

Among the 955 participants, 49.2% (470/955) did not have a mobile phone caller tune, and 50.8% (485/955) had mobile phone caller tune (see Table 1).

Table 1. Demographic characteristics of blood or nonblood donors with or without caller tunes.

Characteristic	Total, n (%)
Gender	
Male	633 (66.6)
Female	317 (33.4)
Age in years	
18-20	365 (38.3)
21-30	469 (49.2)
31-40	85(8.9)
41-50	26(2.7)
51-60	5(0.5)
>60	3 (0.3)
Blood donation status	
Nonblood donor	477 (49.9
Blood donor	478 (50.1)
Mobile phone has caller tune	
No	470 (49.2)
Yes	485 (50.8)
Education	
Primary	19 (2.0)
Middle school	11 (1.2)
Junior high school	68 (7.1)
Senior high school	345 (36.2)
Above senior high school	509 (53.5)

Measurement

Data from the survey were divided into four subsets based on blood donation status and the use of caller tune, namely blood donors with caller tuners, blood donors who do not use caller tunes, nonblood donors with caller tunes, and nonblood donors who did not have caller tunes. The data from each subset (with sample sizes 200-278) were analyzed using descriptive statistics, exploratory factor analysis, and confirmatory factor analysis or structural equation modeling. Results based on non-normality tests showed that each data for a subgroup was not normally distributed as revealed by significant values for Shapiro-Wilk test statistics and high values of kurtosis.

We used TAM for structural equation modeling analysis with the aid of maximum likelihood estimation routines in IBM SPSS AMOS version 25 (IBM Corp). We selected maximum likelihood estimation approach because it performs reasonably well for non-normal data under analytic conditions such as excessive kurtosis and small sample sizes [59], especially those less than 1000 [60].

There were five measures in the model: perceived usefulness, perceived ease of use, attitude, free of cost, and intention to use. Confirmatory factor analysis was conducted for perceived ease of use (seven items for those with caller tunes and three items for those without caller tunes), attitudes to using caller tunes (four items), and perceived usefulness (three items), but not for free of cost and intention to download caller tunes because each had only one item. Multimedia Appendix 1 outlines all items and their corresponding statements. Single items for measuring intention have been used in previous TAM research [61], especially when the aim was to shorten the survey [62].

Reliability and Validity

Results based on use of IBM SPSS version 24 (IBM Corp) for descriptive analyses of the constructs showed that composite reliability scores were all well above the 0.7 level threshold, and Cronbach alpha scores were also well above .7 threshold [63] for blood donors with caller tunes (see Table 2), nonblood donors with caller tunes (see Table 3), blood donors with no caller tunes (see Table 4), and nonblood donors with caller tunes (see Table 5). We assessed discriminant validity—the extent to which a given construct is different from the others indicated in the instrument—by using the average variance extracted (AVE), which determines the mean variance shared between a given construct and how it was measured. Discriminant validity is established when the AVE is at least 0.50 [63]. Such a figure shows that the construct indicated at least 50% of the measurement variance. Tables 2-5 show AVE scores greater than 0.5 and Cronbach alpha values of at least 0.7, thus suggesting that the instrument used for the study met acceptable validity and reliability levels.

Table 2. Factor analysis, reliability, and validity of measures for blood donors with caller tunes. Multimedia Appendix 1 outlines all items and their corresponding statements.

Item	Internal reliability			Convergent validity	
	Cronbach alpha	Item-total correlation	Factor loading	Composite reliability	Average variance extracted
Perceived ease of use (PEU)	.893			0.92	0.61
PEU1		0.63	0.72		
PEU2		0.74	0.82		
PEU3		0.74	0.82		
PEU4		0.67	0.76		
PEU5		0.70	0.79		
PEU6		0.74	0.82		
PEU7		0.64	0.74		
Perceived usefulness for blood donation (PUBD)	.862			0.92	0.77
PUBD1		0.75	0.89		
PUBD2		0.74	0.89		
PUBD3		0.74	0.88		
Attitudes to using caller tunes for blood donation (BDA)	.851			0.90	0.70
BDA1		0.74	0.87		
BDA2		0.65	0.80		
BDA3		0.77	0.89		
BDA4		0.63	0.79		

Table 3. Factor analysis, reliability, and validity of measures for blood donors with no caller tunes. Multimedia Appendix 1 outlines all items and their corresponding statements.

Item	Internal reliability			Convergent validity	
	Cronbach alpha	Item-total correlation	Factor loading	Composite reliability	Average variance extracted
Perceived ease of use (PEU)	.859			0.92	0.78
PEU1		0.76	0.90		
PEU2		0.83	0.93		
PEU3		0.63	0.82		
Perceived usefulness for blood donation (PUBD)	.811			0.89	0.73
PUBD1		0.61	0.82		
PUBD2		0.76	0.90		
PUBD3		0.63	0.84		
Attitudes to using caller tunes for blood donation (BDA)	.792			0.87	0.63
BDA1		0.67	0.83		
BDA2		0.56	0.76		
BDA3		0.66	0.82		
BDA4		0.57	0.77		

Table 4. Factor analysis, reliability, and validity of measures for nonblood donors with caller tunes. Multimedia Appendix 1 outlines all items and their corresponding statements.

Item	Internal reliability			Convergent validity	
	Cronbach alpha	Item-total correlation	Factor loading	Composite reliability	Average variance extracted
Perceived ease of use (PEU)	.84			0.88	0.51
PEU1		0.63	0.75		
PEU2		0.58	0.71		
PEU3		0.58	0.71		
PEU4		0.44	0.56		
PEU5		0.58	0.70		
PEU6		0.65	0.77		
PEU7		0.63	0.75		
Perceived usefulness for blood donation (PUBD)	.84			0.90	0.75
PUBD1		0.64	0.83		
PUBD2		0.78	0.91		
PUBD3		0.68	0.86		
Attitudes to using caller tunes for blood donation (BDA)	.82			0.88	0.65
BDA1		0.65	0.81		
BDA2		0.60	0.78		
BDA3		0.65	0.81		
BDA4		0.66	0.82		

Table 5. Factor analysis, reliability, and validity measures for nonblood donors with no caller tunes. Multimedia Appendix 1 outlines all items and their corresponding statements.

Item	Internal reliability			Convergent validity	
	Cronbach alpha	Item-total correlation	Factor loading	Composite reliability	Average variance extracted
Perceived ease of use (PEU)	.88			0.93	0.81
PEU1		0.78	0.91		
PEU2		0.85	0.94		
PEU3		0.69	0.85		
Perceived usefulness for blood donation (PUBD)	.90			0.94	0.84
PUBD1		0.72	0.86		
PUBD2		0.89	0.95		
PUBD3		0.83	0.93		
Attitudes to using caller tunes for blood donation (BDA)	.92			0.95	0.82
BDA1		0.82	0.90		
BDA2		0.85	0.92		
BDA3		0.84	0.91		
BDA4		0.78	0.87		

Results

Descriptive Analysis

The means of the constructs as indicated in Table 6 show that respondents had positive views about using mobile phone caller tunes for promoting blood donation given that the 7-point Likert scale ranged from 1 (strongly agree) to 7 (strongly disagree).

Model Fit and Structural Models

Three of the research models had goodness of fit indices showing good fit to the data as shown in Table 7. Only the model for nonblood donors with caller tunes had values of normed fit index (NFI), comparative fit index (CFI), and incremental fit index (IFI) not meeting recommended levels [64]. The root mean square error of approximation (RMSEA) value for blood donors with no caller tune was 0 and that for nonblood donors with caller tunes was 0.11, whereas that for blood donors with caller tunes was 0.07 and nonblood donors with no caller tunes was 0.08 (Table 8). At 90% CI, the *P* values of the RMSEA for all but the model involving nonblood donors with caller tunes were not statistically significant (Table 7). All the models met the recommended values of chi square or degree of freedom ratio [65].

Hypothesis Tests

Most of the results support the proposed hypotheses (Table 8).

We hypothesized that perceived ease of use will have a positive effect on perceived usefulness of caller tunes. The path coefficient was positive for blood donors or nonblood donors with or without caller tunes and statistically significant for all models except that for blood donors with no caller tunes (see Table 8 and Figures 2-5).

We hypothesized that perceived ease of use will have a positive effect on attitudes to caller tunes. All the path coefficients were positive. However, other than nonblood donors with no caller tunes, which was statistically significant (*P*=.001; see Figure 5,Table 8), all the other models had statistically nonsignificant relationship between perceived ease of use and perceived usefulness of caller tunes.

We hypothesized that perceived usefulness will have a positive effect on attitudes to caller tunes. The findings show that all the models supported this hypothesis.

Table 6. Means and SDs of the constructs for blood or nonblood donors with or without caller tunes.

Construct	Blood donors with caller tunes (N=278), mean (SD)	Blood donors with no caller tunes (N=200), mean (SD)	Nonblood donors with caller tunes (N=208), mean (SD)	Nonblood donors with no caller tunes (N=270), mean (SD)
Intention to use caller tunes for promoting blood donation	1.08 (0.27)	1.15 (0.35)	1.86 (1.05)	2.07 (1.13)
Perceived ease of use caller tunes for promoting blood donation	1.97 (1.05)	2.19 (0.61)	1.90 (0.75)	2.05 (1.15)
Perceived usefulness for blood donation	1.87 (0.95)	1.90 (0.81)	2.23 (1.06)	2.15 (1.13)
Attitudes to using caller tunes for blood donation	1.66 (0.68)	1.73 (0.66)	1.87 (0.67)	1.90 (0.92)
Free of cost	2.88 (2.17)	2.90 (2.29)	2.34 (1.67)	2.53 (1.88)

Table 7. Model fit indices for blood or nonblood donors with or without caller tunes.

Model or Fit Index	Blood donors with caller tunes (n=278)	Blood donors with no caller tunes (n=200)	Nonblood donors with caller tunes (n=208)	Nonblood donors with no caller tunes (n=270)	Recommended value	Reference
NFI[a]	0.95	0.97	0.92	0.97	≥0.95	64
IFI[b]	0.97	1.02	0.94	0.94	≥0.95	64
Tucker–Lewis index	0.90	1.07	0.78	0.96	≥0.95	64
CFI[c]	0.97	1.00	0.94	0.98	≥0.95	64
RMSEA[d] (90% CI; *P* value)	0.07 (0.00-0.13; .24)	0 (0.00-0.09; .80)	0.11 (0.05-0.18; .046)	0.08 (0.03-0.14; .12)	<0.06	64
Chi square or degree of freedom ratio	2.3	0.6	3.5	2.9	<5.00	65

[a]NFI: normed fit index.

[b]IFI: incremental fit index.

[c]CFI: comparative fit index.

[d]RMSEA: root mean square error of approximation.

Table 8. Path models for blood or nonblood donors with or without caller tunes.

Type of participant	Blood donors with caller tunes (n=278)			Blood donors with no caller tunes (n=200)			Nonblood donors with caller tunes (n=208)			Nonblood donors with no caller tunes (n=270)		
Causal path	Estimate	SE	*P* value	Estimate	SE	*P* value	Estimate	SE	*P* value	Estimate	SE	*P* value
PUBD[a]←PEU[b]	0.27	0.05	<.001	0.06	0.09	.41	0.30	0.09	<.001	0.41	0.06	<.001
BDA[c]←PUBD	0.60	0.04	<.001	0.46	0.05	<.001	0.50	0.04	<.001	0.64	0.04	<.001
BDA←PEU	0.08	0.03	.09	−0.04	0.07	.48	0.03	0.06	.70	0.19	0.04	<.001
IUBD[d]←PUBD	0.293	0.02	<.001	0.165	0.031	.02	0.278	0.064	<.001	0.164	0.063	.01
IUBD←BDA	0.056	0.028	.44	0.351	0.038	<.001	0.384	0.101	<.001	0.539	0.077	<.001
IUBD←CFDBD1[e]	−0.049	0.007	.39	−0.089	0.01	.16	0.104	0.035	.067	0.169	0.026	<.001

[a]PUBD: perceived usefulness for blood donation.

[b]PEU: perceived ease of use caller tunes for promoting blood donation.

[c]BDA refers to attitudes to using caller tunes for blood donation.

[d]IUBD: intention to use caller tunes for promoting blood donation.

[e]CFDBD1 implies free of cost.

Our hypothesis that perceived usefulness will have positive effects on intention to use caller tunes among blood donors with or without caller tunes was supported for all the path models (Table 8). Perceived usefulness had significant effect on intention to use caller tunes among blood donors with caller tunes (beta=.293, *P*<.001), blood donors without caller tunes (beta=.165, *P*=.019), nonblood donors with caller tunes (beta=.278, *P*<.001), and nonblood donors without caller tunes (beta=.164, *P*=.01).

Our hypothesis was that attitude will have positive effects on intention to use caller tunes among blood donors or nonblood donors with or without caller tunes. Attitudes had significant effect on intention to use caller tunes among blood donors without caller tunes (beta=.351, *P*<.001), nonblood donors with caller tunes (beta=.384, *P*<.001), nonblood donors without caller tunes (beta=.539, *P*<.001), but a statistically nonsignificant effect with blood donors with caller tunes (beta=.056, *P*=.44).

We hypothesized that making caller tunes free to download will have positive effects on intention to use caller tunes among blood donors or nonblood donors with or without caller tunes. The effect of free of cost caller tunes on the intention to download and use for blood donation was statistically significant (beta=.169, *P*<.001) only in the case of nonblood donors without caller tunes (Figure 5), whereas this path was statistically not significant in the models for blood donors with caller tunes (Figure 2) and without caller tunes (Figure 4), as well as nonblood donors with caller tunes (Figure 3).

Perceived usefulness and attitudes to caller tunes explained 10.7% of the variance in intention to use caller tunes for blood donation among blood donors with caller tunes, with the variance in intention increasing slightly to 11.2% when free to download was added to the model (Table 9).

Among blood donors with no caller tunes, perceived usefulness, attitudes to using caller tunes for blood donation, and free of cost explained 21.1% of the variance in intention. Without free of cost, the variance in intention was 19.7%. The greatest variance in intention was obtained among nonblood donors, with perceived usefulness, attitudes, and free of cost explaining 34.4% and 47.4% of the variances in intention to use caller tunes among those with caller tunes and those without caller tunes, respectively.

Free of cost reduced the variance in intention to download and use caller tunes for blood donation only in the case of nonblood donors with caller tunes (from 34.7%-34.4%), while slightly increasing the variances in intention for blood donors with caller tunes (from 10.7%-11.2%), blood donors without caller tunes (from 19.7%-21.1%), as well as nonblood donors without caller tunes (46.2%-47.4%). Results for the research models without free of cost have not been reported.

Compared with perceived usefulness, attitudes to using caller tunes for blood donation had the stronger effects on intention to use caller tunes for promoting blood donation (Table 9), with the model for nonblood donors without caller tunes having the largest effect (55%), followed by that for blood donors with caller tunes (39.2%).

Moreover, 39.2% of the variance in attitudes to caller tunes for blood donation was explained by perceived ease of use and perceived usefulness of caller tunes for promoting blood donation among blood donors with caller tunes. The greatest effect of perceived ease of use and perceived usefulness on variance in attitudes to using caller tunes for promoting blood donation (55%) was seen among nonblood donors without caller tunes (Table 9).

Figure 2. Path model for blood donors with caller tunes. ***P<.001.

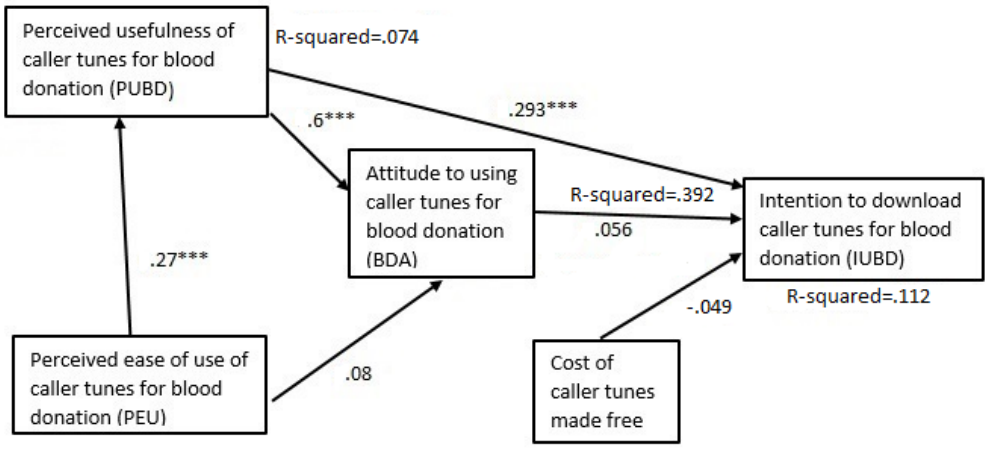


Figure 3. Path model for nonblood donors with caller tunes. ***P<.001.

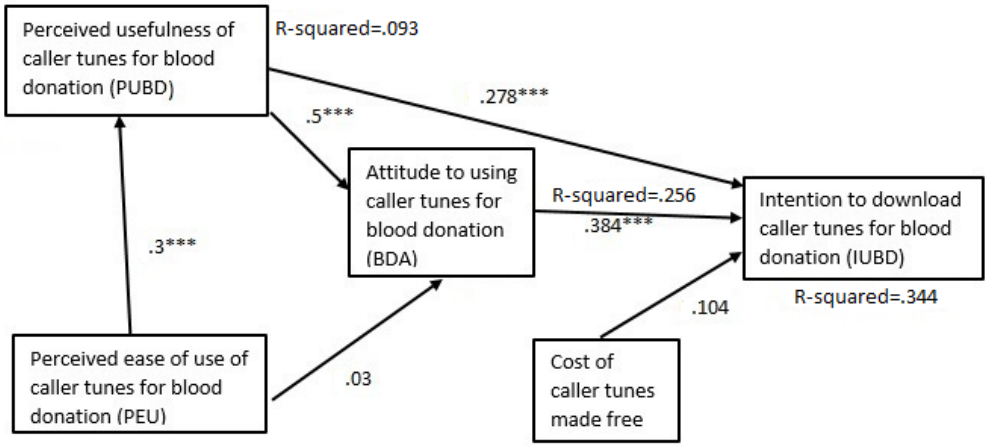


Figure 4. Path model for blood donors with no caller tunes. *P=.019; ***P<.001.

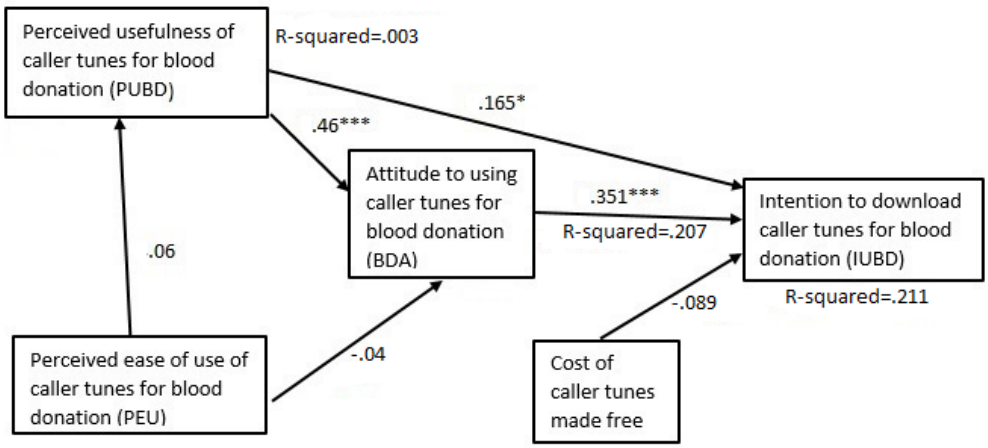


Figure 5. Path model for nonblood donors with no caller tunes. *P=.01; ***P<.001.

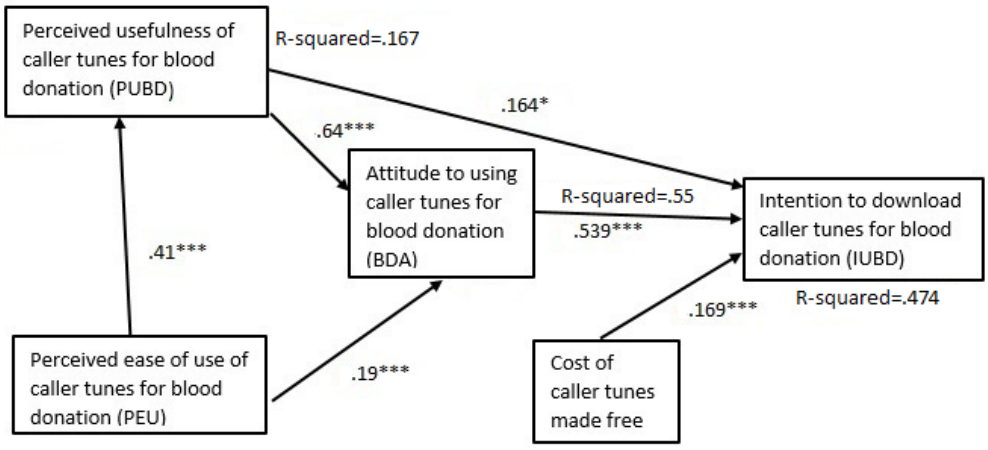


Table 9. Squared multiple correlations for blood or nonblood donors with or without caller tunes.

Original	Blood donors with caller tunes (n=278)	Blood donors with no caller tunes (n=208)	Nonblood donors with caller tunes (n=208)	Nonblood donors with no caller tunes (n=270)
Perceived usefulness for blood donation	0.074	0.003	0.093	0.167
Attitudes to using caller tunes for blood donation	0.392	0.207	0.256	0.55
Intention to use caller tunes for promoting blood donation	0.112	0.211	0.344	0.474

Discussion

Principal Findings

Overall, our results provide empirical evidence for factors that could influence the intention of using mobile phone caller tunes for increasing blood donations. The findings mirror studies elsewhere that found significant relationship between perceived usefulness and attitudes to a health information [31,40,41] and intention to use technology [31,33,42]; and significant relationships between perceived ease of use and attitudes to technology [32,34-37] and perceived usefulness of the technology [38-40,42].

Despite considerable research having been conducted on the TAM, especially in the health care sector, our study is innovative for two reasons. It explores primary exogenous TAM variables— perceived ease of use and usefulness—in the context of the utility of mobile phone caller tunes for promoting blood donation. However, although blood donors or nonblood donors may believe that caller tunes are easy to download and could be useful for promoting blood donation, they may not have the resources or money to enable them to download the caller tunes. Our inclusion of free of cost as an additional variable yields useful information for determining whether caller tunes for blood donation should be free of cost to nonblood or blood donors.

With most of the fit indices within the recommended values, there is likelihood of good fit [64]. However, RMSEA value for blood donors with no caller tune was 0, indicating exact model fit to the data [66]. This is a rare finding in surveys and might have research implication for the specified model for blood donors with no caller tunes. With RMSEA *P* value of .802 for this model (Table 7) based on 90% CI, our data appear to have good fit to the model. At samples sizes of at least 200 such as in this study, the use of 90% CI for estimating RMSEA provides comparable results with 95% CI [67]. RMSEA values of 0.05 to 0.08 indicate close fit [68], thus making the model for nonblood donors with caller tunes the only one that appears not to fit the data. This model also had statistically significant RMSEA (*P*=.046) and had NFI, IFI, Tucker Lewis index, and CFI values outside those recommended, suggesting that it may have implications for further research.

This study did not explore actual use of caller tunes for promoting blood donation because caller tunes for promoting blood donation are yet to be created. Nevertheless, our study is a necessary step for designing behavioral interventions using caller tunes to increase the number of first time donors and to encourage existing donors to donate regularly. It was surprising that perceived ease of use and perceived usefulness (Table 9) explained the greatest variance in attitudes to using caller tunes for blood donation among nonblood donors with no caller tunes (55%). However, although perceived usefulness significantly impacted the attitudes to using caller tunes among all four groups of participants, perceived ease of use significantly impacted the attitudes of only nonblood donors with no caller tunes (*P*=.04). This finding may be because nonblood donors with no caller tunes may be unaware of the ease with which they could get caller tunes onto their phones for promoting blood donation. Thus, should the caller tunes on blood donation be created, more efforts or promotion would be needed to positively influence the attitudes of nonblood donors without caller tunes.

This finding suggests that efforts to promote uptake of caller tunes for blood donation should particularly target nonblood donors who do not already use caller tunes. Given that making caller tunes free to download was statistically significant in increasing intention to use caller tunes among only nonblood donors with no caller tunes, intervention designers would need to ensure that caller tunes for promoting blood donation become free. For example, affordability was found to be a statistically significant predictor of intention to use portable coagulometer devices for self-testing of the international normalized ratio among outpatients attending outpatient anticoagulation services [33].

Perceived ease of use, perceived usefulness, and attitudes are all important factors that could determine blood donors' and nonblood donors' intentions to use caller tunes to promote blood donation, should blood donation-themed caller tunes be designed. A caller to a mobile phone with a caller tune in Ghana may first hear "If you like this caller tune, press star to download," reflecting the ease with which caller tunes may be downloaded. The standardized coefficients for the impact of perceived usefulness on attitudes to using caller tunes for all four groups of participants were positive and statistically significant (Table 9). This finding suggests that perceived usefulness is a strong motivator to developing positive attitudes to using caller tunes, which could in turn increase intention to use caller tunes for blood donation. This finding provides practical implications for designing caller tune-based interventions for promoting blood donations. First, should caller tunes for blood donation become available, blood center staff may need to keep reminding both blood donors and nonblood donors about the usefulness of using caller tunes for promoting blood donation. Second, instead of the standard message "If you like this caller tune, press star to download," if feasible, perhaps mobile telecommunication companies may need to consider customizing such a message. For example, it could be "If you want to save lives with this caller tune on blood donation, press star to download."

A surprising finding of this study is that making caller tunes free to download appears to have significant positive effect on intention among only nonblood donors with no caller tunes. Conversely, it had negative effect on intention among blood donors, although the effects were nonsignificant. One reason might be that donors were already donating blood and those nondonors were already using caller tunes. Thus, free download did not have a significant impact on these types of participants. Another potential explanation for this finding may be that blood donors may be more willing to promote blood donation by paying the current cost of caller tunes (which is usually about 10 cents per month). For nonblood donors with no caller tunes, cost may be a factor in their current nonuse of caller tunes.

The findings of our study suggest that TAM has a high explanatory power for behavioral intention to use caller tunes—an information system—especially among nonblood donors (Table 9). This is because the variance in behavioral intention in our study was 34.4% for nonblood donors with caller tunes and 47.4% for nonblood donors with no caller tunes compared with those for blood donors with caller tunes (11.2.%) and blood donors with no caller tunes (21.1%).

Conclusions

This study is innovative because it applies the TAM to mobile phone caller tunes, a technology that is yet to be explored for promoting blood donation. The study also introduces an external factor—free of cost—and finds that it is particularly relevant for nonblood donors with no caller tunes. Our finding that making caller tunes free of cost could significantly increase intention of nonblood donors with no caller tunes to download them offers insight into the use of caller tunes for blood donation. To the best of our knowledge, this is the first study to explore the determinants of intention for downloading caller tunes to promote blood donation.

Thus, this research contributes to TAM in the context of mobile phone caller tunes. Our research models provide theoretical and practical implications for designing caller tunes for blood donation in Ghana and elsewhere. A major strength of our study is that it helps explain relevant variables that influence intentions for downloading caller tunes for those with or without caller tunes.

Our study contributes to information technology or information systems research in at least three ways. We applied TAM in a new context (ie, mobile phone caller tunes for blood donation), which is distinct from prior studies targeting health information systems. Our findings are consistent with those of many studies showing that perceived ease of use and perceived usefulness are significant predictors of behavioral intention [31,33,38,42]. Our study supports others that have showed significant positive relationship between cost and intention to use information technology [33,44]. However, it is important to note that free of cost is a significant factor particularly for those who do not already have the technology (in our case mobile phone caller tunes) and are also not currently adherent to the intended behavior (in our case blood donation). Measures of perceived ease of use were adapted from prior studies and differentiated for those who have or are without the technology under study. Scholars in Ghana and elsewhere could build on them for studying behavioral intention to use mobile phone caller tunes for promoting blood donation.

Limitations

This study has some limitations. Unlike mobile phone SMS text messages, mobile phone caller tunes for blood donation is relatively new. More research is needed to help generalize the findings in other populations. This is particularly relevant given that this study relied on a convenience sample that excluded participants who were absent at blood donation sites. In addition, we did not differentiate between different types of blood donors such as regular or paid donors. Future research may require a need to identify intention among different types of blood donors to download caller tunes for promoting blood donation. The study also lacks additional variables for explaining intentions for using caller tunes for blood donation. These factors could include social norms. Moreover, the construct for measuring behavioral intention was based on a single-item variable. A study of single-item variables [69] showed that such items are reliable for constructs that are unlikely to be misunderstood by respondents. Future research may need more items for measuring intentions. Furthermore, because our findings were obtained

from cross-sectional data, longitudinal studies are needed to help predict intention to use caller tune for blood donation over time. This is because as people gain experience, beliefs or intentions could change.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Operationalization of constructs.

[PDF File (Adobe PDF File), 93KB - mhealth_v6i5e117_app1.pdf]

Multimedia Appendix 2

Supplementary questionnaire focusing only on blood donation and caller tunes.

[PDF File (Adobe PDF File), 48KB - mhealth_v6i5e117_app2.pdf]

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Abbreviations

ADR: adverse drug reaction
AVE: average variance extracted
BDA: refers to attitudes to using caller tunes for blood donation
CFDBD1: implies free of cost
CFI: comparative fit index
IFI: incremental fit index
IUBD: intention to use caller tunes for promoting blood donation
mHealth: mobile health
NFI: normed fit index
PEU: perceived ease of use caller tunes for promoting blood donation
PUBBD: perceived usefulness for blood donation
RMSEA: root mean square error of approximation
TAM: technology acceptance model
WHO: World Health Organization

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Original Paper

Designing a Tablet-Based Software App for Mapping Bodily Symptoms: Usability Evaluation and Reproducibility Analysis

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Abstract

Background: Symptom drawings are widely used as a qualitative and quantitative method of assessing pain symptoms for both clinical and research purposes. As electronic drawings offer many advantages over classical pen-and-paper drawings, the last years have seen a shift toward tablet-based acquisition of symptom drawings. However, software that is used in clinical care requires special attention to usability aspects and design to provide easy access for physically impaired or elderly patients.

Objective: The aims of this project were to develop a new tablet-based software app specifically designed to collect patients' and doctors' drawings of pain and related bodily symptoms and test it for usability in 2 samples of chronic pain patients (Aim 1) and their treating doctors (Aim 2) as well as for test-retest reliability (Aim 3).

Methods: In 2 separate studies, symptom drawings from 103 chronic pain patients and their treating doctors were collected using 2 different versions of the app. Both patients and doctors evaluated usability aspects of the app through questionnaires. Results from study 1 were used to improve certain features of the app, which were then evaluated in study 2. Furthermore, a subgroup of 25 patients in study 2 created 2 consecutive symptom drawings for test-retest reproducibility analysis. Usability of both app versions was compared, and reproducibility was calculated for symptom extent, number of symptom clusters, and the whole symptom pattern.

Results: The changes we made to the app and the body outline led to significant improvements in patients' usability evaluation regarding the identification with the body outline (P=.007) and the evaluation of symptom depth (P=.02), and the overall difficultness of the drawing process (P=.003) improved significantly. Doctors' usability evaluation of the final app showed good usability with 75.63 (SD 19.51) points on the System Usability Scale, Attrakdiff 2 scores from 0.93 to 1.41, and ISONORM 9241/10 scores from −0.05 to 1.80. Test-retest analysis showed excellent reproducibility for pain extent (intraclass correlation coefficient, ICC=0.92) and good results for the number of symptom clusters (ICC=0.70) and a mean overlap of 0.47 (Jaccard index).

Conclusions: We developed a tablet-based symptom drawing app and improved it based on usability assessment in a sample of chronic pain patients and their treating doctors. Increases in usability of the improved app comprised identification with the body outline, symptom depth evaluation, and difficultness of the drawing process. Test-retest reliability of symptom drawings by chronic pain patients showed fair to excellent reproducibility. Patients' usability evaluation is an important factor that should not be neglected when designing apps for mobile or eHealth apps.

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KEYWORDS

pain drawing; symptom drawing; body outline; usability testing; reproducibility; tablet computers; eHealth; app; chronic pain

Introduction

Bodily symptoms, such as pain, headache, discomfort, or paresthesias, are among the most common reasons to see a doctor [1,2]. Quantification of these symptoms has been challenging ever since because of their purely subjective nature, often leaving patient self-report as the only available source of information. Common tools to measure bodily symptoms include questionnaires [3], rating scales [4], and symptom drawings (better known as pain drawings [5] or discomfort drawings). In the latter, the patient receives an outline of the human body or parts thereof and marks or shades the location and distribution of his different symptoms. Such drawings can then be used to extract features such as the body area affected by the symptom, the number of sites, or the average intensity. The spatial distribution of symptoms may also carry valuable information for diagnosis, such as patterns of segmental or peripheral innervation or association with the location of internal organs.

Several groups have developed symptom drawing approaches that were based on tablet computers [6-11]. Such electronic drawings have many advantages over pen-on-paper drawings, the most important being the ability to analyze drawings right after their completion without the need for prior digitization. Of particular interest are tablets with an electronic pen (stylus) as they have 2 main advantages: a much higher precision than drawing with the finger [12,13] and high similarity with pen-on-paper drawings [7]. High reproducibility of electronic drawings has been validated by Barbero et al for chronic low back and neck pain and acute induced pain [6,14].

The aims of this project were to develop a new tablet-based software app and test it for usability in 2 samples of chronic pain patients (Aim 1) and their treating doctors (Aim 2) as well as for test-retest reliability (Aim 3). This app is specifically designed to collect patients' and doctors' drawings of pain and related bodily symptoms. Aiming toward high drawing precision, the app contains 4 different views of the human body, and the drawings were collected on a stylus-based tablet.

Therefore, we developed and tested a prototype app (study 1) following in part the suggested design guidelines by Jaatun et al, that is, using action buttons instead of icons, limiting written textual instruction, avoiding rapid changes on the screen, and using a paper metaphor [11]. Usability results, obtained through questionnaires and user observation, led to several improvements of the user interface and other parts of the app, which were then tested again in a similar sample (study 2). Using the improved version of the app, we further conducted a test-retest analysis of symptom drawing reproducibility in chronic pain patients (pain duration ≥3 months).

Methods

Study Design

The project comprised 2 consecutive studies: study 1 aimed at evaluating the usability of a prototype of our app. Study 2 was designed to evaluate the final app with all improvements that had been made. The final app version was also used to assess reproducibility of our symptom drawing approach in a test-retest design. The reproducibility study is reported according to the guidelines for reporting reliability and agreement studies (see Multimedia Appendix 1) [15].

Participants of both studies were chronic pain patients and their treating doctors from a pain outpatient department. The project was conducted in accordance with the Declaration of Helsinki and had been approved by the Ethical committee of Hannover Medical School (#2987-2015). All participants were informed about the purpose of the project and gave written informed consent.

Patients were asked to draw their pain and related symptoms before their appointment with the doctor. All of them were using the app for the first time. Following data entry, each patient filled out a usability questionnaire and continued with the routines of the pain outpatient department, namely, filling out standard pain questionnaires and having the appointment with the clinician.

Doctors were asked to enter the findings of their anamnesis and bodily examination during or shortly after seeing the patient. All participating doctors had been briefly trained by one of the authors (TN) on how to use the app.

Study Participants

Pain Patients

In both studies, participants were recruited consecutively from patients of the Pain Outpatient Department of Hannover Medical School. Inclusion criteria were chronic pain (pain duration of ≥3 months), age ≥18 years (legal age in Germany), physical ability to draw symptom drawings on a tablet personal computer (PC), and ability to give written informed consent. Due to our consecutive recruiting approach, our sample should reflect the normal composition of patients in outpatient departments similar to ours.

We screened 70 patients in study 1, of which 52 were included, 15 declined participation, and 3 had to be excluded because they did not fulfill the inclusion criteria. In study 2, we screened 58 patients, of which 51 were included, 5 declined participation, and 2 were excluded because they did not fulfill inclusion criteria.

The mean age was 56.2 (SD 16.1) years in study 1 and 60.4 (SD 15.7) years in study 2. There were no significant differences between both study populations regarding age, sex, body mass index, educational level, number of pain clusters, years of pain treatment, number of previous therapeutic consultations, and usage frequency of tablet computers or comparable devices (Table 1).

Table 1. Demographics of our study populations.

Characteristic	Study 1	Study 2	*P* value[a]
Age (years), mean (SD)	56.2 (16.1)	60.4 (15.7)	.19
Age range, n (%)			
18-39	9 (17)	4 (8)	
40-59	21 (40)	24 (47)	
60-79	20 (38)	16 (31)	
80+	2 (4)	7 (14)	
Women, n (%)	32 (62)	34 (67)	.59
BMI[b] (kg/m²), mean (SD)	27.6 (7.4)	27.0 (6.8)	.67
Education level ISCED[c] 1997, mean (SD)	2.7 (1.1)	2.4 (0.8)	.25
Number of pain clusters, mean (SD)			
Front	3.7 (4.5)	5.5 (7.3)	.12
Back	3.6 (3.4)	4.9 (5.7)	.16
Left	2.9 (3.4)	4.5 (5.2)	.06
Right	2.7 (3.0)	4.2 (5.4)	.07
Years of pain treatment, mean (SD)	4.0 (1.8)	3.8 (2.2)	.70
Number of previous therapeutic consultations, mean (SD)	10.2 (11.1)	14.1 (17.7)	.18
Usage of comparable electronic devices, n (%)			**.18**
Daily	30 (58)	32 (64)	
3-4 times/week	6 (12)	6 (12)	
1-2 times/week	4 (8)	2 (4)	
1-2 times/month	0 (0)	0 (0)	
Almost never	7 (13)	1 (2)	
Never	5 (10)	9 (18)	

[a]Two-tailed *t* test or chi-square test.

[b]BMI: body mass index.

[c]ISCED: International Standard Classification of Education.

Doctors

All doctors who evaluated the app were anesthesiologists with at least 5 years of clinical experience. Moreover, 6 of them participated in study 1, of which 2 were pain specialists and 4 were in training for pain specialization. The specialists examined 48 of the study patients, whereas those in training examined 30.

Of the 4 anesthesiologists involved in study 2, 2 were pain specialists and 2 were in training for pain specialization. This time the specialists examined all 51 patients, of which 35 were additionally examined by a specialist in training.

Tablet Computer

All symptom drawing data were collected on a Samsung Galaxy Note 2014 edition 10.1 (SM-P600) tablet computer running on Android 4.1.2 (study 1) or Android 5.1.1 (study 2). This tablet has a 10.1-inch touch screen with a resolution of 800×1280 pixels and is equipped with an electronic pen (stylus) that was used for all data entry. In contrast to entering data by finger, which uses the capacitive touchscreen, the tablet records stylus interactions with a separate inductive digitizer, which allows for a higher resolution while eliminating unwanted activation of the screen, for example, by the palm.

Software App

General Design

The software app was organized into 3 different modules: drawing instructions, symptom specification, and drawing (Figure 1). App versions for patients and doctors used the same modules but with different content. In the following sections, we will describe all elements that were left unchanged between studies 1 and 2.

Drawing Instructions

The first screen instructed the user how to make a correct symptom drawing. Following the suggested design guidelines by Jaatun et al [11], we used a paper metaphor and limited the written textual instructions as much as possible. Central elements were instructions to draw every symptom or finding that users found disturbing or abnormal and to draw it on each view of

the body outline showing the respective body region. Users were further asked to color every point of the body outline where a certain symptom or finding was present. Other possible ways to mark a body region, such as hatching, ticking, or marking by symbols, like arrows, were explicitly prohibited. Finally, users were told to specify the symptom or finding by choosing descriptors from a list. Then, the use of the visual analog scale (VAS) and the rating of depth was explained.

Specification of Symptoms

After acknowledging the drawing instructions, a new screen was displayed asking users to specify any pain-related symptom in an iterative process. They were first asked to choose the type of sensation from the following list of descriptors (in German): burning, cold, cramping, dull, electric, heavy, hot, numb, pressing, pricking, radiating, shooting, stabbing, tearing, tender, throbbing, tingling, and tugging. In the next step, they rated the intensity of the sensation on a VAS, ranging from "no sensation" to "strongest imaginable intensity." Next, they entered the perceived depth of the sensations by choosing one of the following descriptors: skin, muscle, organ, and bone. The initial version of the app contained an additional classification of the symptom into major or minor symptom. Following this textual specification, the drawing module was initialized.

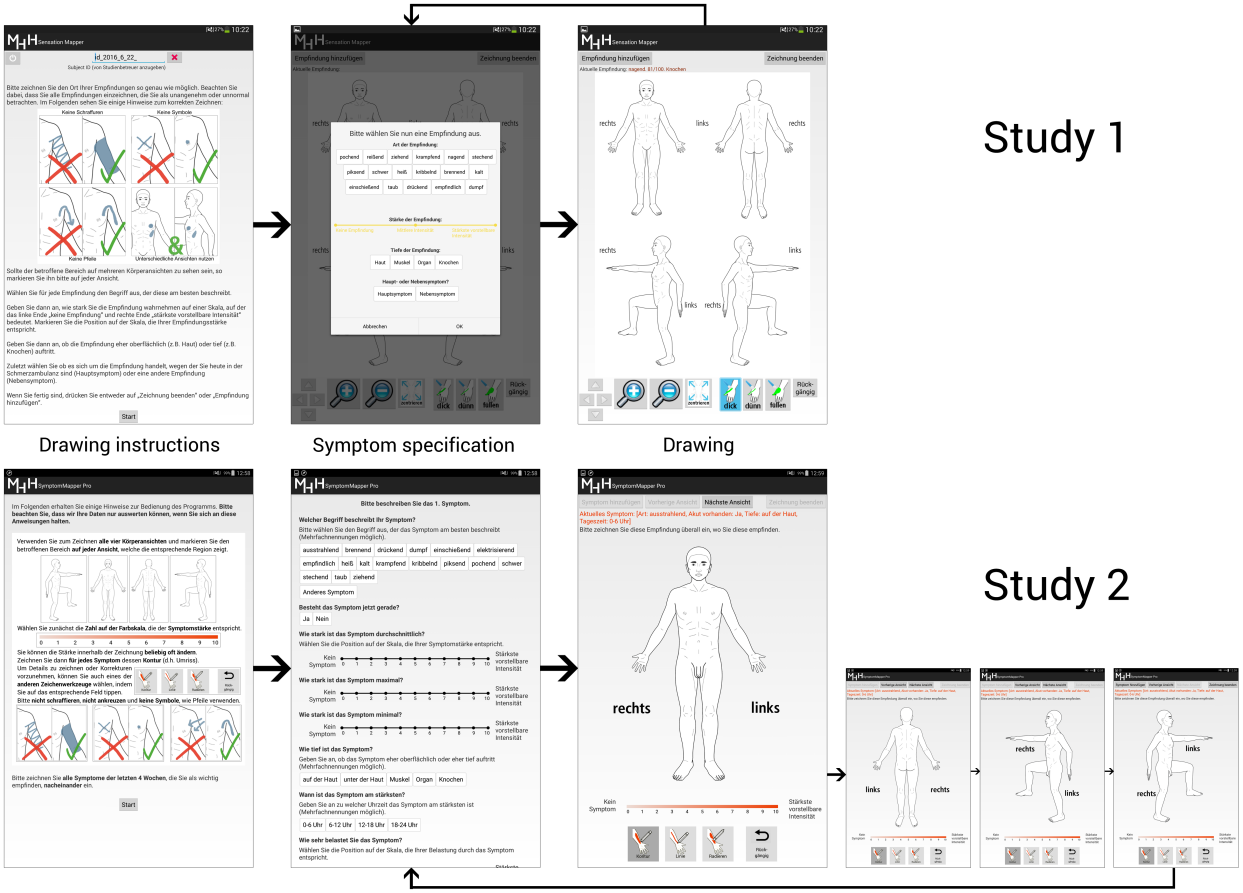
Specification of Diagnostic Findings

The doctors' version of the app had an additional variation of the symptom specification module to enter common diagnostic findings in a bodily examination. This screen contained German translations of the following findings: allodynia, anesthesia, atrophy, dysesthesia, hyperalgesia, hyperhydrosis, and hypesthesia. The VAS and depth rating was similar to that of the symptom specification module.

Drawing Module

In the final module, users were shown a body outline to draw the location of the symptom or finding specified in the previous module. It had been specifically developed for this purpose based on photographs of a human body. The sex of the initial version was undetermined. Although previous screens allowed data entry by finger, drawings could only be made using the tablet's stylus. Users were free to choose from a set of drawing tools (line, autofilled shape, or undo). Drawing was restricted to within the borders of the body outline. After finishing the drawing, users could either choose to end data entry or to add another symptom, which would bring them back to symptom specification.

Figure 1. General structure of both app versions. Users were first instructed on how to make a correct symptom drawing (drawing instructions). Then, an iterative process was started, in which users characterized each of their symptoms (symptom specification). Finally, users were asked to mark the location and extent of the symptom on a body outline (drawing).



Improvements

We made several improvements to the graphical user interface (GUI) of the prototype app, most of which were inspired by the results of the usability assessment of study 1 as well as requests from the doctors. Furthermore, we completely abandoned the use of pop-up windows as suggested by Jaatun et al [11].

Drawing Instructions

Changes to the drawing instructions largely reflect the changes made to the other modules, for example, the newly added VAS of the drawing module (see below). In addition, we added a short explanation of the different drawing tools. As a general rule, we tried to move as much information as possible from instructions to symptom specification, because it seemed a more natural place to explain the choice of descriptors, symptom depth, and the use of the VAS and reduced the amount of information that needed to be memorized by the user. Finally, we reduced ambiguity of the app results for patients by specifying the time interval of the symptoms to be drawn (last 4 weeks).

Specification of Symptoms

Many patients asked for the possibility to choose more than one descriptor for the single symptom, which is why we added this feature in the final version. Patients were also allowed to add their own descriptors if they were not happy with the available choices. Furthermore, the list of depth descriptors was changed following patients' requests. As many of them found it difficult to localize the depth of their symptoms in either "skin" or "muscle," the term "skin" was split into "on the skin" and "beneath the skin," whereas the other terms were left unchanged.

Symptom specification was expanded relative to study 1, which was largely motivated by considerations other than usability. Briefly, we asked for each symptom for the maximal and minimal intensity, if the symptom was currently present, the time of day when the symptom was worst (in intervals of 6 hours), and the perceived burden associated with the symptom. The perceived burden replaced the classification into major or minor symptom, because for the majority of the patients all symptoms were rated as major symptom. Maximal and minimal symptom intensity as well as perceived burden were rated on a VAS ranging from 0 ("no symptom" and "no burden") to 10 ("strongest imaginable intensity" and "strongest imaginable burden") and anchored by numbers from 0 to 10. All changes were applied after consulting the participating doctors.

Specification of Diagnostic Findings

In study 2, finding specification for doctors was also expanded. Besides the possibility to choose multiple symptom descriptors and depth categories, the second app contained an expanded list of findings (Table 2). In addition, doctors were able to add their own descriptors, and the depth descriptor were modified in the same way as for the patients' version.

Drawing Module

Several profound design changes were made to the drawing module, all inspired by user feedback. To allow users to indicate local differences in symptom or finding intensity, we added a VAS to the drawing module. Different intensities in the drawing were indicated by different saturation values of the drawing color. We also changed the body outline and the way it was presented. First, we added the possibility to choose the gender of the outline (female, male, not specified). Sex-related changes to the outline were kept as small as possible to maintain comparability between the drawings from the different sexes.

Second, we changed the mode of presentation. While the four views (front, back, left, right) of the body outline had been presented on one screen in the prototype (Figure 1), the final app showed each view on a separate consecutive screen and users had to click through each of them. The motivation for this was that it allowed us to double the available screen area for drawing and to encourage patients to make use of all available body views.

We also changed the controls (ie, icons) at the bottom of the screen. Buttons for zoom (magnification glass) and scrolling (arrows) were removed because they had only been used by a minority of users. Furthermore, we reduced the line drawing tool to one thickness and added an eraser tool.

Outcome Measures

Usability Assessment

Usability of the app and data acquisition method were assessed separately in patients (Aim 1) and doctors (Aim 2).

Table 2. Specification of diagnostic findings for doctors (used in study 2).

Category	Diagnostic finding
Pain/paresthesia	Burning, cold, cramping, dull, electric, heavy, hot, numb, pressing, pricking, radiating, shooting, stabbing, tender, throbbing, tingling, tugging, other
Symptom depth	On the skin, beneath the skin, muscle, organ, bone
Skin (sensitivity)	Allodynia, analgesia, anesthesia, dysesthesia, hypoesthesia, hyperalgesia, hypoalgesia, pallanesthesia, pallhypesthesia, thermanesthesia, thermhypesthesia, other
Skin (perfusion)	Cyanosis, hyperthermia, hypothermia, pallor, redness, swelling, other
Skin (autonomic)	Anhidrosis, atrophy, hyperhidrosis, hypertrophy, piloerection, other
Muscle	Allodynia, atrophy, disturbed proprioception, fasciculation, hyperalgesia, hypotonia, muscular defense, myogelosis, rebound tenderness, rigor, spasm, tenderness, other
Organ	Tenderness, hypertrophy, induration, other

Patients' Evaluation

To evaluate the app and the tablet-based data acquisition, we designed a usability questionnaire. It contained a common part aimed at comparing usability between studies 1 and 2 and an individual part with items specific to each of the studies. The common part consisted of 8 Likert-type questions (possible answers from 0 to 10) and 2 open questions with free text answers. The individual part contained 3 dichotomous and 1 multiple-choice question for study 1 and one Likert-type question for study 2. A translated version of the 2 questionnaires can be found in Multimedia Appendix 2.

Doctors' Evaluation

We observed doctors' evaluation during data entry at several timepoints of the project and asked them to report any problems or ideas for improvement. These were collected in a list and later analyzed. Furthermore, a meeting with the participating doctors was arranged after the first study to discuss the study results and plans for app improvements.

At the end of study 2, we evaluated usability from the doctors' perspective through a Web-based survey comprising the following questionnaires:

The System Usability Scale (SUS) [16] is a questionnaire for measuring usability for hard- and software products. It consists of 10 items and its results range from 0 to 100. Adjective rating scales were used for better interpretability [17].

The Attrakdiff 2 questionnaire [18] measures pragmatic and hedonic quality of a product. It consists of 4 subcategories: pragmatic quality, hedonic quality identity, hedonic quality stimulation, and attractiveness. The evaluation of these attributes is based on the ratings of 28 items, each of which is an adjective rating scale, ranging from −3 to 3.

The ISONORM 9241/10 questionnaire [19,20] assesses ergonomic principles for software dialogues according to ISO standard 9241 part 10. It consists of 7 categories: suitability for the task, self-descriptiveness, controllability, conformity with user expectations, error tolerance, suitability for individualization, and suitability for learning. Each category is evaluated through five 7-step items, ranging from −3 to 3.

Reproducibility Study

To evaluate test-retest reliability of our acquisition method (final app version on tablet PC) for symptom drawings, we planned to include 25 of our patients in the second study. The rational for this sample size was that previous studies had shown excellent test-retest reliability of pain extent with intraclass correlation coefficients (ICCs) between 0.92 and 0.97 [6]. Aiming at a 95% CI width of 0.1 with an alpha level of .05, we used formula 6 from Giraudeau and Mary [21] for our sample size estimation, which showed that 15 patients would be enough. As we planned to run additional reproducibility analyses for the number of clusters and the symptom pattern, we decided to include 25 patients. Thus, we asked 26 of our 51 patients to repeat their data entry after finishing the first one (1 patient had to be excluded because the image was not saved by the tablet PC). The second data entry was started 20 min after the first one, a period during which participants filled out other pain questionnaires of the pain outpatient department. When preparing their first drawing, patients were not aware that they would have to draw a second one. To avoid interference with clinical routines and bias by the consultation, only those patients who had waiting periods of more than 20 min were included for a second symptom drawing.

Data Analysis

Usability Analysis

Mean values, SDs, and two-tailed *t* tests for all types of questionnaires for patients and doctors were calculated using Microsoft Excel (Microsoft Corporation, Redmont, WA).

Reproducibility Analysis

We used a script written in Python 2.7 (Python Software Foundation [22]) to transform image data originally saved as Portable Network Graphics into Neuroimaging Informatics Technology Initiative file format [23]. Tools from FMRIB Software Library [24] were used to extract image information, such as symptom extent (number of pixels), number of clusters, intersection, and union of symptom clusters, all of which were restricted to within the body outline. We calculated Jaccard index of symptom patterns as well as a two-way, mixed model ICC (ICC(3,1); according to Shrout and Fleiss classification [25]) for symptom extent (overall number of pixels) and number of symptom clusters for each of the 25 test-retest pairs using Microsoft Excel (Microsoft Corporation) and Real Statistics Resource Pack software (Release 5.4.1) [26]. Results were calculated independently for each body view. We then assessed the maximum and average values of all body views for each patient. Body views not used by the patients in both test and retest were excluded from the analysis. In case the patient drew multiple symptoms, these were merged for reproducibility analysis and the maximum VAS value was used for each pixel. Symptom extent was further plotted as a Bland-Altman plot (ie, mean difference of the drawings of each patient against the mean of both drawings) [27] using Microsoft Excel (Microsoft Corporation).

Results

Usability Evaluation

Patients' Evaluation

A total of 52 questionnaires entered the final analysis for study 1 and 51 for study 2. In study 1, 87% (45/52) of the study patients were content with the body outline. In total, 8% (4/52) of the patients proposed changes in its size and 4% (2/52) requested gender-specific changes. Moreover, 75% (39/52) of the patients agreed with the available choice of descriptors, whereas 23% (12/52) asked for additional or different terms to describe their sensations. In addition, 71% (37/52) of the patients were contempt with the terms to describe the depth of their sensations, whereas 27% (14/52) were not. Several patients used the free text option to suggest adding a multiselect option for sensations and depth descriptors. Furthermore, free text entries demanded the possibility to rate multiple symptom intensities over the day or criticized the restriction of the drawings to within the borders of the body outline. All translated free text answers

of patients' usability questionnaire can be found in Multimedia Appendix 3. Finally, 23% (12/52) of all patients of study 1 stated that they had used the zooming option. However, only 6% (3/52) of all participating patients used the magnification buttons for this.

The part of the questionnaire comparing the app versions of studies 1 and 2 showed significant differences for 3 of the 8 Likert-type items, indicating improved usability of the final app (Table 3): (1) The difficulty of the drawing process decreased from 3.38 (SD 2.89) to 1.86 (SD 2.16; *P*=.003), (2) the ability to identify oneself with the given body outline increased from 7.54 (SD 2.59) to 8.73 (SD 1.71; *P*=.007), and (3) the difficulty to select a depth descriptor decreased from 4.71 (SD 3.18) to 3.27 (SD 2.77; *P*=.02).

In study 2, 4% (2/51) of the patients found the size of the body outline too small. One patient of 51 (2%) reported problems using the VAS while drawing and another one proposed to use a table to support the tablet during data collection. Finally, the difficulty of drawing the symptom pattern from different angles of the human body was rated as 1.78 (SD 2.16) on a Likert-type scale from 0 ("not difficult at all") to 10 ("very difficult").

Table 3. Usability assessment by patients comparing app versions from study 1 to study 2.

Likert-type questions	Study 1		Study 2		*P* value
	N	Mean (SD)	N	Mean (SD)	
How precisely does your drawing represent your actual sensations? (0=very imprecisely, 10=very precisely)	52	7.31 (2.33)	51	7.20 (3.05)	.84
How difficult was it to draw your sensations? (0=not difficult at all, 10=very difficult)	52	3.38 (2.89)	51	1.86 (2.16)	.003[a]
How well could you identify yourself with the body outline? (0=not at all, 10=very well)	52	7.54 (2.59)	51	8.73 (1.71)	.007[a]
How precisely do the chosen terms describe the nature of your sensations? (0=very imprecisely, 10=very precisely)	52	6.58 (2.54)	51	7.20 (2.47)	.21
How difficult was it to evaluate the depth of your sensations (ie, skin, muscle, etc)? (0=not difficult at all, 10=very difficult)	52	4.71 (3.18)	51	3.27 (2.77)	.02[a]
How precisely do you rate your drawing with the electronic pen in comparison with a pencil drawing? (0=very imprecise, 10=very precise)	52	7.52 (2.30)	51	7.10 (3.27)	.45
How much physical or mental stress was the drawing of your sensations? (0=no stress, 10=very much stress)	51	1.43 (2.18)	51	1.65 (2.21)	.62
How comprehensible were the drawing instructions (eg, drawing examples and written instructions) for you? (0=not comprehensible, 10=very comprehensible)	52	7.71 (2.41)	50	8.32 (2.07)	.18

[a]Statistically significant difference (*P*<.05).

Table 4. Usability assessment by doctors.

Questionnaire	Result (SD)
System Usability Scale (range 0 to 100)	75.63 (19.51)
Attrakdiff 2 (Range −3 to 3)	
Pragmatic quality	1.07 (1.41)
Hedonic quality: identity	1.14 (1.08)
Hedonic quality: stimulation	1.25 (1.00)
Attractiveness	1.14 (0.93)
ISONORM 9241/10 (range −3 to 3)	
Suitability for the task	1.00 (1.62)
Self-descriptiveness	0.95 (1.50)
Controllability	−0.05 (1.43)
Conformity with user expectations	1.25 (1.59)
Error tolerance	0.65 (1.31)
Suitability for individualization	−0.15 (1.79)
Suitability for learning	1.80 (1.24)

Doctors' Evaluation

The results of the doctors' usability assessment are displayed in (Table 4). We collected data through the Web-based questionnaire from the 4 doctors participating in study 2. The mean score on the SUS was 75.63 (SD 19.51), indicating good usability. The subscales of the Attrakdiff questionnaire all received ratings between 1.07 and 1.25. Both the hedonic (self-centered) and pragmatic (action-oriented) quality of the tablet app had similar values. There was no indication of hedonic or pragmatic dominance in the final app.

Assessment using the ISONORM 9241/10 questionnaire showed good results in the categories "suitability for learning," "suitability for the task," "self-descriptiveness," "conformity with user expectations," and "error tolerance." Only in the categories "suitability for individualization" and "controllability" the results were slightly below the average.

Reproducibility Analysis

Results of the test-retest analyses are shown in Table 5 and Figures 2-4. The Jaccard index was 0.47, indicating a mean overlap between test and retest symptom patterns of almost 50%. The ICC showed excellent reproducibility for symptom extent (ICC=0.92) and good reproducibility for Cluster count (ICC=0.70). Bland-Altman plots for symptom extent are shown in Figure 2 and Figure 3. There was no indication of a systematic difference between the measurements. Patients who drew larger areas also showed higher variability between test and retest drawings.

Table 5. Test-retest reliability.

Analysis	Result
Jaccard index of symptom pattern (SD)	0.47 (0.22)
ICC[a] of symptom extent (95% CI)	
Whole drawing (all body views)	0.92 (0.88-0.95)
Single views	
Front	0.93 (0.84-0.97)
Back	0.90 (0.78-0.96)
Left	0.94 (0.86-0.97)
Right	0.92 (0.82-0.97)
ICC number of symptom clusters (95% CI)	
Whole drawing (all body views)	0.70 (0.58-0.79)
Single views	
Front	0.66 (0.36-0.83)
Back	0.56 (0.20-0.79)
Left	0.75 (0.49-0.89)
Right	0.87 (0.73-0.94)

[a]ICC: intraclass correlation coefficient.

Figure 2. Bland-Altman plot of symptom extent. The central bold lines represent the mean difference. The dotted lines represent the 95% upper and lower limits of agreement. The mean symptom extent of the first and second symptom drawing (D1 and D2) is plotted against the difference in symptom extent between D1 and D2.

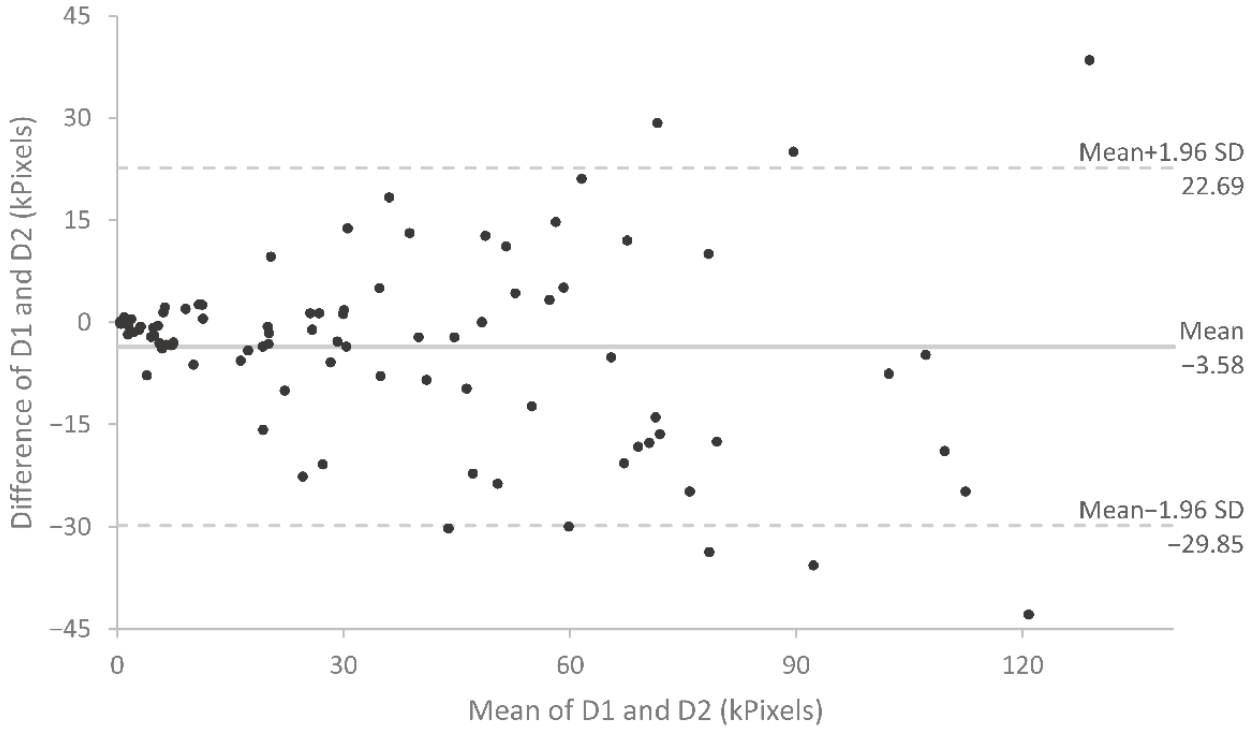


Figure 3. Bland-Altman plot of symptom extent. The central bold lines represent the mean difference. The dotted lines represent the 95% upper and lower limits of agreement. The mean symptom extent of first and second symptom drawing (D1 and D2) is plotted against the percentual difference (of the mean) between D1 and D1.

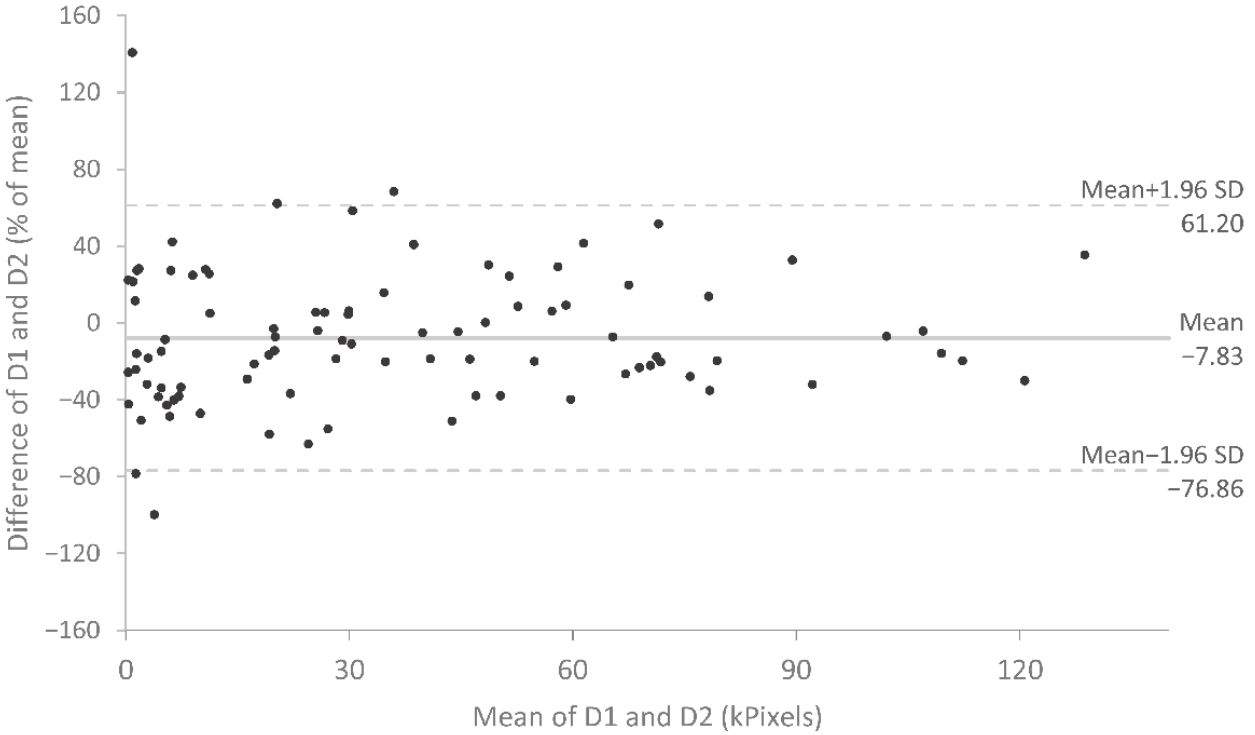
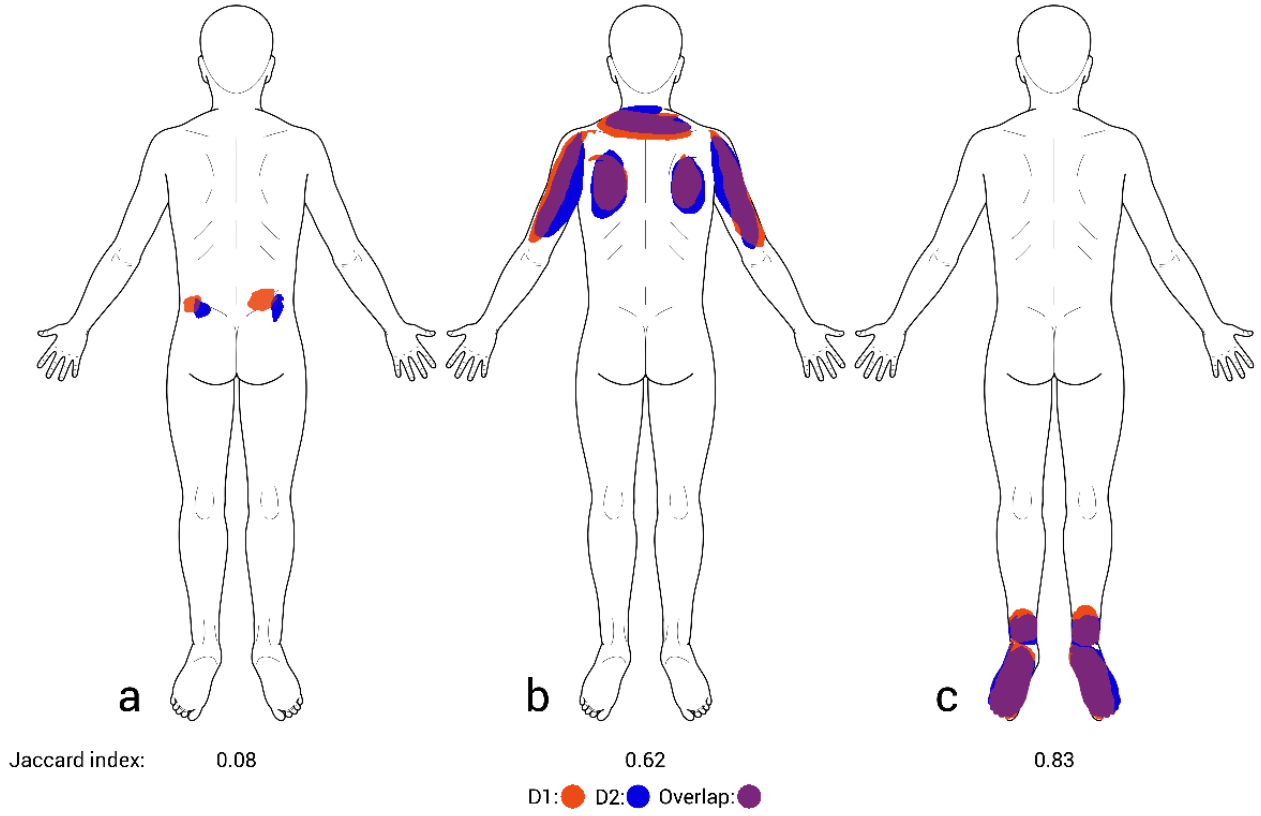


Figure 4. Test-retest reliability results and problems with the Jaccard index exemplified by symptom drawings of 3 different patients: (a) low, (b) average, (c) high reliability. The first drawing (D1) of each patient is colored in red and the second drawing (D2) in blue. Purple color indicates the overlap of the 2 drawings. Jaccard indices calculated from the consecutive drawings are reported below each drawing. From a clinical standpoint, D1 and D2 would still lead to the same clinical judgment.



Discussion

We have developed a new tablet-based app (SymptomMapper) to collect electronic drawings of pain and related bodily symptoms. Following the suggested design guidelines by Jaatun et al [11], we limited written textual instruction, used a paper metaphor, and avoided pop-ups and other fast changes on the screen. Two versions of the app were tested for their usability and reproducibility in a sample of chronic pain patients and their treating doctors.

Usability Evaluation

Patients' Evaluation

Usability assessment comparing the pilot app from study 1 with the final app from study 2 showed 3 areas of significant improvement as rated by the patients: evaluation of symptom depth, identification with the body outline, and overall difficultness of the drawing process. Although we did not assess explicitly which changes of the app led to a particular improvement in usability, we will speculate in the following sections on the most likely causes and discuss them in the light of the relevant literature.

Regarding the improvement in depth evaluation, we must note that unless the pain is entirely superficial, a pain map has to display the complex three-dimensional geometry of the painful area onto a flat, two-dimensional surface [5]. It can be assumed that this is the main reason why depth assessment has never played a major role in pain drawings despite being used from the very beginning. In the famous McGill pain questionnaire, the letters E and I were used in the pain drawing part to distinguish between "external" and "internal" pain [3], whereas Margoles used the letter D to identify deep pain [28]. Jamison et al tested depth assessment within a three-dimensional assessment of pain drawings [29], and recently, Tucker et al have developed a visual rating instrument to assess the depth of experimental back pain by calculating the "percentage of depth to center" [30]. They could show that depth and lateral position may be the most critical descriptors to determine the source of acute lumbar muscular pain. Indeed, the differentiation between different layers is not only significant in regard to diagnostic purposes but also to different therapeutic approaches, such as in acupuncture, where needles are placed in different structures according to the underlying condition. Concerning evaluation of symptom depth, we made 2 related improvements, namely, splitting the depth category "skin" into "on the skin" and "beneath the skin," and adding the possibility to choose multiple depth descriptors at once. The latter option was used by the majority of patients in study 2. In total, 26 out of 51 patients (51%) selected more than one depth category.

Concerning identification with the body outline and overall difficultness of the drawing process, we believe that the improvements seen here were largely due to 2 major modifications we made to the drawing module, namely, the introduction of gender-specific body outlines and the consecutive rather than joint presentation of the single body views. The change from a genderless to a gender-specific body

outline had been requested by patients and may have improved patients' ability to identify themselves with the body outline. Egsgaard et al have shown that gender aspects of body outlines can influence the quality of the drawing as well as the patients' drawing experience [31]. In their study, 85% of the female study population preferred a female body chart.

On the other hand, the consecutive presentation of the body views constitutes a more guided approach compared with the joint presentation allowing patients to focus on one view at a time. This may also have improved identification with the body outline as compared with the pilot app. Finally, the size of the body outline was almost twice as large in the consecutive presentation approach as compared with joint presentation. Interestingly, however, the enlargement of the body outline did not have an effect on patients' perceived exactness of the drawings.

Doctors' Evaluation

At the end of study 2, the 4 participating doctors were asked to evaluate the tablet app through a Web-based usability survey consisting of the SUS, Attrakdiff 2, and ISONORM 9241/10 questionnaires. A score of 75.63 on the SUS indicates an overall good usability of the final app [17,32], which is in line with the results from the patients' evaluation. With the Attrakdiff 2 questionnaire, we assessed pragmatic and hedonic qualities of the app, 2 dimensions that are independent from each other. Pragmatic quality perception evaluates the effectiveness of a product (task-related), whereas hedonic quality evaluates how the user-product interaction is stimulating the user and how the product is communicating the identity of the user (nontask-related) [33,34]. Attractiveness is the perceived property that is influenced by both pragmatic and hedonic qualities. However, although the pragmatic and hedonic qualities of a product are usually not altered by repeated use, its attractiveness can change, which Hassenzahl explains by a different weighting of these qualities based on the intention of the product usage [35]. We expected higher pragmatic than hedonic ratings, because the layout of the app was clearly task-oriented. However, the ratings of hedonic and pragmatic quality both showed comparable ratings around 1 on the scale from −3 to 3. According to these results, the final app as rated by doctors was neither a solitary "self-product" nor a pure "act-product" [34]. In general, the app received positive evaluations in all categories of the Attrakdiff 2.

The ISONORM 9241/10-questionnaire evaluates several aspects of software usability including suitability for the task, controllability, conformity with user expectations, and error tolerance. All categories were evaluated above average by our doctors, except for "suitability for individualization" and "controllability." Both categories received slightly negative ratings, which may reflect the fact that doctors and patients used the same app in our study that only differed in the lists of available symptoms. As one of the design goals of this app was to increase homogeneity and validity of symptom drawings, we tried to reduce sources of between-subject variability that are due to unnecessary freedom in the drawing process. Therefore, the final app version used a rather rigid succession of data entry steps, for example, by presenting all body views in a defined order of by fixing the symptom descriptor(s) once the drawing starts. A possible way to improve this in future releases would be to add features that allow doctors to circumvent some of the restrictions and to enter data more freely.

Reproducibility Analysis

After testing and improving the usability of our app, we used its final version to assess test-retest reliability of symptom drawings by a typical sample of chronic pain patients consulting a pain outpatient clinic. The analysis of pairs of consecutive drawings separated by 20 min and drawn by the same patients showed excellent reproducibility for symptom extent (ICC=0.92) and fair reproducibility for the exact symptom pattern (Jaccard index: 0.47). It is worth noting that we used 4 instead of the usual 2 views of the human. Although this complicates the drawing process, it allows for much more detailed assessment of lateral body regions. To our knowledge, this was the first study analyzing test-retest reliability for more than 2 body views.

Our results closely replicate a study by Barbero et al [6], who in 2 samples of pain patients (chronic low back pain and neck pain) reported an ICC of 0.92 and 0.97, respectively, for pain extent and a Jaccard index of 0.46 and 0.49, respectively, for pain location. We can also confirm their observation that the difference between the first and the second drawing increases with the total number of pixels drawn, whereas the percentual difference is constant. As Barbero et al note further, it is questionable if the Jaccard index is the optimal measure to assess the reliability of pain location as it demands very high precision in pain reporting. We completely agree with the authors here. Figure 4 shows the test-retest results of 3 of our study patients to illustrate this. There is no doubt that the first and second drawings of patients (b) and (c) with Jaccard indices of 0.62 (average) and 0.83 (high) would be considered identical from a clinical point of view. However, although a Jaccard index of 0.08 as exhibited by patient (a) indicates a very low test-retest reliability, his drawings still seem to convey the same clinical information. Thus, further investigations on symptom drawings and their association with clinical judgment are warranted. Furthermore, more useful measures of similarity that do not rely on exact overlap are needed.

Limitations

As in every study, we must note some limitations. Our attempt to quantify symptom depth relied on verbal descriptors, which may have led to mistakes arising from different interpretations of expressions, such as "beneath the skin," whose German translation may have been interpreted by some as meaning "in every tissue layer beneath the skin." Descriptors should be carefully checked for all possible meanings they convey. Furthermore, there are alternative approaches to assess symptom depth, for example, the aforementioned visual rating of the "percentage of depth to center" by Tucker et al [30] or depth assessment based on three-dimensional pain drawings as used by Jamison et al [29].

Our test-retest results may have been biased by several uncontrolled factors. First, patients did not simply wait for 20 min between test and retest but used the time to fill out clinical pain questionnaires in preparation for their appointment with

the doctors. The occupation with different aspects of their pain induced by the questionnaires may have influenced the second drawing, for example, by reminding patients of previously forgotten pain foci. Second, we cannot estimate the effect of learning. Roach et al showed that patients may complete pain drawings more reliably after they have been exposed to them several times [36]. In our study, patients only drew twice, and none of them underwent a training for using the app correctly, except for the drawing instructions given on the first screen. Finally, some patients reported during their second drawing that they had forgotten a symptom or complete body view in the first drawing. Despite the negative impact on test-retest reliability, we decided against excluding these patients, because their behavior probably reflects that of general pain patients.

Conclusions

We developed an app for symptom drawing acquisition and assessed the usability of it in a sample of chronic pain patients and their treating doctors. We measured increases in usability of the improved app in terms of identification with the body outline, symptom depth evaluation, and difficultness of the drawing process according to patients' evaluation (Aim 1). Furthermore, usability evaluation through treating doctors showed good overall usability and balanced hedonic and pragmatic values (Aim 2). Test-retest reliability of symptom drawings by chronic pain patients showed fair to excellent reproducibility for symptom pattern, symptom extent, and number of symptom clusters (Aim 3). Patients' usability evaluation is an important factor when designing apps for mobile or eHealth apps and should not be neglected.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

GRRAS checklist for reporting of studies of reliability and agreement.

[PDF File (Adobe PDF File), 115KB - mhealth_v6i5e127_app1.pdf]

Multimedia Appendix 2

Usability questionnaires (patients).

[PDF File (Adobe PDF File), 99KB - mhealth_v6i5e127_app2.pdf]

Multimedia Appendix 3

Free text answers of usability questionnaires (patients).

[PDF File (Adobe PDF File), 25KB - mhealth_v6i5e127_app3.pdf]

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Abbreviations

D1: first symptom drawing
D2: second symptom drawing
ICC: intraclass correlation coefficient
ISCED: International Standard Classification of Education
PC: personal computer
SUS: System Usability Scale
VAS: Visual analog scale

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Original Paper

Multistakeholder Perspectives on Maternal Text Messaging Intervention in Uganda: Qualitative Study

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Abstract

Background: Despite continued interest in the use of mobile health for improving maternal health outcomes, there have been limited attempts to identify relevant program theories.

Objectives: This study had two aims: first, to explicate the assumptions of program designers, which we call the program theory and second, to contrast this program theory with empirical data to gain a better understanding of mechanisms, facilitators, and barriers related to the program outcomes.

Methods: To achieve the aforementioned objectives, we conducted a retrospective qualitative study of a text messaging (short message service) platform geared at improving individual maternal health outcomes in Uganda. Through interviews with program designers (n=3), we elicited 3 main designers' assumptions and explored these against data from qualitative interviews with primary beneficiaries (n=26; 15 women and 11 men) and health service providers (n=6), as well as 6 focus group discussions with village health team members (n=50) who were all involved in the program.

Results: Our study results highlighted that while the program designers' assumptions were appropriate, additional mechanisms and contextual factors, such as the importance of incentives for village health team members, mobile phone ownership, and health system factors should have been considered.

Conclusions: Our results indicate that text messages could be an effective part of a more comprehensive maternal health program when context and system barriers are identified and addressed in the program theories.

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KEYWORDS

maternal health; telemedicine; community health workers; Uganda; evaluation studies

Introduction

Background

Maternal mortality is decreasing in many countries, yet over 300,000 women still die annually, particularly in low- and middle-income countries (LMICs) [1]. The utilization of mobile health (mHealth) has been proposed as a potential solution to improve maternal health outcomes in LMICs [2-4]. There is evidence in a growing body of research that despite indications of positive outcomes, the continued focus of mHealth research on activities and inputs and less on the mechanisms behind program success and failure have contributed to gaps in evidence on the effectiveness on mHealth interventions [5-8]. These

authors have suggested that a greater attention to program theories could contribute to a deeper understanding of mHealth interventions.

Program theories, also referred to as theories of change, have various definitions but usually involve relating program input and activities to expected outcomes. For the purposes of this study, we approach the idea of a program theory from the perspective of "realist evaluation." Realist evaluation emphasizes not only inputs and outcomes but attempts to answer the question of what works for whom (outcomes), how (mechanisms), and under what conditions (context) [9,10]. We did not undertake a full realist evaluation in this study; however, we utilized the principles of this form of theory-driven evaluation in understanding of the underpinnings of mHealth interventions. In our research, we aimed first to explain the assumptions of program designers, which we call the program theory; and second to contrast this program theory with empirical data to gain a better understanding of mechanisms, facilitators, and barriers related to the program outcomes.

Intervention Description

The Ugandan National Health Commission (UNHCO), a nongovernmental organization in Kampala, designed and implemented a multisite intervention centered on the use of text messaging (short message service, SMS) for maternal health in 3 districts of Uganda. The main objective of the intervention was to improve demand and utilization of maternal sexual and reproductive health services of mothers through increased communication about recommended maternal health services and maternal health rights and responsibilities. The project took place between 2011 and 2014 in 3 districts in Uganda and was primarily targeted at women between the ages of 15 and 49 years, but other community members, including men, were also recruited onto the platform. Village health team (VHT)members received training from UNHCO and subsequently registered primary beneficiaries on an SMS platform during home visits. Primary beneficiaries then received tailored text and audio messages regarding upcoming antenatal care (ANC) visits and recommended reproductive health practices. The SMS messages were developed by UNHCO staff in consultation with maternal health professionals and Ministry of Health officials who were familiar with and worked within the local context. The messages were developed in Luganda and aimed to address evidence-based recommended health practices for improved maternal health outcome such as the need for ANC attendance and delivery and health facilities. The intervention developers also gave consideration to the rights-based approach and created messages addressing the rights and responsibilities of patients. They also included a feedback mechanism within the SMS platform, which allowed users to send feedback via free SMS messages. Table 1 contains additional information on the intervention design and implementation.

In 2015, UNHCO conducted a postintervention study and randomly sampled 1048 respondents from the intervention districts; 482 respondents were registered and 566 were not registered on the UNHCO SMS platform. Study results indicated that the SMS platform, radio programs, health workers, and VHTs had a significant joint influence on uptake of maternal health services. However, the SMS had the highest effect (odds ratio 19.086, 95% CI 10.683-34.099). Furthermore, women whose husbands received a text message within the last year were more likely to seek maternal health services compared with those whose husbands had not received messages. Despite these positive reports, there remained gaps between program developers' expectations and the program outcomes. For example, although UNHCO received reports from health facilities that first ANC visits and delivery at health facilities had increased, the numbers remained below program designers' expectations. In addition, only 54.4% (117/215) of the registered users surveyed indicated that they had heard about maternal health rights.

Program developers acknowledged that with consideration to these mixed results, there was a need to understand mechanisms, barriers, and facilitators to program outcomes. This study had 2 aims, first, to explicate the assumptions of program designers, which we call the program theory and second, to contrast this program theory with empirical data to gain a better understanding of mechanisms, facilitators, and barriers related to the program outcomes.

Table 1. Intervention description.

Input	Activities	Description
Funding	Catholic Organization for Relief Development Aid	A three and a half-year grant
Setting		
Districts	In all, 3 districts selected	One rural and one semiurban district selected per district; In total, 6 subdistricts
Intervention components		
Short message service (SMS) messages	Information was sent via weekly text messages on the following: antenatal care, postnatal care, immunization, nutrition, danger signs during pregnancy, delivery services, family planning, prevention of mother to child HIV, health education on self-care and child care, nutrition and breastfeeding and maternal rights and responsibilities	• Women were the intended targets of the SMS messages. However, monitoring reports indicated that in some households, men owned the phones. Men were then also enrolled on the SMS platform. • Messages were sent only via written text messages at first but midway through the program was modified to include voice messages also. • Messages were sent in biweekly in Luganda, most commonly spoken local language in the regions. • Feedback messages could be sent in response. These could be about experiences at the health center, additional questions, or issues with the SMS intervention itself. • In all, 100 feedback messages were received through the SMS platform. • As part of the intervention, on a quarterly basis, RH experts would develop answers to questions received through the platform, and these would be sent back as general awareness messages.
Radio programming	Information provided based on feedback questions received through the SMS intervention	• Radio programs were aired biweekly on different stations depending on the district. • They addressed questions that had been sent to the SMS platform and provided additional maternal health information.
Participants		
1. Village health teams (VHTs)	Prepare work plans for reaching out to the primary beneficiaries; deliver services on a reach out basis; screen, advise, and refer as required; follow-up and assess response of the primary beneficiaries to the maternal, sexual and reproductive health services	• One VHT consisting of 10 individuals was invited per sub-district. • In total, 60 VHT members were invited and agreed to be part of the programs. • In all, two trainings per year were carried out as planned per district; one in maternal health technical content and another on the use of information communication technology tools. • All VHTs received a bicycle, monthly allowance of 20,000 Uganda Shillings, and t-shirts.
2. Primary beneficiaries	Demand and seek maternal, sexual and reproductive health services; demand for downward accountability; provide feedback on quality of service delivery	• Primary beneficiaries could be men and women of reproductive age. The program reached 2341 men and women.
3. Service providers	Provide maternal, sexual and reproductive health services; provide feedback on utilization, outcomes, and impact; provide facility data on outcomes and impact	• Health workers at all health facilities within the sub districts were enrolled in the program and offered training. In total, 18 health providers were trained. However, high turnovers within health facilities disrupted the ability to measure.

Methods

Study Design

A qualitative retrospective study was undertaken between May and August 2016. Data collection occurred in 2 phases. The first phase involved concurrent discussions with the program developers, as well as a review of all relevant program documents. In the second phase, semistructured interviews explored perceptions of primary beneficiaries (women and men) and health service providers. Focus group discussions (FGDs) were used to investigate the perceptions of VHTs about the intervention.

Program Theory

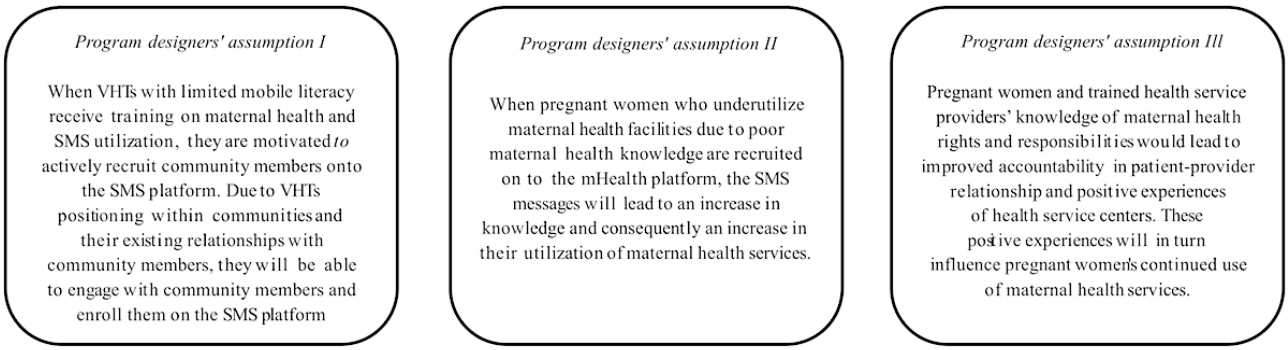
Through interviews with intervention developers (n=3) and review of the literature, we summarized the assumptions about preexisting conditions within the intervention communities and how they relate to the intervention and the expected outcomes into 3 broad statements. These statements constitute the program theory and serve as the conceptual framework for this study and are presented in Figure 1.

The intervention included a component to train VHTs. Subsequently, the VHTs were expected to recruit community members to register on an SMS platform. Linked to this was the assumption of program designers that the VHTs were motivated and that their relationships with the communities was good. If this was met, then the second assumption was that pregnant women would benefit from the text messages if their maternal health knowledge was poor and they currently underutilized health facilities. Receipt of these messages would lead to an increase in maternal health knowledge and translate to increased utilization of health facilities of this specific group of pregnant women. The third assumption was that the increased maternal health knowledge of SMS recipients and trained health service providers, particularly with respect to maternal health rights and responsibilities, would lead to positive experiences at health service centers. These positive experiences at health service centers would be crucial in sustaining improved maternal health-seeking behaviors.

Study Population and Sampling

The study recruited participants from all 6 subcounties and 3 participant groups: primary beneficiaries (men and women), VHTs, and service providers. Criterion sampling was utilized based on the predetermined criteria listed in Textbox 1 [11].

Figure 1. Program theory. SMS: short message service; VHTs: village health teams.



Textbox 1. Inclusion criteria for study participants.

Women

- Reproductive age (18-45 years)
- Pregnant within the intervention time frame
- Living within the intervention subcounties
- Registered on the mHealth platform

Men

- Reproductive age (18-45 years)
- Partner pregnant between 2014 and 2015
- Living within the intervention subcounties
- Registered on the mHealth platform

Village health teams

- Trained within the program
- Active within the intervention subcounties

Service providers

- Health professionals, including nurses, midwives, and doctors at the health centers in intervention subcounties who had received Ugandan National Health Commission training

Primary Beneficiaries (n=26)

In total, 15 women were recruited from local health centers offering maternal and pediatric care within the selected subcounties. Research assistants approached women awaiting health services at the centers, with approval from health service providers, and invited them to participate in an interview. In addition, 11 men were recruited from the community by UNHCO local supervisor and VHT program members and invited for an interview. Primary beneficiaries were most frequently farmers, with all participants having some level of formal education.

Village Health Team Members (n=50)

All 60 VHT members, with 20 VHT members from each district, who received the training, were invited to participate in an FGD, of whom 50 responded. District supervisors explained that the nonresponding VHT members were invited but were generally considered to be inactive, both with respect to the intervention as well as their general duties. In total, 6 FGDs were conducted with 50 VHT members in the 6 subcounties (5 of the 6 FGDs had 6-8 participants, while 1 FGD had 10 participants). All VHT members interviewed had a primary occupation, which ranged from paid positions within the health system to farming.

Health Service Providers (n=6)

The 18 trained health service providers who were involved in the program training and supervision of VHTs were eligible to participate. However, due to frequent staff turnover, we were only able to contact 6 health service providers who were involved in the intervention; all agreed to participate in an interview.

Data Collection

Interviews with primary beneficiaries were conducted with the aid of vignettes [12], while semi structured guides were used for the FGDs with VHTs and service providers. Guides were pilot-tested in another district not involved in the project, and corrections were made. General themes for all participant groups included maternal health-seeking behavior, relationships between VHTs and communities, and experiences with the SMS intervention. Additionally, VHTs and health service providers were asked about their experiences with training. FGDs lasted between 90 and 120 min, and individual interviews ranged between 30 and 60 min.

Data Management and Analysis

All interviews were conducted, recorded, and transcribed by 2 local research assistants. Verbatim translation and transcription were conducted from Luganda (local language) to English and analyzed in MAXQDA version 12 (VERBI GmbH, Germany).

Data analysis was executed by means of content analysis for which a codebook was developed based on the conceptual framework and research questions. On the basis of the assumptions (conceptual framework) and research questions, an initial codebook was designed [13]. After data collection, 2 researchers utilized this framework to code one purposively selected data rich transcript from each participant group. The codebook was then modified based on conversations between both researchers. During the coding process, codes were reviewed and when necessary, codes were revised and new codes that emerged from the data were added. In the code scheme, each code was categorized under a corresponding theme, and quotes from the participants were collected throughout the coding process. Themes were identified in a deductive manner, using the conceptual framework as a guide. All coding and analysis were performed in MAXQDA version 12 (release 12.1.4).

Ethical Considerations

The study was granted ethical approval by the Vrije Universiteit Amsterdam, the Netherlands, and Makerere University, Uganda. Depending on the literacy level of the participant, fingerprint or written consent was collected from participants. The interviewer/translator read the consent form in the appropriate language to the participant. Assurance was provided to participants that data collected would be used for research purposes only. No identifiable personal data or health data were collected from participants. All participants were offered refreshments for their participation in the interviews. This was deemed appropriate and not significant enough to be coercive within the local context.

Results

Program Designers' Assumption I

For VHTs to perform their duties according to the expectations of program designers, training is essential, particularly in a context where VHTs themselves may be unable to navigate mobile phone functionalities such as text messaging. However, in addition to the contents of the training program, factors such as the duration and frequency of training, as well as the provision of incentives and the relationship between VHTs and their communities contributed to the expected outcome of Assumption I.

Perceptions of Training

Overall, most of the VHT members interviewed had positive accounts of the training they received. VHT members explained that before the training they had limited knowledge about reproductive health issues, including family planning and ANC, and maternal or sexual and reproductive health rights and responsibilities. All of the VHT members reported that they were unable to send text messages before the training:

> *When UNHCO was training, they used chats, they asked us questions to find out how much we know and before they introduced a topic, they always tested our knowledge about it. Secondly, they taught us how to send messages from our phones and we understood it well and we also in turn went back into the community to teach the same information on how to utilize their phones in health messages.* [FGD 4, Participant 5]

The notable complaint was with the timing, frequency, and consistency of trainings, which varied between groups. Four of the VHT members particularly found these inconsistencies to affect their learning.

Due to high staff turnover, not all health workers in the intervention districts benefited from the training. Only one health service provider in each of the districts indicated that they received training by UNHCO. The other 3 health workers had been involved in meetings and were aware of the SMS intervention but had not received any training. The 3 health service providers who had received training had positive perceptions of the trainings they had participated in.

The Role of Incentives

In all FGDs, VHT members discussed the importance of incentives. Incentives were discussed as the unmet need for incentives (as well as the fact that incentives had been promised but were not awarded). In general, VHT members linked their ability to utilize what they learned in the training to the enabling conditions provided through the incentives offered to them by the nongovernmental organization. These incentives were both financial and nonfinancial and included financial compensation for transportation or food, bicycles, rain boots, and t-shirts. VHT members viewed the provision of incentives as inadequate:

> *We also, as the advocates are inadequately facilitated. We don't get fed in meetings and we receive only a small allowance to facilitate us back to our residencies. So UNHCO has to change its approach first in the handling of its advocates. We serve a radius of 15 kilometers of each of the two villages, so it has to polish on the transportation within those areas of operation.* [FGD4, Participant 6]

VHT members were also critical about what they perceived as unfairness in the distribution of the incentives that were provided. For example, only a handful of people received bicycles. They viewed this as favoring one VHT member's work over the other. However, UNHCO records indicated that all VHT members received a bicycle, a monthly allowance of 20,000 Uganda Shillings (equivalent to US $5), and t-shirts. We could not identify the underlying reasons for these differences in VHT management.

Additionally, 2 groups of VHT members also discussed the need to incentivize participation on the SMS platform. The primary beneficiaries, mothers and fathers in the communities, on the contrary, did not express any need to be incentivized to participate in the SMS intervention. The two most frequently cited reasons of primary beneficiaries for registering on the mobile platform were that the messages were free and would improve quality of maternal and neonatal health outcomes:

> *Reason number one is that when they were registering us, they told us these messages are for free with no cost attached. Secondly these were health messages and I thought when I inform others the number of death rates in our community would reduce.* [Male participant 4]

Relationships Between Village Health Teams and Communities

VHT members reported a positive relationship with communities. Some VHT members shared previous negative experiences. These poor relationships were related to communities' initial resistance of VHT instructions, a belief that the VHTs received financial compensation for the work, mockery because they were not health professionals, or a perception that the VHTs were nosy. However, these views reportedly changed with evidence of positive outcomes arising from VHTs' activities. Many VHT members felt increasingly valued by the communities:

> *For example, when I had just joined VHT I had a neighbor who used to mock me saying "what can that one do" but one day one of the grandchildren she was staying with fell sick…I tested the child and gave her medicine and when the grand child was better the following day, she started spreading the news that VHTs are real doctors…The relationship is generally good, apart from a few individuals.* [FGD 6, participant 4]

For the trust relationship between VHTs and the communities, all but 3 of the primary beneficiaries expressed trust in the VHTs. Among those who indicated low levels of trust the major reason was a belief that VHTs did not maintain confidentiality. Those who expressed trust in VHTs cited reasons ranging from the selection process for VHTs, preexisting relationships between VHTs and women, and women's perception of the usefulness of the maternal health information provided by VHTs:

> *These VHTs were selected by the people of this community. They are people who are committed to doing volunteer work… Because women elected them, it makes it easier to trust.* [Woman, participant 6]

Program Designers' Assumption II

While maternal health knowledge is an important factor in maternal health-seeking behavior, additional relevant factors influenced community members' ability to engage with the intervention such as literacy level, mobile phone ownership, and male involvement in reproductive health decision making.

Literacy

The concept of an SMS platform was well received by the community and there were no complaints about network or power outages in relation to using mobile phones or receiving text messages. However, high illiteracy levels in the implementation district meant that SMS messages had a limited impact. The introduction of voice messages was a welcomed improvement to the program:

> *The voice messages are very good because at least all people apart from the deaf have ears and therefore can listen directly to what is being said and understand it well but written messages are limited to the educated.* [Woman, participant 22]

An unintended effect of primary beneficiaries' limited literacy was that women would sometimes consult VHT members when they received messages. This was raised by VHT members themselves, as well as by most of the primary beneficiaries who suggested that women who could not read the SMS could ask their VHTs for help.

Mobile Phone Ownership

For an SMS intervention that does not distribute free mobile phones to have the intended impact, it was essential that the intended message recipients already possessed mobile phones. However, about half of the study respondents indicated that they or their spouses did not possess personal mobile phones. Of the participants who indicated that they or their wives owned a personal mobile phone, low mobile literacy among women was a frequently cited problem. Low mobile phone ownership and literacy among women meant that the messages had to be received on their husband's, neighbor's, or a friend's mobile phone. When men received the messages, there was an unintended positive outcome of men getting more involved in maternal health care:

> *Since in most homes it is the men who have phones, these messages used to come directly to them and in the long run it has also improved male involvement in maternal health issues.* [FGD6, participant 3]

Male Involvement in Reproductive Health Decision Making

Participants defined male involvement as men having knowledge about required maternal health behavior and taking an active role in their pregnant spouse's health seeking. This included attending ANC visits, getting tested for HIV and other sexually transmitted infections, as well as supporting their partners in their decision to seek care.

Although men could be and were registered on the SMS platform as primary beneficiaries, they were not the intended target group. However, study participants frequently discussed the importance of male involvement in reproductive health-seeking behaviors, and husbands were often mentioned in the interviews as the decision makers. Husbands' objections to HIV testing, family planning, and facility delivery were frequently cited as potential barriers to women's ability to seek reproductive services at health facilities:

> *I have an example, a woman had not attended any antenatal services by the time she was seven months pregnant. When I asked her why she was not going to the hospital, she said her husband had not given her permission to go to the hospital and (there was) no transportation money* [FGD 3, participant 5]

Most of the participants—primary beneficiaries, VHT members, and health service providers—acknowledged that it was important for a woman to have an input in her health care decision making and that maternal health decisions should be made jointly. The majority of the men interviewed indicated that they had now started taking joint health decisions with their wives and were more involved in her maternal health. There was a general consensus that overall the situation had improved since men started receiving the SMS messages.

Program Designers' Assumption III

Results showed indications of improved accountability in client-provider relationship and increased positive experiences of primary beneficiaries at the health centers. However, our results highlighted significant individual and health barriers that influenced participants' experiences at health centers.

Individual-Level Factors

In this study, individual factors identified were knowledge of sexual and reproductive rights and responsibilities, and the relationships between primary beneficiaries and health service providers.

Knowledge of Sexual and Reproductive Rights and Responsibilities

Client's knowledge of their rights and responsibilities included the right to know the medical professionals' name, the results from the medical checkup, and to get proper prescription of medicine. Responsibilities included, following the health providers' instructions and taking medication as directed. Program developers expected that this knowledge of rights would influence relationships between service providers and their clients. All VHT members and primary beneficiaries interviewed could name at least one health right and responsibility, and they attributed this knowledge to their training or receipt of SMS messages. VHT members and health service providers shared that when women knew their health rights and responsibilities, it reduced their workload and improved their ability to provide care. VHT members also emphasized that this knowledge had helped improve the relationship between health service providers and clients:

> *Having knowledge about patients' health rights has helped us to bridge the gap between the health professions and the community members because everyone is aware of what they must do…* [FGD6, participant 8]

Primary beneficiaries agreed that the text messages had improved their knowledge about rights and responsibilities and empowered them to demand answers and appropriate treatment from the health professionals. Although VHTs and health service providers shared multiple anecdotal stories of their community members demanding treatment and actions from health service providers based on their knowledge, only one participant shared an example of actively demanding her rights when a health service provider attempted to treat her poorly.

Relationships Between Primary Beneficiaries and Health Service Providers

Despite the increase in the knowledge on health rights and responsibilities, in all interviews with VHTs, there were reports of poor treatment of clients by health service providers. However, in all but one of the intervention districts, the situation was reported to have improved considerably during the intervention period. Reasons for this improvement varied, but overall the consensus was that training of health professionals and informing primary beneficiaries of their health rights and responsibilities through the SMS platform contributed to better treatment of clients:

> *There is a large difference because those who are registered [on the SMS platform] are no longer afraid to come to the hospitals but some of the people who*

> *are not registered have a negative attitude towards hospitals.* [FGD 4, participant 2]

Responses from primary beneficiaries were similar to those of the VHTs. There were multiple accounts of past experiences with unpleasant or harsh health professionals. Although most participants reported improved treatment of clients, a few respondents from one district discussed the continued presence of disrespectful care from health service providers; this included speaking to pregnant women sarcastically or ignoring them.

At the Level of the Health System

Relevant factors that were classified at the level of the health system were related to the integration of levels of care and existing barriers to accessing care

Contributed to Better Integration of Levels of Care

The intervention contributed to improved referral. Primary beneficiaries in the intervention districts received their maternal health care from 2 levels of service providers: VHTs and health service providers (nurses, midwives, medical doctors). For participants to have positive experiences of maternal health services, the integration of these 2 levels was important. Overall primary beneficiaries, VHTs, and health service providers judged the working relationship between VHTs and health service providers positively. VHT members shared that health workers treated them as colleagues, respected their input, and worked well with them. Program beneficiaries echoed the positive collaboration between VHTs and health service providers to achieve the mutual objective of improved maternal health service delivery. The beneficiaries' experiences were related to observing the daily interactions between VHTs and health service providers; the perception that VHTs brought health education to communities on behalf of health service providers and finally, the understanding that VHTs reduced the work load of health service providers. For example, when VHTs thought that a woman needed professional medical care, they issued referral forms. Women in possession of these forms experienced that health service providers promptly addressed their cases. More effective referral systems can be considered indicative of improved health service delivery:

> *They treat her well and work with her very quickly once they have seen the referral from the VHT. The people who come with these referral forms don't even wait in the line. They are worked upon as soon as they reach the hospital.* [Woman, participant 10]

Barriers to Accessing Care

Participants also highlighted other system-level factors that influenced their overall health service experience. These included difficulties in reaching health facilities due to transportation issues and referrals to far-away district hospitals. Although UNHCO provided "mama kits" that contained required items such as bandages and clothing, this was not standard practice for every patient, and many respondents reported insufficient funds to purchase the required items (bandages and clothing) as a barrier to access care. Women shared their view that an inability to purchase these items could result in harsh words or treatment from health workers and could discourage women from seeking care. In addition, problems at the health facility, such as drug supply stock outs, lack of ambulances, staff shortage, and poorly maintained or no equipment, negatively affected experiences of maternal health seeking. The SMS intervention was not geared at fixing these health systems–related issues, but they arose consistently in interviews with all study participants as significant barriers in accessing care and their experiences of care received at health facilities.

Discussion

Principal Findings

The overall goal of the maternal SMS platform was to create an intervention in line with national health policies to improve demand and utilization of maternal health services at the community level. This paper sought to provide an additional understanding of the program outcomes by analyzing the fit between 3 implicit assumptions of a maternal SMS intervention and perceptions of program participants, including primary beneficiaries, VHTs, and health service providers. In our study, program developers' assumptions were partially supported; however, relevant mechanisms, facilitators, and barriers related to the program outcomes were identified. These are presented in Figure 2 and discussed further within this section.

