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Viewpoint

Five Lessons Learned From Randomized Controlled Trials on Mobile Health Interventions: Consensus Procedure on Practical Recommendations for Sustainable Research

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Abstract

Background: Clinical research on mobile health (mHealth) interventions is too slow in comparison to the rapid speed of technological advances, thereby impeding sustainable research and evidence-based implementation of mHealth interventions.

Objective: We aimed to establish practical lessons from the experience of our working group, which might accelerate the development of future mHealth interventions and their evaluation by randomized controlled trials (RCTs).

Methods: This paper is based on group and expert discussions, and focuses on the researchers' perspectives after four RCTs on mHealth interventions for chronic pain.

Results: The following five lessons are presented, which are based on practical application, increase of speed, and sustainability: (1) explore stakeholder opinions, (2) develop the mHealth app and trial simultaneously, (3) minimize complexity, (4) manage necessary resources, and (5) apply behavior change techniques.

Conclusions: The five lessons developed may lead toward an agile research environment. Agility might be the key factor in the development and research process of a potentially sustainable and evidence-based mHealth intervention.

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KEYWORDS

mHealth; mobile apps; pain; behavior change techniques (BCTs); recommendations

Introduction

Forecasts suggest that digital health might disrupt health care [1]. However, the increasing importance of mHealth technology such as tracing apps against COVID-19 has highlighted that such disruption is already happening. In Germany, the new Law for Digital Health Applications (Digitale-Versorgung-Gesetz [DVG]) [2] might provide further support for this trend. The DVG aims at achieving better coverage of patients through digitization and innovation by implementing the entitlement of insured individuals to digital health apps and allowing physicians to prescribe apps such as mobile Health (mHealth) interventions, which are then reimbursed as medical interventions by the statutory health insurances. The DVG also aims to expand the telematics structure in health care, entitle patients to digital apps, promote the development of digital innovations, and hence financially support developers in the

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field in cooperation with the statutory health insurance companies [2,3]. Given these new opportunities for the integration of mHealth interventions in Germany, the quality of their development is of major importance.

In digital apps, continuous therapy support and finely graduated feedback on user behavior have great potential not only to affect the health professional-patient relationship but also to change the mode of treatment [4] and prevention in general. Modern medical treatments are usually based on an evidence-based medicine (EBM) approach integrating individual clinical expertise, best external evidence, and patient preferences [5]. Some mHealth app interventions have been able to apply the EBM structure [6], and evaluation frameworks [7] for these interventions have been developed. However, to date, it seems that mHealth rarely follows this EBM principle [3,8]. The main reason for this lack might be that established research methods cannot follow the pace of technological advances and accompanying digital business models. Although the development of a new drug might take 10 to 15 years, a new iPhone, including its new operating system, is released every year, and an app can even be developed within a few months, or even weeks when resources are unlimited. App development for commercial information technology projects is usually realized by professional multidisciplinary teams often lacking clinical trial expertise. These competencies exist in academic and commercial clinical research. In turn, these organizations might greatly benefit from knowledge of the commercial technology sector, including expertise in design, product, or business development. According to a review of mindfulness apps [9], 606 iPhone apps could be identified, but only 23 of these apps actually provided mindfulness training, and only 1 app was supported by a randomized controlled trial (RCT) [10]. Thus, to develop a sustainable evidence-based mHealth app, we consider it necessary to bring these different perspectives closer together.

Ben-Zeev et al [11] shared their experiences and strategies of developing mobile interventions in a review in 2015, mentioning some mHealth challenges such as evolving technology, mobile phone selection, mHealth system “bugs and glitches,” and others. However, technological advances in the last 5 years have shifted mHealth research strategies away from technical concerns toward sustainability and multidisciplinary integration.

In this paper, we provide five recommendations for future app developers based on our expertise gained from four mHealth RCTs for the pain conditions dysmenorrhea [12-14], and back pain and neck pain [15] in a clear concise way. These lessons might accelerate the development of mHealth interventions and their evaluation by RCTs.

Methods

Approach and Aims

We are a German research team with expertise in integrative medicine and cognitive behavioral therapy consisting of two medical doctors, one public health researcher, and one behavioral cognitive psychologist. Moreover, the team is experienced in nondigital as well as digital clinical research using RCTs, mixed-methods approaches, and stakeholder engagement. Since 2012, we have developed and evaluated four app-based mHealth interventions for the pain conditions dysmenorrhea [12-14], and back pain and neck pain [15].

This paper aims to support developers of mHealth interventions in the early stages of their career. Toward this end, we applied a continuous consensus procedure. Content units were identified by discussions in multiple rounds to cluster the selected topics using inductive and deductive coding strategies, as well as mind mapping. Topics were categorized by two reviewers (AR and DP) and any discrepancies were resolved in face-to-face discussions.

The lessons described in this paper are based on our experience conducting the four app-based mHealth RCTs described in the following section.

App-Based mHealth RCTs

Luna.

The evidence-based app Luna. [14] (pronounced “Luna period”; trial registration: ClinicalTrials.gov NCT03432611) aims to reduce menstrual pain in women with primary dysmenorrhea (aged 18 to 34 years) by providing different self-care strategies such as self-applied acupressure, exercise, and yoga. In this randomized pragmatic trial, one group of women had access to a full-featured study app consisting of a combination of acupressure and additional self-care features, while the two control groups had either access to acupressure or self-care features only. The primary outcome of the study was the mean pain intensity measured with the in-app numerical rating scale (NRS), ranging from 0 (no pain) to 10 (most intense pain imaginable), on the painful days during the sixth menstruation after starting the intervention. Follow-up measures were collected during 12 menstruation cycles. The app was developed together with an external agency for the iOS platform using the Apple ResearchKit framework. We aimed to include 594 participants in the study.