Program developers assumed that training of VHTs would result in motivated VHTs who engaged with the mHealth platform. Our study found that while training was important to ensure that VHTs had the necessary knowledge, other incentives were also very relevant. VHT members discussed the importance of receiving the promised incentives and the desire for additional incentives. Previous research on the importance of incentives for community health workers (CHWs), which VHTs are classified as, have shown that when CHW perceive their incentives as not commensurate to their efforts or when the incentives are not delivered consistently, motivation is negatively affected [14,15]. Despite the sustained conversation around incentives, the impact of remuneration in mHealth interventions generally focuses on the need of funds for airtime or data purchases on mobile phones [16,17]. It must be noted that UNHCO's incentive delivery records and the report of VHTs were misaligned, but this could not be further explored in this study.

Figure 2. Revised theory of change. SMS: short message service; VHTs: village health teams.

In the program designers' first assumption, VHTs by virtue of the training received and their position in the communities would be able to recruit primary beneficiaries onto the SMS platform. Our results highlight that the relationship between VHTs and community members is influenced by various factors. This included previously researched factors, such as the selection

process of VHTs, community members' trust in VHTs, and community members' perception of the suitability of selected VHTs to provide services [18]. Consistent with findings by Musinguzi (2017), participants in our study, including VHTs, had past negative experiences with health professionals [15]. However, these experiences decreased during intervention implementation and contributed to a joint approach to providing health services; VHT members expressed that they felt the health service providers appreciated their work. Despite the intricacies of the relationship between VHTs and community members, our results did not indicate that there were any existing problems, which influenced the overall enrollment onto the SMS platform.

The second assumption—women's health-seeking behavior would improve based on information received from the SMS platform—was inconclusive due to contextual factors beyond maternal health knowledge that influenced women's health-seeking behavior. The 3 critical barriers observed were low literacy, the gender differential in mobile phone ownership, and males as decision makers in matters related to reproductive health. The effects of low literacy levels, including mobile literacy, have been highlighted as a limitation of program outcomes for health workers and patients in Uganda and similar countries [19,20,4]. UNHCO recognized low literacy level as a barrier and modified the platform to include voice messages, which primary beneficiaries and VHTs reported to be beneficial. However, the issues of male mobile phone ownership could not be addressed directly in this intervention. The intervention was modified to allow husbands to receive the text messages, but as they were not the intended targets, the messages were not tailored for them. However, the inclusion of men on the SMS platform had the unintended positive effect of improving male involvement in maternal health decision making. Given the higher levels of mobile phone ownership by men and the common role of men as decision makers in the intervention districts, these could be significant in understanding why ANC attendance and facility delivery increased, although the program designers' expectations were not met.

Finally, the third assumption explored the idea that an increase in knowledge of maternal health rights and responsibilities would lead to improved accountability in client-provider relationship and consequently positive experiences of health service centers and continued utilization of these services. However, the interviews revealed that while this knowledge was helpful and did lead to some improvements in experiences, other health system factors still negatively influenced health service experiences and continued utilization of services. These factors included accounts of mistreatment of pregnant women, payment of bribes, insults to women, and harsh treatment by health professionals—factors which were also found in previous research [21,22]. This lack of change could, in part, be ascribed to the high turnover of health service providers, which meant that a limited number (35%) of the staff in the intervention districts had actually received training on maternal rights and responsibilities. There were also issues around the availability of equipment and drugs that meant that services, which were meant to be fee exempted, still had costs. These findings indicate that while the cooperation between health service providers, VHTS, and primary beneficiaries improved, barriers to seeking care still exist and these could have impacted the intervention outcomes.

Limitations

The main limitation of this study is that while this intervention assessed perceptions of VHTs and primary beneficiaries of the SMS platform, UNHCO had other ongoing programs in the same sites. Some of these were specifically related to maternal health accountability, such as the installation of suggestion boxes at health facilities and the training of maternal and perinatal death review committees. Furthermore, the health facilities had to close down due to theft and reopened after renovations. The multiplicity of interventions as well as the time elapsed (retrospective design) since the end of the intervention might have affected the recall of participants. To address this, participants were consistently probed and asked follow-up questions to ensure that they were referring to the SMS intervention. Another possible limitation arises from the decision to utilize health centers as the recruitment location of female primary beneficiaries. This might mean that our respondents are a select subgroup who actively utilize health services. However, recent statistics report high attendance of at least one ANC and high uptake of infant vaccination [23]. Thus, clients at health center during routine clinic hours were likely to represent a spectrum of health-seeking behaviors such as those found in the general population. In addition, within our sample, we conducted interviews until no new information emerged, ensuring that data saturation was reached. As with all research that relies on self-reported data, there was a risk that participants gave socially desirable answers. We attempted to minimize this risk by reassuring participants that all the information they provided would be kept confidential. We also ensured that no staff member of the UNHCO team or health center was within the vicinity when the interviews took place. Finally, we were unable to test the assumptions raised in this study as we focused more on understanding how the assumptions played out during intervention implementation. This could be an interesting starting point for future research. For example, future research could involve systematically assessing the relationship between VHTs and their community members and the effect of this on intervention outcomes.

Conclusions

In reflecting on the role of SMS messaging as a tool to achieving maternal health outcomes, some key messages emerged. The utilization of a program theory allows for the unpacking and testing of intervention designers' assumptions. Our results highlight the importance of using program theory to highlight the need to address the broader contextual factors that could limit the achievement of their intended mHealth outcomes. In contexts when there are health system barriers, such as informal payments, frequent staff turnover, drug stock outs, and the lack of integration of service platforms, the study shows that program designers could adapt program outcome expectations or modify the intervention to address these system factors. We conclude that SMS interventions such as this could be most effective when incorporated in comprehensive multilevel programs, which address health system barriers and constraints.

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Conflicts of Interest

None declared.

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Abbreviations

ANC: antenatal Care
CHWs: community health workers
FGD: focus group discussion
LMIC: low- and middle-income countries
mHealth: mobile health
SMS: short message service
UNHCO: Ugandan National Health Commission
VHTs: village health teams

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Original Paper

"The Doctor Needs to Know": Acceptability of Smartphone Location Tracking for Care Coordination

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Abstract

Background: Care coordination can be highly challenging to carry out. When care is fragmented across health systems and providers, there is an increased likelihood of hospital readmissions and wasteful health care spending. During and after care transitions, smartphones have the potential to bolster information transfer and care coordination. However, little research has examined patients' perceptions of using smartphones to coordinate care.

Objective: This study's primary objective was to explore patient acceptability of a smartphone app that could facilitate care coordination in a safety net setting. Our secondary objective was to identify how clinicians and other members of primary care teams could use this app to coordinate care.

Methods: This qualitative study was conducted at a federally qualified health center in metropolitan Chicago, IL. We conducted four focus groups (two in English, two in Spanish) with high-risk adults who owned a smartphone and received services from an organizational care management program. We also conducted structured interviews with clinicians and a group interview with care managers. Focus groups elicited patients' perceptions of a smartphone app designed to: (1) identify emergency department (ED) visits and inpatient stays using real-time location data; (2) send automated notifications (ie, alerts) to users' phones, asking whether they were a patient in the hospital; and (3) send automated messages to primary care teams to notify them about patients' confirmed ED visits and inpatient stays. Focus group transcripts were coded based on emergent themes. Clinicians and care managers were asked about messages they would like to receive from the app.

Results: Five main themes emerged in patient focus group discussions. First, participants expressed a high degree of willingness to use the proposed app during inpatient stays. Second, participants expressed varying degrees of willingness to use the app during ED visits, particularly for low acuity ED visits. Third, participants stated their willingness to have their location tracked by the proposed app due to its perceived benefits. Fourth, the most frequently mentioned barriers to acceptability were inconveniences such as "false alarm" notifications and smartphone battery drainage. Finally, there was some tension between how to maximize usability without unnecessarily increasing user burden. Both clinicians and care managers expressed interest in receiving messages from the app at the time of hospital arrival and at discharge. Clinicians were particularly interested in conducting outreach during ED visits and inpatient stays, while care managers expressed more interest in coordinating postdischarge care.

Conclusions: High-risk primary care patients in a safety net setting reported a willingness to utilize smartphone location tracking technology to facilitate care coordination. Further research is needed on the development and implementation of new smartphone-based approaches to care coordination.

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KEYWORDS

delivery of health care; primary care; health information technology; smartphone; mHealth

Introduction

Care coordination—the deliberate organization of information transfer and care processes to facilitate the appropriate delivery of health services—is a pillar of high-functioning primary care practices [1,2], but can be highly challenging to carry out. In many communities, such as large urban areas, care is fragmented across health systems and providers [3,4]. Resulting failures in care coordination can lead to adverse outcomes such as hospital readmissions [5] and wasteful health spending [5,6].

Health information technology (IT) and targeted chronic care interventions can support care coordination, but the reach and effectiveness of these approaches is limited. Electronic health records (EHRs) are often unable to facilitate care coordination between organizations [4,7], and less than half of US hospitals [8] and providers [9] participate in an operational health information exchange (HIE). While interventions that prioritize care coordination, such as disease management and transitional care programs for chronically ill patients, have reduced hospital admissions [10-12] or improved patient-reported outcomes [11,12], their replicability and scalability are limited by a lack of global cost-savings [10,13]. New, high-value approaches to care coordination are urgently needed.

Smartphones are increasingly ubiquitous among adults [14,15] and have the potential to bolster information transfer and care coordination in health care. For example, if a patient is discharged from an inpatient stay, smartphone location tracking technologies might be able to identify the discharge in real time, and then send a message to the patient's primary care provider (PCP) to initiate postdischarge care coordination. Although one prior study evaluated the use of smartphone-based geofencing (ie, the creation of virtual geographic boundaries to define a particular location) to ascertain hospitalizations [16], to our knowledge no prior research has examined patients' perceptions of using smartphones to coordinate care.

The primary aim of this study was to explore patient acceptability of a smartphone app that could facilitate care coordination in a safety net setting. Our secondary aim was to identify how clinicians and other members of primary care teams could use this app to coordinate care. We hypothesized that the proposed app would be acceptable to patients if it was minimally disruptive and easy to use.

Methods

Study Design and Setting

This qualitative study was conducted at Erie Family Health Center (described henceforth as "Erie"), a federally qualified health center (FQHC) in metropolitan Chicago, IL that serves a largely Hispanic patient population; 73% of Erie patients are Hispanic, and 47% are best served in Spanish [17]. Between November 2015 and January 2016, we conducted four patient focus groups (two in English, two in Spanish), structured interviews with clinicians, and a group interview with care managers. All study protocols were approved by Northwestern University's Institutional Review Board.

Erie owns and operates seven adult primary care clinics, all of which have achieved Joint Commission Primary Care Medical Home certification. The majority of Erie's patient population is low income, over 80% are racial/ethnic minorities, and approximately 60% have Medicaid coverage [17]. Since 2014, Erie has had a care management program for high-risk patients; this program is funded through an Accountable Care Organization and a Medicaid Managed Care Organization that was established during Illinois' Medicaid expansion under the Affordable Care Act [18]. Care managers are colocated with clinicians at each clinic and work with patients on tasks such as chronic care planning and coordination of care following emergency department (ED) visits and inpatient stays. Patients screen into the care management program through criteria such as repeated ED or inpatient use, inpatient stays for chronic illnesses, or the presence of numerous social and clinical risk factors.

Erie also partners with several local organizations to support coordination of care. Erie clinicians have read-only access of EHRs at some local hospitals and specialty care providers. Erie providers can also access real-time data on the use of several local EDs for patients in one local Medicaid plan. However, Chicago does not have an operational citywide HIE [19,20], and Erie providers cannot comprehensively detect hospital use across the Chicagoland metro area.

Participants

Patients were eligible for focus group participation if they were: an adult (age 18-89) whose preferred language was English or Spanish; receiving services from an Erie care manager; and self-reported ownership of a smartphone. Patients were excluded if they were pregnant, or they had dementia or another behavioral health condition where Erie staff felt it would be inappropriate to contact them. We recruited patient participants by mailing them a lead letter about the study and a number to call to opt out of recruitment. Approximately one week later, a bilingual Erie research assistant called patients to tell them about the study and screen for study eligibility. Eligible, interested patients who elected to participate in the study provided written informed consent at the beginning of each in-person focus group; participants received a US $30 gift card at the end of each focus group, which averaged approximately 90 minutes.

Clinicians were recruited for individual phone interviews via convenience sampling. The group interview included all attendees at a monthly meeting for Erie's care management program. Clinicians and care managers voluntarily participated in interviews and provided informed consent at the beginning of each interview.

Figure 1. Proposed push notification sent to patient's smartphone after app detects a potential hospital visit (left: English; right: Spanish).

Interview Guide and Data Collection

Prior to each focus group, patient participants completed a brief questionnaire about their demographic characteristics, comorbidities, and smartphone usage. The moderator then used a semistructured guide to elicit participants' perceptions of a smartphone app designed to: (1) use real-time smartphone location data to identify potential ED visits and inpatient stays at Chicago-area hospitals; (2) send automated push notification s (ie, alerts) to users' phones, asking them whether they were a patient in the hospital, such as the messages presented in Figure 1 (image on the left presented at English focus group; image on the right presented at Spanish focus group); and (3) send automated messages to Erie primary care teams to notify them about patients' confirmed hospital visits.

The moderator asked participants about their willingness to respond to push notifications from the app. Participants were also asked about their preferred wording and frequency of alerts, their perceptions of "false alarms" (ie, push notifications sent at times when they were not receiving emergency or inpatient care), as well as potential privacy concerns and desirable/undesirable app features.

Clinicians and care managers were asked about the timing and modality (eg, secure message, telephone call) of automated messages they would like to receive from the app, data points to include in messages, and how to integrate messages into existing clinical workflows. Patient-facing study documents were drafted in English and translated into Spanish by a certified translation service. Clinician and care manager interviews were conducted in English. All focus groups and interviews were audio recorded and transcribed.

Analysis

Patient focus group transcripts were analyzed by two members of the research team (DTL and JW analyzed English transcripts; ES and KN analyzed Spanish transcripts) in multiple rounds to organize the content into emergent themes [21,22], where we derived basic concepts (themes) from the data and compared them with other data to facilitate meaningful categorizations [23,24]. After an initial round of analysis by each coder, coders met to generate a list of common thematic categories across focus groups. In the second round of analyses, each coder assigned theme-based codes to the qualitative results, and discrepancies between coders were addressed based on further discussion and consensus within each coding dyad. See Multimedia Appendix 1 for a complete list of themes and codes. Coders then reviewed the transcripts together and selected quotes that exemplified major themes. Clinician and care manager responses to interview questions were reviewed and summarized by two members of the research team (DTL and JW).

Results

Patient Focus Groups

The four patient focus groups took place in November and December 2015, with 16 patients participating. Baseline

characteristics are shown in Table 1. Most participants were aged either 30-49 or 50-64 years, the majority were female, and half were Latino/Hispanic. As might be expected of patients under active care management, there were high rates of self-reported chronic illness, with seven (7/16, 44%) reporting diabetes, four (4/16, 25%) reporting asthma, and eight (8/16, 50%) reporting hypertension. Nine of 16 participants (56%) reported owning smartphones with the Android operating system, and only one reported owning a smartphone with the iOS operating system. One participant had a Windows phone, and five (5/16, 31%) reported other/missing operating system.

Five main themes emerged in patient focus group transcripts (Table 2). First, participants expressed a high degree of willingness to use the app and respond to push notifications during inpatient stays. Participants felt that the app would keep their PCP informed about important developments in their care, which would in turn promote communication with the PCP during the inpatient stay or soon after discharge. When asked about their willingness to respond to the proposed push notifications after being admitted to the hospital, one participant stated, "Well, yeah, the doctor needs to know."

Second, patient participants expressed varying degrees of willingness to use the app during ED visits, particularly for low acuity events. Some participants described using the ED as an alternative source of primary care or a source of after-hours primary care. Selected participants, some of whom were relatively new patients at Erie and may have been uninsured prior to the Affordable Care Act Medicaid expansion, stated that they might respond "No" to a push notification if they were in the ED for a nonsevere condition.

Third, participants stated their willingness to have their location tracked by the proposed app, due to its perceived benefits; they had prior experience with location tracking and seemed to accept it as a part of smartphone ownership and modern society. As one participant stated, "We're being followed and watched every day, all day long so what's the problem with a[n] app locating where you at?" Perhaps most importantly, participants implied or explicitly stated that the app was serving a desirable function and they understood how location tracking was being used to achieve this goal.

Table 1. Participant characteristics for patient focus groups (N=16).

Characteristic	n (%)
Age (years)	
18-29	3 (18.8)
30-49	6 (37.5)
50-64	6 (37.5)
+65	1 (6.2)
Sex	
Female	9 (56.2)
Male	7 (43.8)
Race/ethnicity	
Non-Hispanic white	2 (12.5)
Non-Hispanic black/African American	6 (37.5)
Hispanic/Latino	8 (50.0)
Chronic illnesses	
Diabetes	7 (43.8)
COPD[a], chronic bronchitis or emphysema	1 (6.2)
Asthma	4 (25.0)
Hypertension	8 (50.0)
Coronary artery disease	0 (0)
Heart failure	1 (6.2)
Smartphone operating system	
Android	9 (56.3)
iOS	1 (6.2)
Windows Phone	1 (6.2)
Other/missing	5 (31.3)

[a]COPD: chronic obstructive pulmonary disease.

Table 2. Emergent themes from qualitative analysis of patient focus groups.

Theme	Related quotes
Acceptable overall, willing to use app during inpatient stays	• I think what's good about it is to let him know that I'm in the hospital now and come see you soon, because evidently something really seriously happened to me to be in the hospital and to be, like you said, to be sitting in there in a hospital bed. So of course I would want him to know. I think that would be a good app, to let him know. • It's easy, it's one button.[a]
Limited willingness to use app during low-acuity emergency department visits	• I don't want to bother my doctor with the fact that nobody could get me in, but my fever's 101, I think I need an antibiotic but it's not an emergency but my doctor couldn't see me until next Thursday. So I say, "No," I'm not actually here, even though I'm here. • If I am in the emergency room, I think it would be [good to respond] after you are admitted and they tell you what you have.[a]
Willingness to have location tracked to share important information	• I think that it's really good that it does know where you're at. • Facebook has [location tracking], Google has it, Twitter has it, Instagram has it. Everything has your information. So, to have something that is necessary, something important, it won't bother me. If all apps have my information, it won't bother me to have one more.[a]
Barriers to acceptability	• The location - the number one thing for me is I am not going to download the app if it is completely going to drain my battery. If it's just going to use up my whole entire battery from running in the background, I'm not going to want it on my phone and I think a lot of people would agree. • If like you said, every time I pass the front of the hospital, I receive an alarm, I'd rather delete it.[a]
Usability: tension between adding features and increasing user burden	• If it's your app, okay, you [have] got to make it personal because if it's your app, you know, you see apps sometimes, they say hello [name], or hello so and so, it should know that it's you. See what I'm saying? So maybe when you first get it you would put your name on there and everything. When that alert comes on it's going to say [name], are you in the hospital? Are you in the emergency room? • Well I think the correct thing would be for [my doctor] to know exactly why they are seeing you.[a] • The only thing [my doctor] needs to know is that you're in the hospital and after you're out you can go to her and take all the paperwork or she asks you why you were in.[a]

[a]Quote from Spanish-speaking participant translated into English.

Fourth, inconveniences to app users were the most frequently mentioned barriers to acceptability. Participants did not want to receive "false alarm" notifications if they were not in the hospital, and they thought that push notifications should not fire too soon after they entered a hospital building. If they initially did not respond to push notifications, they did not want these notifications to repeat too frequently, since their initial failure to respond could signify that they were unavailable due to factors such as being unconscious or asleep. One participant stated that other apps with location tracking functions had drained his phone's battery, and that he was unwilling to use any apps with this flaw.

Finally, there was some tension between how to maximize usability without unnecessarily increasing user burden. On one hand, a limited number of participants said they would like to use the app to send clinical information about their hospital visit (ie, their admitting diagnosis or which inpatient unit they were in) to their primary care team. Some participants also expressed a desire to personalize the app through features such as customizable app settings (eg, tailored push notification sounds) or including their name in push notifications. However, there was not a high degree of agreement between participants about which clinical data points to share with primary care teams, or about the most desirable features to include in the app.

One area of participant agreement was the confusing wording of the question in proposed push notifications (Figure 1), which asked app users whether they were in the hospital, without distinguishing between patients receiving hospital-based medical care and other hospital visitors, such as those visiting a hospitalized friend or family member. In one focus group, several participants agreed that this question should be changed to, "Are you a patient in the hospital right now?"

Clinician/Care Manager Interviews

Three clinicians (two physicians, one nurse practitioner) participated in phone interviews. In the care management group interview, nine respondents (seven care managers, the care management program coordinator, and the program manager) participated. Clinicians and care managers expressed interest in receiving messages from the app at both the patients' time of hospital arrival and at discharge. Clinicians were particularly interested in acting on messages received at arrival in order to conduct outreach to the emergency/inpatient care team, while care managers expressed more interest in acting on alerts received at discharge in order to coordinate postdischarge care. Respondents were interested in obtaining automated data from the app, such as hospital name, phone number, and the patient's approximate time of arrival and discharge. Clinicians expressed interest in receiving EHR-based alerts (ie, flags) about patients' hospital arrival during times when they were seeing patients in clinic; they were interested in receiving text messages at other times. Care managers were most interested in receiving EHR-based alerts about hospital arrival and discharge.

Some clinicians and care managers expressed interest in obtaining clinical information that would require manual data entry by app users, such as admitting diagnosis, discharge diagnosis, or changes in medication regimens. However, these sentiments were counterbalanced by a desire to limit both the number of messages sent to care teams and the extent to which patients would expect real-time responses from their care teams.

Discussion

Principal Results

In these focus groups, high-risk primary care patients reported a willingness to utilize smartphone location tracking technology to facilitate care coordination. Notably, study participants already received care coordination services through their FQHC's care management program, yet they saw value—and opportunities for potential improvement—in the proposed smartphone-based approach to facilitating information transfer and care coordination. Participants were particularly willing to respond to push notifications about inpatient stays, although some expressed limited willingness to use the app to notify care teams about low-acuity ED visits. Participants expressed concern about barriers to acceptability, such as "false alarm" notifications and draining their phone's battery. While usability might be increased by allowing users to tailor the look and feel of the app, there was a lack of agreement—and the potential for decreased usability—about data that should be manually entered into the app.

Comparison With Current Evidence

These results are informative in the context of the current health IT landscape and may represent an opportunity for developing new approaches to care coordination. The inability to transfer clinical information between organizations remains a persistent barrier to care coordination, as evidenced by a recent decrease in the number of operational HIEs [9] and the challenges primary care practices face in using health IT to coordinate emergency and inpatient care [4]. The potential benefits of the proposed app may be especially high in regions with no HIEs, particularly in population centers with multiple hospitals. The proposed app may also have high utility in settings where information transfer is fragmented during care transitions, such as small outpatient practices that are not affiliated, or lack formal information sharing protocols, with local hospitals.

Our findings seem to align with those of a prior qualitative study, in which consumers expressed willingness to make tradeoffs between privacy and security if a mobile health (mHealth) intervention offered increased convenience or benefits [25]. Additionally, given that over three-fourths of American adults own smartphones [15], the potential scalability of the app proposed in these focus groups is extremely high.

These findings are also noteworthy in the context of health IT use in safety net settings and among racial/ethnic minorities. Although minorities are disproportionately likely to own a smartphone [14] and to have chronic conditions requiring care coordination [26,27], past research has found that racial/ethnic minorities had lower uptake of technologies such as patient portals [28,29] or a longitudinal mHealth intervention with daily text messaging [30]. In contrast, high-risk FQHC patients in this study expressed a willingness to use the proposed app, which leverages automated location tracking technologies in a way that could enhance information transfer to PCPs, while requiring minimal human effort from app users.

Limitations

This study has several limitations of note. The smartphone app proposed in these focus groups may be unnecessary in settings such as communities with operational HIEs, or in integrated delivery systems with well-organized care coordination workflows between the primary care, emergency, and inpatient settings. This was an exploratory study that was conducted in a single urban FQHC, and our findings may therefore not be generalizable to other organizations or populations. Further research on the proposed app is needed in other populations and settings (eg, privately insured patients, non-FQHC sites) to examine the external validity of our findings. Additionally, the study sample consisted of high-risk patients in a care management program who owned smartphones; these participants may have been more knowledgeable about care coordination, and more motivated to address current gaps in information transfer, compared to lower-risk groups or patients who lack a source of comprehensive, team-based primary care. Individuals who voluntarily participate in focus groups about a smartphone app may also be more comfortable with health IT than the general population. By design, we only held a small number of focus groups and interviews at this early stage of the app development process. This small sample size was sufficient for addressing our study aims but may further limit the generalizability of findings. Unfortunately, nearly one third of focus group participants did not provide data on their smartphone's operating system. However, most of those who provided data for this questionnaire item had an Android phone; this finding is consistent with published national data showing much higher rates of Android ownership (compared to iOS) among low income groups [31]. Early app development efforts in the patient population under study here should therefore prioritize an Android-based app, followed by an iOS app.

Conclusions

A proposed smartphone-based approach to facilitating care coordination was acceptable to high-risk adults in an urban FQHC. Further research is now needed on the feasibility of developing and implementing this type of smartphone app within an organizational care coordination initiative, and its potential effects on information transfer and care coordination.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

List of themes and codes from analysis of patient focus group transcripts.

[PDF File (Adobe PDF File), 24KB - mhealth_v6i5e112_app1.pdf]

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Abbreviations

ED: emergency department
EHR: electronic health record
FQHC: federally qualified health center
HIE: health information exchange
IT: information technology
mHealth: mobile health
PCP: primary care provider

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Original Paper

Novel Method to Efficiently Create an mHealth App: Implementation of a Real-Time Electrocardiogram R Peak Detector

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Abstract

Background: In parallel to the introduction of mobile communication devices with high computational power and internet connectivity, high-quality and low-cost health sensors have also become available. However, although the technology does exist, no clinical mobile system has been developed to monitor the R peaks from electrocardiogram recordings in real time with low false positive and low false negative detection. Implementation of a robust electrocardiogram R peak detector for various arrhythmogenic events has been hampered by the lack of an efficient design that will conserve battery power without reducing algorithm complexity or ease of implementation.

Objective: Our goals in this paper are (1) to evaluate the suitability of the MATLAB Mobile platform for mHealth apps and whether it can run on any phone system, and (2) to embed in the MATLAB Mobile platform a real-time electrocardiogram R peak detector with low false positive and low false negative detection in the presence of the most frequent arrhythmia, atrial fibrillation.

Methods: We implemented an innovative R peak detection algorithm that deals with motion artifacts, electrical drift, breathing oscillations, electrical spikes, and environmental noise by low-pass filtering. It also fixes the signal polarity and deals with premature beats by heuristic filtering. The algorithm was trained on the annotated non–atrial fibrillation MIT-BIH Arrhythmia Database and tested on the atrial fibrillation MIT-BIH Arrhythmia Database. Finally, the algorithm was implemented on mobile phones connected to a mobile electrocardiogram device using the MATLAB Mobile platform.

Results: Our algorithm precisely detected the R peaks with a sensitivity of 99.7% and positive prediction of 99.4%. These results are superior to some state-of-the-art algorithms. The algorithm performs similarly on atrial fibrillation and non–atrial fibrillation patient data. Using MATLAB Mobile, we ran our algorithm in less than an hour on both the iOS and Android system. Our app can accurately analyze 1 minute of real-time electrocardiogram signals in less than 1 second on a mobile phone.

Conclusions: Accurate real-time identification of heart rate on a beat-to-beat basis in the presence of noise and atrial fibrillation events using a mobile phone is feasible.

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KEYWORDS

atrial fibrillation; arrhythmia; heart rate variability; MATLAB Mobile; mobile device

Introduction

Background

An algorithm that runs in real time and precisely calculates the heart rate from electrocardiogram (ECG) signals on a beat-to-beat basis can serve as the core of a mobile system to remotely monitor patient health [1] and issue alerts in the case of cardiac events [2,3]. Due to their increasing computational power, wireless and Bluetooth connectivity, and the ability to store data on the cloud, mobile phones and tablets can run real-time algorithms to alert the patient and communicate with the medical staff. The main challenge in designing such a mobile bundle is to develop robust, automatic algorithms that provide

real-time results and can work on noisy data recorded using a portable ECG monitor, while consuming low power. Importantly, to detect potentially fatal arrhythmogenic events, very accurate detection of R peaks on the ECG is required (in addition to other waves). For example, atrial fibrillation (AF) events characterized by an irregular and often rapid heart rate [4] are currently identified retrospectively by screening the ECG signal or using other pulse signals. Because AF can lead to stroke and ventricular fibrillation, early detection of these episodes has enormous clinical impact. It has been known for a while that the R-R pattern can be used to detect AF events when they occur or even predict them [5]. The first step in identifying AF events in real time is precise, automatic detection of R peaks to calculate the heart rate on a beat-to-beat basis.

Heart rate variability (HRV) indexes can be used to detect AF events [6-8]. To precisely calculate HRV indexes, the beat interval should be identified at each heartbeat as a first step. The R peak is the dominant point in the ECG and serves as an ideal fiducial point to calculate the heart rate.

Prior Work

Although apps to monitor heart rate using mobile device sensors do exist, they have several drawbacks. First, they work poorly on patients with heart disease versus individuals with normal heart rhythm [9]. Although a breakthrough was recently achieved in dealing with arrythmic recordings and other noise [10], it still does not provide real-time results [3]. Furthermore, only an average heart rate over a time window is provided and not the beat-to-beat interval (which is necessary for HRV analysis). Certain artifacts specific to the ECG signal can limit automated detection of the heart rate [10]: (1) sudden movement of the patient, (2) drift of the signal, (3) breathing noise, (4) wrong polarity (the ECG leads are set upside down), (5) electrical spikes from the device, (6) high frequency noise from the environment, (7) premature ventricular contraction, and (8) enlarged P or T waves. Several techniques to accurately decode the ECG have been suggested, including Fourier transform [11], Hilbert transform [11], and Wavelet transform [12], among others. These techniques require long ECG signal recordings; thus, they cannot serve as the core of a system that provides real-time R peak detection.

The recently developed MATLAB Mobile environment platform allows any algorithm, even one with high computational demands, to be converted to run on a mobile app, but its suitability for mHealth apps was never tested.

Goal

We aim (1) to evaluate the suitability of the MATLAB Mobile platform for mHealth apps and whether it can run on any phone system, and (2) to embed in the MATLAB Mobile platform a robust real-time ECG R peak detector with low false positive and low false negative detection in the presence of AF, the most frequent arrhythmia. Because our main goal is to implement an ECG R peak detector on a mobile device, the mobile app should be compatible with any phone system.

We first present our algorithm for peak detection. The algorithm works by filtering the signal with high polynomial fit, decoding the first and second derivatives of the signals, filtering peaks that have low probability to be the R peak, and outputting the R peak location. We show that the algorithm can deal with the previously mentioned artifacts. Moreover, it can accurately identify the R peaks, as demonstrated by evaluating the algorithm's performance on the MIT-BIH database (gold standard database from Physionet) and comparing it to other algorithms [13-15]. Later, we demonstrate how the MATLAB Mobile platform can be used to implement the algorithm on a mobile phone. Finally, we show that the algorithm can identify R peaks in real time from data acquired by a mobile ECG device.

Methods

Database

The proposed algorithm was tested on the MIT-BIH Arrhythmia Database [16], which includes data from patients who suffer from AF (n=25) and from healthy subjects (n=23). For each recording, the data was analyzed in its entirety regardless of whether artifacts appeared. Each record contains more than half an hour of continuous data, sampled at a rate of 360 Hz. The database is approved by an institutional review board, publicly available, and the patient information was deidentified. A total of 48 records of ECG strips from two leads (one channel) were originally obtained from 47 subjects (there are two records from the same participant) between 1975 and 1979 in Boston's Beth Israel Hospital Arrhythmia Laboratory. The actual database contains 23 recordings of 30 minutes that were randomly chosen from a set of 4000 24-hour ambulatory ECG recordings collected from a mixed population of AF inpatients (approximately 60%) and outpatients (approximately 40%) at Boston's Beth Israel Hospital. It also includes 25 recordings selected from the same set to include less common but clinically significant arrhythmias that are not usually present in a small random sample. The ECG recordings were made using Del Mar Avionics model 445 two-channel reel-to-reel Holter recorders. The recordings were digitized at 360 samples per second per channel with 11-bit resolution over a ±10 millivolts range and a notch filter was used to remove 60 Hz power line interference (Del Mar Avionics model 660 playback unit). Because of problems in the digitization, the analog signals from the playback unit were filtered to limit saturation in analog-to-digital conversion and for antialiasing, using a passband of 0.1 to 100 Hz relative to real time. The digitized 11-bit samples were converted into 8-bit first differences on the fly, thus limiting the slew rate to 225 millivolts per second (no major effect on the data). Two or more cardiologists independently annotated each record; disagreements were resolved and annotations for each beat (112,415 annotations overall) were included with the database.

General Approach

Our method for detecting the R peak includes six mathematical manipulations (Figure 1A) and nine steps (Figure 1B). The algorithm deals with sudden movement of the patients, electrical drift, breathing noise, electrical spikes, environmental high frequency noise, reverse polarity, premature ventricular contraction, and enlarged P or T waves. See Figure 1B for a step-by-step description of how the R peaks were detected. We used both physiological and data-sample criteria. To define the frequency above or below the R-R interval, we used

physiological criteria (explained subsequently). However, the definition of the kernel width is based on data sampling frequency (explained subsequently).

R Peak Detection in the Presence of Sudden Patient Movement

Sudden movement of the patient leads to low frequency noise in the ECG signal (Figure 2A-D). As demonstrated in Figure 2A, this type of noise increases the ECG amplitude (making it higher than the R peak itself), interfering with R peak identification. To filter this artifact and others, 34th order polynomial fit was applied to each 15-second interval (Moore-Penrose pseudoinverse), which was subtracted from the accumulated 15-second signal segment (see Equation 1 in Figure 3).

We used the data from healthy subjects to find the degree of the polynomial and we tested it on the entire database (Multimedia Appendix 1). Multimedia Appendix 1 shows the percentage of true positive (see subsequent definition) results as a function of the filter order (the entire MIT-BIH Arrhythmia Database was used). The 34th polynomial order provides the optimum results (minimal polynomial number that provides the highest true positive results) for this and other noise sources.

Figure 1. Flowchart of (A) the mathematical manipulations necessary to deal with each artifact/noise type and (B) the algorithm for identifying R peaks.

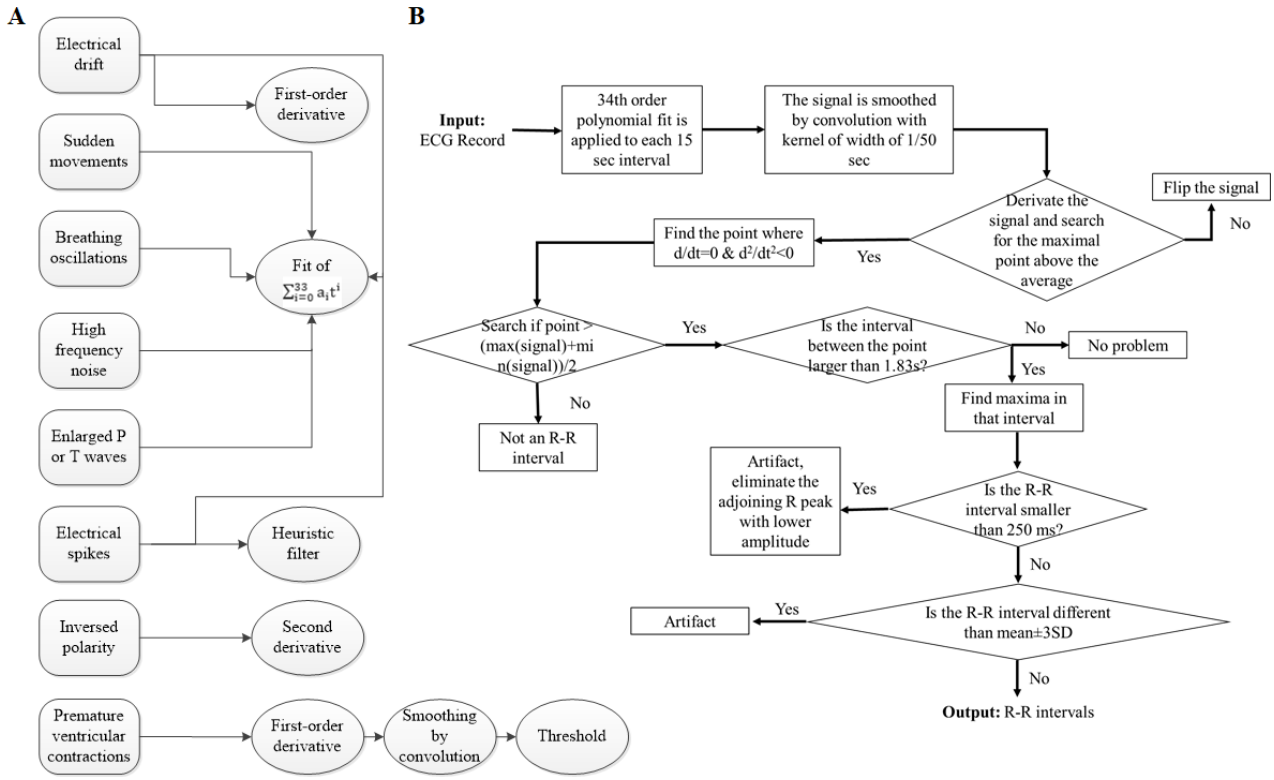


Figure 2. A representative example of a sudden movement artifact in the (A) time and (B) frequency of the ECG signal. Representative examples of ECG signals in (C) time and (D) frequency domains after filtering of the movement artifact. Data from MIT-BIH Arrhythmia Database #101.

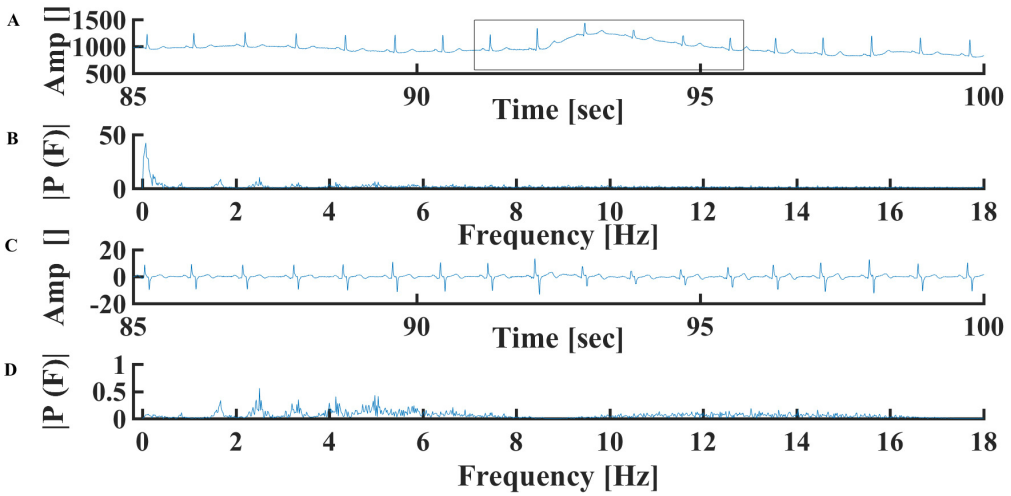


Figure 3. Equations. FN: false negative; FP: false positive; TN: true negative; TP: true positive; PPV:positive predictive value; Se: Sensitivity; Balanced F score (F1).

$$(1)\ S = S_{orig} - S_{est}\ ,\ S_{est} \equiv \sum_{i=0}^{33} a_i t^i\ ,\ \text{where } a_i \text{ of } S_{est} \text{ was found by argmin} \sqrt{S_{orig}^2 - S_{est}^2}$$

$$(2)\ (f * g)[n] = \sum_{m=-M}^{M} f[n-m]g[m]$$

$$(3)\ g[n] = \begin{cases} \frac{1}{50}, & |n| < 25 \\ 0, & else \end{cases}$$

$$(4)\ TP = \begin{cases} 1, & \Delta T \leq 150[ms] \\ 0, & \Delta T > 150[ms] \end{cases}$$

$$(5)\ FP = \begin{cases} 1, & \Delta T > 150[ms], Physionet = 0, Our = 1 \\ 0 \text{ otherwise} \end{cases}$$

$$(6)\ FN = \begin{cases} 1, & \Delta T > 150[ms], Physionet = 1, Our = 0 \\ 0 \text{ otherwise} \end{cases}$$

$$(7)\ PPV = \frac{TP}{TP + FP} x100$$

$$(8)\ Se = \frac{TP}{TP+FN}.$$

$$(9)\ F_1 = \frac{2TP}{2TP+FN+FP}.$$

R Peak Detection in the Presence of Breathing Oscillations

Patient breathing (due to chest movement) leads to slow fluctuation (<1 Hz) of the ECG signal (Figure 4A). To filter this artifact, a midlow polynomial fit is required. Because the signal is filtered by the high-order polynomial fit (described previously), no additional signal filtering is needed (Figure 4B).

R Peak Detection in the Presence of High Frequency Environmental Noise

High frequency artifacts appear at 50 or 60 Hz (electrical net) or at 100 Hz (fluorescent lamps). These artifacts are filtered out by the high degree of the polynomial fit. Because the original data were notch filtered, no such examples can be illustrated.

R Peak Detection in the Presence of Enlarged P or T Waves

As demonstrated in Figure 4C, the enlarged T wave may be detected as an R wave. To filter that noise, a middle-high polynomial fit degree must be applied (filtered by the same 34th degree polynomial fit; Figure 4D). The same steps are applied for enlarged P waves.

R Peak Detection in the Presence of Electrical Drift

Fluctuation in room temperature, heating of the device, or changes in the battery demand of the device (ie, power management) may lead to drift in the electrical signal. As demonstrated in Figure 5A, the drift appears as a slow and monotonic gain change of the device's electrical signal. Because the signal is filtered by the high-order polynomial fit (described previously), no additional signal filtering is needed (Figure 5B). Note that derivation of the signal to eliminate other sources of noise also reduces low frequency drift.

R Peak Detection in the Presence of Electrical Spikes

Random spikes often appear in the ECG signal (Figure 5C-F). These spikes are distinguished from premature beats because they are not repetitive and the consecutive R peaks are normal. Two kinds of spikes appear: (1) relatively low frequency (Figure 5C) and (2) high frequency (Figure 5E). The former artifact is filtered by the high-order polynomial fit (described previously; Figure 5D). Assuming heuristic minimal temporal distance between two adjacent R peaks, the high frequency spikes are filtered. In short, we searched for consecutive beats with temporal distance of less than 250 milliseconds (far from the maximal heart rate). In the case of adjacent peaks with distance lower than 250 milliseconds, the R peak with lower amplitude is eliminated. Such a filter is called a heuristic filter (because it is based on empirical physiological knowledge). Figure 5F demonstrates that indeed an electrical spike is not recognized as a peak.

R Peak Detection With Reverse ECG Polarity

Swapping between ECG leads can cause negative polarity of R peaks relative to the electrical signal (Figure 6A). To overcome this problem, the signal derivative is used and maximal points are searched. If the majority of maximal points have negative values, the signal polarity is swapped (Figure 6B). In addition, the second derivative of the signal is calculated to verify that, in the case of regular polarity, the peaks are indeed maxima points, and in the case of negative polarity, the peaks are minima points.

Figure 4. Representative example of (A) slow respiratory oscillation noise (the box represents a breathing cycle) and (B) ECG signal after respiratory oscillation filtering. Data from MIT-BIH Arrhythmia Physionet database #101. Repetitive examples of (C) enlarged T wave and (D) ECG signal after enlarged T filtering. Data from MIT-BIH Arrhythmia Database #230.

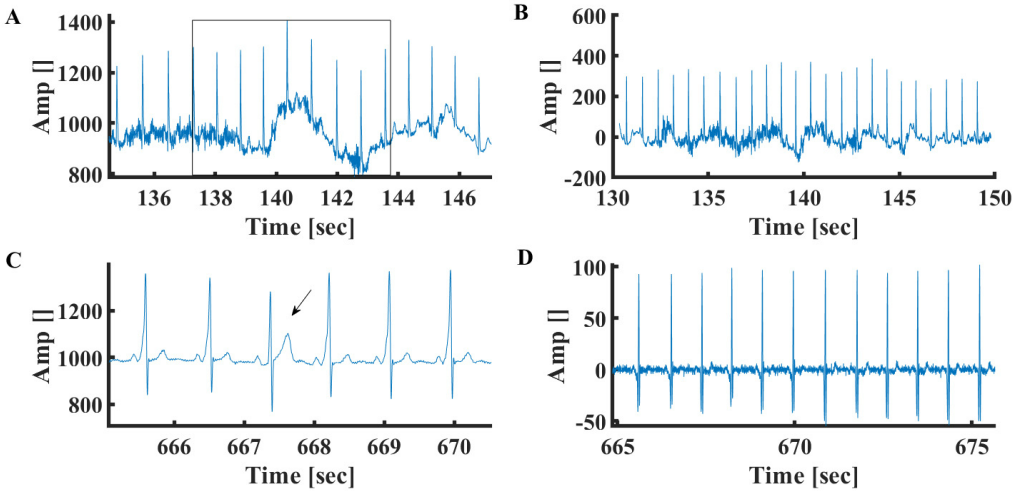
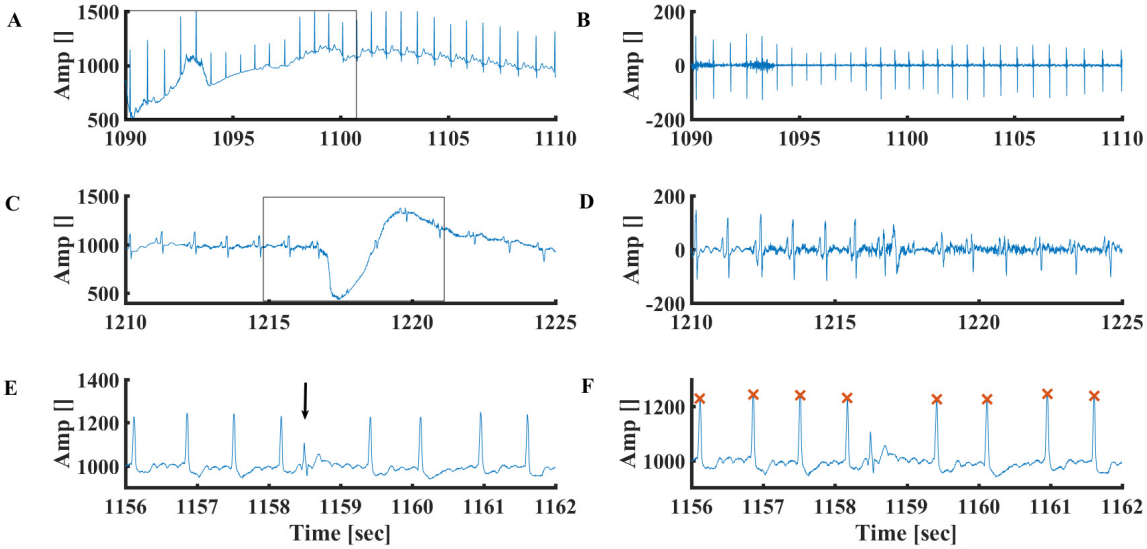


Figure 5. Representative example of (A) drift in the device electrical signal and (B) ECG signal after drift filtering. Data from MIT-BIH Arrhythmia Physionet database #103. Representative examples of relatively low frequency artificial electrical spikes (C) before and (D) after filtering. Data from MIT-BIH Arrhythmia Physionet database #105. Representative examples of relatively high frequency artificial electrical spikes (E) before and (F) after R peak detection. The "x" symbol represents the R peak detected by the algorithm. Data from MIT-BIH Arrhythmia Database #210.



R Peak Detection in the Presence of Premature Contraction

As illustrated in Figure 7A, premature ventricular contractions (PVCs) lead to early beats with similar appearance as R peaks. In the first case, the PVC polarity is positive and the algorithm detects them as R peaks; thus, no additional steps are needed (ie, the algorithm successfully finds R peaks in the presence of PVC). In the second case, premature atrial contractions (PACs) are illustrated. To overcome this problem, the signal derivative is used, and only a signal with a derivative above a certain threshold is chosen (ie, a PAC signal has a higher derivative than a regular signal). To ensure that the PAC will be detected as a peak, the ECG signal derivative was smoothed by convolution with kernel of width of 1/50 second to find the R peak (because the MIT-BIH Arrhythmia Database was sampled at 256 Hz, for this database a moving average was applied with a window width of five samples).

The convolution of two finite sequences is defined by extending the sequences to finitely supported functions on the set of integers (Equation 2 in Figure 3). When the sequences are the coefficients of two polynomials, then the coefficients of the ordinary product of the two polynomials are the convolution of the original two sequences. This is known as the Cauchy product of the coefficients of the sequences. Because we used 15-second segments, the inner product is defined (Equation 3 in Figure 3).

Figure 6. Representative examples of inverse polarity of the ECG signal (A) before and (B) after correction. Data from MIT-BIH Arrhythmia Database #108.

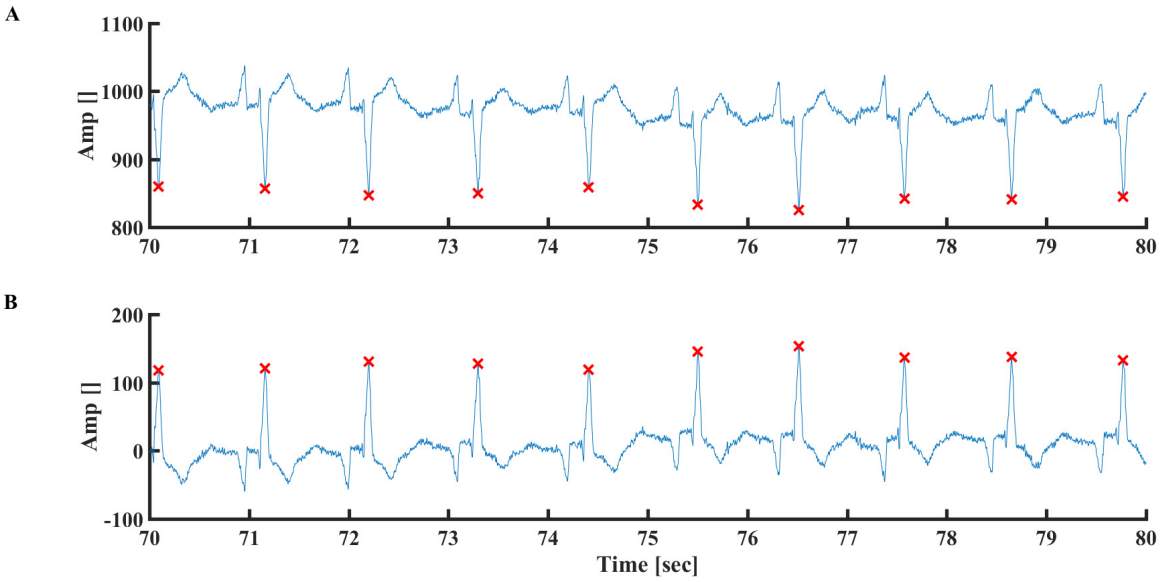
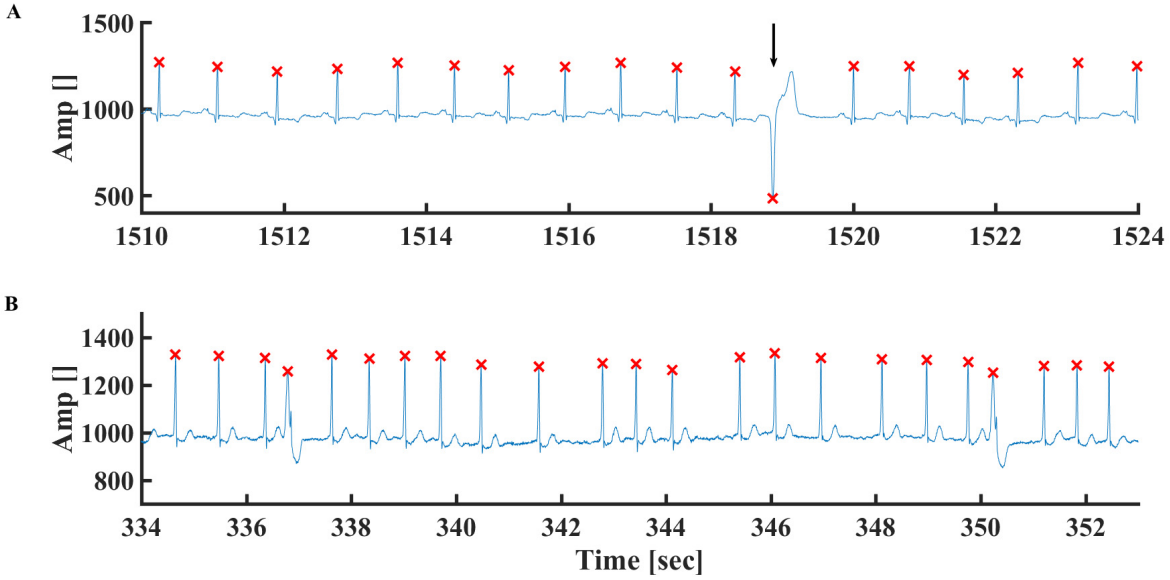


Figure 7. (A) Premature ventricular contraction. Data from MIT-BIH Arrhythmia Database #101. (B) Premature atrial contraction (PAC). Data from MIT-BIH Arrhythmia Database #221. The "x" symbol represents the R peak detected by the algorithm. The arrow represents PAC.



Statistical Measures

Detection of R peak was performed with an assumption of causality (ie, each annotation was based on current and past R detections and not on future data). Our automatic R peak algorithm annotations were compared to the reference annotations provided by Physionet [17]. The annotations produced by the algorithm were divided into three groups as defined in Physionet [17]. If the detected R peak was in a proximity of 150 milliseconds to the reference annotations, it was identified as true positive (see Equation 4 in Figure 3). A false positive was defined if our algorithm detected a peak that did not exist in the corrected Physionet annotations in a proximity of 150 milliseconds (Equation 5 in Figure 3). Thus, false positive detection was the number of false positive events divided by the number of reference annotations.

A false negative was defined if our algorithm did not detect a peak that exists in the corrected Physionet annotations in a proximity of 150 milliseconds (Equation 6 in Figure 3). Thus, false negative detection was the number of false negative events divided by the number of reference annotations.

The positive predictive value (PPV) is defined in Equation 7 in Figure 3, sensitivity is defined in Equation 8 in Figure 3, and balanced F score is defined in Equation 9 in Figure 3.

Other Detectors

We compared our results to three gold standard QRS detectors that show good detection in the MIT-BIH Arrhythmia Database:

(1) Physionet gqrs [17], (2) Pan et al [13], and (3) Behar et al [15] (jQRS). Pan et al's [13] QRS detector is energy based. The main operations performed by the algorithm are bandpass filter, derivative, squaring, and integration. The bandpass filter is used to reduce the influence of muscle noise, 60 Hz interference, baseline wander, and T wave interference. The signal is then differentiated to provide the QRS complex slope information, squared to make all data points positive, and a nonlinear amplification of the derivative filter is performed (which will thus emphasize the higher frequencies, contained mainly in the R wave). Next, a moving window is used to integrate the signal. Finally, an adaptive threshold is used on the integrated signal to discriminate the locations of the QRS complexes. Behar et al [15] (jQRS) used similar mathematical steps as Pan et al [13] with the following parameters: 0.6 detector threshold, 15-second window size, 150-millisecond refractory period, and 7-sample integration window.

Mobile System

A Universal 3-12 Lead ECG Sensor (Beecardia Ltd, Haifa, Israel) was connected through a USB to a Lenovo tablet (A7-30 with CPU MTK8382-QC 1.3GHz, system memory of 1 GB RAM, and 8 GB storage capacity) with the Android 4.4 operating system. We recorded our own data, sampled at 500 Hz and uploaded to the cloud. The detector program and the acquired data were uploaded to the MATLAB Cloud. An iPhone 6s (32 GB capacity, 1.85 GHz A9 processor 64-bit architecture, 1715 mAH battery) with the iOS 10 operating system or Galaxy Note 3 (16 GB capacity, 1.3 GHz Hexa-core processor, 3200 mAh battery) with the Android 5.1.1 operating system and the MATLAB Mobile (MathWorks, Natick, MA, USA) app were used to identify the R peaks. The performance of the mobile system was compared to the performance of Lenovo Thinkpad W541 (Intel core i7pro-Quad core, clock speed 2.8 GHz processor, 16 GB RAM) with Microsoft Windows 7 Professional 64-bit edition operating system. The open-source R peak detector program can be found in Multimedia Appendix 2.

Results

We chose the MIT-BIH Arrhythmia Database because it includes ECG strips with representative noise types and arrhythmia (see Methods) and because 40% of the ECG strips in this database include AF events (the most common arrhythmogenic events). We ran our algorithm on the entire MIT-BIH Arrhythmia Database (a total of 112,415 annotations in the 48 records). On average, our algorithm produced 0.26% false negatives and 0.58% false positives, for sensitivity of 99.7% and positive prediction of 99.4%. Note that these results were obtained after exclusion of ventricular flutter (ie, when there is no sinus rhythm at all). For statistical data, see Table 1.

Next, we compared our algorithm to some state-of-the-art QRS detectors (Pan et al [13], Physionet gqrs [17], Behar et al [15]) using the MIT-BIH Arrhythmia Database. On average, our algorithm yielded higher sensitivity, PPV, and F_1 than the others. Note that these results were also obtained after exclusion of ventricular flutter. For statistical data, see Table 1. For statistical data of each algorithm on each record, see Multimedia Appendix 3.

To test whether the algorithm can deal with AF episodes (on which our algorithm was not trained but only its performance checked), we tested it on the AF patient data. Table 1 shows that, on average, our algorithm provided good quality results. No significant difference was found between the statistics of AF and non-AF patients. Figure 7B shows an example of how, even in the presence of AF, the algorithm can detect the R peak. Multimedia Appendix 3 shows that, on average, our algorithm's performance in the presence of AF is superior to the others.

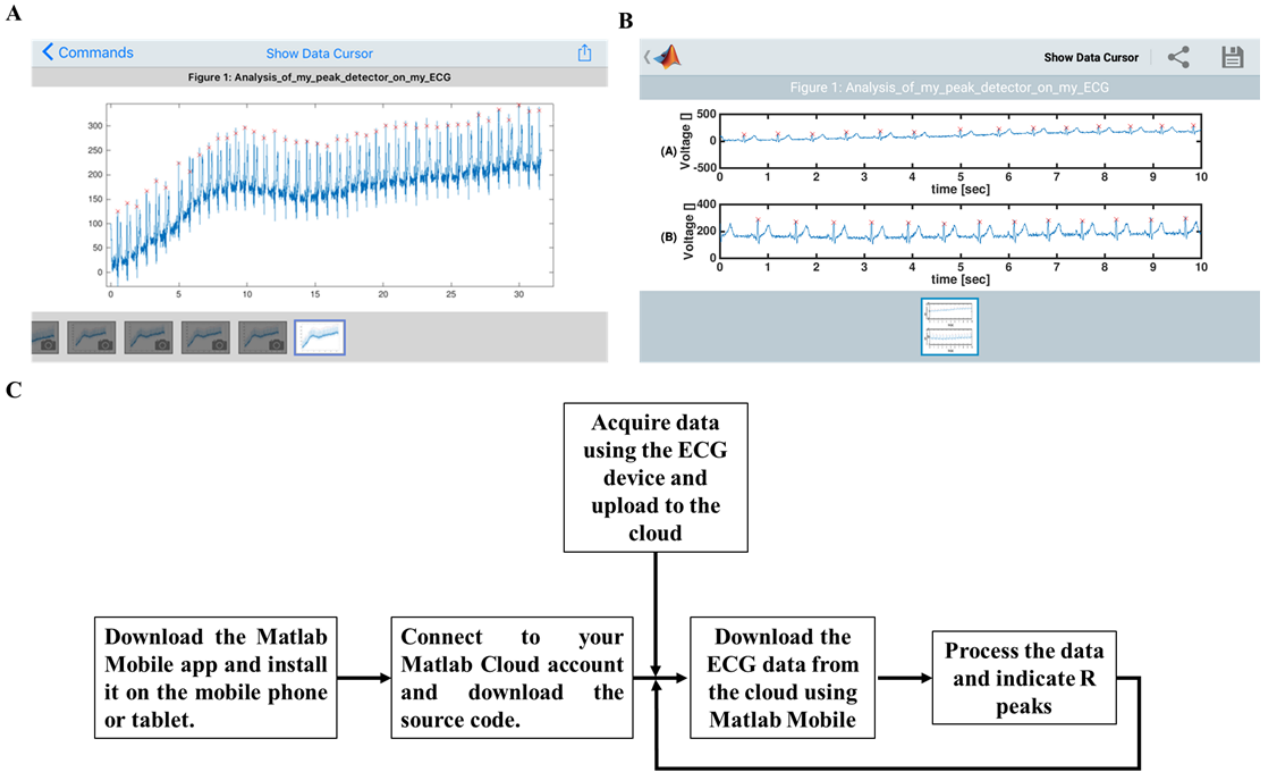
We then checked whether our algorithm produced different results for male and female subjects and compared the results to those of the other algorithms. We used data from 10 male and 13 female AF patients and 15 male and 10 female non-AF patients. For statistical data, see Multimedia Appendixes 4 and 5. On average, the false negative rate was higher for females than for males. Similar results were obtained for other algorithms. We also checked whether age affected the results produced by our algorithm. We used data from 17 AF patients older than 60 years, 8 AF patients younger than 60 years, 15 healthy subjects older than 60 years, and 7 healthy subjects younger than 60 years. For statistical data, see Multimedia Appendixes 6 and 7. On average, total false detections were higher in patients younger than 60 years. Similar results were obtained for other algorithms.

After proving the robustness of the algorithm on the "gold standard" database and proving that its performance was superior to other existing algorithms, we implemented it on a mobile phone using mobile ECG data and the MATLAB Mobile app. Figure 8A shows the MATLAB Mobile graphic user interface on both iOS and Android systems. The mobile bundle can successfully detect R peaks even in the presence of noise and drift. On average, one minute of data recording was processed by a PC (see specification in Methods) in 0.1 second and by the mobile bundle in 0.99 seconds. Figure 8B describes the steps to run the algorithm on the mobile device. Note that to compute the heart rate, the mobile device was connected to the cloud only once to download the app and once when the ECG data were download (see the flowchart in Figure 8B). Thus, it consumes low energy for communication. Indeed, 30 minutes of continuous data analysis by the app reduced the battery by only 2%.

Table 1. Mean statistics for the tested algorithm's performance detecting R peaks in atrial fibrillation (AF), non-AF, and the total strips in the MIT-BIH Arrhythmia Database.

Statistic	gqrs algorithm			Pan et al algorithm			Behar et al algorithm			Our algorithm		
	AF (%)	Non-AF (%)	Total (%)	AF (%)	Non-AF (%)	Total (%)	AF (%)	Non-AF (%)	Total (%)	AF (%)	Non-AF (%)	Total (%)
False negative detection	0.4	0.1	0.3	0.7	0.5	0.3	2.1	0.5	1.2	0.4	0.3	0.3
False positive detection	0.8	0.4	0.6	0.7	0.3	0.6	5.4	1.2	3.9	0.7	0.2	0.6
Sensitivity	99.5	99.8	99.7	99.3	99.5	99.7	97.7	99.5	98.6	99.6	99.7	99.7
Positive predictive value	99.2	99.6	99.4	99.3	99.7	99.4	95.7	98.8	97.2	99.2	99.7	99.4
F_1	99.4	99.7	99.5	99.3	99.6	99.5	96.2	99.2	97.4	99.4	99.7	99.6

Figure 8. MATLAB Mobile graphic user interface with recorded data from Beecardia ECG device on (A) iOS and (B) Android systems. The "x" symbol represents R detection.



Discussion

Principal Findings

A mobile health app with a robust R peak detector is necessary to calculate heart rate to diagnose diseases, evaluate the patient's condition, and trigger alerts if potentially fatal events are about to occur or have just occurred. To identify real-time R peak intervals, the algorithm must deal with many kinds of common artifacts before it can be implemented on a mobile bundle. The first contribution of this paper is a new R peak detector implemented on a mobile app in approximately 2 hours of computing work. We showed that it can deal with many kinds of common artifacts, such as motion artifacts, electrical drift, breathing oscillations, electrical spikes, environmental noise, signal polarity, and premature beats. We tested its performance on a "gold standard" database that includes AF and arrhythmia events. We also showed that its performance is superior to other well-cited detection algorithms [13,15,17]. Moreover, we proved that the algorithm is robust enough to detect R peaks in real time from ECG signals recorded by a mobile device. Thus, the algorithm can be run either on either gold standard data recorded by a stationary ECG device or on other data recorded by a mobile ECG device. Most importantly, we showed that the algorithm can be run on the MATLAB Mobile platform without reducing its complexity or the ability to quickly detect R peaks.

Real-time R peak detection of healthy subjects is challenging. Performing such analysis on ECG data from patients with AF who also exhibit other arrhythmias adds a new dimension of complexity to the real-time R peak detection. Our algorithm was trained only on non-AF patients. As demonstrated in Table 1, the performance of our algorithm does not decrease in the case of AF events. Moreover, although our algorithm is only slightly better than the gqrs [17] for healthy subjects, it is superior to it for recordings with AF events.

Other state-of-the-art R peak detectors, such as that of Elgendi [18], do exist. However, such algorithms are not open source and thus it is not possible to reproduce their results. In addition, our work focuses on designing an R peak detector that can be easily used on any mobile device running MATLAB Mobile.

The second and most important contribution of this paper is an open-source code that runs on the MATLAB Mobile app, which can be used by any mobile phone. The MATLAB Mobile platform makes it possible to run the R peak detection algorithm without having to reduce its complexity. To the best of our knowledge, this is the first time that MATLAB Mobile has been used as a tool to test a mobile health app. Importantly, the MATLAB source code of our R peak detector was contributed to MATLAB Cloud, which means that any mobile device running the MATLAB Mobile app can easily download and run the code.

Clinical Insights

Precise beat-to-beat detection of R peaks is essential for accurate HRV analysis. Even under resting conditions, ECG recordings in mammals exhibit complex beat-to-beat variations in the heartbeat intervals [19]. Although a decrease in this complexity in humans with cardiovascular diseases correlates with increased morbidity and mortality [19], an increase in HRV above a certain threshold leads to the abnormal electrical impulse propagation defined as arrhythmia (for a review see [20]). On average, AF is associated with increased HRV [20], but reduced HRV quantifying indexes are observed just before arrhythmogenic events [21]. Although the correlation between changes in heartbeat complexity and the prevalence of AF has been acknowledged for over three decades [22-24], currently there is no clinical tool that exploits this correlation to predict AF. The lack of clinical tools was largely due to the lack of a high-quality real-time automatic R peak detection algorithm. Our algorithm, and the ability to embed it on mobile device, may help to realize such a tool.

Limitations

We cannot quantitatively test the performance of the R peak detector on the mobile device because no public annotated database exists for such devices. Nonetheless, the applicability of the algorithm is ensured by its ability to detect R peaks with low false negative and false positive detections on the gold standard database, even in the presence of all possible artifacts and types of noise. A large clinical test of the device on patients will prove its quality.

Unfortunately, because most published R peak detector algorithms are not open source and not in MATLAB language, we could not run them on MATLAB Mobile. However, because our algorithm exhibits superior performance and its running time on the MATLAB Mobile app is short, we believe that testing other algorithms on the mobile platform will not bring further insight.

Future Work

We showed here that MATLAB Mobile is suitable to run our algorithm and find R peaks in real time. In the future we would like to use MATLAB Mobile for “hybrid” calculations: the simpler parts of the calculation will be done on a mobile phone and the more complex parts will be done in the cloud. MATLAB Mobile will switch between the two parts of the calculation.

We used AF data to demonstrate the suitability of the MATLAB Mobile platform for mHealth apps and showed that it can run on any phone system (aim 1). Thus, similar mHealth apps might also prove useful for other cardiac diseases or for diseases that require tracking of bioelectric signals from a wireless device.

Conclusions

Our first goal in this paper was to evaluate the suitability of the MATLAB Mobile platform for mHealth apps and determine whether it can run on any phone system. We showed here that an open-source code can run on the MATLAB Mobile app and can be used to identify the R peaks. Our second goal was to embed in the MATLAB Mobile platform a robust real-time ECG R peak detector with low false positive and low false negative detection in the presence of the most frequent arrhythmia, AF. We showed here that our algorithm can deal with many kinds of common artifacts, such as motion artifacts, electrical drift, breathing oscillations, electrical spikes, environmental noise, signal polarity, and premature beats. We also showed that its performance is superior to that of other well-cited detection algorithms [13,15,17]. Moreover, we proved that the algorithm is robust enough to decode R peaks in real time from ECG signals recorded by a mobile device.

Acknowledgments

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Authors' Contributions

VG and YY designed the study. VG developed the algorithm and the mobile app. JB contributed to data analysis. YY and VG drafted the manuscript. JB reviewed the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Percent of true positive results as a function of polynomial fit degree. The entire MIT-BIH Arrhythmia database was used. A polynomial order higher than 34 filters important information and decreases the percentage of true positive results.

[PNG File, 3MB - mhealth_v6i5e118_app1.png]

Multimedia Appendix 2

Open source code.

[ZIP File (Zip Archive), 134MB - mhealth_v6i5e118_app2.zip]

Multimedia Appendix 3

Comparison of failed detection per recording of each algorithm run on the MIT-BIH Arrhythmia database.

[PDF File (Adobe PDF File), 34KB - mhealth_v6i5e118_app3.pdf]

Multimedia Appendix 4

Average statistics for the tested algorithm's performance on male subjects from the MIT Arrhythmia database.

[PDF File (Adobe PDF File), 19KB - mhealth_v6i5e118_app4.pdf]

Multimedia Appendix 5

Average statistics for the tested algorithm's performance on female subjects from the MIT Arrhythmia database.

[PDF File (Adobe PDF File), 19KB - mhealth_v6i5e118_app5.pdf]

Multimedia Appendix 6

Average statistics for the tested algorithm's performance on patients younger than 60 in the MIT Arrhythmia database.

[PDF File (Adobe PDF File), 20KB - mhealth_v6i5e118_app6.pdf]

Multimedia Appendix 7

Average statistics for the tested algorithm's performance on patients older than 60 in the MIT Arrhythmia database.

[PDF File (Adobe PDF File), 20KB - mhealth_v6i5e118_app7.pdf]

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Abbreviations

AF: atrial fibrillation
ECG: electrocardiogram
HRV: heart rate variability
PAC: premature atrial contraction
PVC: premature ventricular contraction

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Original Paper

Development and Validation of a Multidisciplinary Mobile Care System for Patients With Advanced Gastrointestinal Cancer: Interventional Observation Study

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Abstract

Background: Mobile health apps have emerged as supportive tools in the management of advanced cancers. However, only a few apps have self-monitoring features, and they are not standardized and validated.

Objective: This study aimed to develop and validate a multidisciplinary mobile care system with self-monitoring features that can be useful for patients with advanced gastrointestinal cancer.

Methods: The development of the multidisciplinary mobile health management system was divided into 3 steps. First, the service scope was set up, and the measurement tools were standardized. Second, the service flow of the mobile care system was organized. Third, the mobile app (Life Manager) was developed. The app was developed to achieve 3 major clinical goals: support for quality of life, nutrition, and rehabilitation. Three main functional themes were developed to achieve clinical goals: a to-do list, health education, and in-app chat. Thirteen clinically oriented measures were included: the modified Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events questionnaire, Scored Patient-Generated Subjective Global Assessment (PG-SGA), distress, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, International Physical Activity Questionnaire–Short Form, Low anterior resection syndrome score, satisfaction rate, etc. To validate the system, a prospective observational study was conducted. Patients with gastric cancer or colon cancer undergoing chemotherapy were recruited. We followed the subjects for 12 weeks, and selected clinical measures were taken online and offline.

Results: After the development process, a multidisciplinary app, the Life Manager, was launched. For evaluation, 203 patients were recruited for the study, of whom 101 (49.8%) had gastric cancer, and 102 (50.2%) were receiving palliative care. Most patients were in their fifties (35.5%), and 128 (63.1%) were male. Overall, 176 subjects (86.7%) completed the study. Among subjects who dropped out, the most common reason was the change of patient's clinical condition (51.9%). During the study period, subjects received multiple health education sessions. For the gastric cancer group, the "general gastric cancer education" was most frequently viewed (322 times), and for the colon cancer group, the "warming-up exercise" was most viewed (340 times). Of 13 measurements taken from subjects, 9 were taken offline (response rate: 52.0% to 90.1%), and 3 were taken online (response rate: 17.6% to 57.4%). The overall satisfaction rate among subjects was favorable and ranged from 3.93 (SD 0.88) to 4.01 (SD 0.87) on the 5-point Likert scale.

Conclusions: A multidisciplinary mobile care system for patients with advanced gastrointestinal cancer was developed with clinically oriented measures. A prospective study was performed for its evaluation, which showed favorable satisfaction.

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KEYWORDS

mobile health; health apps; mobile phone; mobile care system

Introduction

Cancer is a major cause of death worldwide. It is one of the leading causes of morbidity and mortality with approximately 14 million new cases in 2012. Moreover, cancer accounted for 8.8 million deaths in 2015 and is the number 1 cause of death in Korea [1]. Although the survival rate of cancer has increased due to the advancement of diagnostic and therapeutic modalities, the majority of patients still suffer from numerous physical, psychological, and social difficulties [2,3]. Chemotherapy is the most common treatment modality for patients with advanced cancer. Although these treatments can improve the survival of patients, quality of life remains poor because of the adverse effects of the treatments [4-6].

Lifestyle modification, good nutritional status, and appropriate exercise are extremely important because they mitigate treatment effects and the morbidity, mortality, and quality of life of patients [7]. However, most patients fail to acquire sufficient information that is applicable to daily living [8]. Moreover, patients rarely use tools to report subjective information such as pain, fatigue, anorexia, and distress [9,10].

Mobile health apps have emerged as supportive tools in the management of cancer. A well-established health app can be beneficial for patients with cancer because it reduces financial burden, provides access to information, and facilitates communication [11-13]. However, only a few apps have self-monitoring features, and they often lack standardized validation in terms of benefits, acceptance, costs, and risks [14-16]. In order to set up a clinically validated service, a multidisciplinary team of health care experts must be involved in all stages of the design of the app architecture [17].

This study aimed to develop and validate a multidisciplinary mobile care system that can provide health education and self-management features to improve multiple clinical measures for patients with advanced gastrointestinal cancer.

Methods

Overview

This study comprised a development phase (May 2016 to October 2017) and a validation phase (September 2016 to December 2017). The study was approved by the institutional review board of the study site (2016-05-010).

System Development

In this study, the establishment of a mobile health management system comprised 3 steps: (1) establishment of the service scope and standardization of the measurement tools, (2) organization of service process, and (3) development of the mobile app (Life Manager).

Establishment of the Service Scope and Standardization of the Measurement Tools

For the preparation of the multidisciplinary mobile care system and service flow, scope of service was established, and the health care users were identified. Health care professionals (N=13) were recruited from a comprehensive cancer center in Seoul. Medical professionals including 6 gastrointestinal oncologists, a specialist oncology nurse, 2 oncology rehabilitation physicians, 2 nutrition specialists, a cancer education specialist, and a customer relationship manager expert joined the team. In multiple rounds of meetings, the team agreed on the final selection of clinically measurable outcomes with 3 major clinical goals: quality of life, supporting rehabilitation, and improving nutritional state (Table 1).

In addition, we reviewed nutritional assessment tools such as the Malnutrition Universal Screening Tool and the Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition Consensus Statement [18-20] and quality of life tools such as the Medical Outcome Study Short Form–36 and EuroQol-5 dimension [20,21]. The following measures were consequently selected based on their feasibility and reliability.

For online measurements, the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) [22-24], nutritional survey, and rehabilitation survey were collated. The Common Terminology Criteria for Adverse Events (CTCAE) is maintained by the US National Cancer Institute. The CTCAE for each item represents a discrete event that is graded for severity on a 5-point scale based on clinical criteria.

For offline measurements, 9 indices were included. For quality of life, the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-30) was included. It was developed to assess the health-related quality of life of cancer patients and has been validated in various studies. Distress is a frequent symptom patients suffer from during their journey with cancer and has been a major focus recently, and thus distress was included as a quality measurement [25,26]. For the nutritional goal, the Scored Patient-Generated Subjective Global Assessment (PG-SGA) was included. It is already used internationally as a reference method for proactive risk assessment (screening), assessment, monitoring, and triaging for interventions in patients with cancer [27]. For rehabilitation, the International Physical Activity Questionnaire–Short Form (IPAQ-SF), Low Anterior Resection Syndrome (LARS) score, and Brief Fatigue Inventory–Korean (BFI-K) were chosen as measurements [28-32].

Organization of Service Process

To complete the multidisciplinary mobile care system, the service protocol must be clearly defined. The service protocol consists of an offline and online protocol. The service protocol consists of offline care flow (face-to-face–based care flow) and online care flow (mobile-based care flow). Our primary goal in the clinical service protocol is to create an optimal mobile health demonstration model that can be followed by anyone.

The offline service flow was designed not to interfere with the preexisting clinical process. The online service was carefully organized so that the same treatment goal can be achieved with the offline service. To date, the service flow of the mobile care system with clinical basis has been meticulously established based on literature review and expert opinion (Figure 1).

Table 1. Measurements of clinical outcome and system performance of the Life Manager.

Goals	Online measurements	Offline measurements
Quality of life	Modified PRO-CTCAE[a]	EORTC QLQ-STO22[b] (gastric)
	—	EORTC QLQ-CR38[c] (colon)
	—	EORTC QLQ-30[d]
	—	Distress
Nutrition	Nutrition survey	Scored Patient-Generated Subjective Global Assessment
Rehabilitation	Rehabilitation survey	International Physical Activity Questionnaire–Short Form (gastric)
	—	Low Anterior Resection Syndrome score (colon)
	—	Brief Fatigue Inventory–Korean
Satisfaction	—	Satisfaction survey

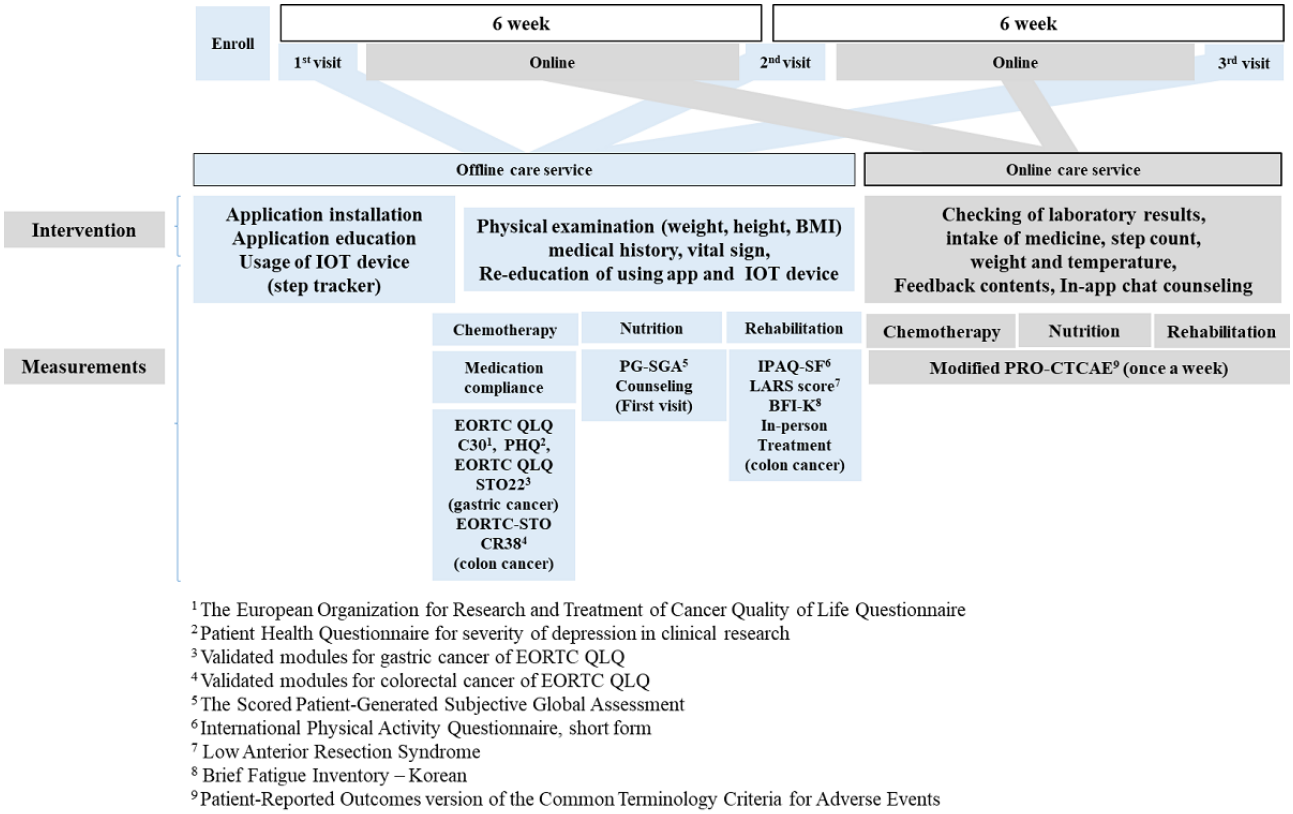
[a]PRO-CTCAE: Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events.

[b]EORTC QLQ-STO22: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Gastric module.

[c]EORTC QLQ-CR38: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Colorectal module.

[d]EORTC QLQ-30: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire.

Figure 1. User service diagram. Patients with advanced gastrointestinal cancer are able to use this care service for 12 weeks. The user can receive comprehensive care service from health providers (medical doctors, nurses, nutritionists, and rehabilitation specialists).



[1] The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire
[2] Patient Health Questionnaire for severity of depression in clinical research
[3] Validated modules for gastric cancer of EORTC QLQ
[4] Validated modules for colorectal cancer of EORTC QLQ
[5] The Scored Patient-Generated Subjective Global Assessment
[6] International Physical Activity Questionnaire, short form
[7] Low Anterior Resection Syndrome
[8] Brief Fatigue Inventory – Korean
[9] Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events

Development of the Mobile App (Life Manager)

System Architecture

The core function of the mobile health app was established by gathering opinions from various health care professionals. Technicians and developers designed an architecture model to functionally support those main themes selected by the clinical part members.

The number of steps through the activity tracker, body temperature, and weight are collected in the patient app via Wi-Fi, Bluetooth, and manual input. The collected information was recorded automatically and checked on the administrator webpage. It was used by health providers to design clinical interventions. For security, personal information was stored as unidentified code, and the OAuth 2.0 protocol, a standardized security method, was used [7] (Figure 2).

Designing the User Interface

The main themes, including the core function of the mobile app, aimed to maintain the quality of care even if the patient is outside of the hospital. It uses a standard health domain to provide a high level of clinical evidence based on the services provided by various clinical professionals. The mobile app comprised 3 main themes. Figure 3 shows the main functions implemented on each screen.

The Final App

Three main application themes were used. First, the To-Do list theme was used. When the patient installs the Life Manager app and logs in, they first see the To-Do list screen. The patient can check the Daily tasks on this screen. The user can see the core function of the mobile questionnaire (PRO-CTCAE) and feedback contents; check the medications to be taken, achievement in walking exercise, and schedule of a hospital visit in the screen; and measure temperature and weight. When the patient completes the daily task, the color of the task screen changes to confirm the achievement rate of the patient.

Second, the Health education theme was used, which addresses common questions that patients have. The common contents of this theme include drug information, general side effects, and countermeasures against the side effects of chemotherapy. Third, the In-app chat service theme was used, which can facilitate communication with experts anytime and anywhere (Figure 4).

Activity information is measured through the wearable device that is linked to the app via Bluetooth. The step counts and calorie expenditure are recorded in real time. The log file is presented in the form of a statistical graph in the management system, and the patient's health record can be used for checking using the Life Manager app. Health data that are automatically collected from the wearable device and health data that are manually entered by an individual are recorded from the Life Manager's server to its platform. Collection and life log are encrypted by the Life Manager platform and then processed for transmission.

Figure 2. System architecture of Life Manager. Data from patients were collected through the app and processed with predesigned rules. API: application programming interface.

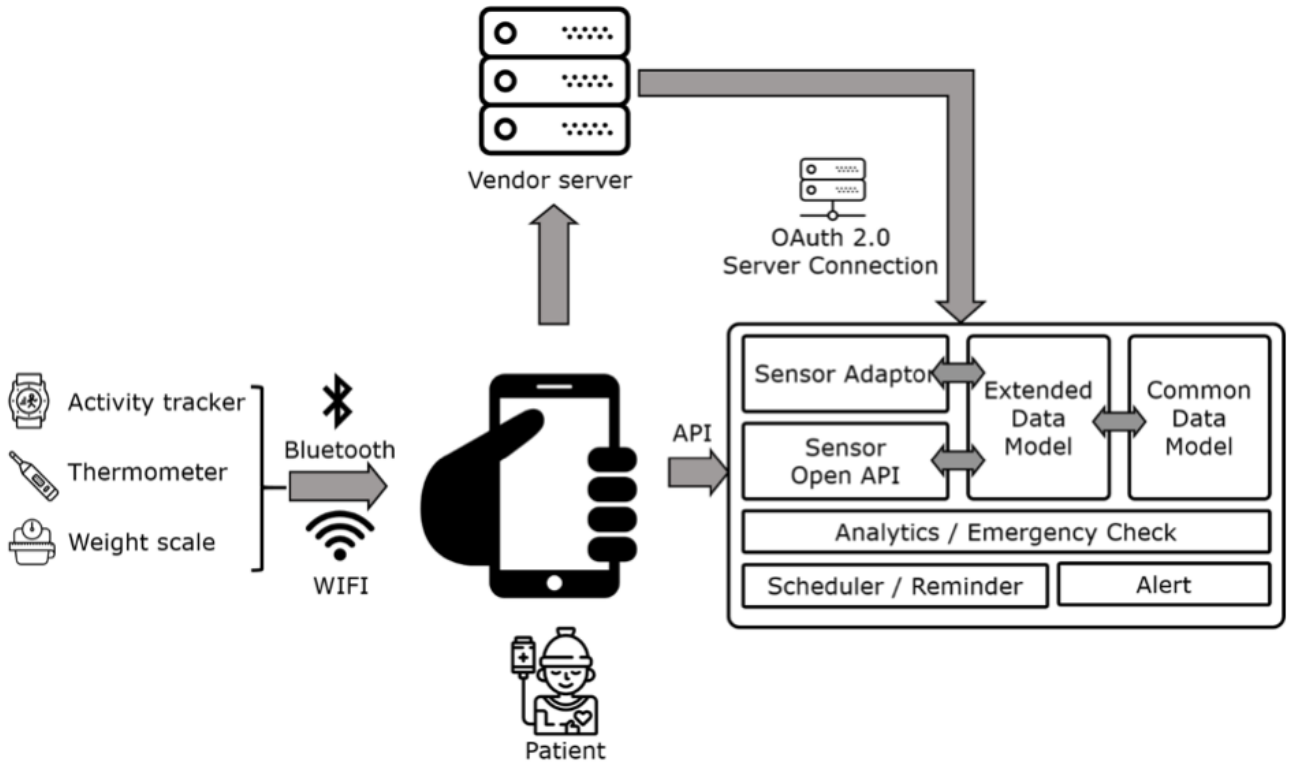


Figure 3. General concept of the Life Manager. The app has 3 main screens. Screen 1 shows the To-Do list theme, screen 2 depicts the Health education theme, and screen 3 shows the Telecommunication (In-app chat) theme. PRO-CTCAE: Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events.

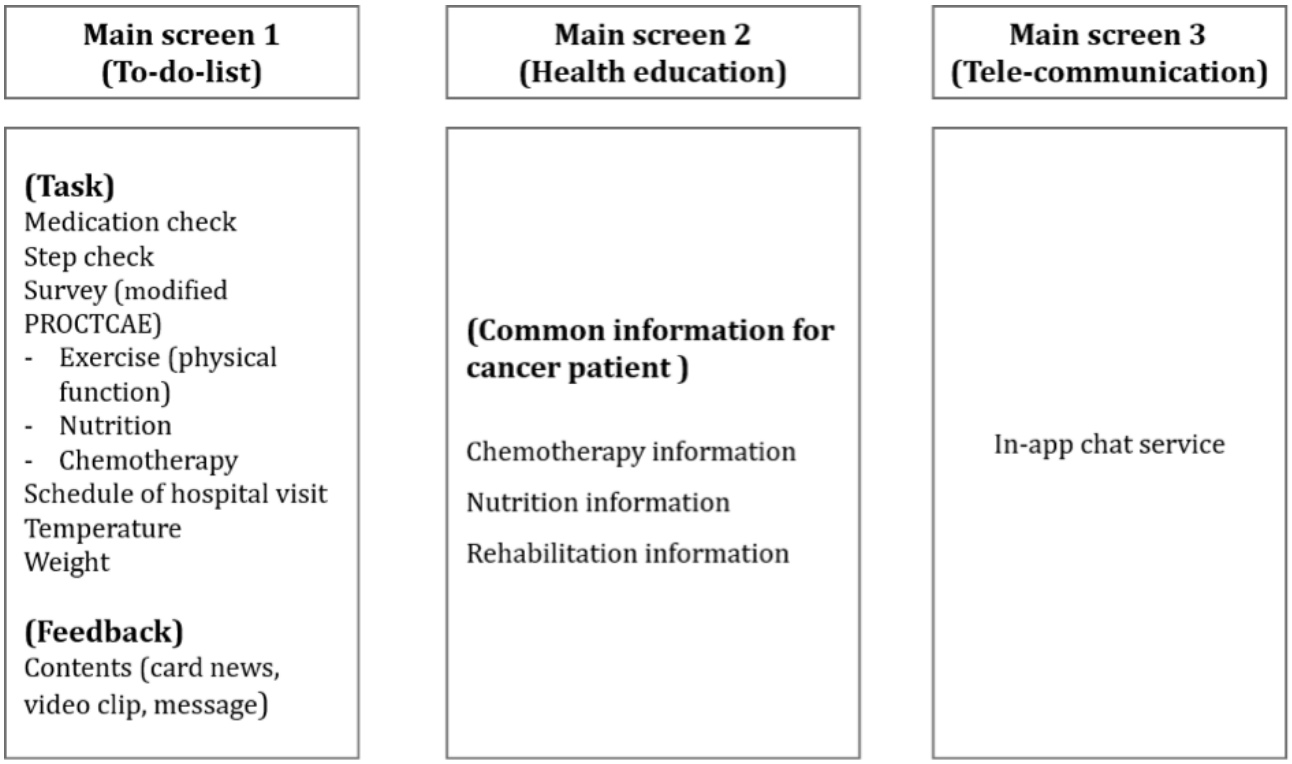
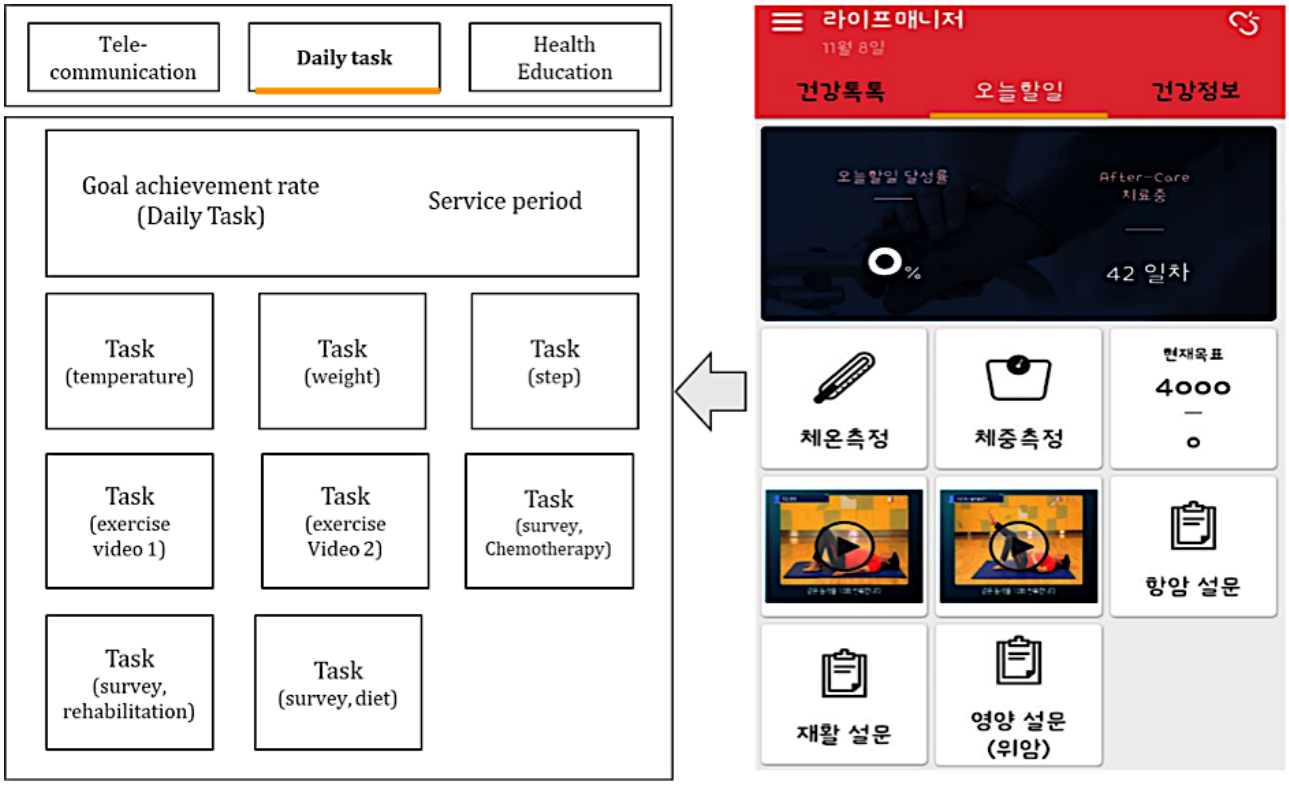


Figure 4. Main screen of the Life Manager app. Image on the right is an actual screen capture from the app, while image on the left is its translation to English. After patients log in to the app, they can first see the To-Do list screen. Patients can check the Daily tasks on this screen, which can be changed every day depending on the condition of the users.



Validation of the System

Study Design and Setting

We carried out a single-center prospective descriptive study to validate the system. The site of the study was a tertiary academic center with 2000 inpatient beds. There are approximately 8000 outpatient visits and 200 emergency visits per day.

Study Participants

Patients with gastric cancer and colon cancer were the main subjects of the study. The inclusion criteria were as follows: colon or gastric cancer diagnosis, underwent surgery for the cancer diagnosis, receiving chemotherapy for the cancer, have an Android mobile phone version 4.3 or higher, aged older than 18 years, and consented to participate in the study.

The exclusion criteria were as follows: not eligible for offline follow-up (eg, home very far away), active Do Not Attempt Resuscitation order, confusion or altered mental status, and could not follow the instructions of the study coordinators at the initial demonstration.

Outcome and Measurements

The primary outcome was systemic measurement of subject satisfaction. The secondary outcome was response rate to the clinical measurements described in Table 1. Subject demographic data along with information regarding disease status and treatment plan were also gathered.

Statistical Analysis

A simple descriptive analysis was performed to observe the outcome. The outcome was described based on patient cancer types.

Results

Characteristics of Study Participants

A total of 203 participants were recruited for the study, 101 and 102 of whom had gastric and colon cancer, respectively. There were more males than females. While 55.4% (56/101) of gastric cancer patients were receiving adjuvant therapy, 44.6% (45/101) were on palliative treatment. For colon cancer, the adjuvant group comprised 44.1% (45/102), and the palliative group comprised 55.9% (57/102; Table 2).

Participant Completion Rate and Response Rate for Each Measurement

Completion was defined if a subject could respond to all of the offline surveys. Overall, 176 out of 203 (86.7%) subjects completed the program successfully. The most common reason for dropout was change in physical condition of subject, followed by difficulty of app use (Table 3).

Tables 4 and 5 show the response rates of subjects for each measurement. For the offline surveys, the response rate was relatively high excluding early dropouts. Measurements from the third visit were lower than those from the second. Surveys for medication compliance showed the lowest response rate. The online surveys were individualized according to subjects' clinical settings. The response rate ranged from 17.6% to 57.4%.

Health Education Content Views

For health education, a total of 2338 contents were viewed by the gastric cancer group and 3071 by the colon cancer group. The overall frequency of views is described in Table 6. For gastric cancer, the most commonly viewed content was "gastric cancer general information" (322 times), and for colon cancer "warming up exercise" was viewed 340 times (Table 6).

Satisfaction Rate

The satisfaction rate was measured on a 5-point Likert scale (5=very good, 4=good, 3=neutral, 2=bad, 1=very bad). The most valued components were "appropriateness to management" and "continuous visit to this hospital." The lowest satisfaction rate was seen in "this program assists the medical doctor" (Figure 5).

Table 2. Demographic information of study participants.

Characteristics	Gastric cancer (n=101), n (%)	Colon cancer (n=102), n (%)
Sex		
Male	71 (70.3)	57 (55.9)
Female	30 (29.7)	45 (44.1)
Age, years		
Less than 40	12 (11.9)	4 (3.9)
40s	24 (23.8)	15 (14.7)
50s	37 (36.6)	35 (34.3)
60s	22 (21.8)	35 (34.3)
Over 70	6 (5.9)	13 (12.7)
Treatment plan		
Adjuvant	56 (55.4)	45 (44.1)
Palliative	45 (44.6)	57 (55.9)

Table 3. Study completion rates of study subjects.

Characteristics	Gastric cancer (n=101), n (%)	Colon cancern (n=102), n (%)
Subjects with successful completion	85 (84.2)	91 (89.2)
Subjects who dropped out	16 (15.8)	11(10.8)
Physical condition change	8 (50.0)	6 (54.5)
Difficulty manipulating the app	5 (31.3)	4 (36.4)
Transfer to other hospital	2 (12.5)	1 (9.1)
Other reason	1 (6.3)	0 (0)

Table 4. Response rate for the offline surveys.

Task	Gastric cancer (n=101), n (%)		Colon cancer (n=102), n (%)	
	2nd visit	3rd visit	2nd visit	3rd visit
Medication compliance	90 (89.1)	78 (77.2)	66 (64.7)	53 (52.0)
PG-SGA[a]	90 (89.1)	85 (84.2)	91 (89.2)	88 (86.3)
IPAQ-SF[b]	90 (89.1)	85 (84.2)	91 (89.2)	89 (87.3)
BFI-K[c]	90 (89.1)	85 (84.2)	—	90 (88.2)
LARS[d] score	—	—	92 (90.2)	89 (87.3)
EORTC QLQ-C30[e]	90 (89.1)	85 (84.2)	92 (90.2)	89 (87.3)
EORTC QLQ-STO22[f]	90 (89.1)	85 (84.2)	—	—
EORTC QLQ-CR38[g]	—	—	92 (90.2)	89 (87.3)
PHQ-9[h]	91 (90.1)	85 (84.2)	92 (90.2)	89 (87.3)
Distress	90 (89.1)	85 (84.2)	91 (89.2)	88 (86.3)

[a]PG-SGA: Scored Patient-Generated Subjective Global Assessment.

[b]IPAQ-SF: International Physical Activity Questionnaire–Short Form.

[c]BFI-K: Brief Fatigue Inventory–Korean.

[d]LARS: Low Anterior Resection Syndrome.

[e]EORTC QLQ-30: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire.

[f]EORTC QLQ-STO22: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Gastric module.

[g]EORTC QLQ-CR38: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Colorectal module.

[h]PHQ-9: Patient Health Questionnaire–9 item.

Table 5. Response rate for online surveys.

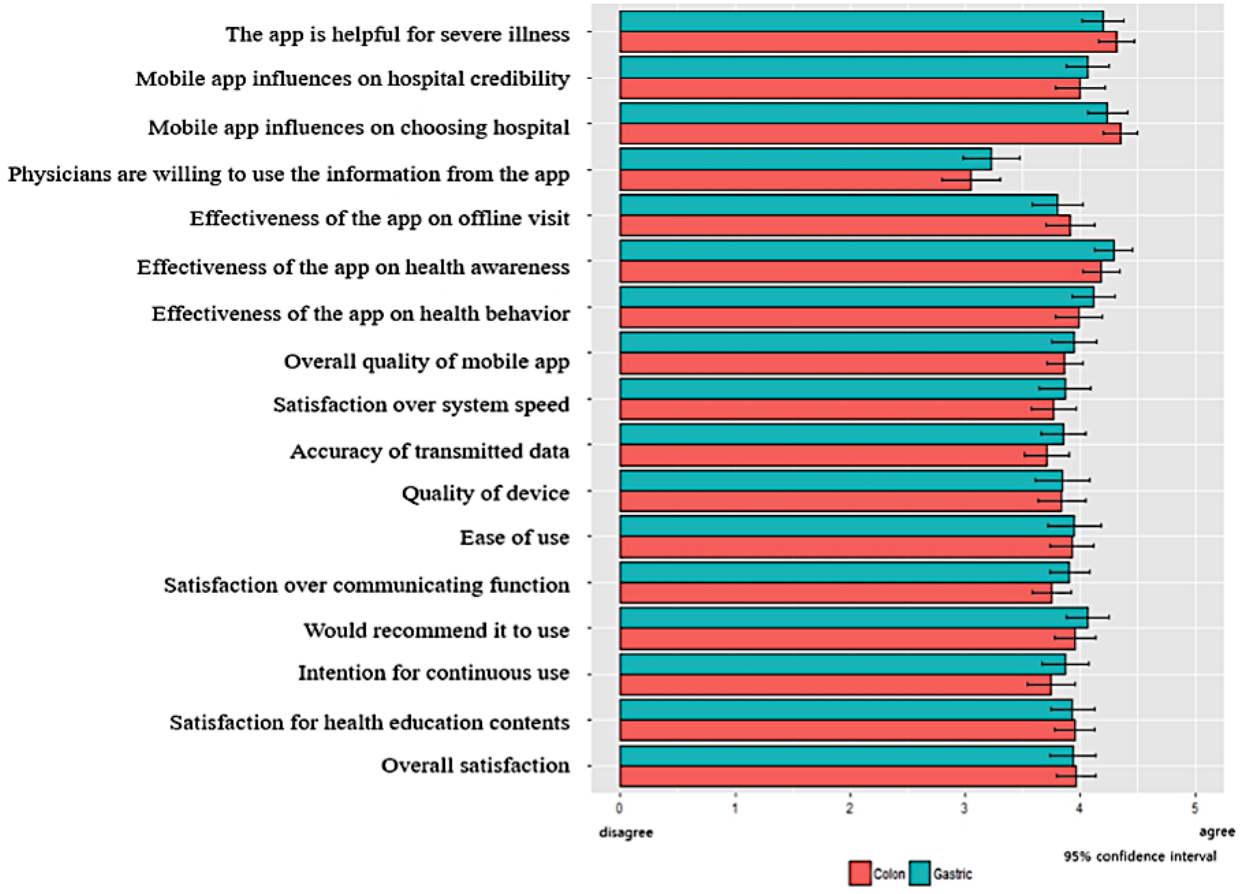
Online survey category	Gastric cancer		Colon cancer	
	Sent, n	Response, n (%)	Sent, n	Response, n (%)
Modified PRO-CTCAE[a]	940	502 (53.4)	1000	527 (52.7)
Nutrition	820	471 (57.4)	854	150 (17.6)
Rehabilitation	756	343 (45.4)	794	387 (48.7)
Total	2516	1316 (52.3)	26,481	1064 (40.2)

[a]PRO-CTCAE: Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events.

Table 6. Health education content views by participants.

Rank	Gastric cancer (n=2338)	Views	Colon cancer (n=3071)	Views
1	Cancer general information	322	Warming-up exercise	340
2	Warming-up exercise	284	Muscle strength exercise 2	320
3	Muscle strength exercise 1	275	Flexibility exercise	292
4	Flexibility exercise	255	Pelvic floor muscle exercise	260
5	Skin problem	76	Cancer general information 3	220
6	Sleep problem	67	Cancer general information 2	143
7	General exhaustion	59	Sleep problem	132
8	Hand and foot swelling	58	Hair loss	118
9	Constipation	53	Skin problem (clammy)	116
10	Skin problem (colorization)	44	Skin problem (dry)	115

Figure 5. Satisfaction rate of study participants.



Discussion

Development Process

Many mobile health apps have been developed for cancer patients, although it was not easy to find apps that apply personalized interventions for nutrition, rehabilitation, and side effects in patients who are undergoing chemotherapy. Only a few of such apps showed details of how nutritionists, rehabilitation therapists, cancer nurses, doctors, and various health providers intervened when providing personalized intervention through apps and communicating with patients [33-35].

During this study, we successfully developed a multidisciplinary mobile care system that could provide health education and self-management features for clinical improvement. Measures were chosen based on clinical evidence by experts who were actively involved in the treatment process of patients. This is contrary to the fact that many apps developed for patients do not acquire data which could be readily used in real clinical settings [36].

Also, this program joined the processes of offline and online interventions, which is said to be an important factor impacting the success of mobile apps. Mobile app developers need to analyze the process of hospital-based care in order to effectively help patients. By recruiting caregivers of such a process, we could develop a study program which could infiltrate patient predefined treatment processes with minimal discomfort, resulting in a high completion rate.

Validation Process

We enrolled 203 subjects from September 2016 to December 2016. The online survey completion rate was over 40%, and 80% completed the offline survey. The overall program completion rate was about 85%. Considering patients' poor general conditions and older ages, these figures are somewhat encouraging [37]. Patient-oriented user interfaces with user-friendly services like in-app chat service could be reasons for good compliance.

Throughout the study, coordinators freely contacted participants using the app, providing chat service and preproduced educational content; they could also meet patients when they had arrangements in the outpatient department or during scheduled chemotherapy sessions. This environment could have affected the favorable outcome of clinical validation. However, continuity of care with the physician offices was not observed in this study, which was also revealed by in-depth satisfaction analysis (Table 5).

Summary of the Implications of the Research

First, the mobile care system enabled patients with severe conditions to obtain personalized health management and remote monitoring. The management of side effects, diet, exercise, and questions related to treatment can be carried out anytime and anywhere using a mobile phone, and patients with cancer can have continuous personalized care.

Second, the mobile care systems can continuously provide both offline and online management services, and the partnership between the service provider and the patient can be strengthened. These systems can maintain the quality of ongoing daily care for patients on long-term chemotherapy or early chemotherapy.

Third, the mobile care system can provide accurate information based on clinical and professional knowledge. Patients can easily access various information related to cancer. Thus, health experts can provide real-time information based on experience.

Fourth, the possibility of online management of cancer patients with a mobile app was demonstrated in this study. Since the population undergoing cancer treatment is on the increase, the system should be enhanced by improving the quality of contents and user interface, which will also motivate patients to achieve a better quality of life.

Limitations

This study has several limitations. First, the standardized methodologies related to the development such as biodesign process were not applied [38]. Thus, it may be difficult for others to benchmark our development process. Second, the study did not include a control group for comparison. This could limit the interpretation of the results from the outcome. Third, raw data as logs from apps were not available. These data could have made it possible to analyze details of patients' behaviors with the app and devices. Fourth, we did not use standardized questions for the usability survey. Although satisfaction is a very important factor for usability, it does not solely represent it. Lastly, we did not describe values of specific clinical measures because they were not within the scope of this paper. This information would be available in future studies with specific knowledge of each topic: rehabilitation, chemotherapy, and nutrition.

Conclusions

Through this study, we successfully developed and validated a multidisciplinary mobile care system that can provide health education and self-management features to improve clinical measures for patients with advanced gastrointestinal cancer. The system showed a high rate of program completion by patients with good satisfaction.

Acknowledgments

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Conflicts of Interest

HK is now an employee of the company that developed the app.

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Abbreviations

BFI-K: Brief Fatigue Inventory–Korean
EORTC QLQ-CR38: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Colorectal module
EORTC QLQ-STO22: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire–Gastric module
EORTC QLQ-30: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire
IPAQ-SF: International Physical Activity Questionnaire–Short Form
LARS: Low Anterior Resection Syndrome
PG-SGA: Scored Patient-Generated Subjective Global Assessment
PRO-CTCAE: Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events

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Original Paper

Health Care Professionals' Attitudes Toward, and Experiences of Using, a Culture-Sensitive Smartphone App for Women with Gestational Diabetes Mellitus: Qualitative Study

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Abstract

Background: The increasing prevalence of gestational diabetes mellitus (GDM) among women of different ethnic backgrounds provides new challenges for health care professionals, who often find it difficult to provide information about the management of this disease to such individuals. Mobile health (mHealth) may act as a useful tool for blood sugar control and care process enhancement. However, little is known about health care professionals' experiences and attitudes toward the use of mHealth for women with GDM.

Objective: The aim of this study was to explore how health care professionals perceived the provision of care to pregnant women who managed their GDM using the culture-sensitive Pregnant+ app in a randomized controlled trial.

Methods: Individual interviews with 9 health care professionals providing care for women with GDM were conducted. Braun and Clark's method of thematic content analysis inspired the analysis. This study included health care professionals who were primarily responsible for providing care to participants with GDM in the Pregnant+ randomized controlled trial at 5 diabetes outpatient clinics in Oslo, Norway.

Results: Health care professionals perceived mHealth, particularly the Pregnant+ app, as an appropriate tool for the care of women with GDM, who were described as individuals comprising a heterogeneous, motivated group that could be easily approached with health-related information. Some participants reported challenges with respect to provision of advice to women with different food cultures. The advantages of the Pregnant+ app included provision of information that women could access at home, the information provided being perceived as trustworthy by health care professionals, the culture sensitivity of the app, and the convenience for women to register blood sugar levels. Technical problems, particularly those associated with the automatic transfer of blood glucose measurements, were identified as the main barrier to the use of the Pregnant+ app. Strict inclusion criteria and the inclusion of participants who could not speak Norwegian were the main challenges in the recruitment process for the randomized controlled trial.

Conclusions: The findings of this study suggest that mHealth is a useful tool to enhance the care provided by health care professionals to women with GDM. Future mobile apps for the management of GDM should be developed by a trustworthy source and in cooperation with health care professionals. They should also be culture sensitive and should not exhibit technical problems.

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KEYWORDS

mHealth; gestational diabetes mellitus; antenatal care; culture sensitivity

Introduction

Gestational diabetes mellitus (GDM) is defined as glucose intolerance recognized for the first time during pregnancy [1]. The development of GDM may lead to short- and long-term health consequences for the mother and the newborn child [2,3]. The risk factors for GDM include advanced maternal age, maternal obesity, family history of diabetes, ethnicity, polycystic ovarian syndrome, and history of GDM [3,4].

The prevalence of GDM is increasing globally, and the rates may range from 1% to 20% depending on the screening procedures employed and the characteristics of the population [5-7]. In Norway, the prevalence of GDM is approximately 3.8% [8], although a cohort study in a suburb of Oslo reported an overall prevalence of 13%. Moreover, the prevalence rates were 14.6% among women of non-European origin and 11% among ethnic Norwegians [9]. Comparison of these findings with the national statistics suggests that the number of pregnant women with GDM in the general population is underestimated.

The increasing prevalence of GDM provides new challenges for health care professionals in antenatal care. In Norway, the team responsible for the care of women with GDM includes obstetricians, internists, midwives, and nurses with a specialization in diabetes care. At the time of this study, women with 75 g oral glucose tolerance test (OGTT) values of ≥9.0 mmol/L (2 h plasma glucose) received specialized care at diabetes outpatient clinics (DOCs) [10]. However, the new guidelines for GDM now recommend that only women with OGTT values of ≥11.0 mmol/L should receive care at DOCs [11], whereas those with values ranging between 9.0 mmol/L and 11.0 mmol/L should be followed up by primary health care professionals. The implication of this is that more health care professionals without specialized training in diabetes management will now be involved in the care of women with GDM.

The first-line treatment for GDM includes provision of information on the advantages of a healthy diet, physical activity, and regular blood sugar level measurements [12,13]. Previous research has shown that pregnant women, particularly those with GDM, can be easily approached with health-related information [14-16]. However, our previous study [Borgen, to be submitted for publication] focusing on a multi-ethnic population of pregnant women revealed poor levels of knowledge about GDM among this population at the time of first consultation. Moreover, non-native Norwegian speakers exhibited significantly poorer levels of knowledge about GDM compared with native Norwegian speakers. It has been previously shown that knowledge regarding the possible consequences of a disease acts as a motivator of behavioral change [17]. Therefore, it is of utmost importance that health care professionals provide women with sufficient information on the importance of controlling their blood sugar levels and the possible consequences in terms of future health.

Women diagnosed with GDM emphasize the need for individually tailored, culturally appropriate information [18]. The current care plan for women with GDM in Norway includes teaching them how to record their own blood glucose levels and providing them with verbal information on health and nutrition with or without accompanying it with written information. However, health care professionals find it challenging to communicate information about diet and physical activity, particularly when faced with a multicultural and socially diverse population [19,20]. There is general agreement that health promotion efforts in multicultural societies must be culture sensitive [21,22], and mobile health (mHealth) technologies can potentially serve as a new tool for the management of disease and promotion of healthy behavior [23]. Previous studies have shown that mHealth interventions may help patients control their blood sugar levels [24-26] and elicit patient engagement [27]. However, although mHealth can offer tailored information for different groups of individuals [28], there is still limited evidence on its effectiveness with regard to culture-sensitive interventions, one of the main challenges of which is the recruitment of participants with limited language skills [29]. The acceptance of mHealth among health care professionals plays a key role in the success of mHealth interventions, and two systematic reviews examining this previously reported divergent results [30,31]. White et al [30] concluded that health care professionals exhibited high levels of acceptance of mHealth, whereas the other systematic reviews on health care professionals' acceptance of mHealth reported varied results based on different studies [31]. Little is known about the health care professionals' experiences and attitudes toward culture-sensitive mHealth interventions for the management of GDM in antenatal care.

This study was part of the Pregnant+ randomized controlled trial (RCT) which tested the addition of a culture-sensitive mobile phone app to the standard care protocol for GDM and compared the findings to those of the standard care protocol alone in five different DOCs in Norway [32]. A total of 238 women were included in the study, of which 108 were native Norwegian speakers and 130 were non-native Norwegian speakers. The inclusion criteria were as follows: <33 weeks pregnant, a 2 h OGTT value of ≥9 mmol/L, age above 18 years, owning a mobile phone (iPhone or Android), and understanding Norwegian, Urdu, or Somali. The aim of the RCT was to determine whether use of the app resulted in better blood glucose values (measured using an oral glucose test 3 months postpartum) in women with GDM [32]. Nearly 40.0% of the non-native Norwegian speakers were Asian (39.5%), 22.5% were African, and 15.5 % were from Eastern Europe [Borgen, January 2018, manuscript submitted for publication]. The mobile phone app analyzed in this study supported automatic transfer of blood glucose values from the measurement device and provided a graphic overview of blood glucose values over time. Moreover, the Pregnant+ app included aspects of the surface structure of culture sensitivity, as defined by Resnicow et al [33]. This dimension of culture sensitivity included the use of

pictures of people and food familiar to and preferred by the target population [21]. In addition, the app was available in Norwegian, Urdu, and Somali [34]. To tailor the contents of the app, the users could create their own profiles by providing the following information at the time of first login: (1) the outpatient clinic where they received health care and the hospital where they would give birth; (2) their perceived level of physical activity before pregnancy; (3) their preferred food culture; and (4) their weight and height before pregnancy. Pictures illustrating healthy eating varied in accordance with the patient's chosen food culture, and emoticons were used to overcome language barriers. Patients with high blood sugar levels were immediately sent information on healthy eating and ways to control the levels. Patients could also register the amount of time spent in performing physical activities and were provided feedback if they met the recommendations of the national health authorities [24]. They also received information about physical activity that was tailored for their levels before pregnancy. Health care professionals involved in the care of participants were asked to refrain from using the Pregnant+ app as a communication tool in their consultation to avoid confounding.

The aim of this RCT targeting a multi-ethnic study population was to explore the attitudes and experiences of health care professionals using a culture-sensitive mobile phone app to manage GDM. In addition, the health care professionals' general experiences with regard to provision of care to women diagnosed with GDM were also analyzed and described because previous evidence on this topic was very limited.

Methods

This study included individual interviews with 9 health care professionals who provided care to pregnant women with GDM participating in the Pregnant+ RCT. A qualitative study design was chosen because mHealth interventions are considered to be complex to evaluate due to their novelty and different outcome measurements [35,36]. Moreover, the study design provided insights into the personal experiences of health care professionals [37].

Interviews

The interviews were conducted by the second and third authors at the working sites of the participants between May and June 2017 and lasted for approximately 16–35 min. A semistructured interview format was pilot tested with one of the participants, and the main themes in the interview guide were (1) general experiences of providing care to women with GDM; (2) attitudes toward the use of mHealth; (3) experiences of recruiting participants for the Pregnant+ RCT; (4) and experiences of providing care to participants in the Pregnant+ RCT.

Selection of Participants and Recruitment

The researchers aimed to interview all health care professionals responsible for recruitment and/or provision of care to participants in the Pregnant+ RCT. In total, the interviewers asked 11 health care professionals to participate in the study, of which one refused because he or she believed that they did not have much to contribute and another declined as he or she was unavailable. The 9 health care professionals who were willing to participate received verbal and written information about the study, and the study protocol was approved by the Norwegian Social Science Data Services (ID number: 2014/38942).

Analysis

The interviews were audiotaped and transcribed by the second and third authors. The transcripts were read by the first author and randomly compared with the audiotapes to ensure accuracy of the transcription process. Braun and Clark's method of thematic content analysis inspired the analysis [37] and included the following steps: (1) repeated reading of each informant's transcripts to become familiar with the data; (2) generating initial codes (words or short phrases in the transcripts) relevant to the research questions; (3) organizing the codes into sub-themes; (4) arranging the sub-themes into overarching themes; and (5) defining and naming the themes. The second and third authors conducted the analysis and discussed potential codes and themes with the other authors.

Results

Characteristics of Study Participants

Table 1 shows the educational backgrounds and work experiences of the participants. One participant was a medical secretary who was involved in the recruitment process for the RCT but did not take part in patient care. A majority of the participants comprised midwives (n=6), and the remaining were nurses specialized in diabetes care (n=3). All the participants worked at DOCs, with a high population of women from different ethnic backgrounds. The participants' involvement in the care of women with GDM depended on the working site because the organization of care varied with the DOCs. For instance, midwives were not responsible for the management of blood glucose levels at one DOC.

Data analysis identified three themes representing the participants' attitudes toward and experiences of caring for pregnant women with GDM participating in the Pregnant+ RCT, and these were as follows: (1) general experiences of caring for women with GDM depicted the health care professionals' motivation and perceived challenges toward caring for women with different ethnic backgrounds; (2) attitudes toward and experiences of using mHealth illustrated their personal attitudes toward mHealth tools and their previous experiences of using them for disease management and patient-client communication; and (3) experiences of using the Pregnant+ mobile phone app in the follow-up of women with GDM revealed the health care professionals' evaluation of the Pregnant+ app, the facilitators and challenges of providing care to participants who had access to the Pregnant+ mobile phone app, and the professionals' experiences of the recruitment process.

Table 1. Educational backgrounds and work experiences of the study participants. Fictional names have been used.

Participant	Educational background	Work experience
Kari	Midwife	• Nurse for 6 years • Midwife for 10 years • 7 years at a DOC
Anne	Midwife	• 20 years at a DOC • Specialization in diabetes care
Kristin	Midwife	• Midwife for 20 years • 5 years at a DOC
Nina	Midwife	• Midwife for 10 years • 5 years at a DOC
Linn	Diabetes specialist nurse	• 7 years at a DOC
Anette	Diabetes specialist nurse	• Diabetes specialist nurse for 16 years • 14 years at a DOC
Gunn	Diabetes specialist nurse	• 10 years at a DOC
Lise	Midwife	• 16 years at a DOC
Julie	Midwife	• Midwife for 15 years • 8 years at a DOC

General Experiences of Caring for Women with Gestational Diabetes Mellitus

This overarching theme included 3 sub-themes: (1) motivation to provide care to women with GDM; (2) description of the characteristics of women with GDM; and (3) experiences of providing information about diet and physical activity.

The majority of the participants reported that they were strongly motivated professionally to provide continuous care to women with GDM. The participants described the women with GDM as being a very heterogeneous group with regard to their ethnic and socioeconomic backgrounds and were surprised to meet women who had developed GDM despite not exhibiting any of the known risk factors. In general, pregnant women with GDM were perceived as being very motivated and easy to approach with health-related information. This was illustrated by the following statement made by a participant who described the reaction of women after being diagnosed with GDM:

> *Women take it very seriously. Some get very sad. It happens very rarely that they don't care.* [Lise]

The participants reported that it was very important for them to provide women with information about healthy eating and physical activity, especially because they found that the women appeared to have little knowledge about GDM. They felt that the majority of the women followed their advice, and it was very important for them to achieve long-term changes in the women's health behaviors. All of the participants focused on the prevention of diet-related diseases in their consultations, as illustrated by the following statement by a midwife:

> *There should be more focus on preventing disease instead of treatment.* [Nina]

One midwife felt that it was important to build a good relationship with the women to achieve behavioral changes. However, the participants also reported experiencing challenges in providing dietary advice, mainly because the pregnant women were often confused by contradictory dietary information obtained from different health care professionals or the media. The participants also reported that women with GDM were often advised to adopt a low-carb diet or to stay away from all foods containing sugar.

All of the participants had experienced providing dietary advice to women with different ethnic backgrounds, and a majority of them did not find it difficult to adjust their advice to other food cultures. In fact, they emphasized that it was important for them to have this knowledge about different food cultures. However, two midwives reported finding provision of dietary advice to women with different food cultures challenging, and one statement made by a midwife suggested that she believed ethnic Norwegian women had more knowledge about diet than immigrant women:

> *Ethnic Norwegian women do often know what they have to do, but struggle to accomplish it; whereas immigrant women often get surprised about what they should do.* [Nina]

Another midwife reported challenges related to non-verbal communication with non-ethnic Norwegian women. For instance, she was unsure if women from South Asia understood what she told them because they were less expressive in their communication and provided fewer responses than ethnic Norwegian women. Several participants also experienced difficulties with consultations that included an interpreter and felt that pregnant women who needed an interpreter did not receive equal care. One midwife stated that they were unable

to prioritize patients requiring an interpreter due to their busy schedule.

Experiences and Attitudes Toward mHealth

The following sub-themes were identified within this theme: (1) former experiences with mHealth and (2) attitudes toward mHealth. All of the three nurses specialized in diabetes care and one midwife had previously experienced using mHealth in their consultations. The participants stated that a mobile app could be a useful tool during consultations, and one nurse specialized in diabetes care stated the following:

> *I use an app to provide information about carbohydrates. That's useful since you always have it with you, because these leaflets always get lost.* [Linn]

However, two participants expressed barriers associated with using mobile apps during consultations with women with GDM. One participant felt that the app would not let a pregnant woman communicate all the emotions she was feeling adequately upon being diagnosed with GDM, and this would affect the participant's communication/relationship with the woman.

Although half of the participants did not use mHealth apps personally, participants who had no previous experiences with mHealth mentioned several advantages of using mHealth during consultations. For instance, one midwife stated the following:

> *We have this information material that we show to the women, but I think this could get too much in the first consultation and I experience that I have to repeat things several times. So I think it would be good to have an app you can read undisturbed.* [Kari]

Other perceived advantages included those related to the management of GDM by women. Participants assumed that it would be more convenient for women to register their blood sugar values on a mobile phone compared with a booklet because the latter could be easily lost. They also thought that the use of mHealth would increase in the future and felt that it was important for them to keep up with new developments.

Experiences with the Pregnant+ Mobile Phone App for the Management of Women with Gestational Diabetes Mellitus

Four sub-themes were identified in this theme: (1) professionals' evaluation of the Pregnant+ app; (2) experiences with the Pregnant+ app in the care of women with GDM; (3) experiences with recruitment of participants for the RCT; and (4) organizational challenges. Eight of the participants had prior knowledge about the contents and features of the Pregnant+ app and felt that it had several advantages with regard to the follow-up of these women as well as their ability to manage their own GDM. For instance, health care professionals liked that the app contained a lot of different information that women could access repeatedly at any time after the consultation. Several participants mentioned that they had confidence in the contents of the Pregnant+ app and that the information was in agreement with their advice. They sometimes meet women with apps to manage their diabetes that were unknown to them and expressed that it could be difficult to know if they could rely or would approve of the content of these apps.

Although the health care professionals were asked to refrain from using the Pregnant+ app as an active communication tool during their consultations, their experiences of providing care to women who had access to it were recorded. Several participants had asked the pregnant women about their experiences with the Pregnant+ app and found that they preferred registering their blood sugar levels in the app and liked how the information was presented. On the other hand, the participants also encountered women who had experienced technical difficulties with the app, particularly with regard to the automatic transfer of blood sugar values from the measuring device to the mobile phone. The participants believed that technical issues could be a major barrier to the use of mHealth, both for self-management of GDM as well as during consultations.

Moreover, the participants stated that the Pregnant+ app could be a very useful tool for women with different backgrounds, mainly because it used simple and culture-sensitive illustrations that made the text more understandable. Although none of the participants could report experiences of using the Somali or Urdu versions of the app, they believed that English would be the most important language to reach women with different ethnic backgrounds. One participant was surprised that women from Somalian or Urdu ethnic backgrounds did not use the app in their own mother tongues. She related this to her experience of recruiting study participants for the RCT where it was difficult to include participants who could not speak Norwegian:

> *I was surprised that there were not more women who used the Somali or Urdu version of the app. It seems that those women who wanted to participate in the study, have good knowledge of the Norwegian language.* [Anne]

Although the participants felt that they received sufficient help from the research team, they found the recruitment process for the RCT challenging due to its strict inclusion criteria. Others struggled with the organization of care for women with GDM at their hospitals, and some participants stated that the lack of cooperation between the different health care professionals involved in the care process was a barrier to the recruitment process as well as the use of mHealth.

Discussion

Principal Findings

The results of this study showed that health care professionals perceived mHealth, particularly the Pregnant+ app, as an appropriate tool for the care and follow-up of women with GDM, who were described as individuals comprising a very heterogeneous and motivated group that could be easily approached with health-related information. Some participants reported challenges associated with providing advice to women with different food cultures. The advantages of the Pregnant+ app were provision of information that women could access at home, the provided information being trustworthy, the culture sensitivity of the app, and the convenience of automatic transfer

of blood sugar levels to the mobile phones. Technical problems were mentioned as the main barrier to the use of the Pregnant+ app, whereas the strict criteria and inclusion of participants who could not speak Norwegian were the main challenges in the recruitment process.

There is growing evidence in support of the impact of mHealth interventions on the management of diabetes [26,38]. However, given that there is as large variety of different mHealth tools currently available, the most effective method and setting for the management of GDM remain unclear [39]. A previous systematic review concluded that there was insufficient evidence showing that the use of telemedicine technology was superior to the use of the standard care procedure for women with GDM [39]. Riga et al [40] reported promising results with regard to the acceptance of mobile phone telemedicine among pregnant women with GDM. However, little is known about the use of mobile phone apps for the management of GDM [25,41]. Health care professionals play an important role in the implementation and effectiveness of mHealth tools, irrespective of their type [31]. The findings of this study showed that health care professionals exhibited positive attitudes toward the use of mobile phone apps in the care of women with GDM. Previous studies examining health care professionals' acceptance of mHealth have reported varying results [31], thus illustrating the need to examine the perceived advantages and disadvantages of using these tools in different settings. Although the participants exhibited positive attitudes toward the Pregnant+ app, some reported experiencing challenges in the recruitment of women for the RCT due to the strict inclusion criteria. Women with gluten or lactose tolerance were excluded from the RCT due to the lack of specific nutritional guidance for these women. To measure the effect of the app during pregnancy, women had to be able to have the app for at least 1 month before the second measurement point at 36 weeks of pregnancy; thus, women could not be included after 33 weeks of pregnancy. Twin pregnancies were excluded because the mode of delivery might have influenced the secondary outcomes might be influenced as mode of delivery. In addition, the app was only available in three languages due to the lack of resources necessary for translation.

One of the key advantages of mHealth, particularly the Pregnant+ app, was the possibility of providing vast quantities of health-related information that women could access repeatedly at their own convenience after the consultation. The participants in our study, who were strongly engaged professionally in the care of women with GDM, often felt that the women had difficulty remembering all of the information given to them. This was in agreement with other studies that had reported an information overload among pregnant women [16,42]. Similarly, another pilot test of an app that monitored gestational weight gain reported that it could help pregnant women cope with the great amounts of information provided to them by different sources [43]. Moreover, given the rapid increase in apps available for the management of GDM [44], the participants in our study stated that it was important that they could trust the developer and the information provided by the app. This finding was in agreement with another qualitative study examining pregnant women in Norway, where health care professionals were considered to be the most trustworthy source of health-related information [16].

Similar to previous reports, some participants in our study experienced difficulties providing diet-related information to women with different ethnic backgrounds [19] and stated that the Pregnant+ app could facilitate care for such women. There is a general agreement that efforts made to promote health need to be culture sensitive [45]. As described previously, the Pregnant+ app included features of the surface structure of culture sensitivity, as defined by Resnicow [33]. Participants in our study liked that the illustrations of diet-related information were adjusted for different food cultures. Another surface structure was the translation of health material into other languages, and many participants had previously experienced challenges with providing care with the help of an interpreter. Therefore, they appreciated that they could provide the women with the Pregnant+ app in their mother tongues. Although mHealth can offer tailored information for different groups of individuals [28], there is still limited evidence on the effectiveness of culture-sensitive mHealth interventions. For instance, an evaluation of meditation mobile phone apps that were culturally tailored found that this approach may be unnecessary [46]. As previously mentioned, one of the main challenges faced during the recruitment of women was limited language skills necessary for culture-sensitive mHealth interventions. Although the Pregnant+ app was available in Somali and Urdu, HCPs had difficulties in recruiting women who only understood these languages. Lopez-Class [29] previously developed strategies for the recruitment of immigrant participants, and the most relevant of these was customization of incentives for specific ethnicities and involvement of local community organizations relevant to immigrants.

To increase the effectiveness of mHealth interventions, possible disadvantages have to be overcome. Several participants reported technical issues as being the main barrier to using mHealth and the Pregnant+ app. The participants emphasized the convenience of automatic transfer of blood sugar levels as one of the most important advantages of the Pregnant+ app. However, this was also the feature that exhibited the most technical problems, and these challenges were mainly linked to software updates, either of the protocol being used to send the data from the glucometer to the mobile phone or of the operating system of the phone itself. A standard Bluetooth interface was used during the test and verification stage, while in the clinical intervention the meters had changed using Bluetooth low energy. As a result, not all phones used by the study participants were able to use Bluetooth low energy, and thus were hampered by a more cumbersome set-up and data exchange. This kind of incompatibility between older and newer versions of equipment is imminent in digital studies and cannot be avoided. However, sensor communication has developed considerably, and more than 97% of phones in countries like Norway are currently equipped to easily exchange data with sensors such as glucometers, suggesting that these problems are avoidable in the future. A recent review of health care professionals' acceptance of eHealth also reported technical problems as a key limitation of mHealth tools [30]. In addition, one participant in our study was afraid that mHealth could

interfere with her personal communication with the patient during their consultations, although there is some evidence that the use of mHealth tools can improve communication between health workers and their patients [47]. In the Pregnant+ study, health care professionals were asked to refrain from using the Pregnant+ app as a communication tool in their consultation to reduce possible confounding. Previous studies have reported that successful development and implementation of mHealth interventions should involve both the health care professionals and their clients [36,48]. For instance, a narrative review of mHealth technologies in the prevention and management of type 2 diabetes mellitus found that such technologies, with added support from the health care professionals, resulted in better outcomes for patients with type 2 diabetes mellitus than interventions that did not involve health care professionals [48].

Limitations

The first limitation of this study was the small sample size, which is typical for qualitative studies [37]. However, the majority of the health care professionals involved in the Pregnant+ study participated in this study. Moreover, this study design was chosen as it could contribute to the complex evaluation of mHealth interventions [35]. Interviews were conducted among health care professionals who were involved in the recruitment process of the Pregnant+ study. Thus, experiences from other health care professionals such as the women's general practitioners or internists were not included in this study, and these may affect the results. The health care professionals' attitudes toward the app may be influenced by their knowledge of its contents. The participants of this study exhibited good knowledge of the contents of the app, and this must be taken into consideration when comparing the results of this study with those of previous studies examining the attitudes of health care professionals toward mHealth. Moreover, our findings suggest that the Pregnant+ app could be a useful tool for the improvement of communication between health care professionals and women of different ethnic backgrounds. However, this study was limited owing to the difficulties associated with recruitment of women who did not understand Norwegian, and further research targeting immigrant women is necessary.

Comparison with Prior Work

To the best of our knowledge, this is the first study to investigate the experiences of health care professionals providing care for women managing GDM using a mobile phone app. The findings of this study showed high levels of acceptance of mHealth among the participants, and this was in agreement with a previous study [31]. Technical problems were identified as the main barrier to the use of mHealth in the care of patients [30,31]. This study also investigated the health care professionals' experiences with immigrant women, although there is still limited evidence on the effectiveness of culture-sensitive mHealth interventions. Contrary to another study investigating the effectiveness of a culture-sensitive mobile phone app [46], the participants of the current study stated that the Pregnant+ app could be an appropriate tool for the care of immigrant women. Moreover, in accordance with a previous study [49], the participants reported difficulties associated with the recruitment of women from different ethnic backgrounds who did not speak the local language.

Conclusions

The findings of this study suggest that mHealth acts as a useful tool to enhance the health care professionals' experience of caring for women with GDM. Future mobile apps for the management of GDM should be developed by a trustworthy source and in cooperation with health care professionals. Moreover, efforts should be made to ensure that they are culture sensitive and do not exhibit technical problems. Further research targeting immigrant women who do not speak the local language are needed to determine the effects of culture-sensitive mHealth interventions.

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Authors' Contributions

LGH was involved in development of the study design, analysis, and interpretation of the interviews and writing the manuscript. THA conducted, transcribed, analyzed, and interpreted the interviews and commented on this manuscript. MWS conducted, transcribed, and analyzed the interviews and commented on this paper. ML was involved in the development of the study design, analysis and interpretation of the interviews, and writing the manuscript. JN was involved in development of the study design and the Pregnant+ app and was the technical expert during implementation of the RCT.

Conflicts of Interest

None declared.

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Abbreviations

DOC: diabetes outpatient clinic
GDM: gestational diabetes mellitus
RCT: randomized controlled trial

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Original Paper

Holding It Together—Patients' Perspectives on Postoperative Recovery When Using an e-Assessed Follow-Up: Qualitative Study

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Abstract

Background: There is an emerging trend to perform surgeries as day surgery. After a day surgery, most of the recovery period takes place at home, and patients are responsible for their own recovery. It has been suggested that electronic health (eHealth) technologies can support patients in this process. A mobile app has recently been developed to assess and follow up on postoperative recovery after a day surgery.

Objective: The aim of this study was to explore experiences associated with postoperative recovery after a day surgery in patients using a mobile app to assess the quality of their recovery.

Methods: This is a qualitative interview study with an explorative and descriptive design. Participants were recruited from 4 different day surgery units in different parts of Sweden. The study included 18 participants aged >17 years who had undergone day surgery and used the Recovery Assessment by Phone Points, a mobile app for follow-up on postoperative recovery after day surgery. Participants were purposively selected to ensure maximum variation. Semistructured individual interviews were conducted. Data were analyzed using thematic analysis.

Results: A total of two themes and six subthemes emerged from the data: (1) the theme *Give it all you've got* with the subthemes *Believing in own capacity*, *Being prepared*, and *Taking action*, where participants described their possibilities of participating and themselves contributing to improving their postoperative recovery; and (2) the theme *The importance of feeling safe and sound* with the subthemes *Feeling safe and reassured*, *Not being acknowledged*, and *Not being left alone*, which describe the importance of support from health care professionals and next of kin.

Conclusions: It is important that patients feel safe, reassured, and acknowledged during their postoperative recovery. They can achieve this themselves with sufficient support and information from the health care organization and their next of kin. Using a mobile app, both for assessment and to enable contact with the day surgery unit during the postoperative recovery period, can improve care and create a feeling of not being alone after surgery. We propose that postoperative recovery starts in the prerecovery phase when patients prepare for their recovery to get the best possible outcome from their surgery.

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KEYWORDS

ambulatory surgical procedures; mobile apps; postoperative period; qualitative research

Introduction

Day surgery is preferred by many patients because it is thought to be fast and effective and causes minimal interruption to daily life [1]. Patients are admitted and discharged from the day surgery unit on the same day that the surgery is performed or at the latest 24 hours postsurgery [2]. Mortality is low after day surgery [3,4], and benefits such as lower costs, as well as technical advances in surgery and anesthesia, have contributed to the number of day surgeries expanding internationally [5,6]. Day surgery currently accounts for 70% to 75% of all surgeries in Sweden, the United Kingdom, and the United States [2,7,8].

Recovery after surgery starts immediately after completion of surgery and anesthesia and can last up to several months [9]. Recovery can be a time-consuming process that affects the patient's physical and psychological status [10] and includes regaining their preoperative social, habitual, psychological, and physical functions [9]. During recovery, patients may experience several different surgery and anesthesia-related symptoms, such as nausea, vomiting, pain, dizziness [11], and postoperative cognitive dysfunction [12]. As most of the recovery occurs outside the hospital after day surgery, self-care can be a central part of recovery [13,14].However, it has been reported that patients can feel lonely and unsure about how the recovery is proceeding [15], and some feel that there was a lack of support after discharge [14].

After the patient has been discharged from the day surgery unit, it is common practice to perform a follow-up call on one of the first postoperative days [16,17]. However, the routines differ, and some units do not have a routine for follow-up. Between 10% and 100% (average 56%) of day surgery units in Norway, Sweden, Denmark, Finland, Iceland, the United Kingdom, the Netherlands, and Portugal have been reported to perform postoperative telephone follow-ups [17].

It has been suggested that eHealth technologies can be used to support patients in their recovery after being discharged from the day surgery unit [14]. The use of mobile phones is constantly increasing, and in 2016, there were 7.509 billion mobile cellular subscribers globally [18]. A large increase has also been seen in Sweden, where today, 81% of the population has access to a mobile phone [19]. When used in health care, mobile phones can improve treatment [20] because of the possibility to provide caregiving activities, such as communication, education, and self-care support [21,22], and can be used in disease prevention [20]. Mobile apps have been tested in many different health conditions such as diabetes [23], chronic obstructive pulmonary disease [24], asthma [25], and postoperative recovery [26-29]. The use of a mobile app in the postoperative period has been shown to be feasible [26,27] and to have positive effects on the quality of postoperative recovery [29]. However, it is important to gain a deeper understanding of patients' perspectives on how the use of a mobile app in the postoperative context may influence their recovery. To our knowledge, patients' experiences have not previously been described using a qualitative method. Therefore, the aim of this study was to explore the experience of postoperative recovery after day surgery in patients using a mobile app for systematic assessment of the quality of their recovery.

Methods

Design

This qualitative study has an explorative and descriptive design with an inductive approach [30]. This study is part of a mixed method study embedded [31] in a multicentre randomized controlled trial (RCT) evaluating cost-effectiveness and other aspects of an e-assessed follow-up using the Recovery Assessment by Phone Points (RAPP) after day surgery, compared with no e-assessed follow-up. The findings have been published in 2 previous papers [28,29]. The RAPP is a mobile app including the Swedish Web version of the Quality of Recovery questionnaire, which measures postoperative recovery [32], as well as asking the question whether the patient wants to be contacted by a nurse, in total consisting of 25 questions. The patients in the intervention group answered the questions on their smartphone daily for 14 days postoperatively. Patients who answered that they wanted to be contacted by a nurse were given a follow-up call within 24 hours (on weekdays only) [33].

Procedure

The RCT was conducted from October 2015 to July 2016, and the interviews were performed between December 2015 and July 2016. For the RCT, inclusion criteria were adults (aged >17 years) undergoing day surgery, understanding written and spoken Swedish, and having access to a smartphone. Exclusion criteria were visual impairment, known memory impairment or known alcohol abuse, drug abuse, and surgical abortion [34]. Participants were eligible for the interview study if they were allocated to the intervention (RAPP) group and if they had at least once requested contact with a nurse via the RAPP. A total of 91 individuals initiated contact, and of these, 25 were purposively selected to include maximum variation [35] regarding day surgery unit, gender, age, and type of surgery and anesthesia. Because this study was embedded in the RCT, recruitment of participants was done throughout the entire study period and with the aim to conduct the interview 1 month after the surgery. Information about the study was sent out to the selected individuals (n=25) by email 14 to 30 days after surgery. Between 3 and 7 days after the email was sent, they were contacted via phone by the first author (KD) and informed about the study and invited to participate. Furthermore, 18 agreed to participate. Reasons for declining were lack of interest, time constraints, or impaired health. The participants consisted of 8 men and 10 women aged between 21 and 80 years (median age 52 years) who had undergone day surgery under general (n=14) or local/regional anesthesia (n=4). Surgeries performed were general (n=5); orthopedic (n=7); hand (n=5); or ear, nose, and throat surgery (n=1). All participants chose when and where they wanted the interview to be conducted.

Data Collection

A semistructured interview guide was used, which included open-ended questions [35]. All participants were interviewed face-to-face by the first author (KD), except for 1 participant who was interviewed via Skype. On average, interviews were

conducted 36 days after the surgery (range 22-57 days). The interviews were performed in the participants' home (n=8), at participants' workplace (n=3), or at the university (n=7) and with only the interviewer and participant present. Initially, a pilot interview was conducted to test the interview guide (Textbox 1). As no changes were made to the guide subsequent to this, the pilot interview was included in the analysis. During the interviews, probing questions were asked such as *You mentioned...Could you tell me more about that?* to gain a deeper understanding. All interviews were audio-recorded and lasted between 30 and 99 min (mean 49 min). After the last interviews, it was found that no new information was obtained, and therefore, the assumption was made that data saturation had been reached. This was confirmed during the data analysis.

Analysis

The interviews were analyzed using thematic analysis. Inductive semantic analysis included the 6 phases described by Braun and Clarke [36].

Phase 1: Familiarizing Yourself With Your Data

The recorded interviews were transcribed verbatim by the first author (KD; n=1) and a professional transcriber (n=17). All transcribed interviews were checked against the recorded interviews by the first author (KD) to ensure accuracy. The transcripts were then read repeatedly by the first and last authors (KD and SO) to familiarize themselves with the data, and notes about the data were made.

Phase 2: Generating Initial Codes

Coding was done structurally, interview by interview, and coding data of interest, in view of the aim of the study, were extracted. The coding of the data was performed by the first author (KD), and thereafter, the codes were discussed and refined with the last author (SO).

Phase 3: Searching for Themes

The codes were then searched for patterns and grouped into preliminary subthemes and themes. These were discussed with the second author (MJ), who had not taken part in the coding process or the sensemaking of the codes, and the interpretation of the data up to this phase was confirmed.

Phase 4: Reviewing Themes

The themes and subthemes were discussed and reviewed to ensure their correspondence with the original data and the aim of the study. This resulted in both dividing and merging of subthemes before the final themes and subthemes were decided.

Phase 5: Defining and Naming Themes

The naming of themes and subthemes took place in discussion between all authors to capture the essence of the themes. This included repeated discussions and repeated renaming of the themes and subthemes.

Phase 6: Producing the Report

Writing the paper for publication. During the analysis, the researchers moved back and forth between the different phases of the analytical process. All 5 authors participated in phases 4 to 6 [36]. Examples of the analyses are presented in Table 1.

Ethical Considerations

This study was conducted in line with ethical principles for clinical research and was approved by the regional ethical review board in Uppsala, Sweden (reference number: 2015/262). The participants received both written and verbal information about the study and gave their written consent. They were informed that participating in the study was voluntary and that they would be able to withdraw from the study without this having negative effects on them or their care.

Being interviewed about private experiences during postoperative recovery can be sensitive and can give rise to unpleasant memories. For this reason, there was an opportunity for the participants to contact the researchers by email or mobile phone for further support. None of the participants contacted the researchers after the interviews.

Textbox 1. Interview guide.

Do you have any previous experience of undergoing surgery?
What type of surgery have you undergone at this time?
Could you describe your experiences of the first days after the surgery?
What were your thoughts when you received information that the surgery would be performed as day surgery?
How was your recovery affected by the fact that it was a day surgery procedure?
If you reflect on your previous surgery and compare with this surgery, can you describe any pros and cons of your postoperative recovery?
How have you used the app during your postoperative recovery?
What do you think about using this type of information technology (IT) solution after surgery?
Can you describe the contact with the nurse, which was initiated via the app?
What were your expectations on this contact?

Table 1. Examples from the analysis.

Theme and subtheme	Codes	Data extract
Give it all you've got		
Believing in own capacity	Knowing your capacity	*...It's like when you have experience of having had an operation and coming home; you kind of know what you can manage.*
Being prepared	Exercising to be more prepared for recovery	*So I went and did a bit of exercise to try to be a bit more...mobile...when... before the operation. Yeah, quicker recovery.*
Taking action	Self-care for constipation	*...then I was constipated...maybe for the first 3 or 4 days and that was unpleasant. So then I tried to drink a lot and have a lot of fluids and vegetables, and so on; the things I ate were actually very light.*
The importance of feeling safe and sound		
Feeling safe and reassured	Support from RAPP[a]	*It's fantastic, I can just click in the app and somebody rings me.*
Not being acknowledged	Frustration because of insufficient information	*...it went very fast, did everything, and maybe that was what was a bit frustrating too—that on top of everything you didn't know what had been done and what would be done later.*
Not being left alone	Support from family	*I did get help from...my husband, and my sister brought me food and things...*

[a]RAPP: Recovery Assessment by Phone Points.

Results

Overview

A total of 2 themes and 6 subthemes emerged from the data: *Give it all you've got* with the subthemes *Believing in own capacity*, *Being prepared*, and *Taking action*; and *The importance of feeling safe and sound* with subthemes *Feeling safe and reassured*, *Not being acknowledged*, and *Not being left alone*.

Give It All You've Got

Believing in Own Capacity

As it was decided that the operation would be performed as day surgery, the participants felt chosen and deemed themselves capable of having day surgery. Hence, they wanted to fulfill the expectations from the health care organization that they were capable of undergoing day surgery. This expectation from the health care professionals contributed to a feeling of confidence and strengthened their belief in their own capacity to handle the postoperative recovery. Once the participants felt confident, they felt comfortable and secure and experienced the postoperative period as positive, and they described that being at home after surgery promoted a faster and safer recovery:

> *...then if it's just for 1 day—well, then I kind of manage it myself.* [Participant 6]

Staying positive and encouraging themselves was described as a way to compensate for the feeling of insecurity about handling the recovery process the participants sometimes felt. One thing that facilitated believing in their own capacity was being familiar with the health care system and knowing when and whom to call if support was needed:

> *...if I want contact with a person I make sure I get it. I usually don't settle with...if you know what I mean...* [Participant 2]

Even if they experienced problems during the recovery process, they trusted themselves and believed in their own capacity should they have to undergo day surgery again. Some participants who experienced problems during recovery expressed self-doubt as to whether they should have undergone the surgery at all.

Being Prepared

The participants considered barriers and facilitators in their everyday life based either on previous experiences or on assumptions regarding having surgery and recovering at home. When they had negative expectations based on previous negative experiences, it made them more cautious about trusting health care. Many participated actively in the decision making regarding anesthesia and the surgery. They prepared themselves mentally, physically, socially, and practically for the recovery to influence the recovery in the best possible way. These preparations might include strategies such as searching for information, physical training, preparing for rehabilitation, arranging support from next of kin, preparing for school work or housework, having enough food in the house, and preparing food. Being prepared reduced worries and anxiety during the recovery period:

> *I had prepared things at home in a different way. I had sort of put the pillows up in the bed, and so on...my mother-in-law and mum were more on stand-by in a different way than last time...A bit like, prepared a bit more, maybe in the fridge at home also.* [Participant 16]

Taking Action

The participants were determined to fulfill their desire to recover, get back to normal, and be able to do things that had been impossible before the surgery or during recovery. They described this as allowing the recovery to be important, taking time and letting go of all other things besides the recovery process. The participants described themselves as active

participants who took responsibility for their recovery. They handled postoperative symptoms and prevented complications. Some used a relative's or friend's pain medications because they perceived their own pain medication as insufficient:

> *I actually got to borrow my mum's, she actually had Citodon, I'd used them before and so I did actually take them. Ehm, I took them so I'd sleep a bit better at night, otherwise I'd never have coped.* [Participant 1]

Some of the participants said that a good recovery was something they themselves were responsible for, not the health care staff. They described feelings of happiness and relief when the recovery proceeded as planned, and they blamed themselves when it did not turn out as expected.

The Importance of Feeling Safe and Sound

Feeling Safe and Reassured

Being treated professionally and as an individual made the participants feel safe. Being treated professionally included being able to get sufficient information, discuss worries, and get reassurance. The participants felt reassured when they received a follow-up call or paid a visit to the health care to confirm that everything was proceeding as expected and get assistance with symptoms and concerns. The option to decide to call the day surgery unit when needed created feelings of safeness and patient participation:

> *...that they say, "Yes, but this actually looks fine," it is good to hear that too. It's almost nicer to hear it...when both the hospital, or yes, the nurse says, "Oh, this looks really good," that's quite relieving.* [Participant 14]

The RAPP was described as a solution that could help deal with negative experiences like those the participants had suffered after previous day surgeries, when it had been difficult to get in contact with health care. The RAPP enabled the participants to report how they felt and further made them reflect on their postoperative recovery. The opportunity to be contacted by a nurse on request was described as improving their postoperative recovery because it created a feeling of safety and of not being left alone after discharge. The participants suggested that the RAPP should be implemented more widely so that all patients could use it in their postoperative period:

> *I think everybody who is going to have an operation should get the app. You feel better, you can see an improvement...or a worsening.* [Participant 13]

They related that the nurse reassured them, gave advice, and explained the symptoms or concerns they experienced. The nurse contacted other health care expertise if needed. This alleviated their anxiety and worries during recovery. The support enabled by the RAPP was described as a lifeline because for some, it was the only way to get support from health care in their recovery process:

> *...was actually my lifeline. "Yes, please contact me." Because when I felt that something was amiss I just clicked in (the app) and then the nurse rang me up.* [Participant 5]

Not Being Acknowledged

The participants experienced that insufficient information and support as well as lack of acknowledgment from health care created a feeling of being forsaken. This lack of support and information left them by themselves to deal with their worries about symptoms and distress, and this made them feel abandoned by the health care service:

> *...the pain scale actually goes from 0 to 10. Ten is insufferable...hmm, that doesn't even cover it. So that...it was really hard. When I rang in the next day, she, the nurse, actually said, "No, you can't have any [pain medication]!"...But yes, I didn't get any so every day has been a struggle.* [Participant 8]

In 1 case, lack of information about the operation had almost spoilt the participant's chance of recovery and function of the hand because besides not receiving information about what was done during the surgery, the participants had not been told what not to do during the recovery. Insufficient information also made participants feel misled, which could result in more postoperative discomfort such as pain:

> *Very negative thoughts, a lot of anxiety and kind of anger, and so on, and that's never good in a healing process—to be surly and sort of unhappy, and so on. It doesn't actually get better, the pain doesn't actually feel better if you sort of focus on the wrong things; nothing gets better that way.* [Participant 5]

The participants experienced that it was a challenge to get in contact with health care. They did not know whom to approach with questions and concerns and were restricted to specific telephone hours for calling. Some described technical issues they had experienced with RAPP. Others had needed to get in contact with a health care professional after the intervention was completed (ie, after 14 days postoperatively). When they did not manage to get in contact, they felt hopeless. A visit to the emergency department seemed the only solution:

> *We actually have the best care in the world so that it shouldn't be that difficult to make contact. Right?...maybe I should have managed to get in, I'm actually…well the last thing I thought was kind of, if I don't get in now then I have to get to the ER [emergency room]...* [Participant 7]

Some participants felt disappointed in the RAPP. Having to wait 24 hours for a follow-up call seemed too long. Some also felt that they had been unprofessionally treated by the nurse, for instance, when receiving 2 conflicting pieces of advice or getting advice such as "just deal with it."

This lack of support, concerning information and acknowledgment, created feelings of unsafety and resulted in participants not trusting the health care service, which led to them not wanting to return to hospital or undergo any more surgeries.

Not Being Left Alone

During the recovery, the participants experienced distress and symptoms such as dizziness, feeling groggy, nausea, and vomiting, or difficulties with mobility. It was important to have

support from a next of kin, and they thought that the recovery would have been difficult, perhaps impossible, without the help and support of next of kin:

> *...you just want to go home. On the condition of course that you know that you will be taken good care of at home...I am very lucky, I have had it quite easy, I haven't need to bother about anything...* [Participant 4]

To feel safe, physically, mentally, and in practical things, the participants needed support. They described their next of kin as someone who provided company and lifted the atmosphere and someone who helped with everyday life, housework, hygiene, and issues related to the surgery. The participants had received advice from their friends and relatives on how to handle issues and symptoms. Some said they were more confident in the support from their next of kin than in the support they got from the health care professionals. Insufficient support from their employer, such as a persistent workload, or not having arranged a substitute, created stress as well as worries and had a negative effect on the recovery. Those participants who were self-employed described it as a challenge to manage demands from their work during recovery because they had no one to support them and had to manage their work on their own.

Discussion

Principal Findings

The findings in this study resulted in 2 main themes: *Give it all you've got* and *The importance of feeling safe and sound*, both of them describing the experiences of postoperative recovery as well as how an e-assessment can influence postoperative recovery in persons undergoing day surgery. The best conditions for an optimal postoperative recovery may be a balance between *Give it all you've got* and *The importance of feeling safe and sound*. The participants described feeling safe and secure as something central and said that these feelings had a positive impact on their recovery. On the basis of the findings in this study, a feeling of safety could be created by efforts from the patients themselves; however, this cannot be done unless the health care services provide patients with sufficient information and support to manage the recovery process by themselves and unless the patients feel supported by health care and/or next of kin. It has previously been described that day surgery patients who report insufficient support from health care tend to have a poorer recovery [37]. It is important for patients to have enough information to manage their recovery [10,15,38-40]. Insufficient information can lead to anxiety and increased pain after surgery [41,42]. Although previous studies [10,15,38-40] have reported the need for sufficient information, this seems still to be a problem. Lack of information can have a negative effect on patients' recovery because it affects them emotionally and physically as they experience the symptoms as worse. Lack of support and information can result in complications and can even harm the patient when they are not aware of what aspects to be cautious about, as described in this study.

Postoperative recovery is a process starting directly when the surgery and anesthesia have ended [9] and can be divided into 3 phases: early, intermediate, and late recovery. Early and intermediate recovery occurs at the day surgery unit, whereas late recovery occurs at home [43,44].Our suggestion is that the recovery process in fact starts before surgery in a prerecovery phase. Hence, the recovery process starts when the decision is made to undergo surgery and the participant starts to prepare for the surgery and the subsequent recovery process, just like an athlete prepares for a race. The participants in our study took an active part to be prepared mentally, physically, socially, and practically. Our findings are supported by previous studies with day surgery patients and inpatients preparing emotionally and practically for their surgery [15,45]. Being prepared can also be seen as a coping strategy for dealing with the postoperative recovery [46,47]. Therefore, it is important that health care supports patients to start their prerecovery phase, by informing them and discussing how they can best manage their postoperative recovery and deal with and ease postoperative symptoms [42,48,49].

The participants in this study experienced support from health care and described feelings of safety. One reason for this positive result could be the use of RAPP. Previous studies have discussed the importance of support and contact with health care professionals after discharge [10,14,15] and report that effective follow-up can reduce anxiety in patients undergoing day surgery [50]. The results of our main study (in which this study is embedded) show that participants who were allocated to the RAPP group reported significantly better quality of postoperative recovery compared with participants in the control group who did not use the RAPP [29]. This may indicate that the support they experienced from using the RAPP had a positive impact on their postoperative recovery. Day surgery patients need support to manage their symptoms, and they need answers to their questions about the recovery in general, not only on the first postoperative day, as often is the routine. They need the possibility to decide for themselves when in the recovery process they want to have contact with the health care service; they also want an easy way to get this contact if needed. This finding has been confirmed by others [50-52]. Patients have symptoms and recovery-related questions that need attention also during the subsequent 3 to 5 postoperative days [50,52], and it has also been argued by others that patients should have the possibility to get the support they wish for whenever they need it [50].

It is possible that our participants were more positive toward the RAPP because they had experienced the need for initiating contact with a nurse during the recovery. It may also be that the participants in this study experienced more concerns and issues as they had experienced the need to be contacted by a nurse via RAPP. Therefore, the results from this study may not be transferable to all day surgery patients. However, many of the findings in this study can be confirmed by previous studies performed on a day surgery population, as described earlier [14,15,52], as well as positive attitudes toward using a mobile app during the postoperative period [26,27].

Support from health care is important, but the support of next of kin is just as important. On the basis of our clinical experience and the results of this study, as well as earlier research showing that patients may experience anesthesia and surgery-related symptoms and that quality of recovery is poorer on the first

postoperative day [53,54], we recommend that patients should always be informed about the importance of not being alone the first night(s) after discharge from surgery. Furthermore, patients need assistance from next of kin during the first postoperative days, or even weeks in some cases, to increase the feeling of safety and help them cope with the recovery [15,47]. In Sweden and many other European countries, it is not mandatory that patients have someone accompanying them for the first 24 hours [17]; however, this is recommended by the International Association of Ambulatory Surgery [55] as well as by researchers [43,56,57]. The patients may underestimate how much help is needed in the postoperative period [51,52] and therefore may not arrange the support they need from next of kin.

Self-care is a central part of handling postoperative recovery after day surgery [15,51]. Our participants described taking great responsibility for their self-care and also believing in their capacity to handle the recovery process.

The ability to cope with and handle the recovery process can be related to a patient's self-efficacy. Self-efficacy is a person's beliefs in their own capacity to handle a situation and has 4 different sources: *enactive mastery experience*, *vicarious experience*, *verbal persuasion*, and *psychological and affective states* [58]. The sources of self-efficacy were not used in the analysis in this study as ours was an inductive analysis. However, it seems that our findings reflect the participants' sources of self-efficacy. Thus, regarding *enactive mastery experience*, the participants used their previous experiences to judge how they would be able to handle the situation and also what actions were needed to influence the recovery in a positive way. Negative experiences resulted in them doubting their capability to undergo surgery again. Regarding *vicarious experience*, participants with no previous experience of undergoing surgery considered their situation and assumed what actions they had to take to enhance their recovery. In *verbal persuasion*, participants felt that health care had faith in them and therefore had the ability to handle the recovery. In *psychological and affective states*, feeling safe and experiencing support from health care staff or next of kin during recovery had a positive impact on recovery. It has been described that self-efficacy has a positive influence on postoperative recovery after hip replacement surgery [59], and it has been suggested that self-efficacy is central for patients undergoing day surgery [60]. Moreover, in 1 report, self-efficacy improved when support after surgery was increased in a telephone follow-up intervention after total knee arthroplasty [61]; in another, a telehealth intervention after coronary artery bypass graft surgery had a similar positive effect [62].

The contact with the nurse via the RAPP function was described as reassuring. It is possible that the nurses knew that the patients were participating in a study and therefore behaved in a special way. One advantage of using RAPP for contact with the nurse is that nurses have the possibility to be prepared and read the patients' medical records before calling them. Furthermore, we think that it is better for both the nurse and the patient if the nurse performs the follow-up call when they have time to talk to the patient, rather than answering the phone while performing other tasks. Phone call interruptions in primary care have been described as negative for care both by health care staff and patients [63].

Participants were positive toward the use of digital technology during postoperative recovery. One of the inclusion criteria was to have access to a smartphone, which explains why participants were familiar with, and positive toward, the technology. It would be natural to assume that other issues concerning the RAPP would have emerged had we included participants not comfortable with smartphone technology. A barrier to using digital health technology is older age, a lower educational level, a lower income level [64], and low health literacy [65]. However, it has been shown that these sociodemographic factors are becoming less important in the context of using mobile phone–based health solutions [66].

Methodological Considerations

Only participants who were allocated to the intervention group and had initiated contact with a nurse by using the RAPP function were eligible for inclusion in this study. This inclusion criterion may have affected the findings and also their transferability [67].

The analysis was performed individually by the researchers and was confirmed in the early stages of the analysis process by the second author (MJ) who was not part of the initial analysis. This increases the credibility of the findings [67]. To ensure credibility, all authors discussed the interpretation of the data on several occasions during the analysis process. Quotations from the participants have been included to support the findings. To enhance confirmability [67], the authors' preunderstanding was taken under consideration, and the authors strove to be open toward the text. Three of the authors (KD, MJ, and UN) had clinical experience, and four authors (KD, MJ, UN, and ME) had research experience on postoperative recovery, day surgery, and research of the RAPP. This may have affected the results as an analysis is always a product of the researcher performing the analysis. On the other hand, two researchers (ME and SO) did not have experience of working clinically with day surgery or postoperative recovery, and SO had never been involved in any research or development involving RAPP. There were a constant reflection and discussion between the authors during the analysis. SO is a senior researcher in qualitative research, and 3 authors had experience of conducting qualitative research (KD, UN, and ME).

Conclusions

Our findings emphasize the importance of day surgery patients feeling safe, reassured, and acknowledged during their postoperative recovery at home. This can partly be achieved by the patients themselves, when they believe in themselves and prepare for their recovery as well as take actions and responsibility for improving their recovery. However, support, information, acknowledgment, and reassurance from health care staff and next of kin during their recovery are of great importance. Using a mobile app for assessment and to enable contact with the day surgery unit during the postoperative recovery period can improve care and create a feeling of not being left alone. The postoperative recovery starts in the *prerecovery phase* when patients prepare for their recovery and

proactively aim for the best possible outcome of the surgery, anesthesia, and postoperative recovery. A balance between patients' ability to *Give it all you've got*, on the one hand, and information and support from health care and next of kin, on the other hand, appears to be the best condition for reaching an optimal postoperative recovery.

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Conflicts of Interest

UN and Orebro University Enterprise AB hold shares in RAPP-AB.

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Abbreviations

IT: information technology
RAPP: Recovery Assessment by Phone Points
RCT: randomized controlled trial

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Original Paper

Acceptability of an mHealth App Intervention for Persons With Type 2 Diabetes and its Associations With Initial Self-Management: Randomized Controlled Trial

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Abstract

Background: Mobile health interventions are increasingly used in health care. The level of acceptability may indicate whether and how such digital solutions will be used.

Objective: This study aimed to explore associations between the level of acceptability of a mobile diabetes app and initial ability of self-management for patients with type 2 diabetes.

Methods: Participants with type 2 diabetes were recruited from primary health care settings to a 3-armed randomized controlled trial in the Norwegian study in the RENEWING HEALTH project. At the 1-year follow-up, 75 out of 101 participants from the intervention groups completed an acceptability questionnaire (The Service User Technology Acceptability Questionnaire). In the randomized controlled trial, the 2 intervention groups (n=101 in total) received a mobile phone with a diabetes diary app, and one of the groups received additional health counseling given by telephone calls from a diabetes specialist nurse (n=50). At baseline, we collected clinical variables from medical records, whereas demographic data and self-management (The Health Education Impact Questionnaire) measures were self-reported. Log data from the use of the app by self-monitoring were registered continuously. Associations between initial ability to self-manage at baseline and acceptability of the diabetes diary app after 1 year were analyzed using linear regression.

Results: We found statistically significant associations between 5 of the 8 self-management domains and *perceived benefit*, one of the acceptability factors. However, when adjusting for age, gender, and frequency of use, only 1 domain, *skill and technique acquisition*, remained independently associated with *perceived benefit*. Frequency of use of the app was the factor that revealed the strongest association with the acceptability domain *perceived benefit*.

Conclusions: Our findings indicate that persons with diabetes may accept the app, despite its perceived benefit being associated with only one of the 8 domains of their initial level of self-management.

Trial Registration: ClinicalTrials.gov NCT01315756; https://clinicaltrials.gov/show/NCT01315756 (Archived by WebCite at http://www.webcitation.org/6z46qPhWl)

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KEYWORDS

diabetes mellitus, type 2; patient acceptance of health care; acceptability of health care; self-care; mobile apps; smartphone; telemedicine; regression analysis; factor analysis; statistical

Introduction

Background

Self-management is important for persons with chronic illnesses to maintain their own health. Health care providers should engage in self-management support when there is a need for assistance to manage health challenges [1].Both self-management education and support are reported to improve metabolic control as measured by glycated hemoglobin (HbA_{1c}) levels for persons with type 2 diabetes [2]. Furthermore, mobile health (mHealth) interventions developed for diabetes self-management have shown some effects, although little is known about the full potential benefit of using mobile diabetes apps [3-7]. Successful use of mHealth tools and services requires an active user and cooperation with health professionals [4]. Use of mHealth often includes the possibility of sharing data between health professionals and their patients with diabetes, which could enhance the support to improve their self-management [6,7].

The acceptability of the provided mobile-based technology is important for their use and for its implementation into practice [8]. However, only sparse knowledge exists about factors that make mobile technology acceptable for persons with type 2 diabetes [9-11]. Findings from the Whole System Demonstrator (WSD) study indicate a positive association between self-management and higher levels of acceptability [12]. Other studies have found associations between satisfaction with the device and improved diabetes management [9], but to our knowledge, little is known about the associations between the acceptability of an app and the initial ability to self-manage one's own health, before introducing the app. We hypothesized that a person with a high degree of self-management at baseline would have the skills and confidence to accept and implement the use of available technical tools in self-care.

Objectives

The aim of this study was to explore associations between the initial ability of self-management and the level of acceptability of a mobile diabetes app.

Methods

Participants and Setting

The study sample in this study consisted of participants from the Norwegian randomized controlled trial (RCT) of the European Union project RENEWING HEALTH, which has been described in detail elsewhere [13-15]. Participants were persons with type 2 diabetes mainly recruited through general practitioners between March 2011 and September 2012. Eligibility criteria were (1) adults aged ≥18 years with type 2 diabetes, (2) HbA_{1c} levels ≥7.1%, and (3) capacity to use the equipment and to fill in questionnaires in Norwegian. The study was a 3-armed RCT with 2 intervention groups and 1 control group. Both intervention groups (n=50+51) received a mobile phone with a diabetes diary app developed at the Norwegian Centre for E-health Research [16] and a blood glucose meter (OneTouch Ultra Easy from LifeScan Inc. West Chester, PA, USA), equipped with an adapter for enabling Bluetooth communication (Polytel GMA from Polymap Wireless). One of the intervention groups received additional health counseling through telephone calls by a diabetes specialist nurse for the first 4 months of the study. At the 1-year follow-up, 75 out of 101 participants from the intervention groups completed an acceptability questionnaire (The Service User Technology Acceptability Questionnaire) after having finished the study.

Both intervention groups received the training needed to manage the mobile phone and the app provided by a team of researchers and assistants in meetings with the participants, in addition to a technical support telephone service available at daytime.

Despite the eligibility criteria "capacity to use the app, some participants expressed a lack of motivation or capacity to learn to use the app. Some therefore received additional training in face-to-face meetings with the technical supporters or others in the research team. In the health counseling intervention group, the diabetes specialist nurse focused on diabetes self-management and motivation, and at the same time, when needed, encouraged the participants to use the app [13,14]. Currently, we report findings from the 2 intervention groups that were assessed at the 1-year follow-up; in total, 75 of the originally enrolled 101 participants completed the self-report questionnaires (response rate; 74.3%).

Measures

The Service User Technology Acceptability Questionnaire

The Service User Technology Acceptability Questionnaire (SUTAQ) was developed, designed, and psychometrically evaluated for the WSD study, a large telehealth study performed in England. The 22 items aim to measure the users' beliefs and perceptions of the equipment. An expert panel of researchers and clinicians developed the questionnaire. Factor analysis from the original WSD study reported 5 domains: *perceived benefit*, *privacy and discomfort*, *care personnel concerns*, *kit as a substitution*, and *satisfaction* [12]. The answers to the statements for each item were rated on a Likert scale from 1 to 6, ranging from strongly agree to strongly disagree [12]. The psychometric evaluation of the Norwegian language version of SUTAQ is reported elsewhere, and the factor analyses only confirmed the domains *perceived benefit* and *care personnel concerns* [17].

Table 1. Sample characteristics at baseline for those who responded at 1-year follow-up (Service User Technology Acceptability Questionnaire, n=75).

Variables	Median	Range
Age (years)	59	35-80
Diabetes duration[a] (years)	9	1-36
HbA_{1c}[b], %		
Baseline	7.8	7.1-12.4
1-year follow-up[c]	7.6	5.6-13.0
Health Education Impact Questionnaire domains		
Health-directed activity	2.75	1.00-4.00
Positive and active engagement in life	3.20	1.60-4.00
Emotional distress	3.00	1.17-4.00
Self-monitoring and insight	3.00	2.33-3.83
Constructive attitudes and approaches	3.00	1.80-4.00
Skill and technique acquisition	3.00	2.00-4.00
Social integration and support	3.00	2.00-4.00
Health service navigation	3.00	2.00-4.00

[a]Missing from baseline: n=6.

[b]HbA_{1c}: glycated hemoglobin.

[c]Missing from baseline: n=2.

The Health Education Impact Questionnaire

The Health Education Impact Questionnaire (heiQ) was developed in Australia [18] to measure self-management after participation in education and or self-management support interventions for persons with chronic diseases. This questionnaire has later been adapted for multiple settings. In addition, Osborne has suggested new ways of use, such as incorporation of the instrument, or some of the scales, into standard assessment and as a care planning tool [1]. Each of the 40 items is rated on a Likert scale from 1 to 4, from "strongly disagree" to "strongly agree." They are organized into 8 domains as listed in Table 1, with 4 to 6 items in each domain. For all domains, high scores indicate a high level of self-management abilities, except for *emotional distress*, where high scores reflect high distress. The heiQ questionnaire has been validated in a Norwegian primary health care context in patients with different chronic conditions, including diabetes [19]. In this study, we used heiQ data from baseline measures before any intervention to investigate the users' initial ability to self-manage.

Log Data, High and Low Frequency of Use

The researchers in the team defined high frequency of use as ≥5 blood glucose measurements and ≥50 keystrokes in the app each month for at least 6 months of the 1-year intervention to differentiate between participants who used the app regularly, sporadically, or did not use the app. The app enabled registration of blood glucose level, diet and physical activity, setting of goals, and gave access to a diabetes-specific dictionary. The Bluetooth technology enabled automatic sending of blood glucose values from the blood glucose meter to the app. Diet and physical activity data were self-reported and entered manually into the app through graphical user interface. Keystrokes were registered for use of all the graphical user interface functionalities. Measurements of blood glucose, diet, and physical activity that were recorded with the app were sent to a secure server continuously during the study.

Demographic and Clinical Data

Demographic data such as age, gender, education, diabetes duration, and any comorbidities were self-reported through questionnaires at baseline. HbA_{1c} baseline values were obtained from the general practitioners' medical records.

Statistical Analysis

Sample characteristics are presented as counts and percentages for categorical variables and as median and range for continuous variables. Differences between the intervention groups and between the participants lost to follow-up and the responders were assessed using Pearson chi-square test for pairs of categorical data and the nonparametric Mann-Whitney Wilcoxon *U* test for continuous data. We modeled associations between initial ability to self-manage (heiQ) and equipment acceptability (SUTAQ) with univariate linear regression models, and thereafter adjusted for possible confounders such as age, gender, and frequency of use in multiple models. *P* values <.05 were considered statistically significant. All tests were two-sided. All analyses were performed using IBM SPSS Statistics (v 23; IBM Corp, Armonk, NY, USA).

Ethics

The Norwegian Regional Committees for Medical and Health Research Ethics approved the study, and the participants signed an informed consent when they entered. In addition, we performed risk analysis before start of the study.

Results

Sample Characteristics

Of the 75 participants analyzed, 42 (56%) were female, the median age was 59 years (age range 35-80 years), 37 (49%) had 12 years or more of education, only 10 (13%) had no comorbidities, and the median diabetes duration was 9 years (range 1-36 years). Almost half of the participants, that is, 48% (36/75), were high-frequency users of the diabetes diary app (Tables 1 and 2). No statistically significant differences in self-reported acceptability (SUTAQ) of the equipment or in baseline measures between the 2 intervention groups were revealed. Furthermore, between the participants lost to follow-up at 1 year (nonresponders) and the remaining responders in the interventions groups, there were no differences in baseline values regarding age, gender, education, diabetes duration, or HbA_{1c}; however, we did find a difference in the frequency of use of the app. According to the log data, only one of the participants lost to follow-up used the app frequently. Overall, heiQ baseline values were in the slightly higher ranges of possible values for all the measured items (Table 1).

Associations Between Self-Management Assessed With Health Education Impact Questionnaire and Acceptability Measured With Service User Technology Acceptability Questionnaire

We explored the 2 acceptability factors *perceived benefit* and *care personnel concerns*, which were the only domains of the original scale that were confirmed by the factor analysis [17]. The domain *perceived benefit* (SUTAQ) was significantly associated with 5 of the 8 heiQ (self-management) domains at baseline (Table 3).

In addition, our data revealed a significant crude association between gender and *perceived benefit*, where men experienced more benefit from the app than women (estimated beta=−.57, 95% CI −1.05 to −0.09, *P*=.02). Moreover, an association was revealed between gender and frequency of use, where 69% (25/36) of the high-frequency users were men (*P*=.02).

Furthermore, linear regression models confirmed that frequency of equipment use was the factor that was strongest associated with *perceived benefit* (SUTAQ), even when controlled for all of the heiQ domains separately, as well as for age and gender. Only the heiQ domain *skill and technique acquisition* remained associated with *perceived benefit* when adjusted for age, gender, and frequency of use (Table 3). No association was found between initial ability to self-manage (heiQ) and the SUTAQ domain *care personnel concerns* (results not shown).

Table 2. Sample characteristics at baseline, 1-year follow-up responders (Service User Technology Acceptability Questionnaire); n=75.

Variables	n (%)
Gender	
Female	42 (56)
Male	33 (44)
Education	
<12 years	38 (51)
12 years	7 (9)
>12 years	30 (40)
Comorbidities	
0	10 (13)
1-2	51 (68)
≥3	14 (19)
Use of app, log data[a]	
Low frequency of use	37 (49)
High frequency of use	36 (48)
Familiar with technology	
Familiar with use of computer	69 (92)
Familiar with use of mobile phone	75 (100)

[a]Missing from baseline: n=2 (3%).

Table 3. Linear regression and crude and adjusted values (adjusted for age, gender, and frequency of use), dependent variable *perceived benefit* (Service User Technology Acceptability Questionnaire).

heiQ[a] domains	Crude		Adjusted (age, gender, and frequency of use)	
	Estimated beta (95% CI)	*P* value	Estimated beta (95% CI)	*P* value
Health-directed activity	.44 (0.11 to 0.78)	.01	.31 (−0.03 to 0.64)	.07
Positive and active engagement in life	.40 (−0.19 to 0.98)	.18	.17 (−0.40 to 0.73)	.56
Emotional distress	.37 (−0.03 to 0.78)	.07	.20 (−0.20 to 0.59)	.32
Self-monitoring and insight	.89 (0.05 to 1.74)	.04	.53 (−0.30 to 1.36)	.21
Constructive attitudes and approaches	.45 (−0.01 to 0.91)	.06	.29 (−0.16 to 0.74)	.21
Skill and technique acquisition	.74 (0.17 to 1.32)	.01	.60 (0.03 to 1.17)	.04
Social integration and support	.69 (0.21 to 1.18)	.005	.37 (−0.15 to 0.90)	.16
Health service navigation	.64 (0.14 to 1.14)	.01	.40 (−0.11 to 0.92)	.12

[a]heiQ: Health Education Impact Questionnaire.

Discussion

Principal Findings

We explored associations between initial ability to self-manage and equipment acceptability using the 2 acceptability factors *perceived benefit* and *care personnel concerns*, which were the only 2 domains confirmed in the factor analysis. As hypothesized, we found a linear relationship between higher self-management and a positive experience of the mobile diabetes app as being beneficial for health care. However, after adjusting for age, gender, and frequency of use, this association was no longer statistically significant, except for the domain *skill and technique acquisition*. Furthermore, according to our findings, the use of the app turned out to have the strongest association with app acceptability.

The SUTAQ domain *perceived benefit* contains statements regarding improved health, increased involvement in health treatment, and the use of the app and the equipment as a supplement to usual care. In contrast to what we assumed, the initial ability to self-manage did not seem to be associated with acceptability; however, the participants who used the mobile phone app reported benefits of the app independent of the level of perceived self-management before its use. There are several barriers for persons with type 2 diabetes concerning the use of digital tools in their treatment. These barriers could be related to the potential user, to the technology, or to the health care offered [20-22]. Technical difficulties [9] and technological illiteracy [20,21], in addition to low health literacy [23,24], are associated with less engagement with technology for persons with type 2 diabetes. We did not find initial low self-management to be a barrier in our study, as our nonresponders had similar levels of all items of heiQ. However, it may not have been a coincidence that the domain that remained statistically significant in the analyses was skills to manage symptoms, which include skills to make use of equipment [1,18]. The participants were motivated to use the technology when they volunteered to enter the study, and inability to use the technology was an exclusion criterion. We can speculate that a lower self-management could have been a barrier at an earlier stage with regard to showing interest in the study. This is a limitation to the generalizability of our findings as all our participants scored relatively high on heiQ. In contrast to our findings, Hirani et al found an association between several of the heiQ domains and the SUTAQ domains, which indicates that those who accepted the intervention reported higher levels of self-management [12]. However, Hirani et al did not report the baseline values of heiQ. Therefore, it remains unclear whether their findings reflect a change in self-management during the use of the digital tools, where use of the tools enhances self-management skills and attitude, or whether the level of self-management was unchanged from baseline.

Strengths and Limitations of the Study

The participants' technical literacy, which was an inclusion criterion in our study, could bias our findings, as all participants were able to manage the equipment at some level, increasing the probability of acceptability. Nevertheless, we experienced a noticeable diversity in technical skills, and we gave technical support when needed through the study, implying that participants with different levels of technical experience and preferences were included, although persons with lack of technical skills were not eligible. It would have strengthened our study if we had measured the initial level of technological skills in more detail than only their experiences with mobile phones and personal computers. All the participants had previous experiences with use of mobile phone, yet not necessarily smartphones. Another possible limitation is the definition of frequency of use. It is difficult precisely to define an anticipated use because of between-persons differences in needs and stage of progression of their disease. Our definition of use aimed to differentiate between the participants' use of the app regularly and the ones who had sporadic or no use of the app.

In addition, it would have been interesting to know their level of motivation to enter the study, as we do not know much about who were initially eager to try new technology or whether they attended for other reasons. However, we have performed a qualitative study with interviews at the end of the RCT when the participants left the study and gained more in-depth knowledge about the participants' acceptability. These findings have recently been corroborated (A Torbjørnsen et al, unpublished data, May 2018).

In our analysis, we pooled together 2 heterogeneous groups of participants testing the app, with 1 group receiving initial health counseling. Potentially, the group receiving health counseling could have responded differently to the acceptability questionnaire than the intervention group that only had the equipment with the app. As an example, the health counseling group could have reported higher acceptability caused by enhanced access to health care and technical support; to the contrary, the health counseling could add a burden, and exhausted the participants, and thus, resulting in lower acceptability by some. As we did not find any differences between the groups, neither for acceptability nor for other measures, we pooled the 2 groups. We have previously discussed the effect and intensity of the health counseling [14,15].

Implications for Future Research and Clinical Practice

Our findings suggest that use of a diabetes diary app could be acceptable regardless of initial ability to self-manage, as the crude correlation between the 2 scales disappeared when adjusting for age, gender, and frequency of use, except for the domain *skill and technique acquisition*. Further research on which factors may influence the use and benefit of an mHealth solution would be of interest.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V.1.6.1).

[PDF File (Adobe PDF File), 1MB - mhealth_v6i5e125_app1.pdf]

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Abbreviations

HbA $_{1c}$: glycated hemoglobin
heiQ: Health Education Impact Questionnaire
mHealth: mobile health
RCT: randomized controlled trial
SUTAQ: Service User Technology Acceptability Questionnaire

WSD: Whole System Demonstrator

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Original Paper

Usefulness of a Novel Mobile Diabetes Prevention Program Delivery Platform With Human Coaching: 65-Week Observational Follow-Up

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Abstract

Background: It is widely recognized that the prevalence of obesity and comorbidities including prediabetes and type 2 diabetes continue to increase worldwide. Results from a 24-week Diabetes Prevention Program (DPP) fully mobile pilot intervention were previously published showing promising evidence of the usefulness of DPP-based eHealth interventions on weight loss.

Objective: This pilot study extends previous findings to evaluate weight loss results of core (up to week 16) and maintenance (postcore weeks) DPP interventions at 65 weeks from baseline.

Methods: Originally, 140 participants were invited and 43 overweight or obese adult participants with a diagnosis of prediabetes signed up to receive a 24-week virtual DPP with human coaching through a mobile platform. At 65 weeks, this pilot study evaluates weight loss and engagement in maintenance participants by means of repeated measures analysis of variances and backward multiple linear regression to examine predictors of weight loss. Last observation carried forward was used for endpoint measurements.

Results: At 65 weeks, mean weight loss was 6.15% in starters who read 1 or more lessons per week on 4 or more core weeks, 7.36% in completers who read 9 or more lessons per week on core weeks, and 8.98% in maintenance completers who did any action in postcore weeks (all $P<.001$). Participants were highly engaged, with 80% (47/59) of the sample completing 9 lessons or more and 69% (32/47) of those completing the maintenance phase. In-app actions related to self-monitoring significantly predicted weight loss.

Conclusions: In comparison to eHealth programs, this pilot study shows that a fully mobile DPP can produce transformative weight loss. A fully mobile DPP intervention resulted in significant weight loss and high engagement during the maintenance phase, providing evidence for long-term potential as an alternative to in-person DPP by removing many of the barriers associated with in-person and other forms of virtual DPP.

(JMIR Mhealth Uhealth 2018;6(5):e93) doi:10.2196/mhealth.9161

KEYWORDS

prediabetes; body weight; behavioral interventions; mHealth; mobile app; diabetes prevention

Introduction

It is widely recognized that the prevalence of obesity and comorbidities such as prediabetes and type 2 diabetes continue to increase worldwide [1,2]. In the United States, 84.1 million persons have prediabetes while 30.3 million have diabetes [3]. Recent reports show 35% of men and 40% of women with obesity [4]. Large longitudinal clinical trials have shown the effectiveness of lifestyle interventions and behavior change for weight loss and type 2 diabetes risk reduction [5-10], performing better than medication. The original National Diabetes Prevention Program (NDPP) intervention study provided an intensive lifestyle intervention focused on weight loss of at least 7% of body weight through a low-fat diet and a minimum increase of 150 minutes of weekly physical activity [7]. The intervention resulted in reduced incidence of diabetes of 58% at 3 years [7]. At 15 years' follow-up, incidence was reduced by 27% in the intensive lifestyle intervention group [5]. Therefore, lifestyle and behavior interventions have become the standard recommendation for risk reduction in persons with overweight or obesity [11]. Lifestyle in-person programs can be very effective, but the cost may be unsustainable [12]. With the advent of digital technology, evidence points to the noninferiority and at times superiority of mHealth and eHealth, telecommunications translations of lifestyle interventions such as the Diabetes Prevention Program (DPP) [13] to prevent and manage chronic conditions.

A recent review of DPP-based lifestyle interventions via electronic, mobile, and telehealth or eHealth interventions with remote counseling up to 15 months from baseline, looking at predominantly white and educated samples, found mean sustained weight loss of 4.31% compared to 4.65% with a counselor in-person [13]. There is promising evidence of the usefulness of DPP-based eHealth interventions on weight loss. In participants over 65 years, a single-arm study showed 7.5% weight loss at 12 months for those who completed a 12-month program with a Centers for Disease Control and Prevention (CDC)-based DPP with human coaching [14].

We previously reported findings from a 6-month fully mobile DPP intervention in a group of overweight and obese hyperglycemic adults [15]. Briefly, at 24 weeks core completers (84% of the sample) lost 7.5% of body weight. The purpose of this pilot study is to report 65-week weight loss from baseline and at completion of the maintenance component of the mobile DPP intervention. We hypothesized that clinically and statistically significant weight loss at 65 weeks would be maintained (>5% body weight).

Methods

Recruitment

A detailed intervention description was previously published [15]. Briefly, participants were recruited by email or regular mail by a large Northeast-based insurance company that offered its employees the Noom app free of cost; employees did not receive additional compensation for their participation. The email or regular mail invitation contained information describing the study. Potential participants across different departments and states were included if they had an elevated hemoglobin A_{1c} (HbA_{1c}) status (5.7% to 6.4%) in their medical records, reflecting a diagnosis of prediabetes. Interested participants were assigned to a virtual NDPP coach who had successfully completed a CDC-recognized training course.

Men and women with an HbA_{1c} of 5.7% to 6.4% between the ages of 18 and 75 years who signed up for Noom's NDPP program (Figure 1, n=140) between June 22 and September 7 (recruitment phase 1 as previously reported [15]) and September 8 and November 30, 2015 (phase 2 added 19 participants), were included in the study. Out of 140, individuals were considered interested (n=73) if they performed at least 1 in-app action during the first week of the NDPP curriculum. Sixty-seven participants did not perform any in-app actions during the first week of the NDPP curriculum and were not included in the study. From 73 interested participants, those having <2 weigh-ins (n=13) and who did not read more than one article per week for 4 or more weeks were considered nonstarters and were excluded from final analyses. Participants who attended (ie, read content) during at least any 4 of the initial 16 weeks were considered to have started, in accordance with the CDC's definition (n=60) [16]. We excluded a single participant because that person failed to provide more than 1 weigh-in, thus resulting in 59 participants making up our final sample of starters. Out of the starters, participants were considered completers (n=47) if they attended any 9 of the 16 weeks of the core program [16]. Only participants who completed the core phase were eligible for the maintenance phase, and those who attended at least 7 maintenance sessions were considered maintenance phase completers (n=32). As multiple maintenance session topics are delivered each month, attendance at 7 sessions exceeded the 50% minimum Diabetes Prevention Recognition Program standard [16].

During the first week of the study, participants received orientation on what the DPP program entails, learned how to use the Noom app, how to interact with their coach, and the importance of maintaining motivation throughout the program. The Noom Coach app (Figure 2) offers an interactive interface with coach-participant messaging, group messaging, daily challenges for behavior change, the DPP-based education articles, food logging with color coding, and automated feedback based on food choices. Participants received daily DPP content through informative articles and were asked to log their weight by self-report, meals, and physical activity within the app on a weekly basis. NDPP-certified coaches securely monitored participant progress through a dashboard. The emphasis of the intervention is on lifestyle change and finding a system of healthy living that fits into the context of each user's individual life. Therefore, the objective was that the participant interacted with the coach, the group, and the app in general in a way that seamlessly integrated into their life. Participants were instructed to communicate as much or as little as needed to support their individual journey. Participants were informed that they could expect to hear from their coach every day (an individual message or a message addressed to the entire group). Basic instructions encompassed the message "You get out of it what you put into it. Be as present as you can in the app. Log as much as possible, as this gives me (your coach) insight into your health habits and

gives context to all discussions. The more engaged you are with the app, the more likely you will be to stay on track toward your health goals."

Participants engaged in the program by completing actions that included meals logged (meals per week), green foods logged (logged per week), exercise logged (times per week), exercise time registered (minutes per week), steps recorded (steps per week), weigh-ins logged (times per week), articles read (articles per week), group posts (posts per week), group comments (comments per week), messages sent to their coach (messages per week), and group likes (likes per week). This pilot study reports 65-week results including the maintenance DPP phase.

Figure 1. Flowchart for study recruitment, starting, and completion or core and maintenance status.

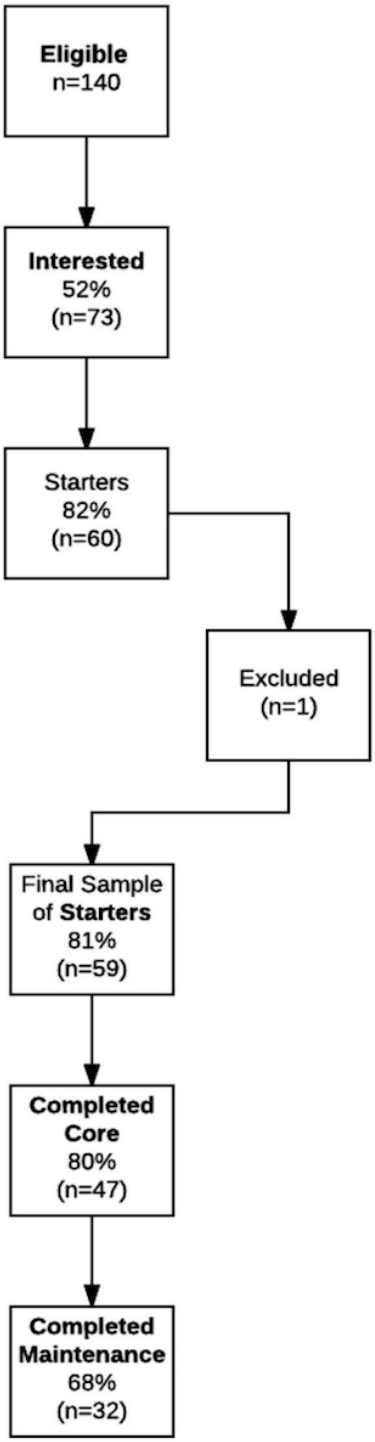
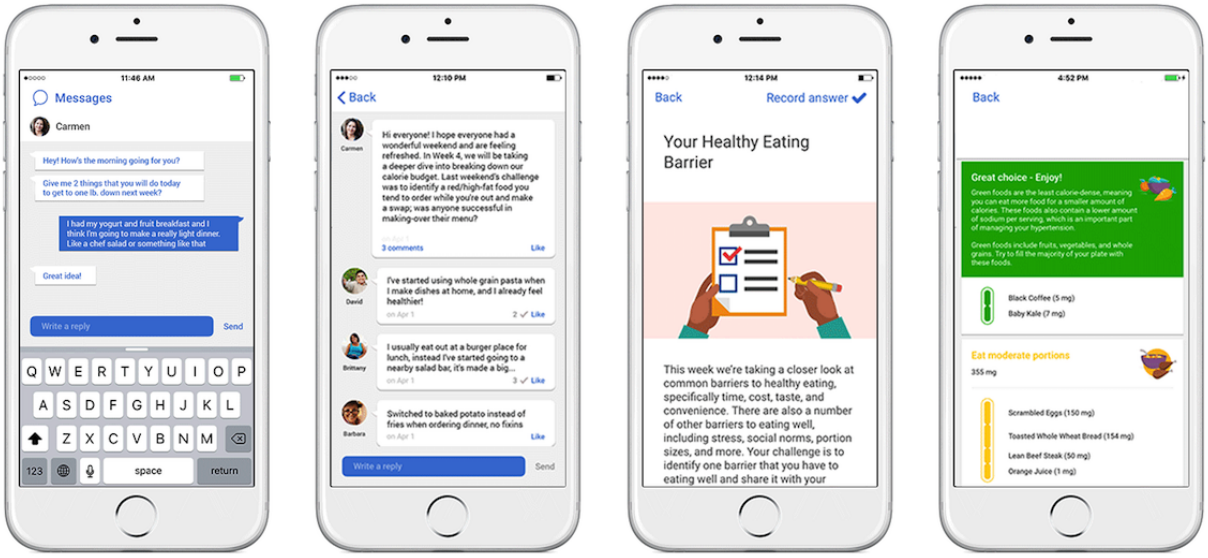


Figure 2. The Noom Coach app's interactive interface with coach-user messaging, group messaging, daily challenges, food logging with color coding and automated feedback based on food choices.



Statistical Analysis

Descriptive statistics, expressed as means and standard deviations or frequencies and percentages for continuous and categorical variables, respectively, were calculated for subject baseline characteristics. Mean weekly in-app action variables were calculated as means and standard deviations from baseline to 65 weeks for starters, completers, and maintenance completers. Last observation carried forward was utilized for endpoints. Repeated measures analysis of variance examined the effect size of the change in weight and body mass index (BMI) from baseline to 24 weeks and 65 weeks in starters, completers, and maintenance completers based on the CDC standards [16]. Multiple linear backward regression analyses examined whether in-app engagement variables predicted weight loss at 65 weeks. This method was used to evaluate which variables accounted for the most variance in the model, removing those that did not render a good fit and providing insight into what user behaviors predicted weight loss. Significance tests are 2-sided with a significance of $P<.05$. Statistical analyses were performed using SPSS Statistics version 21 (IBM Corp) software.

Results

At baseline, 81% (48/59) of the sample was female with a mean BMI of 34 kg/m^2 and mean age of 51 years (Table 1). Relative to baseline, starters lost 5.93 kg at 65 weeks and BMI was reduced by 2.12 kg/m^2. Among completers, weight loss was 7.05 kg and BMI change was –2.53 kg/m^2. Maintenance completers lost 8.78 kg of body weight and BMI was reduced by 3.14 kg/m^2, all $P<.001$. Among starters, 44% (26/59) lost ≥5% body weight while 53% (25/47) of completers and 66% (21/32) of maintenance completers lost ≥5% body weight, respectively (Table 2).

In maintenance completers, mean body weight decreased significantly by 7.64 kg between baseline and 24 weeks and was sustained over time by 8.77 kg from baseline to 65 weeks (both $P<.001$). Weight change at 65 weeks was not different to that at 24 weeks (–1.13 kg, $P=.29$) (Table 3). BMI at 24 and 65 weeks did not differ and was significantly lower than at baseline (Table 3). Raw data are shown in Multimedia Appendix 1.

Mean in-app engagement variables are shown in Table 4. Multiple linear backward regression examined in-app engagement variables as predictors of weight loss controlling for age and sex (Multimedia Appendix 2). The variables that remained in the model were mean weekly logged meals, exercise, articles read, group posts, and messages to coach. Participants with higher engagement and self-monitoring through meal logging and group posts had higher weight loss, whereas messaging the coach, logging exercise, and reading articles predicted weight gain.

Table 1. Baseline characteristics of study starters, completers, and maintenance completers. BMI: body mass index.

Characteristics	Starters (n=59)	Completers (n=47)	Maintenance completers (n=32)
Gender, female, n (%)	48 (81)	37 (79)	26 (81)
Age, years, mean (SD)	51.27 (9.25)	51.45 (9.47)	51.34 (9.55)
Height, cm, mean (SD)	166.75 (9.38)	167.62 (9.16)	167.44 (9.04)
Weight, kg, mean (SD)	95.36 (22.11)	95.66 (23.10)	96.83 (24.94)
BMI, kg/m^2, mean (SD)	34.19 (6.75)	33.90 (6.83)	34.39 (7.41)

Table 2. Weight loss from baseline to 65 weeks, *P*<.001. BMI: body mass index.

Characteristics	Starters (n=59)	Completers (n=47)	Maintenance completers (n=32)
Weight change, kg, mean (SD)	–5.93 (6.78)	–7.05 (7.10)	–8.78 (7.71)
Weight change, %, mean (SD)	–6.15 (6.50)	–7.36 (6.67)	–8.98 (7.12)
BMI change, kg/m^2, mean (SD)	–2.12 (2.43)	–2.53 (2.54)	–3.14 (2.76)

Table 3. Weight change from baseline to 24 weeks and 65 weeks in maintenance completers (n=32). BMI: body mass index.

Characteristics	Baseline	24 weeks	*P* value[a]	65 weeks	*P* value[b]
Weight, kg, mean (SD)	96.83 (4.41)	89.18 (4.29)	<.001	88.06 (4.27)	.29
BMI, kg/m^2, mean (SD)	34.39 (7.41)	31.66 (7.22)	<.001	31.24 (7.11)	.28

[a]Change from baseline to 24 and 65 weeks.

[b]Change from 24 weeks to 65 weeks.

Table 4. Mean in-app[a] weekly engagement variables over 65 weeks.

Weekly engagement variable	Starters (n=59)		Completers (n=47)		Maintenance completers (n=32)	
	n[b]	mean (SD)	n	mean (SD)	n	mean (SD)
Meals logged (meals/week)[c]	57	15.28 (3.99)	45	15.89 (3.87)	30	16.39 (3.26)
Green foods (logged/week)[d]	59	0.27 (.13)	47	0.27 (0.13)	32	0.29 (0.14)
Exercise (times/week)	57	4.52 (2.70)	47	4.60 (2.34)	32	4.70 (2.07)
Time exercised (minutes/week)	57	169.68 (113.93)	47	175.06 (111.06)	32	188.65 (119.18)
Steps recorded (steps/week)	52	23,427.95 (14,709.14)	43	24,397.80 (15,311.71)	29	23,696.13 (13,845.60)
Number of weigh-ins (times/week)[e]	59	1.40 (0.85)	47	1.48 (0.93)	32	1.53 (0.99)
Articles read (articles/week)	59	8.12 (3.34)	47	8.59 (2.97)	32	8.56 (2.73)
Group posts (posts/week)[f]	53	1.88 (1.10)	43	1.91 (1.13)	30	1.93 (1.14)
Group comments (comments/week)[g]	53	2.85 (1.52)	44	2.90 (1.46)	30	3.08 (1.40)
Messages to coach (messages/week)	56	3.92 (1.67)	45	4.09 (1.96)	31	4.48 (1.83)
Group likes (likes/week)[h]	49	2.34 (1.46)	42	2.28 (1.55)	30	2.33 (1.76)

[a]In Michaelides et al [15], it was previously reported that in-app actions related to self-monitoring over 24 weeks significantly predicted weight loss.

[b]n represents the number of starters, completers, or maintenance completers that engaged in with the app feature.

[c]Meals logged refers to the times breakfast, lunch, snack, and dinner were logged per week.

[d]Green foods refers to food items logged that contain low calorie density (calories per grams in a serving).

[e]Number of weigh-ins refers to times per week of in-app weight self-reports.

[f]Group posts refers to times per week a participant posted to their group in an in-app common conversation.

[g]Group comments refers to responses to group posts per week.

[h]Group likes refers to times per week a participant liked a group comment.

Discussion

Principal Findings

This 65-week pilot study shows that a mobile DPP intervention is capable of producing weight loss outcomes that are comparable to those seen in in-person NDPP or similar virtual programs [7,17,18]. Core completers represented 80% of the final sample (47/59), and maintenance completers represented 69% of core completers (32/47). Core completers lost 7.36% of body weight and maintenance completers lost 8.98%, comparable to outcomes seen in other observational DPP studies. Findings suggest that a mobile DPP program can facilitate transformative weight loss in participants as well as significant weight maintenance after 1 year. At 6 months, in-app engagement predicted weight loss, with key indicators including weekly weigh-ins, meals logged, and weekly posts to the group [15]. In the same study, those who made more group posts also logged more meals, and meal logging partially mediated the relationship between group posts and percentage weight loss [15]. Follow-up results at 65 weeks in this maintenance study did not show mediation but further support the conclusions from the 6-month findings [15]. Mean weekly logged meals, exercise,

articles read, group posts, and messages to coach predicted weight loss. Participants with higher engagement and self-monitoring through meal logging and group posts had higher weight loss, whereas messaging the coach, logging exercise, and reading articles predicted weight gain. It is known that monitoring weight and following structured lessons are predictors of weight loss [19] and sustained weight loss over time. In this pilot study, some engagement variables were correlated, potentially leading to collinearity and contradiction among variable predictions (reading articles, messaging the coach, and exercising more) in the model. Another interpretation, however, could be that users who reach out to their coach more frequently may be struggling more with weight loss compared with those who reach out less and manage weight loss more effectively. This warrants further investigation in a larger sample and shows that a platform that combines a low-barrier self-monitoring method is highly relevant to successful facilitation of a virtual DPP.

Comparison With Prior Work

While there has been extensive research on eHealth approaches to diabetes prevention [13,20-24], to our knowledge this study is the first fully mobile (mHealth) translation of the DPP with more than 1-year follow-up. This study shows that a fully mobile DPP is similar in producing desired weight loss outcomes in comparison with Web-based or telehealth programs. These findings are particularly significant given that the use of mobile phones is expected to reach over one-third of the world's population by 2018 [25].

At 65 weeks, maintenance completers lost 8.98% of their starting weight, which exceeds the CDC's NDPP requirement of 5% loss of body weight at 6 months and 12 months [3]. Other eHealth interventions for diabetes prevention have reached different levels of weight loss at 12 months. For example, Fisher et al [26] found a 2.31 kg weight loss in the intervention group of a text message–based intervention, and Sepah et al [18] found a 5.13 kg weight loss at 12 months in a Web-based intervention [18], while our study showed a mean weight loss of 7.05 and 8.78 kg in core completers and maintenance phase completers, respectively, at 65 weeks.

Furthermore, in comparison with recent in-person DPP trials, which have scalability and cost-effectiveness challenges [27], results indicate that weight loss outcomes may even be higher in virtual DPP [28,29]. One possible reason for these outcomes is that virtual DPP allows for a participant to interact with a group and facilitator more than once per week. Daily delivery of content combined with real-time access to facilitators has resulted in greater engagement and longer retention when compared to in-person or digital programs offered once per week. This is supported by the positive association between engagement metrics and weight loss outcomes seen in our results. Furthermore, the assumption that virtual DPP programs can be just as, or more, effective than in-person DPP programs is supported by virtual DPP research beyond this pilot. A similar single-arm trial resulted in participants losing 7.5% of body weight [14] while meta-analyses have also shown promising evidence of the efficacy of virtual DPP programs [13,20].

Limitations

While the results are promising, there are limitations to this pilot study. As this is a pilot study, the sample size is small (n=59). Furthermore, this was an observational study; thus, the participants were self-selected and likely highly motivated individuals, resulting in limited generalizability. Nonetheless, per observational study design, participants were both self-selected and self-monitored, which mimics real-world applications of a virtual DPP program. An additional limitation is the lack of HbA_{1c} values. However, the main outcome of the DPP is weight loss above the transformative value of 5% as established by the CDC. Medication history, which could influence weight loss, was not collected. Participant/coach and group interactions were assessed quantitatively, which could have provided more insight into participant attitudes and behaviors and better explain weight loss and behavior change, instead of qualitatively. To validate the findings of this pilot study, future long-term randomized controlled trials should aim to include biometric data such as HbA_{1c} level and quality of life metrics.

Conclusions

This pilot study of a fully mobile DPP intervention found significant weight loss and high engagement during the maintenance phase, providing evidence for long-term potential as an alternative to in-person DPP by removing many of the barriers associated with in-person and other forms of virtual DPP.

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Authors' Contributions

TTR, JM, AM, EP, and YK cowrote the manuscript, and TTR and AM conducted data analyses. AM is the principal investigator. AM is also the guarantor of this work and, as such, had full access to all data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis. MW is the research coordinator, reviewed the manuscript, and oversaw the conduct of the study. MW is also the coach manager and provided oversight to coaching and training with AM.

Conflicts of Interest

All authors are employed by Noom, Inc, and receive a salary and stock options. AM and MW hold a patent pending (3492.004US1) with Noom, Inc. Noom Coach is a mobile application owned by Noom, Inc.

Multimedia Appendix 1

Raw weight change data at baseline, 24 weeks, and 65 weeks for maintenance completers.

[PNG File, 80KB - mhealth_v6i5e93_app1.png]

Multimedia Appendix 2

Backward multiple linear regression of engagement variables as predictors of weight loss in maintenance completers.

[PDF File (Adobe PDF File), 64KB - mhealth_v6i5e93_app2.pdf]

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Abbreviations

BMI: body mass index
CDC: Centers for Disease Control and Prevention
DPP: diabetes prevention program
HbA $_{1c}$: hemoglobin A_{1c}
NPDD: National Diabetes Prevention Program

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Original Paper

mActive-Smoke: A Prospective Observational Study Using Mobile Health Tools to Assess the Association of Physical Activity With Smoking Urges

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Abstract

Background: Evidence that physical activity can curb smoking urges is limited in scope to acute effects and largely reliant on retrospective self-reported measures. Mobile health technologies offer novel mechanisms for capturing real-time data of behaviors in the natural environment.

Objective: This study aimed to explore this in a real-world longitudinal setting by leveraging mobile health tools to assess the association between objectively measured physical activity and concurrent smoking urges in a 12-week prospective observational study.

Methods: We enrolled 60 active smokers (≥3 cigarettes per day) and recorded baseline demographics, physical activity, and smoking behaviors using a Web-based questionnaire. Step counts were measured continuously using the Fitbit Charge HR. Participants reported instantaneous smoking urges via text message using a Likert scale ranging from 1 to 9. On study completion, participants reported follow-up smoking behaviors in an online exit survey.

Results: A total of 53 participants (aged 40 [SD 12] years, 57% [30/53] women, 49% [26/53] nonwhite) recorded at least 6 weeks of data and were thus included in the analysis. We recorded 15,365 urge messages throughout the study, with a mean of 290 (SD 62) messages per participant. Mean urge over the course of the study was positively associated with daily cigarette consumption at follow-up (Pearson r=.33; *P*=.02). No association existed between daily steps and mean daily urge (beta=-6.95×10^{-3} per 1000 steps; *P*=.30). Regression models of acute effects, however, did reveal modest inverse associations between steps within 30-, 60-, and 120-min time windows of a reported urge (beta=−.0191 per 100 steps, *P*<.001). Moreover, 6 individuals (approximately 10% of the study population) exhibited a stronger and consistent inverse association between steps and urge at both the day level (mean individualized beta=−.153 per 1000 steps) and 30-min level (mean individualized beta=−1.66 per 1000 steps).

Conclusions: Although there was no association between objectively measured daily physical activity and concurrently self-reported smoking urges, there was a modest inverse relationship between recent step counts (30-120 min) and urge. Approximately 10% of the individuals appeared to have a stronger and consistent inverse association between physical activity and urge, a provocative finding warranting further study.

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KEYWORDS

activity trackers; cigarette smoking; exercise; fitness trackers; mobile health; mHealth; physical activity; smartphone; smoking; text messaging; texting

Introduction

Smoking is the leading cause of preventable death in the world [1]. Although public health campaigns, antismoking laws, and new pharmacotherapies have successfully reduced smoking rates [2], further progress has proven difficult due, in part, to the complex psychosocial nature of tobacco addiction [3]. Although many smokers wish to quit smoking because of knowledge of its harmful effects [4], self-quitting initiatives have shown largely unsuccessful outcomes [5], suggesting that interventions are necessary to assist smokers in cessation. To that end, counseling and pharmacotherapy (ie, nicotine replacement, bupropion, and varenicline) are established smoking cessation interventions, but not effective in most individuals. Although nicotine replacement therapies have been shown to boost smoking cessation efforts twofold compared with placebo [6], 70% to 80% of smokers who use these therapies relapse [7].

Physical activity (PA) has been proposed as an aid for smoking cessation [8] and as a means for harm reduction among smokers who do not wish to quit [9]. A 2014 review that examined 20 trials assessing exercise as an aid for smoking cessation found the evidence for such a recommendation to be insufficient [10]. However, this review presents evidence that exercise may be an effective means for reducing tobacco cravings among smokers who are not presently motivated to quit [10], thereby suggesting exercise as a mediator of harm reduction. A 2014 pilot randomized trial—Exercise Assisted Reduction then Stop (EARS)—found that PA coupled with support for smoking reduction was effective in promoting reduction and cessation among smokers who did not wish to quit immediately [11]. A subsequent study examining data from the EARS trial provided further evidence for the role of PA on smoking reduction but did not find that this association was related to an increase in PA [9]. Rather, evidence suggests that the act of self-monitoring PA [12] and smoking behaviors may improve self-regulation [13] and thus decrease smoking [14] and likelihood of relapse [15] by reinforcing the notion of PA as an aid for smoking reduction [11].

Previous interventional studies have suggested that acute exercise decreases smoking urges [16-22], with activities of medium-long duration and moderate-vigorous intensity displaying the most substantial effects [18]. A systematic review and meta-analysis of individual-level data from 17 trials reported that PA acutely reduces cigarette craving [23]. Using a 2-stage independent participant data meta-analysis, this study assessed the effects of PA on desire to smoke as measured by a 7-point Likert scale and found an average standardized mean difference (SMD) of −2.03 (95% CI −2.60 to −1.46) between PA and control conditions [23]. However, these studies may be limited in clinical applicability because of experimental design and scope of measurement. Regarding the former, most acute studies have involved moderate to heavy smokers, where smoking urges were manipulated by periods of imposed smoking abstinence. These measures were taken to reduce the likelihood of a flooring effect: if participants had been allowed to smoke before these experimental trials, cravings and withdrawal symptoms might have been reduced to none, allowing for no further reduction as a result of exercise. Despite this important consideration, these experimental conditions were not reflective of the everyday circumstances that contribute to the complex manifestation of smoking urges in the natural environment.

Regarding the scope of measurement, these studies only assessed acute effects of exercise on smoking urges, leaving uncertainty around the longitudinal association. Several studies exploring longer-term associations between PA and smoking behaviors [24-30] showed that exercise improved follow-up abstinence rates [24,26,27], increased time until next cigarette [30], led to reductions in smoking and cravings [25,29], and was associated with lower smoking intensity and reduced likelihood of smoking [28]. However, both smoking behaviors and PA measures in these studies were primarily obtained through self-assessment and recall, thus rendering these data susceptible to bias [31,32].

Further studies with improved methodological rigor are needed to address the aforementioned limitations in both acute and longitudinal analyses of PA and smoking behavior [23]. To that end, mobile health (mHealth) technologies have the potential to allow continuous, accurate, and patient-friendly monitoring of health data, including subjective and objective behavioral information [33]. These technologies are especially practical for ecological momentary assessment (EMA) research, designed to sample subjects' real-time behaviors and experiences in the natural environment and minimize recall bias [34]. Importantly, use of mHealth also brings the potential to address health equity, given the rapidly increasing use of mHealth technologies in low-income individuals [35]. Several studies have validated the utility of activity trackers [36] and text messaging [37] for the measurement of PA and smoking urges, respectively. These technologies have also proven successful in behavioral interventions: leveraging activity tracking and text messaging to promote increased PA [38] or using personalized text messages to enhance smoking cessation [39]. Using both these mHealth tools in the natural environment of individuals who are active smokers, we aimed to assess the real-time association between objectively measured PA and concurrently reported smoking urges by examining the relationship between daily steps and mean daily urges. Secondarily, we sought to examine the acute associations of steps and urges in varying short-term time windows and to assess changes in smoking and PA behaviors over time in association with self-monitoring.