AKUD

The app-based mHealth intervention AKUD [13] was the precursor study to Luna. [14], which aimed to investigate the effectiveness of acupressure. In this two-armed randomized pragmatic trial, 221 women aged 18 to 34 years with cramping pain during their menstruation were included and randomized either to the acupressure or usual care group. The primary outcome was the mean pain intensity measured with the in-app NRS, ranging from 0 (no pain) to 10 (most intense pain imaginable), on the painful days during the third menstruation. This app was developed together with an external agency for the iOS and Android platform.

RelaxBack and RelaxNeck

RelaxBack (trial registration: ClinicalTrials.gov NCT02019498; https://www.clinicaltrials.gov /ct2/show/NCT02019498) for chronic back pain and RelaxNeck (trial registration: ClinicalTrials.gov NCT02019134; https://www.clinicaltrials.gov/ct2/show/NCT02019134) for chronic neck pain [15] were evaluated in separate randomized pragmatic trials with the same research design. In both trials,

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the intervention group received digital instructions on three relaxation techniques as self-care strategies aiming to reduce pain, whereas the control group only documented their symptoms. In total, 270 participants (aged 18 to 65 years) were included in the trials. As the primary outcome, the mean pain intensity during the first 3 months of app usage was measured. These apps were based on the source code of the app AKUD with design changes according to the intervention needs.

Results

Lesson 1: Explore Stakeholder Opinions

Research is often conducted from the perspectives of health professionals or researchers, and other perspectives such as those of the patients, customers, and policymakers are neglected. As described in previous research, the sustainability of a developed mHealth intervention often meets obstacles when not in line with the interests of the ministries of health (eg, national strategic goals and laws), especially when it comes to data security; hence, the app developed might not be appropriate for the present infrastructure [16]. Moreover, most mHealth interventions in the form of RCTs are developed as single-stage interventions; however, popular apps usually combine multiple-stage interventions. Hence, the sustainable use of a well-developed app might not only be dependent on its effectiveness but also on its multipurpose applicability to the target group [17]. Accordingly, neglecting the opinions of stakeholders can lead to trials that do not meet the needs of their target group, evaluate irrelevant outcomes, and are therefore not sustainable. Moreover, the user's app experience is greatly influenced by factors such as design, language, and adaptivity; in turn, the effects of these factors might broadly be influenced by user characteristics such as age, gender, and education. Therefore, we recommend involving stakeholders to understand the target group as early as possible for ensuring a sustainable app and trial.

> *Example: We involved stakeholders (college students, affected young women, a teacher, a gynecologist, and researchers) in the preparation of our AKUD trial on menstrual pain. In focus group discussions and interviews, stakeholders (potential trial participants) argued against the originally planned relaxation component as part of the intervention due to its length, which resulted in excluding this part from the trial. Moreover, the stakeholders favored an increase of the frequency of questions at the cost of the number of items in each questionnaire.*

Lesson 2: Develop the mHealth App and Trial Simultaneously

To show efficacy, effectiveness, and cost-effectiveness [18,19] of an mHealth intervention, a clinical trial is required. An app and trial each come with their own specific characteristics and needs. An app may be determined by the platform it is available for, its design language, its respective features, or its possible dependencies on valid sensor data or a server. These aspects of the app directly affect the complexity (eg, study sample and adherence) and privacy aspects (eg, data sharing) of the corresponding trial, thereby affecting the necessary resources and development time. Moreover, the choice of hardware and software may influence the structure of the trial, since not every feature is available on a given operating system or device, which may significantly shape the scale of the intervention [11]. On the other side, a trial may be determined by the target group, the clearly defined intervention and control settings, and its research outcomes. These aspects of the trial directly affect the choice of app platform (eg, platform preferences of target populations have to be considered), design of the app (eg, use of age-specific graphical elements), included features (eg, questionnaires), and their technical realization (eg, use of the smartphone's camera). Previous research has shown that approximately half of study results in mHealth interventions are either unclear or negative; however, the number of mHealth interventions and their popularity are consistently increasing [17,20]. This clearly shows a gap necessary to explore in this field of research, and emphasizes the urgent need for well-planned and performed RCTs that are flexible to the field of mHealth interventions.

Therefore, we recommend that an mHealth app always be developed simultaneously with its respective trial to avoid a waste of time and resources.

> *Example: During development of the Luna. app [14], we decided to use the data collected for outcome measurement, the NRS for pain ranging from 0 (no pain) to 10 (most intense pain imaginable), and number of activities against period pain as an additional feature for the app dashboard. In this way, the study participants could directly benefit from the data collected for the trial. Moreover, sharing these data with the study participants also impacted the app intervention itself, as this new feedback feature could be considered as a behavior change technique (BCT) [21]. With this approach, we not only added a new feature to the app but we also might have even improved the participants' study adherence.*

Lesson 3: Minimize Complexity

Currently, mHealth apps need to be developed by multiprofessional teams with expertise in areas such as iOS and Android development, design, backend development, regulatory affairs, psychology, and business development; hence, complexity is already high. Considering the amount of time, expertise, and resources needed for a clinical trial, the appropriate clinical evaluation of mHealth apps substantially adds a magnitude of complexity. Many factors of app and trial development cannot be neglected because of increased user expectations as well as technological and regulatory standards. Moreover, it is difficult to ensure a focused analysis of the interventional effect because mHealth apps are complex interventions including features such as BCTs, combinations of different therapeutic approaches (eg, exercise and diet), and connected devices and services, which are prone to regulation within the health care sector. Knowing that three-quarters of mobile phones are being used in low- or middle-income countries, minimizing complexity might also be beneficial for the sustainability of the mHealth interventions developed, since

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the latest versions of devices or repair services might not always be within the user's reach, especially in rural areas [22]. The market of mHealth interventions is often trend-based and dependent on current preferences of the target group. An evidence-based mHealth intervention must therefore not only focus on the quality of the interventions provided but also be able to react timely to changes in the market (eg, software or hardware update) so as to maintain interest of the target group or avoid user frustration. In addition, with a less complex app, the development team might be able to react to bugs or market changes more quickly. To increase the speed of development and the availability of the mHealth intervention for users, we recommend minimizing complexity.