Methods

Study Design

For this longitudinal study spanning 12 weeks, the Fitbit Charge HR—a wrist-worn triaxial digital accelerometer with a built-in optical heart rate (HR) monitor that allows for continuous monitoring of activity throughout the day—and

smartphone-based short message service (SMS) text messaging were used for data collection. SMS text messaging was also used for participant monitoring; after a face-to-face enrollment visit with the study coordinator, communication occurred via text messages to answer questions, troubleshoot, and send reminders to address nonadherence with the study protocol. Participants who had gaps in their data (ie, missing days of data capture) by the end of 12 weeks were asked if they would voluntarily prolong the duration of their participation to ensure complete data capture.

Recruitment

We recruited 60 participants from April 7 to September 2, 2016, using several modalities, including on-site advertisements, social media, and physician referral. Before enrollment, participants were screened for eligibility via email and met in-person with a study coordinator to review the consent form and study information. To satisfy inclusion criteria, participants were required to be aged 18 years or older, smoke at least 3 cigarettes per day on average, and own a smartphone. Participants were excluded from enrollment if they were prohibited from normal PA for previously diagnosed health reasons. Face-to-face visits were not required after enrollment.

Baseline Data Collection

During the in-person meeting with the study coordinator, participants completed an online enrollment questionnaire to record baseline demographic characteristics, PA, and smoking behavior. Baseline PA was assessed using the short form of the International Physical Activity Questionnaire (IPAQ)—a 9-item questionnaire assessing time spent walking, in vigorous- and moderate-intensity activity, and in sedentary activity over a 7-day period [40]. Baseline smoking behavior was obtained using the Arizona Smoking Assessment Questionnaire (ASAQ)—a 27-item questionnaire that assesses past and present tobacco use by recording different types of exposure, quit attempts, and age of smoking onset [41]. In a sample of 600 participants, the ASAQ showed that the number of daily cigarettes and portion of cigarette smoked were significantly predictive of plasma cotinine levels (P<.001) [41].

Measurement and Monitoring of Physical Activity

PA was measured in steps over at least 6 weeks using the Fitbit Charge HR. During the in-person interview with the study coordinator, participants were guided through on-screen instructions for setup. The study coordinator emphasized that participants were expected to wear the device throughout the day, including during exercise; device removal was only advised for swimming or showering, and wearing it to sleep was optional.

Data flowed from the Fitbit device through the smartphone to encrypted Fitbit servers, which stored minute-level data up to 7 days and day-level data for up to 30 days. Fitbit data for all study participants were compiled in Fitabase—a research platform that collects real-time data from activity-tracking devices and stores it in high-security data centers. Fitabase has been used in more than 200 studies as a data analytics platform for Fitbit devices [42]. Fitabase stores data at various levels of granularity—from second-level to day-level—and allows for data export in individualized or batch formats. At the conclusion of the data collection phase, all participant data were downloaded from the Fitabase server and exported as comma separated values (CSV) files, where it was organized and uploaded into Stata (version 14.2; StataCorp, College Station, TX, USA) for analysis.

Fitabase's live device monitoring feature also allowed for monitoring participants in real-time by reporting syncing activity, battery life, and activity data on a single project dashboard. With access to real-time surveillance, investigators were able to monitor nonadherence, such as delayed syncing activity or failure to wear the device, which was addressed through a series of reminder text messages, emails, and phone calls.

Measurement of Smoking Urges

Time-stamped smoking urges were quantified via SMS text messages sent by participants. Recurring automatic text message reminders were scheduled for delivery 3 to 4 times per day using an automated messaging service (Boomerang, Baydin Inc, Mountain View, CA, USA). Prompting was used to promote study engagement—an evidence-based strategy that has been shown to improve participant engagement with digital interventions compared with no strategy [43]. Timing of text messages was customized based on participant preference. Each text contained an identical message, asking participants to express their instantaneous urge for smoking on a 9-point Likert scale—a previously validated measure of self-reported craving [44,45] consistent with EMA data sampling methods [34]. Low urge was indicated by a value of 1. Participants were permitted and encouraged to send as many text messages as possible, with or without prompting, but were asked to send a minimum of 3 messages per day. Participants also received weekly recurring messages that included brief instructions and reminders to sync their Fitbit devices. Additional reminder messages were scheduled for participants who displayed consistent patterns of nonadherence.

Follow-Up Data Collection

At the conclusion of the study, participants were asked to complete an online exit survey to provide their perceptions about the associations between PA and smoking urges and behavior. The IPAQ-short form and ASAQ were readministered in the exit survey, allowing for a comparison of these measures between baseline and follow-up.

Statistical Analyses

We estimated that a sample size of 50 participants each contributing at least 20 days of complete data capture and accounting for intraindividual correlation of the repeated data measurement would yield 90% power to detect a correlation of .12 between steps per day and mean reported smoking urges per day.

Baseline characteristics were summarized using descriptive statistics—frequency (percentage) for categorical data, and mean (SD) and median (interquartile range) for continuous data. Follow-up data were summarized in an identical manner and compared with baseline characteristics for variables of interest.

Trends in mean daily urge and daily steps between baseline and follow-up were also examined categorically. To do so, a midpoint was calculated for each participant, which represented the day at which study participation was 50% complete. Mean daily urge and mean daily steps were calculated before and after this midpoint for each participant. This categorization allowed for broad changes in these 2 measures to be assessed between the first and second halves of the study. Furthermore, this grouping allowed for mean daily steps and mean daily urge to be included in comparisons of other baseline and follow-up measures, such as self-reported PA and smoking behavior. Outliers were defined as values 1.5 times the interquartile range above the upper quartile or below the lower quartile.

A series of protocols were developed to distinguish between wear and nonwear time. Because participants were not required to wear their devices to sleep, we targeted the time window of 10:00 AM to 10:00 PM in determining wear time. We determined HR data to be the most reliable predictor of wear time, as the Fitbit Charge HR is designed to record HR data at 1-s intervals during exercise and at 5-s intervals all other times [46]. Thus, we interpreted the presence of HR data as evidence of wear time. Drawing from prior literature on determining wear time criteria [47], we defined nonwear time as 90 consecutive minutes of missing HR data. Days that included 2 or more of these 90-min consecutive nonwear windows were excluded from day-level analysis. These criteria were implemented to avoid imposing arbitrary cutoffs on our determination of data validity. Days in which total wear time was less than 6 hours within our target time window were also excluded. At least 6 total weeks of recorded data were required for participants to be included in the analysis.

Change in daily cigarette consumption was defined as the difference between the number of cigarettes smoked per day at baseline and follow-up as reported by participants in the enrollment and exit surveys, respectively. In addition, linear regression models were run to assess the change in daily steps and daily urge over time, as measured by the beta coefficients in the regression models. To assess the acute effects of PA, prespecified analyses were performed to assess minute-level associations between steps and urge within 5-, 30-, 60-, and 120-min time windows before urge reporting. These time windows were informed by results from prior studies, which found that acute bouts of low-intensity exercise reduced smoking urges for anywhere from 20 min [48] to 50 min [30] postexercise. The 120-min time window was included to assess whether and to what extent this effect might be prolonged after an acute bout of PA.

Structurally, the data contained both longitudinal and cross-sectional dimensions and can thus be best classified as panel data [49]. Feasible generalized least squares (FGLS) regression models were used to analyze the relationship between mean urge per day (dependent variable) and daily steps (independent variable). This procedure is recommended for panel data that are unbalanced or unequally spaced [50], and appropriate when the number of time points (T) exceeds the number of cross-sections (N) [51]—both of which are characteristic of our data. Furthermore, this model allowed us to correct for heteroscedasticity—unequal variance of the dependent variable across a range of values of an independent variable—which can lead to inefficient parameter estimates and faulty inferences [52].

Analyses were performed to explore interactions by age, sex, baseline PA and smoking levels, race/ethnicity, and intention to quit during the study period. For these analyses, binary definitions of demographic variables were used based on the following cutoffs: age ≥40 years, cigarettes per day ≥10 for baseline smoking level, high activity or not for IPAQ-measured baseline PA, white/nonwhite for race/ethnicity, and yes/no for intention to quit during the study period. Given the sample size, a *P* value of .10 or less was considered evidence of interaction. Furthermore, exploratory subgroup analyses were performed to examine heterogeneity in individuals, allowing for the identification of certain participants that showed a consistently strong association between steps and urge. This approach was used in an effort to account for individual variability in outcomes, consistent with the focus of the precision medicine initiative (PMI) [53]. To explore heterogeneity in individuals, linear regression models were run to calculate the association between daily steps and mean daily urge for each participant. Point estimates and CIs were analyzed for each participant, allowing us to determine which particular individuals exhibited strong associations between daily steps and mean daily urge.

Results

Participant and Data Flow

The study flow diagram is shown in Figure 1. A total of 53 participants recorded data for at least 6 weeks and were thus included in the analysis. Of 53 participants, 49 participants completed the online exit survey at the conclusion of the study, and 4 participants were lost to follow-up.

Baseline Characteristics

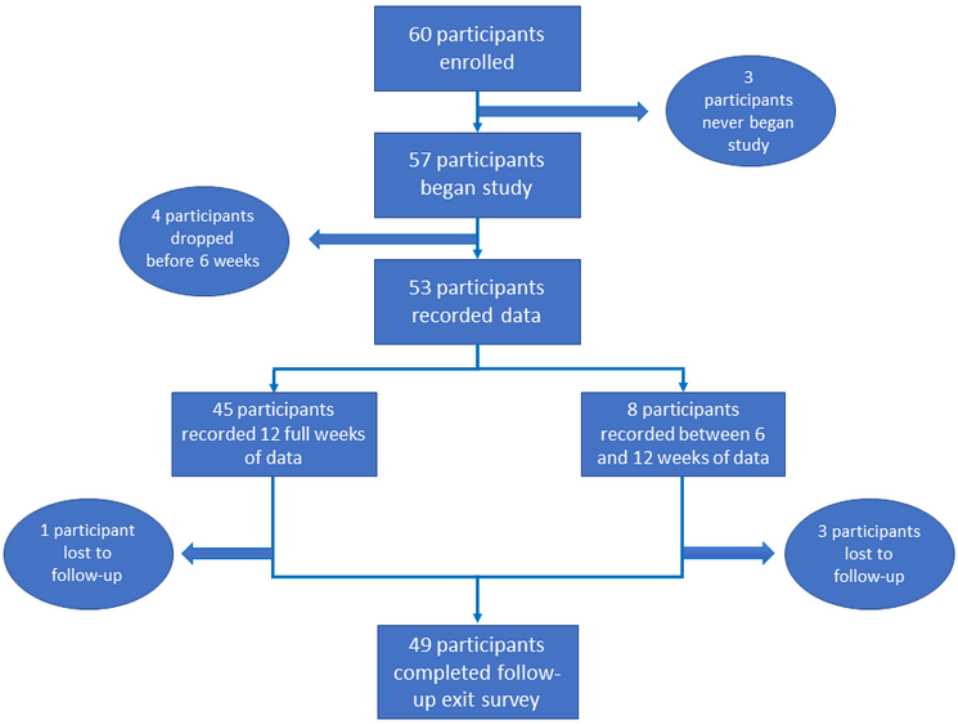
Mean age was 40 (SD 12) years, with 57% (30/53) women and 49% (26/53) nonwhite participants. Moreover, 30% (16/53) had a Bachelor's degree or higher and 38% (20/53) were obese, whereas 53% (28/53) were in the high activity category as defined by IPAQ assessment. Participants smoked 12 (SD 8) cigarettes per day and had been smokers for 19 (SD 12) years (Table 1).

Data Capture

In total, participants recorded 4445 complete days of data, with a mean of 84 (SD 12) days per participant; 866 days were eliminated from analysis based on nonwear criteria. A total of 3579 of all days (81%) were eligible for analysis after applying exclusion criteria. Participants sent a total of 15,365 urge messages throughout the study, with a mean of 290 (SD 62) messages per participant. The majority (approximately 80%) of urge messages sent by participants were prompted.

Men reported modestly higher mean urges than women: 5.56 (95% CI 5.50-5.62) versus 5.19 (95% CI 5.13-5.24), respectively. Men also recorded significantly higher mean daily steps than women by 2994 (95% CI 2693-3294; *P*<.001).

Figure 1. Participant flow.



Urge Validation

Participants' mean urge over the course of the study was positively associated with the number of cigarettes smoked per day as reported in the exit survey (Pearson r=.33, *P*=.02). Furthermore, mean urge over the last week of each participant's study duration was significantly correlated with daily cigarette consumption (r=.37; *P*=.01).

Association Between Steps and Urge: Day-Level and Acute

Considering the day-level association, as shown in Figure 2, there was a wide range of PA levels and a full representation of urges, without clear relation between them. In formal quantitative assessment, we found no significant association between daily steps and mean daily urge (beta=-6.95×10^{-3} per 1000 steps; *P*=.30). In an adjusted model controlling for age, sex, baseline PA and smoking levels, and race/ethnicity, our primary outcome between daily steps and mean daily urge remained null (beta=-1.18×10^{-2} per 1000 steps; *P*=.11).

Regression models of acute effects, however, did reveal modest inverse associations between steps within 30-, 60-, and 120-min time windows of a reported urge, which were all significant at the *P*<.01 level (Table 2). The strongest association was observed for 30 min of accumulated steps before an urge, with a 0.0191 lower urge per 100 steps accumulated in this time. This translated to an approximately 0.2 lower urge for 1000 steps accumulated over 30 min. The estimate for the effect was reduced by approximately 50% for the 1-hour time frame and another approximately 50% for the 2-hour time frame.

Exploratory Subgroup Analyses

For the interaction of steps per day with demographic factors, *P* values for interaction were as follows: .73 for age; .10 for sex (significant inverse relationship in men only, beta=-2.65×10^{-2} per 1000 steps, 95% CI -4.36×10^{-2} to -9.27×10^{-3}); .45 for race/ethnicity; <.01 for baseline PA (significant inverse relationship in *high-activity* participants, beta=-3.14×10^{-2} per 1000 steps, 95% CI -5.0×10^{-2} to -1.28×10^{-2}; significant positive relationship in non-high-activity participants, beta=3.45×10^{-2} per 1000 steps, 95% CI 1.58×10^{-2} to 5.32×10^{-2}); .71 for baseline smoking level; and <.01 for intention to quit (significant inverse relationship for *yes* respondents only, beta=-3.5×10^{-2} per 1000 steps, 95% CI -5.6×10^{-2} to -1.5×10^{-2}).

One participant exhibited a consistent positive association between steps and urge, whereas a subset of 6 participants (11%) exhibited a consistent inverse relationship between steps and urge. At the day-level, these so-called extreme responders to PA exhibited a mean individualized point estimate of −0.15 decrease in urge per 1000 steps (95% CI −0.22 to −0.09; Figure 3). In the analysis assessing the relationship between steps and urge in the 30-min time window preceding an urge, these individuals showed a mean individualized point estimate of −1.66 decrease in urge per 1000 steps (95% CI −2.48 to −0.84). In addition, data from the 30-min window before an urge for these 6 individuals were stratified around a step cutoff of 500 (Figure 4); episodes in which 500 or fewer steps were taken had a mean urge of 6.22 (95% CI 5.90-6.54), whereas episodes in which more than 500 steps were taken had a mean urge of 4.80 (95% CI 4.55-5.05). Acute inverse associations between steps and urge were largely driven by these 6 individuals, and results became null on excluding them from the analysis.

Table 1. Baseline characteristics of mActive-Smoke participants.

Characteristic	mActive-Smoke Participants (N=53)
Sex, n (%)	
Men	23 (43)
Women	30 (57)
White race, n (%)	27 (51)
Age in years, mean (SD)	40 (12)
Married, n (%)	15 (28)
Education, n (%)	
HS[a] diploma or less, including general education diploma (GED)	8 (15)
Associate's degree/some college credit	29 (55)
Bachelor's degree or higher	16 (30)
Employed, n (%)	43 (81)
BMI[b] (kg/m^2), mean (SD)	29 (6)
≥30, n (%)	20 (38)
IPAQ[c], n (%)	
Low	6 (11)
Moderate	19 (36)
High	28 (53)
Sedentary hours on a weekday, mean (SD)	6.8 (3.3)
Cigarettes smoked per day, n (%)	
≤10	34 (64)
>10	19 (36)
Age started smoking, mean (SD)	18 (5)
Years as a smoker, mean (SD)	19 (12)
Pack-years[d], mean (SD)	14 (12)
Type of recruitment, n (%)	
On-site advertisement	30 (56)
Social media	20 (38)
Physician referral	3 (6)

[a]HS: high school.

[b]BMI: body mass index.

[c]Categories defined by International Physical Activity Questionnaire (IPAQ) guidelines.

[d]Defined as (mean cigarettes per day/20) × number of years as a smoker.

Figure 2. Mean urge per day plotted against daily steps, after applying exclusion criteria and omitting outliers.

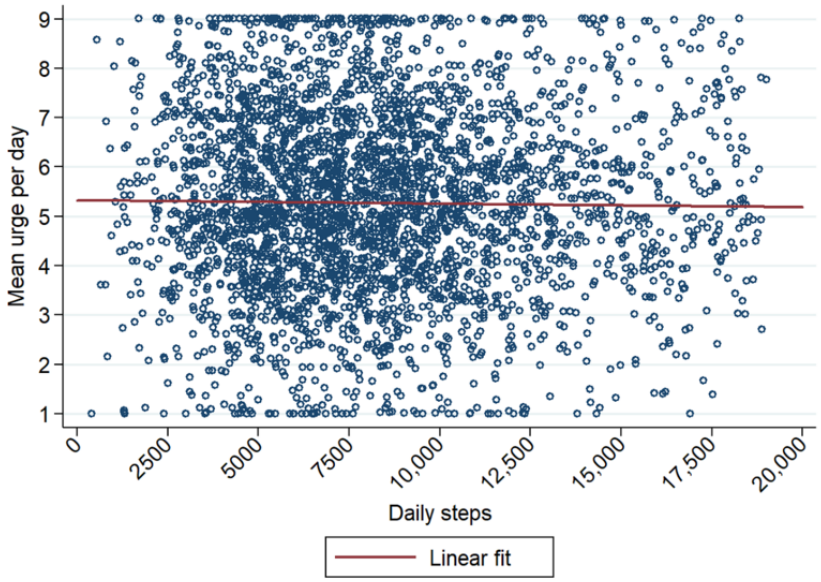


Table 2. Feasible generalized least squares regression results of smoking urge versus steps over various time windows before urge reports.

Steps accumulated within various time windows of urge reporting	Association of urge with steps (beta coefficient, per 100 steps)	*P* value	95% CI (per 100 steps)
30 min before	−0.0191	<.001	−0.0284 to −0.0098
60 min before	−0.00891	.003	−0.0147 to −0.0031
120 min before	−0.00495	.007	−0.00851 to −0.00138

Figure 3. Mean urge per day plotted against daily steps for the 6 “extreme responders,” after applying exclusion criteria and omitting outliers.

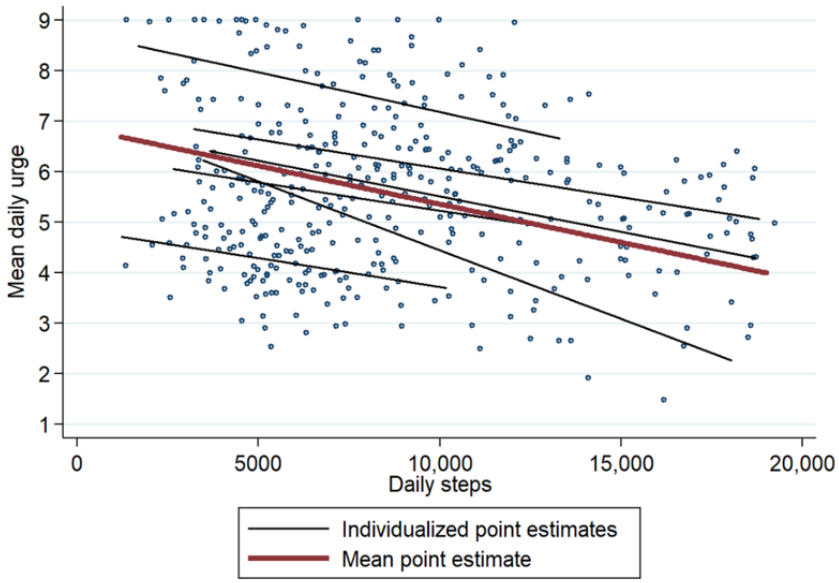


Figure 4. Boxplot of urge for the 6 "extreme responders," stratified by episodes in which ≤500 or >500 steps were taken in the 30-min time window before an urge report.

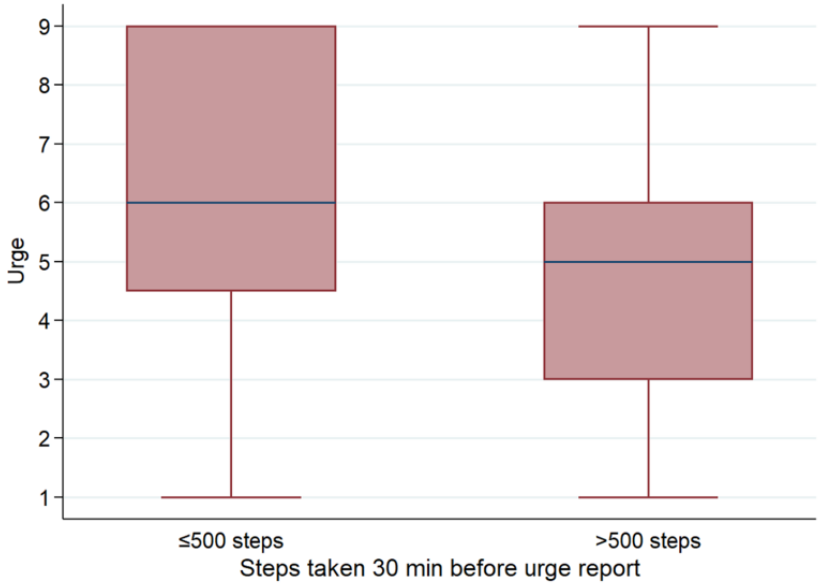
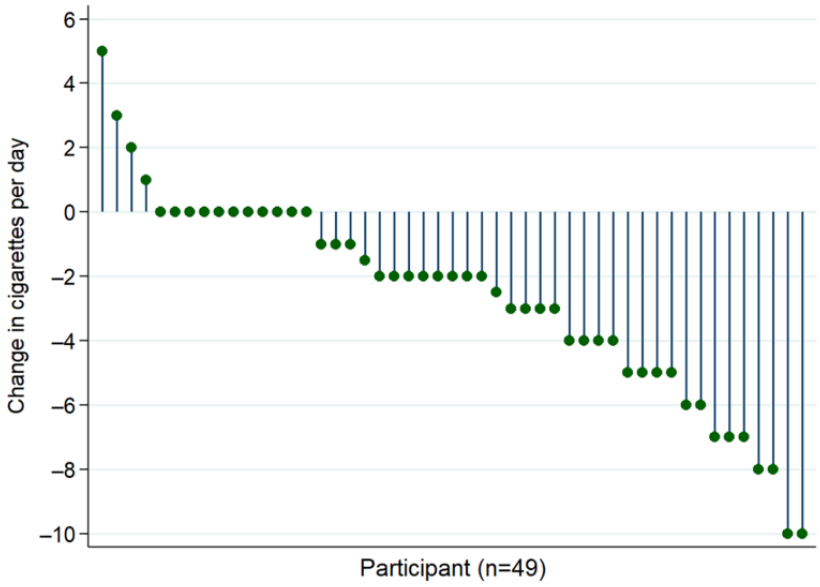


Figure 5. Change in cigarettes per day between baseline and follow-up.



Changes in Measures Over the Course of the Study

Longitudinal trends in PA, smoking urges, and self-reported cigarette consumption between baseline and follow-up were examined to assess these behavior changes in the context of self-monitoring. After excluding outliers, participants' mean daily urge increased by 0.10 (SD 0.82), whereas mean daily steps decreased by −82 (SD 1019); neither of these results was statistically significant. Self-reported number of cigarettes smoked per day significantly decreased from 12 (SD 8) at baseline to 9 (SD 8) at follow-up (Figure 5). Four participants quit smoking by the end of the study.

Exit Survey Perceptions

Participants' exit survey responses are summarized in Table 3. The majority of participants (68%) thought that PA influenced their smoking urges; among these, 76% believed that PA decreased their smoking urges. Fewer participants (37%) thought that higher smoking urges influenced their PA; among these, 61% believed that higher smoking urges decreased their PA. Just over half (59%) of participants thought the study helped them reduce smoking; among these, 79% reported decreases in cigarettes per day between enrollment and follow-up.

Finally, participants reported high levels of satisfaction with the study. Among exit survey respondents, the majority (67%) were extremely satisfied, and an additional 27% were moderately satisfied with the study.

Table 3. Results from follow-up online exit survey.

Characteristic	mActive-Smoke participants (N=49), n (%)
IPAQ[a]	
Low	6 (12)
Moderate	17 (35)
High	26 (53)
Cigarettes smoked per day	
0	4 (8)
1-10	32 (65)
>10	13 (27)
During the past 3 months, have you tried to stop smoking?	
Yes	24 (49)
No	25 (51)
Does physical activity influence your smoking urges?	
Yes	33 (68)
No	10 (20)
Maybe	6 (12)
How does physical activity influence your smoking urges?	
Increases the urge	8 (16)
Decreases the urge	25 (51)
No response	16 (33)
Did wearing the Fitbit increase your awareness about daily physical activity?	
Yes	48 (98)
No	1 (2)
Do you think this study helped increase your daily physical activity?	
Yes	40 (82)
No	3 (6)
Maybe	6 (12)
Did this study increase your awareness about smoking urges?	
Yes	44 (90)
No	1 (2)
Maybe	4 (8)
Do you think this study helped you reduce smoking?	
Yes	29 (59)
No	12 (25)
Maybe	8 (16)

[a]IPAQ: International Physical Activity Questionnaire.

Discussion

Principal Findings

In the mActive-Smoke study, we found no day-level association between PA and smoking urges in the overall population, yet minute-level analyses of acute effects revealed modest inverse relationships between steps and urge for 30-, 60-, and 120-min time windows before urge reporting. There was also a small group of extreme responders who exhibited a more consistent and larger inverse relationship between steps and urge in both day- and minute-level analyses. Nevertheless, it is important to emphasize that analysis of extreme responders is highly exploratory and limited by a small sample size and not knowing times of prior smoking episodes.

Comparison With Prior Work

This study was the first to leverage mHealth devices to evaluate the real-time association between PA and smoking urges in a longitudinal study of smokers in their natural environment. This study builds on prior literature leveraging digital technologies and EMA methods to collect real-world and real-time data on smoking behaviors [54-56]. Methodologically, this study sought to address limitations from prior studies exploring the relationship between smoking and PA under controlled conditions and with unreliable measurement tools. Regarding the former, a 2013 systematic review and meta-analysis concluded that short bouts of PA acutely decrease cigarette cravings by an average SMD of −2.03 between PA and control conditions [23]. Results from our 30-min level analysis were most comparable with those reported in this review, where PA interventions ranged in duration from 5 to 40 min. Despite the large effect size reported in this review, these results may be limited in generalizability because of study conditions. By conducting interventions in a controlled environment, behaviors observed in these studies were likely unrepresentative of those that might be observed in a real-world setting. Furthermore, these studies were limited to acute effects of PA on smoking urges, providing no evidence for how this interaction might play out in the long term. In the mActive-Smoke study, the use of Fitbit—an accurate and reliable wearable PA tracker [57]—allowed us to collect longitudinal PA data in participants' natural settings in an effort to better capture real-world behaviors. Although the direction of our effect size was concordant with that reported in this review, its magnitude was far lower (approximately 0.2 reduction in urge on a 9-point Likert scale per 1000 steps). This discrepancy could be due, in part, to the lack of control over when the last cigarette was smoked before a bout of PA—a measure commonly implemented in prior experimental studies. Thus, it is possible that the decreased magnitude of association in the mActive-Smoke study resulted from a "flooring effect," wherein a smoking episode in close proximity with urge reporting could significantly reduce the acute urge to smoke, leaving minimal room for subsequent changes in urge as a result of PA. On the other hand, the magnitude of our effect size may suggest that the effect of PA on urge may be less robust in a real-world, longitudinal setting.

Another batch of studies examined more longitudinal relationships between PA and smoking urges but relied on participant recall for data collection. For instance, Abrantes et al [27] conducted an exercise intervention study in which participants self-reported exercise in weekly activity logs. Prapavessis et al [26] also designed an exercise-intervention smoking cessation trial in which participants self-reported cigarette consumption on a weekly basis. As such, both studies were limited by subjective measurement tools, and their results were likely compromised by recall bias [31]—a major threat to the internal validity of studies using self-reported data [58,59]. In the mActive-Smoke study, use of Fitbit devices facilitated the objective collection of PA data, mitigating participant bias. Although smoking urges in our study were self-reported, the real-time nature of these measures likely rendered them less susceptible to recall bias compared with studies that relied on weeklong retrospective recall.

The design of the mActive-Smoke study allowed us to assess the association between PA and smoking behavior using approaches ranging from global to more granular. First, using a global approach, we analyzed daily steps and mean daily urge, allowing for a day-level comparison of these 2 measures. In addition to evaluating broad associations, secondary analyses were performed to explore more granular associations within hour and minute time intervals preceding urge reports, which allowed us to assess whether increased PA might acutely affect smoking urges. The presence of an inverse association between steps and urge in various granular time windows confirms findings from prior acute studies and extends them by suggesting that this effect may be particularly present in approximately 10% of individuals. Importantly, each of our analyses was performed in the participant's natural environment, rather than a controlled research setting.

This study also highlights the potential benefits of integrating mHealth tools in the collection and assessment of behavioral data in translational research. Previous studies have suggested that mobile phone–based approaches are efficacious, user-friendly means for communicating with participants, providing instructions and modifying behaviors [60]. In addition to their practical utility, mHealth technology may also be leveraged to promote health equity. A 2016 survey by the Pew Research Center found that 92% of low-income adults own a cell phone and 64% own a smartphone [61]—a 14% increase since 2014 [35]. Among this demographic, one-fifth (21%) is smartphone dependent [61]—they rely heavily on their smartphones for Internet access and lack traditional broadband service in the home—and 63% report having used their smartphone to retrieve information about a health condition [35]. Thus, mHealth technology may provide a promising means of disseminating information and engaging members of these communities to make more health-conscious decisions [62].

Furthermore, the prevalence and frequency of mHealth use have been shown to be high among smokers, particularly those who are motivated to quit [63]. In the mActive-Smoke study, 98% of participants reported that wearing the Fitbit increased their awareness of daily PA, and 90% thought that the study increased their awareness about smoking urges. These findings strengthen the evidence behind self-monitoring and awareness on behavior change. Taylor et al [11] showed that the self-monitoring of smoking and PA behaviors led to reductions in smoking, which were determined to be independent of increases in PA [9]. In the mActive-Smoke study, no meaningful longitudinal changes were observed in PA or smoking urges, although daily cigarette consumption decreased by approximately 3 cigarettes per day between baseline and follow-up (P<.001). Given that this study was not focused on smoking reduction or cessation, these findings support the notion that greater self-awareness may lead to changes in smoking [9,11]. Taken together, this evidence suggests integration of mHealth devices in future smoking cessation and harm reduction trials in an effort to improve participant engagement and achieve desired behavioral outcomes.

Finally, this study offers provocative results when considering individual versus population-averaged effects that may inform precision medicine. Although population-averaged results were collectively null, 7 individuals—13% of our study population—showed a significant relationship between urge and steps in both day- and minute-level analyses. Among these extreme responders, 6 (11% of our study population) exhibited a consistently inverse association. Although these results are exploratory and hypothesis generating in nature, they suggest that PA could be targeted as a means to curb smoking urges among select individuals, an insight consistent with the PMI's focus on individual variability in genes, environments, and lifestyles [64]. Further research is needed to determine whether equally robust inverse relationships between steps and urge could be replicated among these select individuals in an interventional study, which might help illuminate the underlying genetic, environmental, and lifestyle factors associated with these behaviors.

Limitations

Although each participant contributed large quantities of individual data, the small number of participants in this pilot study may have limited our power to perform stratified analyses according to age, sex, and race. In addition, we did not collect data on daily cigarette consumption or on time since last cigarette because burdening participants with additional text messages may have reduced overall study adherence. These data, however, would have provided additional insight into the relationship between daily steps and mean daily urge by allowing us to assess an additional daily measure of smoking behavior. Furthermore, our failure to capture time since last cigarette may have resulted in a flooring effect, reducing our ability to measure the impact of PA on smoking urges because of the potential confounding effect of recent smoking episodes.

Although we were unable to control for time since last cigarette, we found a significant positive correlation between participants' daily cigarette consumption in the exit survey and their mean urge over the course of the study, suggesting that these self-reported urges were valid indicators of smoking behavior. However, by allowing participants to report urges spontaneously and to dictate when they received the prompting messages, it is possible that some reporting bias was present.

In both primary and secondary analyses assessing the relationship between steps and urges, we did not control for intensity of exercise. In their 2014 meta-analysis [18], Haasova et al found that moderate and vigorous intensity exercise had the most benefits for reducing smoking cravings, although modest reductions were also reported for light exercise. Without controlling for exercise intensity in this study, the effect size seen in our secondary analyses may have been diluted by individuals with largely accumulated step counts made up of periods of low-intensity exercise. Although controlling for exercise intensity was outside the scope of this paper, we anticipate assessing its impact on urges in a future study.

For our primary and secondary analyses of steps versus urge, we chose to use FGLS because of the structure of data wherein the number of time points (T) exceeded the number of cross-sections (N). One limitation of this model was an inability to control for autocorrelation effects because of unbalanced panels in our dataset. Nonetheless, assessment of additional models, such as linear random effects, revealed no meaningful difference in effect size after controlling for autocorrelation. Another limitation is that FGLS, which originated in econometrics, has since been replaced by more modern methods in this field because it has been shown to produce inefficient estimates for data structures commonly seen in econometrics where N>T [51,65,66].

Finally, the sample of smokers in this study was very active, given that smokers tend to be considerably less active, on average, than the general population. Thus, it is possible that a ceiling effect was observed, wherein high levels of baseline PA limited participants' abilities to further augment their PA during the study. Furthermore, our sample contained less heavy smokers compared with most prior studies, which generally used a minimum of 10 cigarettes per day as the threshold for study inclusion. Thus, results from this study ought to be interpreted with caution because of deviations in smoker demographics observed in our sample.

Conclusions

Given the lack of a population-averaged longitudinal real-time association between PA and smoking urges, our results do not support broadly focusing resources on PA as a means to reduce smoking urges. Our data confirm results from prior studies, supporting the notion that acute bouts of PA can modestly curb smoking urges. This study also suggests that PA may significantly influence smoking urges among select individuals, an insight that aligns with the precision medicine model to focus on individual variability in health behaviors and outcomes. Furthermore, this study highlights the potential value of mHealth methods for assessing the interrelationships of cardiovascular health behaviors in the real world.

Acknowledgments

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Conflicts of Interest

GNG and ABS have received salary support from Aetna Inc. SSM has received grant/research support (all significant; all paid to institution, not individual) from the PJ Schafer Cardiovascular Research Fund, Aetna Foundation, American Heart Association, Google, and Apple. He has served on Scientific Advisory Boards for Quest Diagnostics, Amgen, and Sanofi/Regeneron (all

outside the subject matter of this manuscript). He is a coinventor on a pending patent filed by Johns Hopkins University for a novel method of low-density lipoprotein cholesterol estimation (outside the subject matter of this manuscript).

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Abbreviations

ASAQ: Arizona Smoking Assessment Questionnaire
CSV: comma separated values
EMA: ecological momentary assessment
FGLS: feasible generalized least squares
HR: heart rate
IPAQ: International Physical Activity Questionnaire
mHealth: mobile health
PA: physical activity

PMI: precision medicine initiative
SMD: standardized mean difference
SMS: short message service

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Original Paper

Reach and Acceptability of a Mobile Reminder Strategy and Facebook Group Intervention for Weight Management in Less Advantaged Adolescents: Insights From the PRALIMAP-INÈS Trial

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Abstract

Background: Although information and communication technology interventions appear to be a promising means of reducing the health inequality gap in overweight and obesity prevention, research on information and communication technology interventions is lacking outside the Anglo-Saxon world.

Objective: The aim of this study was to assess the reach and acceptability of 2 information and communication technology interventions delivered as part of a French nutritional program: an SMS text messaging (short message service, SMS) attendance-reminder for collective sessions strategy and a Facebook challenge group.

Methods: This study sample comprised 262 socially less advantaged overweight adolescents aged between 13 and 18 years. The information and communication technology interventions were carried out during the 2013-2014 academic year in 33 French state-run schools. For the SMS attendance-reminder for collective sessions strategy, at the start of the academic year, adolescents were asked to give their mobile number. SMS attendance-reminders were sent shortly before each of the 5 collective sessions. For the Facebook challenge group, adolescents were invited to join a closed Facebook group in which challenges on physical activity and on diet were posted weekly. Process data and 2 sets of face-to-face interviews were also used to interpret participation rates and access to Facebook. Appreciation for both interventions was evaluated by a questionnaire at the end of the academic year.

Results: Of the recruited adolescents, 79.0% (207/262) gave their mobile number, reflecting high access to a mobile phone. Giving a number was significantly more likely for girls (odds ratio [OR] 2.1, 95% CI 1.1-3.9; *P*=.02) and adolescents in a vocational or general high school as opposed to middle school (OR 1.0, 95% CI 0.4-2.7; OR 0.2, 95% CI 0.1-0.5; *P*<.001). Indicating a mobile number at the start of the year was not significantly associated with participation in collective sessions. Of the adolescents seen at the start-of-year face-to-face interviews, 78.1% (153/196) declared an interest in the Facebook challenge group, which implies having a Facebook account or being able to have access to one. However, only 21 adolescents went through the process of joining the group. Although there was satisfaction with the Facebook group among the participants, the low participation rate in the Facebook group does not allow conclusions to be drawn with confidence.

Conclusions: The results are in line with the claim that using information and communication technologies in health programs is unlikely to widen health inequalities. However, in this population of French adolescents, mobile phone strategies seem more adapted to a high school context, and caution should be exercised with a younger audience. Although there is positive appreciation of the SMS attendance-reminders and a Facebook intervention is initially highly appealing to less advantaged adolescents, no evidence of impact could be demonstrated. These results highlight the difficulty in assessing the impact of specific interventions in complex health programs.

Trial Registration: Clinicaltrials.gov NCT01688453; https://clinicaltrials.gov/ct2/show/NCT01688453 (Archived by WebCite at http://www.webcitation.org/6yy6EQ0SM)

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KEYWORDS

adolescent; social media; text messaging; overweight; socioeconomic factors; weight loss

Introduction

Background

Although there is evidence to suggest that the rates of obesity and overweight have stabilized in recent years, social disparities persist, both for adults and children, in developed countries [1,2]. Indeed, there is an inverse relationship between income category and the prevalence of obesity. The social gradient is clearly evidenced by all measures of social inequality: profession, level of education, family income, and even perception of wealth [1-5]. In France, the latest data show that the crude prevalence of obesity is 15%, but this figure rises to 24% for individuals belonging to the lowest income category [3], and social differences in obesity and overweight prevalence seem to be increasing not only for adults but also for children and adolescents [6,7].

It is, therefore, essential to develop health programs that do not widen health inequalities and tackle the different levels of social disadvantage, particularly in the field of obesity and overweight reduction. However, the features of such a program and the interventions it should encompass are as yet unclear and an urgent need for research on this topic has been expressed [8-10]. To fight against health inequalities, information and communication technologies (ICTs) are increasingly used in health programs, particularly social networking sites and mobile phones [11-13]. One of the main arguments for the use of ICTs in health programs is that it has the potential to engage with hard-to-reach populations [14-17]. Indeed, evidence is accumulating, particularly in developed countries, to suggest that ICTs transcend social class; young people especially seem to use social networks and mobile phones regardless of ethnicity, education or gender, and this appears to be true on a worldwide scale, including France [18-21].

More specifically, several studies have shown promising results of SMS text messaging (short message service, SMS) attendance-reminders especially in adolescent populations [22-26]. Adolescents are very receptive to the use of social media and especially Facebook [21,27-29]. Indeed, Facebook in particular was found to have the most widespread use relative to online support groups and blogging [18,30], as well as being the social networking site most used for research [11]. Furthermore, at a European level, Facebook is still being reported as the most used social networking site, with between 77% and 85% of adolescents aged between 13 and 16 years having a Facebook account [28]. It has also been shown that adolescents of low socioeconomic status (SES) may actually be more likely to have a Facebook account relative to those of higher SES [28]. A further argument for the use of Facebook is that several interventions using social media to reduce weight have found some evidence of a significant effect of social ties and post sharing, which are essential features of Facebook [31-35]. Although there is an increasing use of social media in health care contexts, recent reviews highlight several research gaps that still need to be filled including, for example, the need to report, precisely describe and evaluate such interventions but also specifically assessing the impact of social media in specific populations, such as minority groups [29,36-38].

Objectives

The aim of this study was therefore to assess the reach and acceptability of an SMS attendance-reminder for collective sessions strategy and a Facebook challenge group for socially less advantaged adolescents, delivered in a health program addressing weight management in French adolescents.

Methods

Promotion de l'ALIMentation et l'Activité Physique-INEgalité de Santé (PRALIMAP-INÈS) Trial

This study was carried out during the 2013-2014 academic year within a larger research program running over a 3-year period for the prevention of overweight and obesity aimed at overweight and obese adolescents aged between 13 and 18 years attending grades 9 and 10 in 33 state-run middle-schools and high-schools in the Vosges department (north-eastern France). The full protocol of the PRALIMAP-INÈS (Promotion de l'ALIMentation et l'Activité Physique-INEgalité de Santé) trial is described elsewhere [39]. A letter was sent to adolescents' home addresses, and they were included in the study unless their parents or legal guardian returned a refusal slip. Parents could return written consent, but this was not a requirement for inclusion and, not returning a refusal slip was considered as tacit consent leading to inclusion in the study. The trial was registered (Clinicaltrials.gov NCT01688453) and approved by the French consultative committee for treatment of information in health research (no. 12.299), the French National Commission for Data Protection and Liberties (no. 912372), and the French Persons Protection Committee (no. 2012/15). The core

component of the PRALIMAP-INÈS program comprised 5 collective sessions offered throughout the school year. The adolescents were offered several other interventions, two of which were based on ICTs that are the focus of this study: an SMS attendance-reminder for the collective sessions and a Facebook challenge group. The PRALIMAP-INES program was multicomponent and designed so that all students could benefit from several, none, or all possible interventions, which were independent from each other. This study focuses on a subsample of the population enrolled in the main program consisting of 262 overweight and socially less advantaged adolescents, corresponding to the low and medium categories of the Family Affluence Scale (FAS) [40]. Recruitment strategies belong to the overall program and not specifically to the subpopulation.

Short Message Service Attendance-Reminder Strategy for Collective Sessions

The first ICT intervention was an SMS attendance-reminder strategy to encourage participants to attend the collective sessions organized in the schools. The 5 collective sessions were conducted in small groups and allowed participants to discuss themes related to healthy eating and physical activity. While filling in the questionnaires at the start of the academic year (T0), adolescents gave their mobile number or indicated that they did not have a mobile phone. For all participants, who gave their mobile phone number, SMS text messages were sent shortly before each collective session to remind them of the time and place of the session. For adolescents who did not give a mobile phone number, reminders were sent by email. Some school nurses took the initiative of providing further reminders to attend the collective sessions.

Facebook Challenge Group

The second ICT intervention, which was completely independent from the collective sessions and their associated SMS attendance-reminders, was a Facebook challenge group which was chosen among other possible interventions by a regional committee of student representatives and designed using The Reader-to-Leader Framework [41]. A test phase of the Facebook challenge group took place during the 2012-2013 academic year, at the end of which qualitative face-to-face interviews were carried out to assess appreciation and improve implementation for the 2013-2014 academic year. Changes following the test phase included: handing out a leaflet during the start-of-year screening process, using peer mediators to post the challenges after discussion with the coordinator, and adding a points system rewarding sharing of experience, peer support, and user-generated challenges. These strategies were aimed at increasing engagement, as this has been shown to be a key mediator of successful social media interventions [42]. Adolescents were invited to join a closed Facebook group in which 2 nutritional challenges, one on physical activity and one on diet, were posted on the group page on a weekly basis. As this intervention was only intended for the less advantaged subsample of the PRALIMAP-INÈS program, the Facebook group was closed so that only invited participants could join. To access the group, adolescents had to invite the group coordinator to be a Facebook friend. Indeed, some research has suggested that a private group may be acceptable and effective in certain contexts, as it may provide a judgment-free space facilitating goal achievement [43,44]. It was then possible to sign up for a challenge by clicking the *like* feature of Facebook. There were 2 types of challenges: those concerning physical activity, for example: “Twice a week, jump up and down 50 times. It’s even more fun using a jump-rope!,” and those concerning healthy eating such as: “For 1 month, cook a healthy meal for yourself and your family. Share your recipes by posting them on this page so everyone can enjoy!” The 2 peer mediators contacted the group coordinator with a challenge idea and following approval, posted it on the group page. See Multimedia Appendix 1 for an example screenshot.

Data Collection

Reach

Access to the mobile phone intervention refers to indication of a mobile phone number when filling in the start-of-year questionnaires (T0). Access to Facebook is implied from having answered “yes” or “maybe” in terms of willingness to participate in the challenge group to the coach in the 2013-2014 start-of-year interviews (T0). Intention to participate was considered to indicate having a Facebook account or being able to have access to one. Participation was also considered an important indicator of reach. Adolescents were considered to have participated in the SMS-reminder strategy if they provided a mobile phone number. They were considered to have participated in the collective sessions if they were present for at least one of the sessions. The level of participation was also described using the number of attended collective sessions. Regarding the Facebook challenge group, adolescents were considered to have participated if they were a member of the group. Furthermore, process data was recorded to inform on participation in the individual nutritional challenges of the Facebook group. The following sociodemographic variables were also collected to describe the sample of participating students for both interventions: age, gender, FAS score, school type, boarding school status, family status, and type of parental consent given. Obesity status was determined by the obesity thresholds for age and gender according to the International Obesity Task Force [38].

Acceptability

Acceptability was evaluated using a mix of qualitative and quantitative indicators. Appreciation of SMS attendance-reminders was evaluated in the end-of-year questionnaire (T1) by asking adolescents whether they appreciated this mode of communication. Replying “completely agree” or “mostly agree” to the question asking adolescents whether they appreciated receiving SMS attendance-reminders for collective sessions were taken into account as positive appreciation.

For the Facebook group, appreciation and acceptability were collected in 2 waves of face-to-face qualitative interviews. The first was at the end of the test phase of the Facebook group in 2012-2013 academic year and the second at the start of the 2013-2014 academic year. Both were embedded in the PRALIMAP-INÈS general assessment: the 2012-2103 follow-up

session and the 2013-2014 inclusion session. Both were organized through close collaboration between the school and research teams [39]. All eligible adolescents were, therefore, invited to participate in the interviews if they attended these sessions. The interviews consisted of a mix of closed and brief open-ended questions, and adolescents' answers were noted directly during the interview. The interviews, at the end of the test phase, were carried out with 28 adolescents. Adolescents were asked to share their experience of the activity, particularly exploring barriers to participation. In the face-to-face interviews, with a coach at the start of the 2013-2104 academic year, adolescents were encouraged to give reasons explaining their interest or lack of interest in joining the Facebook group. Adolescent appreciation of the Facebook group was also evaluated in the end-of-year questionnaire (T1). Replying "completely agree" or "mostly agree" to any one of the following 3 propositions was considered to be positive appreciation: the challenges which were offered corresponded to what they expected, they found it useful to participate in the challenges, and they would recommend participating in the challenges to a friend.

Analyses

Study sample characteristics, access to ICT, participation, and appreciation were described using percentages for categorical variables and mean (SD) for quantitative variables. Logistic regression models were used to identify sociodemographic factors, overweight status, and type of parental consent associated with access, participation, and appreciation. Bivariate analyses were used to assess independent associations. In bivariate analyses, a variable was made eligible for multivariate analyses if *P* value was ≤.02 in order to identify potential confounding factors [45]. For multivariate analyses, a stepwise selection method was used with a .05 level of entry and retention in the model. With each regression model, the odds ratio (OR) with 95% CI and *P* value were calculated. Statistical analyses were carried out using SAS 9.4 (SAS Inst, Cary, North Carolina, United States).

Results

Sample Characteristics

Sample characteristics are described in Table 1. The average age was 15.4 years and 56.5% (148/262) were girls. Of this sample of less advantaged adolescents, 24.4% (64/262) were obese, and 8.4% (22/262) were at the very low end of the FAS (having a FAS score of 1 or 2). In terms of school type, 44.7% (117/262) attended vocational high schools, 34.7% (91/262) general high schools, and 20.6% (54/262) middle schools. The vast majority lived with both their parents (76.3%, 200/262) and consent to participate in the program was mostly given tacitly (82.1%, 215/262). Out of the recruited adolescents, 77.9% (204/262) completed the end-of-year questionnaire. There was no difference in sociodemographic factors, overweight status, and type of parental consent between the adolescents who filled out an end-of-year questionnaire and those who did not. However, there was a significant difference between adolescents answering the specific questions on program appreciation and those who did not. The 115 adolescents answering were younger (*P*=.004) and more likely to have written, as opposed to tacit, consent from their parents with 31.3% (36/115) of those answering having written consent versus only 7.5% (11/146) of those not answering having written consent (*P*<.001).

Access, Participation, and Appreciation

Flowchart

The flowchart describing the rates of access, participation, and appreciation for the Facebook intervention and the SMS attendance-reminder for collective sessions is presented in Figure 1.

Quantitative Data

Results describing access to a mobile phone and Facebook, as well as participation and appreciation of both the SMS attendance-reminder for collective sessions and the Facebook challenge group are presented in Table 2.

Of the adolescents considered in this study, 79.0% (207/262) provided their mobile phone number. Moreover, 25.2% (66/262) adolescents were not able to benefit from a start-of-year face-to-face interview with a coach. Of the adolescents that did attend the interview, 78.1% (153/196) declared an interest in participating in the Facebook group, which implies access to a Facebook account.

Only 8.0% (21/262) adolescents in the study sample participated in the Facebook group, and 64.1% (168/262) participated in at least one collective session. The average number of collective sessions attended was 3.4 of the 5 offered.

Of the adolescents who responded to the question on SMS attendance-reminder for collective sessions appreciation, 80.9% (93/115) had a positive appreciation of the SMS attendance-reminders. For the Facebook group, of the adolescents who responded to the questions on appreciation, 77% (10/13) had a positive appreciation of the Facebook group.

Qualitative Data

At the end of the test phase in 2012-2013 academic year, out of the 28 adolescents that were seen, 7 had participated in the Facebook group. For the participants, the main advantages of the group were that the challenges were motivating as they provided objectives, that the challenges gave ideas, and that they were perceived as fun. Several adolescents, however, mentioned lack of time to look at the challenges and not being able to spend time on Facebook at certain busy periods of the year. One adolescent girl also spontaneously mentioned: "there was not much point since I couldn't do it with my friends." Of the adolescents who did not participate, many reported not remembering being informed of the group, and several mentioned that the process to join the group seemed complicated so they did not take the time to look into it. However, 3 adolescents explained a general lack of interest in Facebook, and 3 others said they did not want to participate in any of the PRALIMAP-INÈS activities. None of the adolescents, who were interviewed, declared a lack of access to Facebook.

Table 1. Sociodemographic characteristics of the study sample (N=262).

Characteristics	Statistics
Age in years, mean (SD)	15.4 (0.8)
Gender, n (%)	
Boys	114 (43.5)
Girls	148 (56.5)
Obesity status, n (%)	
No	198 (75.6)
Yes	64 (24.4)
FAS[a] score, n (%)	
Very low FAS (1-2)	22 (8.4)
Low FAS (3-4)	123 (46.9)
Average FAS (5)	117 (44.7)
School type, n (%)	
Vocational high school	117 (44.7)
General high school	91 (34.7)
Middle school	54 (20.6)
School boarding status, n (%)	
Nonboarder	63 (24.4)
Half-boarder	130 (50.4)
Full boarder	65 (25.2)
Family status, n (%)	
Two-parents	200 (76.3)
Single parent	51 (19.5)
Other	11 (4.2)
Type of parental consent, n (%)	
Written parental consent	47 (17.9)
Tacit parental consent	215 (82.1)

[a]FAS: Family Affluence Scale.

At the start of the 2013-2014 academic year (T0), of the 196 students benefiting from a face-to-face interview with a coach, 43 adolescents declared a lack of interest in the Facebook group. Only 17 adolescents mentioned a lack of access to Facebook. Other reasons for declaring not being interested in the Facebook challenge group and concerning 6 adolescents each were: not wanting to participate in any of the PRALIMAP-INÈS activities and not liking Facebook in general. The overwhelming reason for declaring being interested in the Facebook challenge group was to benefit from the rewards that could potentially be obtained through participation. Furthermore, 4 adolescents particularly mentioned liking Facebook in general and being happy with any intervention on this platform.

Factors Associated With Access, Participation, and Appreciation

Significant results from the multivariate regression models for access, participation, and appreciation of the Facebook intervention and the SMS attendance-reminder strategy are presented in Table 3.

In terms of access to ICT, gender and school type were significantly associated with mobile phone access. Girls provided their mobile phone number more often than boys (84.5%, 125/148 vs 71.9%, 82/114; OR 2.1, 95% CI 1.1-3.9; P=.02). Over 80% of the adolescents in high school provided a mobile phone (85.5%, 100/117) in vocational high schools and 82.4% (75/91) in general high schools), but this was only the case for 59.3% (32/54) of adolescents in middle schools. This difference in access by school type was highly significant (P<.001; middle school OR 0.2, 95% CI 0.1-0.5, reference vocational high school).

No significant association was found for overweight status, SES, family status, and school boarding status. No variables were significantly associated with declared interest in joining the Facebook group and hence access to a Facebook account. However, it is important to note that adolescents providing a

mobile phone were also more likely to have access to Facebook than those not having a mobile phone (81.3%, 126/155 vs 65.9% 27/41; χ^2_1=4.5; OR 2.2, 95% CI 1.1-4.8, *P*=.03).

Participation in at least one of the collective sessions was neither associated with indication of a mobile phone number at the beginning of the year nor access to a Facebook account. Furthermore, participation in the Facebook group was not associated with any demographic variables or participation in the collective sessions.

None of the demographic factors were associated with appreciation of the SMS attendance-reminders for collective sessions or the Facebook group, although there was a tendency toward a greater appreciation of receiving SMS reminders for older adolescents (OR 2.2; 95% CI 0.9-5.4; *P*=.06).

Figure 1. Flowchart describing rates of access, participation, and appreciation for the Facebook intervention and the intervention of short message service (SMS) attendance-reminders for collective sessions.

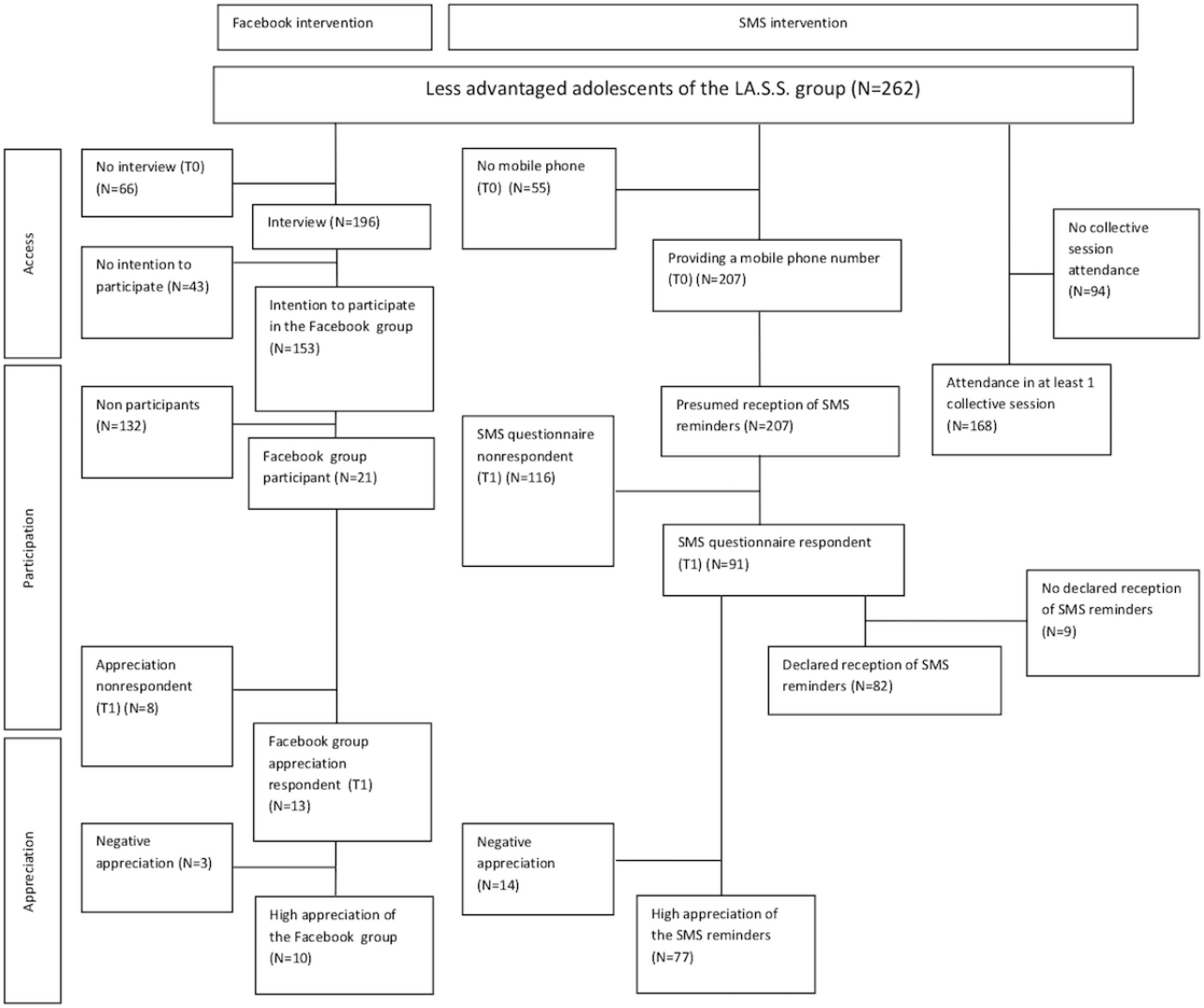

Table 2. Access, participation and appreciation of information and communication technology (ICT) interventions (N=262).

Access, participation, and appreciation of interventions	Statistics, n (%)
Access	
Declared interest in Facebook group[a] (n=196)	153 (78.1)
Providing a mobile number at the start of the academic year	207 (79.0)
Participation	
In at least 1 collective session	168 (64.1)
In the Facebook group	21 (8.0)
Declared reception of SMS[b] attendance-reminders for collective sessions (all adolescents; n=116)	93 (80.2)
Declared reception of SMS attendance-reminders for collective sessions (of adolescents concerned[c]; n=91)	82 (90.1)
Appreciation	
Positive appreciation of the Facebook group (n=13)	10 (76.9)
Positive appreciation of SMS attendance-reminders for collective sessions (all adolescents; n=115)	93 (80.9)
Positive appreciation of SMS attendance-reminders for collective sessions (of adolescents concerned[c]; n=91)	77 (84.6)

[a]Among adolescents seen by the coach in the 2013-2014 start-of-year interviews (n=262 minus number missing for the item).

[b]SMS: short message service.

[c]Among adolescents both answering the questionnaire and having given a mobile phone number (n=207 minus number missing for the item).

Table 3. Multivariate regression models for access to a mobile phone and participation in collective sessions.

Characteristics	Short message service attendance-reminders							
	Mobile phone access				Collective session attendance			
	N	n (%)	Multivariate regression[a]		N	n (%)	Multivariate regression[a]	
			OR (95% CI)	*P* value[b]			OR (95% CI)	*P* value[b]
Age[c] (OR for 1 year age increase)	262	207 (79.0)			262	168 (64.1)	0.7 (0.5-1)	.04
Gender				**.02**				
Boys	114	82 (71.9)	1 Reference value		114	68 (59.6)		
Girls	148	125 (84.5)	2.1 (1.1-3.9)		148	100 (67.6)		
School type				**<.001**				
Professional high school	117	100 (85.5)	1 Reference value		117	76 (65.0)		
General high school	91	75 (82.4)	0.8 (0.4-1.6)		91	53 (58.2)		
Middle school	54	32 (59.3)	0.2 (0.1-0.5)		54	39 (72.2)		
Parental consent								**<.001**
Written consent	47	35 (74.5)			47	45 (95.7)	1	
Tacit consent	215	172 (80.0)			215	123 (57.2)	0.1 (0-0.3)	

[a]Only factors with a significant association at .2 alpha risk in the bivariate regressions were candidates for entering into the multivariate model (n=89).

[b]*P* value is the level of significance of the test of the OR against 1.

[c]For age, N, n, and % describe the total sample and as age is a quantitative variable, the OR corresponds to 1 year age increase.

Discussion

Principal Findings

A high level of ownership of mobile phones was found in adolescents of lower SES and was greater among girls and high school students. In this sample, sending SMS attendance-reminders for collective sessions had no association with attendance at face-to-face sessions. Facebook seems largely accessible across school type and gender and adolescents manifest widespread interest in a health intervention using this platform. However, the uptake of the Facebook intervention was very low.

Strengths and Limitations

Outside of the Anglo-Saxon world, research on ICT interventions is severely lacking in the scientific literature. This paper endeavors to address this issue by presenting results on the development and implementation of 2 ICT interventions in France. A main strength of this study is the all-inclusive nature of the intervention. All state-run high schools in the Vosges department, comprising just under 400,000 inhabitants [46], participated in the study along with some middle schools who committed to the project following a special request by the PRALIMAP-INÈS steering committee. All adolescents attending these schools in grades 9 or 10 were weighed and measured and, if concerned, invited to attend the program. Another strength of this study is its systematic measurement of SES, which made it possible to focus particularly on adolescents from less advantaged backgrounds. Limitations of this study include the indirect measurement of access: not providing a mobile phone number was taken to mean not having one, and willingness to participate in the Facebook challenge group was considered to imply access to Facebook. Another limitation may be that over half of the adolescents included in the study did not answer the specific questions in the end-of-year questionnaire under study. However, the adolescents who did complete these questions only differed in that they were younger and more likely to have written, as opposed to tacit, consent from their parents which may suggest obtaining support from parents may improve response rates, although this is particularly difficult with older adolescents. Finally, the low participation in the Facebook challenge group can also be considered a limitation, as no statistical conclusions can be drawn with confidence.

Using Mobile Phones and Facebook in Health Programs

Access to a mobile phone seemed to be very widespread across this sample of less advantaged adolescents and this was likely to be an underestimation since some adolescents may have deliberately chosen not to provide their mobile phone numbers. Adolescent girls seemed more likely to provide their phone numbers than boys, which may reflect greater distrust by boys for sharing their number in a health program. In fact, it was generally observed that girls had a higher participation rate in the PRALIMAP-INÈS program as a whole. Another explanation could be that girls, possibly more communicative, are actually more likely to own a mobile phone and this has been reported in French and Swiss reports [21,47], although these gender differences have been not found in Europe [48]. These findings suggest more research needs to be carried out in order to confirm a potential gender bias in mobile phone ownership or use in France. The result of more mobile phone numbers being provided in high schools as compared with middle schools reflects the well-established increase in mobile phone ownership with age, even if the age of first phone ownership is steadily decreasing [21,28,47]; and it has been stressed that it is frequent for adolescents to receive a mobile phone at certain life stages such as changing to a more senior school [28]. This seems to be particularly the case between middle school and high school in France [47]. These findings support the use of mobile phones as a strategy which is unlikely to widen the inequality gap when used at high school level, but they also raise the question of use of mobile phones at middle school, at least for less advantaged adolescents. The results of this study also support the claim that Facebook can reach all audiences, regardless of SES [14,27]. The fact that very few adolescents in the face-to-face interviews stated that they did not have a Facebook account further supports this claim. Interestingly, unlike mobile phones, there was no association between age or gender and access to Facebook suggesting that in terms of ICTs, Facebook may be better suited to reaching boys and younger audiences than mobile phones.

In terms of acceptability, adolescents seem to appreciate receiving attendance-reminder SMSs, and this finding is in line with other qualitative studies which indicate adolescent satisfaction with this mode of communication [24,49,50]. The tendency toward a greater appreciation of receiving SMS attendance-reminders for older adolescents is a further argument for their appropriate use at high school level. Despite widespread reach and high levels of acceptability in this sample, provision of a mobile phone number at the beginning of the year was not associated with participation in at least one collective session. It is likely that this result is due to the fact that adolescents were encouraged to participate in the collective sessions with several channels of information, which varied among participating schools and included: information given at the end of each session for the next one, written notes distributed in class on the day of the sessions, oral reminders by the school nurses, and collecting students directly from the classroom. It is therefore not possible to isolate the SMS component from attendance, and further research is necessary to establish the impact of these reminders.

Perhaps the most surprising result is the gap between initial interest in the Facebook challenge group, which is higher than the reported interest in Facebook use in another recent study [51], and the low participation rate. The fact that the Facebook intervention was chosen among others by the regional committee of student representatives and the high reported interest rate suggest that Facebook is an appropriate medium for this sample of adolescents. However, increasing visibility following the test phase was evidently not sufficient to address the perceived complicated process of joining the group, as suggested in the interviews carried out at the end of the 2012-2013 academic year. Although clearly favorable to a Facebook health intervention, it is likely that adolescents do not naturally associate Facebook with health-related goals and this may have been a barrier to the process of joining the group. Beyond access to the group itself, a major challenge is the difficulty of obtaining interaction and initiative from the participants [52,53]. Despite various strategies to encourage active participation and sharing found to be effective in other contexts [50] such as the use of peer mediators, Facebook polls, or a points system which rewarded comments and user-generated challenges, adolescents did not take an active role in the Facebook group. In the interviews, participating adolescents mentioned that they used the group to set themselves personal targets and to get new ideas which confirms that the group was used on a personal level, and the collective component was not perceived. This is consistent with the finding that the main motivation to join the group was to obtain potential rewards and no social motivation

was reported. Perhaps the number of participants was too few to create a dynamic environment with core members creating content [54]. However, a more likely reason is that the Facebook challenge group in this study was a *closed* group to allow cross-group comparisons among PRALIMAP-INÈS program participants, and this may have been contrary to the principle of social media as an attract-and-join space, in particular including existing friends in the intervention [35]. Indeed, it has been suggested that school-aged adolescents use Facebook in order to maintain and strengthen social ties primarily within their existing close-knit friendship networks rather than looking outwards to publicly expose their opinions or create new social ties [55-57]. It therefore seems important to tap into preexisting friendship networks to encourage mutual support and increase motivation rather than create an artificial group composed of health program participants. Given the rapidly evolving nature of the connected world, it may be worth considering other, more instantaneous and increasingly popular platforms such as Instagram, WhatsApp, or Snapchat [58]. However, more research is needed to ascertain whether these mobile apps are not likely to widen health inequalities, especially, if they require a smartphone with mobile internet connection.

Conclusions

The results of this study are consistent with the claim that using ICTs in health programs is unlikely to widen health inequalities: access to mobile phones and Facebook is high, and the acceptability of both SMS attendance-reminders and a nutritional challenge Facebook group is evidenced by the positive appreciation given for both interventions. However, no evidence of impact of the SMS attendance-reminders or the Facebook challenge group could be demonstrated in th**is** study. These results highlight the difficulty in assessing the impact of specific interventions in multisite complex health programs, especially in school settings. In terms of recommendations for future health programs in France, using mobile phones seems particularly adapted in a high school context but caution should be exercised as a gender bias is possible. Taken together, the results of the Facebook group suggest that Facebook, as a social media platform, is appealing to French adolescents of low SES and may be particularly suited to reach younger adolescents and boys. However, key improvements are necessary to increase participation, in particular adding adolescents directly to the group and enabling adolescents to do the challenges with their own friends. Given the rapidly evolving nature of social media, it is also crucial to continue assessing interest in various social media platforms and usage by the target population before health interventions, especially as there may be differences according to SES.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshot of one of the Facebook challenges.

[PDF File (Adobe PDF File), 131KB - mhealth_v6i5e110_app1.pdf]

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Abbreviations

FAS: Family Affluence Scale
ICT: information and communication technology
SES: socioeconomic status
SMS: short message service

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Original Paper

A Mobile App for Identifying Individuals With Undiagnosed Diabetes and Prediabetes and for Promoting Behavior Change: 2-Year Prospective Study

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Abstract

Background: To decrease the burden of diabetes in society, early screening of undiagnosed diabetes and prediabetes is needed. Integrating a diabetes risk score into a mobile app would provide a useful platform to enable people to self-assess their risk of diabetes with ease.

Objective: The objectives of this study were to (1) assess the profile of Diabetes Risk Score mobile app users, (2) determine the optimal cutoff value of the Finnish Diabetes Risk Score to identify undiagnosed diabetes and prediabetes in the Chinese population, (3) estimate users' chance of developing diabetes within 2 years of using the app, and (4) investigate high-risk app users' lifestyle behavior changes after ascertaining their risk level from the app.

Methods: We conducted this 2-phase study among adults via mobile app and online survey from August 2014 to December 2016. Phase 1 adopted a cross-sectional design, with a descriptive analysis of the app users' profile. We used a Cohen kappa score to show the agreement between the risk level (as shown in the app) and glycated hemoglobin test results. We used sensitivity, specificity, and area under the curve to determine the optimal cutoff value of the diabetes risk score in this population. Phase 2 was a prospective cohort study. We used a logistic regression model to estimate the chance of developing diabetes after using the app. Paired *t* tests compared high-risk app users' lifestyle changes.

Results: A total of 13,289 people used the app in phase 1a. After data cleaning, we considered 4549 of these as valid data. Most users were male, and 1811 (39.81%) had tertiary education or above. Among them, 188 (10.4%) users agreed to attend the health assessment in phase 1b. We recommend the optimal value of the diabetes risk score for identifying persons with undiagnosed diabetes and prediabetes to be 9, with an area under the receiver operating characteristic curve of 0.67 (95% CI 0.60-0.74), sensitivity of 0.70 (95% CI 0.58-0.80), and specificity of 0.57 (95% CI 0.47-0.66). At the 2-year follow-up, people in the high-risk group had a higher chance of developing diabetes (odds ratio 4.59, P=.048) than the low-risk group. The high-risk app users improved their daily intake of vegetables (baseline: mean 0.76, SD 0.43; follow-up: mean 0.93, SD 0.26; t_{81}=–3.77, P<.001) and daily exercise (baseline: mean 0.40, SD 0.49; follow-up: mean 0.54, SD 0.50; t_{81}=–2.08, P=.04).

Conclusions: The Diabetes Risk Score app has been shown to be a feasible and reliable tool to identify persons with undiagnosed diabetes and prediabetes and to predict diabetes incidence in 2 years. The app can also encourage high-risk people to modify dietary habits and reduce sedentary lifestyle.

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KEYWORDS

diabetes mellitus; prediabetes; prediabetic state; mobile apps; lifestyle

Introduction

Prevention of diabetes is at the top of the agenda for health promotion worldwide and in Hong Kong [1-3]. Target populations for diabetes prevention include those who have not had a diagnosis of diabetes and those who are in the stage of prediabetes [4]. Early detection of individuals with undiagnosed diabetes and prediabetes (UDPD) would enhance the implementation of lifestyle modification interventions, which have been shown to prevent the progression to diabetes or further complications [5]. It is estimated that 193 million people, or nearly half of those with diabetes, around the world have undiagnosed diabetes [6].

mHealth has been used for different purposes in health promotion and maintenance. The proliferation of mobile phones and software apps has provided a new channel for health promotion, including symptom recording [7], smoking cessation [8], and weight control [7]. The advantage and convenience of the compact size and mobility of mobile phones allows users to access health information and health assessment tools at any time and at any place that best suit individuals' pace of living. A research study found that 75 million adults in the United States used their mobile phones for health information and as tools [9]. Among those aged 55 years and older who owned mobile phones or tablets, half used the devices for health purposes [9]. The use of mobile apps has been evolving and becoming popular in Chinese society as mHealth is considered as not only trendy but also practical and layman friendly. In Hong Kong, 12 free-of-charge health and fitness apps in the Android app market have been labelled as the most popular apps, and each app has had more than 250,000 downloads as of 2011 [10]. However, scarce evidence about mHealth in assessing diabetes risk has been documented in the Chinese population.

Integration of a diabetes risk score into a mobile app is an innovative and potentially powerful tool for promoting diabetes self-assessment. Evidence has shown that the Finnish Diabetes Risk Score (FINDRISC) has supported diabetes screening and prevention because of its cheap, easy-to-administer, convenient, and noninvasive features [11]. Laypeople can easily use FINDRISC to assess their risk of developing diabetes, without any training. It is now being used in various European countries, including Finland, Belgium, Sweden, Greece, Germany, and Spain [12-17]. Because of the popularity, reliability, and user-friendly nature of FINDRISC, we chose it as the key measurement of the Diabetes Risk Score (DRS) mobile app.

The DRS app was developed by a university project team comprising a nursing faculty with rich experience in health literacy interventions, 2 family medicine experts, a professor in endocrinology, and a statistician. User tests were conducted with 22 Chinese adults in April 2013. Half of the participants of the user test had secondary education or above. Comments were collected from these app users on the clarity of the instructions given in the app, the logic of the sequence of the questions in the app, and the ease of data input by the participants. The app was then revised according to their comments. The DRS app (version 2) was officially launched on August 28, 2014 in a media interview with 11 newspapers and 1 electronic media, who reported its launch. The Quick Response code of the app was posted on the university website to promote the app. This free-of-charge app could be downloaded from both the Google Store (for Android devices) and the App Store (for iOS devices; eg, iPad, iPhone) by searching the term "HKUDRS."

The DRS app included the Chinese FINDRISC and questions related to lifestyle (such as smoking, drinking, dietary pattern, and physical activity engagement). In the DRS app, the exact diabetes risk score was not shown, but the risk level was shown in a figure in which a pointer fell in one of the two color zones, with red indicating high risk and green indicating low risk.

The objectives of this study were to (1) assess the profile of DRS mobile app users, (2) determine the optimal cutoff value of the diabetes risk score to identify UDPD in the Chinese population, (3) estimate users' chance of developing diabetes within 2 years of using the app, and (4) investigate high-risk app users' lifestyle behavior changes after ascertaining their risk level from the app.

Methods

The 2-Phase Study

We divided the whole study into 2 phases. We conducted phase 1 from August 2014 to October 2016, using a cross-sectional design. Phase 1a assessed the users' profile, while phase 1b assessed the appropriate cutoff value of the diabetes risk score to identify UDPD in the Chinese population. We conducted phase 2 from October 3, 2016 to November 6, 2016 with a prospective cohort design. Phase 2a followed up the app users to estimate their chance of developing diabetes within 2 years. Phase 2b assessed the app users' lifestyle changes after knowing their risk of diabetes from the app.

Samples

Since this is a free app in the app stores, anyone who was capable of accessing the internet and app stores and of reading and understanding Chinese could download the app to their mobile phones. On the first screen of the app, we indicated that

it was developed for research purposes, and its use implied that users agreed to join the research study and consented to having the project team use their data in aggregate for research purposes and future analysis. We included those who met the following criteria in the analysis in phase 1a: (1) aged 18 years or over, and (2) having a phone number indicating the country code 852 (for Hong Kong). We selected participants for phase 1b from phase 1a who met the following criteria: (1) provided phone or email addresses in the app and agreed to allow the project team to approach them, (2) had never had a diagnosis of diabetes (of any kind), and (3) were willing to attend a comprehensive health assessment (including blood taking) in a university campus. Participants in phase 2 were those who (1) used the DRS app in 2014 and 2015, (2) provided email addresses in the app, and (3) were willing to complete an online survey. We excluded those with known diabetes in 2014 and 2015 or those who used the app less than 1 year from the time we conducted the online survey.

Sample Size Calculation

We calculated the sample size for phase 1b for the receiver operating characteristic (ROC) curve analysis using MedCalc software version 15.8 (MedCalc Software bvba). We assumed that an area under the curve (AUC) of 0.70 for a particular test was significant from the null hypothesis value of 0.5. The prevalence of people with UDPD in Hong Kong was almost 14% [18,19], and the number of negative cases was approximately 6 times that of positive cases. Assuming the type I error rate was 0.05 and the type II error rate was 0.20, the sample size required for phase 1b was 133.

We calculated the sample size for phase 2a using G*power version 3.1.9.2. With reference to the previous studies, the OR of developing diabetes among persons with UDPD was 4.5 [20], the prevalence of UDPD in Hong Kong was nearly 14% [18,19], and the incidence rate of diabetes among persons with normoglycemia was 0.05 [21]. To achieve a statistical power of 80% and a 5% level of significance to detect the assumed OR, 292 participants were needed.

Measures

We calculated diabetes risk score by using the FINDRISC formula and the score for the following 8 items in the app: age (<45 years=0, 45-54 years=2, 55-64 years=3, >64 years=4), body mass index (BMI; <25 kg/m^2=0, 25-30 kg/m^2=1, >30 kg/m^2=3), waist circumference (for men: <94 cm=0, 94-102 cm=3, >102 cm=4; for women: <80 cm=0, 80-88 cm=3, >88 cm=4), history of using drugs for high blood pressure (no=0, yes=2), history of being told by health professionals about the possibility of having high blood glucose (no=0, yes=5), participation in physical activity every day (yes=0, no=2), habit of consuming fruit and vegetables every day (yes=0, no=2), and family history of diabetes (no=0, yes=5). We calculated the total risk score by adding the scores of all items, with a possible range from 0 to 26 [15]. App users could key in their body weight (in kilograms or in pounds) and body height (in meters or in inches). The app automatically converted the figures and calculated the BMI using the formula body weight (in kilograms) divided by the square of the height (in meters). App users were also asked to key in their waist circumference to the nearest 0.5 cm.

Procedures

In phase 1a, users input data into the app on their own, and the data included the 8 items (such as daily intake of fruit and vegetables and daily physical activity) that we used to calculate the users' diabetes risk. Following the launch of the app, we periodically monitored the number of downloads and ensured that the app was downloadable from the app stores. For the sake of protecting privacy, only the principal investigator (AYML) had right of access to the server. Before passing the data to the trained research assistant for data cleaning and to develop the database for this study, the principal investigator removed all app users' personal data to protect privacy.

In phase 1b, we sent emails to the app users and invited them to receive a 1-hour comprehensive health assessment in the university campus between June and August 2015. The inclusion criteria were stated clearly in the invitation emails, and the app users replied to the emails and indicated their willingness to join the health assessment. In the assessment, a research nurse took 5 mL of venous blood from each participant. The blood samples were sent to the laboratory of a regional public hospital in which glycated hemoglobin (HbA_{1c}) was measured by high-performance liquid chromatography (Variant II Turbo Hemoglobin Testing System, Bio-Rad Laboratories, Inc, Hercules, CA, USA). According to the American Diabetes Association, HbA_{1c} of 48 mmol/mol (6.5%) or greater is considered to indicate diabetes, while HbA_{1c} of 39 mmol/mol (5.7%) or greater but less than 48 mmol/mol (6.5%) is considered to indicate prediabetes [22].

We contacted app users with HbA_{1c} levels higher than 48 mmol/mol (6.5%) by phone and encouraged them to consult their family doctors. We did this for ethical reasons, so that the app users with abnormal readings were not placed at a disadvantage by not receiving necessary treatments.

For phases 2a and 2b, we sent invitation emails to the app users and encouraged them to complete a follow-up questionnaire via Zoho Survey (Zoho Corporation) from October 3, 2016 to November 6, 2016. We identified duplicate inputs by checking the respondents' email addresses. We deleted a few duplicate inputs before doing the analysis. Diabetes incidence was recorded when the app users self-reported having diabetes during this period. If the app users had a diagnosis of diabetes, we asked them to provide the dates of receiving the diagnosis (month and year). We also asked app users to input their daily intake of fruit and vegetables, daily physical activity, and the relevant diabetes-related items in the questionnaire.

Ethics Approval and Consent to Participate

We obtained approval from the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster. The consent form was embedded on the first screen of the app. App users clicked a button on the app to indicate their consent to join the study.

Statistical Analyses

We considered duplicate inputs, incomplete inputs, or inputs that were exactly the same as the default figures in blood pressure, body height, and body weight as invalid inputs and excluded these from the analysis. We computed descriptive statistics, including means, standard deviations, frequencies, and percentages, to present the participants' sociodemographic information and the distribution of diabetes risk scores. In phase 1b, we used ROC curve analysis to determine the optimal cutoff level of diabetes risk scores with reference to the usual clinical practice for suspecting the risk of diabetes (or the stage of prediabetes) in Hong Kong. We also determined the optimal cutoff point of the diabetes risk score by the sensitivity, specificity, maximum value of the Youden index (sensitivity + specificity – 1), and Cohen kappa of the diabetes risk score with reference to the agreement with HbA_{1c}. Cohen kappa values of zero or less indicated no agreement, 0.01 to 0.20 none to slight, 0.21 to 0.40 fair, 0.41 to 0.60 moderate, 0.61 to 0.80 substantial, and 0.81 to 1.00 almost perfect agreement [23].

In phase 2a, we used multiple logistic regression models to examine the OR of diabetes incidence between the high-risk group and the low-risk group (classified by the recommended FINDRISC cutoff value found in phase 1b). Educational level is a confounder in diabetes. Many studies have proved that people with a higher educational level have a better lifestyle in their daily lives, and people with a healthy lifestyle will have less risk of developing diabetes in the future [24]. A meta-analysis also demonstrated that higher educational levels were consistently associated with lower incidence of diabetes [25]. As sex and education were correlated, we adjusted both sex and education in the regression models. We used the Hosmer-Lemeshow test to assess the goodness of fit for the logistic regression models [26]. The model fits the data well when the *P* value is greater than .05 [26]; this implies the model has acceptable fitness.

In phase 2b, we applied paired *t* tests to compare the means of lifestyle variables at the baseline with those at follow-up for the high-risk group. We analyzed the data using IBM SPSS version 22.0 for Windows (IBM Corporation).

Results

Phase 1a: Profile of Diabetes Risk Score App Users

We collected data in the period of August 28, 2014 to December 31, 2016. A total of 13,289 Chinese residents downloaded the DRS app and self-assessed their risk. After cleaning the data, we considered 4549 as valid data in phase 1a. A total of 3171 (69.71%) were Android users and the rest were iPhone users. The mean (SD) diabetes risk score was 9.10 (SD 4.85). A total of 1042 (22.91%) were shown to be at risk of developing diabetes. Table 1 shows the demographics of the app users in all phases. Most app users (2738/4549, 60.19%) were male; 1328 (29.19%) were aged 55 to 64 years and 1606 (35.30%) were aged 65 years or above. Nearly two-fifths of the app users had tertiary education or above (1911/4549, 42.01%).

Phase 1b: Determining the Optimal Value of Diabetes Risk Score for Identifying People With Undiagnosed Diabetes and Prediabetes

A total of 972 people left their contact information for the project team and were included in the invitation in this phase. Only 210 participants (21.6%) agreed to attend the health assessment. Of these, we excluded 22 people who had type 1 or type 2 diabetes from the study, so eventually we included only 188 app users in the analysis.

Table 1. Demographics of the users of the Diabetes Risk Score mobile app.

Variables	Phase 1a (n=4549)	Phase 1b			Phases 2a and 2b (n=127)		
		HbA_{1c}[a] <39 mmol/mol (5.7%), (n=109), n (%)	HbA_{1c} ≥39 mmol/mol (5.7%), (n=79), n (%)	*P* value	DRS[b]<9, n (%)	DRS≥9, n (%)	*P* value
Sex							
Male	2738 (60.19)	66 (60.6)	50 (63)	.62	82 (64.6)	122 (61.3)	.56
Female	1811 (39.81)	43 (39.5)	29 (37)		45 (35.4)	77 (38.7)	
Age (years)							
≤44	1005 (22.09)	14 (12.8)	4 (5)	.43	23 (18.1)	4 (2.0)	<.001
45-54	610 (13.4)	45 (41.3)	31 (39)		15 (11.8)	26 (13.1)	
55-64	1328 (29.19)	41 (37.6)	36 (46)		35 (27.6)	79 (39.7)	
≥65	1606 (35.30)	9 (8.3)	8 (10)		54 (42.5)	90 (45.2)	
Educational level							
Primary or below	914 (20.1)	2 (1.8)	4 (5)	.76	17 (13.4)	29 (14.6)	.31
Secondary	1724 (37.90)	63 (57.8)	49 (62)		60 (47.2)	76 (38.2)	
Tertiary or higher	1911 (42.01)	44 (40.4)	26 (33)		46 (36.2)	85 (42.7)	

[a]HbA_{1c}: glycated hemoglobin.

[b]DRS: diabetes risk score, based on the Finnish Diabetes Risk Score.

Most of these participants were aged between 45 and 64 years (153/188, 81.4%) and 116 (61.7%) were male. These app users had a relatively higher educational level than the general public, with 182 (96.8%) reporting secondary school or higher qualifications [27].

Results of HbA_{1c} Tests

Among the 188 users who participated in blood tests, 79 (42.0%) had HbA_{1c} of 39 mmol/mol or greater (ie, 5.7%). Thus, we considered them to have UDPD. Of these 79 participants, 14 (17.7%) had an HbA_{1c} even higher than 48 mmol/mol (ie, 6.5%), and we considered them to have undiagnosed diabetes. There were no significant differences in age, sex, and educational level between app users with UDPD and those with normal HbA_{1c} level (Table 1).

Optimal Cutoff Value for Diabetes Risk Score in the Chinese Population

Table 2 shows the sensitivity and specificity of various FINDRISCs in relation to UDPD. The sensitivity and specificity of a FINDRISC greater than 8 were 0.70 (95% CI 0.58-0.80) and 0.57 (95% CI 0.47-0.66), respectively, with positive predictive value of 0.54 (95% CI 0.44-0.64) and negative predictive value of 0.72 (95% CI 0.61-0.81). A FINDRISC of greater than 8 also had the greatest Youden index of 1.27. When using a FINDRISC greater than 9, specificity increased to 0.62 (95% CI 0.53 to 0.72), sensitivity decreased to 0.61 (95% CI 0.49 to 0.72), and the Youden index decreased to 1.23. The AUC of a FINDRISC greater than 8 was 0.67 (95% CI 0.60-0.74; *P*<.001; Figure 1).

Phase 2a: Estimating the Chance of Developing Diabetes Within 2 Years

In phases 2a and 2b, 326 app users replied to the invitation emails and completed the online survey. Nearly half of the app users were aged 65 or over (144/326, 44.2%), and only 27 (8.3%) were aged 44 years old or younger. Most of these app users were male (204/326, 62.6%). Regarding their educational level, 136 (41.7%) of these app users had secondary qualifications and 131 (40.2%) had tertiary qualifications or higher. Among these, we considered 199 app users (61.0%) to be in the high-risk group when a diabetes risk score of 9 or higher was applied. People in the high-risk group were older than those in the low-risk group (*P*<.001; Table 1). There were no significant differences in sex and educational level between the 2 groups.

The mean follow-up time of the app users was 22.66 (SD 5.83) months. After a nearly 2-year follow-up, 15 participants had developed diabetes. The mean time of diagnosis of diabetes during follow-up was 12.93 (SD 8.28) months, ranging from 1 to 25 months. The incidence rate of diabetes was 25.56 per 1000 person-years. For the high-risk group, the incidence rate of diabetes was 36.50 per 1000 person-years. For the low-risk group, the incidence rate of diabetes was 8.59 per 1000 person-years. Fisher exact test showed that the association between the risk groups and diabetic incidence was marginally insignificant (*P*=.06).

Table 3 shows the association between the risk groups and diabetes incidence. In model 1 (the unadjusted logistic regression model), there was a marginally insignificant association between the risk groups and diabetes incidence (OR 4.37, 95% CI 0.97 to 19.69; *P*=.06). However, in model 2, after adjustment for sex and educational level, app users in the high-risk group had a significantly higher chance of developing diabetes (OR 4.59, 95% CI 1.01-20.81; *P*=.048) than did the low-risk group. The Hosmer-Lemeshow test gave a *P* value of .91, which implied that the regression model had an acceptable fitness.

Phase 2b: Lifestyle Changes Among High-Risk App Users

App users who were informed that they had a higher risk of developing diabetes improved their daily intake of vegetables (baseline: mean 0.76, SD 0.43; follow-up: mean 0.93, SD 0.26; t_{81}=–3.77, *P*<.001) and daily physical activities (baseline: mean 0.40, SD 0.49; follow-up: mean 0.54, SD 0.50; t_{81}=–2.08, *P*=.04). However, we found no significant change in their smoking status (baseline: mean 0.15, SD 0.36; follow-up: mean 0.09, SD 0.28; t_{81}=1.92, *P*=.06) or their alcohol consumption (baseline: mean 0.07, SD 0.26; follow-up: mean 0.04, SD 0.19; t_{81}=1.35, *P*=18).

Table 2. Characteristics of the Finnish Diabetes Risk Score (FINDRISC) using different cutoff values to predict undiagnosed diabetes and prediabetes (glycated hemoglobin ≥39 mmol/mol, or 5.7%).

FINDRISC cutoff values	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)
>6	0.78 (0.68-0.87)	0.39 (0.30-0.49)	0.48 (0.40-0.57)	0.72 (0.59-0.83)
>7	0.75 (0.64-0.84)	0.48 (0.38-0.58)	0.51 (0.41-0.60)	0.72 (0.60-0.82)
>8[a]	0.70 (0.58-0.80)	0.57 (0.47-0.66)	0.54 (0.44-0.64)	0.72 (0.61-0.81)
>9	0.61 (0.49-0.72)	0.62 (0.53-0.72)	0.54 (0.43-0.65)	0.69 (0.59-0.78)
>10	0.52 (0.40-0.63)	0.75 (0.66-0.83)	0.60 (0.48-0.72)	0.68 (0.59-0.77)
>11	0.41 (0.30-0.52)	0.82 (0.73-0.88)	0.62 (0.47-0.75)	0.65 (0.57-0.73)

[a]FINDRISC >8 was the optimal value.

Figure 1. Receiver operating characteristic (ROC) curve analysis of the performance of the Finnish Diabetes Risk Score (FINDRISC) in identifying undiagnosed diabetes and prediabetes. Diagonal segments are produced by ties. The area under the ROC was 0.67 (95% CI 0.60-0.74). When the FINDRISC cutoff value was >8, its sensitivity was 0.70 (95% CI 0.58-0.80) and specificity was 0.57 (95% CI 0.47-0.66).

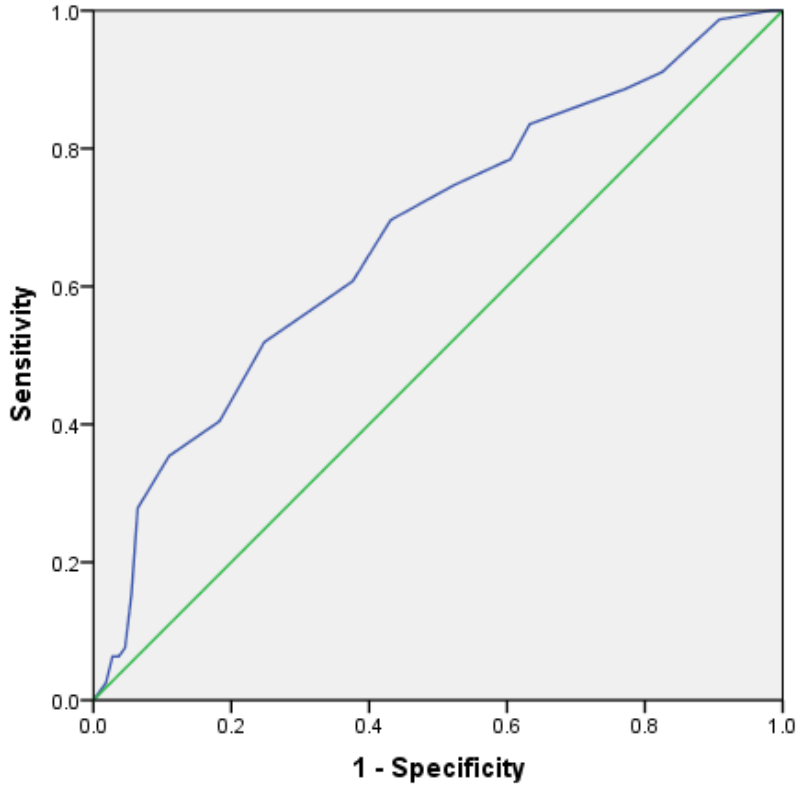

Table 3. Logistic regression model of diabetes incidence between the high-risk app users and low-risk app users.

Covariates	Model 1 (unadjusted)			Model 2 (adjusted)		
	Odds ratio	95% CI	*P* value	Odds ratio	95% CI	*P* value
Diabetes risk group						
High	4.37	0.97-19.69	.06	4.59	1.01-20.81	.05
Low (reference)	1	–	–	1	–	–
Sex						
Male	–	–	–	1.21	0.38-3.88	.74
Female (reference)	–	–	–	1	–	–
Educational level						
Primary or below	–	–	–	1.33	0.42-4.31	.63
Secondary	–	–	–	0.96	0.19-5.00	.96
Tertiary or higher (reference)	–	–	–	1	–	–

Discussion

Principal Findings

This study examined the development of a mobile app for identifying people with UDPD and its use over a period of 2 years. Both Android and iPhone users found this app accessible, and more than 13,000 people had downloaded and used this app. Although we included only app users in Hong Kong in the analysis, we noted that many downloads were from countries in Asia, the United States, and Europe. This showed the potential for expanding the use of this mobile app to people who can read and understand Chinese around the world. To the best of our knowledge, this app was the first DRS app targeted at a Chinese population for diabetes risk self-assessment in 2014. The American Diabetes Association recommends screening for diabetes at 3-year intervals after the age of 45 years, particularly for those who are overweight (whose BMI is ≥25 kg/m^2) [28]. However, not many people comply with this recommendation [29]. As many people are reluctant to go for blood tests, this DRS mobile app provides the general public a means for self-assessment before consulting doctors.

This DRS app, adopting FINDRISC as the key measure for estimating diabetes risk, has been shown to be a reliable tool, although it cannot replace diagnostic investigations such as the oral glucose tolerance test, HbA_{1c} level, and clinical judgment. Validated with HbA_{1c} measures, this DRS app performed well in detecting people with UDPD. The ROC curve analysis suggested that a FINDRISC greater than 8 had sufficient properties for identifying persons with UDPD. We considered other values such as FINDRISC greater than 9; however, the sensitivity of this score decreased dramatically to 0.61. Therefore, we would recommend a FINDRISC of 9 as the optimal cutoff point for identifying UDPD in a Chinese population. The sensitivity and specificity of the recommended cutoff points are reasonably good. The new recommended cutoff points in this DRS app could identify nearly 70% of persons at high risk of diabetes. Approximately 1 million of the Hong Kong population were not aware of their UDPD status [18,19]. If they use this app, which has a sensitivity of 70%, at least 0.7 million of them could know their risk earlier and could start preventive actions.

The new recommended optimal cutoff value of FINDRISC in the DRS app was comparable with the cutoff values in other populations (Multimedia Appendix 1), although there was a slight difference [20,30,31]. In the United States, the optimal cutoff value of FINDRISC for identifying undiagnosed diabetes was 11 [31], while in Bulgaria the cutoff point was recommended as 12 (there was no differentiation between sexes) [30], and in Colombia it was 14 (for both men and women) [20]. Our finding was similar to the recommended cutoff point in a study in Isfahan, Iran, but the specificity of the recommended point in our study was much higher than the one shown in the Iranian population [32]. This Iranian study adopted a robust method to evaluate the ability of the FINDRISC to predict diabetes incidence in 7.8 years among 1537 high-risk persons [32]. Thus, this is a good reference for our study. Variations in the recommended cutoff points in different populations may be related to the variation of referenced tests. In these studies, a variety of blood tests (oral glucose tolerance test, fasting blood glucose, and HbA_{1c}) were used. Although the cutoff values vary, most of the recommended points are within a reasonable range of scores, as suggested by the original developers of FINDRISC [11]. The findings of our study therefore provide additional information about the cutoff value of FINDRISC in the Chinese population.

In this prospective study, two important pieces of evidence were worth noting. First, this DRS app had not only a concurrent but also a predictive nature (indicating the chance of developing diabetes in the next 2 years). Evidence showed that app users in the high-risk group had a significantly higher chance (4.59 times) of developing diabetes than those in the low-risk group. This finding echoed the findings of previous studies in other populations. In Colombia, the risk of incidence of type 2 diabetes in 1 year among participants with high risk scores was 4.8 times that among the low-risk group [20]. Similar results were also found in another longitudinal study by Janghorbani et al, the risk of diabetes in the second quartile (9≤FINDRISC<13) being 4.3 times that of participants in the lowest quartile (FINDRISC<9) [32]. These results showed that FINDRISC in the mobile app was a useful tool for predicting the incidence of diabetes in the Chinese population.

Second, the app encouraged people to change their lifestyle. App users who were informed of having a high risk of developing diabetes by the DRS app significantly improved their daily intake of vegetables and did more physical activities in the follow-up period. This showed that the DRS app was a practical tool in health promotion for the general public. App users seemed to be more cautious about their lifestyles and started to develop healthier habits that could protect them from serious health problems such as diabetes [33].

Some researchers have developed different sets of diabetes risk score models for the Chinese population in recent years. Tian et al developed the Dagang dysglycemia risk score model to identify UDPD for the oil field working-age population [34]. Another risk score model for detecting type 2 diabetes for a rural adult Chinese population was developed by Zhang and colleagues [35]. Although these two risk models have high AUCs (0.791 and 0.766, respectively), both models consist of invasive items (such as blood taking) and therefore are not recommended for use in mobile apps. A simpler and noninvasive diabetes risk score was developed based on age, waist circumference, and family history of diabetes for undiagnosed diabetes [36]. Nonetheless, its specificities were rather low (0.211 in men and 0.436 in women). Considering the availability of diabetes risk score models, FINDRISC seemed to be an appropriate measure to adopt in a mobile app.

Limitations

This study has some limitations that need to be addressed. First, we used only the HbA_{1c} test as the diagnostic standard to identify people with UDPD; however, the 75-g oral glucose tolerance test is the reference standard for diagnosing diabetes. We considered HbA_{1c} because it was more convenient and time saving than the oral glucose tolerance test. Second, the BMI and waist circumference cutoff values used in the calculation of FINDRISC are for white populations [15]. These cutoff values might not be the optimal values for Asian populations, which might have affected the sensitivity of the FINDRISC model. Therefore, future studies could revise the BMI and waist circumference cutoff values to ones that are optimal for Asian people. Third, diabetes incidence should be interpreted with caution. We determined the incidence rate of diabetes based on self-reported diabetes at follow-up assessment. Participants with undiagnosed diabetes might have reported themselves as nondiabetic, or participants might have had a diabetes diagnosis much earlier than the follow-up assessment time, and this may have caused detection bias and interval-censored bias. We could not directly communicate with the respondents of the online survey or perform body measurements or blood tests after the online survey. Future studies could use blood samples to validate the incidence of diabetes.

Implications for Future Research

First, future studies could explore the existence of other predictors such as dietary sodium, beverage, and fat intake to improve the predictive validity of FINDRISC in the Chinese population. Predictors of diabetes have been used to modify

FINDRISC. Studies in Germany and the Philippines modified and simplified FINDRISC for their populations [13,37]. Second, the determination of cutoff values of FINDRISC specific for various sociodemographic groups could make the classification of UDPD more accurate for different groups of people. Many other FINDRISC validation studies have analyzed subgroups. Studies in the United States, Colombia, and other countries set up cutoff scores for various groups according to sex, age, or ethnicity [20,31]. The results of our study indicated that educational level was one of the covariates of risk score groups and diabetes. Therefore, future studies involving a larger population sample and focusing on educational level are required to identify the FINDRISC cutoff scores in different sociodemographic groups in the Chinese population.

Conclusion

This DRS app was a reliable tool for identifying persons who had UDPD. The odds of developing diabetes were much higher among the high-risk app users than among the low-risk users, evidencing the predictive power of the app in diabetes incidence. The app can also encourage high-risk app users to modify their lifestyle for the sake of reducing their progression from prediabetes to diabetes. This is an illustration of the use of a mobile app in health promotion and disease prevention.

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Authors' Contributions

AYML contributed to the study design, data analysis, interpretation of the findings, intellectual input, and revision of the manuscript. XYX and MKTC contributed to data collection, data analysis, interpretation of the findings, and drafting of the manuscript, and read and approved the final manuscript. PHC, YTEY, and JYHW contributed to study design, data analysis, and interpretation of the findings. CKHW and DYTF contributed to data analysis and interpretation of the findings. CLKL contributed to study design, intellectual input, and revision of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Finnish Diabetes Risk Score (FINDRISC) cutoff values for the detection of undiagnosed diabetes, prediabetes, and hyperglycemia in various populations.

[PDF File (Adobe PDF File), 23KB - mhealth_v6i5e10662_app1.pdf]

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Abbreviations

AUC: area under the curve
BMI: body mass index
DRS app: Diabetes Risk Score app
FINDRISC: Finnish Diabetes Risk Score
HbA_{1c}: glycated hemoglobin
ROC: receiver operating characteristic
UDPD: undiagnosed diabetes and prediabetes

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Original Paper

User Needs in the Development of a Health App Ecosystem for Self-Management of Cystic Fibrosis: User-Centered Development Approach

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Abstract

Background: Digital self-management in cystic fibrosis (CF) is foreseen as a means toward better understanding of the disease and its treatment and better adherence to the treatment. Mobile apps hold the potential to provide access to information, motivate, and strengthen compliance. However, to deliver high-quality apps, the development should be based on thorough knowledge about user needs. Empirical research on the user-centered development of mobile apps for health care is, however, still limited.

Objective: The aim of this research is to develop and evaluate an app ecosystem for self-management in CF. It targets not only those directly affected by CF but also parents and health care professionals involved in the treatment. This paper covers the first step of the design process that aims to analyze the context and the user requirements. The primary research question is as follows: what digital support has the potential to usefully support persons with CF and their caregivers in the CF care? To answer this question, we address two preliminary questions: what important factors in everyday life affect the care of persons with CF? and how is the CF care delivered today and what are the limitations of CF care services?

Methods: The overall research adopts a user-centered design approach in which future users are involved in the development process from the very beginning to ensure that the apps developed best suit the potential users. The research presented in the paper follows an interpretative case study research strategy seeking to understand the concerns and needs of persons with CF and their caregivers. Data were collected through semistructured qualitative interviews involving 74 participants in seven European countries and from internet forums.

Results: The results of the analysis phase show a strong need for individuality of the digital support, as well as for its adaptability to different contexts. The paper presents the concerns and needs of the participants in the study and extracts a set of relevant features for a self-management app ecosystem. Education, enzyme dosage calculation, nutrition management, treatment organization, health diary, treatment follow-up, practical guidelines for treatment, communication with doctors, and communication with peers are foreseen as useful features.

Conclusions: The results indicate the readiness for self-management in the CF care even in countries that provide well-functioning health care services for CF care. The large diversity of user requirements identified reflects the crucial role user integration plays in developing apps for a chronic condition such as CF. The need for personalization stemming from the individuality of the patients and the need for communication with health care professionals support the idea of an app ecosystem for the self-management of CF.

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KEYWORDS

self-management; cystic fibrosis; mobile health; user centered design

Introduction

Background

The market for wearables and mobile apps for monitoring health data and receiving information and guidelines on health-related issues is growing. Half of the participants in recent user surveys would use an app to manage their health, or had already downloaded one [1,2]. Health management through apps may be particularly beneficial for persons with chronic conditions who often require daily care and sustained self-management. In fact, different reviews [3,4] have observed a positive effect of the use of information and communication technology (ICT) for facilitating self-management of chronic diseases. At the same time, the number of persons living with a chronic health condition is increasing across countries [5,6], and they are responsible for most deaths in the world [7]. This puts health services under pressure. Thus, the overall need to promote self-management in health care is strong.

Self-management is seen as a means to better understand and cope with a disease and its treatment, for example, by supporting behavior change and treatment compliance [8]. Effectively pursued self-management may contribute to increased life expectancy and a better quality of life (QoL). One way to support self-management is to increase the person's knowledge about the condition and to foster perceived self-efficacy [9]. For successful engagement, patients need to feel empowered and enabled to participate in the management of their health [10].

In this paper, we present a case study aiming at understanding the concerns of persons affected by cystic fibrosis (CF) and their needs, and we derive implications for the design of an app ecosystem for self-management of CF. CF is a congenital, chronic metabolic disorder that affects the digestive and respiratory tracts resulting in generalized malnutrition and chronic respiratory infections. There is still no cure for the disease. CF is a lifelong condition that often begins to affect the daily routine of parents and patients right after birth. It is a very complex and heterogeneous disease and affects more than 40,000 people in Europe, with the number rising. The health condition of persons with CF can change rapidly. It can be positively influenced by good treatment, which renders daily, lifelong therapy essential. Many persons with CF tend not to adhere to parts of the therapy [11], making it necessary to develop an efficient way for self-managing the disease.

The MyCyFAPP Vision

The research presented in this paper is part of a comprehensive user-centered development process performed in the European Union–funded research project MyCyFAPP [12]. The aim is to develop an app ecosystem (ie, an array of interconnected apps) that addresses persons directly affected by CF, parents of affected children, as well as health care professionals (HCPs) involved in the treatment. This app ecosystem is envisioned to bridge the gap between medical check-ups by providing the following:

- Tablet-based games for children to increase their knowledge about the disease and encourage to compliance with the daily therapy
- An app for teenagers to help them to take responsibility for the treatment
- An app for parents and adults with CF to organize the treatment and follow up the health status
- Support for health care professionals (HCPs) to follow up patients

The CF care experts involved in MyCyFAPP identified enzyme dosage as a key challenge for persons with CF. Most CF patients have to follow a pancreatic enzyme replacement therapy, where enzymes have to be taken with each meal to help digest food. The amount of pills to take depends on the type of food and in particular, on the interactions between fat and other nutrients in each meal. MyCyFAPP is also researching on the role of individual digestion conditions, but regarding this, no conclusion can be presented yet. Enzyme dosage is an essential part of the CF therapy, with practices on recommended dosage still varying across Europe [13]. A wrong dosage can lead to malnutrition and gastrointestinal problems [14]. In parallel with the design of digital support, the medical team in MyCyFAPP is currently developing an algorithm for dosage calculation. An aim is to integrate this algorithm in the digital self-management support.

The research in MyCyFAPP adopts a user-centered design approach following the European standard ISO 9241 in which potential users are involved in all stages of the development [15]. This is to ensure that the apps developed best suit the potential users. When developing an app for persons who are dependent on complex, precisely planned, and time-intensive daily treatment routines, this inclusion is crucial. In line with this approach, the following user-centered design steps are conducted in the project:

- Analysis of context and user requirements
- Iterative codesign workshops with all target groups for the creation of ideas
- Iterative user tests of first concepts and prototypes for the idea selection, realization, and evaluation of the solution
- Evaluation of the final prototypes in a 6-month clinical trial for a final evaluation of the solutions

This paper focuses on the first step of the user-centered design process, that is, the analysis of context and user requirements.

Patient-Centered Care

Patient-centered care is a comprehensive approach to the patient-HCP relationship, which includes aspects of self-management, patient education, and clinical practice [16]. Self-management is particularly relevant for persons with CF. CF typically shows a high degree of individuality with great variability of the disease and related differences in treatment schedules and patient needs. Therefore, it may be argued that

it is crucial for CF patients to be able to act as an active partner in their relationship with the HCPs.

A patient-centered approach to care will influence the relationship between the patient and the HCPs [17]. Irwin and Richardson [16] explain why both parties' needs and perceptions are fundamental: they have to collaborate and share knowledge about the treatment and the course of the disease. This also implies that the patient accurately reports activities and symptoms and actively complies with the treatment routines by changing behavior in line with changing health needs. The HCP has a crucial role in determining individual treatment routines together with the patient. HCPs can support the patients' self-management behavior between consultations, for example, by providing them with the necessary knowledge. Collaborative roles of patients and HCPs are discussed in more detail in other studies [10,18].

Self-Management of Cystic Fibrosis

One way to foster patient self-management is through personalized apps. However, to deliver high-quality apps, one should base the development on thorough knowledge about user needs, which stems from a user participation methodology. To our knowledge, little research work has been conducted in the area of mobile digital self-management of CF. A search in the Scopus database for articles containing the key words "cystic fibrosis" and either the keyword "app" or "mobile application" returned only two relevant results in May 2015 [19,20]. Cummings and colleagues [19] describe a trial to evaluate the use of an app for CF patients to self-report symptoms and communication with mentors. Their research indicates that digital self-management for CF is promising. The trial demonstrates that the use of an app is feasible with a geographically dispersed CF population. The app was generally considered to be useful and allowed CF individuals to focus on changes in symptoms. However, the functionalities covered by the app were determined by the nature of the experiment rather than the users' requirements. Building an app on top of user wishes, as it is being done in this research, is more likely to match their needs and converge into a highly usable and acceptable solution [21].

Hilliard et al [20] focus on user needs. Their study is built on questionnaires and semistructured interviews with adults (older than 18 years) with CF. Participants were asked about their preferences for an app for self-management. They found that persons with a smartphone would have the app to help them manage the disease. The study identified a list of preferred features for such an app. This list of features included, but was not limited to, access to health information, communication with other people with CF, communication with health providers, automation of the process to order medication, and tracking and visualizing health behavior. Hilliard et al [20] also describe some nonfunctional concerns such as the need to tailor the app to CF therapy in contrast to generic apps; the need of an app interface that requires little interaction from the user's side (that does not take much of their scarce free time), the need of having a single app with multiple features instead of multiple apps, the possibility to customize app features, and privacy settings.

Hilliard and colleagues [20] present some initial expectations for a CF self-management app ecosystem that are highly relevant for our study. We go beyond the scope of both previously discussed studies as we include multiple stakeholders (parents, patients, and doctors), patients from different age groups (children, teenagers, and adults), and participants from multiple countries across Europe.

Study of Existing Cystic Fibrosis–Related Apps

In addition to the literature search, searches on Google Play Store and Apple App Store (the two biggest app Stores) for CF-related apps revealed 35 apps that were available for free and could be used for self-management of CF. Apps used for fundraising for CF and one e-book app for a scientific journal about CF were excluded. All apps were downloaded and tried. The app search gave an overview of what is currently available to persons with CF. We found that the most frequent features are educational information, reminders for medications or events, medicine registration, symptoms registration, social networking, and guidance on how to perform treatment (specifically the chest massage). The few CF-related games available are about educating the patient; one about helping the child to perform respiratory therapy by blowing in the phone. The search inspired our interviews as it gave us ideas about features that could be included in an app for CF. It showed that some needs expressed in the study by Hilliard and colleagues [20] are not yet addressed by any app. In particular, there are no apps that facilitate communication with health providers, or that track and visualize health behavior. Looking back at the apps after the case study to be described in the paper, we see that none of them cover all the nonfunctional concerns raised by users. The apps often revolve around a single functionality, offer no customization, and often require time-consuming data input.

Methods

Research Strategy

Figure 1 provides an overview of the strategies for the ICT research conducted in MyCyFAPP using the research model process and terminology proposed by Oates [22]. Other research activities in the project, that is, medical research and food engineering research, are not included. Different research strategies are taken in use for the user-centered design steps:

- A case study is applied for the analysis of context and user requirements. A case study is an inquiry that focuses on one aspect to be investigated with the aim to obtain a rich detailed insight into the life of the case and its complex relationships and processes [22]. In our work, we study the context of care of persons with CF in depth. Related to the holistic framework proposed by van Gemert-Pijnen et al for the development of electronic health technology [23], this step maps to the "contextual inquiry" and "value specification" activities.
- Design and creation is applied for codesigning, developing, and testing ICT artefacts [22]. The artefacts are not solely software prototypes but also include paper prototypes and mock-ups. This step maps to the "design" activity in the framework of Gemert-Pijnen et al [23].

- Finally, a pilot trial will be conducted to evaluate the final software prototypes and provide evidence of the usefulness of the solutions. The trial is conducted by the CF care experts involved in MyCyFAPP as an experiment [22], investigating changes in physiological parameters and QoL following the introduction of the solutions. In the ICT research study, we do, however, not plan to compare the situations "before" and "after" the trial.

The case study, as well as design and creation, follow an interpretive research approach. We do not prove or disprove a hypothesis but rather aim at understanding the social context for the systems we develop.

This paper covers the case study, aiming to analyze the context and user requirement. We follow an interpretative case study research strategy [24,25] to answer the primary question, "What digital support has the potential to usefully support persons with CF and their caregivers in the CF care?"

This requires us to understand the current situation, and we therefore define the preliminary questions, "What important factors in everyday life affect the care of persons with CF?" and "How is the CF care delivered today and what are the limitations of CF care services?"

The context of the case study is the everyday life of persons with CF and their caregivers in seven European countries. We seek to shed light on the tasks needed for the CF care, the challenges encountered in the care, and to derive the implications for ICT support.

As a starting point for the study, we use different sources that were earlier summarized in the paper. First, the vision of MyCyFAPP was developed by experts in the CF care, working in six different CF competence centers in five European countries. In addition, a study of the state-of-the-art for digital self-management in health and the testing of available CF-related apps provided us with an initial understanding of the context. During the case study, data were collected through netnography and semistructured interviews.

Netnography: Data Collection and Analysis

An online forum research based on the concept of netnography was first performed. This gave us a broader overview of the patients' needs and concerns. Netnography is "a written account resulting from fieldwork studying the cultures and communities that emerge from on-line, computer mediated, or internet-based communications, where both the field work and the textual account are methodologically informed by the traditions and techniques of cultural anthropology" [26]. The method allows to collect questions and concerns from a broad audience among the CF community. It offers additional insights as the interaction is more anonymous than direct interviews. This potentially leads to more open discussion than during personal contact with a stranger. Five internet platforms (two in the English-language [27,28] and three in German [29-31]) were researched for entries about enzyme therapy, food intake, as well as details about patients' daily life with CF.

All forums that were accessed were registration free, and the researchers did not participate actively in any discussion. The data collected were analyzed using the coding software Dedoose provided by SocioCultural Research Consultants, LLC (Manhattan Beach, California).

Figure 1. Strategies for the information and communication technology (ICT) research in MyCyFAPP. CF: cystic fibrosis.

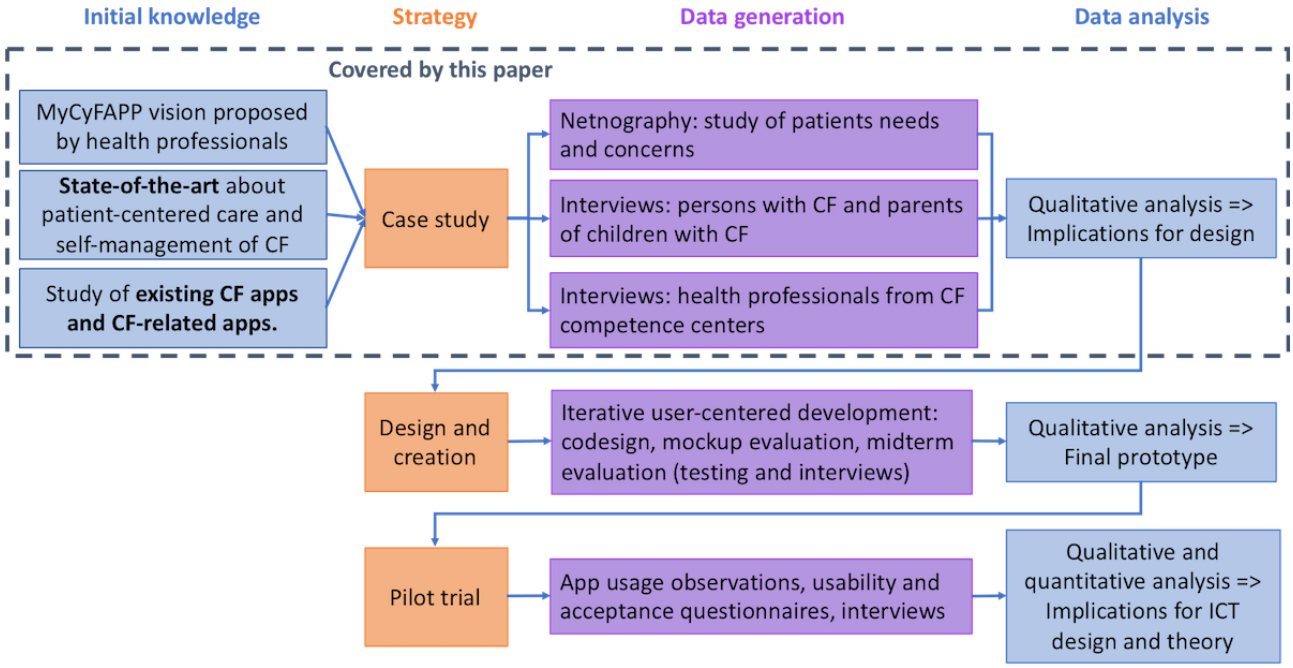


Table 1. Overview of the participants across countries and target groups.

Country	Target group						Total
	4-12 years	13-16 years	16+ years	Parents	Association	HCP	
Belgium	—	—	1	2	—	2	5
Germany	2	—	2	2	—	10	16
Italy	—	2	2	2	—	2	8
Netherlands	2	2	—	1	—	3	8
Norway	—	—	1	3	1	5	10
Portugal	1	2	2	2	—	3	10
Spain	1	1	3	5	1	6	17
Total	6	7	11	17	2	31	74

Semistructured Interviews: Data Collection and Analysis

Qualitative semistructured interviews with persons with CF, caregivers, and HCPs with CF care expertise were performed face-to-face, as well as over the phone. Although persons with CF and caregivers describe personal concerns and needs, HCPs share general experience and experience-based advice. These viewpoints are complementary. All interviews were conducted individually, except for practical reasons that of three doctors and one nurse at the Norwegian CF center and of three doctors and dietitians in a Portuguese CF center. The study includes all relevant user groups: children and teenagers with CF in the age range of 4 to 16 years, young adults with CF older than 16 years, parents, and HCPs. HCPs include doctors, nutritionists, and nurses. In addition, members of CF associations were also interviewed, so that a total of 74 participants were included. They were recruited through national CF associations and hospitals in seven European countries. The participants could choose between face-to-face or phone interviews. Table 1 gives an overview of the participants across countries.

A central element of the study is to include several countries. Different countries organize their CF health services differently, have different digital routines, and cultural differences. The goal of including equal numbers per target group in all countries could not be achieved. Given that the treatment is time-consuming, accessibility to patients was a major challenge as it sometimes involved a lot of extra time and effort for the participants. Further challenges in recruitment were the fact that young children could not be interviewed over the phone leading to occasionally long travels to CF centers and that patients could not meet for group interviews because of cross-infection risks. In addition, children and teenagers who are supposed to be included in the planned clinical trial later in the project were not involved in the interviews to avoid a bias.

Slightly adapted interview guidelines were provided for children, parents, and HCPs. Individual interviews lasted between 30 and 60 min and the group interviews 3 hours. Topics included:

- Demographics, personal details, technology usage (all groups)
- General needs, fears, hassles, typical day in a life, motivation (persons with CF and parents)
- Self-management of the treatment vs support with treatment, motivational factors, obstacles or problems (persons with CF and parents)
- Experiences and expectations about food recording and enzyme dosage calculation (all)
- Communication between patients or parents and HCPs (all)
- Communication with other patients and parents (persons with CF and parents)
- Apps they like and/or use regularly (persons with CF)
- Expected features in a self-management app (all)

All participants were given information about the research and the management of collected data. They signed under a letter of consent. The interviews were recorded and transcripts of those written and notes taken for data collection and analysis. The transcripts were sent to interviewees for feedback.

The analysis of collected data was performed in an inductive way. The framework and the principles of Klein and Myers were used in this process [32]. The researchers read the written interview transcripts and performed a first independent round of thematic analysis [33] resulting in a number of initial topics. Then, a refined working set of topics was iteratively created through collaboration among the participating researchers.

Results

A Large Diversity of Needs

Over 450 needs were identified across the target groups. The participants in the study did not only describe their own experience and express their own needs. Parents explained difficulties encountered by their children. They have expectations about how children should tackle the disease, and they foresee useful app features for children. On the basis of experience from the past, parents with older children and adults with CF expressed needs on behalf of parents with younger children, children, and teens. Although the vision of MyCyFAPP includes a management tool for HCPs, HCPs found it difficult to express needs for a tool intended to support their own work. Their main concern was the digital support for the patients.

Topics Identified Through Netnography

Results from the netnography research show that under a total of 32 main topics identified, enzyme is the most discussed one

in user forums (51 mentions), followed by motivation and discipline (44), diet (38), weight (36), exercise (21), supplements (20), and time management (16). Topics can be further classified according to whether the user is a parent or a patient. The most important themes discussed by parents are difficulties with their children not eating enough, not gaining enough weight, and not taking their enzymes. Physical exercise appears to be more of interest for older patients. Issues such as time management and discipline are more often discussed by adults with CF. These results indicate the relevance of the topics suggested in the MyCyFAPP vision, in particular, support of enzyme dosage calculation and nutrition management.

"What Important Factors in Everyday Life Affect the Care of Persons With Cystic Fibrosis?"

We identified the following main factors that influence the daily life of patients and parents of children with CF:

- CF is a serious disease and its treatment demanding.
- It takes time for caregivers and persons with CF to gain experience in the treatment and to establish routines necessary to handle it. The level of experience with the disease and the ability to set up routines lead to varying needs.
- Whenever there is a change in life circumstances, when the health condition changes, or when the patient grows older, daily life and the connected needs are affected.
- Patients behave differently, and the level of compliance to the treatment varies. They also accept the disease differently. Behaviors change over time too. Accordingly, the level of support to comply with the daily treatment and make life easier varies as well.

In the following, we describe these main influencing factors and, for each factor, derive implications for the design of digital support. A summary of the implications and their relations to the identified factors is presented in Figure 2.

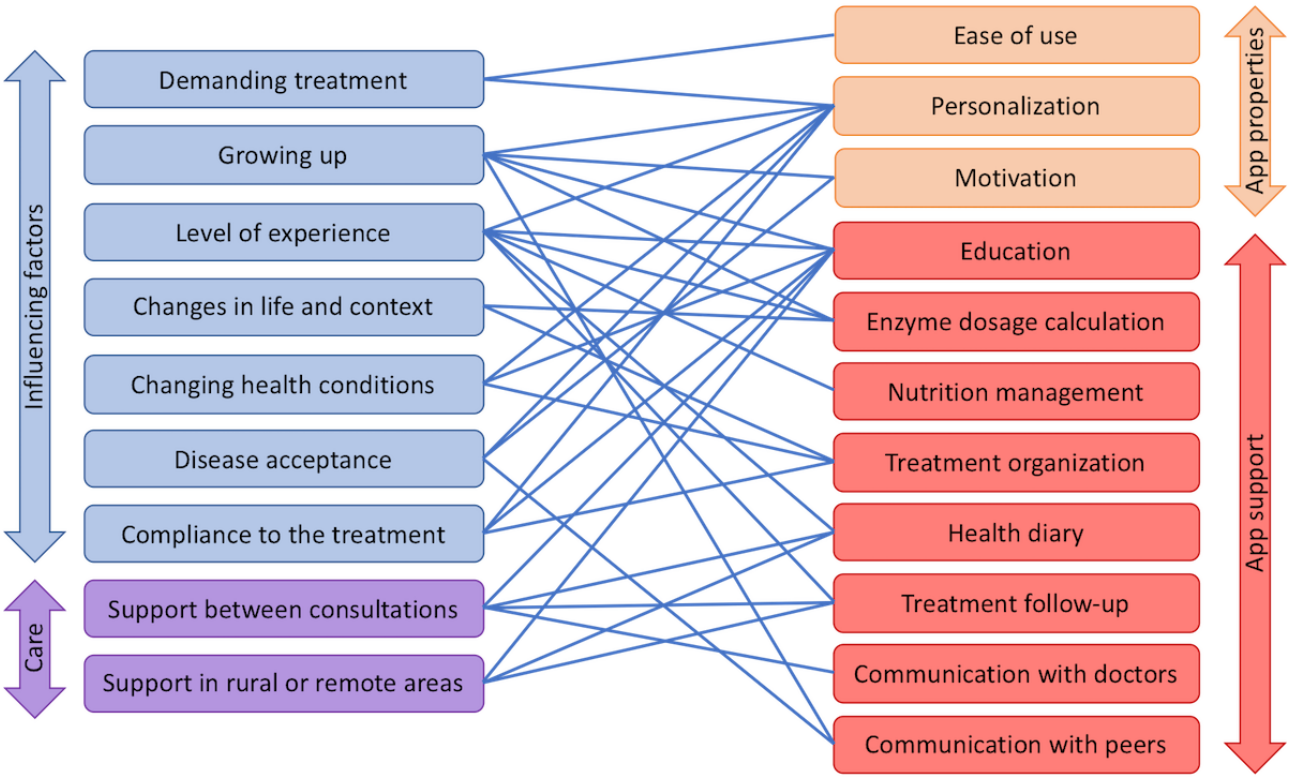
The interviews were conducted in different languages and most quotes included in this paper were translated by the authors. When English was used, participants were not English native speakers. Many participants in the study use Creon as medication for enzyme replacement, and therefore, referred to Creon instead of enzyme in the interviews. In the following, we use "parents or mother or father" and "child or teen or adult" for "parents or mother or father of child or teen with CF" and "child or teen or adult with CF," respectively.

A Demanding Treatment

The treatment of CF is time-consuming. Every day, people with CF do some form of airway clearance, for example, chest physiotherapy, to clear the lungs from the thick, sticky mucus. This is associated with inhalations that help keeping the airways clean. Inhaled medicines may contain antibiotics to fight lung infections. A session takes between 20 to 40 min. Clearance may be needed more than once a day. The equipment used has to be kept clean to avoid infections. People with CF are also recommended to practice physical exercise regularly to improve their lung function, as well as heart and muscle function. One parent stated the following:

> *Yes, the day is busy. It starts early. First, 20 minutes medication and then getting everything else ready. And then there are times with infections, and he is in a bad shape and tired, and his motivation is low. We cannot say that it is not demanding. It is.* [Mother of 8-year-old child]

Figure 2. Overview of relevant app properties and features and relations to influencing factors.



All users targeted by the apps in this study have a very tight daily schedule and limited time available, as illustrated in the following quote:

> *...usually one to one and a half hour[s] of treatment each day. The double if she has a serious infection… Lack of time is the most challenging problem* [Mother of 7-year-old child]

The experienced lack of time can make it difficult to keep motivated and to adhere to the treatment, especially to do airway clearance, the most time-consuming part of the treatment. A teenager stated:

> *It is hard to find the time to do physiotherapy.* [17-year-old teenager]

The lack of time conflicts with the wish to live as normal as possible, as illustrated in the following quote:

> *Time is the biggest problem. Most patients want a normal life. They have to go to school. Some adults want to work. They want to have a family. CF is not about just taking the pills in the morning and then everything is solved.* [Doctor]

It is important to set up routines and structure the day to both meet the needs of the treatment and give room to other activities. Two parents stated the following:

> *The nutritional aspects, the Creon, the medications, the physio, the aerosols, the homework...There is not much time during a day. I go to work in the morning while she is at school and then I dedicate all my time to her. Every day. However, we have automated this since she was born.* [Mother of 10-year-old child]

> *Follow-up of CF takes time and needs caution on a daily basis. It is paramount if the routines, for instance training, are integrated in the family life.* [Mother of 8-year-old child]

Implications for design: following the limited time available, ease of use and real added value are found to be of the highest importance for a future app. An app can hardly reduce the treatment load in daily life, but it can help enforcing routines. One parent stated the following:

> *The parents need tools to make the life easier and to have to be dependent as less as possible on the disease. To try to live as normal as possible.* [Mother of 4-year-old child]

It is not realistic to expect, neither should the HCPs require, that an app is being used every day. In the following, we will see that particular situations, for example, eating a new type of food or taking new medication, can make an app particularly useful.

Experience With the Disease

When the disease is first diagnosed, nowadays, usually a short time after birth, parents are eager to find out more information about the disease and its treatment, as illustrated in the following quote:

> *People with recent diagnosis often contact the organization before they visit the CF Competence Centre. They search on Google and get in contact with us often the same day as they are diagnosed.* [Patient association representative]

CF is a complex disease. It takes time to acquire understanding about the disease and its treatment. Parents with young children describe more problems with the treatment than other groups in our interviews. They need more support and contact their CF center more often, as illustrated in the following quotes:

> *Parents with new-borns need more communication.* [Nurse]

> *The patients contact the Centre when they need advice. Usually parents with young children contact us often.* [Dietitian]

It is important for persons with CF to have a good nutrition. Many persons with CF, as well as parents, fear that the diet is not healthy or rich enough. They worry that the enzyme dosage is not appropriate and might ultimately lead to nutritional imbalances:

> *Many of the telephone requests are about enzyme dosage. Many patients struggle with stomach pain [...]. Sometimes this is, because the patients are unable to calculate the correct amount of enzymes. Compliance to correct enzyme dosage is difficult in all age groups.* [Patient association representative]

Parents of newborns and young children face additional challenges, as illustrated in the following quotes:

> *Initially it was difficult to find out what was the right amount of Creon. Especially when he was a baby and he was still on mother milk [...]. It gets easier when the kids are able to eat by themselves.* [Mother of 9-year-old child]

> *The Creon before meals, it is a problem when the child doesn't want to eat.* [Parents of 3-year-old child]

Even after more experience with the disease, parents and adults may find it difficult to calculate enzyme dosage, and some are uncertain about doing the right thing, as illustrated in the following quote:

> *It is a challenge to find out how much Creon to take.* [19-year-old adult]

However, the disease is individual. People with CF have different symptoms and challenges. Persons with CF and parents also learn to tackle the symptoms:

> *I have no problem with Creon. I am used to it. It also works well when I am not at home.* [21-year-old adult]

About enzyme dosage, parents said:

> *In the beginning, I had to search, but now I know it is 8 or 10 pills.* [Mother of 15-year-old teenager]

> *He gets 4-5 capsules a day, but I wonder if it is too little. I see on the internet that other children take much more at the same age. But he is growing, he is active and he has no constipation, so I assume he gets enough.* [Mother of 2-year-old child]

> *Maybe I am giving too much, but I do not think so, because he is doing well. There was a moment where*

> *he was not growing that much and was not taking weight very much. I tried to give more Creon and it seems that it was the problem because it was much better afterwards.* [Mother of 17-year-old teenager]

As parents and people with CF gain experience, they also establish routines to deal with the treatment. Although enzyme dosage was most often mentioned in relation to acquiring experience, routines relate to all parts of the treatment, as illustrated in the following quotes:

> *Her day is busy with exercising, medicine intake, school homework […]. We have to be well organized. We have routines that help to not forget anything, especially medication and physiotherapy.* [Parents of 10-year-old child]

> *Especially at the beginning when the routine was not in place, we had a paper sheet with a weekly table. In the rows, we had the different times for medication, what kind of medication. This sheet also serves today when he is going to his grandparents, when we organize the treatment and the therapy to be taken there. For us, no longer, because we have the daily routine.* [Mother of 9-year-old child]

Implications for design: the level of experience influences what digital support is needed. An app can help parents and patients to acquire knowledge about the disease and the treatment. It can also support them to develop experience in dealing with the disease and, particularly, to get more confident with enzyme dosage calculation. Furthermore, an app is well suited to set up and schedule activities and therefore, support the management of the disease. One participant stated the following:

> *Vitamins and antibiotics can sometimes be complex. It can be useful to set reminders for them. And to set the range of dates, because I may take a specific vitamin twice a month...* [23-year-old adult]

Growing Up

Growing up is another factor with a great impact on the life of children and teenagers with CF and their caregivers. Such as everyone else, children and teenagers with CF go through different phases as they grow up and mature. In different stages of their life they have different needs. Growing up, they take more and more responsibility and mature to young adults. An app has to take into account these different needs and levels of maturity and should support patients and parents at different stages of their development.

When children are still very young and first diagnosed, HCPs mostly speak to their caregivers about the disease; they teach them how to take care of their child and what to focus on. Very early support for parents and children is important, as ensuring the right nutrition at this early age is especially important for the further course of the disease, as illustrated in the following quote:

> *It is important for CF patients to have a good nutritional status. It is important that the dieticians can begin to give parents advices very early or directly to the children if they are old enough.* [Dietitian]

For young children with CF, most information from the HCPs is targeted to the parents. The children are often present in these conversations but may not be very interested in them, as illustrated in the following quote:

> *The parents get a lot of information, they learn about what they should do. The children are often no so interested. They play or do other things when the doctors explain.* [Patient association representative]

Therefore, young children mostly have only a general idea of their disease and treatment or even a false one: a father of a 5-year-old child explains to his child, “that he needs it [the treatment] because he ‘works’ in this way.” A mother of a 4-year-old child (on how she motivates her child to stick to the treatment): she tells her daughter that “she needs to take the pills and do the exercise because she is growing up.” When asked by her child, why her mother doesn’t have to take the pills, the mother answers, “I did, when I was a child.”

When the children become older, their knowledge about CF becomes a little bit more concrete, as illustrated in the following quote by a child when asked about what he knows about his disease:

> *That there is something not working perfectly with my lungs and that I have to do all the inhalation and take enzymes to feel better.* [9-year-old child]

This knowledge is very important, as when growing up, it is important for children and teenagers to start being able to deal with the treatment themselves. Children go to school where their parents can’t watch out for them, and teachers are not necessarily acquainted to the treatment of CF. One dietitian stated the following:

> *It is sometimes difficult to estimate the dosage of enzyme. It is easier with young children because the parents always observe the stool. When children get older, the parents don’t observe the stool all the time [...]. It is a bigger challenge for school-age children. Children have to learn when they are old enough about how much fat the food they like contains and how the stool should look like.*

However, starting to take this responsibility for their treatment can be very difficult for some children and teenagers, as they are missing knowledge about their disease, as illustrated in the following quotes:

> *When they get to the point where they should take responsibility, the doctors forget that they have [only] taught the parents. They have the expectation that young people know, but may be one should start educating again.* [Patient association representative]

> *Facing adolescence it is important that she [the child] starts to become autonomous and to have that information without the mother being pending. So having a dual app will be important in the transition to adult ages. The idea is to “replace” the mother role and be more independent. For this, if there is an*

> *app to help it would be fantastic.* [Mother of 10-year-old child]

Therefore, one of the associations involved in the research exploited events for young people to educate them. For example, they organized quizzes and sessions to exchange experiences, as illustrated in the following quote:

> *Young people like games, so games might be used for learning. It's more fun than listening to a doctor.* [Patient association representative]

Implications for design: an app can support HCPs and parents in teaching young children about CF in a way that is easy to understand and exciting. It can raise their interest and help avoid a knowledge gap for older children, allowing children and teenagers to slowly take over more responsibility for their treatment.

Starting to take responsibility for the treatment can be difficult for older children because they are missing information about CF, which earlier was mostly targeted to their parents. But also because puberty is a difficult time in general and especially difficult when having a severe chronic disease. HCPs and a young adult with CF stated the following about the difficulties of motivating teenagers to stick to the treatment:

> *Teenage time is the most difficult. They cannot participate to the same activities as their peers. Some think about suicide. At 20, one gets more mature.* [Patient association representative]

> *Teenagers often need more motivation. It is important to follow them up more. But this is for some teenagers, not all. Sometimes they find it difficult to follow the treatment because the transition from child to adult is not an easy period, as girls often want to be thin and boys want a lot of muscle mass.* [Dietitian]

When asked about problems for patients and parents regarding treatment, one nurse stated:

> *The rebellion phase of teenagers—it is very difficult. They want to know exactly why the drugs are important for them.* [Nurse]

One teenager stated:

> *When I was a teen, there were sometimes periods where I did not want to talk about CF.* [19-year-old adult]

As explained above, in general, parents take most of the responsibility for the treatment of their children before they go to school; starting school, children have to start taking responsibility and manage their disease more on their own; as teenagers, they have to become even more independent but often miss the motivation for it.

Despite this subdivision in very general age groups for the level of independent managing of the disease, there is much variation about how early children start taking responsibility. This depends on the children but also on their parents. Some parents give responsibility to their children very early. Other parents are very protective, and children are used to rely on them, even when they become young adults.

Some children and teenagers tell us that they started to take responsibility for their treatment (especially for their medicine intake) before or when starting school, as illustrated in the following quotes:

> *At 5 years old I took them [pills] by myself, at 7/8 years I did it all on my own...* [15-year-old teenager]

> *She knows everything since she was 4 years old. I give her the pills.* [Mother of 8-year-old child]

> *She got a lot of responsibility when starting at school, including taking medication on her own.* [Mother of 7-year-old child]

Other patients start taking responsibility only as teenagers, as illustrated in the following quote:

> *I started to be responsible for medication at 12 years old, for physiotherapy at 14 years old.* [17-year-old teenager]

There are different levels of responsibility. Some parts of the treatment are easier to adhere to than others. Often children start to take responsibility for their enzyme intake (Creon) first. For physiotherapy and other medications (eg, irregular medicine like antibiotics), as well as inhalation, they take over the responsibility later on, as these tasks seem to be more demanding, as illustrated in the following quote:

> *As a parent, you have responsibility. It is a question of maturity. We are not yet there. The Creon is much easier because he knows that before eating he has to take some pills, but we have to "stay behind [ie, supervise] for the aerosol and the physiotherapy. He won't do that alone.* [Mother of 9-year-old child]

When asked about when they started self-management, two teenagers said:

> *Medication: 12 years old; Physiotherapy: 11 years old; Creon: 6 years old; I use the same methods as my mother to put them into boxes. My mum still reminds me for some new pills, but I'm independent.* [17-year-old teenager]

> *I started to manage Creon at 7 years old. My parents still remind me to take aerosols [inhalation] and Creon with snacks.* [13-year-old teenager]

But the more complex the diagnosis is, the more children and teenagers with CF have to rely on their parents, the more difficult it is to take over responsibility for the treatment, as illustrated in the following quote by mother of a child with very complex diagnosis:

> *She is totally dependent on me. She takes a lot of different medications that can cause negative interactions. I need something to manage this and be safer or to promote her independence once she grows; I control if she needs more Creon because she has diarrhea or less because she is constipated.* [Mother of 10-year-old child]

Furthermore, some parents find it difficult to give responsibility to their children as they want to protect them, as illustrated in the following quote:

> *We have to remind him. Maybe I am a too protective mother. I still prepare things for him. In the morning, everything is prepared, so he can start inhalation. Also when he comes to the table, the number of Creon is near his plate.* [Mother of 15-year-old child]

However, for most cases, the following rule applies: no matter the age and maturity level, most of the parents stay very involved in the treatment of their child, even when their children are already young adults. The role of the parents is to remind their children to not forget any step of their treatment and to do the treatment right, as illustrated in the following quotes:

> *[I stopped reminding him] when he was 8 years old, I still give him a paper, on which all treatments are written down (as a reminder), but he prepares everything on his own.* [Mother of 9-year-old]

> *Most annoying is the time lost, especially in the morning, it is exhausting to remember what to do when, mum sometimes helps with remembering and with instructions.* [15-year-old teenager]

> *At 7/8 years old he did both treatments and Creon intake autonomously. Nevertheless, we still remind him to take pills with him.* [Father of 17-year-old teenager]

> *I take responsibility myself. Sometimes my mother reminds me about the medication at lunch time. This works well. I started to take responsibility for the treatment when I was 16-17 years old.* [21-year-old adult]

Implications for design: with changing age, the purpose of the app changes. At first it is all about explaining CF and the treatment connected to it in an easy and entertaining and playful way, to ensure the attention of young children. Later on, it is necessary, to help children and teenagers to start managing their disease, at first together with their parents (eg, child registers food and follow-up by the parents), then on their own. Additionally, for all age groups, motivational elements play an important role: young children need to be motivated to learn about CF and to stick to the treatment and older children and teenagers have to be motivated to take responsibility for the management of their treatment. A digital support tool can help to ensure that children, teenagers, and young adults with CF can lead an independent life, and it can relieve parents from some of their responsibilities and therefore, make their lives a little bit easier (eg, by giving an overview of the treatment and offering reminders). An app has to be very flexible and adaptive to work for these different needs of users of different age groups.

Changes in Life and Context

Even though experience has been acquired and a well-functioning daily structure has been found, changes occur in life that affect the established routines. The first kinds of changes are those relating to life situations, for example, starting school or changing school, having the first job, or moving to another place, as illustrated in the following quotes:

> *She loves school, teachers and school mates. We were very nervous, teachers didn't know anything about CF, we had to tell them all...It is very complicated...It worries me when she will go to the next school, we have to do the whole process again...* [Mother of 10-year-old child]

> *There have been some problems at school with bullying from the other children… There have also been problems with lack of understanding of the seriousness of the illness from some of the new teachers, because the child does not look ill in any way.* [Mother of 7-year-old child]

> *It went well when he was a child. [...] for 9 years he has been with the same friends. His friends know about him and they tell him to not forget his Creon. He changed school when he was 13. Then he was shy about it. He did not want to show that he was taking medicine.* [Mother of 17-year-old teenager]

> *It might be difficult to fulfil the diet and the pancreatic enzyme replacement therapy when they go to school or other activities out with friends.* [Dietitian]

Another kind of changes are short-term changes in the environment, such as eating out, going on holidays, or doing things out of the routine. Such changes were mentioned repeatedly as challenging situations, as illustrated in the following quotes, with the first quote on enzyme dosage:

> *When we go to restaurants, we don't know how the meal is cooked.* [17-year-old teenager]

> *I have also an aerosol that I take three times a day, morning, midday and evening. The one at midday, I often forget because I am not always at home and I have no other aerosols at this time. At the university, I also lack time at lunch time to take the aerosol.* [21-year-old adult]

Furthermore, distractions can make people forget about their medication, as illustrated in the following quotes:

> *When many things happen, when things are joyful, then he forgets about it [Creon]. Afterwards he has so much pain that he knows this was wrong.* [Mother of 9-year-old child]

> *I know that I must take the Creon. Sometimes something happens that I have to take care of, and then I don't know if I have taken it or not.* [23-year-old adult]

Implications for design: an app can help to tackle these different kinds of changes. Support for explaining other people, enzyme calculation, and reminders can be useful.

Changing Health Conditions

The health condition may change rapidly. For instance, the lungs of people with CF are prone to infection; treating these infections require antibiotics. For many, it is challenging to take a new medication, when the same medication has been taken for a long period, as illustrated in the following quote:

> *At a certain moment we had to go from 2 aerosol to 4 per day. [...] It was challenging to make it all fit before he is going to school. [...]. Mainly time is challenging, and if he has to get up earlier, motivation is also a challenge.* [Mother of 15-year-old teenager]

It is not always easy to learn about new medication. One patient association representative stated the following:

> *There are many things to learn when you get new medication. People get too little information about what the side effects are and how to administer the drug.*

The health condition can have an effect on the ability to adhere to the treatment, as illustrated in the following quote:

> *When I am sick, I lose appetite and I lose weight.* [21-year-old adult]

The severity of the disease increases over time, and related diseases such as diabetes may occur, as illustrated in the following quote:

> *Now the treatments are harder than when I was younger. I had less things to do before...Physiotherapy is the most stressful.* [17-year-old teenager in severe condition]

The following quote is about diabetes:

> *It increases the complexity of managing the nutritional aspects. From the CF viewpoint, I need to take more fats and eat more and, from the diabetes viewpoint, I need to reduce sugars and fats.* [23-year-old adult diabetic]

The interviewed parents and persons with CF did not share their worries about health deterioration with us, but HCPs describe health deterioration as an important concern, as illustrated in the following quotes:

> *Nutritional problems increase with the disease severity, and often when the lung disease escalates...Creon and nutrition often stabilize when patients grow up before lung diseases appear again and ruin it.* [Doctor]

> *Some have a disease such that whenever they are at the consultation, we identify a new complication or a new disease, and a new negative message enters the line of others. This is hard.* [Nurse]

> *They fear that they get worse or their nutritional status deteriorates.* [Dietitian]

Implications for design: it is not realistic to expect that an app can solve all challenges risen by the severity of the disease, but helping to maintain the health condition as good as possible is a leading motivating factor for an app in the first place. An app can support tackling new medication and can help learning about new diseases. An app can also motivate to adhere to the treatment.

Disease Acceptance and Openness

Another important factor affecting the life of children and teenagers with CF and their caregivers seems to be how open they deal with the disease, as well as their acceptance of the disease and all that comes with it.

This level of openness as well as the acceptance differs quite a lot between patients: some children as well as teenagers with CF try to hide their disease, they don't want others to know about their disease, or only tell close friends about it, as illustrated in the following quotes:

> *Some are ashamed of their disease, they try to hide it in school. They use a bag for sweets to hide the medicine.* [Nurse]

> *Youngsters [...] don't want to do the therapies/enzymes in school, they don't want to show that they are sick.* [Doctor]

A mother of an 8-year-old child sees CF connected with a public stigmatization and tries to protect her child from this by making him look like an "ordinary schoolboy," as illustrated in the following quote:

> *We have taken over the responsibility for physiotherapy...He is an ordinary schoolboy with physiotherapy in the evenings. Thus he is released from the stigma attached to CF at school.*

On the other hand, some patients speak about the great support they are receiving, especially from their friends because of being open about their disease, as illustrated in the following quote:

> *When I was little, it was a little difficult, the people in my class helped me. I have lots of friends, they all help and motivate me...* [15-year-old teenager]

Especially, friends seem to have a great positive impact on the motivation of young persons with CF and can help them to stick to their treatment.

In the experience of patient association representative, dealing with the disease is easier for those who speak openly about it, as illustrated in the following quote:

> *Some people are open about their disease while others never tell anyone. Those that are open often handle things better. Some are afraid that they would not get any job, if they tell.*

Not only do some children and teenagers try to hide their disease, some also find it very difficult to accept the disease or having to do treatment because of the disease, as illustrated in the following quote:

> *It is difficult for her to understand or accept the illness—in her eyes she does not need the medication. She gets pain in her stomach if she does not take Creon, but even so she forgets or ignores to take Creon when she gets something to eat from others, for example an ice cream at a friend's house.* [Mother of 7-year-old child]

Accepting the disease or the treatment seems to be especially difficult for younger patients, as illustrated in the following quote:

> *My mum sometimes tells me that I have a better life than many kids—but that is not true, they don't have to do all the treatments. [...] My family wants me to go to Amrum for rehab, but I don't want to! It will be like being in a hospital for weeks! My grandma told me she will get an Ipad for me when I go, but I don't want to!* [9-year-old child]

Other children too don't want to do the treatment or they don't do it properly, as illustrated in the following quote:

> *They watch TV, cartoons, while doing the aerosols. For physiotherapy is different, the child needs to be concentrated...Sometimes, it is difficult because he just wants to play.* [Parents of 5-year-old child]

To help parents and young children with a lack of acceptance at this age, a nurse explains to the children in an easy way the benefits of sticking to the treatment. Especially important seems to be to explain to them that with sticking to the treatment, they will feel better, as illustrated in the following quote:

> *They [young patients] need to know that they could live well, if they take the medicine. I often ask them: "what do the enzymes in your body?" At the age of 5-6 I start teaching them about enzymes. [...] I help them to get around obstacles. I tell them that many scientist are working on the disease to find better treatments, I show them adults. I help parents to meet each other. I help them to motivate to take the medicine so they are better. I tell them: "you're growing, congratulations!"* [Nurse]

Other than the younger patients, most teenagers seem to have understood that without compliance their well-being or even their life is at risk. They seem to have accepted the extensive treatment and the limitations caused by the disease pragmatically. When asked about problems with the treatment they stated the following:

> *I have to do it [the treatment], because I have a disease.* [15-year-old teenager]
>
> *I know that my wellness depends on it and I have internalized the processes. I don't think too much, I do it.* [17-year-old teenager]

Overall, openness about the disease and acceptance of the disease seem to be very important for the compliance to the treatment. Openness about the disease makes support from others possible. Acceptance has a great impact on the compliance to the treatment, and the acceptance of the necessity of the treatment seems closely connected to the realization that only compliance to the treatment can ensure feeling well and staying alive.

Implications on digital support: to foster openness and acceptance, especially young patients need support in form of explanation of the disease and motivation to stick to the treatment. Easy to understand knowledge about the disease and treatment should be made available. Additionally, prejudice must be reduced to avoid stigmatization, and patients need support to be able to easily educate other people about their disease, so social support becomes possible, which seems very important for increasing and holding up the motivation of patients.

Compliance to the Treatment

Persons with CF are more or less concerned about following the treatment and food recommendations. Some strictly adhere to the treatment, as illustrated by this quote:

> *I do not have to do anything to motivate him to comply with the treatment. He knows that he has to do it if he wants to be healthy. It is not the right word. To be as good as he is now.* [Mother of 15-year-old teenager]

One teenager stated the following about the daily treatment:

> *I have to do it, so I do it...because without I don't survive...* [15-year-old teenager]

There are different reasons for not being compliant. It is important to be well-structured. Two participants stated the following:

> *It's sometimes difficult to remember if I have taken the medication or not. Maybe I am doing something else or something arises, and then I don't know [...] I have a [...] brother with CF. He is not responsible at all, so I take care of him.* [23-year-old adult]
>
> *Some physiotherapy and medication can be missed because she forgets.* [Parents of 10-year-old child]

Sometimes persons with CF downplay some aspects of the treatment to "live a normal life," as illustrated in the following quote:

> *Youngsters, they don't eat enough, they don't eat the right food. They don't want to do the therapies and take enzymes at school. They don't want to show that they are sick.* [Doctor]

Different parts of the treatment are difficult to adhere to, as illustrated in the following quotes:

> *It is not easy to take enzymes. And, in all age groups, compliance with Creon intake is difficult.* [Doctor]
>
> *Physiotherapy is very important. [...] The patients really do not like to do it. It is time consuming. Coughing out sputa is also annoying.* [Doctor]

As earlier explained, age also plays a role for compliance. Both physiotherapy and nutrition were often mentioned as challenging for young children. Parents said the following regarding physiotherapy:

> *Physiotherapy works only if the child collaborates.* [Parents of 3-year-old child]

Regarding nutrition, some parents and a dietician stated:

> *The little one doesn't want to eat at the kindergarten, because he doesn't feel like home there.* [Mother of 4-year-old child]
>
> *Especially in the kindergarten, he is a very bad eater. He doesn't like a lot of things.* [Mother of 3-year-old child]
>
> *Sometimes children have eating problems. An app that motivates them to eat is useful for those patients.* [Dietitian]

And as also explained earlier, teenage time is a difficult period. Some teenagers wish to focus on other aspects of life than on health issues and daily treatment, as illustrated in the following quotes:

> *Regularity and discipline are important. [...] It is tough to motivate teenagers.* [Doctor]
>
> *Girls from 10/12 years on don't want to gain weight.* [Doctor]

Doctors and parents also explained that children do not always understand the need of lung therapy, which has a long time effect. It is therefore important to motivate to adherence to that part of the treatment, as illustrated in the following quotes:

> *Physiotherapy and inhalation are challenging. The effects of not adhering are not visible at once as for Creon. Young people do not think about that life may be some years shorter.* [Patient association representative]
>
> *Patients don't always feel a negative influence if they don't follow their physiotherapy or do not do inhalation. This part of the treatment is important for their future, but it is challenging to spend more than 2 hours a day for long time effect. Most of the patients take their Creon because they get stomach pain when they don't. Taking pills does not take time either. Inhaled drugs require time.* [Doctor]

Parents use different approaches to motivate their children, as illustrated in the following quotes:

> *We run together everyday. We often run past a shop and buy ice cream or candy to motivate him. We have trails of different lengths. I try to make it fun...It is important that training is not something he must do alone. He must do this every day of his whole life, and therefore it's important to do something nice. At the same time, he is "allowed" to have some bad days. Then we walk instead of running.* [Mother of 8-year-old child]
>
> *If things are done properly, we take the bicycle, we go for a quick walk, we go to eat an ice cream. Things like that. Small things. I do not want to promise things totally out of scope.* [Mother of 9-year-old child]
>
> *Medication was like a game played with my mother.* [23-year-old adult]

It can be hard to motivate over a long time, as illustrated in the following quote:

> *It is sometimes difficult to motivate. It feels unfair to be different...We have used stickers as awards, and we had agreed upon some items after collecting a certain number of awards, but it loses appeal after a while.* [Mother of 8-year-old child]

Most of the children in our study receive good support within their family. But the level of support may also vary, as illustrated in the following quotes:

> *We had family problems and were not motivated to learn [...] I started very early in my life to take care of my young brother.* [23-year-old adult]
>
> *We have regular consultation with the dietician in the context of the quarterly control. We receive advice to improve his appetite [...]. We follow as much as we can.* [Mother of 9-year-old child]

Implications for design: support for learning about the disease and for understanding the purpose of the treatment and how it works are important for compliance. Reminders and checklists are simple means for those who forget. Additionally, support for motivating, for example, through gamification or playful interfaces, should be considered.

People are, however, more or less rigorous. It is not realistic to expect that an app will solve the problem of compliance. One HCP said the following with respect to considering a diary as a means for learning and reporting to doctors:

> *Who will reveal they are not doing what you have told them? Registering information is demanding and revealing. People are very different. Some do not have any overview and others have neat handwritten notes about everything that has happened day by day.*

"How Is the CF Care Delivered Today and What Are the Limitations of Cystic Fibrosis Care Services?"

CF is a complex disease whose care requires a multidisciplinary team approach. All countries involved in the study have established CF centers with specialized expertise [34]. The patients meet regularly at the center for consultation, usually every 3 months, and even more depending on the severity of the disease. A HCP, an adult with CF, and a parent stated the following:

> *The centre has a multidisciplinary clinic where patients come and are seen individually by pediatrics, nurses, physiotherapists, sometimes by a psychologist and sometimes by a dietician. The patients come every 3 months for consultation. Some caregivers, the physiotherapists and dietician do not see the patients every time they come. They try to see every patient at least once in a year. If they have problems or special questions, they see them more often.* [Doctor]
>
> *Normally I go to the doctors every three months, except if things do not go well.* [21-year-old adult]
>
> *We are going every three months to the control. It is a multidisciplinary team. When you go, it is often half a day, one afternoon for example. You see the dietician, the physician and the lung doctor. All these professions because they cover the disease together...Between the controls, they are always reachable by phone.* [Mother of 9-year-old child]

A more thorough control is often done every year and might require collection of food records and a stay at the hospital. One HCP stated the following:

> *Depending on needs, the yearly control lasts from one to three days. For some it may be a bit longer.* [Doctor]

Besides regular consultations, patients also contact their CF centers via other communication channels. Nurses are the first contact point for the patients, as illustrated in the following quotes:

> *Patients can communicate with the CF centre between consultations every 3 months. The centre has a central phone number and email address. The nurses and*

> *secretaries take care of messages. The nurses may answer themselves. If they think a doctor has to answer, they forward to one of the doctors. If every patient contacts a specific doctor, the centre loses overview of what is happening. Using phone and email, the patients avoid coming to the centre when they have a small problem.* [Doctor]

> *We have continuous contact with most patients by phone and letter. We do phone consultations. [...] We are now establishing a new video communication service. [...] We have contact with the vast majority of patients every year. The threshold to contact us is low. The critical issues are handled face-to-face.* [Nurse]

> *I do not usually contact the doctors between consultations, except if I get really bad...Normally I send an email and the nurses handle the request. I never contact the doctors directly. This works well. I get answers rapidly.* [21-year-old adult]

Allocating staff for phone communication might be challenging, as illustrated in the following quote:

> *All patients say that telephone consultations are annoying during the daytime. Everyone is at work during the daytime. Phone works in the afternoon and evening.* [Nurse]

Sometimes information is not properly registered, as illustrated in the following quote:

> *The information is not always correctly registered. For instance, when a patient contacts the centre to tell about a problem with a drug. Somebody may tell the patient to change to another drug, but not record it in the system. So when and why the change is done is not recorded.* [Doctor]

Besides health follow-up, the CF centers also teach and provide recommendations to the patients, as illustrated in the following quotes:

> *Inhalation is challenging. This is a big responsibility for the nurse and for the physiotherapist. They try to instruct the patient in the correct way and to evaluate. When the patients start a new drug, they try it for the first time during the consultation to see if they can do take it properly.* [Doctor]

> *I communicate with patients also by phone and email, if they have questions or problems. I give advice for the enzyme supplement. I look at the weight evolution, at the height evolution, and adapt the enzyme supplement in order to increase weight and height.* [Dietitian]

Some CF centers also provide external support, as illustrated in the following quote:

> *We travel to schools and kindergarten and provide recommendations. Local physiotherapists may also ask for assistance.* [Doctor]

An important part of the care is the daily physiotherapy. Although some parents learn to do the physiotherapy themselves, some prefer to rely on physiotherapists. Physiotherapists may do home visits. However, not depending on physiotherapists is also important with respect to independence. A HCP and two parents stated the following:

> *Patients can learn to do physiotherapy themselves. This is what most patients do. Patients know what they have to do, to clear their secretion. However once or twice a week, they go to the physiotherapist. The physiotherapist can apply more pressure on the thorax and feel, where secretions are, so it is better.* [Doctor]

> *As far as the treatment is concerned, he is very conscious and does it in a responsible way. He goes to physiotherapy every day, 7 days a week, even Saturday and Sunday. [...] We have learnt ourselves too, but do not do it as good as professionals. We know just enough to be able to go on holidays...Now he is older, so if we are doing something wrong, he can tell how to do it.* [Mother of 15-year-old teenager]

> *Physiotherapy depends on his status of coughs. It can be one, two or more times a day. [...] Fortunately, the physiotherapist is coming to our home. On the weekends and if we go on vacation, we give the physiotherapy ourselves. It is preferable that a professional gives the physiotherapy.* [Mother of 9-year-old child]

A good nutritional balance is extremely important for CF patients. It is, however, challenging to keep track of the nutritional status. The CF competence centers involved in the study sometimes ask their patients to perform a 4-day collection of detailed food records. Recording can be done in connection to the yearly in-depth consultation, or requested by HCPs when a particular problem occurs. Regular nutritional protocols can help centers to keep an overview of the nutritional intake of the patients and to identify possible reasons for occurring symptoms. But neither the patients and caregivers nor the HCPs are pleased with the procedure and the results of it.

For patients and caregivers, the tracking of the food intake can be very inconvenient, time-consuming, and difficult, as illustrated in the following quotes on difficulties with filling in the nutritional protocol:

> *Recording the quantities. You forget any ingredient and then it must be rechecked.* [17-year-old teenager]

> *The weight of each ingredient. You should introduce it in grams but it would be easier to introduce "standard" measures (a small spoon, a glass, a cup of coffee...). Additionally, there are many different ways to cook the same plate. It should be personalized as you cook and the ingredients that you use for doing a plate and how to cook them.* [Mother of 10-year-old child]

For HCPs, precise information within the protocol is very important; often they would need more detailed, accurate, and complete information in the protocols:

> *It [the nutritional protocol] must be as precise as possible regarding ingredients, amounts and cooking process.* [Dietitian]

One HCP stated the following about typical difficulties with the nutritional protocol:

> *Not enough details, incomplete information and too vague amounts.* [Doctor]

Although overall the CF centers function well, and patients expressed satisfaction in the care services they get, the availability of services is not always good for those living in rural areas, or those followed up by overloaded CF centers in large cities, as illustrated in the following quotes:

> *Some patients live quite far away, it is very expensive for them to come to the consultations and check-ups. It is very expensive. And transit doesn't get paid.* [Doctor]

> *In comparison, at our centre it is good, 4-5 doctors for 120 patients, this is good. In Munich [big city in Germany] for example, 4-5 doctors are responsible for 400 patients. The amount of patients is increasing, the relevance is increasing. There are rural areas, where the care key doctor/patient is worse.* [Doctor]

In Norway, the care is organized differently than in the other countries involved in the research. The country is large with few people with CF spread all around the country. The policy is to give care to inhabitants close to the place they live. People with CF have their regular follow-up at a local hospital and a yearly consultation at the CF center (except those living in the Health Region South-East who are followed up by the CF center outpatient clinic). This organization of the care service received much critic both from HCPs and patients, as illustrated in the following quotes:

> *It is a challenge to establish good medical and interdisciplinary disciplines in Norway, which is necessary to deal with a condition as complex as CF. [...] It is important to understand that professionals in local hospitals, who may have one to three patients, do not have the opportunity to accumulate sufficient experience.* [Doctor in Norway]

> *Today, we have the main follow-up at the CF centre once a year. In between the follow-up is done at the local hospital once a month...I am concerned with nutrition and do not always agree with the local nutritionists, those who are not CF specialists...It is difficult because the doctors at the competence centre sometimes say something else than the doctors at the local hospital, for instance about taking antibiotics or not...* [Mother in Norway]

Beyond the policy encouraging local care, the transition to adult care also rises challenges, as illustrated in the following quote:

> *In ages from 15 to 25 [...] Moving from pediatrics care to adult care can also be challenging. Children often get more support than young people.* [Patient association representative]

As physiotherapy is concerned, people in Norway cannot count on a service available 7 days a week. Such does not exist. Parents are encouraged to take responsibility. One parent stated the following:

> *I give the daily physiotherapy following instructions from the local physiotherapist. The local physiotherapist was trained by the CF competence centre. The local physiotherapist comes home once a week.* [Mother of 2-year-old child]

Implications for design: the CF service care functions mostly well. In the case of rural areas or large cities, where the availability of the services or the expertise might be enhanced, we observe that patients are eager to take responsibility and manage CF by themselves. This indicates a readiness for the adoption of digital support for self-management. Additionally, in the case of a well-functioning care service and tight follow-up, we understand that there is a potential for letting patients manage more by themselves and understand more. Furthermore, some processes such as recording food could be simplified for all involved parties by supplementing or replacing them with a digital solution. Furthermore, we understand that there is a need for support between consultations, as illustrated in the following quotes:

> *Sometimes when I ask a mother more details about symptoms, for example "when does it happen?" she cannot always answer, and I see that she feels bad about not remembering. It is difficult for me too. I know that she spends a lot of time caring for her child. It would be helpful with an app that helps remembering what happened.* [Doctor]

> *When you go to the doctor, you tell about how you experience things, and you may tell in different ways. What cannot be measured objectively is your own experience. An app can help the patients and parents to structure their experience and to reflect about what happened. People may have the same disease, but experience it in different ways.* [Patient association representative]

"What Digital Support Has the Potential to Usefully Support Persons With Cystic Fibrosis and Their Caregivers in the Cystic Fibrosis Care?"

On the basis of the data gathered as described above, we derived a list of main properties and support functions our CF app (or apps) should have to support patients in an optimal way. These properties and functions will be explained in more detail in the following section. Figure 2 gives a summary of this list and shows how app characteristics correspond to the identified needs of the users.

Ease of Use

Keeping in mind the very *demanding treatment* and very busy schedules of children and teenagers with CF and their families, providing support through an app makes it important to develop an app that is not "just another thing to do." The app has to provide an added value to existing support structures and routines, make life easier, and save time. Therefore, the ease of

use of digital support tools is exceptionally important, as illustrated in the following quote:

> *The app should be easy to use! Easiness and quality should be pointed out!* [Doctor]

On being asked if they would be willing to use a CF self-management app, parents stated:

> *I would register yes. It must be simple and easy. No writing, just select options after one first configuration.* [Parents of 3-year-old child]

Personalization

Not only is the ease of use of apps for children and teenagers with CF and their families essential, such apps also have to be customizable. The need for such *personalization* is stemming from the variability of the disease and the individuality of the patients. Despite having the disease in common, the patients do not necessarily share the same treatment routines, knowledge about CF, and other personal characteristics such as hobbies and life circumstances.

The *level of experience* of patients and relatives varies quite a lot: some patients and parents need more knowledge, for example, especially when they are newly diagnosed. Others, who are not confident yet with the dosage of enzymes, need more help with this, whereas others only need support, calculating the right amount for special occasions. Digital support has to be adaptable for these different needs.

Furthermore, when *growing up*, the purpose of the app changes: at first, gaining knowledge about CF is most important; teaching children in an entertaining way has high priority. Older children are supposed to start managing CF on their own. Motivating elements are needed at all times, but they have to be adaptable to the needs of the different age groups as well.

Furthermore, depending on the patients' *health condition*, diverse functionalities within an app are needed. Patients with a deteriorated condition need different support to manager their disease. One parent stated the following when asked about the necessity of an alert or alarm:

> *Not for Creon, it is usual, [...] (And asked about the necessity of reminders for other treatments): Not, if they are as now. But if they would increase, it could be useful.* [Father of 5-year-old child]

When asked about the need for reminders for other treatments, another parent said:

> *It could be useful for antibiotics because it is distracting the routine of the daily treatment. It would not be a bad idea to have a reminder. It is true that sometimes the antibiotics treatment can be hard to follow.* [Mother of 8-year-old child]

With differences in the level *of acceptance of the disease,* needs may differ in terms of how much children and teenager with CF would like to communicate with peers or other HCPs. On the other hand, for persons with CF who are having trouble accepting their disease, motivational elements are immensely important, and education about CF within the app could be more helpful than for others.

Finally, the *access to specialized medical CF care* varies between countries, as does the *availability of education* about CF. In the case of Norway, for example, there is only one CF competence center, as compared with a large number of specialist CF care centers across Germany. The way the specialist CF health services are organized can hence influence access to expert consultation and *support* that some patients would ideally need.

Motivation

Parents and doctors express a need to increase awareness of possible negative consequences of noncompliance with the treatment. This is strongly linked to a need to get *motivational support.* Low motivation may lead to decreased treatment compliance. To bolster motivation should hence be explicitly targeted by the app. This is a challenging task, as illustrated in the following quote:

> *[Motivation] is difficult because it [the treatment and the disease] is individual for each patient. You cannot tell a patient that if you do your physiotherapy, your lung function will improve by 5%. We cannot say that because it is like a promise which may not come true.* [Doctor]

Participants stressed that a focus on the positive aspects of compliance with treatments and nutritional recommendations will increase motivation more than information on risks connected to noncompliance, as illustrated in the following quotes when asked about ideas for the app(s):

> *Please very positive messages! Supportive!* [Nurse]
>
> *You can better motivate with height [...] A game is helpful, how the disease works, understanding what doctors are saying [...] a quiz is always good! Rewards also!* [Doctor]

Education

There is a need to explain the disease and the importance and purpose of the treatment to young children in an entertaining and motivating manner, to ensure their interest and compliance to the treatment, and to avoid that they are missing important knowledge about their disease when they are already supposed to start taking responsibility for their treatment. This also can improve the compliance to the treatment in early years and can help parents to speak about CF with their children. Later on, there is also a need to gradually teach older children and teenagers how to take responsibility with respect to their treatments, as illustrated in the following quotes:

> *It is important that the app gives information directly to the child so they get motivated to eat well and take their Creon well. It is important that the children get motivated and that they get knowledge about their food and Creon.* [Dietitian]
>
> *For the children, it is important to educate them by entertainment. It is important that children know what they are doing and why. Often parents do all what they have to do, but 9-10 years old children cannot tell why they are doing it. Children should be instructed from the beginning.* [Doctor]

> *A Game would be helpful. How the disease works, understanding what the doctor is telling. [...] A Quiz is always good, rewards also!* [Doctor]

As elaborated above, especially parents of newly diagnosed children need support in learning about this disease, which is complex and difficult to understand. Educational elements in an app can help them to learn about the disease and treatment and to gain experience in dealing with it faster and therefore to help reduce some of the concerns of the parents.

Furthermore, educational elements in an app can be used to explain CF more easily to others. This is important when deviating from daily routine (eg, eating out) and especially at times of *changes in the life* of children and teenagers with CF (eg, changing school). It can also help children and teenagers with CF, as well as their caregivers, to be more open about the disease and to avoid stigmatization, as illustrated in the following quotes:

> *She does not like to talk about the disease. It could be easier if she had an app and could give her phone to an adult when she is visiting them, and tell them "look, this is how it works".* [Mother of 7-year-old child]

> *He has to take his medication at school. We (I and his father) met the teachers and the director of the school to present CF and the implications in terms of treatment. They are following up for the intake of Creon. But you have to train them first to make sure they are following up.* [Mother of 9-year-old child]

> *Some are afraid that they would not get any job, if they tell. It could be useful with quiz etc. for those that are around them.* [Patient association representative]

Furthermore, an app can support patients and parents in learning about new medication or possible new diseases caused by CF and therefore, help them to better handle and to more easily adapt to a *change in their health status*, as illustrated in the following quotes:

> *Information for medicine usage would have been useful. There are a lot of questions about it in the Facebook groups.* [Mother of 7-year-old child]

> *It would be useful if doctors/dieticians can explain possible side effects related to food or medicines.* [16-year-old teenager]

Some patients seem to struggle with the practical aspects of the treatment, such as doing inhalation, taking care of the equipment, or performing physiotherapy. An app may provide information about practical aspects of the treatment in an instructive way. A parent stated the following about inhalation:

> *It would be nice to have some app that takes the time. Something that also shows him how to do it correctly. He has to close his mouth, to put it right in his mouth. Also, the breathing he does—it would be nice if there was something that shows him and takes the time.* [Mother of 17-year-old]

One patient association representative stated:

> *There are many things to learn when you get new medication. People get too little information about what the side effects are and how to administer the drug.*

Enzyme Dosage Calculation

Enzyme management is especially important when routines are not yet in place or when patients and parents find themselves in *new situations they are not used to*, for example, when eating at a restaurant, and also when children *start taking responsibility* for their enzyme intake. But even teenagers and young adults who have been taking enzymes for many years are sometimes still *uncertain about whether they take the right dosage* or not. Supporting persons with CF and their caregivers with the help of an enzyme dosage calculation feature can improve the compliance to the treatment and foster their confidence with the calculation of the enzyme dosage. Some participants stated their wishes for a CF self-management app:

> *An app where one can take pictures of food, enter information about height and weight, how much Creon is taken, and then provide information about how much Creon is actually needed.* [Mother of 8-year-old child]

> *I would consult it [app] if I think the actual Creon dose is not enough for what I'm going to eat...and the app recalculates the Creon dose.* [17-year-old teenager]

> *An app that calculates the amount of Creon for various types of food would be useful.* [20-year-old young adult]

Enzyme management provides a personalized proposed dosage of enzymes depending on the composition of each meal and an individual correction factor of the patient. *Food recording* is thus a necessary feature for the calculation of enzyme dosage. For this food recording, the same level of detail is required as for the nutritional protocols mentioned above. Also mentioned above, this food recording has to be as easy, fast, and effortless as possible to avoid burdening patients and parents with this and to ensure added value by using the app(s). Cumbersome usage can be a reason to not use the app(s) at all, as illustrated in the following quote:

> *A calculator for Creon would be nice because sometimes it can be difficult to know what caused stomach pain. This may be due to too little Creon, or caused by other things...I am not sure how much time I want to spend to register food to get recommendation about Creon.* [19-year-old adult]

Nutrition Management

A good nutrition is essential for maintaining good health. Persons with CF have to follow a high caloric diet. A high amount of fat is the easiest path to achieve it, but it is not optimal for the health. One HCP stated the following:

> *Patients have a high caloric diet. It is a challenge for the health. It is important that they have a varied diet. People should not only eat biscuits, chips, ice cream. They should eat fruit and vegetables too.* [Dietitian]

Parents wish to compose meals that are both nutritious and healthy. Sometimes children get bored with eating. Dietitians provide advice during consultation, and this is something teenagers, adults, and parents would like to retrieve through an app. Two adults with CF stated the following:

> *It would be good with food recipes and advices. Often, I get sweet recipes, but I prefer salty food.* [21-year-old adult]
>
> *It would have been useful to get an overview of what is good to eat. I have lacked this. It is important to get good eating habits.* [19-year-old adult]

Furthermore, parents and adults wish variation in their food. They would like to be able to share recipes with other people in the same situation, as illustrated in the following quote:

> *It would be useful to exchange recipes and ideas about food as a source of inspiration.* [Mother of 7-year-old child]

Some parents, especially when not experienced with the disease, are keen about a detailed follow-up. They spend time calculating the nutritional composition of meals, especially fat, when their children are young. One parent stated the following:

> *When he was little, we used to calculate nutrition, especially fat, in all ingredients. [...] As for now, the calculations are routine based.* [Mother of 7-year-old child]

An app can support such calculation. Additionally, an app can also help to enable the dietitian to set up personalized nutrition goals in terms of energy and percentages of fat, proteins, and carbohydrates and to follow up the progress with respect to goals.

As already mentioned, today, patients are sometimes asked to provide detailed food records, but no tools are provided to support recording, as illustrated in the following quote:

> *We newly made a food record for four days when the dietician asked for it, and then one day a week later. The dietician provided a list but it was rather complicated because we had to fill it manually. Finally, I gave her an Excel sheet with meals and details about the food.* [Mother of 7-year-old child]

Food records are not useful if not precise. Dietitians think it is not realistic to expect detailed recording over a long time. An app should simplify recording for usage over long time. Two HCPs stated the following about food records:

> *Normally, they have to be as specific as possible. I ask for ingredients and make a caloric calculation. When I ask for a longer period, the calculation is not so good.* [Dietitian]
>
> *The app should support food recording, but asking to record for more than 3-5 days is difficult. The motivation is getting lower over time.* [Dietitian]

As an alternative to detailed food records, some would like an approximate recording as support for a consultation with the dietitian, as illustrated in the following quote:

> *It would be useful with support to note approximately what he has eaten during a day in order to give information to the nutritionist.* [Mother of 7-year-old child]

Treatment Organization

Routines are important with respect to making life easier and for the compliance to the treatment. An app can support the management of the different tasks related to the treatment. Reminders for medication, medicine purchase, and consultations were often mentioned during interviews. Although mobile phones provide reminder support, parents and persons with CF tend to prefer support integrated in a self-management app for CF. They wish to get all support for CF in a single app. Reminders are especially useful for new medication and medication that has to be taken at specific times, as illustrated in the following quotes:

> *For antibiotics, especially when a particular number of hours should pass between intake.* [Mother of 7-year-old child]
>
> *It would be good with reminders. It is true that sometimes the antibiotics treatment can be hard to follow.* [Mother of 9-year-old child]
>
> *It is difficult to remember unusual medication, especially when medication has to be taken outside the meals [when other medication is taken].* [21-year-old adult]
>
> *An app should support reminders: when and how to take drugs, when to go to the physio.* [Doctor]

Reminders are also useful for Creon when children start taking responsibility, or for the members of the family who do not usually follow the child tightly, as illustrated in the following quotes about reminders, with the first being on reminders for Creon:

> *For the child and the father!* [Mother of 7-year-old]
>
> *For the pancreatic enzyme. Some kind of reminder in a nice funny way. [...] When he is on holidays, when he visits the grand-parents.* [Mother of 9-year-old child]

Health Diary

A health diary supports the recording of the health status, symptoms, and other events related to the management of the disease. When discussing the influencing factors and the limitations of care, we saw that the motivation for keeping a diary is manifold. Most importantly, patients and parents expect a diary to be useful during consultations. They would better remember past events and be able to answer to the doctors' questions more precisely. The HCPs also mentioned that parents sometimes feel embarrassed when they cannot describe symptoms. In addition to support for consultations, a diary is a means to understand the disease and the effects of the treatment. Furthermore, keeping a diary, for instance using a checklist, can provide satisfaction that the treatment is performed well, as illustrated in the following quotes:

> *An app which makes it possible to cross out when a task is done...There are many tasks to accomplish in*

> *a day, so it's nice with a checklist. It's a good feeling to see that assignments are "checked out"...One can go back and see what has been done. It's nice for remembering afterwards what was done.* [Mother of 2-year-old child]
>
> *Collecting information with an app is more systematic than what you can say over the phone, or when you sit and fill out a form and then insert it in a PC.* [Doctor]
>
> *Patients often forget what has happened between consultations. An app for following day-by-day would allow more correct estimations. The patients could keep a diary without sending it systematically to the doctor, allowing them to answer the questions of the doctors. The diary could contain information about coughing during night, coughing during exercise, shortness of breath, stomach pains, diarrhea, problems taking pills, feeling bad. A list with ticking would make it easy. A weekly diary may be sufficient.* [Doctor]

A diary is most useful for parents with *little experience* with the disease or when *health conditions are changing*, as illustrated in the following quote:

> *We remember well [his health condition] because he is stable. I imagine that it would be nice with an agenda or something like this if he was not stable.* [Mother of 17-year-old child]

Keeping a dairy should be simple to handle in an otherwise busy day. One HCP stated the following:

> *It should be focused on things that are important to report. And it should be easy, for instance in form of a check list. Very concrete things such as "Did the child cough during the night?" "Did the child have stomach pain?" should be covered. There could also be a field for notes.* [Patient association representative]

Treatment Follow-Up

When a diary is kept, it is possible to visualize the health status over time. It is also possible to relate health to the different parts of the treatment such as enzyme management and nutrition management. Without visualization, the motivation for recording the health status is low, as illustrated in the following quote about diary:

> *It would have been nice, also with a space for noting changes in condition, so that one can compare over time. If not, there's no point.* [Mother of 2-year-old child]

Following progress over time and effect of medication is also important for doctors. One HCP stated the following:

> *Anything that can increase compliance will be fine. [...] It could be useful to detect the effect of antibiotic cures and the side effects. It is important for the therapists to know how the previous cure worked when setting up a new antibiotic cure.* [Doctor]

It is important to support and encourage people with a serious disease, for example, through keeping focus on things that work, as illustrated in the following quote:

> *It is important to provide a positive educational solution. An app should put attention to what works well. And maybe a graphical overview where the patients can see how the daily life looks like and how things change. May be a score, and then they can check off [entries] throughout the day, and get points for the day. And it is important that those who are very sick also score high.* [Nurse]

Communication With Doctors

The parents and adults in the study were mostly satisfied with the current means in place for communicating with the HCPs. However, a self-management app that supports nutrition management and health diary makes it possible to offer new forms of communication. Collected data can be shared with HCPs. Parents and persons with CF in the study are willing to share data and believe sharing is positive for their health, as illustrated in the following quotes:

> *I would share my diary with the doctor so he could quickly see information about me. I have nothing to hide. It is best for me, when he knows more about me.* [21-year-old adult]
>
> *To register information and share it with doctors would be nice. It would be easier to inform the doctor.* [19-year-old adult]

Nonetheless, they feel that it is important that parents and patients can keep control of what is being shared. Two parents stated the following about sharing registered data:

> *It would have been nice, but the patient must make the choice himself and he should decide what information is shared. I believe that most patients would share if this can help them.* [Mother of 2-year-old child]
>
> *There is no guarantee that everyone has a good relationship with their doctor. The sharing of information must be made after agreement with your doctor.* [Mother of 8-year-old child]

As earlier mentioned, a doctor pointed out that noncompliant patients would probably not reveal that they do not follow the treatment.

Most HCPs would study the data during consultations, but they have no time to follow up every patient more often. They were worried that some patients would expect the data studied directly, once it is shared. Indeed, parents and persons with CF have various expectations, as illustrated in the following quotes:

> *It would be nice if the doctor could get one month status for example. The doctor does not have the capacity to follow up on a daily basis, but a regular overview of symptom development would have been nice.* [Mother of 8-year-old child]
>
> *It would be good to register things such as when I am coughing more. It would be good if the doctor can*

> *see that you have this problem now and then. It could be good to tell how you cough or what colour the mucus has. It would be good if the doctor could see more often than every three months. This would make it possible to anticipate, and maybe avoid hospitalisation.* [21-year-old adult]

Other concerns of the doctors are privacy and responsibility when data is being shared, as illustrated in the following quote:

> *You cannot drown in information. And it must be handled privately. As soon as information comes to the hospital, it is sensitive health information. You have to agree how often to register the information as well.* [Doctor]

Communication with doctors covers more than sharing data registered by parents and children and teenagers with CF. The setting of nutritional goals by dietitians and the sending of motivational messages by HCPs were also considered.

Communication With Peers

In some of the countries involved in the study, well-functioning communication channels exist where persons with CF and caregivers can get support and tutoring from peers. For instance, the CF patient association in Norway has set up two closed Facebook groups: one for all members and one for adults with CF. Both groups are very active. One parent stated the following:

> *We use the association a lot. The closed groups on Facebook are very important. There, we can post questions and get answers from the other members. One often gets very many answers right away. There is much happening there. It is very, very helpful.* [Mother in Norway]

The association has also set up a system of "peers," as illustrated in the following quote:

> *The association organises a system of "peers." It is a system where people with CF and parents can talk with other persons with CF and parents. There are 21 "peers" that have been taught through courses. They have guidelines about how to work. They are available almost the whole day.* [Mother in Norway]

Such channels are not available in all countries or do not function well, as illustrated in the following quotes:

> *Sometimes I think that it would be good to talk with somebody who can understand me, rather than to people who tell me "yes, yes." But this is not a critical concern. I have not investigated if there exist forums. The association has a Facebook community, but there is not much happening.* [21-year-old adult]

> *We are members of the CF association. Sometimes I mail to the association. It is more when I need something. It is not active participation. On Facebook they have a page, but I think that it is not so active.* [Mother of 15-year-old teenager]

Digital meeting places may be well-suited communication channels for persons with CF, who should avoid meeting other persons with CF because of the risk of cross-infection. It might be challenging to keep meeting places active. It is important to define appealing activities for the participants. We saw earlier that exchanging recipes is suggested.

Some persons with CF and parents would wish for more communication with others, as illustrated in the following quotes:

> *Really interesting and exciting, to meet and to exchange views with other patients!* [16-year-old teenager]

> *Yes, it is good. We always help each other, giving ideas or options that may help. This would be very helpful!* [Mother of 3-year-old with CF]

Others wouldn't use such a function because in their opinion, tips and tricks of one patient can't be transferred to others, or because they suspect that false information would be spread, as illustrated in the following quotes:

> *Useless, because everyone is different, also as patients.* [16-year-old teenager]

> *No, too risky without a doctor supervision.* [Father of 5-year-old child with CF]

> *There are some Facebook groups, but I don't like it, because they don't have a clinical mediator/controller, so a lot of times other parents talk about incorrect information.* [Father of 17-year-old teenager]

This implies that an app or apps should give the option to communicate with others, but this shouldn't be mandatory.

Discussion

Principal Findings

The findings presented here have been made possible by the overwhelming dedication of potential future users to bring forward developments that could support them in the future. The interest in the research was high, and participants openly provided their ideas and wishes. This interest and the numerous suggestions from persons with CF and caregivers indicate the readiness for self-management in the CF care even in countries that provide well-functioning health care services for CF care.

Some of the functions presented here confirm findings by previous research, such as the wish for reminders for medicine intake, a function for automated medicine refill, or the visualization of treatment progress [19]. We provide more detailed insight regarding the needs related to these functions. In addition, we identify other potentially useful functions such as support for enzyme dosage calculation and nutrition management. A recurrent need was that all functions should be included in a single app. During the search for CF-related apps performed before the interviews, such an app was not yet available on the market. The complexity with respect to the large variety of needs and related functions is one of the biggest development challenges.

An important finding is the need for personalization, stemming from the individuality of the patients, from the level of experience with the disease and treatment, and the changes in

life; "One size does not fit all" in the case of CF self-management. The changing needs as children with CF grow up and gradually take responsibility for the treatment supports the idea of an ecosystem of apps proposed by MyCyFAPP. Additionally, other factors influence the care, indicating that each app in an ecosystem should be customizable. Software engineering approaches for developing adaptive software [35] and end-user development [36] are highly relevant.

The HCPs in the study failed to elicit requirements for a professional tool. Although they were asked about how a tool could facilitate the care and how a tool could fit in their workflow, they were more concerned with discussing the digital support for patients. As a starting point for the design of a professional tool, the functionalities supported by the apps can be reflected in the tool, for example, support for nutritionals goals, educational content, and treatment follow-up. In our future research, it will be important to set more emphasis on self-management as a collaboration between patients and HCPs rather than a delegation of tasks to patients. For this reason, codesign workshops and extensive testing of different versions of the prototypes together with HCPs are planned. This will allow to focus on the development of a professional Web tool covering the needs of this specific user group.

Data sharing on treatment progress with HCPs is potentially useful. Sharing can contribute to providing HCPs with a better understanding about the health status of individual patients and at the same time to increase knowledge about the disease through comparison and analysis of data collected from several patients. Several concerns should, however, be addressed. Most importantly, sharing should not be imposed on patients, but the "what?" and "how?" of sharing should be agreed on between patients and HCPs. For example, they should agree upon how often patients are expected to register data, and they should agree upon how often HCPs are expected to study the shared data. Several HCPs mentioned that the quality of data is not so good when patients are asked to register every day. This is an issue that should be further researched upon to find suiting solutions for it.

A main challenge we met in our work is the diversity of needs and the different priorities of the stakeholders. A main research topic in MyCyFAPP, the enzyme management, is a concern for parents of recently diagnosed children who need more learning support, but not necessarily for experienced parents and patients. Parents are usually more worried about nutrition than children are. Some patients, in particular teenagers, are more worried about gaining too much weight than the dietitians say they should be. HCPs wish for detailed nutritional information, but parents and patients do not wish to spend more time on their treatment, and detailed registration can be time-consuming. Parents wish to share recipes with peers, but HCPs are not always positive, as they wish to approve the advice given to patients. Some parents asked for advanced support for getting advice based on health status, but doctors warn against it. One HCP stated the following:

> *One should avoid giving medical advices. Advices can be dangerous without any medical supervision.* [Doctor]

With the growth of chronic diseases, patient empowerment, where patients manage their own health condition, has emerged as a means to release health care systems under pressure. Two important aspects of empowerment are (1) skills development and (2) choice and responsibility [37]. Choice and responsibility presume care practices that enable shared decision making (ie, the patient is involved in health care decision-making processes) and self-determination (ie, the patient has the power to choose own goals). Choice and responsibility require the patient to hold self-efficacy skills (ie, the patient is confident that he is able to carry out the necessary behavior) and self-management skills (ie, the patient has gained skills to manage lifestyle-related aspects of the disease). These skills in turn require education (ie, the patient is educated to deal with the disease and its treatment). Our study shows that a full patient empowerment is unrealistic in the case of CF. CF is a serious chronic disease that requires high expertise for decision making. The focus should be on giving patients the necessary knowledge to feel confident in carrying out the treatment.

Strengths and Limitations

When developing apps for the therapy support of chronic diseases such as CF, which are additionally characterized by a high individuality in the manifestation of the disease, user integration in the development process is crucial. It helps not only to maximize the added value for the user but also user satisfaction [20] and ultimately influences user experience. The current research is based on a large sample of participants. It includes various perspectives by presenting the views of patients, parents, as well as HCPs. This ensures that needs and challenges of different people involved in the treatment can be considered during development. The participants who contributed to this research come from different countries across Europe and different age groups, which further increases the diversity of the sample.

Although the benefits can be large in terms of developing an app that serves actual user needs, it can be a challenging task. In this study, patients had to be interviewed one at a time to avoid cross-infection risks, so we were not able to organize group interviews allowing discussion of different viewpoints. Additionally, the views of participants represented in here reflect only those who were willing to take part in a research project. Needs or wishes by those who were not interested or prevented from participating may potentially differ significantly. Furthermore, most of the involved participants were in a more or less "stable" condition. Only very few children and teenagers with CF in a severe condition were asked to participant in the study, to not burden this user group even more. However, we were able to collect insights from HCPs, patient association representatives, and the netnography, which represent more general opinions that can partly balance out this knowledge gap. Furthermore, as participants who show interest and or are in a condition that allows them to take part in such a study are potential first adopters of the solutions, it is important to fulfil their needs.

Needs and wishes of very young patients (aged 4-7 years) mostly were collected with the help of interviews with parents and HCPs or with the help of interviews with children together with

their parents. The young children involved found it very difficult to sit through an interview and give answers to questions of the interviewer, especially the more abstract these questions were. Therefore, insights regarding their needs are strongly affected by the opinions of parents and HCPs. To balance this out, this age group will be more involved later on in the project via cocreation workshops and prototype testing sessions as soon as there are more concrete products (mock-ups and prototypes) they can give feedback on.

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Conflicts of Interest

None declared.

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Abbreviations

CF: cystic fibrosis
HCP: health care professional
ICT: information and communication technology
QoL: quality of life

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Review

Mindfulness-Based Symptom and Stress Management Apps for Adults With Chronic Lung Disease: Systematic Search in App Stores

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Abstract

Background: Up to 70% of lung cancer survivors are affected by chronic obstructive pulmonary disease (COPD), a common, debilitating, comorbid disease. Lung cancer and COPD are both characterized by symptoms such as breathlessness, fatigue, and psychological distress. These distressing chronic symptoms are exacerbated by stress and detract from an individual's quality of life.

Objective: The aim of this study was to identify and evaluate evidence-based, commercially available apps for promoting mindfulness-based strategies among adults with a COPD or lung cancer history (ie, chronic lung disease).

Methods: For this review, an interdisciplinary research team used 19 keyword combinations in the search engines of Google and iOS app stores in May 2017. Evaluations were conducted on the apps' (1) content, (2) usability heuristics, (3) grade-level readability, and (4) cultural sensitivity.

Results: The search resulted in 768 apps (508 in iOS and 260 in Google stores). A total of 9 apps met the inclusion criteria and received further evaluation. Only 1 app had below an eighth-grade reading level; the ninth one did not have enough text to calculate a readability score. None of the 9 apps met the cultural sensitivity evaluation criteria.

Conclusions: This systematic review identified critical design flaws that may affect the ease of using the apps in this study. Few mobile apps promote mindfulness-based strategies among adults with chronic lung disease (ie, COPD or lung cancer or both), but those that exist, overall, do not meet the latest scientific evidence. Recommendations include more stringent regulation of health-related apps, use of evidence-based frameworks and participatory design processes, following evidence-based usability practices, use of culturally sensitive language and images, and ensuring that content is written in plain language.

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KEYWORDS

mindfulness; lung neoplasms; chronic obstructive pulmonary disease; mobile apps; review

Introduction

Prevalence of Lung Cancer and Chronic Obstructive Pulmonary Disease

Lung cancer is the second most commonly diagnosed cancer in the United States, accounting for 13.2% of new cases in 2017 [1]. It is expected that 222,000 new lung cancer cases will be diagnosed in 2017 [1], adding to the more than 500,000 individuals currently living with the disease. Chronic obstructive pulmonary disease (COPD) is also a common, debilitating disease characterized by breathlessness and fatigue, which affects almost 15 million individuals and is the third leading cause of death [2,3]. Several studies demonstrate strong links between lung cancer and COPD, such as their common environmental, genetic, and epigenetic risk factors and their similar pathogenic mechanisms for activation [4-6]. In particular, those with COPD are 5 times more likely to develop lung cancer than those individuals without the disease [7]. These links between lung cancer and COPD, in part, explain why up to 70% of lung cancer survivors are affected by COPD and many of the survivors of both diseases describe similar distressing symptoms that negatively affect their daily lives [3,8,9]. Therefore, some researchers are proposing additional studies that not only further elucidate the link between COPD and lung cancer (ie, chronic lung disease) but also generate therapies that can be used to alter the mechanisms involved in both disease processes [4,6].

Mindfulness-Based Stress Reduction for Chronic Lung Disease

The 5-year survival rates have steadily improved over the past decade for chronic lung disease; however, these rates are highly dependent on the stage of disease at the time of diagnosis [10-12]. Efforts to decrease the burden of chronic lung disease (ie, early detection, improved treatments, symptom management, more accessible smoking cessation strategies) will likely lead to a larger population of longer-term cancer survivors [8,9,13]. The American College of Chest Physicians has made recommendations regarding complementary therapy modalities that may improve the quality of life for survivors of chronic lung disease. These therapies are inclusive of mindfulness-based stress reduction (MBSR) strategies such as meditation or yoga, which in turn have shown to relieve symptoms related to chronic lung disease [14,15]. Although MBSR is generally administered in-person, available technologies provide many opportunities for dissemination of these therapies in other ways, to fit individual schedules and needs.

With the growing ubiquity of mobile technologies, survivors are increasingly using the Internet as a resource for health information [16]. According to the Pew Research Center, 72% of Internet users say they have searched online for health information [17]. Another recent national study suggests more than half of mobile phone users have downloaded a health-related mobile app (henceforth referred to as app) [18]. These users were also found to place high trust in these apps' accuracy and experienced positive health effects [18]. Despite the frequency and use of these technologies, there is no regulatory authority to validate the legitimacy of health-related content published through these commercial apps, nor is there a mechanism to enforce standards to ensure that the information is accessible by diverse populations [19].

Objective

Besides Coulon et al's [20] review of stress management apps, there have been no systematic reviews that focused on the evaluation of MBSR apps for individuals with chronic lung disease. Therefore, the objective of our review was to identify and evaluate apps available in the Google Play Store (Android devices) and/or the Apple Store (for iOS-based devices) for promoting mindfulness-based strategies specifically among adults with chronic lung disease. The primary aim was to evaluate whether and to what extent the content of these apps is evidence-based and transparent in its purpose, development, and content (eg, provides contact information for its developers). The secondary aim was to evaluate the usability, readability, and cultural sensitivity of these apps. Our ultimate goal is to determine if these apps can improve the quality of life among racially and ethnically diverse populations of lung disease survivors. Furthermore, we want to make recommendations to improve these apps, so that health information can be more accessible, accurate, and effective for these populations.

Methods

Keywords and App Search

A total of 19 keyword combinations were created using COPD or Lung Cancer, followed by MSBR, meditation, breathing, diaphragmatic, stress management, progressive muscle relaxation, or yoga. Each combination was searched in Google and iOS app stores in May 2017 using compatible mobile devices (see Textbox 1).

App Review Overview

We adapted existing procedures by Coulon and colleagues [20]. We evaluated the apps for content, usability heuristics, readability, and cultural sensitivity. Evaluation was conducted in a multidisciplinary group setting involving 5 to 6 reviewers (ie, group evaluation) for content and usability. Readability and cultural sensitivity was conducted independently by 1 and 2 reviewers, respectively (ie, individual evaluation). Drawing on the work of Coulon and colleagues [20], we used 1 level of inclusion criteria. We used app descriptions to determine whether an app met 1 of the following 4 criteria: (1) available in English, (2) targeted adults with chronic lung disease, (3) was not a duplicate within or across app stores, and (4) was not a service gateway, such as required subscriptions beyond the app. The apps were downloaded for further investigation if the 4 criteria could not be determined from the description (Figure 1).

Inclusion Criteria

The 19 keyword combination searches yielded 768 apps—508 apps in the Apple Store and 260 in the Google Play Store. Figure 2 illustrates the procedure for determining if apps met the inclusion criteria. Of these, 37 apps were not in English (criterion 1). Of the remaining 731 apps, 639 did not target adults with chronic lung disease (criterion 2). This left 92 apps, of which 69 were duplicates of each other (ie, failed criterion

3), and 2 required additional subscriptions or purchases (thereby failing criterion 4). Thus, after the inclusion assessment, 21 apps remained. Upon downloading these apps, 4 failed to meet criterion 2 (brief or generic descriptions previously prevented this determination). Moreover, 3 additional apps failed to meet criterion 3 (also because the nature of the content had been obscured until downloading). Of the remaining 14 apps, 5 were irretrievable or malfunctioned during download (ie, failed criterion 5). In total, 9 apps were selected for further evaluation. None of the 9 remaining apps were duplicated across both app stores. In addition, all apps were free, though 1 app had the option to purchase additional breathing exercises.

Textbox 1. App review keywords. COPD: chronic obstructive pulmonary disease; MBSR: mindfulness-based stress reduction.

- COPD breath
- COPD MBSR
- COPD meditation
- COPD mindfulness-based stress reduction
- COPD stress breathing
- COPD stress diaphragmatic breathing
- COPD stress management
- COPD stress progressive muscle relaxation
- COPD yoga
- Lung cancer breath
- Lung cancer MBSR
- Lung cancer meditation
- Lung cancer mindfulness-based stress reduction
- Lung cancer stress breathing
- Lung cancer stress diaphragmatic breathing
- Lung cancer stress management

Figure 1. App review steps. COPD: chronic obstructive pulmonary disease.

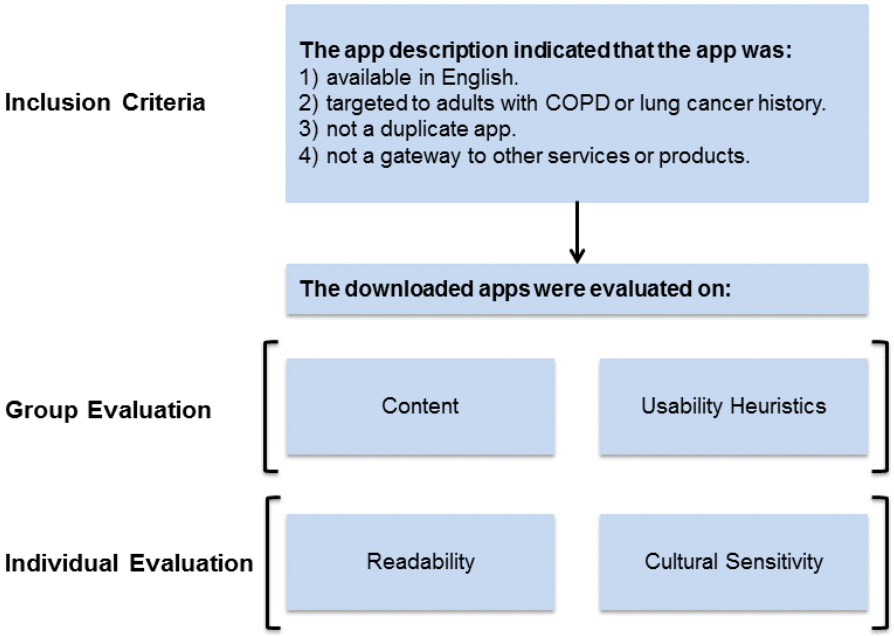
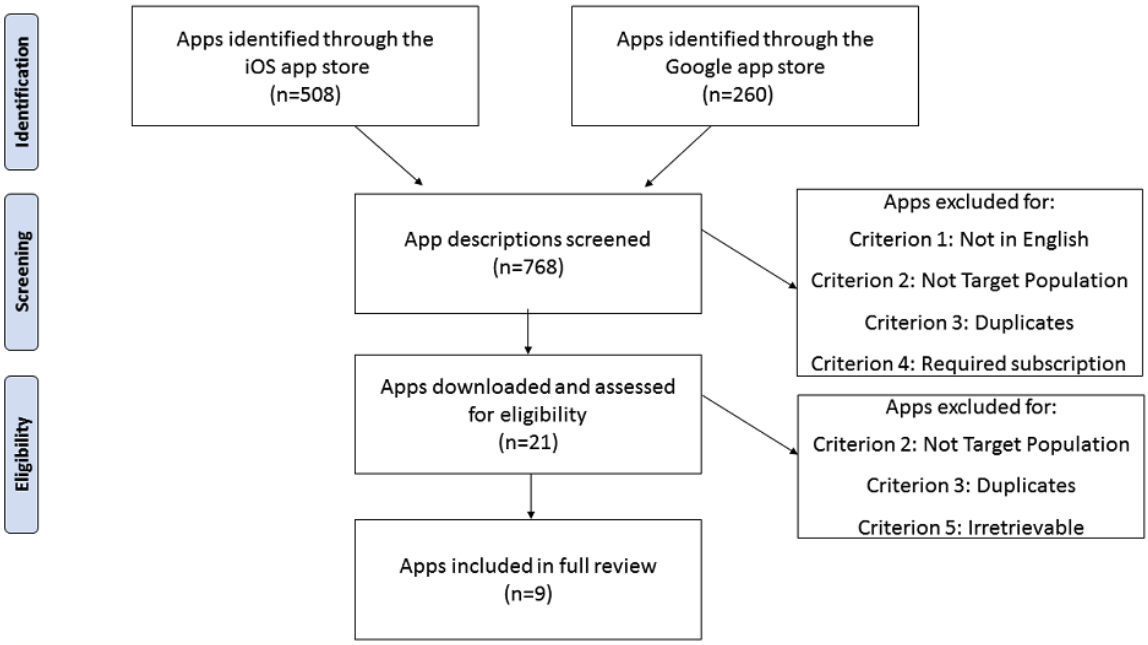


Figure 2. App inclusion flow.



Content Evaluation

We established 4 content evaluation domains: (1) evidence of science, (2) scientific strategy and engagement, (3) evidence-based stress management, and (4) transparency in its purpose, development, and content. Although all of our criteria were adapted from Coulon et al's study, we included 2 of their inclusion criteria as evaluation criteria [20] (see Textbox 2 for domain definitions and their respective criteria). Across the 4 domains, we developed a coding sheet (converted to a Google Form) to determine whether criteria were met, somewhat met, or not met.

The multidisciplinary research team of 5 to 6 reviewers met 5 times to conduct these evaluations in a group setting. We operationalized this evaluation by downloading a given app and projecting it onto a big screen to familiarize ourselves with the app content (for 10-20 min). One reviewer was responsible for navigating through the app. Some discussion ensued if reviewers had uncertainties or questions about a given app that warranted additional explanation. Each researcher then independently scored the content in Google Forms guided by the criteria in Textbox 2. The response options for each of these criteria were as follows: met, somewhat met, or did not meet. Reviewers were also provided with a space to justify their given response. The content evaluation took 20-45 min. All results (including comments) were concatenated using Google Forms, and these results are reported based on majority consensus.

Usability Heuristics Evaluation

An expert in human-computer interaction prepared the usability heuristics evaluation questionnaire based on Nielsen's 10 usability heuristics (see Table 1) [21-23]. The questionnaire was administered via Google Forms. The review team, similar to the process described above for the content evaluation, evaluated usability heuristics of each app as a group and individually assigned a numerical value to rate the severity of each heuristic violation (see Table 1 for the heuristics on which each app was evaluated, accompanied by questions and response options. In addition, similar to our content evaluation, results were determined based on majority consensus).

Grade-Level Readability

Readability was evaluated using the approach employed by Smith and colleagues [20]. Readability was measured using Readibility.io (computer software by Added Bytes, Sussex, England). This software provides grade-level scores according to 5 standardized reading scales (Flesch-Kincaid Grade Level, Gunning Fog Score, Coleman-Liau Index, SMOG Index, and Automated Readability Index) [24] along with an average of the 5 scores. We retrieved the average score using 125 to 150 words of text from each app.

Cultural Sensitivity

To our knowledge, there are no validated measures for evaluating the cultural sensitivity of commercially available apps. Therefore, we adapted the Cultural Sensitivity Checklist (CSC) developed by Friedman and Hoffman-Goetz [25] to evaluate our material for cultural sensitivity for African Americans. We are interested in the apps' sensitivity among African Americans specifically because they have higher rates of lung cancer [26] and earlier onsets of COPD [27]. The CSC checklist was designed to evaluate printed material, but has also been used for online material [28]. The original checklist contains 8 items, of which only 5 were pertinent to our study. (Two items overlapped with our content and readability evaluations and 1 focused on cancer prevention instead of symptom management.) We scored each app on the basis of whether it met, somewhat met, or did not meet the CSC criteria. To establish intercoder reliability, 2 reviewers conducted separate evaluations for each app. Percent agreement was calculated by dividing the total number of agreements by the total possible items. The 2 reviewers reached 100% agreement.

Textbox 2. Domains and criteria of content evaluation.

Domain 1: evidence of science

- App contains terminology (or other form of) evidence, research, science, and/or study
- App contains scientific reference for the app strategy
- App contains evidence that it was developed by an established institution that conducts research

Domain 2: scientific strategy and engagement

- App contains a skill-building, behavior-change component as evidenced by skill-related instructions
- App provides available opportunities for continued engagement

Domain 3: evidence-based stress management strategies and structures

- Strategies
  - *Diaphragmatic breathing* refers to slow, paced breathing in through the nose and out through the mouth by contracting the diaphragm or distending the abdomen; monitoring muscle tension while tensing and releasing muscles sequentially throughout the body
  - *Meditation, mindfulness* refers to intentional focus on thoughts and sensations experienced in the present moment, without judging them positively or negatively
  - *Cognitive restructuring* refers to the identification, evaluation, monitoring, and altering specific thoughts that may be distorted, unhelpful, or maladaptive
  - *Active coping, behavioral activation* refers to goal setting and engagement in activities that may improve mood and a sense of wellness, with the purpose of preventing or decreasing avoidant and isolative behaviors that can occur in times of duress
  - *Seeking social support* refers to engaging with trusted others who may provide emotional or functional supports (eg, calling a friend at a time of distress)
  - Problem solving refers to an attempt to remove a stressor, or to reduce its magnitude, frequency, or duration, by describing the problem, brainstorming solutions, selecting and testing a solution, and refining the solution
  - *Visualization, imagery* refers to the use of the 5 senses to imagine a specific stimulus (eg, a place or thing) in great detail, to achieve a state of relaxation, pleasure, or comfort
- Structures
  - *Assessment:* App provides an opportunity to complete a measure of perceived stress
  - *Self-monitoring:* App provides ongoing opportunities to rate perceived stress and/or behavioral indicators of evidence-based stress management
  - *Psychoeducation:* App provides educational information on the benefits of evidence-based stress management strategies and/or mechanisms of action

Domain 4: transparent app presentation

- *Authoritative:* App should state the qualifications of the app authors or developers; states degrees and/or specific training should be present
- *Complementary:* App should state that the app content should support, not replace, medical care and provider-patient relationships
- *Confidentiality or privacy*: App should state the privacy and confidentiality securities for personal data submitted to the site by the user
- *References:* App should state the source(s) of published information
- *Justification:* App should state the content of published information that supports claims relating to benefits and performance
- *Contact details:* App should provide information for contacting developers or app managers
- *Financial disclosure*: App should identify funding source, company, or publisher
- *Advertising policy:* App should distinguish advertising and paid-service content from editorial content

Table 1. Usability heuristics for user interface design.

Heuristic[a,b]	Definition	Questionnaire items
Visibility	The system should always keep users informed about what is going on, through appropriate feedback within a reasonable amount of time	• Does every screen begin with a title or header? • It is obvious to the user what is going on? • Is the font large enough?
Match between system and real world	The system should speak the users' language, with words, phrases, and concepts familiar to the user, rather than system-oriented terms. Follow real-world conventions, making information appear in a natural and logical order	• Are menu choices and information ordered in a logical way? • Do related and interdependent information appear together? • Is language clear and concise (terminology familiar to users)?
Consistency	Users should not have to wonder whether different words, situations, or actions mean the same thing. Follow platform conventions	• Does the app use a minimal number of colors (ie, color consistency)? • Is there a consistent design scheme across the app? • Do online instructions/information appear in a consistent location across screens?
User control and freedom	Users often choose system functions by mistake and will need a clearly marked emergency exit to leave an unwanted screen without having to go through an extended dialogue. Support undo and redo actions	• Is there navigation on the homepage of the app? • Can users easily reverse their actions? • Is the app explore-able and easy to navigate?
Error prevention	Even better than good error messages is a careful design that prevents a problem from occurring in the first place. Either eliminate error-prone conditions or check for them and present users with a confirmation option before they commit to an action	• Are menu choices logical, distinctive, and mutually exclusive? • Are buttons/commands placed a good distance from one another? • Does the system prevent users from making errors whenever possible?
Recognition rather than recall	Minimize the users' memory load by making objects, actions, and options visible. The user should not have to remember information from one part of the dialogue to another. Instructions for use of the system should be visible or easily retrievable whenever appropriate	• Are instructions visible? • Is it obvious what is clickable? • Does the app require high levels of concentration?
Flexibility and efficiency of use	Accelerators—unseen by the novice user—may often speed up the interaction for the expert user such that the system can cater to both inexperienced and experienced users. Allow users to tailor frequent actions	• Does the app provide function keys for high-frequency commands? • Does the app allow for customization (eg, settings, search)? • Does the app provide customization for frequency users (eg, log in, saves data)?
Aesthetic and minimalist design	Dialogues should not contain information that is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with and diminishes the visibility of relevant information	• Is the layout clearly designed avoiding visual noise? • Does the use of images and multimedia content add value? • Are images well sized and is the resolution appropriate?
Error recovery	Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution	• Are there error messages? • Is sound, images, or haptics used to signal an error? • Are error messages worded so the user understands the problem and what to do next?
Help and documentation	Ideally, the system can be used without documentation, but in the case of questions or confusion, it's important to provide help and documentation. Any such information should be easy to search, focused on the user's needs, list concrete steps to be carried out, and not be too lengthy	• Are there instructions/help/documentation? • Are navigation and instructions easy to find? • Are navigation and instructions procedural (how do I use the app)?

[a]Heuristics are not mutually exclusive.

[b]All questionnaire items ranked on the following scale: 1=cosmetic problem only, 2=minor usability problem, 3=major usability problem, and 4=catastrophic usability problem.

Results

Content Evaluation

Domain 1

Of the 9 evaluated apps, 7 contained no indication that they were supported by science. Of the 2 remaining apps, 1 somewhat met 1 criterion because it included external links to national organizations, though it did not specify whether its content was based on the linked guidelines. The final app almost met the criteria for this domain. It was developed by a company known for conducting research, though it contained no scientific references.

Domain 2

Of the 9 apps, 5 fully met this domain's criteria. Of the remaining 4 apps, 2 only partially met domain 2 criteria—specifically, the criterion for continued engagement (allows users to record and utilize their breathing measurements). However, this app failed to provide instruction on how to use its skill-building content. The 2 remaining apps did not meet any of this domain's criteria.