> *Example: To reach a broad target group, the app AKUD was developed for the two platforms Android and iOS with consideration of their differences in user interface design, general design language, and technological base. However, this approach made it more complex to standardize the intervention, and to develop, test, and support the app, while only gaining a potentially more diverse target group.*

Lesson 4: Manage Necessary Resources

The multidisciplinary team necessary for mHealth app development is usually not available in a research setting. Resources such as designers, frontend or backend developers, and access to technical infrastructure need to be taken into account in addition to the research resources. A lack or insufficient management of these resources leads to a longer time in development, potentially higher financial burden, and less substantial results. We therefore recommend performing prior analyses of existing and necessary resources for app and trial development to adequately manage the mHealth study necessities, and to increase the overall speed of app development to keep up with the rapidly progressing market.

> *Example: The development of our Luna. app [14] was based on previous app and trial experiences of the AKUD trial. During the preparation of the new trial, the effort for ethical approvals in the participating countries, requiring staff and time, was underestimated. Therefore, the development of the app and the study start were substantially delayed, and funding of research staff became more difficult.*

Lesson 5: Apply BCTs

Besides scalability and efficiency, behavior change is a key component of mHealth [21]. Michie et al [23] defined the smallest, observable, replicable intervention component with the potential to bring about change in behavior as a BCT [14,24]. BCTs could also be defined as "a systematic procedure included as an active component of an intervention designed to change behavior" [23]. In digital interventions, app features and functions could be designed based on different BCTs to improve user engagement [25]. For example, "prompts/cues" could be implemented as an app notification to remind users to fill in questionnaires. Feedback on behavior could potentially maintain users' motivation by providing instant feedback. Further, "goal-setting" and "self-monitoring" are also commonly implemented BCTs in smartphone apps. In a systematic review, 344 BCT apps were reviewed and rated [26]; however, on average, these apps only showed low to moderate functionality, meaning that only a slight amount of BCT was used, and therefore the full spectrum of potential behavior change due to BCTs was not unfolded.

We recommend involving behavior change specialists and to perform early user testing. As a fundament, the BCT taxonomy [21] and the behavior change wheel framework [27] might be helpful.

> *Example: The development of our RelaxNeck and RelaxBack studies was based on previous app and trial experiences of the AKUD trial. Although we also included stakeholders in their preparation, we did not involve specialists for BCTs. Therefore, user interaction was neither based on theory nor on defined BCTs. This lack of expertise might have impacted the effectiveness of the app and the results of the respective trial. We had learned from this experience and validated the application of the BCTs implemented in the Luna. app [14] by involving two independent raters with BCT expertise who had experienced the finalized full-featured app but who had not been part of the app development process.*

Discussion

In this project, we have developed five lessons from the practical experience we gained in developing four mHealth interventions and evaluating them with RCTs. Using inductive and deductive coding strategies in this consensus procedure, we developed the following lessons: (1) explore stakeholder opinions, (2) develop the mHealth app and trial simultaneously, (3) minimize complexity, (4) manage necessary resources, and (5) apply BCTs. These lessons might be useful for researchers, entrepreneurs, or other groups dealing with mHealth interventions in an early stage, and might support faster access to evidence-based mHealth interventions that are more sustainable.

We are aware that we cannot cover all aspects of app and trial development for mHealth interventions. The lessons are derived from only four studies of our research group and numerous discussions with startups. Therefore, the applicability of these lessons might be limited due to the focus on one research group, their experiences in Germany only, and the involved professions (medical doctors, psychologists, public health specialist, clinical researchers). These lessons do not cover the important topics of funding, necessary professional qualifications, as well as regulations such as the European Union General Data Protection Regulation and the European Medical Device Regulation. However, these aspects very much depend on individual settings, and therefore general lessons should not be defined. Moreover, the recommendations we made in this project were not tested in a prospective clinical trial; therefore, we cannot make assumptions about the effects (eg, explanation of variance) of each of the recommendations. To conclude about the effectiveness of each lesson (eg, for app engagement),

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two-armed trials with head-to-head comparisons might be necessary.

Based on nearly 10 years of experience with the applications of RCTs for mHealth interventions, all lessons were derived from actual hands-on experience and were later condensed to allow easy access for researchers and entrepreneurs new to the field. In the future, we consider that an implementation science approach would be helpful to actually measure aspects such as sustainability or the importance of a fast development process in mHealth trials. In public health, the Re-Aim framework aims to improve sustainability and implementation of behavioral interventions by focusing on five aspects: reach, effectiveness, adoption, implementation, and maintenance. Transferring this framework to the field of mHealth interventions might also enhance sustainable development and the overall quality of trials. We hope to contribute new aspects in addition to existing guidance documents of other research groups raising concerns to the current development processes in the field of mHealth [19-21,28].

The practical lessons we learned may best unfold in a research environment that uses agile techniques originally borrowed from software development [29], as we believe that agility might be the key factor for the accelerated development of a sustainable evidence-based mHealth intervention.

Authors' Contributions

All authors conceived of the article. AR and DP wrote the manuscript. JW and CW revised the paper. All authors read and approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

BCT: behavior change technique
DVG: Digitale-Versorgung-Gesetz (Law for Digital Health Applications)
EBM: evidence-based medicine
mHealth: mobile health
NRS: numerical rating scale
RCT: randomized controlled trial

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Review

Effects of Smartphone-Based Interventions on Physical Activity in Children and Adolescents: Systematic Review and Meta-analysis

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Abstract

Background: About 70% of children and adolescents worldwide do not meet the recommended level of physical activity (PA), which is closely associated with physical, psychological, and cognitive well-being. Nowadays, the use of technologies to change PA is of interest due to the need for novel, more effective intervention approaches. The previous meta-analyses have examined smartphone-based interventions and their impact on PA in adults, but evidence in children and adolescents still needs further research.