Domain 3

Of the 9 apps, 3 contained at least one evidence-based stress management strategy and at least one structure. Of the remaining 6 apps, 3 did not have at least one strategy and structure. Of the other 3 apps, 1 did not contain any evidence-based strategies, but somewhat included 2 potential, evidence-based structures through a breathing measure. Given that no empirical evidence was provided, we were unable to establish that these structures were evidence-based. The 2 remaining apps partially contained 2 strategies. One of the apps recommended seeking social support but did not provide tools or resources to do so; the other app contained breathing exercises, but we were unable to establish if these were consistent with diaphragmatic breathing. Of the 2 remaining apps, 1 did not contain any evidence-based structures and 1 app somewhat seemed to contain all 3 structures. Again, however, we were unable to establish that these structures were evidence-based. Among the apps that had at least one evidence-based stress management strategy, the most common strategies were meditation and mindfulness, diaphragmatic breathing, and seeking social support. The most common evidence-based structures were self-monitoring and assessment.

Domain 4

Of the 9 apps, 2 did not meet any of this domain's 8 criteria, and none met all criteria. Some of the apps were predominantly educational and did not collect user data; thus, we did not expect these apps to meet the confidentiality and privacy criteria. Only 1 app met 5 criteria, but it, along with all the other apps, failed to meet the references and advertising policy criteria. However, the latter unlikely applied to this app given that it contained no advertisements. The most commonly met criteria were presentation of contact details and indication that app content intended to complement rather than replace professional medical care.

Usability Heuristics Evaluation

Usability varied across the apps (Table 2). Of the 10 usability heuristics, half were critically violated by a majority of apps—visibility, match between system and real world, error prevention, recognition, and help and documentation. We will focus our discussion on these 5 (see definitions in Table 1).

Visibility was problematic in 8 of the 9 apps. In particular, some apps had a complex navigation structure, including a lack of headers and feedback, leading to feeling lost in the app. Moreover, 4 apps utilized a small font size, problematic for many cancer survivors over the age of 50 years.

A mismatch between the system and the real world was another usability issue, problematic in 7 apps. Examples included the use of technical jargon, a disorganized menu, and use of advanced yoga terms not obvious in meaning to novice users.

A third usability heuristic was error prevention. Of the 9 apps, 8 contained issues related to disorganized content or functions, or buttons too close together. Furthermore, some apps that required health information (eg, blood pressure), or self-report of medication practices, did not allow users to edit information they had entered or made it very difficult to enter information (due to font size or entry fields).

All 9 apps contained issues related to recognition rather than recall. Instructions were often hard to find (an issue related to 3 other usability heuristics—visibility, help, and documentation). Some apps had so much functionality that they were overwhelming to first-time users. This led to difficulty in navigation, how to use specific functionality (eg, videos, information trackers), and even how to figure out the app's purpose. There were 2 apps that did offer a tutorial for first-time users, and this feature mitigated some of these recognition or recall issues.

Finally, 8 of the 9 apps contained help and documentation issues. Similar to recognition issues, many of these problems stemmed from a lack of, or difficult-to-find, instructions. Furthermore, developer contact information was often unavailable, making it difficult to request help or report an issue.

Grade-Level Readability Evaluation

Table 3 shows the results from the grade-level readability evaluation. The grade-level readability results showed that 7 of the 8 apps contained content at the ninth-grade reading level or higher. Only 1 app had a reading level below eighth grade, whereas 1 did not have enough text to calculate a readability score.

Cultural Sensitivity

Of the 9 apps evaluated, none met any of the CSC criteria. One of the apps was predominantly intended for tracking symptoms and thus contained minimal text, making it difficult to evaluate cultural sensitivity (same app for which we could not calculate a readability score).

Table 2. Average usability heuristic scores across apps.

App[a]	Heuristic[b]										Mean (SD)[c]
	V	M	CS	CT	EP	R	F	A	ER	H	
1	3.00	3.50	1.17	2.17	2.67	3.33	2.83	2.00	0.67	2.83	2.42 (0.92)
2	1.50	0	0	0.17	0.67	0.67	2.00	0	1.83	0.17	0.70 (0.79)
3	3.00	3.00	2.20	3.00	3.00	3.20	2.60	3.20	1.00	3.00	2.72 (0.67)
4	1.80	2.00	2.00	0.80	1.40	2.40	0.80	2.00	0	2.40	1.56 (0.79)
5	3.50	3.50	3.00	3.50	3.50	3.33	2.50	2.33	3.17	3.83	3.22 (0.48)
6	1.83	2.17	2.00	1.83	2.50	2.33	1.50	2.00	2.67	2.83	2.17 (0.42)
7	0.80	1.20	0	0	0.40	0.80	0.60	0	0	1.20	0.50 (0.49)
8	2.20	3.20	3.00	3.20	2.80	3.00	1.00	0	2.40	2.40	2.32 (1.05)
9	0.50	0.50	2.50	1.75	1.25	2.25	0.50	1.25	1.50	1.50	1.35 (0.71)
Mean (SD)[c]	2.01 (1.02)	2.12 (1.31)	1.76 (1.14)	1.82 (1.29)	2.02 (1.11)	2.37 (1.02)	1.59 (0.92)	1.42 (1.18)	1.47 (1.15)	2.24 (1.11)	—

[a]Apps: 1=COPD Disease (Droid Clinic, United States); 2=Lung+ Pioneering Healthcare (Roche, Indianapolis, Indiana, United States), 3=COPD (Health Tips, United States), 4=Pranayama Free (Sagaara, Ann Arbor, Michigan, United States), 5=Breathcount (Segfoltas, Kaunas, Lithuania), 6=Asthma Tracker and Log (Roving Reptiles Software, Castle Rock, Colorado, United States), 7=My Breathfree (Cipla Digital. Sussex, England), 8=7Pranayama—Yoga Breath Calm (Pixel Point Technology, Jaipur, India), and 9=Loving Meditations—Bring Calm To Cancer (Loving Meditations, New York, New York, United States).

[b]V: visibility; M: match between system and real world; CS: consistency; CT: user control and freedom; EP: error prevention; R: recognition rather than recall; F: flexibility and efficiency of use; A: aesthetic and minimalist design; ER: error recovery; H: help and documentation.

[c]Higher score indicated a greater frequency, impact, and persistence of usability issue. All questionnaire items were ranked on the following scale: 1=cosmetic problem only, 2=minor usability problem, 3=major usability problem, and 4=catastrophic usability problem. Mean and SD were calculated based on average score (1-4) across all heuristics and within each separate heuristic.

Table 3. Grade-level reading scores. COPD: chronic obstructive pulmonary disease.

App name	Grade-level reading score
My Breathefree	7.4
COPD Disease	12.6
Lung+ Pioneering Healthcare	9.4
COPD	9.2
Pranayama Free	12.5
Asthma Tracker & Log	9.1
7pranayama—Yoga Breath Calm	10.5
Loving Meditations—Bring Calm to Cancer	12.8
Breathcount	Unable to calculate

Discussion

Principal Findings

Of the 9 apps evaluated, 3 focused on providing support for individuals with asthma (My Breathefree, Breathcount, Asthma Tracker and Log), 2 aimed to support individuals with COPD (COPD Disease, COPD), 2 provided general relaxation and breathing training (Pranayama Free, 7pranayama—Yoga Breath Calm), and 2 contained videos and exercises to support individuals with lung cancer (Loving Meditations—Bring Calm to Cancer, Lung+ Pioneering Healthcare).

Though all 9 apps were marketed as breathing management and stress reduction, only 3 met the criteria for having both an evidence-based stress management strategy and an evidence-based stress management structure (ie, assessment, self-monitoring, or psychoeducation features; see Textbox 2). For example, Loving Meditations —Bring Calm to Cancer included 5 evidence-based stress management strategies that we assessed—meditation or mindfulness, diaphragmatic breathing, cognitive restructuring, visualization and imagery, and active coping or behavioral activation.

None of the apps fully met the criteria for providing scientific evidence to support claims about information within, or the efficacy of, their app. The 2 apps that somewhat met criteria for having scientific evidence—Lung+ Pioneering Healthcare and COPD—both contained content linked to a corporation (eg, Roche), and neither referenced peer-reviewed literature or other

scientific evidence. In addition, most apps either met or partially met the criteria for being interactive or engaging, and over half of these incorporated a skill-building component. For example, in addition to offering breathing exercises and general lung education, Lung+ Pioneering Healthcare featured a multistage, interactive saxophone player breathing game that challenged players to blow rhythmically into their mobile microphones to the tune of jazz music.

Transparency was variable across the apps with Lung+ Pioneering Healthcare meeting the most criteria (5 of 8). The average grade-level readability in our review was 10th grade, which is 2 grades above the acceptable level [23]. Many of the apps had usability challenges identified as critical violations. Finally, none of the apps met any of the criteria for being culturally sensitive to African Americans, who are more likely to experience lung cancer mortality [29] and may have earlier onsets of COPD [25].

Limitations

This review focused on evaluating apps for the most common, evidence-based stress management techniques (ie, meditation and mindfulness, diaphragmatic breathing, and seeking social support). Therefore, less-common evidence-based stress management strategies may be used but were excluded in our review.

Comparison With Prior Work

Compared with Coulon and colleagues' findings [20], the apps reviewed were less likely to include at least one evidence-based stress management strategy. However, when apps employed these strategies (eg, meditation), they were similar to those found in the previous review. Our findings regarding apps' scientific merits were comparable to those of Coulon and colleagues [20], but their review yielded more apps with scientific references (33% vs our 0%).

Regarding transparency, our review produced results consistent with those of Coulon and colleagues [20], but criteria most and least often met differed. Specifically, apps in both reviews were likely to provide contact information, but other criteria (eg, advertising policy) were satisfied less often in our review. Our assessment of apps for inclusion of skill-building instructions and opportunities for continued engagement demonstrated that most apps met or partially met these criteria. Although Coulon and colleagues did not assess cultural sensitivity or readability, our findings regarding an absence of cultural sensitivity and low readability were consistent with other prior work [28,30,31].

Finally, our review included a comprehensive heuristic evaluation to determine usability, which was more in-depth than the review by Coulon and colleagues [20]. Therefore, we identified critical design flaws that may affect users' ease of use.

On the basis of our evaluation, we make 5 key recommendations for improving the quality of commercially available apps aimed at adults with a COPD or lung cancer history.

1. *Institute more stringent regulation of apps for health*. Apps that make therapeutic claims or present health-related information should be required to cite scientific evidence to substantiate their claims or information. These apps should also contain prominent disclaimers about the outcomes a user should expect, particularly when claims are made about benefiting users' health. Currently, no federal regulatory standards govern the production of commercially available, health-related apps (eg, those that provide health education) [32]. The Food and Drug Administration, Google, and Apple provide some guidance to app developers in their review guidelines for medical and health-related apps. For example, Section 1.4.1 of Apple's App Store Review Guidelines states: "Medical apps that provide inaccurate data or information, or that could be used for diagnosing or treating patients may be reviewed with greater scrutiny. Apps must clearly disclose data and methodology to support accuracy claims relating to health measurements, and if the level of accuracy or methodology cannot be validated, we will reject your app." [33]. Language in Google's Developer Policy Center simply states that it does not allow "apps that contain false or misleading information or claims, including in the description, title, icon, and screenshots" such as "apps that feature medical or health-related functionalities that are misleading or potentially harmful." [34]. Beyond this brief language, however, neither Apple nor Google provide any insight into their review process, such as who reviews the apps they sell (eg, MD-degree holders hired by Apple). Moreover, no information exists for how nonmedical health apps (such as those we evaluated) are reviewed. We recommend that these organizations embrace a rigorous and transparent regulatory process to evaluate the health content within an app. One set of digital health reviewer principles is published by the Health On the Net Foundation [35]. For a more in-depth regulatory process, Google, Apple, or other independent distributors of health-related apps could partner with the clinical and scientific communities to review these apps (similar to an expert or peer-review process). Though the peer review would be voluntary, it could ensure the quality of health-related apps. Furthermore, these organizations should assure greater scrutiny of app descriptions to ensure that developers are accurately reporting the contents of an app, and they should also denote whether or not the app is evidence-based. This could give the user a quick way to determine the legitimacy and scientific merit of the app.
2. *Use evidence-based frameworks and participatory design processes for app design*. Although both Apple and Google provide guidance for app development largely based on industry standards, the apps evaluated were highly variable in the extent to which they executed these guidelines. Usability standards should be updated for mobile devices because most current guidelines were built with desktop layouts in mind. More specifically, Yáñez Gómez and colleagues [22] recalibrated Nielsen's [21] heuristics for mobile devices, which have different usability challenges than desktop computers (eg, screen-size limitations). One recommendation is to not only make apps follow platform conventions but also be consistent across mobile orientations (ie, whether the device is vertical or horizontal) [22]. Conforming to specific guidelines such as these may

increase uniformity across apps while preserving the developers' ability to create unique app designs.

In addition to normal user testing, which is part of a traditional app development cycle, Owens [36] has recommended implementing a community-based participatory (CBPR) design process. There are 8 CBPR principles that encourage active partnership between developers and the target population [37]. Such collaborations can enhance developers' abilities to make optimal decisions, from inception to dissemination, by identifying users' content and usability needs and by jointly creating viable solutions [37]. For example, in Owens's study [38], CBPR was implemented in a computer-based cancer education program for African American men. Small-group reviews, storyboarding, and user testing ensured the program was culturally appropriate, easy to understand, and usable by the target population [36,38]. Though integrating CBPR principles into the app design lifecycle can be more time-consuming, the cultural and contextual relevance and usability of interventions is increased, thereby increasing the likelihood that the app will contribute to positive health outcomes [36,39,40].

3. *Use culturally sensitive language and images in health-related apps.* Although lung cancer mortality is more common among African Americans [26] and this racial group may have earlier onsets of COPD [27], no apps evaluated were rated as culturally sensitive toward this population. Evidence suggest that ethnic minorities have distinct cultural beliefs that affect their beliefs about chronic lung disease, including how they engage in care [41,42]. General cancer-related studies have also demonstrated a desire among ethnic minorities for culturally relevant health information [43,44]. However, many print and online education materials are not culturally sensitive [25,28]. To ensure that apps are culturally sensitive, developers should consider using an existing grading tool or checklist such as the Cultural Sensitivity Assessment Tool (CSAT) for African Americans or CSC [28,45]. These tools are attentive to details in content and imagery that may be overlooked in a general design lifecycle. Implementing a CBPR-focused app design process with a representative sample of the target population (as mentioned above) offers an effective means for ensuring all CSAT or CSC recommendations are implemented.
4. *Ensure that apps are written in plain language.* One objective of the US Department of Health and Human Services' Healthy People 2020 initiative is to improve health literacy [46]. Health literacy is defined as the "degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions." [46,47]. Individuals without an adequate understanding of health information are less likely to adopt healthy behaviors, leading to poorer health outcomes [48]. There are multiple strategies recommended for enhancing health literacy [48]. One strategy is to ensure that health information is written in plain language—ie, in a manner that is easy to understand for the intended audience [49]. The Plain Writing Act of 2010 (H.R. 946/Public Law 111-274) mandates that all federal agencies adhere to strict plain-language standards for government-provided information regarding benefits or compliance with requirements set forth by the government, including health information [50]. One primary measure of plain language is grade-level readability [51]. Although there is some debate regarding the optimal reading level for health information, the standard has generally been sixth to eighth grade [51]. Readability levels can be determined using one of many readability scales, as we used in our review [24]. Many scales have been digitized which enables users to quickly generate readability scores. We recognize that this measurement does not always translate to the easy comprehension of text [52], but it represents an important step toward greater accessibility of health-related information.
5. *Follow evidence.* Our target user group consisted of lung-cancer survivors, typically aged 50 years and older. Apps designed for this population need to use larger font (for better visibility), employ nontechnical language (to improve the user or real world match), have features that mitigate the ability to introduce errors when entering information (including allowing for easy editing), accommodate users' working memory limitations (relying on recognition rather than recall), and provide ample help if or when users encounter problems (help and documentation). These recommendations mirror evidence-based design recommendations for older users [53]. Following usability guidelines will not only ensure ease of use but also increase acceptance and adoption of mobile app technology.

Conclusions

Few mobile apps exist for promoting mindfulness-based strategies among adults with a chronic lung disease. Among those available, few meet the criteria for the 4 content evaluation domains (evidence of science, scientific strategy and engagement, evidence-based stress management strategies and structures, and transparency). Although the usability of apps reviewed varied greatly, most had design flaws that may compromise their helpfulness to populations with low technology usage or self-efficacy or limited experience with apps. In addition, the app content was not culturally sensitive or written for audiences with lower reading levels. To enhance the accessibility of evidence-based, commercially available apps for promoting mindfulness-based strategies among adults with a chronic lung disease, we outlined 5 key recommendations. Future research should assess the feasibility and efficacy of implementing these recommended processes within an app development lifecycle. Additionally, future app reviews should also include an assessment of apps for potentially harmful strategies.

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Conflicts of Interest

None declared.

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Abbreviations

A: aesthetic and minimalist design
COPD: chronic obstructive pulmonary disease
CS: consistency
CSAT: Cultural Sensitivity Assessment Tool
CSC: Cultural Sensitivity Checklist
CT: user control and freedom
EP: error prevention
ER: error recovery
F: flexibility and efficiency of use
H: help and documentation
M: match between system and real world
MBSR: mindfulness-based stress reduction
R: recognition rather than recall
V: visibility

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Original Paper

Managing and Controlling Stress Using mHealth: Systematic Search in App Stores

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Abstract

Background: Traditional stress management techniques have been proven insufficient to tackle the needs of today's population. Computational-based techniques and now mobile health (mHealth) apps are showing promise to enable ease of use and access while educating end users on self-management.

Objective: The main aim of this paper was to put forward a systematic review of mHealth apps for stress management.

Methods: The scenario chosen for this study consists of a sample of the most relevant mHealth apps found on the British and Spanish online stores of the two main mobile operating systems: iOS and Android. The apps have been categorized and scored base on their impact, presence, number of results, language, and operating system.

Results: A total of 433 different mobile apps for stress management was analyzed. Of these apps, 21.7% (94/433) belonged to the "relaxing music" category, 10.9% (47/433) were in the "draw and paint" category, 1.2% (5/433) belonged to the "heart rate control" category, and 1.2% (5/433) fell under "integral methodology." Only 2.0% (8/433) of the apps qualified as high or medium interest while 98.0% were low interest. Furthermore, 2.0% (8/433) of the apps were available on both iOS and Android, and 98% of apps ran on only one platform (iOS or Android).

Conclusions: There are many low-value apps available at the moment, but the analysis shows that they are adding new functionalities and becoming fully integrated self-management systems with extra capabilities such as professional assistance services and online support communities.

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KEYWORDS

apps; control; management; mHealth; stress

Introduction

Work-related mental health problems are one of the main causes of work leave within the countries of the Organization for Economic Co-operation and Development [1]. Research carried out by the European Agency for Safety and Health at Work shows that 28% of employees recognized having suffered stress in their working place; in addition, it is estimated that stress is the main factor in 50% to 60% of lost working days [2-3]. The increased pace at the workplace and in everyday life is dramatically increasing the number of stressful situations to which people are exposed [4].

Stress is strongly associated with mental health problems such as depression [2]. Preventive treatments for high-risk individuals have proven successful in reducing pathologies associated with

mental health problems as a consequence of high stress levels [5-6]. Stress management therapy programs are usually focused on teaching individual techniques for stress relief and generally extend several weeks or months [7-8]. A very small portion of the public health budget is allocated for medical problems associated with stress, with an even smaller amount allocated for preventive interventions [9]. New tools to facilitate welfare self-management should be accessible wherever and whenever they are needed. Stress management therapy refers to the techniques used by therapists, doctors, and psychiatrists who help stressed persons relieve their tension and stress. Some stress management therapies include interaction, biofeedback, relaxation, cognitive behavior therapy (CBT), and different exercises (yoga or meditation) [8].

Personal health technologies look promising in order to support people in health and welfare self-management. For example, several studies have gathered positive impact in the use of Web-based therapies for the treatment of health problems related to stress and anxiety [8-13].

Web-based therapies are accessible 24/7 and can be customized depending on user needs and allow the user to avoid the embarrassment of visiting a professional. The British National Health System (NHS) offers patients 2 different Web-based CBTs, but browser-based interventions aren't as attractive now that mobile apps have become popular [14-16].

User response in terms of estimated delay is characterized by the time window data-cleaning [17-19]. Response times depend on geography, platform (Android or iOS), and other factors. Other authors study mobile device-to-device video distribution that leverages the storage and communication capacities of smartphones [19].

This research tries to study in depth the status of stress-related mobile apps and the different therapies and methodologies being used and tries to forecast the patterns that will define stress-related mobile apps in the near future. In this paper, the apps have been divided into different categories such as self-help, heart rate control, integral methodology for the management and prevention of stress, hypnosis, games, images, meditation and breathing, relaxing music, draw and paint, yoga, guided relaxation, and others. This classification has followed the criteria of the authors and the queries to users.

Methods

In this study, 24 keywords were chosen. On June 2017, 48 searches were carried out in the Spanish and English virtual stores of the 2 main operating systems for mobile phones, Google Play and App Store. Eight searches returned no results. The remaining 40 searches returned a total of 1000 apps, with 606 being relevant (see Figure 1) and 433 unique. Characteristics of these 433 unique apps were recorded, and the apps were categorized.

The 15 most relevant apps have been chosen from the "Most relevant" category in the app stores. If more than 5 consecutives apps were identified as not relevant (eg, games), the apps chosen for that search were limited at all the previous results excluding those 5.

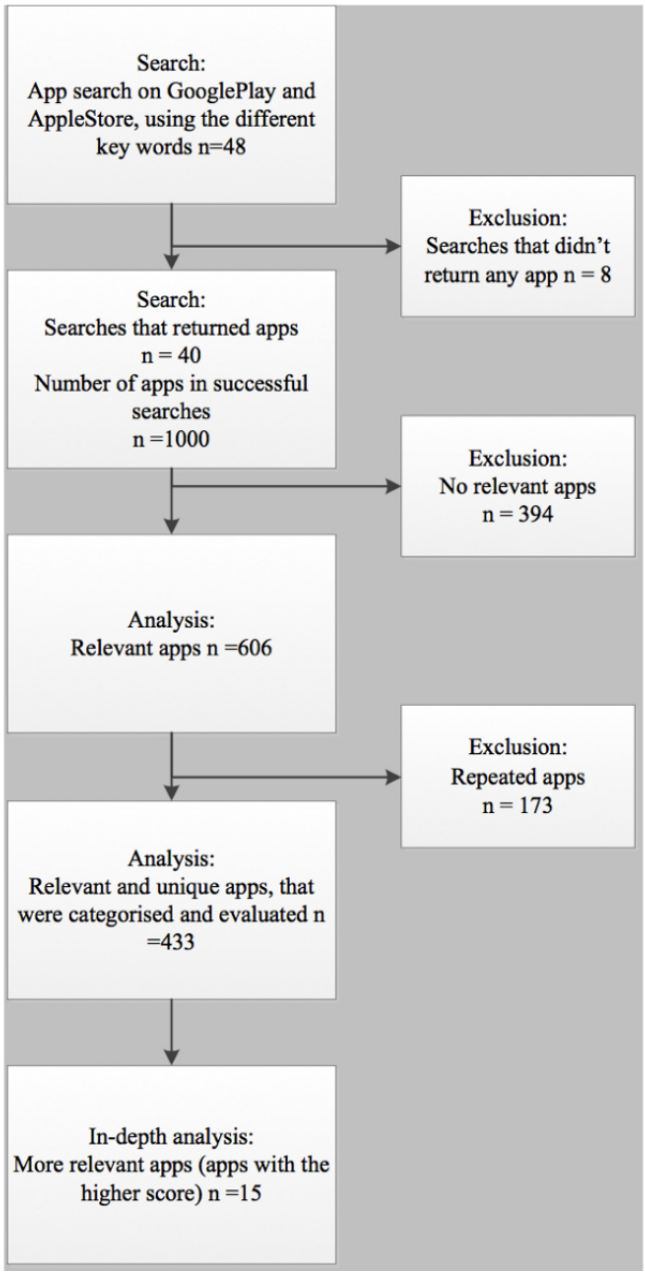
The following information was recorded for each app: country, language, operating system, and free or pay per use. Additionally, after we installed and tested them, all the apps were sorted according to different categories (see Table 1).

After the apps were recorded, they were scored based on the following criteria:

- Language: 2 points were given if the app was available only in English or Spanish; 4 points if it was available in both languages.
- Operating system: 2 points were given if the app was available only in Android or iOS; 4 points if the app was available in both.
- Keywords: 1 point was given for every search where the app appeared.
- Relevancy: 10 points were given to the apps sorted as "high interest," 7 for the apps considered "medium interest," and 0 for the apps with "low interest."

Some of the apps with higher scores were analyzed in depth in order to identify the methodology used in their design.

Figure 1. Flowchart management and control of stress-related mobile app research.



Results

In this section, we analyze stress-related mobile apps currently available in the United Kingdom and Spain. A total of 433 different apps were installed, tested, analyzed, categorized, and scored.

As can be seen in Table 1, about one-fifth (94/433, 21.7%) of the apps belong to the "relaxing music (songs, natural sounds)" category, and these apps included either relaxing songs or sound that are typically associated with relaxation and inner peace like sea, rain, mountains, or lakes. Mandalas have become well known thanks to the media in the last several years and represent most of the 10.9% (47/433) of apps in the "draw and paint" category.

Apps about integral methodology are based on CBTs including cognitive therapy, problem-solving therapy, dialectical behavior therapy, metacognitive therapy, rational-emotive behavior therapy, cognitive processing therapy, mindfulness-based cognitive therapy, cognitive-behavioral analysis system of psychotherapy, and schema-focused therapy.

Of note, 6 apps focused on guided relaxation are also included in the 15 most relevant apps. Its 10 points of median with a standard deviation of 6.77 proved that despite having 6 high scoring apps in this group, most of the apps obtained the minimum possible score points.

When the apps were categorized and relevance was evaluated, only 1.8% (8/433) of the apps qualified as high or medium interest while 98.0% were low interest (Table 2).

Table 1. Mobile app categorization statistics (n=433).

Categories	Amount, n (%)	Scores				
		Max	Min	Average	Median	SD
Self-help	47 (10.9)	16	10	10.7	10	1.67
Heart rate control	5 (1.2)	22	10	13.2	10	4.66
Integral methodology for the management and prevention of stress	5 (1.2)	22	10	18.4	20	4.27
Hypnosis	6 (1.4)	16	10	12.3	11	2.68
Images	1 (0.2)	10	10	10.0	10	0
Games	69 (16.0)	20	10	10.6	10	2.08
Meditation and breathing	66 (15.2)	18	10	10.8	10	1.85
Relaxing music	94 (21.7)	28	10	11.3	10	2.50
Not relevant	47 (10.9)	16	10	10.4	10	1.23
Draw and paint	47 (10.9)	16	10	10.9	10	1.28
Guided relaxation	34 (7.9)	36	10	13.3	10	6.77
Yoga	12 (2.8)	16	10	10.7	10	1.69

Table 2. App interest statistics (n=433).

Interest	Amount, n (%)	Scores			
		Max	Min	Average	Median
Low	33 (10.8)	22	10	10	1.82
Medium	74 (17.0)	17	17	20	0.80
High	107 (24.6)	36	20	27	5.53

Table 3. App platform and language availability (n=433).

Characteristic	Amount, n (%)
Platform	
Android	253 (58.4)
iOS	172 (39.7)
Both	8 (1.8)
Language	
English	225 (52.0)
Spanish	200 (46.2)
Both	8 (1.8)

Only 1.8% (8/433) of the apps are available in both iOS and Android environments (Table 3). Android is the world's most popular mobile platform. According to Gartner [20], Android and iOS accounted for 99.6% of all mobile phone sales in the fourth quarter of 2016. Many apps only run on one platform (Android or iOS), and this is true with health care apps as well.

This study also focused on analyzing the country and language where the apps were found; 46% of the apps were only found in the Spanish store. Only 2% of the apps were available in both Spain and the United Kingdom, even though it is well known that most of the app developers publish their apps in more than 1 country at a time. This is probably happening due to the high number of different apps offered, where being in the top 25 relevant apps in getting more difficult.

Discussion

Principal Findings

App stores are overloaded with different apps that provide no added value to the end user; more people have now access to the tools and knowledge needed to develop their own apps with all their advantages and disadvantages.

Almost a third (304/1000, 30.40%) of the initial group of apps were discarded even before installing them because the

descriptions and screenshots on the app store site showed that they were not stress management apps. After installation and testing of the apps, 10.9% (66/606) were categorized as not relevant and 16.0% (97/606) as games.

It has not been possible to find research that demonstrates that certain type of games would improve the management and prevention of stress. Therefore, it can be concluded that from the initial 1000 apps, 51.00% (51/1000) of the apps do not pertain to the management and prevention of stress even though they were listed as the 15 most relevant apps for the search keywords [10-12].

Focusing on the categorization results, it can be seen that 1 out of every 4 apps was categorized as "relaxing music (songs, natural sounds)." This is likely linked to the traditional believe that relaxing sounds and music can eventually help with stress relief. Studies have proven this point but failed to show improvement on long-term stress management and prevention [10-13]. Similar justification may be why 15.2% of apps are based on breathing and relaxation techniques, which have also been associated with improvement on anxiety and stressful situations.

Several studies have shown the benefits of these techniques and methodologies over stressful situations but have yet been able to prove positive impact on the management and prevention of stress in the long term [21-24].

Limitations

Some of the limitations of this review are the chosen languages of the apps (just Spanish and English), the keywords for the search are limited, and authors cannot guarantee that all the relevant apps have been retrieved.

Conclusions

The methodology applied in this study has simplified the identification of clear patterns that show the trend being followed for the development of mobile apps for the management and prevention of the stress.

Several apps offer very limited exercises or techniques, but these exercises have shown improvement for stress relief. Apps like "Qi Gong Meditation" [25] and "Relax lite" [26] offer activities from yoga exercises, breathing and meditation exercise to painting mandalas and listening to relaxing sound or self-aids.

Apps like Pacifica [27], Calm [28], or SAM [29] based their full program on acceptance and commitment techniques and try to introduce the user to a self-learning introspection process while at the same time offering tools for the self-management of the stress. In additional to offering several different exercises similar to the other group, these apps offer tools to enable the user to track day-to-day activities (sleep time, eating, drinking, or sun time) and dreams and fears. They also offer tools to share and speak about previous stressful situations or evaluate mood rate. They often include online communities for experience sharing.

Professional assistance services provided by some apps like SAM and iDstress [30] serve as an added value and a step forward in the integration of mobile apps and acceptance and commitment therapies.

There is no research that shows the real influence of these apps for the reduction and management of stress, but it is worth mentioning the revolution regarding easy access and learning of techniques and methodologies for stress management. It is expected that the mobile apps related to management and control of stress will evolve in the coming years adding new functionalities until they become fully integrated self-management systems, and more and more apps are likely to include the above mentioned professional assistance services and online support communities.

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Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy
mHealth: mobile health
NHS: National Health System

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Review

Supply and Demand in mHealth Apps for Persons With Multiple Sclerosis: Systematic Search in App Stores and Scoping Literature Review

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Abstract

Background: Multiple sclerosis (MS) is a non-curable chronic inflammatory disease of the central nervous system that affects more than 2 million people worldwide. MS-related symptoms impact negatively on the quality of life of persons with MS, who need to be active in the management of their health. mHealth apps could support these patient groups by offering useful tools, providing reliable information, and monitoring symptoms. A previous study from this group identified needs, barriers, and facilitators for the use of mHealth solutions among persons with MS. It is unknown how commercially available health apps meet these needs.

Objective: The main objective of this review was to assess how the features present in MS apps meet the reported needs of persons with MS.

Methods: We followed a combination of scoping review methodology and systematic assessment of features and content of mHealth apps. A search strategy was defined for the two most popular app stores (Google Play and Apple App Store) to identify relevant apps. Reviewers independently conducted a screening process to filter apps according to the selection criteria. Interrater reliability was assessed through the Fleiss-Cohen coefficient (k=.885). Data from the included MS apps were extracted and explored according to classification criteria.

Results: An initial total of 581 potentially relevant apps was found. After removing duplicates and applying inclusion and exclusion criteria, 30 unique apps were included in the study. A similar number of apps was found in both stores. The majority of the apps dealt with disease management and disease and treatment information. Most apps were developed by small and medium-sized enterprises, followed by pharmaceutical companies. Patient education and personal data management were among the most frequently included features in these apps. Energy management and remote monitoring were often not present in MS apps. Very few contained gamification elements.

Conclusions: Currently available MS apps fail to meet the needs and demands of persons with MS. There is a need for health professionals, researchers, and industry partners to collaborate in the design of mHealth solutions for persons with MS to increase adoption and engagement.

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KEYWORDS

multiple sclerosis; mHealth; fatigue; fatigue management; apps; gamification; user-centered design; usability, physical activity; eHealth; chronic conditions

Introduction

Multiple sclerosis (MS) is a noncurable chronic inflammatory condition of the central nervous system that affects more than 2 million people around the world [1]. Both Europe and North America are considered high prevalence regions for MS [2]. MS impacts mental and physical aspects, the most common symptoms being overwhelming fatigue, altered sensation, cognitive problems, visual disturbances, spasticity, pain, and bladder problems [3]. Persons with MS are negatively affected in their quality of life [4], with periods during which these symptoms worsen [3,5]. They generally have a similar life expectancy as the general population and have to learn to manage their symptoms over long periods of time. It is crucial then for persons with MS to be active patients, more engaged with their health [3]. Living with MS often requires individuals to be more engaged with their health as their quality of life is affected in many ways [6] leading to self-management needs [3]. Current research shows that in order to successfully manage chronic conditions, patients require support both to learn about and manage their symptoms and problems [7-9].

Currently, "the delivery of health care or health related services through the use of portable devices," or mHealth [10], is increasingly being used in many chronic diseases such as diabetes [11], cancer [12], and hypertension [13]. Studies have explored how different health care stakeholders such as patients and their social group, health care professionals, and caregivers can benefit from the use of those technologies [14]. Mobile devices are ubiquitous, being less invasive in day-to-day situations, allowing the tracking of persons' activities, providing real-time feedback, and with a high cost-effectiveness [15-17]. Together with the number of mobile devices per capita, the use of mobile software apps for health and well-being promotion has increased in recent years [18]. Many of them are focused on supporting persons with chronic diseases in managing their conditions. In order to be effective, however, mHealth solutions need to meet users' needs and preferences to provide appropriate features and contents and ensure higher adoption and adherence rates [19-21]. In the case of MS and because of the variety of symptoms and problems that persons with MS may suffer, mHealth solutions should also take into consideration the particular and specific needs that they have. Additionally, the use of game elements in non-game contexts such as health apps (ie, gamification [22]) is now openly used as a strategy for increasing user engagement [23-26]. The current gamification prevalence in MS apps is unknown.

In previous stages of our work, we conducted a qualitative study to identify the desired features and characteristics for mHealth solutions for persons with MS [27] and performed a preliminary review of MS mHealth apps [28]. In this paper, we revise and expand on that work by conducting a methodological review of the commercially available mHealth solutions for persons with MS in the most popular app stores, to assess whether those apps are meeting their needs and preferences. This study addresses the following research questions (RQ):

RQ1: What health apps are available for persons with MS?

RQ2: What is the intended purpose of these health apps?

RQ3: What stakeholders are behind these health apps?

RQ4: What features do these health apps offer?

RQ5: How prevalent is gamification in these health apps?

Methods

Study Design

The methodology used in this study is based on two approaches: scoping review and systematic review methodologies. Scoping review methodology aims to map the key concepts underpinning a research area especially where an area has not been reviewed comprehensively before [29-31]. Systematic review methodology has a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyze data [32]. These approaches have been used in the past to assess features and content of mHealth apps [33-36].

A search strategy was defined to identify all potentially relevant health apps. Since the objective of this study is to identify all apps that target persons with MS, we defined "Multiple Sclerosis" as the main search term. In September 2017, two reviewers (OR-R and ED-Z) used these keywords to look for matching apps whether in titles or descriptions. The two most popular app stores were searched: Google Play Store and Apple App Store. These stores were explored in their versions in the United States and in Spain. Searches for Google Play Store were conducted through its website, taking steps to ensure that no previous searches or cookies influenced our results. The Apple App Store was searched using iTunes App installed on two iOS devices (iPad and iPhone), one for each locale (US and Spain).

Selection Criteria

Apps were included if the title or store description of the app contained specific mention of MS. Duplicate entries were removed and 2 reviewers (OR-R and ED-Z) evaluated the eligibility of the found apps to include only those that met the inclusion criteria and had none of the exclusion criteria. Health apps that had versions in different operating systems were considered the same app [37] and only the Android version was included for analysis. Disagreements were resolved by consensus involving a third reviewer when necessary. The Fleiss-Cohen interrater coefficient was calculated showing high reliability (k=.885).

Inclusion Criteria

We defined the following inclusion criteria: (1) the title or description referred to MS, and (2) it was present in the versions of Google Play Store and Apple App Store for the US or Spain.

Exclusion Criteria

Apps resulting in the searches were excluded if they met at least one of the following conditions: the title or description was not written in English or Spanish, user interface was not available in English or Spanish, the app was intended for other health conditions, or they were duplicates from the same store.

Textbox 1. Desired features and characteristics for mHealth solutions for persons with multiple sclerosis (MS).

Customizable goal setting: challenges need to be tailored to the specific person with MS characteristics

Energy profiles and fatigue management: information and tools that help users in managing their day-to-day activities

Patient education: offer verified information that is helpful and reliable

Data visualization: information must be presented in a way that is meaningful to persons with MS

Positive feedback system: rewards and incentives for completing tasks and objectives

Activity tracking: register metrics such as distance walked or run, calorie consumption, heartbeat, and quality of sleep among others

Exercise library: a collection of different activities beneficial to persons with MS, like fitness or relaxation techniques that can be selected

Game-like attitude: playfulness is a mindset whereby people approach activities as something not serious, in a way that is highly pleasurable and motivating

Strong evidence base: features and information offered should have a solid scientific foundation

Remote monitoring: health care providers can follow persons with MS progress and give feedback

Optional Sociability: ability to opt out of social media features like messaging, feeds, or other kinds of social comparisons

Reminders system: notifications that remind persons with MS to engage in activities

Personal data management: access to personal information and data defined by the user case by case

Data Extraction and Classification

Apps meeting the eligibility criteria were downloaded and installed into testing devices (Android: LG G4 and Motorola G5; iOS: iPad 2 and iPhone 5) for data extraction. GG, ED-Z, and OR-R independently manually extracted data from the included apps.

Descriptive characteristics were extracted where available: (1) app platform, last update date, price, ratings, number of ratings, number of downloads, languages, and developer agency; (2) intended purpose; (3) feature match with previous study; (4) and presence of game elements as defined by Johnson et al [38].

Developer agencies were coded into one category following our classification scheme published in [28] and similar to ones present in other studies [36]. The classification scheme is described below:

- Health care related agency: Hospitals, clinics, or governmental organizations directly related to health care (ie, public health branches)
- Pharmaceutical company: Entities with commercial purposes to research, develop, market, or distribute drugs in the context of health care
- Governmental agency: Any governmental agency or organization not directly involved in health care (ie, IT departments)
- Nongovernmental agency: Any organization that is neither part of a government nor a conventional for-profit business such as societies or organizations that specialize both in general health improvement as well as illness-specific objectives and offer support groups (ie, patient empowerment organizations)
- Educational organization: Any educational organization such as universities, colleges, libraries, or schools not directly related to health care (ie, science school projects)
- Conferences and journals: Scientific journals, patient, or medical conferences
- Small and medium-sized enterprises: Start-ups, software developing companies, or any other private organizations that identified themselves as an enterprise and not individuals (ie, digital health start-ups)
- Individuals: Developers or uploader entities who are listed as individuals or have not identified themselves as enterprises (ie, John Smith)

Classification for the app's main purpose followed the scheme published in [28] and shown below:

- Awareness-raising: Tools to raise public recognition of MS as a problem, tools for fundraising, etc.
- Disease and treatment information: Provide general information about MS (eg, disease or treatment options)
- Disease management: Provide information and practical tools to deal with the medical, behavioral, or emotional aspects of MS
- Support: Provide access to peer or professional assistance

MS app features were matched with the desired features found in our previous study [27] shown in Textbox 1.

Results

Selection

The searches in the Android and iOS markets yielded 581 potentially relevant apps. Removing duplicates and applying the selection criteria resulted in a total of 30 unique MS apps. As mentioned in the selection criteria section, only the Android versions of apps that were present in both platforms were included for analysis. However, due to technical problems with two of these multisystem apps, the iOS versions were included instead (19 Android apps and 11 iOS apps). Additionally, we found that some apps required registration outside of the app interface, so we attempted registration on these sites and excluded those that were private. Figure 1 shows the overall study flow including the number of apps explored in each stage.

General Characteristics

The list of the included apps is shown in Table 1. A summary of the general characteristics of MS apps is shown in Table 2.

The large majority of apps were free to download (26/30, 87%) versus paid apps (4/30, 13%). The prices of paid apps ranged from US $0.99 to $4.99. Using the established 5-star rating system, most Android apps had good ratings with 3 or more stars (16/19, 84%). In relation to the number of downloads, at least half of them had over 500 downloads (58% of the included Android apps, 11/19). The most downloaded Android app, “Multiple Sclerosis Support,” had more than 10,000 downloads. On the other hand, the majority of iOS apps had no ratings (7/11, 64%), and no data on the number of downloads were available as Apple does not provide this information.

The majority of MS apps were available in English (27/30, 90%) with a small number of apps available only in Spanish (3/30, 10%).

App Purpose and Affiliation

Based on our classification schemes, disease management apps were the most predominant (13/30, 43%), followed by disease and treatment information apps (11/30, 37%; see Table 3). Information about the apps affiliation is shown in Table 3.

Figure 1. Study flow.

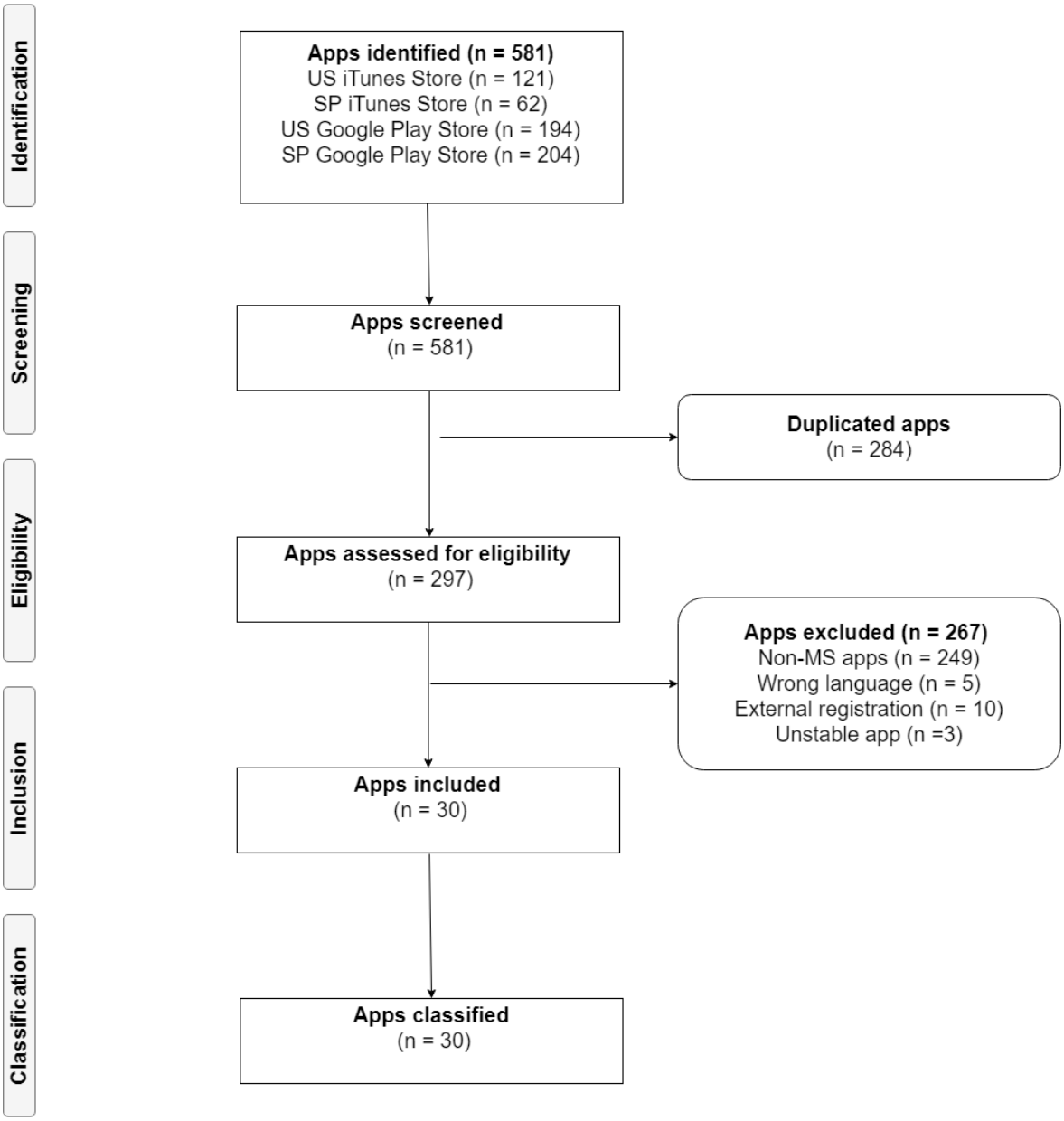


Table 1. List of multiple sclerosis (MS) apps.

Name	Platform
Basic MS Explorer	Android / iOS
Becare MS Link	Android
Con la EM	Android
Control EM	Android
Cure MS	iOS
EM All in One	Android / iOS
Healthstories MS	Android / iOS
MCAMS	iOS
MS Buddy: Multiple Sclerosis	Android / iOS
MS journal	iOS
MS Mate	Android
MS Self Multiple Sclerosis App for MS Patients	Android / iOS
MS Topography	iOS
MSFocus Radio	Android / iOS
MSstation	iOS
Multiple Esclerosis	Android
Multiple Sclerosis	Android
Multiple Sclerosis	Android
Multiple Sclerosis 101-Treatment and Recovery Tips	iOS
Multiple Sclerosis Attack App	Android / iOS
Multiple Sclerosis Chat	Android
Multiple Sclerosis Messenger	Android
Multiple Sclerosis Support	Android
My MS Conversations	Android / iOS
My MS Manager	Android / iOS
My MS-UK	Android / iOS
My Sidekick	iOS
Pre-meet	iOS
Rebilink	iOS
Understanding MRI: Multiple Sclerosis	Android / iOS

App Features

Apps were further analyzed to assess which features were present. Table 3 shows features included in the studied apps. “Patient education” was the most prevalent feature in the dataset, followed by “Social media” and “Data visualization.”

The majority of MS apps used mobile phone media capabilities (text, video, and audio) to deliver content to the user (17/30, 57%). Other features such as data visualization (7/30, 23%), social media (7/30, 23%), and reminders (6/30, 20%) were frequently present. Less popular features were personal data management (3/10, 7%), activity tracking (3/30, 10%), the presence of exercise libraries (2/30, 7%), remote monitoring (1/30, 3%), and energy and resource management (1/30, 3%).

Patient Education

Information for patient education was abundant but references to source materials was scarce (only present in one third of MS apps). Table 3 shows media format selection.

Social Media

The social media features included in the studied apps provided content sharing features through different social media networks. In 5 of the apps with social media features, socialization was optional, allowing users to decide whether to use it to share information with others. Some apps had their own social networks exclusively for patients, such as patient’s forums, chats, or specific platforms, while the rest offered standard social media outlets like Facebook and Twitter.

Data Visualization

Almost a quarter of the apps (7/30, 23%) featured some kind of user-generated data visualization. The data were usually obtained from in-app surveys and questionnaires.

Reminders

Only 6 of the apps had some sort of reminder system that allowed the user to set the notification frequency according to their preferences. The reminders helped users to remember to take medications (5/6), keep track of medical appointments (3/6), use activity tracking (1/6), and note down questions to ask health care professionals in upcoming visits (1/6). Other notifications such as content updates were also included in one of those apps.

Personal Data Management

Entering personal data information was among the first things asked by 10 of the apps. However, allowing users to decide or manage how their personal data was used was a somewhat infrequent feature. Only two apps allowed the user any choice regarding what data could be shared. None of the apps offered any option for the user to choose with whom data were shared. Only two apps included any kind of personalization of content or experience based on personal data collected.

Activity Tracking

Regarding activity tracking, only one MS app provided connectivity to external sensors (in this case Fitbit devices) while the rest relied on integrated capabilities within the mobile phone.

Exercise Library

Only two apps included a physical exercise library, sorting proposed exercises into categories such as body part and physical abilities, or showing lists of exercises without any classification or frame of reference.

Energy and Resource Management

Only one app called “My sidekick” (Figure 2) dealt with energy and resource management for persons with MS in any capacity. It included a user profile for collecting information about mood, symptom-related sensations, energy level, and activities carried out for the day.

Table 2. General characteristics summary.

Characteristics	Android (n=19), n (%)	iOS (n=11), n (%)	Total (N=30), n (%)
Commercialization			
Free	18 (95)	8 (73)	26 (87)
Paid	1 (5)	3 (27)	4 (13)
Rated	18 (95)	4 (36)	22 (73)
Rating (number of stars)[a]			
—	1 (5)	7 (64)	8 (27)
	0 (0)	0 (0)	0 (0)
	2 (10.5)	1 (9)	3 (10)
	7 (37)	1 (9)	8 (27)
	5 (26)	1 (9)	6 (20)
	4 (21)	1 (9)	5 (17)
Number of downloads[b]			
1-5	0 (0)	–	0 (0)
5-10	1 (5)	–	1 (3)
10-50	1 (5)	–	1 (3)
50-100	2 (10.5)	–	2 (7)
100-500	4 (21)	–	4 (13)
500-1000	2 (10.5)	–	2 (7)
1000-5000	6 (31.5)	–	6 (20)
5000-10,000	2 (10.5)	–	2 (7)
10,000-50,000	1 (5)	–	1 (3)
Not available	0 (0)	11 (100)	11 (37)

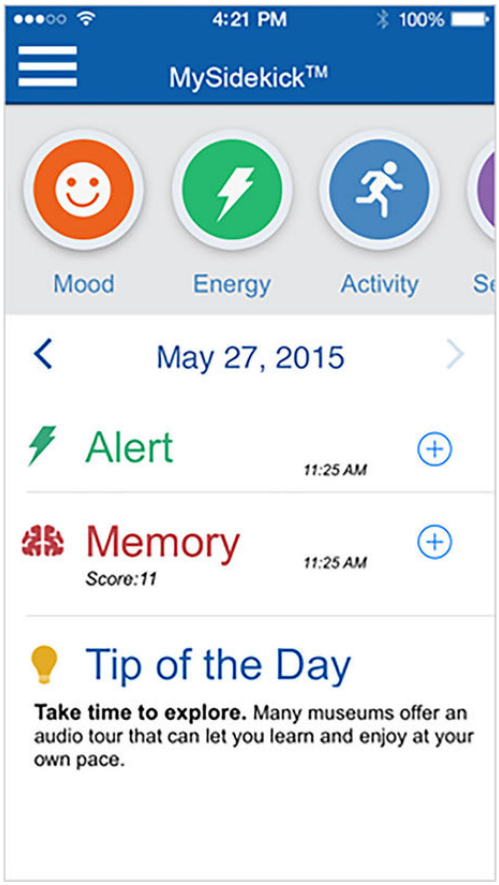
[a]Apps are rated based on a 5-star rating system.

[b]Number of downloads are provided as a range by Google; this information is not provided for iOS apps.

Table 3. Characteristics of multiple sclerosis apps.

Characteristics	n (%)
Purpose	
Disease management	13 (43.3)
Disease and treatment information	11 (36.6)
Support	5 (16.6)
Awareness-raising	1 (3.3)
Origins	
Small and medium enterprises	24 (80.0)
Pharmaceutical companies	3 (10.0)
Health care–related agencies	1 (3.3)
Nongovernmental agencies	1 (3.3)
Individuals	1 (3.3)
Most prevalent features	
Patient education	17 (36.2)
Social media	7 (14.9)
Data visualization	7 (14.9)
Reminders	6 (12.7)
Personal data management	3 (6.4)
Activity tracking	3 (6.4)
Exercise library	2 (4.3)
Remote monitoring	1 (2.1)
Energy and resource management	1 (2.1)
Media formats	
Text	14 (46.7)
Audio	7 (23.3)
Video	2 (6.7)
Game elements	
Progress representation	4 (13.3)
Goal-setting	3 (10.0)
Rewards system	3 (10.0)
Social interaction	2 (6.6)
Avatars	2 (6.6)
Leaderboards	1 (3.3)
Narrative	0 (0)

Figure 2. Example of energy and resource management multiple sclerosis app.



Remote Monitoring

"My MS Manager" app was the only app offering any kind of remote monitoring feature. This app presented users with the option to provide access on symptoms, laboratory results, medications, and side effects with the health care professionals who care for them.

Gamification

The prevalence of different game elements is presented in the Table 3. In general terms, the MS apps included in this study did not make use of gamification. The most popular game design elements were progress representations (progress, feedback, and levels), goal setting (goals and challenges) and rewards, social interaction opportunities, and avatars. No apps included narrative devices as a gamification technique.

Discussion

Principal Findings

To our knowledge, this is the first study to provide an in-depth analysis of mHealth apps for persons with MS available to consumers and contrast it to their reported needs. As it stands, it captures the current landscape for the ecosystem and the active stakeholders involved in it. mHealth apps for MS were classified according to their main features and characteristics. This study also explored the information presented to users and assessed the presence of references to source material to understand its reliability. The current work is also the first to evaluate the extent of gamification elements present in MS mobile apps.

In summary, a total of 30 unique health apps were identified across the two most popular app stores (Google Play and Apple App Store). A similar number of apps were found in both stores. The majority of the apps dealt with disease management and disease and treatment information. Most apps were developed by small and medium-sized enterprises, followed by pharmaceutical companies. Patient education and personal data management were among the most frequently included features in these apps. On the other hand, energy and resource management, and remote monitoring were often not present. Very few MS apps used gamification elements.

Comparison With Prior Work

Patient education is an essential strategy in the management of MS [3]. Self-management interventions typically focus on teaching skills, such as problem solving and decision making that are relevant to promoting engagement in single and multiple behaviors to manage single or multiple symptoms [39]. It is through proper patient education that persons with MS may achieve optimal outcomes and improvements in their quality of life [40]. In this review, patient education features were found to be among the most prevalent. The majority of the apps approached this topic providing information about MS and through some amount of disease management features.

Despite the fact that educational content was included in most of the analyzed apps, reliability of those solutions could use

improvement. First, most MS apps did not reference the sources of their contents. Second, as shown in Table 3 most of the current mHealth apps for MS have been developed by small and medium-sized enterprises with little involvement from health care agencies or nongovernmental organizations. This could be an important factor preventing adoption as MS patients have expressed concerns about the entities responsible for health apps [27]. This was also present in our previous study [27], as persons with MS claimed that "professional endorsement" was a high priority factor for accepting online health information or mHealth solutions. While it is possible that health care professionals may have been involved in the development and design of these mHealth apps, such information is not disclosed or easily accessible. Reliability of content is a common problem in mHealth [28,36,37], as a large number of health apps for patients are not adequate: some do not have correct information, lack transparency, or are inconsistent regarding personal data usage and storage [41]. Further exploration about data security issues should be undertaken to understand how these apps deal with these issues.

Regarding the way the available information was shown in some apps, such as MSFocus radio or Basic MS explorer for example, there seemed to be issues on how content was presented to users. The information did not have a proper information architecture as topics were shown mixed in a timeline feed without any search feature available. This issue has been reported to reduce usability and may result in a poor user experience decreasing the adoption rate and users' engagement [42]. The way that information is presented to users is key for them to be able to relate to it. Representing data visually is an important feature as it allows patients to relate in a meaningful way [43]. Of all the studied apps, only 4 offered some kind of visual reporting.

The chronic care model [44] emphasizes the role of patient as being their own caregiver and the importance of a collaborative partnership between patient and provider and the family and community support. Most of the studied apps do not provide family or other members of the social group a role or use case; the closest this feature got to that level was offering social media connectivity. Additionally, the current solutions do not offer a place for collaborative work with health care providers, which was also identified as a desirable feature for persons with MS [27].

Persons with MS experience severe levels of disability along their life and can suffer disabling fatigue. The lack of mHealth solutions that addresses fatigue management is intriguing and could take advantage of potentially interesting approaches that use mobile phones to monitor sleep cycles and promote physical activity [45,46]. The mobile phone's embedded sensors and its capabilities for using external sensors such as step counters and other wearable devices also present an opportunity for further research [47,48]. Monitoring and influencing physical activity using mobile phones has been proven as a tool to provide average-to-excellent levels of accuracy for different behaviors and as a valid tool for assessment of physical activity [49]. However, only two of the apps made use of these capabilities while the rest relied on manually entered data or none at all.

Evidence suggests that physical activity helps people with MS stay active, reduces MS symptoms, and improves cognitive abilities but still many individuals with MS avoid physical activity [50-54]. Physical activity for MS patients is an important factor for improving and managing the physical demands of MS. Having a variety of exercise programs was a highlighted need that seems to be unmet. In our previous study [27], lack of enjoyment was a big de-motivator for physical activity for persons with MS: many mentioned that perhaps the use of game elements or having a game-like attitude to physical activity would make it more appealing. Only a few apps included gamification elements that could facilitate user retention through the motivation. Future mHealth designers could take some direction from the current gamification design guidelines available [55].

Personal data are often collected but seldom used to improve personalization or remote monitoring functionalities. Issues regarding data confidentiality have been raised [27], but none of the included apps allowed users to select with whom they could share their data. This is of particular note, considering that the second largest group of developers was pharmaceutical companies, and how in our previous study [27], both health care professionals and persons with MS were concerned about the involvement of these type of companies.

Limitations

This study does have limitations. One limitation lies with the way search algorithms work, as they return partial matches as well as full matches, so some apps may have been missed in our search. Another limitation is that we relied on app store descriptions for identification. It is also possible that in some instances developers disclose sources, features, or affiliations once in-app; this seems unlikely given that such features are positive selling points and would be highlighted if present.

The focus of our study revolved around apps available in app stores for the United States and Spain, which might have excluded potentially relevant apps (published in the United Kingdom or Canadian stores, for example). The structural differences between stores also made it impossible to compare certain aspects (eg, iTunes does not disclose number of downloads per app). Restricting app stores to Apple and Android-based mobile phones could also introduce a selection bias as proportions might differ in less popular platforms such as Windows or Blackberry phones.

Additionally, further assessment could have been undertaken for each health app. App quality assessments such as the Mobile App Rating Scale (MARS) methodology [56] are available, and theoretical framework regarding the technology adoption such as the Technology Acceptance Model (TAM) model [57] or Unified Theory of Acceptance and Use of Technology (UTAUT) [58] were considered but found to be beyond the scope of this study.

Finally, while the presence of reference to source materials was explored, the validity of those sources was not assessed in relation to evidence-based guidelines. This is an interesting field for further exploration.

Conclusions

This study analyzed current multiple sclerosis health apps available to consumers. The use of these mHealth apps is appealing, but the current landscape does not seem to match the needs of persons with MS. The lack of involvement from health care professionals and lack of sound quality information is still a major issue. This presents an interesting opportunity to improve these patient-facing apps and address the lack of health care providers' end of the equation. Features such as social support, exercise library, and energy and resource management are not present in most of the MS apps. Among the few MS apps available, most were rated positively, indicating that there is perhaps a strong interest in mHealth solutions for MS. It would be interesting for future research to find more ways of personalizing MS apps to persons with MS specific needs.

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Authors' Contributions

GG led overall study conduct, supported the data collection and analysis and interpretation of the data. ED-Z, EG-F, and OR-R participated in overall study conduct, and collection, analysis, and interpretation of study data. ED-Z led the draft of the manuscript, supported by OR-R, EG-F, and GG. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

mHealth: mobile health
MS: multiple sclerosis
RQ: research question

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Review

Attention and Cognitive Bias Modification Apps: Review of the Literature and of Commercially Available Apps

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Abstract

Background: Automatic processes, such as attentional biases or interpretative biases, have been purported to be responsible for several psychiatric disorders. Recent reviews have highlighted that cognitive biases may be modifiable. Advances in eHealth and mHealth have been harnessed for the delivery of cognitive bias modification. While several studies have evaluated mHealth-based bias modification intervention, no review, to our knowledge, has synthesized the evidence for it. In addition, no review has looked at commercial apps and their functionalities and methods of bias modification. A review is essential in determining whether scientifically validated apps are available commercially and the proportion of commercial apps that have been evaluated scientifically.

Objective: The objective of this review was primarily to determine the proportion of attention or cognitive bias modification apps that have been evaluated scientifically and secondarily to determine whether the scientifically evaluated apps were commercially available. We also sought to identify commercially available bias modification apps and determine the functionalities of these apps, the methods used for attention or cognitive bias modification, and whether these apps had been evaluated scientifically.

Methods: To identify apps in the published literature, we searched PubMed, MEDLINE, PsycINFO, and Scopus for studies published from 2000 to April 17, 2018. The search terms used were “attention bias” OR “cognitive bias” AND “smartphone” OR “smartphone application” OR “smartphone app” OR “mobile phones” OR “mobile application” OR mobile app” OR “personal digital assistant.” To identify commercial apps, we conducted a manual cross-sectional search between September 15 and 25, 2017 in the Apple iTunes and Google Play app stores. The search terms used to identify the apps were “attention bias” and “cognitive bias.” We also conducted a manual search on the apps with published evaluations.

Results: The effectiveness of bias modification was reported in 7 of 8 trials that we identified in the published literature. Only 1 of the 8 previously evaluated apps was commercially available. The 17 commercial apps we identified tended to use either an attention visual search or gamified task. Only 1 commercial app had been evaluated in the published literature.

Conclusions: This is perhaps the first review to synthesize the evidence for published mHealth attention bias apps. Our review demonstrated that evidence for mHealth attention bias apps is inconclusive, and quite a few commercial apps have not been validated scientifically.

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KEYWORDS

attention bias; cognitive bias; smartphone; mHealth; psychiatry; telemedicine; mobile applications

Introduction

Advances in experimental psychology have led to further research into cognitive bias modification. Cognitive biases refer to automatic attentional or interpretational tendencies toward certain stimuli [1]. Cognitive bias is an overarching term and includes other common cognitive biases, such as attentional biases, approach biases, and interpretative biases [2]. These unconscious processes are postulated to be involved in the psychopathologies of various disorders, including social anxiety disorder [3], alcohol use disorder [4], and tobacco use disorder [5]. Cognitive bias modification refers to the retraining of these automatic processes. For addictive disorders, theories such as the opponent process theory or the incentive-sensitization theory have been proposed to explain the causes of the vicious cycle of addiction [6]. However, more recently, the dual-process theory has postulated that, in addictive disorders, automatic processing of substance-related cues is increased, with a corresponding decrease in normal inhibitory control [7]. Thus, these automatic processes would cause an individual to relapse into substance use. While the dual-process model does not apply to other psychiatric disorders, other theoretical approaches have similarly proposed the presence of an enhanced threat-detection mechanism, and that this, in turn, results in socially anxious individuals to be hypervigilant toward threatening or anxiety-invoking stimuli [8].

Experimental psychologists have developed various attention bias assessment tools, such as the dot-probe task, visual-probe task, visual search task, and cognitive bias interpretations [6]. In addition to assessment, these tools are commonly also used for bias modification. For the visual-probe task and the dot-probe task, individuals are required to respond to a probe that replaces either a neutral image or a substance-related image, or for affective conditions, images depicting positive or negative emotional states. Attentional biases are assessed to be present if individuals demonstrate a faster reaction time in responding to probes replacing images associated with high salience [6]. Cognitive bias modification for interpretations involves presenting individuals with ambiguous scenarios and with word fragments that help to disambiguate the scenarios in a positive way [9]. In the visual search task, individuals are required to identify the positive smiling picture among a range of other pictures with a range of emotions [10]. To date, further research has examined the efficacy of bias modifications, and a recent meta-analytical study synthesized the evidence for substance use disorders [11]. In their meta-analysis of trials involving participants with tobacco or alcohol addiction, Cristea et al [11] reported that cognitive bias interventions had a moderate effect on cognitive bias (Hedges g=0.60), but there was no effect of bias modification on other outcomes, such as cravings [11]. Jones and Sharpe [1] in their review of meta-analyses found that there is more evidence for cognitive bias modification in ameliorating anxiety symptoms than in ameliorating depressive symptoms. Jones and Sharpe [1] also reported that the long-term efficacy was evident only in addiction trials. It is essential to note that studies included in these meta-analytical reviews were trials conducted within the controlled environment of a laboratory [1]. Conducting attention bias modification in a laboratory setting reduces the risk of attrition to these highly repetitive tasks, but the results may not be replicable in a less-supervised clinical or community setting.

In parallel with the development of the above, there have been major advances in both eHealth and mHealth technologies in the 21st century. eHealth, or electronic health, refers to the use of Web-based interventions [12] and mHealth, or mobile health, refers to the use of mobile devices, such as smartphones and their accompanying apps, for health care [12]. In psychiatric practice, both eHealth and mHealth technologies have been adopted for the delivery of psychological interventions for conditions such as depression and bipolar disorders to monitor patients' mood state [13] and to reduce drinking among individuals with alcohol use disorder [14]. Advances in technologies have also transformed how conventional attention and cognitive bias modification tasks are being delivered. An evaluation of the efficacy of Web-based attention bias modification interventions by Wittekind et al [15] found that a Web-based approach and avoidance could retrain attention bias among individuals with tobacco use disorder and reported its efficacy in smoking reduction. In a study of individuals with social anxiety disorder, Sportel et al [16] compared the effectiveness of Web-based cognitive bias modification against conventional cognitive behavioral therapy and reported that both modalities of intervention were effective in reducing social anxiety symptoms. These studies highlighted the potential of Web-based bias interventions as an alternative to conventional laboratory-based attention bias modification. Given the proliferation of commercially available health apps and the increased recognition of the role of attention bias in medical and psychiatric disorders, more commercially developed apps that aim to manipulate attention bias are expected to become available. Studies have been published, such as that by Clarke et al [17], that have evaluated whether an attention bias modification task was helpful for individuals with insomnia.

We know of no reviews to date that have synthesized the literature to determine the existing evidence for mHealth-based bias modification interventions. Also lacking is an understanding of the common functionalities and methods of bias modification used in these commercially available apps. By analyzing in parallel both the apps offered in commercial app stores and the apps evaluated in published works on attention and cognitive bias modification, we can determine whether scientifically validated apps are available commercially and estimate the proportion of commercial apps that have been evaluated scientifically.

The primary objective of this review was to determine the proportion of attention or cognitive bias modification apps that have been evaluated scientifically. The secondary objective was to determine whether the scientifically evaluated apps were commercially available. In this review, we also sought to identify commercially available bias modification apps and determine the functionalities of these apps, the methods used for attention or cognitive bias modification, and whether these apps had been evaluated scientifically. The evidence from this review has important implications for clinical care, technological development, and research.

Methods

Phase 1: Identification of Attention and Cognitive Bias Modification Apps in the Published Literature

To achieve the primary objective, we initially searched PubMed and MEDLINE for articles published from 2000 through to September 24, 2017. We performed an updated search from April 14 through 17, 2018 on PubMed and MEDLINE and 2 additional databases, PsycINFO and Scopus. We selected the year 2000 because, before this date, few people had access to personal digital assistants and mobile phones. The search terms we used were “attention bias” OR “cognitive bias” AND “smartphone” OR “smartphone application” OR “smartphone app” OR “mobile phones” OR “mobile application” OR mobile app” OR “personal digital assistant.” We included only English-language articles.

The inclusion criteria were that (1) cognitive bias modification must have been delivered using a mobile device (mobile phone, smartphone, or personal digital assistant), and (2) delivery was in the form of a specific app or game. We excluded articles that simply described how a Web-based intervention could run on a mobile device.

All the articles were initially screened based on their title and abstract by 2 independent authors (MZ and JY). Full copies of the shortlisted articles were then evaluated against the inclusion and exclusion criteria. Any disagreement between the 2 authors was resolved by discussion with the third author (GS). The rationale for inclusion and exclusion was captured on an electronic form, together with the following information: (1) publication details (names of the authors and the year of publication), (2) specific condition targeted, (3) description of the intervention, (4) method of delivery of attention bias or cognitive bias modification, and (5) main outcome and findings arising from the study.

Phase 2: Identification of Commercially Available Apps

We then conducted a manual cross-sectional search between September 15 and 25, 2017 on the apps stores iTunes (Apple Inc, Cupertino, CA, USA) and Google Play (Google LLC, Mountain View, CA, USA). The search terms we used were “attention bias” and “cognitive bias.” The manual search was supplemented in the same period with the use of a mobile app search engine, 42matters (42matters AG, Zurich, Switzerland), to search for all the available apps globally. If an app had both a free and paid version, we analyzed the paid version, as it is commonly recognized that paid versions have more functionalities; free versions of apps tend to offer only limited access to functionalities [18].

We extracted the following information from the identified apps and recorded it on a standardized electronic data collation form: (1) app name, (2) general description of the app, (3) method of attention or cognitive bias modification, (4) other functionalities, (5) range of total downloads, (6) app ratings, (7) reference source, and (8) last date of modification. For the method of attention or cognitive bias modification, we recorded the tool that was being used (eg, visual-probe task, dot-probe task, or visual search).

To determine whether commercially available apps had been evaluated scientifically, we cross-checked the extracted commercial app against those apps that we had previously identified in phase 1. Also, we assessed any references that were cited in either the description or within the app for any scientific evaluation of the app. We contacted developers of the respective apps via email on November 5, 2017 for further information as to whether the app had been evaluated scientifically.

Phase 3: Availability in App Stores of Apps in the Published Literature

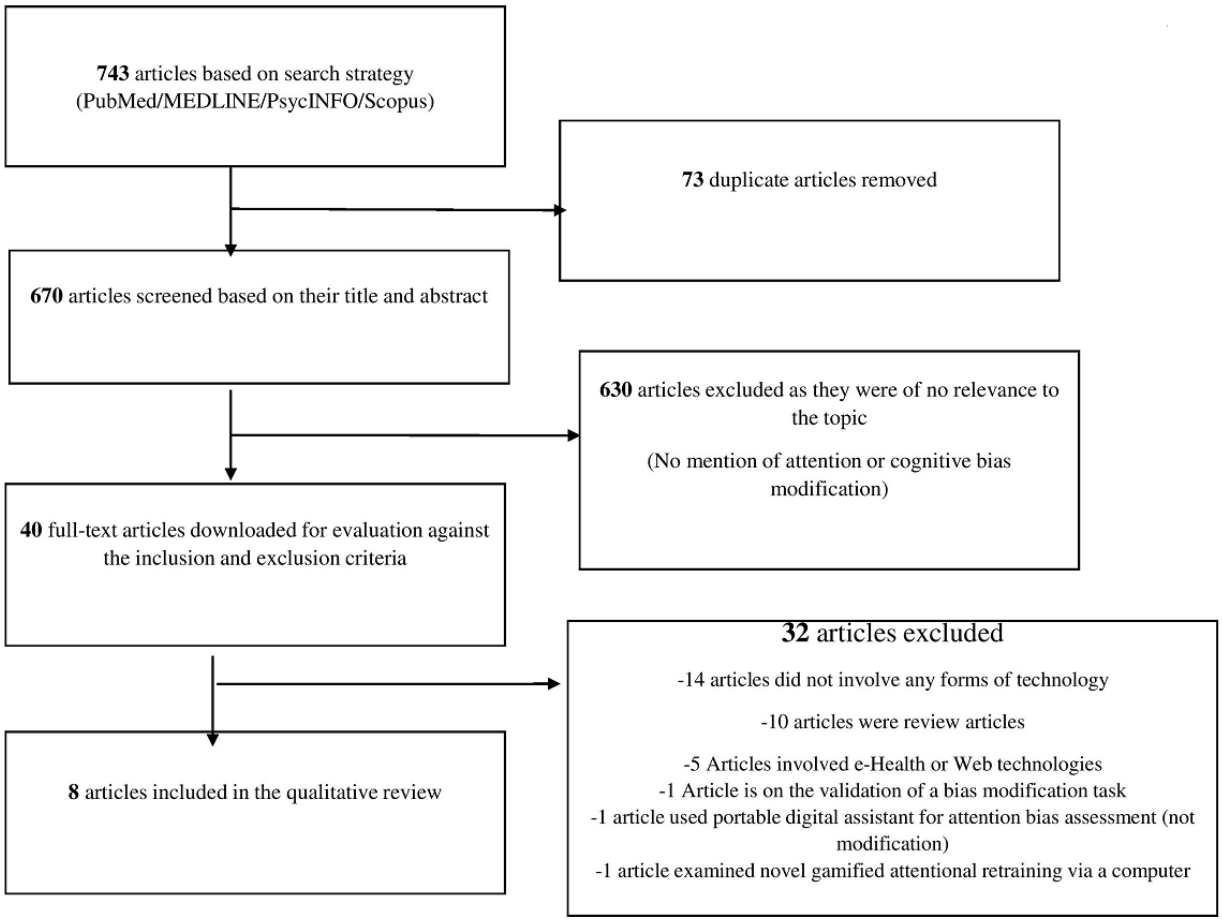
We manually searched the app stores (Apple iTunes and Google Play) for the apps with published evaluations (phase 1). We supplemented the manual search with a mobile app search engine (42matters) to extend the search. We downloaded and evaluated available apps and extracted the following information: (1) app name, (2) general description of the app, (3) method of attention or cognitive bias modification, (4) total number of downloads (if available), (5) app ratings (if available), (6) reference source, and (7) last date of modification of the app.

Results

Figure 1 provides an overview of the study selection process. Our initial and updated search identified 743 citations. Of these, 73 were duplicates, and we screened the 670 remaining articles by their title and abstract, leaving 40 articles. We then downloaded these for further evaluation against the inclusion and exclusion criteria, leaving 8 articles suitable for qualitative review.

The articles described mHealth apps for the delivery of attention or cognitive bias modification for following conditions: insomnia (n=1), social anxiety (n=1), anxiety disorder (n=3), alcohol use disorder (n=1), and tobacco use disorder (n=2). Table 1 [17,19-25] summarizes the main characteristics of the studies that we included. Nearly all of the trials used either the dot-probe or visual-probe task, except for 1 study that used cognitive bias for interpretation intervention, and another that did not specify the task applied. With regard to the outcomes, 7 studies reported effectiveness and only 1 reported no effect. Bias modification was found to be effective, as it helped improve symptoms of insomnia and cognitive symptoms of presleep arousal [17]; reduce subjective anxiety [20]; improve performance on stress task [21]; reduce attentional biases for cigarettes [22,25]; reduce the amount of alcohol consumed [24]; and reduce prenatal stress and anxiety [23]. However, Yang et al [19] reported that bias modification was not effective, as the bias scores among participants with social anxiety disorders were not reduced.

Figure 1. Flowchart of article selection.



Only 1 of the apps described in these articles was commercially available on the app stores (based on our phase 3 search).

In phase 2, we retrieved a total of 15 apps from Google Play and 2 apps from iTunes; 5 of the apps were available in both stores. The flowchart in Figure 2 shows the app selection process from the commercial stores.

We downloaded and further evaluated the commercial apps (n=17). Multimedia Appendix 1 summarizes the main characteristics of the commercially available attention bias or cognitive bias apps. Of 17 apps, 10 were free to download. Most of these apps claimed to target conditions such as stress (n=7), anxiety (n=3), tobacco (n=3), alcohol use disorders (n=2), and grief (n=1). One app (Bias Modification) did not specifically mention in the app description or in the app the targeted condition. Most used attention visual search in bias modification, with only 2 apps adopting the cognitive bias modification for interpretation method. A total of 4 apps used methods of bias modification that differed from visual probe, cognitive bias modification, and attention visual search tools. For the app Quitty, the bias modification task involved using a tobacco product as a projectile to hit other objects. For the apps Stop Smoking-Quit Smoking, Stay Sober, Stop Drinking, and ChimpShop, the paradigm involved an avatar running through an environment, and bias was retrained by avoiding the substances. There were limited additional functionalities for most of the included apps, with 5 apps including questionnaires or other functionalities, such as the ability to customize images (Spot Smile, brighten your day app) or the addition of reminders (AntiAnxiety), to allow for customization of the app for the individual user. Only 4 apps attributed a reference source within the app, of which 1 has been previously evaluated (ChimpShop). On the Android platform, 2 of the apps had been downloaded between 10,000 and 50,000 times. After contacting developers to find out whether their apps had been evaluated previously, 3 replied, but none of the developers were able to offer evidence demonstrating that their app had been evaluated in a prior study (Quitty, Happytap, and AntiAnxiety).

Figure 3 provides a graphical overview of the target conditions for both validated scientific apps and commercial apps. Apps evaluated in a prior study targeted mainly tobacco use disorder and anxiety use disorder; while of the 17 commercially available apps, most targeted stress. Tobacco use disorder appeared to be a common disorder that both validated and commercial apps targeted, with a total of 2 and 3 validated and commercial apps, respectively.

Table 1. Overview of attention and cognitive bias modification apps in the published literature.

Reference	Condition targeted	Description of intervention	Method of ABM[a]	Main outcomes reported	Availability in commercial stores
Clarke, 2016 [17]	Insomnia	ABM task involving 48 word pairs comprising sleep-related threat words paired with nonthreat words.	Dot-probe task	The primary outcome measured was whether the delivery of attention bias task could help reduce symptoms of insomnia and cognitive symptoms of presleep arousal. Participants who received ABM training reported significantly lower presleep arousal and better overall sleep quality. Those assigned to the ABM condition also fell asleep faster and woke less often during the night (based on electrophysiological measures)	No
Yang, 2017 [19]	Social anxiety	CBM-A[b] task involving the presentation of 2 faces as stimulus. CBM-I[c] task based on the presentation of ambiguous scenarios. Attention and interpretation modification involving half the tasks for CBM-A and CBM-I.	Dot-probe task, CBM-I	The main outcome was to compare the effectiveness of 3 types of training program. Delivering cognitive bias modification via smartphone device is feasible. CBM-A and attention and interpretation modification was not effective as measured by the dot-probe attention bias scores.	No
Dennis, 2014 [20]	Anxiety	Gamified ABM app	Dot-probe task	The main outcome of the study was to determine whether the gamified ABM task could help reduce threat bias, anxiety, and the stress reactivity of trait anxious individuals, in a way similar to that of laboratory-based bias modification. The single session helped reduce subjective anxiety and stress reactivity. Long-training bias modification helped reduce threat bias and difficulties with disengagement.	No
Dennis-Tiwary, 2016 [21]	Anxiety	Gamified ABM app (Personal Zen)	Dot-probe task	Subjective anxiety and stress responses measured following the intervention showed that there was no difference in overall self-reported anxiety symptoms. However, behavioral performance improved during the stress task among female participants.	No
Kerst, 2014 [22]	Smoking	Attention retraining via personal digital assistant in natural environment	Modified visual-probe task	The main outcome examined was whether delivering attention retraining on a personal digital device in the natural environment could help reduce attention bias and overall cravings for smoking. Attention bias decreased in the intervention group and overall craving decreased in the intervention group.	No
Denis-Tiwary, 2017 [23]	Anxiety and stress	Gamified ABM app (Personal Zen)	Dot-probe task	Biobehavioral indices of prenatal stress and anxiety were reduced following the intervention.	No
Cox, 2015 [24]	Alcohol	Gamified ABM app (ChimpShop)	Not specified	The main outcome measured was the amount of drinking. The intervention reduced drinking in problematic drinkers by 60%.	Yes
Robinson, 2017 [25]	Smoking	Attention bias retraining	Visual-probe task	Attentional biases in smokers were reduced. Reduction in attention biases did not reduce craving or biological measures of smoking.	No

[a]ABM: attention bias modification.

[b]CBM-A: cognitive bias modification-attention.

[c]CBM-I: cognitive bias modification-interpretation.

Figure 2. Flowchart of the selection of apps from the commercial stores.

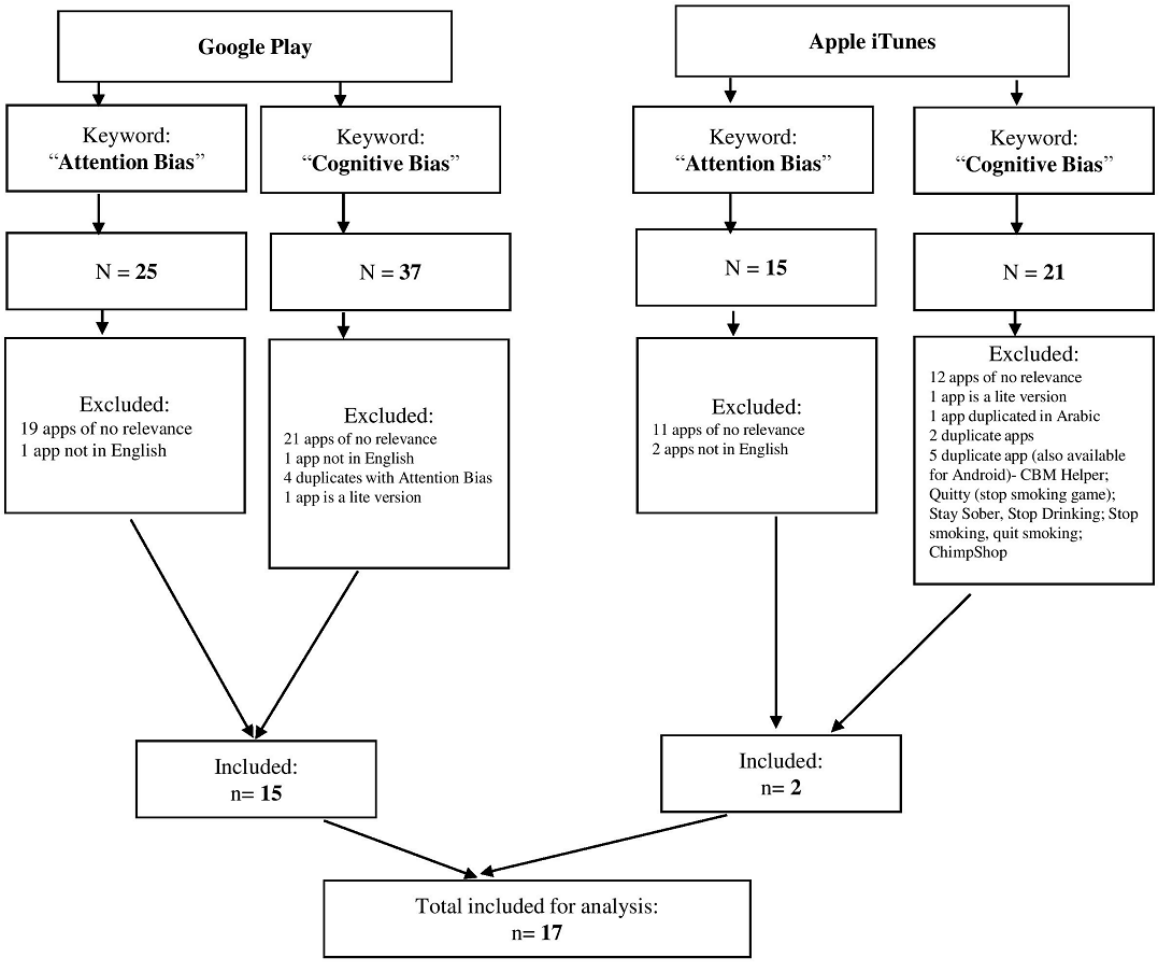
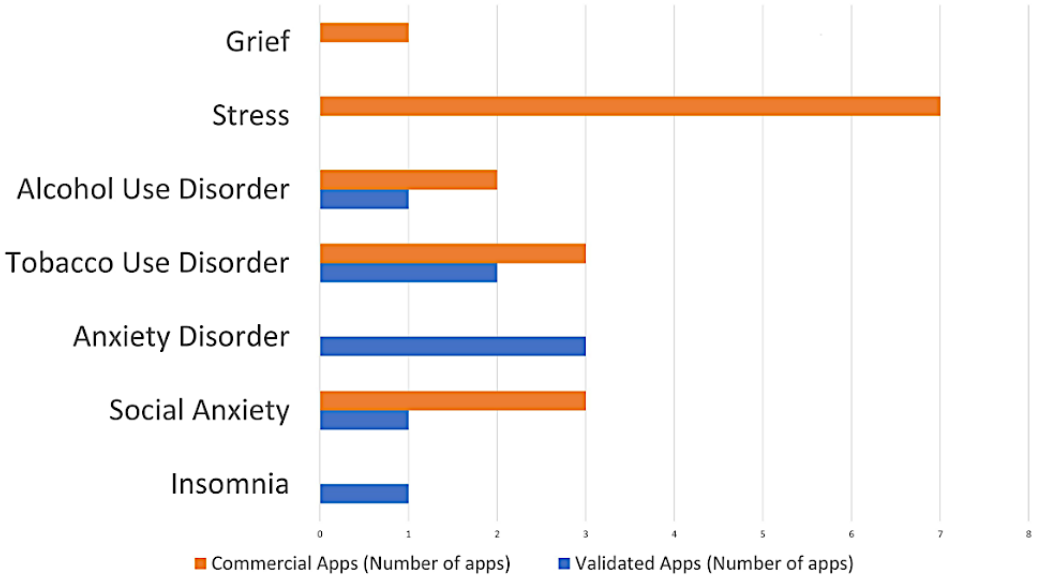


Figure 3. Overview of conditions targeted by both commercial and validated apps.



Discussion

Principal Findings

We reviewed all the cognitive bias modification apps that we identified to be available commercially and those evaluated in the research literature. The effectiveness of mHealth attention bias modification was reported in 7 of 8 previous trials. Only 1 of 8 previously evaluated apps was commercially available. The 17 commercial apps we identified in phase 2 tended to use either an attention visual search or a gamified task. Despite some commercial apps indicating a reference source, we managed to find only 1 app that had been evaluated previously in the published literature. None of the developers who replied could offer further evidence that their app had been validated through prior research.

This review highlighted that the evidence for mHealth-based attention and cognitive bias modification is inconclusive, as we found only 1 trial [19] out of the 8 that reported no effectiveness for bias modification. Our findings are similar to those for Web-based attention bias modification, a precursor to mobile-based interventions. Notably, in psychiatry, Web-based attention bias modification interventions have been evaluated for addictive, depressive, and anxiety disorders [26-28]. For conditions such as tobacco use disorder, while some trials reported the effectiveness of approach and avoidance [15], others, such as Elfeddali et al [29], who administered an approach and avoidance bias modification intervention to 434 participants, reported that bias modification did not lead to a reduction in bias or in the absolute number of cigarettes smoked. Similarly, for anxiety disorders, some trials reported the effectiveness of Web-based interventions, but many reported that Web-based interventions had no effectiveness [30-34]. We postulate that the mechanism of delivery of bias modification could have resulted in some trials having negative results. Of significance, Jones and Sharpe [1], in their recent meta-analytical review of previously published meta-analysis, synthesized the evidence not just for effectiveness but also with regard to training locations. Jones and Sharpe [1] reported that most of their included studies recommended laboratory-based administration of attention bias modification interventions rather than remote administration. Web-based administration of attention bias modification is remote and less controlled than laboratory-based administration. Attention bias modification interventions do typically provide some form of guidance from a therapist at the onset of the intervention, as well as supervision during the intervention, in which the therapist offers feedback if too many erroneous responses are made.

Our review suggests that, while some trials evaluated attention bias apps, only 1 of these apps appears to have progressed to being commercially available. In contrast, there are a variety of commercially available apps without scientific evaluation. Given this, individuals are highly likely to download other nonvalidated apps instead of those that have been validated, after searching for attention or cognitive bias apps in the app stores. In our case, we identified only 1 app that had been scientifically validated, but the download rates of the app were low, and hence it is likely to have ranked low in the stores. Similarly, Haskins et al [35], in their review of smoking cessation apps, reported that among the scientifically validated apps they found in commercial app stores, only 2 ranked among the top 50 apps in the store.

Haskins et al [35] also highlighted that the fact that the numbers of commercially available apps far exceeded the numbers of scientifically validated apps implies that current evaluation strategies are no longer appropriate, as mHealth interventions can be rapidly developed and implemented [35]. While we agree that there need to be alternatives to evaluate the scientific evidence of commercially available apps, we are cautious given that there are very limited tools available for the evaluation of commercial apps, such the Mobile App Rating Scale [36] or the Silberg Scale [37]. We have in this research adopted a framework for such an evaluation, in that we attempted to search for commercial apps in the published literature and to search for any academic references in the app description and within the app itself. We also contacted the developers for further clarification. Our findings also suggest that there is a potential disconnect between academics and app developers. Our findings suggest that most commercial apps were developed independently by companies, based on the attributions of the references (as Multimedia Appendix 1 shows). While the developers of 2 of the apps (ChimpShop and AntiAnxiety) reported some form of collaboration with an academic or academic institution, we found only a trial involving ChimpShop in this review. Clinicians and other health care professionals are rarely involved in app development due to several factors, including the lack of time and technical skills [38]. Even if clinicians or other health care professionals are involved, their role is limited to ensuring that a workflow is appropriate. Taking these factors into consideration, Zhang et al [39] previously recommended strategies that health care professionals can use in the development of cost-effective apps. The involvement of health care professionals and academic centers in the conceptualization of apps is advantageous, given that evidence-based methods can be incorporated into the planned app. Involving health care professionals is one method to help bridge the academic commercial divide. Another method would be to involve not only health care professionals, but also service users or patients themselves in the joint design and conceptualization of evidence-based apps. There has been more recent research recognizing the importance of such a codesign approach [40,41].

Strengths and Limitations

One of the major strengths of our study is that we identified both scientifically validated mobile attention bias modification interventions and commercially available attention bias modification apps. However, our study had several limitations. We do acknowledge that, while we searched comprehensively across several databases, we did not search databases such as Google Scholar for relevant published works. However, we believe that the 4 databases that we searched would have covered all the published articles, and a search of Google Scholar would have yielded few additional articles. The identification of apps was confined to the Apple and Google app stores. While these are the 2 most widely used app stores, it is possible that different apps might be available in other

stores, which we did not review. We acknowledge that we might have left out progressive Web apps from our search. We were unable to systematically search for progressive Web apps, as there was no webstore we could systematically search by keywords. Similarly, we searched only for English apps in our review. This might have excluded relevant apps on attention or cognitive biases that were not in English. We were not able to include apps in other languages, as we did not have the assistance of a translator in this study. Our search was confined to a total duration of a few weeks, which might have left out new apps, given how rapidly new apps are introduced into commercial app stores.

Implications

The most important clinical implication of this study is health care professionals' need for caution when recommending cognitive bias modification apps to their patients. Moreover, as mentioned above, some of these apps presented users with self-assessment questionnaires. Hence, there is a possibility for some individuals to self-diagnose and take the intervention. It is very important to emphasize in any app conceptualization that an assessment by a medical professional is still important. Our work highlights the need for researchers to carefully consider the method of delivery of an attention bias intervention through an app and how the app could compares with the conventional delivery of such an intervention in a laboratory setting, as in this study we found apps that used unconventional methods of bias modification.

Conclusions

Our review highlighted that, while evidence for the effectiveness of mHealth attention bias apps is mixed, a variety of commercial apps are available, with most appearing not to have been evaluated. It is important for future research to take into consideration the findings of this study, in the design, implementation, and evaluation of mHealth attention bias apps.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Characteristics of attention bias in commercial apps.

[PDF File (Adobe PDF File), 43KB - mhealth_v6i5e10034_app1.pdf]

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Original Paper

Acceptability and Feasibility of Real-Time Antiretroviral Therapy Adherence Interventions in Rural Uganda: Mixed-Method Pilot Randomized Controlled Trial

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Abstract

Background: Wireless electronic adherence monitors can detect antiretroviral therapy (ART) adherence lapses and trigger interventions in real time, thus potentially avoiding unnecessary HIV viremia. Evidence about the acceptability and feasibility of these monitors and associated interventions, however, is limited.

Objective: The aim of this study was to assess the acceptability and feasibility of real-time adherence monitoring linked to text messaging (short message service, SMS) reminders and notifications to support adherence among individuals living with HIV who are taking ART in rural southwestern Uganda.

Methods: Individuals living with HIV who were initiating ART were enrolled in a pilot randomized controlled trial and followed up for 9 months. Participants received a real-time adherence monitor and were randomized to one of the following study arms: (1) scheduled SMS, (2) SMS triggered by missed or delayed doses, or (3) no SMS. SMS notifications were also sent to 45 patient-identified social supporters for sustained adherence lapses in the scheduled SMS and triggered SMS arms. Study participants and social supporters participated in qualitative semistructured in-depth interviews on acceptability and feasibility of this technology. An inductive, content analytic approach, framed by the unified theory of acceptance and use of technology model, was used to analyze qualitative data. Quantitative feasibility data, including device functionality and SMS tracking data, were recorded based upon device metrics collected electronically and summarized descriptively.

Results: A total of 63 participants participated in the study. Participants reported that real-time monitoring intervention linked to SMS reminders and notifications are generally acceptable; the predominant feedback was perceived utility—the intervention was beneficial in motivating and reminding patients to take medication, as well as enabling provision of social support. The intervention was found to be technically feasible, as data were obtained from most participants as expected most of the time. Potential challenges included the impact of the technology on confidentiality, shared phone ownership, usability skills, and availability of electricity.

Conclusions: Real-time adherence monitoring integrated with SMS reminders and social support notifications is a generally acceptable (based primarily on perceived utility) and feasible intervention in a resource-limited country. Future efforts should focus on optimized device design, user training to overcome the challenges we encountered, cost effectiveness studies, as well as studying the monitoring aspect of the device without accompanying interventions.

Trial Registration: ClinicalTrials.gov NCT01957865; https://clinicaltrials.gov/ct2/show/NCT01957865 (Archived by WebCite at http://www.webcitation.org/6zFiDlXDa)

(JMIR Mhealth Uhealth 2018;6(5):e122) doi:10.2196/mhealth.9031

KEYWORDS

real-time adherence monitoring; SMS; mobile health technologies; antiretroviral therapy; acceptability; feasibility study

Introduction

Adherence to Antiretroviral Therapy

HIV or AIDS remains one of the biggest public health challenges, especially in developing countries, which accounts for over 70% of the 36.9 million people living with HIV or AIDS (PLWHA) globally. Antiretroviral therapy (ART) adherence is critical for achieving viral suppression, which leads to improved clinical outcomes and reduced secondary transmission. Despite simplification of HIV treatment (eg, single tablet and once daily dosing regimens) and improved access to ART, adherence remains challenging [1]. Nonadherence can result in HIV viremia, ART failure, and drug resistance, which can lead to deaths because of limited or complete inaccessibility of alternative therapies in resource-limited countries. Traditional approaches to adherence monitoring (eg, self-report, pill counts, and pharmacy refills) do not enable real-time interventions, as they may not detect nonadherence until viral suppression has been lost [2].

Potentials of mHealth Technologies

mHealth technologies can potentially improve adherence to long-term medications through real-time medication and pill refill reminders, prompting social support and enabling medication monitoring [3]. Real-time wireless adherence monitors, for example, can detect adherence lapses as they occur, and interventions such as SMS reminders can be instituted before the loss of viral suppression [4]. Widespread cell phone ownership and mobile network coverage in sub-Saharan Africa provide a promising platform for the implementation of mobile-based interventions, which can help overcome structural barriers such as transportation to a clinic and limited human resources and enable frequent intervention when and where it is needed [5,6].

SMS reminders unlinked to real-time adherence monitoring have been shown to improve adherence to ART in resource-limited settings [7-9]. The use of these SMS reminders has been reported as acceptable in Uganda [7], Kenya [8], South Africa [9,10], India [11] Brazil [12], and the United States [13]. Data, however, have been more mixed in China [2,14]. Weekly and twice-weekly SMS text message (short message service, SMS) reminders have been reported to increase adherence in Kenya and Nigeria [8,15]; however, no benefit was seen with daily SMS text messages in another study in Kenya [16]. SMS reminders triggered by lapses in real-time adherence monitors have been shown to improve adherence and reduce lapses in adherence in several but not all settings [2,11,12,17-20]. Compared with standard electronic monitoring, real-time electronic adherence monitoring (using Medication Event Monitoring System—MEMS) plus home visits for sustained interruptions increased average adherence in Uganda [21].

Acceptability and Feasibility of mHealth Technologies

The acceptability and feasibility of SMS reminders in Uganda, however, have not been well studied. SMS reminders triggered by late or missed doses detected by real-time adherence monitors improved overall antiretroviral adherence in China [18] but did not significantly improve adherence in South Africa, although it had fewer sustained adherence lapses [19].

Given the promise of real-time adherence monitoring and mobile-based interventions, the variability in effectiveness, and scarcity of literature, more thorough assessments of their acceptability and feasibility are needed. We conducted a pilot randomized controlled trial (RCT) based on real-time intervention linked to SMS reminders and notifications to support adherence among PLWHA taking ART in rural southwestern Uganda. As previously published [17] (Trial ID number: NCT01957865), adherence significantly improved for participants receiving scheduled SMS reminders that were sent daily and then weekly.

Moreover, participants reported that the intervention encouraged medication adherence through feeling cared about, habit formation, and a desire to show commitment to taking their medication [22]. Within the context of this pilot RCT, we used both qualitative and quantitative methods to assess the acceptability and feasibility of the intervention (a package of real-time adherence monitoring, SMS reminders for patients, and SMS notifications for social supporters).

Methods

Ethical Review

Ethical approvals for this study were obtained from the Institutional Review Committee of Mbarara University of Science and Technology, the Uganda National Council for Science and Technology, and the Partners Human Research Committee at Massachusetts General Hospital. Participants provided signed informed consent before study participation. All participants' data were securely stored electronically and protected by passwords. As a cultural practice in Uganda, participants were given 10,000 Ugandan Shillings (per trip; equivalent of approximately US $4) to cover transportation costs if they came to the research offices for an interview).

Study Site and Participants

This study involved two types of participants: PLWHA (called study participants) and their social supporters. Study participants initiating ART were recruited from the Immune Suppression Syndrome Clinic at Mbarara Regional Referral Hospital

(MRRH), a rural public hospital that dispenses free ART to over 10,000 people living with HIV in southwestern Uganda. We focused on ART initiators because they are not yet accustomed to taking medication; intervening at this level could potentially result in developing medication adherence habits. HIV status was identified by checking participants' medical records Recruitment criteria for study participants are shown in Textbox 1.

Each study participant named one to two social supporters who met the following criteria, as shown in Textbox 2.

Study Procedures

All study participants received a real-time adherence monitor (Wisepill Technologies, Cape Town, South Africa; see below) and training on its function and use (eg, filling and removing antiretroviral medications and device charging). Before enrollment in the study, potential participants were assessed for adequate cellular reception in their homes on a network supported by the technology used in this study (MTN or Airtel). Participants were given solar chargers and sent an SMS to charge the monitor as needed. A simple random number generator was used to determine study arm assignments. After screening and consenting, participants were randomized 1:1:1 as follows:

1. Scheduled SMS (also known as SMS reminders) plus real-time adherence monitoring (scheduled SMS arm)—Study participants received an SMS reminder daily for 1 month, then weekly for 2 months. For the next 6 months, study participants received an SMS only if no signal was received from the monitor within 2 hours of the expected dosing time, and an SMS notification was sent to one to two social supporters if no signal was received for more than 48 hours.
2. Triggered SMS (also known as SMS reminders) plus real-time adherence monitoring (triggered SMS arm)—For the entire 9-month study period, study participants received an SMS only if no signal was received from the monitor within 2 hours of the expected dosing time. For the latter 6 of the 9 months, an SMS notification was sent to one to two social supporters if no signal was received for >48 hours.
3. Real-time adherence monitoring only (called the control)—Study participants in this arm received no SMS reminders.

Literature about the appropriate frequency of SMS texts is mixed up. For example, weekly SMS reminders increased adherence in Kenya [16], whereas no benefit was observed in Cameroon [23]. We therefore used different types of SMS texts as we sought to test SMS communication to patients and social supporters sequentially to efficiently study which ones were most feasible, acceptable, and impactful. For instance, our findings published elsewhere indicate that unlike SMS linked to late or missed doses, scheduled SMS significantly increased adherence [17] and were preferred to linked SMS texts [22].

Social supporters were identified by study participants at enrollment. Social supporters were enrolled into the study at month 3 and were contacted during week 2 before sending them SMS notifications to ensure ongoing relationships with study participants when the SMS notifications began. They were sent SMS notifications during months 4 and 9 after potential lapses in adherence of study participants had been identified. Social supporters were not given specific instructions on the kind of support to be provided but were generally encouraged to support study participants.

Textbox 1. Recruitment criteria for study participants.

- Age ≥18 years
- Personal cell phone ownership
- Ability to read short message service (SMS) messages
- Availability of mobile network at participants' homes
- Willingness to receive SMS reminders
- Ability and willingness to provide informed consent
- Living within 20 km from Mbarara Regional Referral Hospital (to facilitate participant follow-up)
- Ability to identify at least one social supporter to join the study

Textbox 2. Inclusion criteria for social supporters.

- Age ≥18 years
- Ongoing relationships
- Cell phone ownership
- Knowledge of the study participant's HIV status
- Willingness to provide informed consent
- History of providing social support (eg, assistance to travel to the clinic and medication adherence advice) to the study participant

The Intervention Technology: Real-Time Adherence Monitor (Wisepill Device)

Dimagi (a mobile technology solutions company, Cambridge, Massachusetts, United States) and Yo! Voice Solutions (a gateway service provider, Kampala, Uganda) developed the SMS reminder system that was hosted in the open source application, CommCare. This application was then linked to the real-time adherence monitoring system.

The content of SMS reminders was customized and determined by each participant to reduce the risk of unintended HIV status disclosure. Notifications were also customized on request. The default message was "This is your reminder."

Powered by a rechargeable battery, the real-time adherence monitor (Figure 1) is a medication container that can hold up to sixty small pills. When an individual opens it to take pills, the device records a date-and-time stamp. An internal modem and subscriber identity module card enable the device to send a real-time mobile signal to a secure Web server (hosted in South Africa) by General Packet Radio Service (GPRS). Receipt of this signal was taken as a proxy for taking medication. GPRS maintains the data in transit until acknowledgment of receipt by the Web server, which minimizes possible data loss because of power failure or lack of Internet connectivity. Data transmission is backed up by the SMS to mitigate possible temporal GPRS network disconnections. In the event of inadequate mobile network coverage, the monitor stores openings in flash memory and sends them when the network becomes available. The monitor also transmits a daily heart beat that indicates current battery life, remaining airtime balance, and signal strength as indication of its functionality. The monitor can be charged using electricity or a solar device. Its battery life was 3 months at the time of the study but has since been improved to 6 months.

Data Collection

Study participants were seen at baseline, 3 months, and 9 months for collection of socio-behavioral data and viral load assessment. Signals sent after opening the real-time adherence monitor to the study server comprised the adherence data.

Semistructured qualitative interviews were conducted after month 3 (known as interview 1) and after the first 48-hour lapse (known as interview 2), or at study exit if there was no such lapse (also known as interview 2), reflecting two planned interviews per participant. In-depth semistructured interviews with a purposeful sample of social supporters were conducted within 2 weeks of a lapse by their respective study participant. Their selection was based on the study participant's explanation for the lapse, social support characteristics, and variations in the types of social support provided. Closed and open-ended questions were asked of social supporters at exit exploring various aspects such as challenges and experiences to social support and understanding of and responses to the intervention SMS notifications and the type of voluntary and requested help or support presently given to the study participant toward adherence.

Figure 1. The Wisepill device.

Research assistants who were bilingual in English and the local language (Runyankole) and trained in qualitative research and research ethics carried out semistructured in-depth interviews at the research office, participants' homes, or any other place preferred by the participants. Interview topics with study participants covered the following: (1) preferences for content; frequency and timing of SMS reminders, (2) understandings and experiences of SMS reminders, and (3) understandings and experiences of real-time adherence monitoring. Social supporter interviews explored the following topics: (1) selection of social supporter by the study participant, (2) type of social support given, and (3) likes and dislikes of the SMS notification. All questions in the interview guide were translated into the local language (Runyankole) and back translated to English by a different translator. Interviews were conducted in the local language, digitally recorded, and translated to English during transcription for analysis. Following each interview, the research investigators reviewed transcripts for quality, clarity, and detail.

Quantitative effects of the intervention on adherence, qualitative interpretation of the mechanisms for intervention effects, and exploration of the social supporter aspect of the intervention are reported elsewhere [17,22,24].

Feasibility data were obtained by recording the number of adherence monitors reported or detected to malfunction, percentage of functional adherence monitors at the end of the study, number of battery failures or changes, percentage of data lost because of technical issues, and number of SMSs not sent as planned. Some qualitative aspects of feasibility were also explored, including sources for storing ART other than the monitor, use of the monitor to store other medications, and monitor openings for reasons other than pill-taking.