Objective: This systematic review and meta-analysis aimed to determine the effectiveness of smartphone-based interventions for improving PA in children and adolescents.

Methods: Five electronic databases (PubMed, Web of Science, OVID, Scopus, and the China National Knowledge Infrastructure) were searched up to June 29, 2020. Randomized controlled trials with a control group that examine the effect of smartphone interventions on PA among children and adolescents were included. Bias risks were assessed using the Cochrane collaboration tool. Meta-analysis was performed to assess the pooled effect on PA using a random effects model. Subgroup analyses were conducted to examine the potential modifying effects of different factors (eg, types of intervention, intervention duration, age, measurement, study quality).

Results: A total of 9 studies were included in this review, including 4 mobile app interventions, 3 SMS text messaging interventions, and 2 app + SMS text messaging interventions. In general, the risk of bias of included studies was low. Compared with the control group, the use of smartphone intervention significantly improved PA (standardized mean difference [SMD] 0.44, 95% CI 0.11-0.77, P=.009), especially for total PA (TPA; weighted mean difference [WMD] 32.35, 95% CI 10.36-54.33, P=.004) and daily steps (WMD 1185, 95% CI 303-2068, P=.008), but not for moderate-to-vigorous PA (WMD 3.91, 95% CI –1.99 to 9.81, P=.19). High statistical heterogeneity was detected (I^2=73.9%, P<.001) for PA. Meta-regression showed that duration (β=–.08, 95% CI –0.15 to –0.01, n=16) was a potential factor for high heterogeneity. The results of subgroup analyses indicated that app intervention (SMD 0.76, 95% CI 0.23-1.30, P=.005), children (SMD 0.64, 95% CI 0.10-1.18, P=.02), "≤8 weeks" (SMD 0.76, 95% CI 0.23-1.30, P=.005), objective measurement (SMD 0.50, 95% CI 0.09-0.91, P=.02), and low risk of bias (SMD 0.96, 95% CI 0.38-1.54, P=.001) can significantly improve PA.

Conclusions: The evidence of meta-analysis shows that smartphone-based intervention may be a promising strategy to increase TPA and steps in children and adolescents. Currently, app intervention may be a more effective strategy among smartphone

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intervention technologies. To extend the promise of smartphone intervention, the future needs to design comparative trials among different smartphone technologies.

Trial Registration: PROSPERO CRD42019148261; https://tinyurl.com/y5modsrd

(JMIR Mhealth Uhealth 2021;9(2):e22601) doi:10.2196/22601

KEYWORDS

adolescents; children; mHealth; physical activity; smartphone

Introduction

Childhood and adolescence are critical periods of growth. Engaging in enough physical activity (PA) has been demonstrated to benefit children's physical and mental health, such as reducing health risks, preventing obesity, and developing cognitive function [1,2]. To achieve health benefits through PA, the World Health Organization (WHO) recommends that children and adolescents accumulate moderate-to-vigorous intensity PA (MVPA) exceeding 60 minutes per day [3]. However, the rising prevalence of physical inactivity is a serious concern worldwide. Globally, about 70% of children and adolescents do not meet the recommendations on PA [4]. For example, a Chinese PA and fitness survey showed that two-thirds of children and adolescents did not meet the recommended PA [5]. Insufficient PA is closely related to obesity, coronary heart disease, and other health problems [6-8]. Hence, it is of paramount importance to promote and facilitate PA safely and effectively during this critical period. In response to this difficult situation, researchers have carried out a series of intervention studies on PA. However, many intervention strategies not only suffer from high cost, but are also difficult to maintain and implement on a large scale [9-11]. Therefore, how to use cost-effective and innovative intervention strategies to improve the PA level of children and adolescents effectively remains a major public health problem.

To date, the popularity of smartphones in the world is extremely high: 73.1% of children and adolescents own a smartphone in China [12], and this trend can also be seen in the United States [13] and other countries [14]. Given the global scale of noncommunicable diseases, there is a need to provide preventative interventions to reach a large population at a low cost. Therefore, many researchers have applied smartphone technologies, such as mobile apps and SMS text messaging, to health-related fields and have achieved rich research results, such as weight management, cancer nursing, and chronic obstructive pulmonary disease self-monitoring [15-17]. It is gratifying that more researchers have tried to introduce smartphone technology into the field of PA. The participants included not only adults [18-21], but also children and adolescents who urgently need attention [22-30]. This undoubtedly provides a new perspective for solving the aforementioned problems. Therefore, at the 65th Annual Meeting of American College of Sports Medicine (ACSM) and the 9th World Congress on Exercise is Medicine held in the United States in 2018, the promotion of smartphones for PA was highlighted [31].

To date, many researchers have explored the effect of smartphone interventions on improving the PA of children and adolescents through randomized controlled trials (RCT), but there are controversies about inconsistent research results. Some studies have found that smartphone interventions can significantly improve the level of PA relative to their baseline than the control group, such as Garde et al [22] (1758 steps/day, 95% CI 133-3384; 31.3 total PA [TPA] minutes/day, 95% CI 3.9 to 58.9), Chen et al [23] (0.4 PA day per week, 95% CI 0.15-0.66), Garde et al [25] (2934 steps/day, 95% CI 1434-4434; 46 TPA minutes/day, 95% CI 20-72), but other studies have not found a significant positive effect, such as Mendoza et al [24] (MVPA, –4.5 minutes/day, 95% CI –35.9 to 27), Direito et al [26] (MVPA, –1.82 minutes/day, 95% CI –16 to 12.36), Armstrong et al [28] (MVPA, 10 minutes/day, 95% CI –2.5 to 30), Thompson et al [29] (MVPA, 1.73 minutes/day, 95% CI –5.1 to 8.5; step, 318 steps/day, 95% CI –466 to 1102), and Newton et al [30] (step, –22 steps/day, 95% CI –1407 to 1364). Although there was 1 meta-analysis of smartphone intervention on adolescents to improve PA [32] and found a significant improvement on MVPA (standardized mean difference [SMD] 0.341, 95% CI 0.02-0.66), only 5 studies were included. Also, 2 of the 5 studies were multicomponent interventions (including smartphone and other components), which made it difficult to identify the true smartphone effect. Furthermore, this review missed some studies in the database [25,27,30]. Given the fact that there have been many new RCTs in recent years [22,24,28], and the previous reviews include comprehensive intervention strategies, it is unclear whether intervention effects were truly due to the smartphone itself, or rather the other intervention components [18]. Therefore, conducting a new meta-analysis on this topic is necessary.

The objective of this review is to evaluate the effectiveness of smartphone interventions to promote PA in children and adolescents, by using systematic review and meta-analysis to combine the most comprehensive and up-to-date literature. The findings of this study are expected to provide insights and practice for the development of future smartphone interventions.

Methods

Registration and Approval

This research program has been registered on the PROSPERO System Evaluation Registration Platform, registration number: CRD42019148261. This study has been reported according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines [33].

Search Strategy

A systematic literature search was conducted to find out relevant studies in 5 electronic databases: PubMed, Web of Science,

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OVID, Scopus, and the China National Knowledge Infrastructure. The core keywords identified include children, adolescents, smartphone, and "physical activity." PubMed MeSH database and other search engines were used to find synonyms of keywords, including the following 4 groups: (1) population: "high school" or youth or teen or "middle school" or "secondary school" or elementary or pupil or "primary school" or pediatric or preschool or kindergarten; (2) intervention: cellphone or "cellular phone" or "mobile phone" or "mobile technology" or mHealth or tablet or accelerometer or actigraphy or "activity tracker" or pedometer or "mobile application" or app or "mobile exergame" or "mobile game" or "text messaging" or "short message service" or SMS or "social media" or Facebook or WeChat; (3) outcomes: PA or activity or inactivity or exercise or sport or steps or "health behavior"; (4) study design: "randomized controlled trial." The search period was all-inclusive up to June 29, 2020 (Multimedia Appendix 1).

Initially, 2 reviewers (ZH and GZ) searched in the databases and exported all studies to reference management software and deleted duplicate studies. Moreover, 2 independent reviewers (TH and ZH) screened the titles and abstracts identified in the electronic databases to obtain eligible articles for the full-text analysis. In addition, both reviewers manually reviewed reference lists from relevant original research and review studies. Disagreements were resolved by group discussion with a third reviewer (MQ).

Selection Criteria of Studies

Inclusion Criteria

Inclusion criteria, according to PICOS (*p*opulation, *i*ntervention, *c*omparison, *o*utcomes, and *s*tudy) [34], were as follows:

1. Participants: children and adolescents aged 6-18 years, based on the PubMed MeSH definition of children (6-12 years) and adolescents (13-18 years).
2. Interventions: smartphone as the intervention tool, which used either app or SMS text messaging or both to promote PA.
3. Control groups included participants not using smartphone technology.
4. Outcomes: PA including daily steps or any intensities of PA. To be included in the meta-analysis, the outcome should be reported as steps, minutes, or hours. Studies that reported PA in other forms (eg, counts per minute, days per week) were included only in the systematic review.
5. The study design was RCTs.

Exclusion Criteria

1. Studies where the intervention technologies were not smartphone based (computer) or incorporated other components (eg, physical education, school seminar).
2. Studies did not report data on PA level (eg, PA score, self-efficacy on PA).
3. Studies were not written in English or Chinese.

Data Extraction

Two authors (GZ and ZH) extracted information and data independently, including study characteristics (the first author, publication year, country, study design, contents of intervention, study duration), subject characteristics (age, sex, sample size), and outcome (measurement strategy, statistical analysis, results). Disagreement was resolved through discussion until a consensus decision was reached. In the case of missing data, this information was requested from the authors a minimum of 3 times over 4 weeks.

Risk of Bias and Quality Assessment

The Cochrane Collaboration risk of bias tool was used to categorize the risk of bias in six domains [35]: (1) sequence generation, (2) allocation sequence concealment, (3) blinding of outcome, (4) incomplete outcome data, (5) selective outcome reporting, and (6) other potential threats to validity. The item blinding of participants and personnel were excluded because it is not feasible in these types of studies [20]. In addition, the risk of bias assessment for blinding of outcome assessment was based on the method of outcome assessment (objective or subjective) [20]. Each domain was scored as low, unclear, or high risk of bias. Overall classification of low, unclear, or high risk of bias in each study was based on the combination of the domains. Figures were generated by Review Manager software (RevMan 5.3; Nordic Cochrane). Disagreement about the risk of bias assessments was resolved by consensus or consulting the third author.

Statistical Analyses

Random-effects models were used in this study for the meta-analysis of the included studies. For studies that only presented data through graphs (eg, Boxplot), we estimated mean and SDs using the y-axis and length of the graphs [22,25,27]. For studies that reported standard errors, CI, or quartile, we converted these data to SDs [36]. We compared the changes from baseline to endpoint data between groups. The formulas for the mean and SD pre- to post-change values were as follows: $Mean_{change} = Mean_{post} - Mean_{pre}$ and $SD_{change} = SQRT\ [(SD_{pre}^2 + SD_{post}^2) - (2 \times Corr \times SD_{pre} \times SD_{post})]$, where the correlation coefficient was set to 0.5 based on the Cochrane Collaboration Handbook guidelines [35]. SMD and 95% CI were calculated in this study because the outcomes of the included studies are measured using different methods [37].