Data Analysis

The unified theory of acceptance and use of technology (UTAUT) model, which has been shown to predict a substantial portion of the acceptance of health information technology, served as the conceptual framework for this analysis [25]. In this model, technology adoption is influenced by four major constructs as perceived by an individual user: (1) performance expectancy or perceived usefulness, (2) effort expectancy or percieved ease of use, (3) social norms (ie, how others perceive the individual's use of the intervention), and (4) facilitating conditions (ie, the availability of technical and organizational infrastructure to support use of the intervention). We used an inductive, content analytic approach to analyze the qualitative data [26]. For this paper, we used the qualitative data management computer software program NVIVO 10 (QSR International., Melbourne, Australia) to organize the data.

With substantial input from JEH, NCW, TW, and MAW, AM reviewed transcripts for content relevant to acceptability drawing from the UTAUT model; developed a coding scheme based on the content identified; coded the data; sorted and reviewed the coded data to develop descriptive categories; and mapped the descriptive categories onto the domains of the UTAUT model (focusing on perceived usefulness, perceived ease of use, social norms, and facilitating conditions). Illustrative citations were then selected from the coded data. Quantitative data about the feasibility of the intervention were recorded and summarized descriptively using STATA 13 (StataCorp., College Station, Texas, USA).

Results

Participant Characteristics

Of 195 screened individuals, 63 were enrolled in the study from September 2013 to October 2014, whose 9-month follow-up ended in June 2015. One participant was later discovered to be HIV negative and was excluded from the analysis. The criteria for excluding the rest is indicated in Textbox 3 (participants could have >1 criterion). Table 1 indicates the participants' characteristics.

We had 63 participants initially; scheduled SMS arm (21 participants), triggered SMS arm (21 participants), and control arm (21 participants). One participant was found to be HIV negative after randomization and disenrolled from the triggered arm. Four study participants were lost to follow-up (2 in the triggered SMS arm, 2 in the control). A total of 41 social supporters completed the study. One social supporter died, one was lost to follow-up, and two were disenrolled per the study participants' requests.

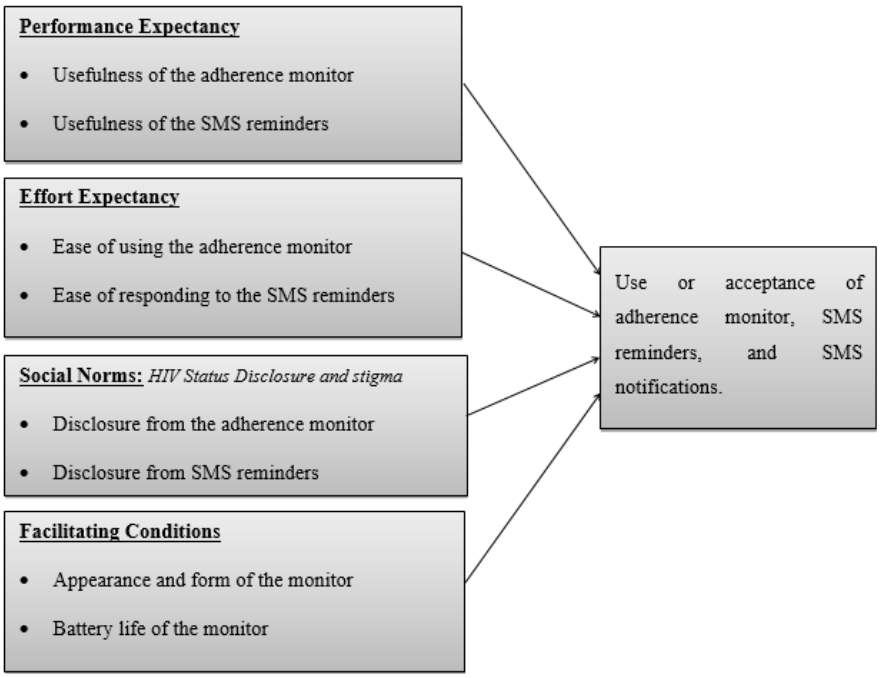
Textbox 3. Exclusion criteria for study participants.

- Living more than 20 km from Mbarara Regional Referral Hospital: 111 (56.9%, 111/195)
- Having no personal cell phone: 72 (36.9%, 72/195)
- Unwillingness or inability to name at least one social supporter: 29 (14.9%, 29/195)
- Unwillingness to have mobile reception tested at home: 10 (5.1%, 10/195)
- Inadequate mobile network reception: 4 (2.0%, 4/195)
- Inability to provide informed consent: 4 (2.0%, 4/195)
- Aged <18 years: 2 (1.0%, 2/195)

Table 1. Participant characteristics.

Characteristic	Statistic
Participants included in the study, n	63
Participants who completed the study, n (%)	58 (92)
Had electricity in their homes, n (%)	38 (65)
Females, n (%)	41 (65)
Able to read and write, n (%)	61 (97)
Median age in years	30
Median follow-up time in months	8.9

Figure 2. Organization of qualitative data on acceptability following the unified theory of acceptance and use of technology (UTAUT) model. SMS: short message service.



Interviews were carried out as follows: (1) semistructured interviews were conducted after month 3 with 41 study participants of the scheduled SMS arm participants (21 participants) and the triggered SMS arm (20 participants) just before completing the first intervention, before switching to the second type of intervention (known as interview 1); (2) semistructured interviews were conducted after the first 48-hour lapse with 30 study participants drawn from the 41 participants of the scheduled SMS and triggered SMS arms (known as interview 2); (3) semistructured interviews were conducted at study exit with 30 participants if there was no lapse (also known as interview 2)—these included 11 participants from scheduled SMS arm and triggered SMS arm that never lapsed and 19 participants from the "control" arm; and (4) semistructured interviews were carried out with 10 social supporters.

Intervention Acceptability

Acceptability results are presented following the UTAUT model (Figure 2) and detail the performance expectations, effort expectancy, social norms, and facilitating conditions associated with the three components of the intervention: the real-time adherence monitor, participants' SMS reminders, and SMS notifications for social supporters.

Performance Expectancy or Perceived Usefulness

Study participants found the electronic monitoring device useful, especially in supporting their pill-taking behavior. They described feeling motivated by the real-time monitoring because they interpreted monitoring as meaning study staff "cared" about them. Accordingly, study participants did not want to be "caught" not adhering to their pills; they felt that such behavior could constrain their ongoing relationships with the study staff and "disappoint" them:

> *I know that every time I open it [device], that light that flashes by its side indicated that a message has been sent to you people telling you that I have opened and taken my pills. I feel it with in my heart not to disappoint you people so I try to open it on time, whenever I can.* [Triggered SMS arm, male, study participant]

> *It [device] reminds me and keeps well my pills I make sure I open it to take my pills because I don't want*

> *you to catch me...I mean I don't want you people to know that I don't take my pills and I get problems with you.* [Scheduled SMS arm, female, study participant]

Participants found the SMS reminders useful in helping them to take their medications on time. SMS reminders addressed forgetfulness to take medications as prescribed, which was a commonly reported problem among study participants who had busy schedules.

Study participants were also more likely to forget taking medication on time while initiating ART as they were not yet used to the medication-taking routine:

> *It was actually in November I had totally forgotten and was on my bed about to fall asleep and I received an SMS on my phone and I got out of bed quickly looked for water and swallowed.* [Triggered SMS arm, female, study participant]

Some participants thought the SMS notifications sent to their social supporters after missed doses were useful. These participants felt motivated to take their medication after social supporters had contacted them to find out why they had not taken their medication on time:

> *I also like it [SMS notification] because when I have many people reminding me it gives great strength. My sister calls me when she receives an SMS reminder and asks why I didn't swallow.* [Triggered SMS arm, female, study participant]

There were some cases of improved relationships between participants and social supporters as a result of participating in the study. These improvements were manifested as more frequent phones calls and in-person visits and expansion of social support networks to include friends of the social supporters. One study participant stated:

> *It [our relationship] has also greatly improved because now she calls me many times to remind me to swallow my pills and sometimes she visits me. Asks me how am using my device...* [Triggered SMS arm, female, study participant]

Social supporters also liked SMS notifications because they reminded them to support the participants in taking their medications. The SMS notifications were especially helpful for participants who often forgot to take their medication or who did not like taking the medication. Receiving SMS notifications was perceived as another helping hand to make participants more committed to taking their medication on time. One social supporter stated:

> *I like the fact that they [SMS notifications] remind us to remind her about her medications. Because I know that by the time I get this message, she has not opened that bottle and I need to find out why and address it. It's her character that she naturally dreads taking medications and having these reminders and someone to remind her is very important and a very good thought from your end...I know it has helped a lot especially knowing that someone else will be told if she doesn't take her medications on time...She doesn't want to disappoint us even after we have united to help her in any possible way.* [Female, social supporter, study participant's sister]

In cases of insufficient resources, however, social supporters could not always help participants take their medicine even after receiving the SMS notifications:

> *The only problem was that he finished his pills and did not have transport back...I could have sent him transport but that time I was so broke, the landlord was on my case, I did not have even enough food in the house.* [Female, social supporter—study participant's wife]

Effort Expectancy or Peceived Ease of Use

Following study participants' initial orientation to using the electronic adherence monitor, they found it easy to use in taking their medication:

> *It was very easy in opening it, moving with it, it was comfortable. It was easy to carry it. Charging it was very easy too. It would contain pills to push me for some good time...* [Control arm, female, study participant]

However, some participants expressed concerns about the long time required for the solar charger to fully charge the battery, especially in periods of rain when little sun was available. Some required additional training on how exactly to charge the device, whereas others were concerned about the inability of the adherence monitor to show battery levels, which created difficulties in knowing when to charge it. One participant stated:

> *The only complaint I have about this device is its inability to show its battery charging levels. I cannot tell whether the battery is full or empty.* [Triggered SMS arm, male, study participant]

Study participants reported no challenges in reading and responding to SMS reminders. Some particularly liked receiving messages in their local language (80% of reminders were in Runyankole, whereas 20% were in English):

> *I thought the SMS reminder would be in English so I wouldn't understand them but they came in my local language so I felt happy and I can't forget this SMS reminder.* [Scheduled SMS arm, female study participant]

Social supporters found it easy to act upon SMS notifications if they were related to participants, lived with participants or near participants' homes or workplace, or had some tangible support to provide. One social supporter stated:

> *There are times when she asks for some support but I fail to help her...Like in giving her good food. When a person is sick, they need to feed well. There are also some tasks that are tiring like fetching water as we get it from far.*
>
> *I know she would want to get the water brought closer to her but I sometimes cannot help her. I would need to fetch the water for her or get her someone to help her fetch the water but it is expensive to pay for this.*

> *So there are such things that you know she needs help with but I am not able to help.* [Male, social supporter—study participant's husband]

Social Norms: HIV Status Disclosure and Stigma

Study participants stated that use of the monitoring device influenced disclosure of their HIV status to the community. For some, the adherence monitor assisted with disclosure that would potentially generate social support to help them cope with having HIV.

The monitor, especially its blinking, attracted people's attention, which became the basis for disclosing HIV status. One study participant stated:

> *They saw it blinking and asked me what it was...I told them it is a bottle where I keep my medicine. And when they asked about which medicine, I told them that I was HIV positive...I thought it was not wise for me to hide my HIV status from my relatives since they had seen my bottle and had also seen me taking the medicine. I might get sick and ask them to help me get the medicine from the bottle. When they do not know the use of the bottle, they will say that we asked you what the bottle was for and you ignored us so why are you bothering us now.* [Scheduled SMS arm, female, study participant]

However, some study participants were uncomfortable traveling with the monitor or keeping it where other people could see it, for fear of HIV status disclosure, which resulted in stigma and discrimination:

> *I had gone to the village and hadn't gone with it [device] because I didn't want people in my village to see it. Thieves broke in my house and stole everything including the device. Later my things were retrieved and people opened it and saw that there were pills for ART so they got surprised and got to know that I was positiveI got ashamed and got it [device] from them but of course some keep talking about me and some felt sorry for me but I just left them had nothing to do for them.* [Triggered SMS arm, male, study participant]

Some participants also reported concerns about potential unintended HIV status disclosure through other people seeing the SMS reminders. To address these concerns, participants preferred keeping their SMS reminders private; they liked SMS reminders that would not directly link them to HIV. Greeting-related SMS reminders were preferred to general SMS messages as they would not easily raise concern if seen by someone else. One study participant stated the following:

> *I decided on a message ["wasiboota" or how was your day] that would not easily connect me to the clinic and my HIV status. Even when you are with people and this message comes, you do not even try to hide the message because someone who sees the message will straight away know someone who cares about you is just greeting you. But if you received a message reminder like "mira emibaazi yawe" (meaning take your medicines), someone might ask you which medicines you are going to take and there, they might know that you are sick or start asking you all sorts of questions.* [Triggered SMS arm, male, study participant]

Even with indirect SMS reminders, participants cited instances where regularly receiving such reminders raised some concern:

> *I had gone to visit at a friend's place and I had spent there like a week. Remember I go with my bottle hiding it such that he does not see it. But he read it and said, "[name], who is this person who is always sending you this kind of message ['obutumwa bwawe' meaning 'this is your message']?" I told him it is my sister who is always greeting me, but I could tell he was not convinced...* [Scheduled SMS arm, female, study participant]

To avoid possibilities of HIV status disclosure and its associated stigma, participants preferred having SMS notifications sent to social supporters who they trusted:

> *I choose my husband because other people normally talk about other peoples' HIV status if they get to know it...If you send the messages to my husband, he reads them and tells me. But other people might start telling the whole village how I am sick and I do not like it. That is why I chose only my husband because he keeps my HIV status a secret.* [Scheduled SMS arm, female, study participant]

Social supporters who lived in the same home with participants were considered to be more helpful in keeping their secrets than those that stayed elsewhere and in reminding participants to take their medications:

> *It is good when you are staying with the person and not like neighbors or people from far. You know someone that stays with you is more likely to be very helpful in reminding you to take your medicine. They also keep your secrets well compared to someone who stays far. At times when they [outsiders] get the message, they might be tempted to talk about you or not even remind you as expected...* [Scheduled SMS arm, female, study participant]

Facilitating Conditions

Participants generally liked the appearance and form of the adherence monitor, which motivated them to use it. Specifically, they liked the monitor's small, portable size that accommodated all of their pills, compared with the standard clinic pill bottles that necessitated participants to carry more than one bottle when traveling. They also liked the monitor's black color, cell phone–like shape, and absence of HIV-related labels that could link them to HIV. Additionally, study participants stated that monitor's hard outer and inside covers kept drugs safe and clean and did not make noise compared with the standard clinic pill bottles:

> *The white one [bottle] makes noise when one is removing the pills but this one doesn't make noise...* [Scheduled SMS arm, male, study participant]

> *This device keeps my HIV status private and there is nothing written on it compared to the bottles I pick from the clinic...* [Triggered SMS arm, female, study participant]

Conditions that facilitated the use of the intervention include the monitor's extended battery life and the availability of mobile network. One study participant stated the following:

> *The network was always ok. There is network here so I haven't found any challenge with it.* [Control arm, female, study participant]

Supplementing solar chargers with electric chargers facilitated the use of the intervention for those with access to electrical outlets, because electric chargers enabled charging the adherence monitor indoors, thus reducing the possibility of unintended HIV status disclosure. One study participant said:

> *There is when you brought me an electric charger I was so happy because I stay in very busy place so charging using solar would have caused them to suspect something or even steal the solar panel. So I thank you for that.* [Triggered SMS arm, female, study participant]

Participants also reported several conditions that hindered the use of the SMS reminders. For example, sharing cell phones with others hampered the intervention, even though personal cell phone ownership was an inclusion criterion for the study. One study participant stated:

> *He [my husband] has been with the phone like for 2 weeks. So I have not seen the messages that have been sent to my phone during the time my husband had the phone.* [Scheduled SMS arm, female, study participant]

Additionally, some cases of phone malfunctioning constrained the receipt of some SMS reminders, and concerns were raised about not receiving SMS reminders when the phones were off or not charged or in cases of lost phones:

> *Yes [I received the SMS reminder] once. Just one message. That was before I lost my phone.* [Triggered SMS arm, male, study participant]

Unanticipated use of the technology limited the feasibility of the intervention in some cases. Due to lack of electricity, some participants allowed others to use the solar charger for their personal use, instead of keeping it to charge the adherence monitor:

> *My wife insisted that she needed to use it [the charger] for her phone and light. We had no power at home and she was convinced the torch would help her while she wakes up to breastfeed the baby. I decided to leave it...* [Triggered SMS arm, male, study participant]

Intervention Feasibility

Data transmission generally worked well with 89% of data transmitted after a delay of 0 to 5 min. Nine percent of the device-opening data was transmitted after device signal delays of ≥60 min (because of unreliable network), which resulted in unnecessary transmission of SMS reminders. Other feasibility issues are summarized in Table 2.

Additionally, qualitative interviews revealed the following data on intervention feasibility:

Using the Monitor Pills Other Than Antiretroviral Therapy

There was an incidence where a participant used the adherence monitor for taking a prophylactic antibiotic (septrin or trimethoprim-sulfamethoxazole) rather than the intended ART. Using the monitor for other pills in this way interferes with the feasibility of the intervention, as use of ART was assumed by study staff. One study participant stated:

> *From the container [device], they [septrin] were in the paper and when ARVs got finished I put septrin in the device...* [Triggered SMS arm, interview 2, male, study participant]

Table 2. Technical feasibility of the electronic adherence monitor.

Issue	Comments
Device malfunction	3 (2%) out of 63 devices malfunctioned and were replaced: one of the devices was damaged by the participant, while the remaining had technical faults.
Data loss	191.6 (3%, 191.6/8365) of data were lost because of technical issues with the adherence monitors.
Device battery changes	Although all study participants had a solar charger and 13 had electric chargers, study staff completed 22 battery changes because of (1) poor mobile network that resulted in repeated attempts to transmit the data, which depleted the battery before its anticipated charging time; and/or (2) inability or failure of the participants to charge the batteries as requested.
Lost to follow-up	One participant was lost to follow-up because of a nonfunctioning phone number.
Change of phone numbers	Five participants changed their phone numbers
SMS[a] reminders not sent	44 (1%) of SMS reminders were not sent because of technical challenges such as poor network coverage
Number of messages sent unnecessarily	1935 (36%) SMS reminders were sent unnecessarily. In these cases, the electronic adherence monitor was opened to take medication, but poor mobile network coverage resulted in a delay or absence of the signals.

[a]SMS: short message service.

Taking Pills From Another Source

Some participants at times took pills from a different source rather than the real-time adherence monitor (ie, they put multiple pills in their pocket or used another bottle for later dosing), again limiting the feasibility of the intervention. In most cases, participants were attempting to avoid possibilities of unintended HIV status disclosure, especially when traveling:

> *I went to Kampala and spent there a few days but I did not take the device. I just packed a few pills and left with them...I went home to find my wife had already packed the drugs for me. She put in an envelope and then folded it to fit in my trouser pockets...Yes, I do not like moving with any luggage and then if the device would fit in my trouser, I could go with it but it cannot even fit there well because my trouser would bulge. And again if I took it, everyone would see it and maybe open it to realize that I am sick and taking my medicine...* [Triggered SMS arm, male, study participant]

Opening the Real-Time Adherence Monitor Without Taking Pills

Some participants reported that their monitors were opened by other people. One opening was the result of a participant's child's inquisitiveness, whereas another participant's social supporter would routinely open the monitor to verify the participant's claim of having taken the pill. One study participant stated:

> *There are times when it [SMS reminder] comes after I have taken my drugs and even gone to sleep. Those are the times when [name of social supporter] tells me that he has have received the message and he asks me whether I have taken my drugs and I tell him that I have...He goes to check on the device to see if the drugs are there to confirm that I have taken...* [Triggered SMS arm, interview 1, female, study participant]

Discussion

Principal Findings

Drawing from the UTAUT model, we found that a real-time adherence monitoring intervention linked to SMS reminders and notifications is largely acceptable and feasible for supporting ART medication in rural southwestern Uganda. Overall, the key factor for acceptability appeared to be perceived usefulness; although the electronic adherence monitor was only initially intended to monitor adherence, it was also beneficial in creating a sense of being "cared for" and a sense of fear of "being caught" not adhering, both of which inspired participants to take medications to maintain their ongoing relationships with the study staff. SMS text messages not only reminded patients to take medication in time but also enabled social supporters to provide medication-taking-related support. Reminding participants to take medication was important given that participants were newly initiating ART and were likely unfamiliar with the required regularities of taking this medication. Reminders significantly improved study participants' medication adherence [17], which helped some develop a habit of medication adherence [22]. SMS text messages have previously been reported to be acceptable among youth living with HIV in central Uganda [7], although this acceptability did not translate into improved medication adherence [27].

SMS notifications to social supporters were also perceived as useful; for example, they triggered social support and improved relationships between social supporters and patients. However, many did not result in participants getting medication-taking assistance. As reported previously, social supporters who were in good relationships with study participants, had enough resources, and lived with or near study participants were more helpful [24]. Training social supporters about the importance of medication adherence, as well as orienting them on how to assist participants with taking their medications, may improve the acceptability and feasibility of social support notifications.

Although acceptability was largely high, concerns about possibilities of HIV status disclosure and stigma or discrimination led to nonuse of the monitor by some participants who opted to take medication from different sources other than the monitor.

Concerns of monitor-related unwanted disclosure have been previously reported in China [2], whereas HIV status disclosure resulting from other people accessing SMS reminders have been reported by youth in Uganda [7]. Privacy and confidentiality remain key issues that can affect the acceptability of electronic adherence monitors [28]. In Uganda, this is accelarated by the prevailing stigma, discrimination, negative attitudes, and mistreatment of PLWHA [29]. HIV-related stigma is known to negatively impact medication adherence as it can limit social support and coping strategies [30]. Measures undertaken by our study to reduce the possibility of unintended HIV status disclosure included using SMS reminder text messages that could not easily be linked to HIV, emphasizing personal phone ownership rather than shared phones, and suggesting that study participants select social supporters who they trust and who already knew the participant's HIV status. It is worth noting that intervention-facilitated disclosure was not entirely negative. For example, some participants who had challenges disclosing their status used the adherence monitor to disclose their HIV status to their potential social supporters.

Our results generally indicate that the intervention is technically feasible in Uganda as malfunctioning was rare. Data were obtained from most participants as expected most of the time. The fact that all participants per enrollment criteria owned personal phones, had the ability to read SMS text message reminders, and had reliable mobile network may have been contributory. The widespread adoption of cell phones and the adequate mobile network in most parts of Uganda [31] facilitates feasibility of mHealth interventions.

By leveraging the existing mobile phone infrastructure, this intervention can potentially overcome some of the barriers to medication adherence, while at the same time empowering patients to take active roles in their own health. However, variations among different populations may influence feasibility. In a survey of phone ownership in Africa, 93% of Ugandans

with at least a secondary education own a cell phone, compared with 61% of those with less education [5]. In our study, 63% (123/195) of the potential participants screened had personal cell phones with adequate mobile networks, while 97% (61/63) could read English or the local language (Runyankole). Wider implementation of this intervention in less educated or resourced populations may yield differing feasibility results.

Despite the general feasibility of the intervention, challenges with access to electricity, lack of technical function when the devices are not charged, inability to charge the monitor, and the monitor's inability to show battery level could limit the impact of the intervention. The reported use of the solar panel to provide light for the family instead of charging the monitor shows the complexity of introducing electronic monitors in resource-limited settings. In Uganda, many people in rural areas still lack access to electricity [32].

Other challenges included shared phone ownership, as well as the potential for disclosure or theft with the solar chargers that had to be charged from outside the house. Providing more training on charging the monitor, incorporating a component of showing battery levels on the monitor, and use of solar chargers could help users promptly comply with its charging demands.

Although reported by a minority of participants, monitor openings because of curiosity and use of the device for other medications could result in misclassification of adherence. Some of this bias can be reduced in analyzing the adherence data (eg, censoring more openings than would be expected per day).

Additionally, complementing adherence monitoring with assessment of biological indicators (such as viral loads), as done in this study [17], can improve the interpretation of adherence reports generated by using the monitor.

Strengths

This analysis has a number of strengths. First, it is grounded in a well-established theory of technology acceptance—the UTAUT model. Second, it is an in-depth qualitative investigation of the experiences of study participants and their social supporters based on the state-of-art adherence measurement technology. Third, the study was conducted in a prototypical rural African setting, which has implications for similar settings, although cultural differences may have an impact on acceptability.

Limitations

However, results may have limited generalizability as they are based on a small pilot study of 63 participants over 9 months of follow-up. It is not clear how they manifest in larger, diverse contexts, with long-term follow-up. Importantly, HIV requires lifelong treatment.

Implications

A number of important implications for further use and development of this type of intervention arise from this study. First, the possibility of dependence on the intervention and its potential consequences on adherence after the withdrawal of the intervention warrants further investigation. We are currently carrying out a follow-up study to explore how these participants feel about the lack of the intervention and how they adhere to their ART after withdrawing the intervention.

Second, concerns of unwanted HIV status disclosure could potentially be further minimized by extending the use of the monitor in other diseases (especially nonstigmatized conditions such as hypertension), so that it is not associated with HIV. Other means for protecting against disclosure include using password-protected phones and training social supporters about the need to maintain patients' privacy.

Additionally, although costing was not addressed in this study, it is clearly important, especially in resource-limited settings. Each real-time adherence monitor costs about US $130, which is expensive for most low-resource countries. This cost may be reduced if the adherence monitors are developed and maintained by local capacity and produced in large quantities. A recent cost-effectiveness analysis indicated that this type of monitoring would be cost-effective at <US $50, thus marking a target for device development [33].

Conclusion

In conclusion, we found that real-time adherence monitoring, SMS text message reminders, and notifications to support ART medication adherence were largely acceptable based primarily on perceived utility and feasible in a research context within a low-resourced setting. Future efforts should focus on optimized device design, user training to overcome the challenges we encountered, cost-effectiveness studies, as well as studying the monitoring aspect of the device without accompanying interventions.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 112KB - mhealth_v6i5e122_app1.pdf]

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Abbreviations

ART: antiretroviral therapy
GPRS: General Packet Radio Service
MRRH: Mbarara Regional Referral Hospital
PLWHA: people living with HIV or AIDS
RCT: randomized controlled trial
SMS: short message service
UTAUT: unified theory of acceptance and use of technology

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Original Paper

Identifying Medication Management Smartphone App Features Suitable for Young Adults With Developmental Disabilities: Delphi Consensus Study

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Abstract

Background: Smartphone apps can be a tool to facilitate independent medication management among persons with developmental disabilities. At present, multiple medication management apps exist in the market, but only 1 has been specifically designed for persons with developmental disabilities. Before initiating further app development targeting this population, input from stakeholders including persons with developmental disabilities, caregivers, and professionals regarding the most preferred features should be obtained.

Objective: The aim of this study was to identify medication management app features that are suitable to promote independence in the medication management process by young adults with developmental disabilities using a Delphi consensus method.

Methods: A compilation of medication management app features was performed by searching the iTunes App Store, United States, in February 2016, using the following terms: adherence, medication, medication management, medication list, and medication reminder. After identifying features within the retrieved apps, a final list of 42 features grouped into 4 modules (medication list, medication reminder, medication administration record, and additional features) was included in a questionnaire for expert consensus rating. A total of 52 experts in developmental disabilities, including persons with developmental disabilities, caregivers, and professionals, were invited to participate in a 3-round Delphi technique. The purpose was to obtain consensus on features that are preferred and suitable to promote independence in the medication management process among persons with developmental disabilities. Consensus for the first, second, and third rounds was defined as ≥90%, ≥80%, and ≥75% agreement, respectively.

Results: A total of 75 responses were received over the 3 Delphi rounds—30 in the first round, 24 in the second round, and 21 in the third round. At the end of the third round, cumulative consensus was achieved for 60% (12/20) items in the medication list module, 100% (3/3) in the medication reminder module, 67% (2/3) in the medication administration record module, and 63% (10/16) in the additional features module. In addition to the medication list, medication reminder, and medication administration record features, experts selected the following top 3 most important additional features: automatic refills through pharmacies; ability to share medication information from the app with providers; and ability to share medication information from the app with family, friends, and caregivers. The top 3 least important features included a link to an official drug information source, privacy settings and password protection, and prescription refill reminders.

Conclusions: Although several mobile apps for medication management exist, few are specifically designed to support persons with developmental disabilities in the complex medication management process. Of the 42 different features assessed, 64% (27/42) achieved consensus for inclusion in a future medication management app. This study provides information on the features of a medication management app that are most important to persons with developmental disabilities, caregivers, and professionals.

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KEYWORDS

developmental disabilities; intellectual disability; mobile applications; self-management; telemedicine; young adult

Introduction

Background

Developmental disabilities (DDs) is a term encompassing a range of disorders that are usually present at birth, last throughout the life span, and negatively affect the course of development of an individual at physical, intellectual, or emotional levels [1]. In the United States, the prevalence of any DD among children aged 3 to 17 years increased from 5.8% to 7.0% between 2014 to 2016 [2]. With improved life expectancy [3], adolescents and adults who have DDs naturally develop several chronic comorbidities over time [4], in addition to those intrinsically associated with their disability. People who have DDs are 2.5 times more likely to develop health problems, particularly neurological and psychological, compared with those who do not have a disability [5]. The increased risk for health problems has been verified from a young age, with adolescents who have disabilities displaying an increased risk to develop cardio-metabolic syndrome, cardiovascular disease, osteoporosis, and malignant diseases compared with their counterparts without a disability [6].

As a result of a high burden of diseases [7-9], polypharmacy, whose definition may vary across studies but most frequently denotes the use of 5 or more medications [10], is frequent among this population [11-14] and nonadherence can be an issue [15]. A study in primary care in the Netherlands revealed that 75% of people with DDs received medication compared with 59% individuals in the matched control group [16]. Data from Australia showed that polypharmacy (use of 5 or more medications) was highly prevalent and increased with age, affecting over 50% of individuals with a disability in the age group of 40 to 59 years [14]. Psychotropic medications are the most commonly prescribed class of drugs with reported use of over one-third of subjects enrolled in 2 different studies [5,13]. Despite high health care needs in this population, significant disparities in health and medical care utilization have consistently been reported [17,18].

Persons with DDs may live with their family (71%) or in a group home (13%) and often rely on caregivers for the performance of instrumental activities of daily living [19]. One such activity is medication management which involves several steps, including obtaining prescriptions from a physician, acquiring medications from a pharmacy, storing/taking/administering medications, monitoring for adverse and intended effects, and refilling medications [20]. Caregivers, with a range of medical knowledge and education levels, are usually required to be involved in each step of the medication use process [21], often encountering challenges in this multistep process [20]. Over the last decade, more emphasis has been placed on increasing the autonomy of people who have DDs, but the literature suggests that there is still considerable work to be done [22].

Technology is on the rise as a tool to promote independence in many areas including mobility, hearing and vision, communication, independent living, and computer use [23]. Existing and new technology can be used to empower persons with DDs to manage their own health issues during the transition to young adulthood [24]. The use of smartphone apps can be one strategy to support young adults who are transitioning to a state of independence to manage medications on their own. A 2016 survey assessing smartphone use among persons with DDs revealed that little difference in ownership rates between this population and the general population existed and that the use of smartphones for text messaging, emailing, using the Internet and social media, and using mobile apps increased among both groups [25].

Medication Management Apps

At present, there are hundreds of medication management apps in the market, some designed to manage all medications [26] and others targeting specific disease states [27-32]. Medication management apps in the first group most often comprise basic features including keeping a medication list and sending reminders for medication taking, and less frequently, more advanced features such as the ability to track missed doses, exporting data for provider analysis, refill reminders, or managing multiple patient profiles [26,33]. Apps in the second group usually include features to monitor specific self-management activities or clinical parameters that are characteristic of different disease states [27]. Even though the evidence linking the use of apps to outcomes is sparse, 1 study showed that the use of an app positively impacted glycemic control and self-management in patients with diabetes [34].

With regard to apps specifically targeting persons with a DD, Dicianno and colleagues [35-37] developed an integrated system to support self-management of several health-related activities among individuals with spina bifida [38], which showed improvements in self-management abilities [35]. The interactive Mobile Health and Rehabilitation (iMHere) system comprises 6 smartphone modules providing reminders to individuals to take their medications, perform their catheterization and bowel management programs, examine their skin, complete a survey assessing depressive symptoms, and send and receive messages to and from the clinician. The medications (MyMeds) module, in addition to sending reminders, includes a list of all the medications taken by the user along with a photo and description, tracks whether medications were taken in response

to reminders sent, and includes the pharmacy contact information to facilitate refill requests [38]. The iMHere system has 2-way communication between patients and providers and allows providers to remotely monitor adherence or address any problems related with medication management via a secure portal based on information provided by the user. Patient-centered technologic support such as iMHere is critical to support persons with DDs in every step of the medication management process.

Objectives

Previous assessments of medication management apps highlighted their low quality [31,33,39] and showed that not a single app combines all the desirable features [33]. Before initiating any app development process, input from stakeholders including persons with DDs, caregivers, and professionals regarding the most preferred features for this population should be obtained. Therefore, the aim of this study was to identify medication management app features that are suitable to promote independence in the medication management process by young adults who have DDs using a Delphi consensus method.

Methods

Development of the Initial Questionnaire

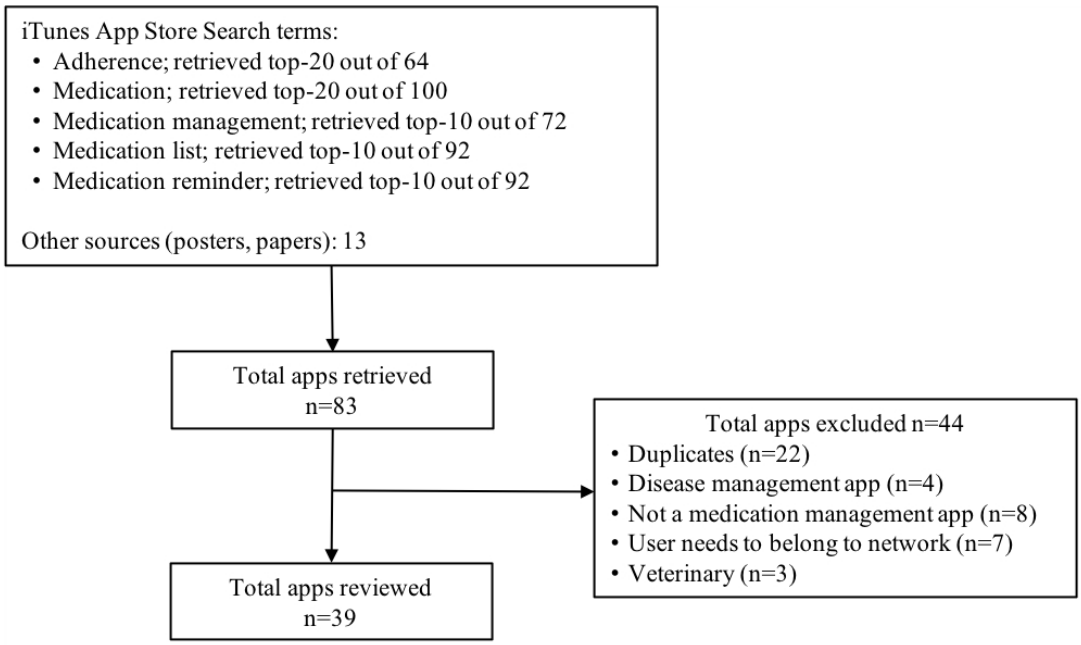
To identify medication management app features to be included in the Delphi questionnaire, a sample of medication management apps was reviewed. The works by Haase et al [40], Dinh et al [41], and Heldenbrand et al [42] served as a starting point to identify medication management app features. Furthermore, an apps search was conducted in Apple's iTunes App Store, United States, in February 2016 to identify other relevant features using the following terms: adherence, medication, medication management, medication list, and medication reminder. Duplicate apps identified from the different search strategies were eliminated. Apps were included if they had any of the following features: medication list, dose reminders, dose documentation, or refill-assistance mechanisms. Apps designed for disease management but that did not include any features related with the medication management process were excluded. A subset of apps of each search strategy employed was reviewed, with a total of 39 apps ultimately being reviewed, to identify a list of app features (Figure 1).

Features of the apps reviewed were identified and summarized by 2 independent researchers (AF and TMS) based on the description included in the App Store and personal experience with the app after downloading and exploring its content and features. The common features identified across the apps, and that served as the basis for the questionnaire development, included the following: medication list, medication reminder, and medication administration report (including recording of medication taking). Additional features identified across the apps included prescription refill reminders; automatic pharmacy refill mechanisms; barcode scan to enter medications; use of a drug directory to enter new medications; ability to take a picture of the pill being added; indication of missed doses; overdose warnings; link to an official drug information source providing information about the disease and the medication; ability to export a file with medication taking data; record of vital signs home monitoring (eg, blood pressure, blood glucose); record of side effects; record of drug allergies; drug interaction checker; scan health documents and upload them to the app; ability to share medication information through the app (family, caregiver, health care provider); notification of caregiver if drug not taken; emergency contacts list; doctor name; doctor appointment reminder; pharmacy name; pharmacy locator; and gamification with rewards for users who adhere to their medication.

After identifying the list of medication app features, the research team evaluated and weighed the inclusion of each of these features in the final questionnaire, as well as the flow, organization, and format of the questions. The final version of the questionnaire (Multimedia Appendix 1) was organized into 4 modules that included (1) the medication list, (2) the medication reminder, (3) the medication administration record, and (4) additional features. Screenshots were selected from existing apps and chosen to illustrate different information presentation formats in the medication list, medication reminder, and medication administration record features. Experts were asked to rank 4 different screenshots per module, from most preferred to least preferred, based on design and visual appeal of the medication list, medication reminder, and medication administration record features. The answer format was a drag-and-drop list. Experts were then asked to rank the importance or essentiality of various specific features within the medication list, the medication reminder, and the medication administration record on a Likert scale (not important or not essential, less important or less essential, important or essential, and very important or very essential). For example, experts were asked to rank the importance of including specific medication, prescription, and pharmacy and prescriber information in the medication list feature. Module 4 presented a list of additional features identified from the reviewed apps and asked experts to rank their importance or essentiality on the same Likert scale. Furthermore, participants were asked to select the 3 most important and 3 least important additional features for inclusion in an app specifically designed for this population. The final portion of each of the 4 modules asked experts to provide comments on the features presented or suggest additional features not included in the initial questionnaire (free text response).

Before recruitment was initiated, the questionnaire was piloted with 3 individuals not directly associated with the research who provided feedback about the clarity of the wording and instructions, the answering format, and the flow of the questions in a *think aloud* fashion. The survey took about 15 min to complete.

Figure 1. Flowchart of app search strategy and retrieval.



Selection and Recruitment of the Delphi Panel

A 3-round Delphi technique was used to gather consensus about medication management app features that would be suitable to assist young adults with DDs to independently manage their medications. The Delphi method utilizes a panel of experts in a field to establish consensus regarding a certain topic, with the ideal number of experts being between 15 and 30 [43]. In this study, a convenience sample of experts including persons with a DD, caregivers, researchers, and professionals who were familiar with the challenges and needs of persons with DDs was gathered to provide their insight on the best features to include in a future app designed specifically for this population and their caregivers. Experts were recruited from 2 sources: (1) the United Cerebral Palsy of Detroit Assistive Technology conference that took place in Detroit (MI) in May 2016 (n=25) and (2) the Technology Increasing knowledge: Technology Optimizing Choice (TIKTOC) Rehabilitation Engineering Research Center (RERC) Advisory Board and their mailing list (n=27). TIKTOC is a collaboration of clinicians and researchers at the University of Michigan whose mission is to develop and implement technology to optimize and support the self-management of personal health care and independence of individuals with physical, cognitive, and neuro DDs. Attendees of the United Cerebral Palsy of Detroit Assistive Technology conference provided their names and email addresses voluntarily to be part of the Delphi panel.

Experts were invited via an email, which included a link to the anonymous questionnaire on Qualtrics. The invitation encouraged experts to participate in all 3 rounds; however, they were not excluded from participating in a round if they missed the previous round(s). Participants were also able to make comments and suggest additional features which were reviewed by the research team at the end of each round, with relevant items being included in subsequent rounds. Each Delphi round lasted 1 week and, in-between rounds, we allowed 1 week before rolling out the following round to minimize respondent fatigue. The first round occurred between July 14 to 22, 2016; the second between July 28 to Aug 4, 2016; and the third between Aug 12 to 19, 2016. E-mail reminders were sent 3 days before the closing of each round to increase response rates. The process ensured anonymity of respondents at each round, and the number of individuals responding per round was noted. This study was approved as exempt by the University of Michigan Institutional Review Board (HUM00113908).

Consensus Criteria and Data Analyses

Consensus criteria were established based on a progressive filtering process, with higher consensus requirements for the first Delphi round and progressively lower consensus for subsequent rounds—≥90%, ≥80%, and ≥75% agreement for the first, second, and third rounds, respectively. Items achieving consensus in each round were removed from the following rounds and not scored again.

For the screenshot ranking-type questions, consensus was calculated by assigning each screenshot a scaled score based on whether it was chosen as the first, second, third, or fourth option. Specifically, for a given screenshot option, we multiplied the number of experts by 1, 2, 3, or 4 (1=most preferred, 4=least preferred) according to how screenshots were ranked, creating a score for each screenshot. Lower scores indicated higher preference for a screenshot based on design and visual appeal.

For the Likert scale-type questions, consensus was calculated based on the percentage of positive versus negative responses for each feature, with positive being the sum of the percentage of experts that selected both important and very important or essential and very essential and negative being the sum of the percentage of experts that selected both not important and less important or not essential and less essential.

Descriptive statistics (percentages) were calculated to rate consensus obtained for each feature in the 3 Delphi rounds and

to determine the 3 most and 3 least important additional features that should and should not, respectively, be included in a future app.

Results

A total of 75 responses were received over the 3 Delphi rounds—30 in the first, 24 in the second, and 21 in the third round. Similar proportions of persons with disabilities and caregivers participated in the study, but most respondents were either researchers or professionals with an interest in DDs. Most respondents were female, with extensive experience and knowledge regarding DDs. Additional respondent characteristics are outlined in Table 1.

Table 1. Characteristics of respondents of each of the 3 Delphi rounds.

Demographic characteristic	Round 1 (n=30)	Round 2 (n=24)	Round 3 (n=21)
Age (years)			
Mean (SD)	52.6 (17.1)	49.1 (18.8)	53.4 (19.6)
Missing responses, n	10	7	9
Gender			
Female, n (%)	13 (59)	9 (50)	10 (77)
Missing responses, n	8	6	8
Role[a]			
Person with a disability, n (%)	4 (17)	3 (16)	1 (7)
Family caregiver for a person with a disability, n (%)	4 (17)	3 (16)	0
Researcher with an interest in DDs[b], n (%)	10 (44)	8 (42)	6 (43)
Professional with an interest in DDs, n (%)	13 (57)	11 (58)	8 (57)
Other, n (%)	2 (9)	1 (5)	1 (7)
Missing responses, n	7	5	7
Level of experience and knowledge regarding persons with disabilities			
Extensive, n (%)	14 (61)	11 (58)	8 (57)
Some, n (%)	8 (35)	6 (32)	3 (21)
Limited, n (%)	1 (4.3)	2 (11)	3 (21)
Missing responses, n	7	5	7
Disabilities individuals had direct experience with[a]			
Autism spectrum disorders, n (%)	12 (55)	11 (65)	6 (46)
Cerebral palsy, n (%)	16 (73)	12 (71)	8 (62)
Down syndrome, n (%)	13 (60)	11 (65)	5 (39)
Fetal alcohol syndrome, n (%)	8 (36)	5 (29)	2 (15)
Fragile X, n (%)	5 (23)	4 (24)	2 (15)
Prader-Willi syndrome, n (%)	8 (36)	2 (12)	2 (15)
Spina bifida	10 (46)	6 (35)	5 (39)
Spinal cord injury, n (%)	14 (64)	14 (82)	9 (69)
Williams syndrome, n (%)	6 (27)	3 (18)	2 (15)
Other[c], n (%)	11 (50)	6 (35)	3 (23)
Missing responses, n	8	7	8

[a]Sum is >100% because participants selected more than 1 option.

[b]DDs: developmental disabilities.

[c]Includes amyotrophic lateral sclerosis, brachial plexus injury, brain injury (traumatic and acquired), Charcot-Marie-Tooth disease, dyslexia, mechanically ventilated patients, muscular dystrophy, other cognitive impairments, other genetic syndromes, Parkinson disease, and sensory-learning-injury.

Module 1: Medication List

Of the 4 screenshots presenting different designs for the medication list, option B (133 points) was the most preferred among experts, but no consensus was achieved as to the best way to present the information. The distribution of experts selecting options C (145 points), D (146 points), and A (166 points) was very similar (Figure 2).

Of the 20 items assessed to be incorporated in the medication list feature of a medication management app, consensus was achieved for 12 (60%) throughout the 3 rounds (Multimedia Appendix 2). In the first round, consensus (≥90% agreement) was reached for the inclusion of instructions on how to take the medicine and quantity of the medicine to be taken. Round 2 resulted in consensus (≥80% agreement) on dosage, indication, number of prescription refills remaining, pharmacy phone number, drug directory to help populate medicines information, and scanning feature to enter medications on the list. In the third round, brand drug name, inclusion of a picture of the pill, name of the prescribing physician, and ability to upload the medication list from the pharmacy records were the items that achieved consensus (≥75% agreement; Multimedia Appendix 2).

Items suggested by participants that were included in further rounds were as follows: ability to upload a medication list from pharmacy records, which achieved consensus in round 3, and a speech-to-text feature to produce a medication list that did not achieve consensus as an essential feature.

Module 2: Medication Reminder

The design and visual appeal of option A (25 points) reached consensus among experts as the best to display medication taking reminders (Figure 3). All 3 items achieved consensus in the first round with experts agreeing that the medication reminder feature should include the options to report that the medication was taken, skipped, or postponed to be taken at another time (Multimedia Appendix 2).

Module 3: Medication Administration Record

No consensus was obtained among experts as to the best design to present the record of medication administration, but the calendar format in option D (127 points) was preferred by most respondents, followed by options B (132 points), C (143 points), and A (152 points; Figure 4).

The report format showing days missed on a monthly calendar was the only one that achieved consensus in the first round. The report format showing days missed on a daily calendar also achieved consensus in the second round, but experts did not agree that showing the percent of doses taken would be helpful for persons with DDs to track medication taking (Multimedia Appendix 2).

Module 4: Additional Features

A total of 63% (10/16) of additional features assessed reached consensus for inclusion in a medication management app. In the first round, experts agreed that the following features should be part of the app: ability to record known drug allergies, ability to share medication information from the app with providers and caregivers, emergency contact list, and prescription refill reminders (Multimedia Appendix 2). In the second round, experts agreed that ability to record side effects experienced, a drug interactions checker, and an overdose warning for maximum daily dose of *as needed* medication should be incorporated in a future app. In the third round, 2 other additional features reached consensus as highly important: automatic refill through pharmacies and doctor appointment reminders through the app. On the basis of expert feedback from previous rounds, 2 more features were included for assessment in the third round, but none achieved consensus: gaming system with rewards for adherent patients and ability to connect with peers through the app to motivate and share experiences with the app.

Figure 2. Medication list screenshots ranked from most preferred (lower score) to least preferred (higher score) based on design and visual appeal and respective scaled scores.

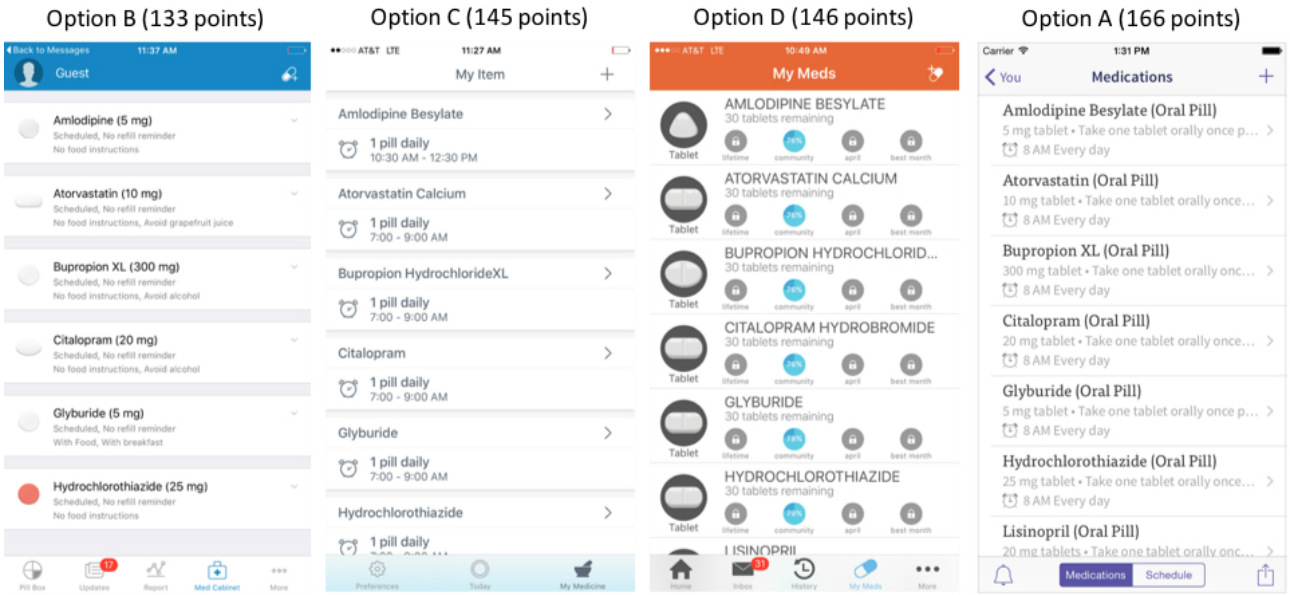


Figure 3. Medication reminder screenshots ranked from most preferred (lower score) to least preferred (higher score) based on design and visual appeal and respective scaled scores.

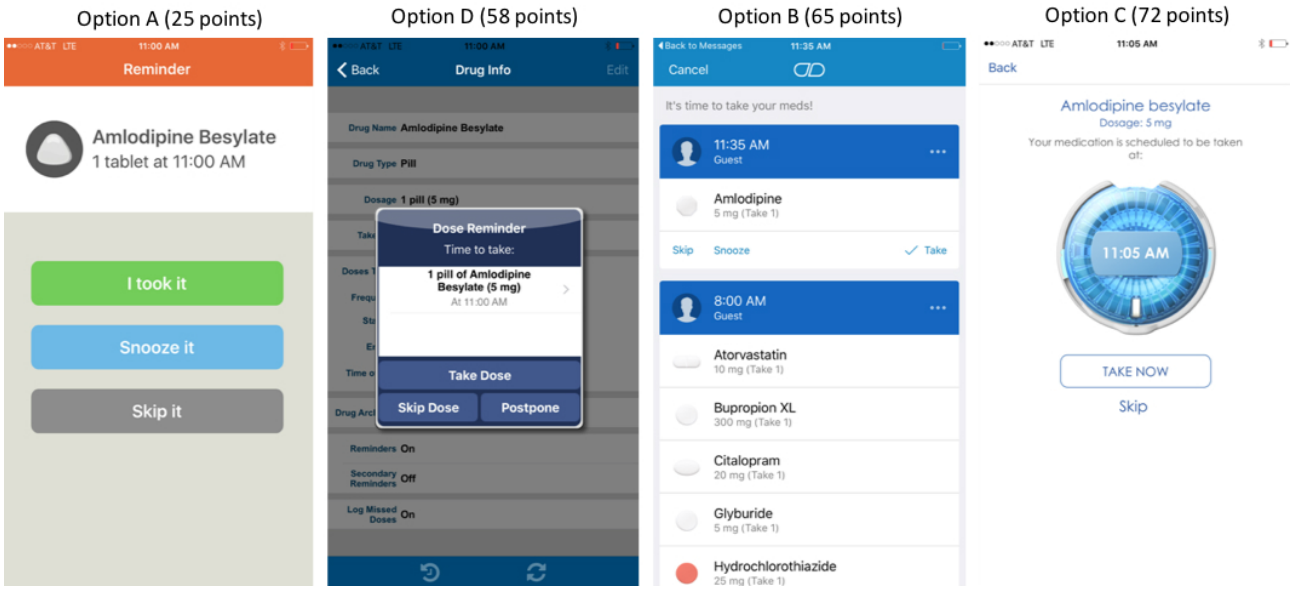
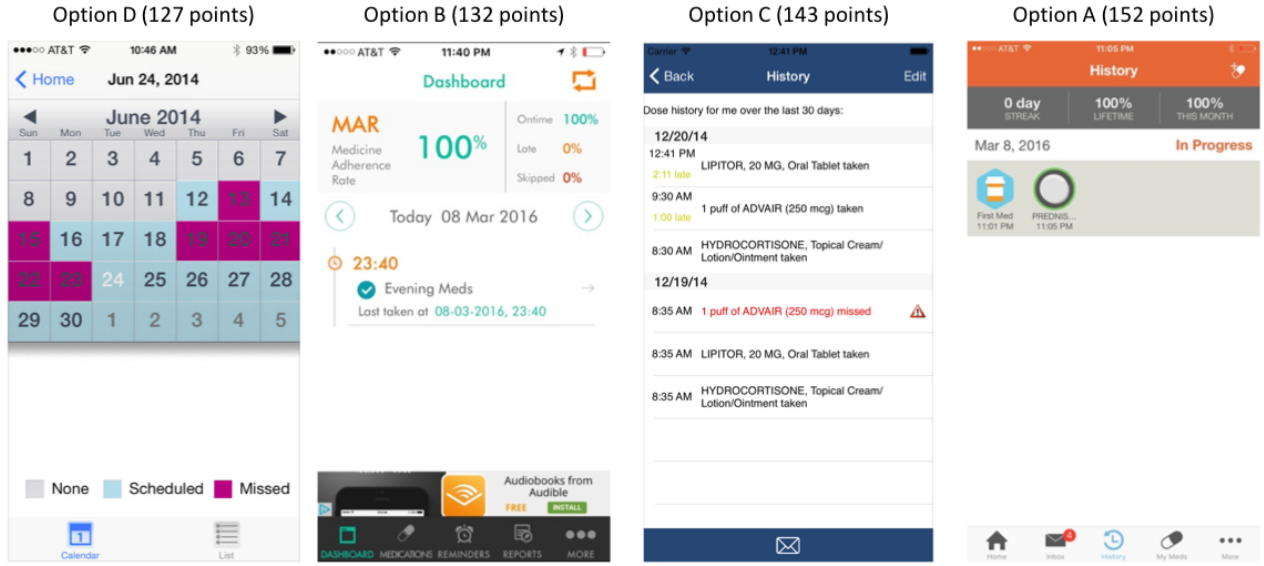


Figure 4. Medication Administration Record screenshots ranked from most preferred (lower score) to least preferred (higher score) based on design and visual appeal and respective scaled scores.



Finally, the top 3 most important additional features elected by experts were as follows: automatic refills through pharmacies; ability to share medication information from the app with providers; and ability to share medication information from the app with family, friends, and caregivers. The top 3 least important features included a link to an official drug information source, privacy settings and password protection, and prescription refill reminders.

In total, at the end of the 3 rounds, 27 of the 42 (64%) features assessed achieved consensus (Multimedia Appendix 2). For 12 out of the 27 (44%) features, unanimous concordance existed among persons with a DD or caregivers and the entire panel of experts; for 9 items (33%), concordance was above 75%; and for 6 items (22%), concordance with the panel was below 68%. The latter included dosage, indication, a report that showed days missed on a daily calendar, record/log of side effects experienced, drug interactions checker, and a picture of the pill highlighting any markings it may have.

The summary of items achieving consensus, and respective percent agreement, in each of the 3 rounds is presented in Multimedia Appendix 3.

Comments From Experts

Overall, comments reflected the importance of apps to be simple, easy to use, customizable, and not overbearing in the amount of information they contain. There should be a balance between including options for individuals to personalize the app to their needs and including only those most important features to achieve the goal of improved adherence and greater independence for young adults with DDs. Respondents suggested that the app included different information depending on whether the user was a caregiver or a person with a DD, with

more complex information being available to the previous and simpler and supportive information for self-management provided to the latter. Additionally, the app should have a system to assess the severity of side effects, provide decision support on how to manage side effects, and follow-up for evaluation.

Within the medication list feature, experts emphasized the importance of pictorial representations of the medication taking times to address low health literacy and suggested that medications be sorted according to the time of the day. Several experts suggested that a picture of the pill be included for each of the medications on the list with the ability to select from all possible shapes, sizes, colors, and manufacturer name to avoid confusion. One expert voiced that the screenshots presented too much information and advocated that end users provide ultimate feedback. Using speech-to-text functionality to enter medications on the list was supported by some experts, but discouraged by others who raised concerns about problems with pronunciation and inaccuracy of the medication entered. The alternative way consisting of having the information autopopulate as the user types in the first few letters of the medication was seen as risky and prone to errors because of the variety of presentations available in the market. Finally, experts believed the app should allow ordering medications from the pharmacy.

With regard to the medication reminder feature, experts suggested that the reminder delivery mode (eg, audio, vibrate, flashing screen) vary depending on whether medications were optional or mandatory and that a sketch of the pill be shown on the reminder screen. Geotagging reminders to go off when the person is at home or at work was another idea. Following the reminder, the app should provide feedback as an audio verbal and as a sound when patients tap the *took* option. Experts discouraged the use of *skip* as one of the options, because they believed this word seemed to give permission to be nonadherent. Rather, it was suggested that *not taken* or other neutral word be used. This should be followed by a text message to notify the caregiver. Several experts commented that the *snooze* option should be coupled with a functionality of how long to snooze the reminder for.

As per the medication administration record feature, comments that the dashboard (daily, weekly, monthly) should depend on the number of medications taken daily (many medications, display daily; few medications, display weekly or monthly) were made. A display of how the user is doing in terms of adherence compared with other peers or a gaming reward system to serve as a motivational effect to promote adherence were also proposed. The ability to email or export an adherence report within the app was deemed helpful, as was the ability to record reasons for missing doses.

A compilation of all the expert remarks is presented in Multimedia Appendix 4.

Discussion

Principal Findings and Comparison With Prior Work

In this study, we reviewed existing medication management apps and identified app features that appeared particularly relevant in supporting independence of young adults who have DDs during the medication management process. Of the 42 different features assessed, almost 65% achieved consensus for inclusion in a future medication management app.

The strength of our study is that the panel of experts included persons with disabilities as well as other stakeholders involved in their care. The number of experts included was within the recommended range [43], and we deliberately used high consensus criteria to ensure that only features that were considered critical by experts were identified. The list of features gathered and assessed by experts was similar to those reported in other studies [33,44-46], lending support to the accuracy of the features selected.

Within the medication list feature, experts considered information on how to take the medication and specific aspects such as dosage and indication essential. It was also important for experts that the app included ways to facilitate the entry of a new medication. This is especially critical for individuals with dexterity or visual impairments, as these are more prone to problems in task completion [47]. Although some forms of adding a medication to the list, such as uploading a medication list directly from the pharmacy records, are difficult to operationalize, others including scanning the prescription bottles or including a drug directory that automatically populates several fields as the user types in the name of the medication are already found in some of the current medication management apps.

The medication reminder feature, which is ubiquitous among medication management apps, should have 3 reporting options in an easy-to-use screen—taken, not taken, or snooze. Previous studies assessing the experiences of app users reported their desire to keep apps as simple as possible to make processes easier [47], including elderly people [48]. Simplicity was a key aspect highlighted by experts. On a similar note, the preferred display format of medication doses taken and missed was a monthly calendar, with doses taken and missed appearing in different colors for easy visualization.

The top 3 most important additional features selected by experts were the ability to perform automatic refills through pharmacies, to share medication information with providers, and to share medication information with family, friends, and caregivers. Of all the apps reviewed, only 1—Medisafe—included the feature to share medication information with caregivers, which would be of great value for young adults transitioning to independence. Previous studies demonstrated that involvement of caregivers through an app gives them a sense of better being able to monitor and control their child's condition [44]. This feature is called Medfriend and it allows caregivers to track in real-time whether individuals take their medications and to be notified if they miss it. This feature assumes that users are able to tap the screen button if the medication is taken or skipped. Depending on the type and level of disability, some individuals may not be able to accomplish this task. The Medisafe app was ranked number 1 in recent quality assessments [33,46]. Currently, a randomized control trial is under way evaluating the impact of Medisafe on blood pressure control and medication adherence in the general population [49].

Several safety-related features such as recording side effects and drug allergies, overdose warning, or checking drug

interactions also achieved consensus among experts. Specifically with regard to the latter, a recent study demonstrated that most of the apps containing a drug interaction checker did not identify all possible interactions associated with a given medication and half were unable to detect drug-herbal medication interactions [50]. Therefore, the accuracy of this feature needs to be ensured before inclusion in any app.

Additional features that did not achieve consensus, but that were initially thought to be important for young adults with DDs, were gamification (earning rewards or prizes for being adherent) and socialization. Mixed opinions about gamification were also found in a previous study assessing preferences of users of apps for cystic fibrosis [51]. However, the same and other studies reported socialization as a desired feature for users to find support in peers with the same condition [51,52].

As implications for future app development, participants in this and other studies emphasized the need for customization options to meet individual preferences, needs, and goals [51]; this may be especially relevant for customization for persons with DD versus their caregivers. More complex informatics systems integrating electronic medical records and pharmacy records would allow more advanced features that support independence of these individuals in the medication management process, including Web-based symptom reporting, automatic prescription refills, or sharing the same medication list with all providers. Incorporating or linking smart technology such as electronic pill bottles to the app would provide additional invaluable information to caregivers and providers to deliver better care to their patients [24].

The methodology used in this study does not provide the depth of information necessary to fully design an accessible app for medication management in this population, but it is a first step toward achieving that goal and provides useful information to adapt existing apps. Of note, as a result of the variety of levels of impairment across different disabilities, apps designed to help in the medication use process may be more applicable to persons who have mild-to-moderate impairment of cognitive or physical function, but this aspect would warrant further research.

Limitations

This study has limitations. First, we selected the screenshots that we thought were the most different from each other and included 4 of them in the questionnaire. Many others could have been selected, yielding different results. However, the screenshots selected allowed the extraction of key design aspects to take into account in future app development. Second, researchers and professionals with an interest in DDs comprised the largest proportion of the panel of experts, which could have affected the results. Third, we did not track individual participation in each round, and this may have prevented input on items previously removed due to consensus being achieved. Finally, 1 limitation with the Delphi method is that the opportunity for experts to elaborate on their choices and produce a dialogue around controversial topics does not exist. This may have been partly addressed by the inclusion of free text comments sections at the end of each module.

Conclusions

Although many mobile apps for medication management exist, few are specifically designed to support persons with DDs in the complex medication management process. This study provides information on the features of a medication management app that are most important to persons with DDs and their caregivers that should be taken into account by researchers, developers, and designers who create apps specifically designed for this population. Two key findings from this study are that simplicity is key and that constant communication between the person with a DD, the caregiver, and the health care professional through the app is critical.

Future research will require that a medication management app specifically designed for persons with DDs be developed or an existing app be adapted to include the features identified in this study. Further assessment of the impact of using an app on independence, medication adherence, self-management behaviors, and health outcomes is critical to guide their future use, widespread adoption, and, ultimately, financial support by payers.

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Authors' Contributions

KBF, TMS, and AF were involved in the study design and conception; KBF, TMS, AF, DRO, and MAM were involved in data collection; KBF, TMS, and AF were involved in data analysis; TMS and KBF were involved in drafting the first version of the manuscript; and MAM and DRO were involved in providing critical feedback about the manuscript. All authors approved the final report.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Final questionnaire used to obtain expert consensus.

[PDF File (Adobe PDF File), 596KB - mhealth_v6i5e129_app1.pdf]

Multimedia Appendix 2

Final items to include and not to include in an app for young adults with disabilities.

[PDF File (Adobe PDF File), 41KB - mhealth_v6i5e129_app2.pdf]

Multimedia Appendix 3

Items achieving consensus in each of the 3 Delphi rounds.

[PDF File (Adobe PDF File), 39KB - mhealth_v6i5e129_app3.pdf]

Multimedia Appendix 4

Expert comments provided at the end of each module of the questionnaire.

[PDF File (Adobe PDF File), 45KB - mhealth_v6i5e129_app4.pdf]

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Abbreviations

DD: developmental disability
iMHere: interactive Mobile Health and Rehabilitation
RERC: Rehabilitation Engineering Research Center
TIKTOC: Technology Increasing knowledge: Technology Optimizing Choice

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Original Paper

The Use of Mobile Health Applications to Improve Patient Experience: Cross-Sectional Study in Chinese Public Hospitals

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Abstract

Background: The proliferation of mobile health apps has greatly changed the way society accesses the health care industry. However, despite the widespread use of mobile health apps by patients in China, there has been little research that evaluates the effect of mobile health apps on patient experience during hospital visits.

Objective: The purpose of our study was to examine whether the use of mobile health apps improves patient experience and to find out the difference in patient experience between users and nonusers and the characteristics associated with the users of these apps.

Methods: We used the Chinese Outpatient Experience Questionnaire to survey patient experience. A sample of 300 outpatients was randomly selected from 3 comprehensive public hospitals (3 tertiary hospitals) in Hubei province, China. Each hospital randomly selected 50 respondents from mobile health app users and 50 from nonusers. A chi-square test was employed to compare the different categorical characteristics between mobile health app users and nonusers. A *t* test was used to test the significance in continuous variables between user scores and nonuser scores. Multiple linear regression was conducted to determine whether the use of mobile health apps during hospital visits was associated with patient experience.

Results: The users and nonusers differed in age (χ^2_2=12.2, *P*=.002), education (χ^2_3=9.3, *P*=.03), living place (χ^2_1=7.7, *P*=.006), and the need for specialists (χ^2_4=11.0, *P*=.03). Compared with nonusers, mobile health app users in China were younger, better educated, living in urban areas, and had higher demands for specialists. In addition, mobile health app users gave significantly higher scores than nonusers in total patient experience scores (t_{298}=3.919, *P*<.001), the 18 items and the 5 dimensions of physician-patient communication (t_{298}=2.93, *P*=.004), health information (t_{298}=3.556, *P*<.001), medical service fees (t_{298}=3.991, *P*<.001), short-term outcome (t_{298}=4.533, *P*<.001), and general satisfaction (t_{298}=4.304, *P*<.001). Multiple linear regression results showed that the use of mobile health apps during hospital visits influenced patient experience (t_{289}=3.143, *P*=.002). After controlling for other factors, it was shown that the use of mobile health apps increased the outpatient experience scores by 17.7%. Additional results from the study found that the self-rated health status (t_{289}=3.746, *P*<.001) and monthly income of patients (t_{289}=2.416, *P*=.02) influenced the patient experience as well.

Conclusions: The use of mobile health apps could improve patient experience, especially with regard to accessing health information, making physician-patient communication more convenient, ensuring transparency in medical charge, and ameliorating short-term outcomes. All of these may contribute to positive health outcomes. Therefore, we should encourage the adoption of mobile health apps in health care settings so as to improve patient experience.

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KEYWORDS

mobile applications; technology; outpatients; patient satisfaction; surveys and questionnaire

Introduction

Background

Patient experience is the overall satisfaction a patient gets during the course of receiving care or treatment. This satisfaction is viewed by patients subjectively or based on objective facts and is derived from the sum of their interactions with different factors at a health care setting that influence their perceptions about the quality of health care delivery at that setting [1,2]. Patient experience is an important outcome of medical care [3] and regarded as one of the central pillars of health care quality [4]. Policy makers worldwide increasingly prefer using patient-experience data rather than performance indicators to assess the quality of health care services [4]. Various patient experience questionnaires such as the Picker scale [5] and the Outpatient Experiences Questionnaire [6] have been developed in efforts to measure patient experience using different factors or dimensions at health care settings and the socioeconomic characteristics of patients. Patient experience is strongly correlated with the quality of health care delivery, which involves outcomes such as adherence to treatments, access to preventative care, and patient safety [7]. Qualitative studies have found that the more positive the experience of patients is in accessing care, facilities, and communication with physicians, the better their overall satisfaction about the quality of health care delivery [8].

In recent years, the emergence of mobile health apps in health care management has helped to overcome geographical and organizational barriers to improve health care delivery [9]. In 2018, about 50% of mobile phone users have at least 1 mobile health app on their mobile phones [10]. The Agency of Healthcare Research and Quality has developed an instrument to measure patient experience in relation to health information technology [11]. Evidence has confirmed that patient experience can be improved by mobile health apps through which reminders and diagnostic information are delivered to patients [12]. A series of research have found that mobile health apps can improve adherence to medication for patients with chronic diseases [13], monitor diet behaviors for patients with diabetes, and encourage the collection of blood pressure readings for hypertensive patients [14].

Objectives

A number of Chinese hospitals have begun applying mobile health apps to improve health care services. These mobile health apps can provide information for many services such as hospital guidance, health care consultancy, visiting appointment and registration, medical result checking, medical charge payment, and inquiry [15]. Patients can freely download a hospital's mobile health app by searching for the app in application stores or scanning quick response codes (two-dimensional codes) available in the hospital and on the hospital website [16]. Those mobile health apps have allowed for more efficient responses to patient demands and reduced the amount of time a patient spends in long queues trying to access care in hospital settings. Thus, mobile health apps play a positive role in improving the efficiency and quality of health care delivery [17]. Despite this surge in the use of mobile health apps in China, evidence to evaluate their effectiveness in improving health care delivery is lacking. Therefore, the purpose of our study was to examine whether the use of mobile health apps improves patient experience and to compare the patient experience between users and nonusers and the characteristics associated with the users of these apps.

Methods

Questionnaire Design

The Chinese Outpatient Experience Questionnaire was the basis of our survey, which included 6 dimensions (physical environment and convenience, physician-patient communication, health information, medical service fees, short-term outcome, and general satisfaction), 28 items, and patient characteristics (gender, age, education, marital status, monthly income, payment, living place, specialty, self-rated health status) with good reliability and validity [18]. In the questionnaire, we added another question in the characteristics section— "Did you use mobile health apps during this visit?"—to divide the users and nonusers.

Sample and Procedure

The survey was carried out in August 2016. A sample of 300 respondents was randomly selected from 3 comprehensive public hospitals (3 tertiary hospitals) in Hubei province, China. We adopted the following inclusion criteria for respondents: aged ≥18 years; completed visit procedure before leaving hospital; consented to participate in the study; and offered their own experience about the visit accurately and independently. We chose 3 hospitals that provided similar mobile health apps (ie, displaying information about hospitals and physicians, communicating with physicians, providing hospital appointment and registration, checking medical results, monitoring status of queues, and paying for medical service fees), had a similar number of outpatients per year, and had full-fledged mobile health apps suited for this survey. Trained interviewers randomly selected respondents who met the inclusion criteria and conducted the face-to-face interviews. If the respondents refused to answer any question, then the questionnaire for that respondent was deleted. After a questionnaire was completed, the interviewer reviewed it to ensure that no errors were made. This was done until each hospital had surveyed 50 mobile health app users and 50 nonusers. Every participant provided a score based on their visit experience. The scores represented not only the patients' evaluation of the health services provided to them but also the extent to which patient experience could be improved.

Measures

In multiple linear regression, the dependent variable was the total patient experience score. We used the Chinese Outpatient Experience Questionnaire to calculate patient experience score. The response to each of the 28 items was given based on a 5-point Likert scale, with 5 representing the best experience and 1 representing the worst. For example, "What do you think of the waiting time in the hospital?" (coded as 1=very long, 5=very short). Each dimension score was calculated by summing all item scores in the dimension and then dividing that sum by the number of items in that dimension. The total patient experience score was the total questionnaire score, which was calculated by summing the scores of the 28 items in the questionnaire and then dividing that sum by the total number of items. The total patient experience score ranged from 1 to 5.

To determine possible areas for improvement, we normalized each respondent item's score to 0-100 by using the following formula: Normalized score=100×(Respondent's selected response value−Minimum response value on scale)/(Maximum response value−Minimum response value) [19]. We determined that the distance between a patient experience score and 100 is the gap that must be improved.

The independent variables included the 9 characteristics and whether mobile health apps were used during a visit (coded as 1=yes, 0=no). The 9 characteristics are presented in Table 1. Education, payment, specialty, and self-rated health status were recoded as dummy variables and set the first indicator as the reference.

Statistical Analysis

Data entry and management were performed using Epidata 3.1 ("The EpiData Association" Odense, Denmark) Double-entry data input was used to ensure accuracy. A chi-square test was employed to compare the different categorical characteristics between mobile health app users and nonusers. A *t* test was used to test the mean difference in patient experience scores between mobile health app users and nonusers. Multiple linear regression was conducted to determine whether the use of mobile health apps during the hospital visit was associated with patient experience. A cutoff of $P<.05$ (in a 2-tailed test) was used to determine the statistical significance for all tests. All analyses were conducted using SPSS Version 20.0, 2011 (IBM SPSS, Inc, Chicago, IL).

Results

Patient Characteristics of Mobile Health Application Users and Nonusers

In the 300 samples, the mean age was 33 years (SD 0.902). Females accounted for 56.3% (169/300), and 56.0% (168/300) of respondents had a college or higher education. Respondents living in urban areas accounted for 74.3% (223/300), and 88.7% (266/300) of respondents had a monthly income more than ￥2000 (the per capita annual disposable income of China was ￥23,821 in 2016 [20]). We combined the category of divorced/widowed/separated, which had a small number of respondents, into the married category, therefore, ever married was 78.0% (234/300). A total of 66.7% (200/300) of respondents paid completely out of pocket for medical service fees. For self-rated health status, 47.0% (141/300) of individuals rated their health as good or better. The 4 major medical specialties—internal medicine, surgery, obstetrics and gynecology, and pediatrics—were the most common services requested by outpatients, which accounted for 75.7% (227/300) of respondents.

The characteristics distributions are presented in Table 1; a chi-square test was used to examine the difference in patients' characteristics. The mobile health app users and nonusers differed in age ($\chi^2_2=12.2$, $P=.002$), education ($\chi^2_3=9.3$, $P=.03$), living place ($\chi^2_1=7.7$, $P=.006$), and their request for specialty services ($\chi^2_4=11.0$, $P=.03$). Compared with nonusers, the mobile health app users were younger, better educated, lived in urban areas, and had more requests for medical specialists.

Differences in Patient Experience Between Mobile Health Application Users and Nonusers

Patient experience scores of mobile health app users and nonusers are shown in Table 2. The *t* test results showed that there was a significant difference in total patient experience scores, the 5 dimensions, and the 18 items between the 2 groups.

In total patient experience scores, mobile health app users gave significantly higher scores than nonusers ($t_{298}=3.919$, $P<.001$). In the dimensions of physician-patient communication ($t_{298}=2.93$, $P=.004$), health information ($t_{298}=3.556$, $P<.001$), medical service fees ($t_{298}=3.991$, $P<.001$), short-term outcome ($t_{298}=4.533$, $P<.001$), and general satisfaction ($t_{298}=4.304$, $P<.001$), mobile health app users obtained significantly higher scores than nonusers as well. The same relationship was observed in the 18 items, as the app users obtained significantly higher scores than their nonuser counterparts (Table 2).

Although the dimension of physical environment and convenience was not significantly different between the 2 groups ($t_{298}=1.285$, $P=.20$), mobile health app users obtained significantly higher scores in the item concerning convenience of the registration procedure, indicating that the apps played a positive role in registering for doctor appointments.

Table 1. Difference in respondents' characteristics of mobile health app users and nonusers.

Characteristic	App users, n (%)	Nonusers, n (%)	Chi-square (*df*)	*P* value
Gender			0.1 (1)	.42
Male	62 (41.3)	69 (46.0)		
Female	88 (58.7)	81 (54.0)		
Age			12.2 (2)	.002[a]
≤44	124 (82.7)	98 (65.3)		
45-64	19 (12.7)	42 (28.0)		
≥65	7 (4.6)	10 (6.7)		
Education			9.3 (3)	.03[a]
Elementary and below	3 (2.0)	12 (8.0)		
Middle school	15 (10.0)	22 (14.7)		
High school	38 (25.3)	42 (28.0)		
College or above	94 (62.7)	74 (49.3)		
Monthly income (￥)			8.3 (4)	.08
≤1999	16 (10.7)	18 (12.0)		
2000-2999	25 (16.7)	42 (28.0)		
3000-3999	35 (23.3)	34 (22.7)		
4000-4999	28 (18.7)	27 (18.0)		
≥5000	46 (30.6)	29 (19.3)		
Marital status			0.1 (1)	.78
Single	34 (22.7)	32 (21.3)		
Ever married	116 (77.3)	118 (78.7)		
Living place			7.7 (1)	.006[a]
Urban areas	122 (81.3)	101 (67.3)		
Rural areas	28 (18.7)	49 (32.7)		
Payment			1.3 (2)	.52
Pay completely out of pocket	104 (69.3)	96 (64.0)		
Partial reimbursement	40 (26.7)	49 (32.7)		
Complete reimbursement	6 (4.0)	5 (3.3)		
Specialty services			11.0 (4)	.03[a]
Internal medicine	41 (27.3)	49 (32.7)		
Surgery	37 (24.7)	42 (28.0)		
Obstetrics and gynecology	29 (19.3)	10 (6.7)		
Pediatrics	10 (6.7)	9 (6.0)		
Others	33 (22.0)	40 (26.6)		
Self-rated health status			6.4 (3)	.09
Poor	8 (5.3)	16 (10.7)		
Fair	62 (41.3)	73 (48.7)		
Good	64 (42.7)	51 (34.0)		
Very good	16 (10.7)	10 (6.7)		

[a]Represents the significance between the 2 groups.

Table 2. Patient experience scores of mobile health app users and nonusers.

Dimension/item	App users scores $\bar{x}$ (S)	Nonusers scores scores $\bar{x}$ (S)	*t* test (*df*)	*P* value
Physical environment and convenience	3.50 (0.54)	3.43 (0.51)	1.285 (298)	.20[c]
Waiting time	2.37 (0.79)	2.41 (0.85)	−0.494 (298)	.62
Easy registration procedure	3.97 (0.89)	3.67 (0.92)	2.808 (298)	.005[a]
Convenient dispensary	3.89 (0.96)	3.69 (0.84)	1.913 (298)	.06
Clear signs	4.05 (0.78)	3.94 (0.85)	1.130 (298)	.26
Clean clinics	4.04 (0.74)	4.02 (0.70)	0.240 (298)	.81
Quiet clinics	2.71 (1.04)	2.81 (0.96)	−0.924 (298)	.36
Physician-patient communication	3.73 (0.59)	3.52 (0.64)	2.930 (298)	.004[a,c]
Clear explanation	4.20 (0.62)	3.96 (0.72)	3.079 (298)	.002[a]
Careful listening	4.02 (0.79)	3.85 (0.87)	1.804 (298)	.07
Enough time for communication	3.28 (0.96)	3.21 (0.99)	0.594 (298)	.55
Courtesy and respect attitude	3.95 (0.78)	3.82 (0.79)	1.474 (298)	.14
Cared about anxieties or fears	3.49 (0.90)	3.28 (0.90)	1.987 (298)	.048[a]
Involve in decision making	3.15 (1.02)	2.94 (1.01)	1.768 (298)	.08
Respect opinions	3.76 (0.76)	3.40 (0.88)	3.812 (298)	<.001[a,b]
Protect personal privacy	3.97 (0.80)	3.69 (0.95)	2.766 (298)	.006[a,b]
Health information	3.91 (0.67)	3.61 (0.80)	3.556 (298)	<.001[a,b,c]
Explanations for your illness	4.13 (0.77)	3.86 (0.87)	2.894 (298)	.004[a]
Dangerous signals at home	4.03 (0.82)	3.74 (1.06)	2.624 (298)	.009[a,b]
Health knowledge	3.74 (0.90)	3.51 (1.16)	1.949 (298)	.05[b]
Explain following examination	3.93 (0.89)	3.51 (1.11)	3.615 (298)	<.001[a,b]
Explain examination result	3.93 (0.94)	3.61 (0.93)	3.034 (298)	.003[a]
Explain drug effects in a way you could understand	3.70 (0.89)	3.37 (1.02)	3.020 (298)	.003[a,b]
Medication precautions	3.93 (0.82)	3.68 (1.07)	2.305 (298)	.02[a,b]
Medical service fees	3.52 (0.67)	3.19 (0.77)	3.991 (298)	<.001[a,c]
Reasonable charge	3.43 (0.68)	3.05 (0.90)	4.117 (298)	<.001[a]
Transparent charge	3.61 (0.90)	3.35 (0.94)	2.504 (298)	.01[a]
Affordable charge	3.53 (0.88)	3.18 (0.86)	3.518 (298)	<.001[a]
Short-term outcome	3.90 (0.63)	3.53 (0.77)	4.533 (298)	<.001[a,b,c]
Reduce/prevent from health problems	4.03 (0.70)	3.63 (0.77)	4.703 (298)	<.001[a,b]
Handle health problems after visit	3.76 (0.73)	3.43 (0.96)	3.390 (298)	<.001[a,b]
General satisfaction	3.93 (0.72)	3.55 (0.82)	4.304 (298)	<.001[a,b,c]
Satisfaction overall	3.80 (0.74)	3.43 (0.87)	3.896 (298)	<.001[a,b]
Choose this hospital again	4.07 (0.80)	3.67 (0.88)	4.117 (298)	<.001[a]
Total patient experience scores	3.72 (0.50)	3.49 (0.56)	3.919 (298)	<.001[a]

[a]Represents a significant difference between 2 groups.

[b]Refers to *t* test.

[c]Represents the dimensions in the questionnaire.

Table 3. Factors associated with patient experience scores in the multiple linear regression.

Variables	β	SE	*t* test (*df*)	*P* value
Constant	2.987	0.169	17.681 (289)	<.001[a]
Whether app was used	.193	0.062	3.143 (289)	.002[a]
Monthly income	.061	0.025	2.416 (289)	.02[a]
Safe-rated health 1	.036	0.116	0.31 (289)	.76
Self-rated health 2	.120	0.118	1.01 (289)	.31
Self-rated health 3	.561	0.15	3.746 (289)	<.001[a]

[a]Represents the variable is significant in the multiple linear regression.

Influence of Mobile Health Application on Patient Experience

Table 3 presents the results derived from multiple linear regression. The initial model included all independent variables, and the final model included only 3 significant variables. Whether mobile health apps were used or not during the hospital visit was a significant predictor that influenced patient experience scores (t_{289}=3.143, *P*=.002). The standardized coefficient of whether app was used was .177; thus, when other covariates were held constant, the use of the mobile health apps increased the patient experience scores by 17.7%. Monthly income (t_{289}=2.416, *P*=.02) was a significant factor that influenced the patient experience scores as well. Meanwhile, the self-rated health status was a factor that influenced patient experience. Patients who rated their health status better, would more likely to have better patient experience (t_{289}=3.746, *P*<.001). Patients who used mobile health apps, those who had higher monthly income, and those who rated their health better were more likely to have a better experience during hospital visit. The model was fitted well to the data ($F_{10,289}$=4.193, *P*<.001). We checked for collinearity by calculating the value of variance inflation factor (VIF). The VIF was between 1.095 and 6.222. As it is <10, there was no collinearity.

Discussion

Principal Findings

We found that the use of mobile health apps improved the overall patient experience. In our study, mobile health app users had a better experience in physician-patient communication, access to health information, payment of medical service fees, short-term outcomes, and general satisfaction. We also found that the mobile health app users were younger, better educated, lived in urban areas, and had higher requests for specialists.

The use of mobile health apps can save patients' time throughout their visits. After choosing a medical specialist for an appointment, the patients can monitor queues on mobile health apps and arrive at the hospital just before their turn for their appointment. Patients can also use mobile health apps to pay for their medical service fees without queuing up for payment after finishing their medical tests and diagnostic procedures. Furthermore, mobile health apps can make medical service fees more transparent [21] by listing the items of medical services for which the patients are billed.

The relationship between physicians and patients in terms of communication has not been at its best in China [22]. Mobile technology can help improve the patient-physician relationship by allowing individuals and health care providers to establish a more effective communication channel [23]. With the emergence of mobile health apps, patients can communicate with physicians before and after their medical appointments through the mobile health apps to obtain medical consultations and other information about their health problems. Studies have confirmed that patient involvement in decision-making processes and effective communication are strongly associated with better self-reported clinical outcomes [24]. Considering previous studies, the effects of self-rated health status and monthly income on the mobile health app users found in our study were similar to the results reported by Bjertnaes [25]. However, as opposed to Esan's research about the influential factors of patient experience [26], our study showed that age and type of payment were less significant in influencing patient experience.

There is increasing evidence that improved health care system delivery improves patient experience [27], which in turn results in better health outcomes for patients [7]. In our study, the overall patient experience was improved when the mobile health apps were used. Thus, we believe that the increased use of mobile health apps in health care settings could contribute to better health care outcomes.

Age, education, living place, and the requests for specialty-related services were associated with mobile health apps in our study, consistent with findings from Carroll and Ernsting [28,29]. Only 4.7% (7/150) of our surveyed users were elderly, which is similar to 5.2% of Chinese Internet users who are aged above 60 years [30]. It is reported that the biggest demographic change in the next 30 years will be the aging population, which will contribute to a dramatically increased incidence of diseases and lead to significantly higher demands for medical services [31]. The developers of mobile health apps

should make the apps easy-to-use for the elderly population. Meanwhile, the broadband network covers 95% of administrative villages in China; the Internet users in rural areas have more tendency to use mobile phones to access the Internet [30]. Thus, health care service providers must encourage persons living in rural areas and those with lower educational attainment to use mobile health apps to access health care, as more people will have mobile phones with Internet access [28]. This will decrease the digital gap in the Chinese population [32].

Limitations

There are some limitations in this study. First, because of the fluidity of the outpatients and the lack of their contact information in Chinese hospitals, we could not survey participants using a rigorous random sampling technique, which can result in selection bias. Second, patients can freely choose to use or not use the mobile health apps. Those who choose to use mobile health apps may have a more positive attitude toward technology than the nonusers. This potential difference could serve as a confounder in masking the patient experience. Third, the experiences of patients with chronic diseases who have to regularly return to the hospital may be different from those patients with acute diseases. However, we did not consider this factor in our survey.

Conclusions

Mobile health app users in China are individuals who were younger, better educated, living in urban areas, and have more requests for specialists. Most importantly, our research provides evidence supporting the use of mobile health apps for improving patient experience. Mobile health apps display more accurate health information and transparent medical charge information. They also provide patients with more opportunities to communicate with physicians and may improve the relationship between physicians and patients. They also ameliorate short-term outcomes and increase general satisfaction of patients. All of these will improve patient experience and may contribute to positive health outcomes. Thus, the use of mobile health apps has great clinical significance. To improve the quality of health care delivery, we should encourage patients to adopt mobile health apps during their hospital visits, and hospitals should take advantage of mobile health apps to improve patient experience during hospital visits.

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Conflicts of Interest

None declared.

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Abbreviations

VIF: variance inflation factor

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Original Paper

Web-Based Telepresence Exercise Program for Community-Dwelling Elderly Women With a High Risk of Falling: Randomized Controlled Trial

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Abstract

Background: While physical exercise is known to help prevent falls in the elderly, bad weather and long distance between the home and place of exercise represent substantial deterrents for the elderly to join or continue attending exercise programs outside their residence. Conventional modalities for home exercise can be helpful but do not offer direct and prompt feedback to the participant, which minimizes the benefit.

Objective: We aimed to develop an elderly-friendly telepresence exercise platform and to evaluate the effects of a 12-week telepresence exercise program on fall-related risk factors in community-dwelling elderly women with a high risk of falling.

Methods: In total, 34 women aged 68-91 years with Fall Risk Assessment scores >14 and no medical contraindication to physical training-based therapy were recruited in person from a senior citizen center. The telepresence exercise platform included a 15-inch tablet computer, custom-made peer-to-peer video conferencing server system, and broadband Internet connectivity. The Web-based program included supervised resistance exercises performed using elastic resistance bands and balance exercise for 20-40 minutes a day, three times a week, for 12 weeks. During the telepresence exercise session, each participant in the intervention group was supervised remotely by a specialized instructor who provided feedback in real time. The women in the control group maintained their lifestyle without any intervention. Fall-related physical factors (body composition and physical function parameters) and psychological factors (Korean Falls Efficacy Scale score, Fear of Falling Questionnaire score) before and after the 12-week interventional period were examined in person by an exercise specialist blinded to the group allocation scheme.

Results: Of the 30 women enrolled, 23 completed the study. Compared to women in the control group (n=13), those in the intervention group (n=10) showed significant improvements on the scores for the chair stand test (95% confidence interval -10.45 to -5.94, P<.001), Berg Balance Scale (95% confidence interval -2.31 to -0.28, P=.02), and Fear of Falling Questionnaire (95% confidence interval 0.69-3.5, P=.01).

Conclusions: The telepresence exercise program had positive effects on fall-related risk factors in community-dwelling elderly women with a high risk of falling. Elderly-friendly telepresence technology for home-based exercises can serve as an effective intervention to improve fall-related physical and psychological factors.

Trial Registration: Clinical Research Information Service KCT0002710; https://cris.nih.go.kr/cris/en/search/search_result_st01.jsp?seq=11246 (Archived by WebCite at http://www.webcitation.org/6zdSUEsmb)

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KEYWORDS

telegeriatrics; resistance exercise; supervised exercise; home exercise; WebRTC; telepresence

Introduction

Falls represent a serious threat to quality of life in the elderly [1]. It has been reported that the yearly incidence of falls among the elderly population aged over 65 years is 30-50% globally [2]. Various factors have been reported to influence the risk of falls among the elderly, including decreasing strength of the lower extremities, cognitive disorders, fear of falling, depression, environmental factors, and problems with walking, balance, vision, feet, or even shoes. Previous studies have shown that there is no single factor responsible for falls, and falling occurs because of complex interactions among multiple factors [3,4]. Nevertheless, the incidence of falls among the elderly can be reduced through preventive activities. Physical exercise has been shown to be very effective in lowering the risk and incidence rate of falls [5]. In particular, resistance exercises are known to be effective at increasing muscle mass, strength, and balance in the elderly [6] and are thus highly indicated to prevent falls in this population. Moreover, balance exercises, such as stepping over a slipper before bending down to pick it up, tandem walking, and side-stepping while holding on to the back of the chair have been shown to be effective in decreasing the risk of subsequent falls [7].

In many countries, including South Korea, elderly people perform unsupervised aerobic exercises in specific places such as senior welfare centers, parks, schoolyards, and public health centers [8]. However, compared to the younger or middle-aged population, the elderly are more affected by weather conditions, as reflected by their lower attendance rate [9]. Moreover, because traveling is typically more difficult for the elderly, the distance between the residence and the place of exercise represents another deterrent for the elderly to join or continue attending exercise programs outside the home. As a result, elderly people are more likely to develop sarcopenia due to the decrease in physical activity, thus increasing their risk of falls [10].

Several solutions have been proposed to overcome the limitations of conventional home exercise, including home fitness equipment, home work-out videos, and fitness apps for mobile phones or computers [11]. However, since these types of unsupervised exercise do not offer direct and prompt feedback to the participant, it is difficult for the elderly to benefit fully from such exercise programs, and the risk of injury is higher. Exergames that employ a three-dimensional depth camera have been introduced over the past few years and have gained attention in the field of physical exercise-based therapy because they can provide real-time feedback to participants using natural user interface technologies [12]. However, most exergames emphasize the fun elements because they target younger age groups; therefore, exergames are of limited use in the elderly population [13]. In addition, in a previous study involving tele-exercise using Skype [14], the user interface and experience were found to not be elderly-friendly. While many technologies for remote supervision are available, such approaches are not readily adopted by elderly people, who generally have a poorer understanding of computers and similar technologies [15].

It is known that falls lead to a fear of falling, depression, and a sense of alienation [16]. The elderly tend to have a passive attitude towards exercising due to fear of falling, as well as depression associated with falling and fall-related injuries. Therefore, this population benefits from steady exercises with interactive feedback, which can help reduce the fear of falling and increase self-confidence related to physical exercise [17]. However, conventional exercise modalities developed for elderly individuals do not provide sufficient fall prevention [18].

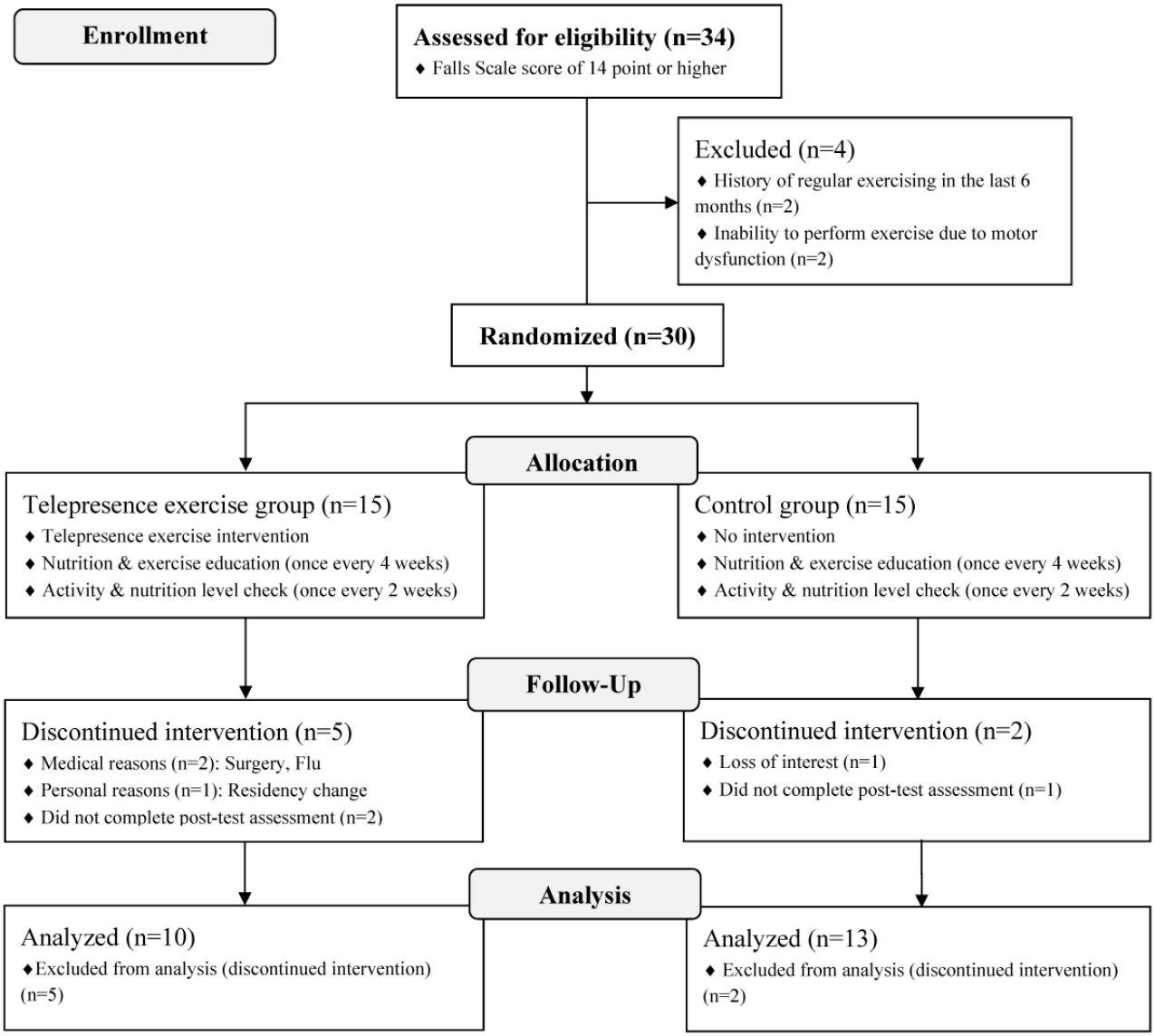
In this study, we propose a home-based telepresence exercising program as a new intervention method to prevent falls among high-risk, elderly individuals. Specifically, we developed a novel telepresence exercise platform using information and communication technology to provide supervised physical training sessions to elderly participants at home, with real-time feedback from a remotely located instructor trained to assess the physical, cognitive, and emotional response of the elderly participant. Finally, we investigated the effect of the telepresence training program on fall-related physical and psychological risk factors in home-dwelling elderly women at risk of falls.

Methods

Participants

This study was designed as a double-blind, parallel-group, randomized controlled trial. Thirty-four community-dwelling elderly women aged above 65 years and having a Fall Risk Assessment Scale [19] score of 14 points or higher were recruited from the Senior Citizen Centre in Gangseo-gu, Seoul, South Korea, from February 10-March 8, 2015. Recruitment was performed in person by a research coordinator. Computer or Internet literacy was not required as an eligibility criterion. Four women were excluded based on the following criteria: history of regular exercise in the 6 months leading up to the study, inability to exercise due to contraindication to training therapy, or mental illness. The remaining 30 women were assigned to either the telepresence exercise intervention group (IG; n=15) or to the control group (CG; n=15). The group allocation scheme, which was based on simple random sampling performed in Microsoft Excel, was obtained by the research coordinator. Of the 30 women enrolled, 7 discontinued the intervention for medical reasons, did not undergo the posttest assessment, or withdrew from the study due to personal reasons (Figure 1).

Figure 1. Flow diagram of the study design.



The remaining 23 participants completed the study (including the pre- and posttest assessments), and their data were included in the present analysis. Power analysis was performed using G*power 3 [20] and revealed that the sample size of 10 and 13 participants for the IG and CG groups, respectively, was sufficient to distinguish an effect size of 0.35 (for lower body strength) with an alpha value (probability of Type 1 error) of .05 and statistical power (1-beta) of .80. The study was approved by the Seoul National University Hospital Institutional Review Board (Approval No. 1412-150-636) and was registered with the Clinical Research Information Service, which is a primary registry of the World Health Organization International Clinical Trials Registry Platform. All participants provided written informed consent before enrollment and were free to withdraw from the study at any time. The trial is reported in accordance with the CONSORT-EHEALTH provisions for improving and standardizing evaluation reports of Web-based and mobile health interventions (see Multimedia Appendix 1 for the CONSORT-EHEALTH checklist [21]).

Procedures

Fall-related risk factors were assessed in person 1 week prior to initiating the intervention. Additionally, at that time, each participant and the exercise instructor were provided with a tablet PC (personal computer), folding chairs, exercise mats, resistance bands, and instructions describing the simple steps necessary to turn on and operate the tablet, facilitating participation in the Web-based telepresence exercise program.

During the intervention period, nutrition guidance and exercise education were provided to all participants once every 4 weeks. Throughout the 12-week intervention period, the participants were encouraged to maintain the same physical activity levels and calorie intake as before participating in the study. During the education sessions, we instructed the participants to inform an instructor holding the education sessions regarding any changes in physical activity levels or nutrition intake. A posttest assessment was performed during the last week of the 12-week program. CG levels of physical activity and nutrition intake were checked every 2 weeks by phone and during the education sessions. An overview of the study design is provided in Figure

1. All data were collected and stored at the Biomedical Research Institute of Seoul National University Hospital in Seoul, Korea.

Telepresence Platform

The Web Real-Time Communication (WebRTC) technology enables the telepresence [22] exercise platform to perform real-time voice calling, video chat, and text messaging in the browser without any plug-in software. The telepresence exercise platform consists of Web, Web application, signaling, and network address translator (NAT) traversal server modules that are set up using appropriate programming languages and runtime environments (Hypertext Markup Language revision 5 [HTML5]; PHP: Hypertext Preprocessor [PHP]; JavaScript; Node.js) according to the WebRTC application programming interface (API), as shown in Figure 2. The telepresence operation server system used in this study had the following specifications: Intel Core i3 3.5GHz central processing unit (CPU), 4 GB random-access memory (RAM), Microsoft Windows Server 2012 operating system with an IIS 8 Web server and PHP v5.16 Web application server. The signaling server module enables the telepresence application on each user's Web browser to set up a call while providing session control messages, media metadata, key data, network data, and error messages. The NAT traversal module is used to cope with gateways or firewalls in real-world networking through the Interactive Connectivity Establishment (ICE), Session Traversal Utilities for NAT (STUN), and Traversal Using Relay NAT protocols (TURN). The actual media and data streaming function in the telepresence application is based on three main WebRTC JavaScript APIs (ie, getUserMedia, RTCPeerConnection, and RTCDataChannel) [23].

We developed the telepresence exercise platform including an operation server system and a website mainly based on WebRTC, which is an open-source technology that works with various operating systems (eg, Windows, Android, iOS) and Web browsers (eg, Chrome, Firefox, Opera, Microsoft Edge). Importantly, WebRTC provides Health Insurance Portability and Accountability Act-compliant security for data transfer (media and signaling) using state-of-the-art encryption standards (Hypertext Transfer Protocol Secure [HTTPS]; Datagram Transport Layer Security [DTLS]; Secure Real-time Transport Protocol [SRTP]) [24]. These properties of WebRTC enhance the usability of this technology in the telepresence service for the elderly. The overall architecture of the telepresence exercise platform is shown in Figure 2.

An elderly-friendly website was developed for the telepresence exercise sessions (Figure 3). The website was accessed via the Web browser (Google Chrome v26) installed on the tablet PC (X50V2 Plus; Shuttle Inc), which had the following specifications: Intel Atom 1.8 GHz CPU, 2 GB RAM, built-in 15-inch touchscreen, and 2-megapixel webcam with a wide-angle lens. Remote-access software (TeamViewer v8.0) was installed to provide the participants with technical support in operating the tablet. Moreover, broadband network access (10 Mbps) was provided to the instructor and the participants. All items associated with the intervention were provided to the participants and the instructor free of charge.

For the developed telepresence exercise platform, adequate user acceptance testing was conducted by focus groups until March 1, 2015. Throughout the intervention period, no bug fixes or content changes were made to the platform. There was no downtime (planned or unplanned) during the intervention period.

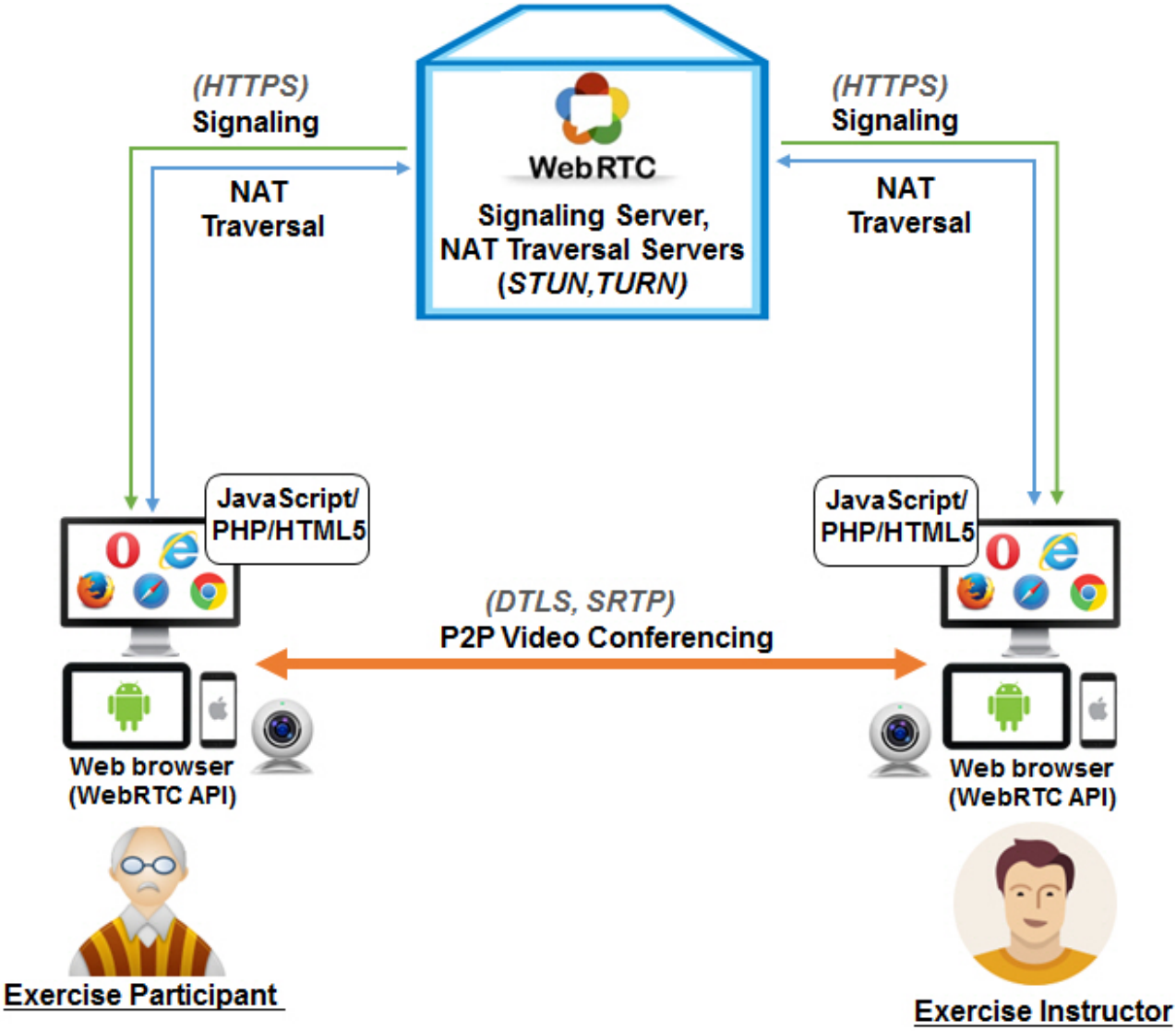
Telepresence Exercise Program

During the exercise session, the participants turned on the tablet PC, watched the instructor perform the exercise, and followed the instructor's movements (Figure 3). In order for the instructor to observe the correct movements of the participants, the resistance and balance exercises were performed in the frontal and sagittal planes. The supervised, progressive exercise protocol for IG was based on fall prevention guidelines issued by the Centers for Disease Control and Prevention [25]. The telepresence exercise program included three sessions per week, which took place on non-consecutive days (ie, at intervals of at least 48 hours) for 12 weeks. Each session consisted of a warm-up activity (5 min), main exercise activity (10-30 min), and cool-down activity (5 min). Exercise intensity was controlled based on the Rating of Perceived Exertion (RPE) on the Borg scale [26], as explained below. The warm-up and cool-down activities included stretching and walking in place ($9 \leq RPE \leq 11$), while the main exercise activity consisted of resistance and balance exercises performed using color-coded resistance bands (Thera-Band; Hygenic Corp.) [27] and a chair ($11 < RPE \leq 15$).