In the following cases, specific statistical procedures were employed: (1) When there were several publications from the same project, the study with the longest follow-up was selected; if there was no intervention during the follow-up, the result of the last intervention was selected as statistical analysis data [22]. (2) If there were multiple intervention groups in the same studies, the data were considered as independent samples for analysis. Moreover, sample sizes from control groups were evenly allocated to each intervention group in the meta-analysis to avoid artificial inflation of the true sample size [26,29]. Similarly, if a study measured 2 or more PA domains (ie, TPA, MVPA, or steps), the sample size of the control group was divided by the number of domains in which the study was measured [22,25,27,29,30]. (3) Studies that reported PA in other forms (eg, counts per minute, day per week) were included only in the systematic review, but not for meta-analysis, because the data cannot be converted into minutes per day [23].

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Additionally, subgroup analysis was based on the characteristics of the review, that is, outcomes (MVPA, TPA versus steps), types of intervention (app, SMS text messaging versus app + SMS text messaging), age (children versus adolescents), intervention duration ("≤8 weeks" versus ">8 weeks"), measurement (objective versus subjective), and risk of bias (low, unclear versus high). Given the consistency of variable units between the same outcome indicator among the continuous variables in TPA, MVPA, and steps, weighted mean difference (WMD) was calculated in this subgroup for statistical analysis.

The statistical heterogeneity was examined using I^2 between included studies and Cochran Q-test; it was defined as very low, low, medium, and high heterogeneity when I^2 values were <25%, 25% to <50%, 50% to <75%, and ≥75%, respectively [38]. Potential sources of heterogeneity were investigated using meta-regression (eg, duration, age, BMI). Egger test was adopted to detect publication bias [39]. Additionally, the "trim and fill" method was performed to estimate the impact of publication bias on the results [40]. Furthermore, to test the robustness of the results of this study, the following methods were used to conduct sensitivity analyses: 1 article was removed each time to examine whether each article had a significant influence on the overall effect (P<.05).

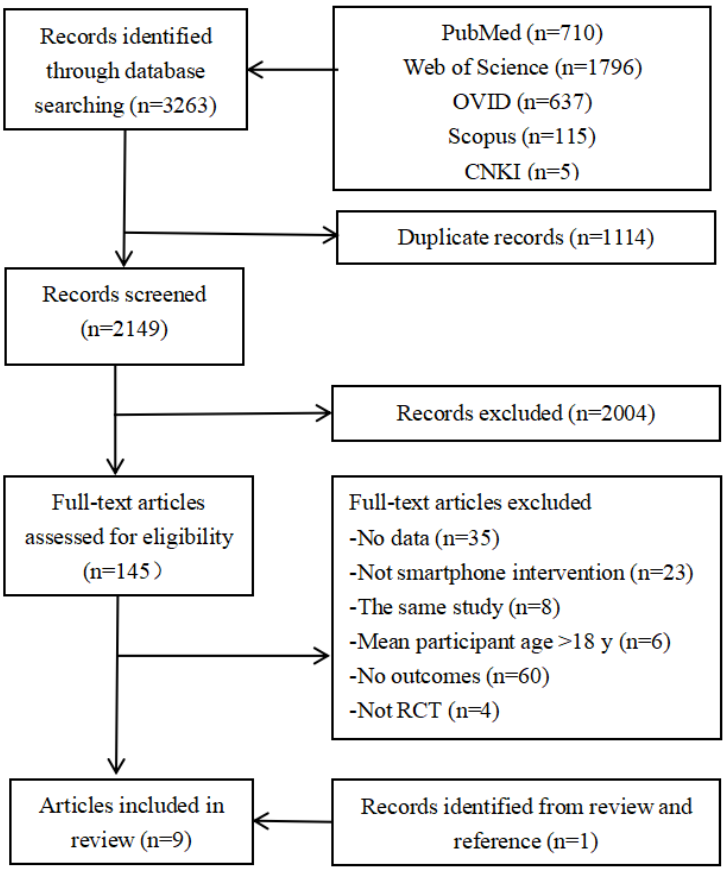
All statistical calculations were performed using the statistical software STATA 15.1 (Release 15.1 College Station, TX, USA); P<.05 was defined as a significant difference.

Results

Overview

There were 3263 studies produced from the electronic database search, and the titles and abstracts of 2149 of them were screened after deleting duplicates. In the screening process, a total of 2004 records were excluded, so 145 full-text studies remained to be assessed. From these, manual searches were conducted for studies that met the inclusion criteria. Finally, 9 studies were included in this review. A flow chart of the systematic literature search is displayed in Figure 1.

Figure 1. Flow chart of study selection.



Characteristics of the Included Studies

All included studies were published after 2009, 8 of which were after 2015. The study areas were distributed in 3 different countries: America (n=4) [23,24,28,29], Canada (n=3) [22,25,27], and New Zealand (n=2) [26,30]. The sample size was 558, the mean age of the participants was 13.2 years, 4 studies included children [22,25,27,28], and 5 studies included adolescents [23,24,26,29,30]. The intervention content is mainly based on smartphone technologies, app, and SMS text messaging, including 4 studies based on app [22,25-27], 3 studies based on SMS text messaging [28-30], and 2 studies based on app + SMS text messaging [23,24]. The study designs were all RCTs. The duration of interventions ranged from 2 weeks to 6 months. In addition, 1 study reporting PA days per week was not included in the meta-analysis because the data cannot be converted into minutes per day [23]. For TPA and MVPA, 6 studies objectively measured PA with an

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accelerometer or Tractivity activity monitor [22,24-27,29], and 3 studies used subjective assessments (questionnaires or self-reports) [23,28,30]. For the measurement of steps, 2 studies used pedometers [29,30], and 3 studies used Tractivity activity monitor [22,25,27] (Multimedia Appendix 2).

Risk of Bias

Figures 2 and 3 show the risk of bias assessment of the 9 included studies; of these, 3 studies were classified as having a low risk of bias, 4 studies were classified as having an unclear risk of bias, and 2 had a high risk of bias rating. Three studies were subjective measurement methods, so the blinded outcome assessment was rated as high risk of bias.