The resistance exercise was performed while sitting on the chair using a yellow (Level 1) band during Weeks 1-4, red (Level 2) band during Weeks 5-8, and green (Level 3) band during Weeks 9-12. This routine, which targeted the major muscle groups in the shoulder, arms, thighs, hips, and calves, included three sets with 8-15 repetitions per set [28]. Specifically, if the RPE was ≤11, the participant was encouraged to increase the number of repetitions performed in the subsequent set (up to a maximum of 15 repetitions); if the RPE was ≥15, the participant was encouraged to decrease the number of repetitions in the subsequent set (down to a minimum of 8 repetitions). The balance exercise included two-legged standing, tandem standing, one-legged standing, semi-tandem standing, tandem walking, turning in a circle around the chair, and exercises such as toe stands, which focused on postural muscle groups. The total exercise time was progressively increased from 20-40 minutes over the course of the intervention period.

To ensure safety and compliance, exercise training was supervised by an instructor who was appropriately trained and had ample experience as an exercise physiologist. The instructor provided one-on-one instructions to each participant, according to the target RPE for each session. All IG participants interacted with the same instructor.

Figure 2. Overview of the telepresence exercise platform using WebRTC technology (API: application programming interface; DTLS: Datagram Transport Layer Security; HTML5: Hypertext Markup Language revision 5; HTTPS: Hypertext Transfer Protocol Secure; ICE: Interactive Connectivity Establishment; NAT: network address translator; P2P: peer-to-peer; PHP: PHP: Hypertext Preprocessor; SRTP: Secure Real-time Transport Protocol; STUN: Session Traversal Utilities for NAT; TURN: Traversal Using Relay NAT; WebRTC: Web Real-Time Communication).



Outcome Measures

Fall-related physical and psychological factors were examined before and after the intervention. All measurements were performed by an exercise specialist blinded to the group allocation scheme. Body composition and physical function parameters were assessed as physical risk factors for falling, while fall-related self-efficacy (falls efficacy) and fear of falling were assessed as psychological risk factors for falling. The primary outcome for this trial was lower body strength (evaluated in the chair stand test) and balance (evaluated using a balance assessment test). Secondary outcomes included psychological risk factors for falling (falls efficacy, fear of falling).

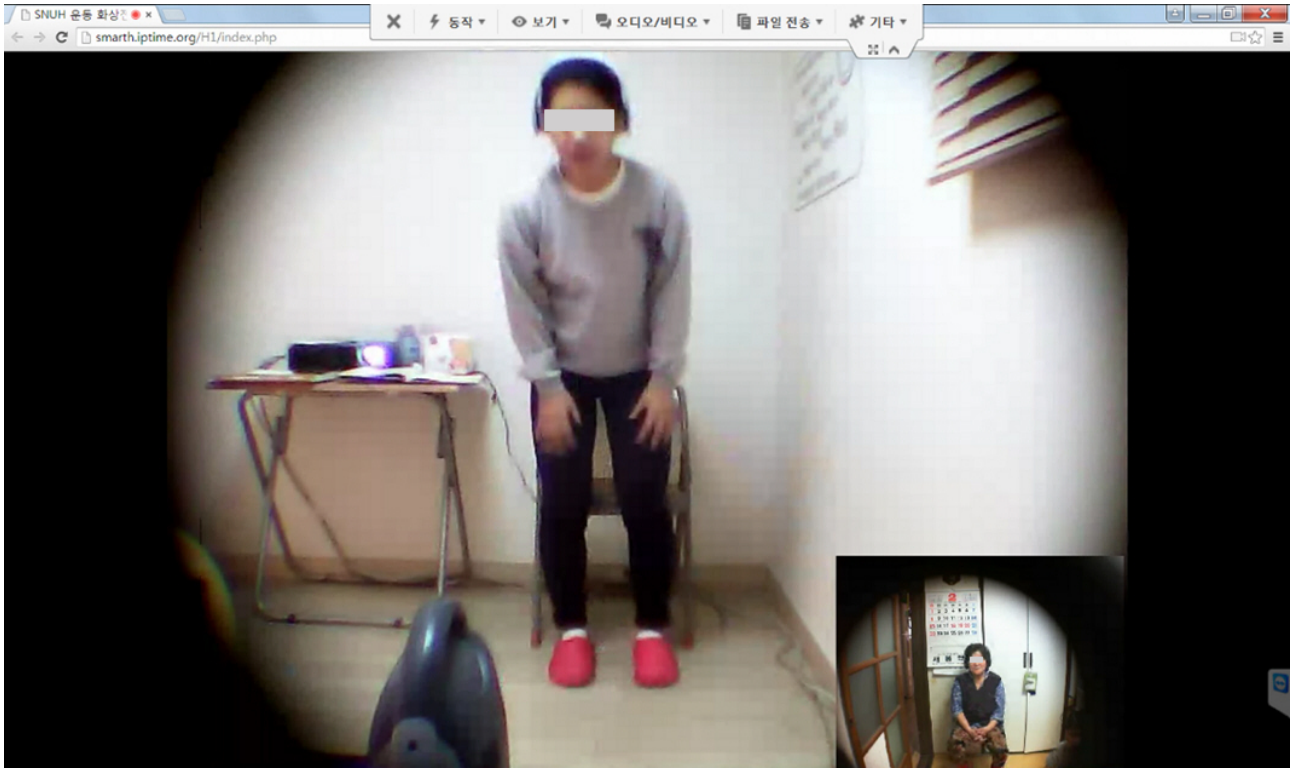
Body Composition

We evaluated body composition in terms of body weight, percentage fat, upper and lower limb muscle mass, and appendicular lean soft tissue (ALST), measured using a dual-energy X-ray absorptiometry device (Lunar Prodigy Advance; GE Healthcare). Total-body skeletal muscle mass (TSM) was calculated using the ALST-based formula proposed by Kim et al [29], as follows: TSM (kg) = 1.13 × ALST – 0.02 × age + 0.61 × sex + 0.97, where sex = 0 for women and 1 for men.

Physical Function

The Senior Fitness Test (SFT) and Berg Balance Scale (BBS) were used to evaluate physical functional ability [30]. The SFT consists of the 2-minute step, chair stand, arm curl, chair sit-and-reach, back scratch, and 8-foot up-and-go tests. The BBS is a 14-item test designed to measure the balance of elderly participants by assessing their performance in specific tasks.

Figure 3. Participant performing telepresence exercises at home using the tablet PC, under the supervision of a remotely located instructor.



In the SFT, the 2-minute step test was used to evaluate cardiorespiratory fitness. The evaluator counted the number of full steps completed by the participant in 2 minutes. A full step was defined as a step performed while raising the knee up to a height corresponding to the midpoint between the patella and the iliac crest. The chair stand test was used to assess the muscle strength and endurance of the lower body, while the arm curl test was used to measure upper body strength. In both these tests, the evaluator counted the number of repetitions performed by the participant in an interval of 30 seconds. The chair sit-and-reach test was used to assess lower body flexibility, while the back-scratch test was used to evaluate upper body flexibility. The 8-foot up-and-go test was used to evaluate agility and dynamic balance. The evaluator noted the time taken by a participant to rise from a seated position, stand up, walk 8 feet, turn, walk back to the chair, and resume the seated position.

In the BBS, each 14-item task is given 4 points on an ordinal scale, ranging from 0 (unable to perform the task) to 4 (performs the task independently). The scores of the 14 tasks are summed to yield a total score ranging from 0-56 points, with a score of 41-56 indicating low risk, 21-40 indicating medium risk, and 0-20 indicating high risk of fall. Higher BBS scores indicate better performance, while scores ≤45 points are predictive of falls.

Falls Efficacy

Fall-related self-efficacy, or falls efficacy, reflects an individual's degree of conviction that they will not fall while performing a certain activity. To measure falls efficacy in community-dwelling Korean women aged >65 years, we used the Korean Falls Efficacy Scale (FES-K) [31], which represents a translated and modified version of the FES-International [32] that takes into account the characteristics of elderly Koreans. The FES-K contains items measuring falls efficacy during activities of daily living and social activities. In our study, falls efficacy was measured on a 4-point Likert scale, and the Cronbach alpha of the FES-K was .87.

Fear of Falling

The Fear of Falling Questionnaire (FOFQ) developed by Tideiksaar [33] was used to measure the fear of falling associated with 11 daily activities. Fear of falling was measured on a 4-point Likert scale. In this study, the Cronbach alpha of the FOFQ was .86.

Statistical Analyses

The fall-related physical and psychological factors were assessed at baseline and at the end of the 12-week study period. An independent *t* test was used to test the homogeneity of physical characteristics between the two groups before the intervention. Two-way repeated-measures analysis of variance (ANOVA) was performed to account for the effect of group (IG and CG), time (pre- and posttest), and interaction between group and time. When there were significant interaction effects, a paired *t* test was used to assess within-group differences between pre- and posttest measurements. The significance threshold was $P<.05$ for all tests. All statistical analyses were performed using SPSS (version 22.0; IBM Corp).

Results

Participant Characteristics

The homogeneity test for physical characteristics and dependent variables showed that, at baseline, IG and CG did not differ significantly regarding age, body weight, body height, percentage fat, ALST, or TSM (Table 1).

Table 1. Baseline physical characteristics.

Characteristics	Intervention group (n=10), mean (SD)	Control group (n=13), mean (SD)	*P* value[a]
Age years	78.10 (5.66)	81.54 (5.07)	.14
Weight, kg	56.18 (6.54)	55.70 (9.03)	.47
Height, cm	150.30 (4.52)	148.76 (5.30)	.89
Percent fat	33.53 (6.48)	31.89 (10.21)	.66
Appendicular lean soft tissue, kg	14.22 (2.03)	13.97 (1.11)	.71
Total skeletal muscle mass, kg	15.49 (2.31)	15.14 (1.23)	.65

[a]*P* values represent homogeneity and were obtained using an independent *t* test.

Table 2. Changes in body composition. *Before* and *After* refer to measurements taken before and after the 12-week intervention period, respectively.

Variable	Intervention group (n=10), mean (SD)		Control group (n=13), mean (SD)		Interaction, *P* value[a]
	Before	After	Before	After	
Weight, kg	56.18 (6.45)	57.39 (7.12)	55.70 (9.03)	55.86 (9.13)	.18
Percent fat	33.53 (6.48)	34.36 (6.59)	31.89 (10.21)	32.33 (9.85)	.52
Upper limb mass, kg	3.63 (0.50)	3.69 (0.78)	3.43 (0.40)	3.31 (0.36)	.10
Lower limb mass, kg	10.58 (1.55)	10.96 (1.82)	10.53 (0.94)	10.37 (0.80)	.04
Appendicular lean soft tissue, kg	14.22 (2.03)	14.65 (2.56)	13.97 (1.11)	13.68 (0.88)	.03
Total skeletal muscle mass, kg	15.49 (2.31)	15.98 (2.89)	15.14 (1.23)	14.82 (0.99)	.03

[a]The interaction effect between time and group was evaluated in terms of the *P* value obtained using two-way repeated-measures analysis of variance.

Body Composition

Table 2 provides an overview of the changes in body composition between baseline (before intervention) and the end of the 12-week intervention period. Significant interaction effects between group and time were seen for lower limb muscle mass (*P*=.04), ALST (*P*=.03), and TSM (*P*=.03). Post hoc analyses revealed no significant change in either group, although IG participants showed a tendency of increase in lower limb muscle mass, ALST, and TSM. No significant changes were noted for body weight, percentage fat, or upper limb muscle mass.

Physical Function

Table 3 provides an overview of the changes in physical function between baseline (before intervention) and the end of the 12-week intervention period. Two-way repeated-measures ANOVA revealed a significant interaction effect between group and time regarding the scores of the chair stand test (*P*<.001) and BBS (*P*=.03). However, there were no changes in the scores for the 2-minute step, arm curl, back scratch, chair sit-and-reach, or 8-foot up-and-go tests. With respect to the chair stand test, which measures lower body strength, a significant increase was found for both IG (*P*<.001) and CG (*P*=.04) participants. Additionally, BBS scores showed a significantly larger increase among IG participants than among CG participants (*P*=.02).

Falls Efficacy and Fear of Falling

Table 4 provides an overview of the change in scores for falls efficacy and fear of falling between baseline (before intervention) and the end of the 12-week intervention period. Two-way repeated-measures ANOVA revealed significant interaction effect between group and time regarding the fear of falling (*P*=.009). Scores for fear of falling showed a significantly larger decrease among IG participants than among CG participants (*P*=.008). There were no changes in falls efficacy.

Table 3. Changes in physical function. *Before* and *After* refer to measurements taken before and after the 12-week intervention period, respectively.

Test	Intervention group (n=10), mean (SD)		Control group (n=13), mean (SD)		Interaction, *P* value[a]
	Before	After	Before	After	
2-min step, steps	54.40 (31.26)	67.00 (41.33)	68.92 (24.22)	64.76 (29.92)	.09
Arm curl reps	12.60 (4.62)	23.70 (5.47)	15.15 (3.55)	23.53 (4.19)	.18
Chair stands	11.00 (4.64)	19.20 (5.99)[b]	13.00 (2.61)	14.15 (2.70)[c]	<.001
Back scratch, cm	-13.60 (11.76)	-15.20 (10.46)	-14.23 (9.01)	-13.15 (8.79)	.31
Chair sit-and-reach, cm	14.10 (10.83)	11.10 (11.42)	16.30 (8.05)	11.92 (8.85)	.73
8-foot up-and-go, seconds	9.55 (4.03)	8.90 (2.76)	8.27 (2.27)	8.52 (1.75)	.40
Berg Balance Scale score	43.00 (6.49)	44.30 (6.32)[e]	44.69 (3.49)	43.84 (3.57)	.03

[a]The interaction effect between time and group was evaluated in terms of the *P* value obtained using two-way repeated-measures analysis of variance.
[b]*P*<.001.
[c]*P*<.05. Values indicate a significant difference between pre- and posttest measurements (ie, Before vs After for the same group).

Table 4. Changes in psychological risk factors for falling. *Before* and *After* refer to measurements taken before and after the 12-week intervention period, respectively.

Assessment tool	Intervention group (n=10), mean (SD)		Control group (n=13), mean (SD)		Interaction, *P* value[a]
	Before	After	Before	After	
Falls efficacy					
Activities of daily living	15.80 (3.93)	15.90 (5.23)	16.53 (3.17)	17.23 (2.68)	.55
Social activities	13.70 (2.31)	14.60 (1.71)	13.23 (2.91)	13.53 (3.45)	.51
Fear of falling	30.50 (7.60)	28.40 (7.74)[b]	29.46 (4.68)	29.53 (4.99)	.009

[a]The interaction effect between time and group was evaluated in terms of the *P* value obtained using two-way repeated-measures analysis of variance.
[b]*P*<.01 indicates a significant difference between pre- and posttest measurements (ie, Before vs After for the same group).

Discussion

Principal Results

The objective of this study was to develop a novel telepresence exercise platform based on WebRTC technology, as well as a suitable telepresence exercise program, and to investigate the effect of such a home-based telepresence program (ie, with real-time supervision and feedback from a specialized instructor) on fall-related risk factors in elderly women. The main finding was that a 12-week telepresence program involving progressive exercise can be effective for enhancing physical performance (chair stand test score), improving balance (BBS score), and reducing fear of falling in elderly women at risk of falls.

Comparison With Prior Work

In the elderly population, falls are an important public health concern, and exercise interventions are essential to fall prevention [5,34]. Decrease in muscle function has been identified as an independent predictor of disability and death [35], and reduced strength in the lower limbs has a detrimental effect on gait speed, balance, and the ability to rise from a chair [36,37]. Increasing physical performance and balance ability is thus an important strategy to improve social participation and quality of life, especially among elderly individuals with high risk of falling. The benefits are reflected as improved ability to perform activities of daily living, reduced fear of falling [38], enhanced physical activity parameters such as walking speed and stair climbing ability, increased muscle fiber cross-sectional area, and increased muscle strength [39]. These benefits are thought to be due to muscle nerve stimulation by regular exercise, and activation of the somatosensory system as a result of lower body bending and extension.

Recent studies have investigated the effectiveness of home-based exercises in reducing fall-related risk factors in the elderly population. Campbell et al [40] reported that home exercises for muscle strength and balance increased physical function and reduced the incidence of falls and injuries among very elderly women (≥80 years). Yates and Dunnagan [41] found that a 10-week home-based exercise program induced significant improvement in lower extremity strength and balance among rural community-dwelling older adults, which is similar to the findings of our study. Overall, these studies support the use of home-based exercises to reduce the risk of falls. Wu and Keyes [42] reported that a home-based Tai Chi exercise program involving videoconferencing provided an increased sense of balance among elderly participants, which is also similar to the findings of our study, although it should be mentioned that the aforementioned study was limited by the lack of a control group.

The findings of our study are contrary to those of Sosnoff et al [43], who found that a 12-week home-based exercise program provided no significant improvement in lower limb strength or BBS scores among older adults with multiple sclerosis. The

discrepancy between these findings is likely due to differences in the intervention methods applied in the two studies. Namely, the participants of our study used a face-to-face method that involved looking at the computer monitor and following the instructor's movements at home, while the participants in the previous study performed exercises at home by consulting a distributed manual and did not receive immediate feedback about their movements. These differences emphasize the importance of direct interactions with the instructors.

Among the elderly, decreased ability to maintain balance translates into an increased incidence rate of falls. Moreover, elderly individuals who are unable to maintain balance often develop a fear of falling, which results in reduced levels of physical activity and reluctance to lead an independent life [7]. Fear of falling, which represents a psychological risk factor related to falls, is defined as a lasting concern regarding falling, which leads an individual to avoid activities that they are otherwise fully capable of performing [44]. Fear of falling can range from a healthy concern about avoiding risky situations, such as navigating an icy sidewalk, to a more severe and disabling anxiety about falling, which can negatively affect an older individual's independence [45]. It is currently accepted that fear of falling can influence the incidence of falls, which suggests that reducing the fear of falling is critical to reducing the incidence rate of falls. The elderly can reduce their fear of falling by exercising regularly and increasing their fall-related self-efficacy (ie, conviction that they will not fall).

In this study, we found that telepresence exercise provided a significant reduction in the fear of falling, which is similar to the observations reported by Liu and So [46] regarding the effect of Tai Chi exercises in elderly individuals living in a health facility. This finding is, however, contrary to that of Schoenfelder [47], who reported that a 3-month supervised program of ankle strengthening exercises and walking did not reduce the fear of falling in older adults. The discrepancy between these findings may be attributed to the fact that the participants in our study were older and had a higher risk of falls. In other words, the participants had a considerably high fear of falling prior to the study and hence demonstrated a greater decrease in their fear of falling after completing the exercise program, according to the principle of initial values [48], which is one of the key principles of exercise training.

It is important to note that the women who participated in our telepresence exercise program interacted with their instructor on a one-on-one and face-to-face basis, rather than performing simple exercises and following an unsupervised education program, suggesting that the decrease in their fear of falling might be related to positive changes induced by real-time and sustained interactions. Several studies highlighted the fact that there are limits to the effect of interventions aiming to prevent falls in very elderly people (≥80 years) and proposed that this population will benefit more from an in-home approach accompanied with one-on-one management, rather than from a group exercise program [7,18].

In our study, there was no statistically significant difference between the intervention and control groups regarding fall efficacy, which was measured with respect to activities of daily living and social activities. While both groups showed an increase in the falls efficacy with respect to social activities, the intervention group exhibited a numerically greater increase. We speculate that exercise training can be expected to lead to an increase in social activity participation among elderly individuals. The increase in participation in activities of daily living and social activities among women in the control group may have been due to an increase in confidence in performing movements involved in these activities, which may have been promoted by nutrition guidance and exercise education.

Our findings offer objective evidence that an at-home exercise routine with real-time feedback represents an effective intervention for improving balance and reducing fear of falling among the elderly. It is important to note that the value of telepresence exercise is not limited to its effectiveness in improving fall-related risk factors among elderly women at risk of falls and provides additional advantages associated with its design. First, the developed telepresence exercise platform appears to be optimally suited for elderly participants, as both the tablet and the website were very user-friendly and allowed the elderly participants to operate them with a minimum amount of effort. Second, the one-on-one exercise approach enabled participants to receive real-time feedback and engage directly with the instructor, which is typically difficult during group exercises. Supervision and timely feedback regarding the exercises not only improved the effectiveness of training (versus that of unsupervised training) but was also important to ensure the safety of the participants, who were elderly. Third, the study was successfully conducted during a period when the risk of falls among the elderly was particularly high owing to cold temperatures and heavy snowfall. However, the weather conditions did not affect the implementation of the telepresence exercise program (attendance or compliance), as such exercises were conducted in the safety of the participants' homes.

Limitations

This study has several limitations. First, the sample size was relatively small, which precludes generalization of our findings. Second, a cost-benefit analysis for the telepresence exercise platform service was not conducted. Third, follow-up evaluation after 12 weeks is needed to confirm the long-term effects of telepresence exercise. Future studies should include a larger number of participants, a quantitative cost-effectiveness analysis, and a long-term effectiveness analysis.

Conclusions

We found that home-based training using our telepresence exercise platform and remote supervision by a specialist improved fall-related physical and psychological factors in home-dwelling elderly women. Telepresence exercise can be used in a broad range of populations that need remote training, including patients with disabilities and older adults with reduced mobility.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 369KB - mhealth_v6i5e132_app1.pdf]

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Abbreviations

ALST: appendicular lean soft tissue
ANOVA: analysis of variance
API: application programming interface
BBS: Berg Balance Scale
CG: control group
FES-K: Korean Falls Efficacy Scale
FOFQ: Fear of Falling Questionnaire
IG: intervention group
NAT: network address translator
PHP: PHP: Hypertext Preprocessor
RPE: rating of perceived exertion
SFT: Senior Fitness Test
TSM: total-body skeletal muscle mass
WebRTC: Web Real-Time Communication

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Original Paper

TEAMS (Tele-Exercise and Multiple Sclerosis), a Tailored Telerehabilitation mHealth App: Participant-Centered Development and Usability Study

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Abstract

Background: People with multiple sclerosis face varying levels of disability and symptoms, thus requiring highly trained therapists and/or exercise trainers to design personalized exercise programs. However, for people living in geographically isolated communities, access to such trained professionals can be challenging due to a number of barriers associated with cost, access to transportation, and travel distance. Generic mobile health exercise apps often fall short of what people with multiple sclerosis need to become physically active (ie, exercise content that has been adapted to accommodate a wide range of functional limitations).

Objective: This usability study describes the development process of the TEAMS (Tele-Exercise and Multiple Sclerosis) app, which is being used by people with multiple sclerosis in a large randomized controlled trial to engage in home-based telerehabilitation.

Methods: Twenty-one participants with disabilities (10 people with multiple sclerosis) were involved in the double iterative design, which included the simultaneous development of the app features and exercise content (exercise videos and articles). Framed within a user-centered design approach, the development process included 2 stages: ground-level creation (focus group followed by early stage evaluations and developments), and proof of concept through 2 usability tests. Usability (effectiveness, usefulness, and satisfaction) was evaluated using a mixed-methods approach.

Results: During testing of the app's effectiveness, the second usability test resulted in an average of 1 problem per participant, a decrease of 53% compared to the initial usability test. Five themes were constructed from the qualitative data that related to app usefulness and satisfaction, namely: high perceived confidence for app usability, positive perceptions of exercise videos, viable exercise option at home, orientation and familiarity required for successful participation, and app issues. Participants acknowledged that the final app was ready to be delivered to the public after minor revisions. After including these revisions, the project team released the final app that is being used in the randomized controlled trial.

Conclusions: A multi-level user-centered development process resulted in the development of an inclusive exercise program for people with multiple sclerosis operated through an easy-to-use app. The promotion of exercise through self-regulated mHealth programs requires a stakeholder-driven approach to app development. This ensures that app and content match the preferences and functional abilities of the end user (ie, people with varying levels of multiple sclerosis).

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KEYWORDS

multiple sclerosis; exercise; therapy; mHealth; user-centered design

Introduction

Regular participation in physical activity continues to gain recognition as a behavioral approach that can safely improve, or help alleviate, both functional (eg, reduced balance and walking capacity) and symptomatic consequences (eg, severe fatigue, depression, and cognitive dysfunction) of multiple sclerosis (MS) [1-3]. However, adults with MS are less physically active than adults without disabilities, with only 20% of adults with MS meeting the US national guidelines of moderate-to-vigorous physical activity required to improve and maintain health [4,5]. Low physical activity participation can lead to the onset or exacerbation of common secondary conditions experienced by people with MS [6], which include pain, fatigue, deconditioning, weakness, falls, and depression [6-9]. One or more of these health conditions can have a negative impact on health and function across the lifespan and, in the aggregate, can limit or restrict participation in general life activities including employment, social and community engagement, and performing instrumental activities of daily living [10-13].

People with MS face varying levels of disability and symptoms, and thus require highly trained therapists and/or exercise trainers specialized in disability populations (eg, Certified Inclusive Fitness Trainers through the American College of Sports Medicine or Certified Special Population Specialists through the National Strength and Conditioning Association) to design personalized exercise programs. Unfortunately for people living with MS in geographically isolated communities, access to trained professionals is limited or nonexistent. This has increased the need for better delivery methods to reach people with MS who do not have access to appropriate care.

Several studies have reported that delivering home-based therapeutic exercises through information and communication technology, referred to as telerehabilitation, can be an equally effective alternative to onsite rehabilitation in the delivery of care to hard-to-reach populations [14-17]**.** The incorporation of this technology in addressing the needs of people with MS has the potential to greatly improve their access to exercise and rehabilitation, while eliminating the barriers of time, cost, and personnel (ie, driver or caregiver) associated with onsite rehabilitation [18].

Mobile health (mHealth) apps can provide a ubiquitous channel for delivering convenient and personalized telerehabilitation to people with MS [19]. These apps can enable researchers to deliver and quantify “precise” doses of exercise that are customized to the unique needs of the end user and can be accessed in the comfort of one’s home [20]. Researchers can also increase the likelihood that participants will engage in the exercise behavior offered by the app by embedding behavior change theory principles within the mHealth app.

One of the more popular theories of behavior change is the Social Cognitive Theory (SCT) [21]. Components of SCT include self-regulation or monitoring, goal-setting, informational advice, and role-modeling [22,23]. While embedding SCT into new mHealth apps increases the potential viability of the product over the long term, in the short term promoting exercise behavior ultimately depends on participants’ perceptions of how easy it is to use the app [24].

While there are thousands of commercially available exercise apps for the general population, there are few, if any, that have been specifically designed for people with MS. Therefore, the purpose of this usability study is to describe the development of a therapeutic exercise app for people with MS. The study is part of an ongoing, multisite randomized controlled trial across 38 locations in Alabama, Mississippi, and Tennessee. The Patient-Centered Outcomes Research Institute (PCORI)-funded study is referred to as the TEAMS project, which stands for Tele-Exercise And Multiple Sclerosis.

Methods

Design

The study incorporated a parallel-iterative design, whereby the project team simultaneously developed both the app features and the exercise content (videos and articles).

User-Centered Design Features

An app that would be useful to people with different functional levels of MS requires a user (participant)-centered design (UCD) that involves their input early in the development process [25]. The choice of a UCD was made to ensure that the app was usable and acceptable to people with MS. Furthermore, the entire project is grounded on patient centeredness. Four UCD principles were employed during this study: (1) early input or feedback from users; (2) tests of usability through quantitative (eg, surveys or questionnaires) and qualitative data (eg, observational or verbal feedback); (3) iterative tests and design; and (4) an integrated design that allows usability issues to be identified and addressed concurrently with the development of the product.

Project Team

Development of the app included 2 project teams (research and development). The research team included 4 members with backgrounds in exercise and recreational technology for people with disabilities. The development team consisted of 2 app developers led by a Health Informatics researcher. The research team conducted and analyzed the evaluation phases (focus group interviews and usability testing) and worked in parallel with the development team throughout the creation of the TEAMS app. Members of both the research and development team conducted the heuristic analysis. The creation of content included an adapted exercise specialist (5 years of experience) and occupational therapist (21 years of experience), which were informed by a stakeholder group and a clinical consultant group. Stakeholders consisted of 10 individuals with MS, researchers, and therapists. Specifically, 5 of the stakeholders are individuals with MS, 2 are health care providers for individuals with MS, one is a caregiver for a person with MS and 2 represent national and regional MS specific organizations. The project consultant group included 2 clinicians, 5 data safety monitoring board members, and a study consultant who was a senior researcher in exercise science for people with MS and contributed to the development of exercise content. The stakeholder group was created specifically for this project to oversee the creation of

the app and content, as well as the implementation of the project. Stakeholders were heavily involved with the development of the app content and oversaw the development of the app through monthly meetings or workshops, which members of each project team attended.

Instruments

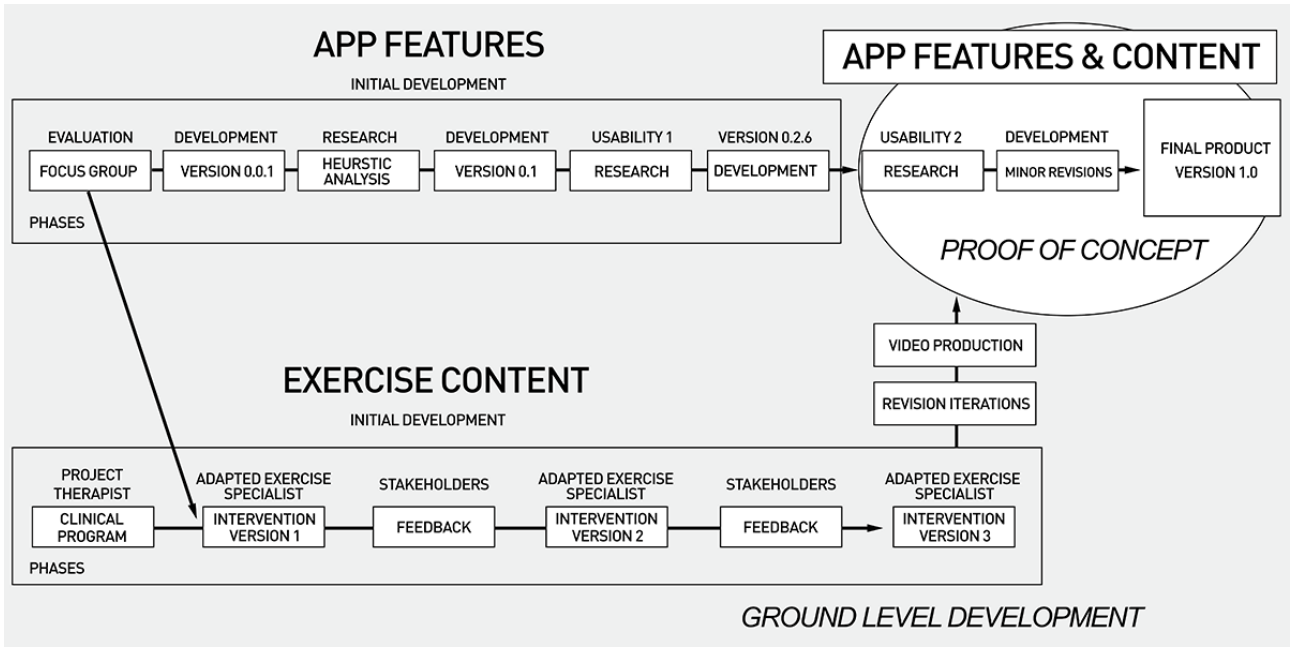
The project aim was to create a comprehensive home tele-exercise program that could be performed by individuals with varying levels of MS using an Android computer tablet (Asus ZenPad 3s 10) and an adjustable floor stand (Standzout Standzfree 48" Universal Pro Tablet Floor Stand). The tablet floor stand could be adjusted to accommodate various exercise positions (lying on the floor, seated, and standing). An example of the setup is shown in Figure 1. Specifically, the custom-designed Android app provided an easy-to-use interface for navigating and viewing the exercise videos. The app is built to operate on any Android or iOS device (of any size) that is a phone or tablet. The app is, and will be, available free of charge. The Android version is currently available for public download; however, users will not be able to sign up for an account until the clinical trial is completed.

TEAMS Development Process

An overview of the entire development process is displayed in Figure 2, which occurred between the years 2016 to 2017 and involved two phases: (1) ground-level creation of app features and exercise content, and (2) proof of concept trials through individual user testing.

Figure 1. Tablet and table stand setup used to complete exercises in the seated position and on the floor.

Figure 2. An overview of the TEAMS development process.



Participants

A range of people with disabilities, including people with MS, were recruited for the study to ensure that multiple functional levels were addressed in the design of the app. Twenty-one participants participated in 1 focus group and 2 individual usability tests. Sample sizes for the usability tests were based on saturation of the qualitative data [26]. This criterion involved completing the usability tests until there were no new themes identified.

Eligibility criteria included: (1) minimum age of 18 years, (2) residence in the local metro area, (3) documented mobility limitation, (4) ability to speak and understand English, and (5) ability to operate an app on a mobile device. In addition, both the focus group and the individual user tests required at least one individual who used a wheelchair. None of the participants had any experience with the mobile app evaluated in the study. The Institutional Review Board of the University of Alabama at Birmingham approved the protocol. Prior to enrollment, written consent was obtained from each participant.

Ground-Level Creation of App Features and Exercise Content

The exercise content team created exercise videos and articles that could be delivered periodically throughout a 12-week program. The exercise videos included yoga, Pilates, and dual-task exercises, which were derived from an onsite program that was developed in 2010 by a group of certified MS Clinical Specialists at a comprehensive MS care center. The exercise content was further adapted to target 4 functional levels of people with MS based on stakeholder feedback and literature review. Every exercise was designed to also include a challenged version and a modified version by using exercise equipment to increase exercise intensity or assist with movement. The exercise equipment included yoga mat, a Swiss ball, half roll, sliders, a small inflatable ball, yoga straps, yoga block, a Pilates disc, and resistance bands. Articles and infographics were also included in the app focusing on exercise, and self-regulatory strategies such as goal-setting, seeking social support, and overcoming barriers. The articles were modified from publicly available information on the National Center on Health, Physical Activity and Disability website (www.nchpad.org) [27].

After embedding the exercise videos and articles into the app, stakeholders and study consultants viewed and tested the content and provided feedback and suggestions for further adaptations. Stakeholder feedback resulted from formal monthly meetings and informal individual meetings that included pilot testing. The adapted exercise specialist recorded stakeholder feedback through written qualitative and observational notes.

Focus Group

The development team began ground-level creation of the TEAMS app from the feedback received from the focus group interview. The purpose of the focus group was to identify what features needed to be included in the initial version of the app. The focus group was held at a community fitness facility. A member of the research team guided the group and took written notes. The group interview contained 6 open-ended questions, which served as general prompts for discussion in the following areas: general types of exercise performed; challenges or issues experienced towards exercise participation; perceptions, experiences, and preferences of using fitness apps; challenges or issues experienced with fitness apps; and preferences for app features. Participant responses were probed in further detail through several follow-up questions. An audio recording device was used to capture participant feedback, which was later transcribed for analysis. The development team utilized the focus group results to build the initial features and user interface of the TEAMS app version 0.1.

Heuristic Analysis

The development team conducted a rapid heuristic analysis to assess general usability issues in the app version 0.1. The heuristic evaluation involved the collaborative efforts of both the development and research teams evaluating the app against accepted usability principles [28]. Any deviations from these accepted principles were referred to as a heuristic violation. Each heuristic violation was assigned a severity rating from 1 to 4, with 4 being the most severe. This heuristic analysis was performed in accordance with Nielsen's 10 Usability Heuristics for User Interface Design [29]. Following the heuristic analysis, the development team further refined the app version 0.1.

After initial versions of the app content and features were created, they were combined for usability testing in individuals with MS. Data recorded from usability tests included both quantitative and qualitative data (ie, a pragmatic mixed methods approach, namely “quan+QUAL”), which were selected or mixed at each evaluation phase to expand our understanding of app usability [30]. The project team anticipated that the creation of the TEAMS app and content would require several iterations and continued the research using the aforementioned UCD principles [31] and saturation point for data completion. This process resulted in a total of 2 usability tests and 2 further development iterations to the app features. Based upon user feedback, new or advanced adaptations to the original exercise content were not warranted.

Usability Test One

Following app revisions, newly recruited participants completed individual usability testing of the latest app (version 0.2). A concurrent thinking aloud process was used, whereby participants were asked to complete representative tasks on an Android tablet, while a researcher observed their actions and asked questions [32]. Participants performed 8 usability tasks, which involved navigating various app pages and testing app functions. Participants were also instructed to locate, play, and perform an exercise video that they felt was suitable to their functional ability. As a preliminary test of app function, exercise content was not included within the first usability test. A research assistant took written notes from their observations of participants during the usability tasks, which were later qualitatively analyzed. The research assistant also recorded the frequency, nature, and location of issues that participants encountered during the usability tasks. These issues included those explicitly reported by participants, as well as the issues observed by the research assistant.

Usability Test Two

After the development team made substantial revisions to the app (version 0.2.6), the research team conducted a second round of usability testing. The second usability test protocol matched that of the former, except for additional tasks to accommodate new app functions and a post-data collection qualitative interview. The interview was added because the development team determined that the app was a near-finalized product based upon results from the first usability test. The face-to-face interview was conducted in a comfortable setting that was chosen by the participant. The goal of this interview was to understand participants' perceptions of the app and determine whether further development changes to the app were necessary. The interview was recorded by an audio device, which was later transcribed for qualitative analysis.

Proof of Concept

Usability Measures

App usability can be defined in terms of effectiveness (ie, the ease at which individuals can use the product in a manner they expect), usefulness (ie, the extent a product can enable users to achieve their goals and willingness to use the product), and satisfaction (ie, the users' perceptions and opinions of the product) [31].

Accordingly, this study assessed three core areas of usability: *effectiveness*, *usefulness*, and *satisfaction.* Researchers evaluated *effectiveness* by observing and recording the frequency of problems that participants experienced during the usability tasks [31]. Since a different sample size was recruited for the usability tests, the research team recorded the mean number of identified problems per participant. Each problem that participants identified was classified under the Usability Problem Taxonomy [33]. This taxonomy allowed usability problems to be classified into both a task and artifact component. The artifact component included problems with visualness, language, and manipulation of the product. In contrast, the task component involved problems related to task-mapping (ie, interaction, navigation, or function) and task-facilitation (eg, task automation, user action reversal, and keeping the user on task). The Usability Problem Taxonomy was incorporated to help the development team pinpoint direct versus implied fixes.

Researchers assessed *usefulness* and *satisfaction* through participants' perceptions of completing the usability tasks via a face-to-face interview. Accordingly, the interview included questions that sought to gain insight into participants' overall perceptions of the app, including its usefulness, their likes and dislikes regarding app features and usability, their suggestions for improvements to the app, and their experience performing exercise videos. Additionally, participants were also asked whether they thought the app was ready to be delivered to the public. This was used as an indicator of whether further revisions to the app or usability tests were necessary. Two members of the research team conducted the interviews. One interviewer was a research staff member that was trained and supervised by the primary interviewer. The primary interviewer had 3 years of experience with qualitative interviews and had a background in adapted physical activity.

Usability Setup and App Content

Equipment included a 10.5-inch Android tablet that was mounted on an adjustable floor stand (Standzfree Universal Stand, Standzout) and came installed with the TEAMS app. The app included the exercise videos and articles that resulted from the ground-level development stage. Specifically, the app included 2 articles and 6 sample playlists of exercise videos, one for each functional level that resulted from the exercise content development process. The app also featured a home page with weekly instructions and goals, earnable badges that were awarded for completing specific tasks such as reading an article, a built-in calendar, and notifications that informed users of newly added content. If required in the video, participants used the following exercise equipment: a Swiss ball, yoga mat, sliders, a small inflatable ball, and resistance bands.

Analysis

The research team's philosophical assumptions aligned with dialectical pluralism [34]. Dialectical pluralism provides a way for researchers, practitioners, clients, policy makers, and other stakeholders to work together and produce new workable "wholes" while concurrently thriving on differences and intellectual tensions. Within this paradigm, the research team held separate theoretical perspectives when analyzing the quantitative and qualitative data. Quantitative data were descriptively reported. Researchers also recorded the age, disability or condition, and mobility information from all participants involved throughout the research process (ie, people who participated in the focus group and usability tests).

Qualitative data were analyzed using inductive thematic analysis [35] framed within Interpretivism (ontological relativism and epistemological subjectivism) [36]. Within this process, the research team first transcribed the qualitative data and then checked the transcriptions for accuracy with the audio recordings. Next, two analysts generated initial codes from segments of transcribed interviews or written notes. These codes were then refined into fewer subthemes for a single transcription. The analysts repeated this process for each transcription and evolved their themes in a case-by-case manner. The analysts then met to discuss their subthemes, which were then integrated and refined into a single set of major themes based on internal and external homogeneity [37]. During this process the analysts acted as "critical friends" [38]. Thus, they voiced their interpretations of the data and underwent critical discussions based upon their epistemological beliefs, with the goal of reaching the most plausible interpretation of the data. One analyst, the primary interviewer, had 5 years of clinical experience in exercise training for people with disabilities and had a background in mixed-methods research. The other analyst also had a background in mixed-methods research, which focused on the development of a grounded theory model to inform adaptive intervention designs for increasing physical activity in people with disabilities.

Results

Overview

Participant demographics for the focus group and usability tests are shown in Table 1, and their clinical characteristics are shown in Table 2. Overall, 21 people with disabilities were involved in the entire research process (mean age 54 years, SD 2; 14 females, 8 males). The 8 individuals included in the focus group represented several functional levels of disability. Eight people with disabilities were included in the first usability test. The final usability test included 5 people with MS who had varying levels of functional mobility.

The following subsections include summaries of the results and accompanied revisions or changes that were made by the project team for both the app features and content.

App Features Findings

Focus Group

Focus group participants noted the following qualitative themes: *barriers to exercise*, *disability-specific exercise content*, and *suggestions for app features*. The *barriers to exercise* theme included several issues with exercise onsite at a fitness facility such as lack of time, convenience, and transportation. To circumvent these issues, participants identified that the home environment was an ideal setting for exercise. However, participants noted that they required *disability-specific exercise content*, which they currently had limited access to. One participant stated:

> *You can find stuff on the internet but some of it you can't adapt [for people with disabilities].*

Specifically, they desired exercises that were suitable to their functional needs and could lead to health benefits or improvements in fitness.

Table 1. Demographics of participants included in the focus group and usability tests.

Participant demographics	Focus group (N=8)	Usability test 1 (N=8)	Usability test 2 (N=5)
Sex, n (%)			
Male	2 (25)	4 (50)	1 (20)
Female	6 (75)	4 (50)	4 (80)
Age (years), mean (SD)	54 (11)	54 (13)	53.6 (8.5)
Ethnicity, n (%)			
Non-Hispanic white	6 (75)	5 (62.5)	2 (40)
Black	2 (25)	3 (37.5)	3 (60)

Table 2. Clinical characteristics of participants the focus groups and usability tests.

Clinical characteristics	Focus group (N=8)	Usability test 1 (N=8)	Usability test 2 (N=5)
Disability, n (%)			
Spinal cord injury	2 (25)	1 (12.5)	N/A[a]
Multiple sclerosis	2 (25)	3 (37.5)	5 (100)
Cerebral palsy	1 (12.5)	2 (25)	N/A
Parkinson disease	1 (12.5)	N/A	N/A
Spina bifida	1 (12.5)	N/A	N/A
Vision impairment	1 (12.5)	N/A	N/A
Stroke	N/A	1 (12.5)	N/A
Hypertension	N/A	1 (12.5)	N/A
Mobility device, n (%)			
Cane	4 (50)	2 (25)	1 (20)
Power wheelchair	1 (12.5)	2 (25)	1 (20)
Manual wheelchair	2 (25)	1 (12.5)	N/A
Orthotic device	1 (12.5)	N/A	N/A
Independent ambulator	N/A	2 (25)	1 (20)
Walker	N/A	1 (12.5)	2 (40)

[a]N/A: not applicable.

Table 3. The Usability Problem Taxonomy (UPT) results from the usability tests.

Characteristics	Usability test 1 (n=8)	Usability test 2 (n=5)
Problems per user, mean (range)	2.13 (1-6)	1.0 (1-2)
Severity, mean (range)	2.17 (1-4)	1.5 (1-2)
Location or screen (area=# of problems)		
Calendar	3	4
Articles	2	1
Menu	6	–
All Screens	4	–
Videos	2	–
Profile	1	–
UPT Artifact Classification (type=# of problems)		
Visualness	5	3
Manipulation	5	2
Language	7	–
UPT Task Classification		
Mapping	12	2
Facilitation	5	3

Participants also desired exercises that could be performed with limited equipment but were also challenging and, most importantly, enjoyable.

Regarding *suggestions for app features*, participants expressed the desire to be able to enter their personal level of physical function into an app and receive a customized workout program based on the type of activities they could perform. They also acknowledged that observing other people with similar functional abilities perform exercises enhanced their motivation to exercise. Additionally, participants stated a desire for app features that could enhance motivation to exercise through easily obtainable achievement rewards. Based upon these themes, the app development team oriented the initial development of the TEAMS app to include the following features: an app that could be instantly tailored to the functional needs of an individual (ie, an app that could quickly alternate between exercise programs of various challenges or movement adaptations), downloadable exercise videos that were directed or modeled by people with MS, and earnable badges for completion of achievements.

Heuristic Analysis

The heuristic analysis resulted in 18 violations with an average *moderate* severity of 2.5 [29,39,40]. The most commonly violated heuristic item was the *match between system and the real world*. In other words, it was suggested that the language used in the app should be changed to reflect everyday user language, instead of system-oriented terms. The most severe violations included the absence a help menu or tutorial, the inability to open a social media post from another user, and the inability to confirm the entry of social media posts. These finding were presented to the development team, which were subsequently integrated into the next version of the app.

Usability Test One

Results from usability tests 1 and 2 are shown in Table 3. The first round of usability testing resulted in an average of 2.13 problems (range 1-6) per participant (15 problems identified by 8 people), with an average severity score of 2.17. Users identified several problems throughout different locations of the app, with most problems located in the Main Menu and Calendar. These issues were related visualization, language, and manipulation, which primarily interfered with task mapping (ie, navigation, function, and interaction). Based upon these results, the development team underwent a complete overhaul of the aesthetics (color, font size, the addition or revision of icons) and problem areas. For example, the default text size within the tablet was increased to the largest size setting, and the Main Menu included weekly instructional content and notifications for newly added video and article content. The development team also made efforts to enhance verbal cues and task navigation by the addition of icon images and more noticeable fonts for buttons.

Usability Test Two

The second round of usability testing resulted in an average of 1.0 problems per participant and were of low severity. Most problems were located in the Calendar menu and were related to visualization, which caused issues both with task mapping and facilitation (eg, staying on task). These results informed the development team that the calendar still required changes to enhance the user-experience, which were included in the app version 1.0.

Qualitative analysis resulted in 6 themes: *high-perceived confidence for app usability, positive perceptions of exercise videos, viable exercise option for the home, orientation and*

familiarity required for successful participation, *app issues*, and that the app was *ready to be delivered to the public after minor revisions.* Specifically, all participants felt confident that they could operate the app independently and noted that the app was similar to other Android apps in the marketplace.

Regarding the exercise content, participants appreciated the precision of the exercise videos that allowed for a wide variety of individuals with different functional abilities to perform the exercise routines. Participants also acknowledged potential benefits of the exercises and that the movements were similar to their past experiences in therapy:

> *I would love to do this because I know it helps your balance… I think the exercise videos are good, because a lot of the movements are what you do in therapy. So, this is along that line to get you moving more* [Participant 4]

Due to these positive perceptions, participants stated that the app was a viable exercise option for individuals with MS to perform at home. Interestingly, participants noted that the app should act as a supplement or transition towards engagement in community exercise (ie, not a substitute). Community engagement fosters interpersonal relationships with the instructor and other members or participants.

Participants identified several minor *app issues*. First, engagement in the program would require more instruction or *orientation and familiarity* with the purpose and pace of the exercises. At first participants expected dynamic exercises of high intensity, as opposed to the slower, mindful, and spiritual nature of the yoga and Pilates movements. Participants also identified *app issues*, particularly with the calendar and badges. The calendar was not saving events that users created and did not have buttons that were visually identifiable. Participants also identified badges that were not successfully being rewarded for completion of a task (eg, reading an article). Nevertheless, participants reported that the app was *ready to be delivered to the public*, assuming the minor issues with the app were revised (calendar and bug problems). When asked whether the app was ready for production, participants were satisfied with the exercise videos and articles, but suggested minor improvements to app function, as noted by Participant 4:

> *I think it [the app] requires just a little bit of tweaks, but as far as the exercises and things that are uploaded on it, yes*

Based upon this qualitative feedback, the project team determined that after the app issues identified by participants were revised, that the app and content be set into production within the app marketplace.

Creation of Exercise Content

The creation of app content resulted from an initial development phase that included 4 stages and several revision iterations. Regarding the initial development phase, the TEAMS exercise intervention was first derived from a comprehensive therapeutic program used at a specialized MS clinic in Birmingham, AL, which aimed to improve overall physical function and wellness of patients with MS through yoga, Pilates, and dual tasking exercises.

Stage One

The first stage began with discussions among the stakeholders and research team to determine the general structure of the exercise intervention, which included the intervention duration, exercise components, session duration, and session frequency. This stage also incorporated feedback from the focus group, which recommended that the exercise videos be customized for different functional levels and led by or included people with disabilities.

Stage Two

During the second stage, the project therapist and the adapted exercise specialist worked together to determine the specific poses and exercise duration for the intervention components. This resulted in the first version of the intervention, which included 20 one-hour exercise sessions consisting of yoga, Pilates, and dual tasking exercises.

Stage Three

The exercise content was further modified based on discussions between the adapted exercise specialist, the project therapist, the stakeholders, and the clinical consultants. These discussions included suggestions for adaptations to the poses and exercises for participants with different functional capacities. Following these discussions, a second version of the intervention was developed to include 4 levels of exercise adaptations to enhance the likelihood of including a more diverse group of people with MS with varying levels of functional mobility. Exercise progression was established across a 12-week intervention.

Stage Four

Stakeholders and clinical consultants conducted internal pilot tests on the intensity, frequency, and duration of the exercise videos. At the end of this stage, session details such as specific duration and repetition for each exercise movement and pose were finalized.

Revision Iterations Phase

The purpose of this phase was to obtain minor feedback on strategies to assign the 4 levels of exercise adaptations to participants and intervention delivery format for video production. Over a period of 3 months, the intervention was iteratively presented to the stakeholders, the research team, and the study consultants for their suggestions on further adaptations. The adapted exercise specialist and the project therapist, which included finalizing dual-tasking exercise content for each level of exercise adaptation, video scripts and exercise equipment, made minor revisions. In addition, 2 modified levels of exercise adaptation for people with osteoporosis were added based on feedback provided by the project consultants. The intervention was then prepared for video development and production and incorporated into the usability tests of the TEAMS app.

Exercise Equipment

The original onsite therapeutic exercise program in the clinic included several pieces of exercise equipment, which the project team adapted into a home-based package. After consultation with the clinical consultant, the total equipment list included the following items: yoga mat, yoga blocks, resistance bands,

half roll, racket ball, yoga straps, sliders, Pilates disk, and a swiss, physio, and bouncing ball. The equipment was organized into 4 different home packages by each functional level.

Final Product

After several revisions, the project team created an easy-to-use therapeutic exercise package that included a tablet, tablet stand, and a set of inexpensive exercise equipment to accommodate the videos. The resultant app included a password-protected feature that allows therapists to quickly alter the exercise videos to meet the functional needs of the individual through six different levels of TEAMS exercise adaptations (examples of the first four levels, TEAMS 1-4, shown in Figure 3):

- TEAMS 1: a level that included all yoga, Pilates, and dual-tasking exercises to be performed on the floor and in standing posture.
- TEAMS 2: a level that included all routines of yoga, Pilates, and dual-tasking exercises to be performed on the floor and in standing posture. All exercises were adapted for participants with MS with mild gait impairments.
- TEAMS 3: a level that includes all yoga, Pilates, and dual-tasking exercises being performed on the floor, in a chair in seated posture, and in standing posture. All exercises were adapted for participants with MS who experience more advanced gait impairments.
- TEAMS 4: a level that includes all yoga, Pilates and dual-tasking exercises being performed in a chair in seated posture. All exercises were adapted for people with MS who use a wheelchair as their main form of mobility.
- TEAMS 3OP: a modified version of TEAMS 3 for participants with MS who have osteoporosis. All exercises that involved trunk bending and twisting motions were removed,
- TEAMS 4OP: a modified version of TEAMS 4 for participants with MS who have osteoporosis. All exercises that involved trunk bending and twisting motions were removed.

Within each level, most exercises also included modifications to increase or decrease the level of difficulty. Participants could choose to perform the standard exercises or modified version based upon their preferences (shown in Figure 4).

Figure 3. An example of exercises included at each of the four intervention levels (TEAMS 1-4).

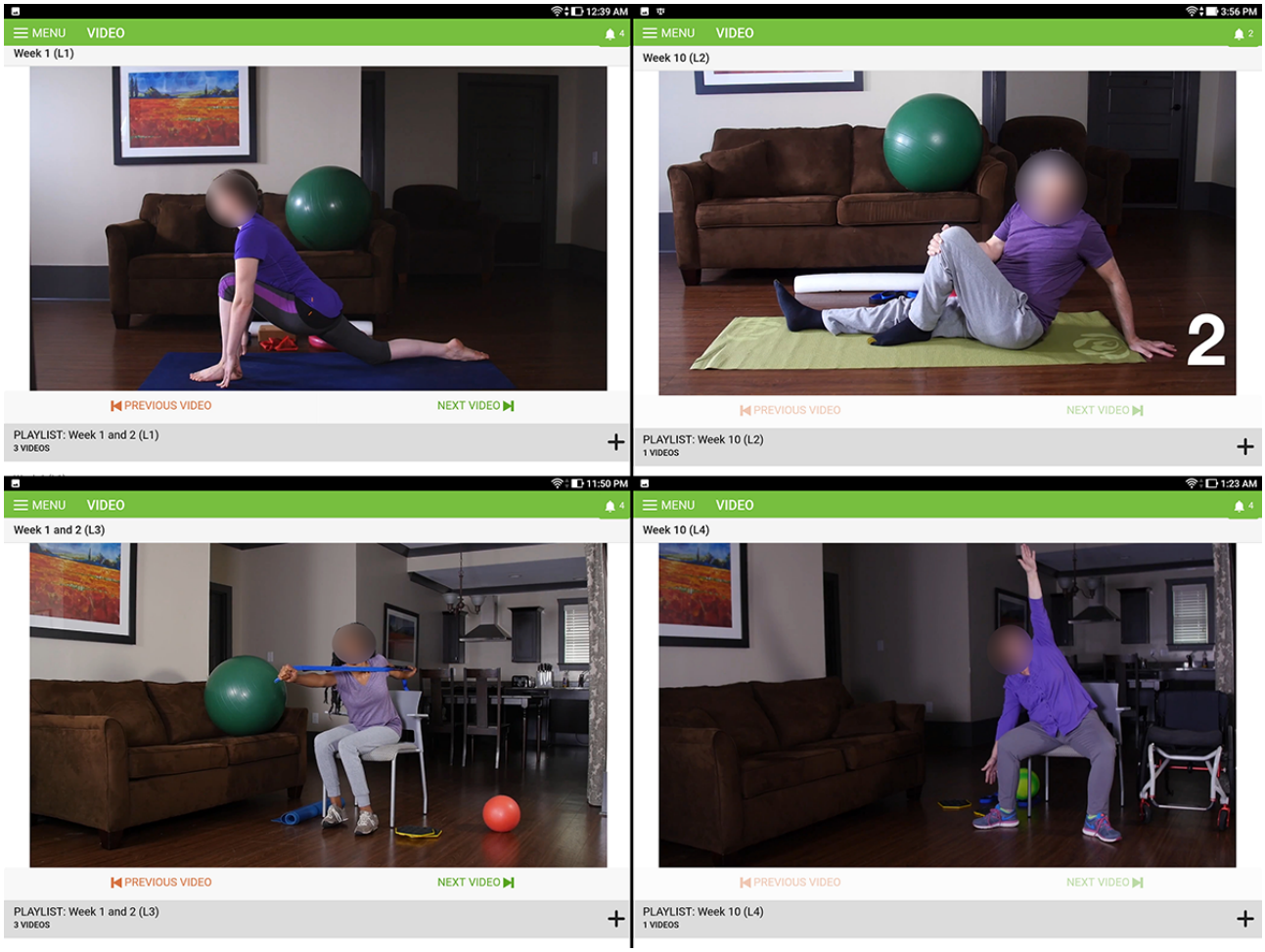
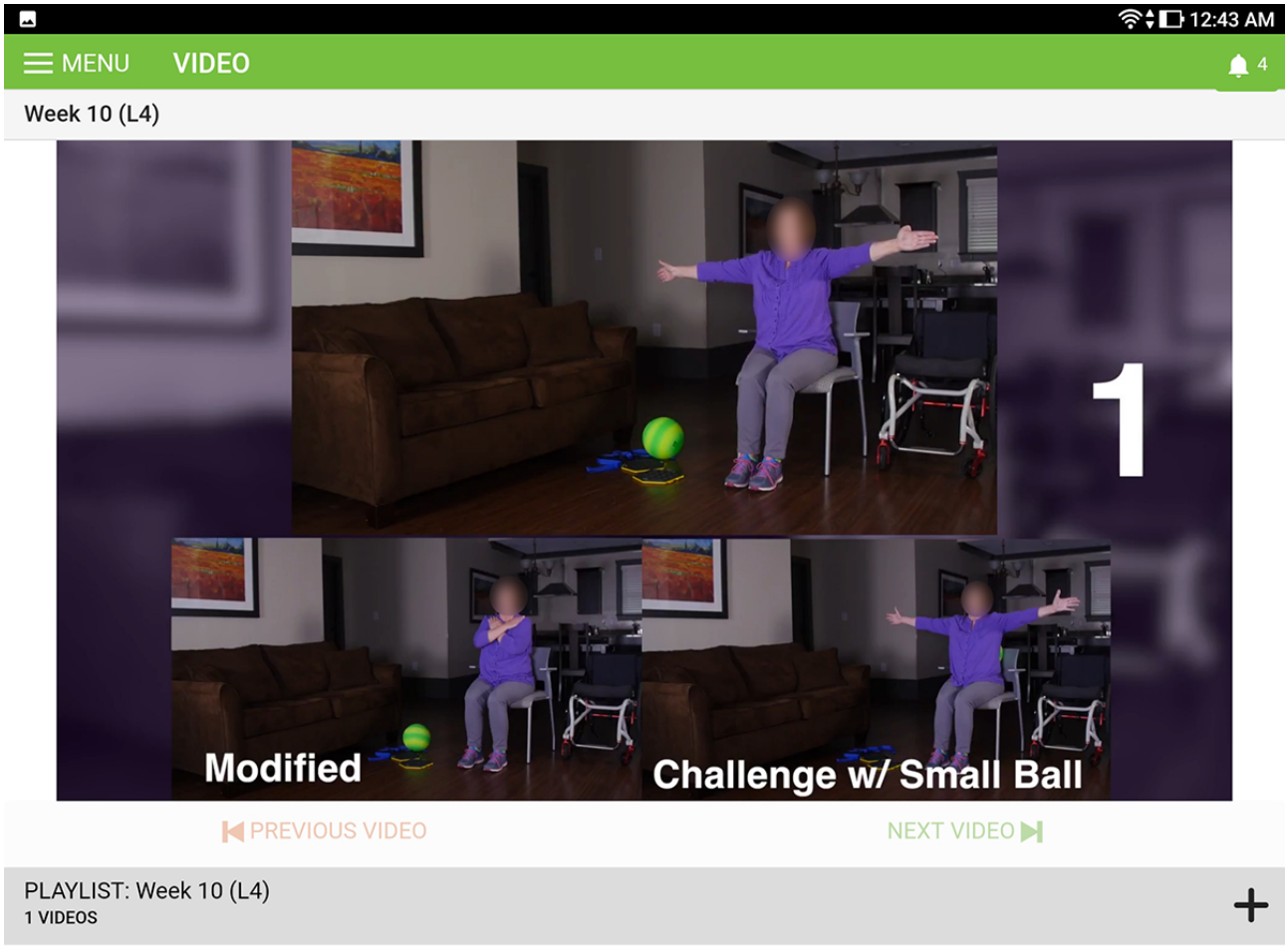


Figure 4. Example of movement modifications included in the app.



Discussion

Principal Findings

This paper describes the iterative development of an inclusive therapeutic exercise app for people with MS with self-reported Patient Determined Disease Steps scores from 0 to 7. The app is currently being used in an ongoing study targeting 820 adults with MS living in the Deep South (Alabama, Mississippi, and Tennessee). In accordance with the participant-centered focus of the agency that provided funding for this project (PCORI), nearly every stage of development was guided by extensive feedback from people with disabilities, including MS. A multidisciplinary team that included software developers, clinicians, consultants, and researchers complemented this feedback.

A novel component of this study was the heavy reliance on stakeholder feedback obtained through qualitative data from the mixed methods inquiry. These data informed the initial development phase, proof of concept testing, and final decision to terminate usability testing. Given that there are numerous ways of defining and measuring usability [31], the determination of an endpoint for usability testing is often hard to define. Within a mixed-methods approach, the research team utilized both quantitative and qualitative data to weigh the decision to halt usability testing. However, using this approach requires a few considerations. First, the research team or staff analyzing the mixed data should have a solid background in both qualitative and quantitative research and share the same ontological and epistemological beliefs. In this study the data analysts held theoretical assumptions within a meta-paradigm known as dialectical pluralism [34]. This approach emphasizes a mutual respect for both quantitative and qualitative data. Specifically, researchers should hold separate theoretical assumptions when analyzing both data types, before jointly merging the data for interpretation. Although this is not the only viable method of a mixed-methods investigation, it is important for the analysts to share similar belief systems. Otherwise, the analysts might disagree on their interpretations of the data or even the consideration of what in fact are *data*.

Second, a priori sample size determination is a highly debated issue within the extant literature for usability testing. Although Turner and colleagues have demonstrated that 5 participants are sufficient for the identification of usability issues [41], higher samples (eg, 10-12 participants) have been recommended [31]. Given that we assumed more problems would be identified in the early evaluations of the app, we chose to include 8 participants in the first usability test. With a more finalized app version, we incorporated a qualitative interview that used a qualitative sampling technique referred to as *saturation* (recruitment of participants until no new relevant themes emerge from their feedback) [42], to determine the final sample size. This method may be a useful tool to enhance the science of usability testing, as our resultant sample size of 5 did agree with

usability recommendations [41]. However, since saturation requires analysts to interpret themes that are relevant to the usability tasks that participants perform, the nature of the usability tasks could influence the size of the sample required for saturation to be achieved. In other words, more complex tasks or products could require larger samples than simple tasks (as performed in the present study), but this notion requires further investigation.

Limitations

This study had limitations. First, participants involved with the usability tests were active exercisers from a fitness facility with adapted exercise programs for people with disabilities. While this active population provides valuable insight towards issues that may prevent successful maintenance of exercise behavior, understanding perceptions of inactive people with MS may help identify issues during the adoption of exercise behavior. To minimize the impact of this limitation, the project team included 8 stakeholders who were inactive adults with MS though greater involvement of the target population would enhance the methodological rigor. Second, although the proof of concept testing included participants with MS, the early stages of development included individuals who had disabilities, but did not have MS. This was done to provide a convenient representation of different impairments (eg, poor vision, manual wheelchair use, power wheelchair use, and the use of other orthotic and walking devices). Third, although saturation was achieved for the qualitative data, the sample size was still small and may not adequately represent the heterogeneous participant characteristics that we might expect in the MS population. Fourth, this study did not contain objective criteria to indicate whether the exercises were suitable for people with MS. Fifth, this study did not incorporate assessments of app feasibility (ie, measures of use at the home) and did not base the exercises off of previously published studies, and, thus, will require evaluation of both the app and the effects of the exercises throughout an exercise intervention.

Conclusions

The promotion of physical activity through mHealth exercise apps will require adaptation of the app and content to match the preferences and functional abilities of people with disabilities. Participants and stakeholders identified several exercise components that required further modification. Participant feedback also heavily impacted the development of app features and functions. Following several iterative evaluations, the project team and participants finalized an exercise app that can be easily operated in the convenience of the home and tailored to the functional needs of individuals with MS. The latest version of the TEAMS app is incorporated into an ongoing randomized controlled trial [43]. Collectively, the study findings emphasize the importance of user-centered designs that include participants throughout several stages of the development process and utilize both quantitative and qualitative data for usability evaluations.

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Authors' Contributions

MT, TM, HJY, JHR, GJ, and BL contributed to the design and implementation of the study. MT, GJ, JW and BL analyzed the study results. HJY was the primary author that was responsible for the adaptation of exercise content. MT led the app development team and the manuscript development. JHR was the lead investigator and oversaw implementation of the project. All authors contributed to the formulation of this paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Usability test 1: classification within the usability problem taxonomy.

[PDF File (Adobe PDF File), 24KB - mhealth_v6i5e10181_app1.pdf]

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Abbreviations

mHealth: mobile health
MS: multiple sclerosis
PCORI: Patient-Centered Outcomes Research Institute
SCT: Social Cognitive Theory
TEAMS: Tele-Exercise and Multiple Sclerosis
UCD: user-centered design
UPT: Usability Problem Taxonomy

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Original Paper

Using Digital Health Technologies to Understand the Association Between Movement Behaviors and Interstitial Glucose: Exploratory Analysis

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Abstract

Background: Acute reductions in postprandial glucose excursions because of movement behaviors have been demonstrated in experimental studies but less so in free-living settings.

Objective: The objective of this study was to explore the nature of the acute stimulus-response model between accelerometer-assessed physical activity, sedentary time, and glucose variability over 13 days in nondiabetic adults.

Methods: This study measured physical activity, sedentary time, and interstitial glucose continuously over 13 days in 29 participants (mean age in years: 44.9 [SD 9.1]; female: 59%, 17/29; white: 90%, 26/29; mean body mass index: 25.3 [SD 4.1]) as part of the Sensing Interstitial Glucose to Nudge Active Lifestyles (SIGNAL) research program. Daily minutes spent sedentary, in light activity, and moderate to vigorous physical activity were associated with daily mean glucose, SD of glucose, and mean amplitude of glycemic excursions (MAGE) using generalized estimating equations.

Results: After adjustment for covariates, sedentary time in minutes was positively associated with a higher daily mean glucose (mmol/L; beta=0.0007; 95% CI 0.00030-0.00103; *P*<.001), SD of glucose (mmol/L; beta=0.0006; 95% CI 0.00037-0.00081; *P*<.001), and MAGE (mmol/L; beta=0.002; 95% CI 0.00131-0.00273; *P*<.001) for those of a lower fitness. Additionally, light activity was inversely associated with mean glucose (mmol/L; beta=−0.0004; 95% CI −0.00078 to −0.00006; *P*=.02), SD of glucose (mmol/L; beta=−0.0006; 95% CI −0.00085 to −0.00039; *P*<.001), and MAGE (mmol/L; beta=−0.002; 95% CI −0.00285 to −0.00146; *P*<.001) for those of a lower fitness. Moderate to vigorous physical activity was only inversely associated with mean glucose (mmol/L; beta=−0.002; 95% CI −0.00250 to −0.00058; *P*=.002).

Conclusions: Evidence of an acute stimulus-response model was observed between sedentary time, physical activity, and glucose variability in low fitness individuals, with sedentary time and light activity conferring the most consistent changes in glucose variability. Further work is required to investigate the coupling of movement behaviors and glucose responses in larger samples and whether providing these rich data sources as feedback could induce lifestyle behavior change.

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KEYWORDS

accelerometry; glucose; physical activity; physiological monitoring; sedentary time

Introduction

Background

Despite the well-documented health benefits of physical activity (PA) for the prevention of chronic diseases [1,2], accelerometry data from nationally representative samples suggest that only a small percentage of individuals are sufficiently active [3-5]. The UK PA guidelines propose that regular PA can reduce the risk of developing chronic diseases such as type 2 diabetes and coronary heart disease [6]. However, this requires individuals to undertake PA *now* to receive their health return on investment *later* in life. In psychology, the term temporal discounting describes how the value of a reward decreases as the delay to attainment increases [7]. Consequently, when the *reward* (eg, decreased morbidity and mortality risk) occurs too far into the future, the immediate costs (ie, effort to be active) outweigh the future benefits, and individuals are unlikely to carry out preventative measures such as engaging in more PA to avoid lifestyle-related chronic disease [8].

One potential solution to this is to show individuals the physiological consequences of their PA (or lack thereof) in a more immediate fashion. Acute physiological changes have been demonstrated by undertaking PA, such as reduced postprandial responses by completing 2 min of light (walking at 3.2 km/h) and moderate intensity (5.8-6.4 km/h) activity breaks every 20 min over a 5-hour period. Compared with uninterrupted sitting, both activity conditions lowered the net glucose response to a standardized drink (light: −1.7 mmol/L; moderate: −2.0 mmol/L) [9]. Similarly, significant attenuations of postprandial glucose were also observed in a large trial of normal weight adults when regular activity breaks were undertaken (−866.7 IU/L·9 h) [10], in postmenopausal women [11], and in office workers when asked to stand for 4 hours (43% lower excursion to a standardized lunch) [12]. The emergence of wearable technologies now allows many people to track their own behaviors and increasingly, their own health, in impressive detail. Given that most wearable technologies measure the volumetric dose of PA as standard, consumers are increasingly seeking more comprehensive information on how their actions are influencing their health [13], and therefore, quantifying the effect of movement behaviors upon acute health outcomes is an exciting development.

Although studies exist that examine the relationship between glucose and PA in a free-living setting, most involve a laboratory component or conditions that stipulate participants conduct a set program of behaviors [14-16]. This lacks some generalizability given that individuals' lives are often not as regimented as a research protocol, and the introduction of between and within participant variation is key to determine if findings are robust. One study investigating behavior and glucose responses in individuals with type 2 diabetes outside the laboratory demonstrated that time spent in hyperglycemia was positively associated with sedentary time [17]. If these physiological consequences of small movement choices can be represented as personalized feedback (ie, glucose concentrations), it may help support individuals to be more physically active or reduce time spent sedentary [18].

Study Aim

There are considerable gaps in our understanding of the acute physiological changes that PA and sedentary time can have upon glucose within free-living settings. Therefore, the aim of this study was to determine if there was a relationship between accelerometer measured PA, sedentary time, and measures of glucose variability over 13 days using glucose monitoring in nondiabetic adults.

Methods

Sample

Data used for this study were collected as part of the Sensing Interstitial Glucose to Nudge Active Lifestyles (SIGNAL) research program which aims to use PA, sedentary time, and glucose data to investigate the physiological consequences of movement. The study took place at the National Centre for Sports and Exercise Medicine at Loughborough University from May 2016 to September 2016. All participants gave their written informed consent, and the study was approved by the Loughborough University Human Participants Ethical Sub-Committee (R15-P142).

Study inclusion criteria required participants to be in the age range of 30 to 60 years and not have a current clinical diagnosis of diabetes (type 1 or type 2). Participants that had fasting glucose concentrations above the prediabetic threshold of ≥5.6 mmol/L were able to participate within the study. Exclusion criteria included taking diabetes medication, being pregnant, having any mobility-related musculoskeletal problems, or undertaking any structured exercise training.

Study Design

Participants attended a 2-hour morning appointment (AM only) and were asked to adhere to the following pretesting guidelines before their appointment: refrain from food or drink (except water) for a minimum of 8 hours before, drink a glass of water at least 1 hour before, and refrain from any strenuous activity 24 hours before.

Study Measurements

After arrival, informed consent was taken, and then, a Physical Activity Readiness Questionnaire was completed to ensure participant safety [19]. Any positive answers were dealt with by a clinically trained member of the study team. Once cleared for participation, a seated blood pressure reading (Omron 705IT, Omron, United Kingdom) and a fasting capillary blood test were undertaken. Two finger prick blood samples were collected and analyzed using point-of-care devices for total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides and glucose (Lipid Profile Glucose Cartridge, Cholestech LDX Analyzer, Alere, Massachusetts, United States), and glycated hemoglobin (Afinion HbA1c, Afinion Analyzer, Alere, Massachusetts, United States). Height, weight, body composition, and waist circumference were measured once using a stadiometer (SECA 213, SECA, Germany), bioelectrical impedance scale (Tanita MC780MA, Tanita, The Netherlands), and tape measure (HaB International Ltd, United Kingdom), respectively. Waist circumference was

measured using the average of two measurements, with a third being conducted if the first two exceeded 3 cm.

It has been demonstrated that the glucose response to PA can be influenced by cardiorespiratory fitness [20]; therefore, fitness assessments in the form of combined left and right hand grip scores (Takeii analogue dynamometer, Takei Scientific Instruments Co, LTD, Japan), quadriceps maximal voluntary contraction (G200 Knee Extension, DAVID Health Solution Ltd., Finland), and sub maximal fitness (modified Canadian Aerobic Fitness Test, mCAFT [21]) were conducted. After completion of all study profiling measurements, participants were given an accelerometer and glucose monitoring device to wear for 14 days (13 of which were complete days).

Accelerometry

An ActiGraph accelerometer (wGT3X-BT Monitor, ActiGraph, Pensacola, United States) was fitted around the waist over the right hip (midclavicular line) of each participant. The activity monitor was worn during waking hours only (ie, removed for sleeping) and was only removed if participants engaged in water-based activities (eg, swimming or bathing). All devices were initialized 1 hour into the appointment (day 1) and were given a stop time of midnight on the last day of wear (day 14) to account for any potential issues in deployment. Measurement frequency was set to 100 Hz, and devices were downloaded into 60 second epoch files using ActiLife (ActiGraph) version 6.13.2. Files were processed using KineSoft (KineSoft) version 3.3.80.

Nonwear was defined as 60 seconds of consecutive zeros with allowance of 2 minutes of nonzero interruptions, and a valid day was defined as ≥600 minutes of valid monitor wear [4]. Counts per minute (CPM) cut-points for vertical axis data were used to define sedentary time (0-99 CPM), light physical activity (100-2019 CPM), and moderate to vigorous physical activity (MVPA; ≥2020 CPM) [4].

Glucose Monitoring

A flash glucose monitor (Freestyle Libre, Abbott Laboratories, Illinois, United States), hereon referred to as a glucose monitor, was used to measure glucose concentrations over 14 days. The sensor is attached to the arm via an adhesive patch, and a handheld reader device downloads data from the sensor via near field communication. Interstitial glucose concentrations were captured by the sensor every 15 min and when users scanned the sensor using the handheld device. Other devices require frequent calibration using a capillary blood sample every 4 to 12 hours; however, the Freestyle Libre is factory calibrated and does not require any finger pricks during wear without significant loss of accuracy [22]. It has also been shown to be accurate in individuals with type 1 and type 2 diabetes against capillary blood measurements, and readings are not affected by body mass index (BMI) or age [23].

After deployment, a Tegaderm patch (3M, Minnesota, United States) was applied over the sensor to encourage a firm attachment. Additional patches were provided to participants in the event that patches became dirty or peeled off. Manufacturer guidelines specify that the sensor be scanned at least once every 8-hour period to avoid data loss. In this study, participants were asked to scan at least once every 7 hours, and they could also see their glucose concentrations in real time in an effort to minimize data loss. Missing data were anticipated as participants may sleep over 8 hours; therefore, participants were encouraged to scan before going to sleep and upon waking. If the sensor was removed prematurely (ie, because of an adhesion issue or a sensor error) during the first few days, redeployment took place. However, if >10 days of glucose and accelerometry data were captured, no redeployment took place.

To associate the glucose information captured by the glucose sensor, three measures of glucose variability were used within this study: mean daily glucose, SD of glucose, and mean amplitude of glucose excursions (MAGE). Mean glucose and SD of glucose were indicated as the most common and easily interpreted metrics [24], and MAGE is considered the gold standard for glucose variability measurement [25]. Glucose data were downloaded and processed using a semiautomated approach. The glucose reader logged data in two ways: (1) via automatic scans (every 15 min) and (2) via user manual scans (frequency dictated by participants). Only automatic scans were used within these analyses. If any data were missing, a manual adjustment using a user scan data point within ±3 min was made, or data were replaced using linear interpolation if below three adjacent data points were missing. Consecutive values ≥90% (86/96) for the day, including both waking and sleeping time, denoted a valid file and was carried forward for analysis. This decision was made to ensure that a true representation of glucose parameters was evaluated against PA. The largest block of data points was then analyzed using EasyGV software (University of Oxford).

Statistical Analyses

For each participant, up to 13 complete days (cases) were available, as the first and last day were partial days. Days that did not meet the valid day criteria for accelerometry or glucose were deemed a nonvalid day overall. Only participants that had ≥7 coupled valid accelerometry, and glucose days were carried forward into the analyses.

Generalized estimating equations (GEEs) were used to estimate associations between sedentary time, light PA, and MVPA with mean glucose, SD of glucose, and MAGE. The correlation structure was evaluated through modeling changes in the quasi-likelihood under independence model criterion (QIC) value. Both unstructured (does not assume the magnitude of correlation between observations) and autoregressive (assumes a closer relationship between two observations taken closer together) correlation structures were assessed [26], with the autoregressive structure indicating a better fit for all models because of lower QIC values. Therefore, the autoregressive correlation structure was utilized for all analyses.

Models were calculated univariably and adjusted for age, sex, accelerometer wear time, and percentage body fat. This analysis extended further to investigate whether fitness-related differences existed for the associations between behavior and glycemic variability. Additional GEE analysis was conducted for those individuals who were deemed as having low fitness levels or had fitness levels within the needs improvement, fair, and good health benefit zones of the mCAFT. Individuals were placed within a fitness category based upon their aerobic fitness

score that was derived using the O_2 cost of the final stage they attained and their weight and age [27]. Wear time adjustment was included within the analyses to account for the variation in the amount of accelerometer wear time. Sensitivity analyses were also run without wear time for all models to investigate the influence of noncompliance on the associations. Although the valid day criterion for this study was ≥600 min, many participants had wear times well above this threshold.

Independent *t*-tests were also conducted to assess if participant characteristics differed between included and excluded participants. Finally, to investigate whether there were significant fitness-related differences in PA behaviors between low fitness and high fitness groups, analysis of covariance (ANCOVA) tests were conducted, adjusted for wear time.

Results

Participant Characteristics

Of the 84 individuals that expressed interest in the study, 76 were screened, and 36 were deemed ineligible to participate. Eight individuals were not screened as they initially expressed their interest but did not reply to our screening requests. Of those that were eligible, 5 withdrew before participating, leaving 35 participants who participated in the study. Six further individuals did not meet the activity and glucose coupled valid day criteria, and therefore, 29 were carried forward for analysis. The participants were aged 44.9 years (SD 9.1), had a mean BMI of 25.3 kg/m^2(45%, 13/29 overweight, 14%, 4/29 obese), and predominantly self-reported themselves as white (90%, 26/29).

All participants had fasted blood glucose concentrations <7.0 mmol/L; however, 4 participants had fasted glucose concentrations suggesting prediabetes (ie, ≥5.6 mmol/L) [28]. Independent *t*-tests confirmed that there were no significant differences in the participant characteristics (demographics, anthropometrics, cardiometabolic risk factors, or fitness) between those who were included in the analysis and those who were excluded. Compared with a representative sample of Canadian adults that underwent the mCAFT, the average age matched (age range); VO_2 max difference was 5.7 mg/kg/min greater for the whole sample and split by sex; both males (10.3 mg/kg/min) and females (2.5 mg/kg/min) had a greater average difference in VO_2 max [29]. Participant characteristics are presented in Table 1.

Device Compliance

In total, 6 participants had sensors prematurely removed because of sensor error (n=3), perceived discomfort wearing the sensor (n=1), or the adhesive failed before the 10-day threshold (n=2). Two participants out of the 6 participants did not receive a redeployment as sufficient data were collected. When participants failed to scan the glucose sensor within 8 hours, data were lost from the device, and the next available data point was the first available automatic scan, 8 hours before the latest scan. This often resulted in a temporal drift of the data, and for this reason, the amount of data points may have been 95 or 97, instead of 96 for a complete file (4 scans per hour). Fortunately, for the 29 participants over 13 days of complete wear, missing data represented only 2.70% (973/36,035) of total data points.

On average, each participant had 34 missing data points over the 13 days, equivalent to 8.5 hours. Two participants accounted for 43.17% of the missing data (420/973 data points), and removing their data reduces the average to 6.75 hours. Only 4 participants had no missing data out of the sample, and an additional 5 had below 2 hours of missing data. An outline of all glucose data processing information is presented in Table 2.

Accelerometry compliance was high with 83% (24/29) of the sample achieving 14 valid days (>600 min) of wear. When both the glucose data and the accelerometry data were overlaid to assess joint sensor compliance, the combined valid days was 11.6 (SD 1.5), which demonstrates an overall high level of device compliance.

Associations Between Glycemic Variables and Behavior

Assumptions of linearity and normally distributed residuals were checked visually using residual and P-P plots, and multicollinearity was assessed using variance inflation factors (VIFs). VIF values were <2.7 in all models, which suggested no issues with multicollinearity.

Comparisons between movement behaviors (sedentary time, light activity, and MVPA) and glycemic variables (mean glucose, SD of glucose and MAGE) using GEE analysis for the whole sample is presented within Tables 3-5. GEE analysis revealed no significant associations between daily mean glucose, SD of glucose or MAGE with sedentary time, light activity, or MVPA for the whole sample.

An age and sex-adjusted health benefit zone was calculated for all participants using the mCAFT submaximal fitness test results. An analysis was calculated to ascertain the effect of only using participants categorized as having low fitness (needs improvement, fair, and good). GEE results for this lower fitness group are also presented in Tables 3-5. Univariable analyses revealed that light activity and MVPA were significantly associated with mean glucose for the low fitness group (P=.03; P=.001), with sedentary time also significant once wear minutes, age, sex, and percentage body fat were adjusted for (P<.001). SD of glucose was positively associated with sedentary time but inversely associated with light activity after adjustment in the low fitness group, with a similar trend occurring for the associations with MAGE.

The results of the sensitivity analyses produced comparable results for the adjusted models; however, sedentary time became nonsignificant without adjusting for accelerometer wear time for mean glucose and SD of glucose within the low fit models. No significant differences were observed for behavioral variables between low and high fitness groups (P>.05). Figure 1 represents daily summaries for behavior (sedentary, light, and MVPA) and MAGE for a typical participant who achieved 13 full valid accelerometer and glucose sensor days of wear.

Table 1. Characteristics of the study sample. Valid accelerometry ≥600 min; valid glucose ≥90% (86/96) of daily data points.

Characteristic	Mean (SD)	n (%)	Median	Interquartile range
Demographics				
Age, years	44.9 (9.1)	—	44.0	15.0
Sex, male	—	12 (41)	—	—
Ethnicity, white	—	26 (90)	—	—
Anthropometrics				
Body fat (%)	27.0 (9.7)	—	25.6	15.7
BMI[a] (kg/m^2)	25.3 (4.1)	—	25.3	6.0
Overweight	—	13 (45)	—	—
Obese	—	4 (14)	—	—
Waist circumference (cm)	85.0 (11.2)	—	82.9	13.2
Cardiometabolic risk factors				
Mean systolic blood pressure (mmHg)	122.4 (11.7)	—	122.0	14.3
Mean diastolic blood pressure (mmHg)	75.6 (7.0)	—	76.0	6.8
Total cholesterol (mmol/L)	4.7 (0.8)	—	4.6	0.9
Low-density lipoprotein cholesterol[b] (mmol/L)	2.9 (0.5)	—	2.9	0.7
High-density lipoprotein cholesterol (mmol/L)	1.5 (0.4)	—	1.4	0.6
Triglycerides[b] (mmol/L)	0.9 (0.2)	—	0.9	0.4
Glucose (mmol/L)	4.9 (0.6)	—	4.9	0.7
Glycated hemoglobin (%)	5.3 (0.4)	—	5.3	0.5
Grip strength (combined kg)	71.9 (22.4)	—	69.5	36.0
Quadriceps maximal voluntary contraction (nm)	139.7 (51.8)	—	132.0	66.0
Fitness				
VO_2 max[c] (mL/kg/min)	41.4 (9.8)	—	39.0	11.2
Fitness score	375.1 (84.3)	—	366.8	131.9
Needs improvement	—	2 (7)	—	—
Fair	—	10 (34)	—	—
Good	—	4 (14)	—	—
Very good	—	7 (24)	—	—
Excellent	—	6 (21)	—	—
Behavior				
Wear time per valid day (min)	895.1 (58.8)	—	883.8	85.4
Sedentary time per valid day (min)	576.4 (67.8)	—	566.9	100.7
Light physical activity per valid day (min)	269.1 (59.8)	—	271.1	86.3
MVPA[d] per valid day (min)	49.6 (29.9)	—	42.3	35.9
Glucose				
Mean glucose (mmol/L)	5.1 (0.5)	—	5.0	0.8
SD of glucose (mmol/L)	0.9 (0.2)	—	0.9	0.3
Mean amplitude of glycemic excursions (mmol/L)	2.4 (0.6)	—	2.3	1.0
Number of valid days				
Valid accelerometry days	13.8 (0.6)	—	14.0	0.0
12	—	2 (7)	—	—

Characteristic	Mean (SD)	n (%)	Median	Interquartile range
13	—	3 (10)	—	—
14	—	24 (83)	—	—
Valid glucose monitoring days (n)	11.7 (1.5)	—	12.0	2.0
7	—	1 (3)	—	—
8	—	1 (3)	—	—
10	—	2 (7)	—	—
11	—	7 (24)	—	—
12	—	8 (28)	—	—
13	—	10 (35)	—	—
Overall valid combined analysis days (n)	11.6 (1.5)	—	12.0	2.0
7	—	1 (3)	—	—
8	—	1 (3)	—	—
10	—	2 (7)	—	—
11	—	8 (28)	—	—
12	—	8 (28)	—	—
13	—	9 (31)	—	—

[a]BMI: body mass index.

[b]VO_2 max=32.0 + (16.0 x VO_2[L/min]) − [0.24 x Age] − [0.17 x weight (kg]) [21].

[c]n=28.

[d]MVPA: moderate to vigorous physical activity.

Table 2. Glucose data processing details. Due to the way the sensor was deployed, data processing information was calculated using full days only (days 2-13) and sensor information refers to the whole monitoring period. The maximum number of points per day was 96. Replaced values were taken from user scans if ±3 minutes; data points were interpolated if ≤2 adjacent values were missing; missing values represent data points not replaced or interpolated; if a sensor was not redeployed, data were treated as missing.

Data processing characteristics	n (%)
Average available data points per day	93 (97)
Average largest continuous block of data	91 (95)
Average number of valid days	12 (92)
Total data points replaced	28 (0.08)
Total data points interpolated	58 (0.16)
Total missing values not replaced or interpolated	973 (2.70)

Table 3. Associations between physical activity and mean glucose for the whole sample and for the low fitness group. Model one represents a univariable association, and model two is adjusted for wear minutes, age, sex, and percentage body fat.

Models	Mean glucose, beta (95% CI)	*P* value
Model one		
Sedentary minutes all	0.00006 (−0.00018 to 0.00030)	.63
Light minutes all	−0.00005 (−0.00040 to 0.00029)	.76
MVPA[a] minutes all	−0.00053 (−0.00128 to 0.00023)	.17
Sedentary minutes low fit	0.00016 (−0.00011 to 0.00043)	.25
Light minutes low fit	*−0.00042*[b] (−0.00080 to *−0.00004*[b])	*.03*[b]
MVPA minutes low fit	*−0.00160*[b] (*−0.00255*[b] to *−0.00064*[b])	*.001*[b]
Model two		
Sedentary minutes all	0.00019 (−0.00018 to 0.00055)	.32
Light minutes all	−0.00005 (−0.00041 to 0.00031)	.77
MVPA minutes all	−0.00053 (−0.00127 to 0.00022)	.17
Sedentary minutes low fit	*0.00067*[b] (*0.00030*[b] to *0.00103*[b])	*<.001*[b]
Light minutes low fit	*−0.00042*[b] (*−0.00078*[b] to *−0.00006*[b])	*.02*[b]
MVPA minutes low fit	*−0.00154*[b] (*−0.00250*[b] to *−0.00058*[b])	*.002*[b]

[a]MVPA: moderate to physical activity.

[b]Significant results.

Table 4. Associations between physical activity and SD of glucose for the whole sample and for the low fitness group. Model one represents a univariable association, and model two is adjusted for wear minutes, age, sex, and percentage body fat.

Models	SD of glucose, beta (95% CI)	*P* value
Model one		
Sedentary minutes all	0.00005 (−0.00021 to 0.00030)	.73
Light minutes all	−0.00019 (−0.00058 to 0.00020)	.33
MVPA[a] minutes all	0.00008 (−0.00043 to 0.00059)	.76
Sedentary minutes low fit	0.00017 (−0.00024 to 0.00057)	.42
Light minutes low fit	*−0.00046*[b] (*−0.00090*[b] to *−0.00002*[b])	*.04*[b]
MVPA minutes low fit	−0.00040 (−0.00146 to 0.00066)	.46
Model two		
Sedentary minutes all	0.00018 (−0.00015 to 0.00051)	.29
Light minutes all	−0.00025 (−0.00063 to 0.00012)	.19
MVPA minutes all	0.00012 (−0.00036 to 0.00059)	.62
Sedentary minutes low fit	*0.00059*[b] (*0.00037*[b] to *0.00081*[b])	*<.001*[b]
Light minutes low fit	*−0.00062*[b] (*−0.00085*[b]to *−0.00039*[b])	*<.001*[b]
MVPA minutes low fit	−0.00044 (−0.00130 to 0.00041)	.31

[a]MVPA: moderate to physical activity.

[b]Significant results.

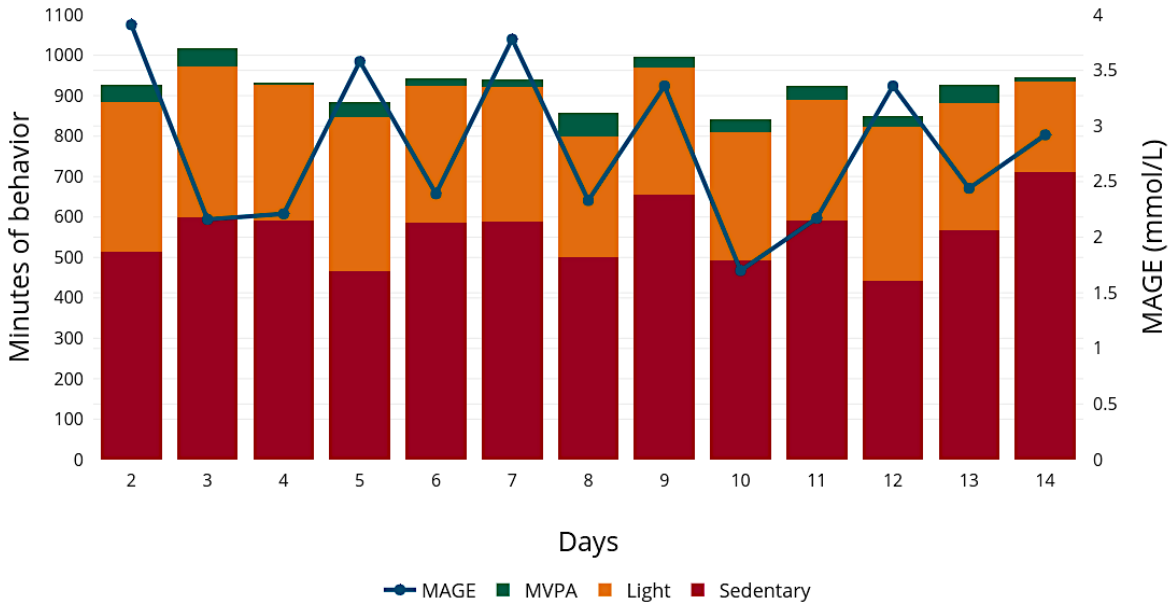
Table 5. Associations between physical activity and mean amplitude of glycemic excursions for the whole sample and for the low fitness group. Model one represents a univariable association, and model two is adjusted for wear minutes, age, sex, and percentage body fat.

Models	Mean amplitude of glycemic excursions, beta (95% CI)	*P* value
Model one		
Sedentary minutes all	0.00035 (−0.00053 to 0.00123)	.44
Light minutes all	−0.00079 (−0.00204 to 0.00046)	.22
MVPA[a] minutes all	−0.00008 (−0.00173 to 0.00157)	.93
Sedentary minutes low fit	0.00074 (−0.00073 to 0.00221)	.33
Light minutes low fit	*−0.00156*[b] (*−0.00291*[b] to *−0.00022*[b])	*.02*[b]
MVPA minutes low fit	−0.00076 (−0.00492 to 0.00341)	.72
Model two		
Sedentary minutes all	0.00088 (−0.00023 to 0.00199)	.12
Light minutes all	−0.00107 (−0.00232 to 0.00018)	.09
MVPA minutes all	0.00004 (−0.00155 to 0.00162)	.96
Sedentary minutes low fit	*0.00202*[b] (*0.00131*[b]*to 0.00273*[b])	*<.001*[b]
Light minutes low fit	*−0.00216*[b] (*−0.00285*[b] to *−0.00146*[b])	*<.001*[b]
MVPA minutes low fit	−0.00130 (−0.00429 to 0.00169)	.39

[a]MVPA: moderate to physical activity.

[b]Significant results.

Figure 1. Minutes of sedentary, light, moderate to vigorous physical activity (MVPA) and mean amplitude of glycemic excursions (MAGE) over 13 days. Days 1 and 15 were half days and were omitted as there was insufficient data. The data represent a randomly selected female participant presenting low fitness.



Discussion

Principal Findings

Using accelerometer-measured PA and sedentary time, this study revealed an observable relationship between movement behaviors and glycemic variability, but only for those presenting lower fitness. The notion that lower fitness individuals can gain greater glycemic benefits from being more physically active is supported by previous experimental research that assessed glycemic responses after implementing light activity breaks [20]. In that particular study, individuals with lower cardiorespiratory fitness gained more favorable glucose responses compared with being sedentary, leading the authors to conclude that those with lower fitness levels may have the most to gain from replacing sedentary time with PA [20]. Additionally, when modeling the substitution of sedentary time for either light activity or MVPA, those with lower fitness

(women <32 and men <35 ml/kg/min) and higher glucose (≥6.1 mmol/L) have been shown to benefit more than high fitness participants, even after adjustment for sex, age, educational level, smoking, and psychosocial stress [30]. These findings appear to support the hypothesis that although those with lower fitness may see daily differences in their glucose concentrations as a result of PA, those with higher fitness may keep their glucose concentrations within healthy ranges as a result of physiological adaptions, such as changes in insulin sensitivity [31,32].

Being physically active, especially after meals, is associated with a blunted glucose response as a result of the body using the supply of glucose already in the blood stream [33]. This may partly explain the observed inverse relationship between light activity and glucose variability in this study. Giving behavioral context to the magnitudes of the associations, if sedentary time is increased by 60 min, representing the duration of an average TV show, mean glucose could rise by 0.04 mmol/L for lower fitness individuals. Alternatively, increasing MVPA by 60 min per day could decrease mean glucose by 0.09 mmol/L, which is greater than the daily mean glucose fluctuations of 0.02 mmol/L of the low fit sample. Additionally, conducting 60 min of light activity could also decrease MAGE by 0.13 mmol/L, which represents 9% of average MAGE values (1.4 mmol/L) for a healthy white individual [34]. Over time, regularly engaging in PA may result in favorable changes to the glucose profile by blunting the glucose response or by initiating a faster return to normal levels (or euglycemia). Although sedentary time and light activity were associated with MAGE, no significant association was found with MVPA. Due to the 95% CIs being comparatively larger than the CIs for both sedentary and light activity, larger samples may be required to decrease the level of error for MVPA.

SD of glucose was associated with both sedentary time and light activity minutes in the low fitness group. Describing the spread around the mean, the average daily deviations were −0.0102 and −0.0001 mmol/L for both the low and high fit participants, respectively. Demonstrating a very low level of daily deviation in this study, SD of glucose may not be a viable marker of glycemic control within nondiabetics and/or populations presenting large fluctuations in glucose concentrations. Nevertheless, larger, more controlled samples would be needed to determine if this measure of glucose variability may be more beneficial in populations experiencing fluctuating glucose (higher SD of glucose); for example, individuals with prediabetes or type 2 diabetes.

It has been acknowledged that the relationship between behavior and glucose variability is complex and may differ depending on the amount of data captured, which is a product of sensor wear. Although the threshold for valid glucose data was set at ≥90% (86/96) of daily values, accelerometer wear time was set at ≥600 min in line with previous studies assessing habitual PA. Although most days comfortably exceeded the valid day threshold, there is some variation in the amount of wear. Indeed, the sensitivity analyses revealed that when wear time was removed from the low fitness models, the associations between sedentary time and mean glucose and SD of glucose became nonsignificant. Indicating that any difference in monitor wear largely influences the accrual of sedentary time, it is therefore important to investigate the influence of wear time when calculating physiological-behavioral models. Nevertheless, it is unknown whether reductions in wear are because of intentional device removal or extended periods of sleep duration. If the reason is the former, it would have important implications for the associations with acute health outcomes such as glucose.

For instance, Figure 1 from day 6 to day 7 illustrates a small difference in wear of 3 min but an increase in MAGE (day 6=2.39 mmol/L, day 7=3.78 mmol/L). It is hard to determine why the increase has been brought about in this instance and whether it is because of activity not captured by the accelerometer despite high wear across both days (day 6=944 min, day 7=941 min). Although wear time was adjusted for within the analyses, if it is imperative for individuals to wear the devices during *all* waking hours to show activity-related declines in glucose, then participant adherence may be challenging, given traditional wearable monitors can accrue steps intermittently, but still sum up to a goal at the end of the day. As a result, encouraging the deployment of 24-hour monitoring may help minimize the influence of missing data because of nonwear.

The data presented in this study provide evidence of the existence of an observable, acute stimulus-response model of increased PA that may yield measured changes in daily summaries of glycemic variability. If this information could be displayed in real time to users as actionable feedback, it may help support individuals to link together action (behavior) with the physiological consequence of their actions (health) [13]. Future research should focus on providing this feedback to users to observe how people respond (ie, do they change their behavior having seen their behavioral and physiological feedback?). However, scientists should not fall into the trap of more data being better by default; the information must be comprehended in a way that motivates action by the user that can be sustained [35].

Using glucose information in real time or at a bout level could further increase the potency of the feedback and also reduce the rate of temporal discounting. Although receiving real-time glucose feedback is potentially a richer feedback source than daily summaries, the physiological responses to movement behaviors are not necessarily routinely predictable. For instance, if a bout of PA is initiated, interrupted, and then recommenced, any change in glucose cannot be solely attributed to the first or second bout. This type of analysis would require highly complex computational algorithms, as the processing pipeline would need to consider, among others, the following issues:

- Behavior bout duration: what duration is considered a bout and can the bout be interrupted?
- Duration of the bout effect: how long does the increase or decrease in glucose last and can it be modified by behavior of a specific intensity?
- Sedentary time or PA: how does historical hourly, daily, or weekly movement behaviors influence the bout duration and effect?
- Glucose concentrations: how do historical glucose concentrations influence future concentrations?

- User characteristics: how do characteristics such as type 2 diabetes risk, fitness, sex, and age modify the associations?

Although there are clearly challenges to overcome, the innovative practice of providing people with daily actionable insights related to the physiological consequences of being more physically active (and/or less sedentary) may act as a potent driver for lifestyle behavior change. Scientists that have an interest within this area of research will be boosted by the new High-level global Commission on Noncommunicable Diseases that urges "...new approaches and action on a dramatically different scale if we are to stop people dying unnecessarily from noncommunicable diseases" [36]. These sentiments certainly resonate with the National Health Service Digital data and information strategy given its mission "…to empower the health and care system to be intelligent in the way it uses data and information to drive improvements in health and care, by delivering world class data and analytics services through the highest level of skills, expertise, tools, techniques and technology" [37].

Limitations

This study is one of the first to investigate glycemic variability and PA behaviors using objective monitoring technologies in a free-living setting over an extended period of wear (13 complete days); however, there are a number of limitations that must be discussed.

The small number of participants within this study was chosen to balance feasibility and cost, although the participant pool could be considered homogenous (University location and ethnicity). Due to the lack of dietary information, which is a significant glucose input mechanism, the estimates should be interpreted cautiously given that dietary intake will likely have influenced magnitudes observed. Food diary information (pen and paper format) was collected for 4 days from second day of deployment. That said, the information was deemed unreliable because of the amount of missing food entries from the diaries and coding database. Self-reported dietary diaries have previously been called into question [38], and although the conclusions of Archer and Blair could be considered too far-reaching [39], alternative methods of food collection should be utilized in the future as it has suggested that self-reported methods should not be used for measures of energy intake [40].

The mCAFT was chosen because of its submaximal nature and the ease of the stepping modality and thus, its successful use in population public health research. That said, the gradings of the progressive stages are not as finely tuned as could be achieved when using a gas analysis system to quantify VO_2 peak. Additionally, menstrual status was not captured, which has been shown to influence postprandial but not fasting concentrations of glucose [41]; therefore, menstruation would need to be adequately modeled in future studies to assess the implications for wearable glucose monitoring interventions, especially those that utilize the Freestyle Libre as interventions may span multiple weeks.

Sedentary time was measured using count-based accelerometry, which has the limitation of not detecting specific postural changes [42] and is instead measuring *stationary* behavior (lying, reclining, sitting, or standing with no ambulation) [43]. Similarly, the choice of cut-points can influence the data [44] and should therefore be taken into account when drawing conclusions. The valid day criterion for glucose data was chosen to be conservative but has not been validated. More work is required to ascertain what level of missing data is acceptable and does not introduce an unacceptable level of variability.

This study faced glucose sensor deployment issues and missing data. Coupled with the invasiveness and recurring costs of glucose monitoring, there are a number of hurdles that researchers need to be aware of when using such devices in research. Additionally, as one of the first studies utilizing physiological feedback, we are unable to determine whether the information given back to the participants had any influence on the direction of glucose and/or movement behaviors. Although most continuous glucose monitoring validation studies (including the Freestyle Libre) have been predominately conducted on individuals diagnosed with diabetes, studies conducted in small samples of Japanese adults suggest that the Freestyle Libre may overestimate glucose levels in response to an isolated meal load [45,46]. Nevertheless, as all measurements from one study fell within zones A and B of the Parkes error grid, further investigation using larger samples are required to confirm the extent of the overestimation. Further analysis and alternative glucose monitoring technologies and future iterations of devices could perhaps ameliorate these hurdles.

Conclusions

This study demonstrates that there are both positive and inverse associations between accelerometry-derived behavioral and glycemic variability within a small sample of white, middle-aged, low fitness adults living without a clinical diagnosis of diabetes. Future research should expand on these findings within populations who may exhibit greater variability. Investigations should also be conducted to ascertain if bout-related information can be extracted, to assess whether this data could be used to educate and influence lifestyle behaviors.

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Authors' Contributions

All authors have contributed to the design of the work, acquisition, and analysis plan. APK, MEW, JPS, LBS, and DWE have been involved in drafting the work or revising it critically for important intellectual content. APK is the guarantor of this work and is responsible for the content within this paper.

Conflicts of Interest

None declared.

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Abbreviations

ANCOVA: analysis of covariance
BMI: body mass index
CPM: counts per minute
GEE: generalized estimating equations
MAGE: mean amplitude of glycemic excursions
mCAFT: modified Canadian Aerobic Fitness Test
MVPA: moderate to vigorous physical activity
PA: physical activity
QIC: quasi-likelihood under independence model criterion
SIGNAL: Sensing Interstitial Glucose to Nudge Active Lifestyles
VIF: variance inflation factor

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