Figure 2. Risk of bias graph: each risk of bias item is presented as percentages.

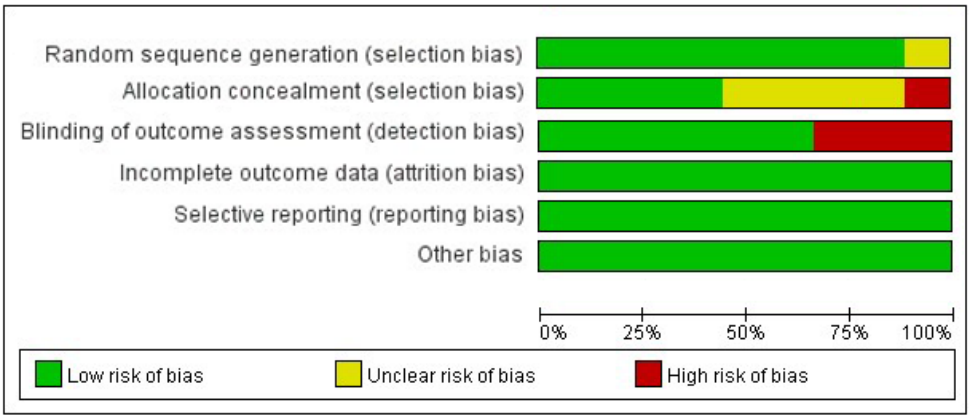
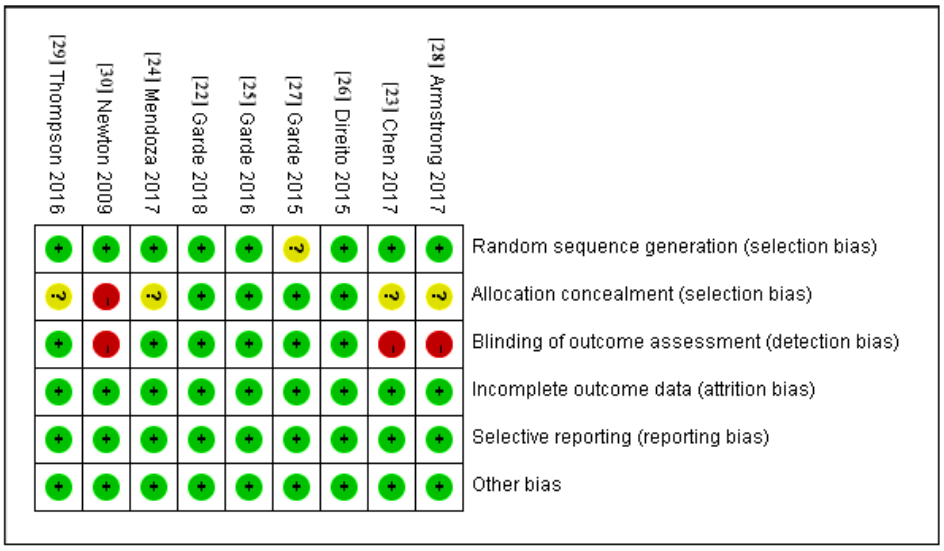


Figure 3. Risk of bias of included studies. Green: low risk of bias; yellow: unclear risk of bias; red: high risk of bias.



Result of Meta-analysis on PA

The Summary Effect Analysis

A random-effects meta-analysis, including 8 studies (16 effects), demonstrated that there was a significant improvement in PA in the intervention group compared to the control group (SMD 0.44, 95% CI 0.11-0.77, P=.009), and high statistical heterogeneity was detected (I^2=73.9%, P<.001; Figure 4). Meta-regression showed that duration (β=–.08, 95% CI –0.15 to –0.01, n=16) was a potential factor for high heterogeneity. The Egger test showed that there was no significant publication bias between the studies (P=.28).

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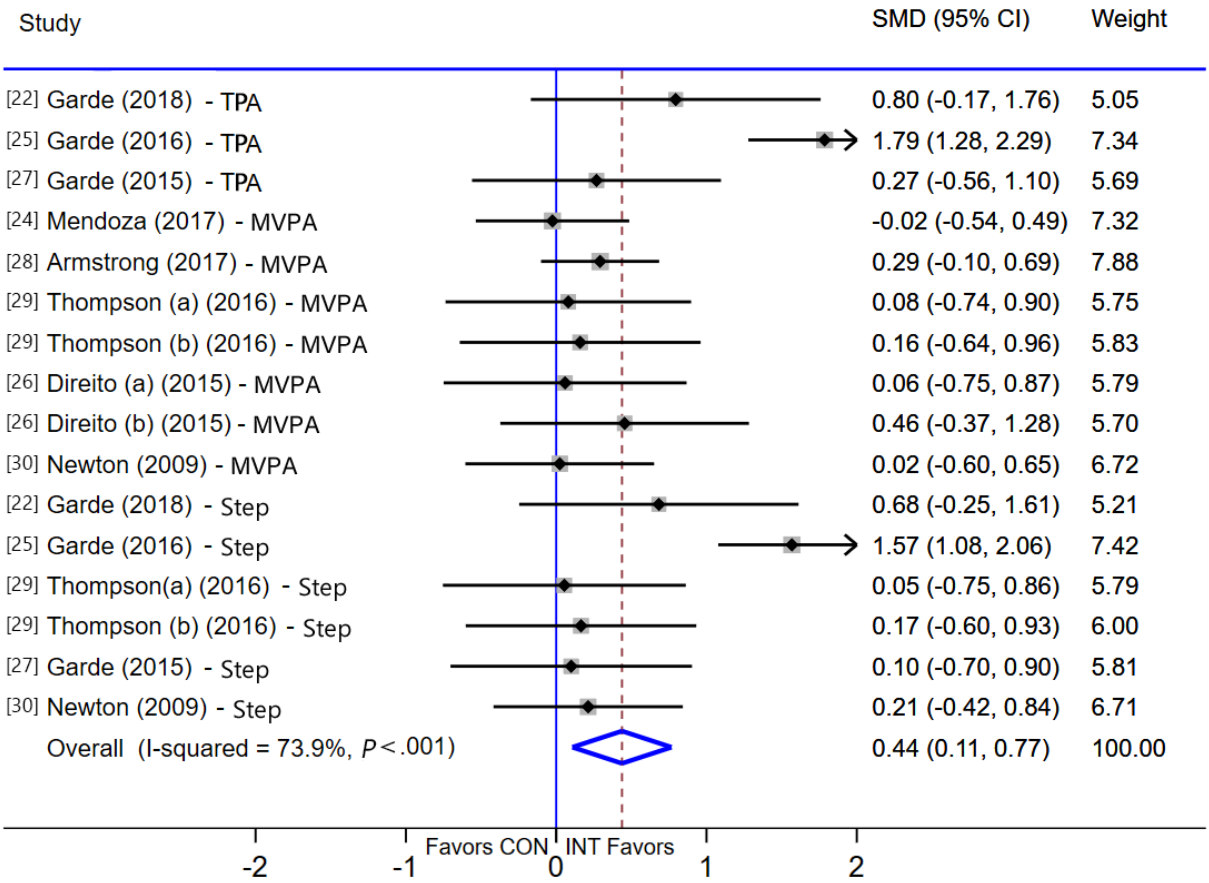
Figure 4. Meta-analysis of effects of intervention versus control on physical activity (PA). MVPA: moderate-to-vigorous-intensity physical activity; SMD: standardized mean difference; TPA: total physical activity.



Subgroup Analysis

The results of subgroup analysis of the effects on outcomes are shown in Table 1. Compared with the control group, subgroups of TPA (WMD 32.35, 95% CI 10.36-54.33, *P*=.004), step (WMD 1185, 95% CI 303-2068, *P*=.008), app intervention (SMD 0.76, 95% CI 0.23-1.30, *P*=.005), children (SMD 0.64, 95% CI 0.10-1.18, *P*=.002), "≤8 weeks" (SMD 0.76, 95% CI 0.23-1.30, *P*=.005), objective measurement (SMD 0.50, 95% CI 0.09-0.91, *P*=.02), and low risk of bias (SMD 0.96, 95% CI 0.38-1.54, *P*=.001) can significantly increase PA.

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Table 1. Subgroup analyses on the effect of intervention versus control on PA in children and adolescents.

Potential modifiers	Studies, n	Effect size (95% CI)	I^2 (%)	*P*-value heterogeneity
All studies	8	0.44 (0.11 to 0.77)	73.9	<.001
Outcome[a]				
TPA[b]	3	32.35 (10.36 to 54.33)	61.8	.07
MVPA[c]	7	3.91 (–1.99 to 9.81)	0.0	.94
Step	6	1185 (303 to 2068)	43.0	.12
Intervention				
App	4	0.76 (0.23 to 1.30)	76.4	<.001
SMS text messaging	3	0.18 (–0.06 to 0.42)	0.0	.99
App + SMS text messaging	1	–0.03 (–0.54 to 0.49)	—	—
Age				
Children	3	0.64 (0.10, 1.18)	74.1	<.001
Adolescents	5	0.32 (–0.12, 0.75)	74.8	.002
Duration				
≤8 weeks	4	0.76 (0.23, 1.30)	76.4	<.001
>8 weeks	4	0.14 (–0.07, 0.36)	0.0	.99
Measurement				
Objective	6	0.50 (0.09, 0.91)	76.6	<.001
Subjective	2	0.22 (–0.08, 0.51)	0.0	.78
Risk of bias				
Low	3	0.96 (0.38, 1.54)	74.9	.001
Unclear	3	0.09 (–0.19, 0.37)	0.0	.99
High	2	0.22 (–0.08, 0.51)	0.0	.78

[a]Outcome: There are studies reporting 2 outcomes, so the total exceeds the total number of included studies; besides, only this subgroup was calculated using weighted mean difference (WMD), whereas for others SMD is reported.

[b]TPA: total physical activity.

[c]MVPA: moderate-vigorous intensity physical activity.

Robustness of the Results

Sensitivity analyses were conducted to test the robustness of the findings. One study was removed each time to perform a meta-analysis again. The results of the effect did not change significantly, which indicates that the results of the meta-analysis in this study were reliable (Multimedia Appendix 3).

Discussion

Principal Findings

The primary objective of this study was to determine the effectiveness of the smartphone-based intervention in improving PA in children and adolescents. The results of this study indicated that smartphone-based intervention has a significant effect on PA, especially for TPA and steps, but not for MVPA.

Comparison With Previous Systematic Review and Meta-analysis

The findings of this study indicated that smartphone-based intervention has a positive effect on PA in children and adolescents, and our results are a valuable extension of recently published systematic reviews and meta-analysis. Previous similar studies mainly focused on the intervention effect of smartphone, app, and a combination of app and wearables on MVPA and step counts in adults, but the results of the studies were not consistent. Gal et al [20] (age range 19-79 years) reported that smartphone-based intervention was effective in promoting MVPA (SMD 0.43, 95% CI 0.03-0.82), whereas a nonsignificant difference on MVPA was observed in Romeo et al [18] (age range 22-63 years; mean difference [MD] –2.16, 95% CI –15.68 to 11.36; MD –3.16, 95% CI –7.85 to 0.63), Flores et al [19] (mean 39 years; SMD 0.40, 95% CI –0.07 to 0.87), and Direito et al's [41] study (age range 8.4-71.7 years; SMD 0.37, 95% CI –0.03 to 0.77). Besides, Gal et al [20] (19-79 years) and Feter et al [21] (mean 40.7 [SD 14.4] years) reported that smartphone-based intervention has a significant positive effect on steps in adults (SMD 0.51, 95% CI 0.12-0.91; MD 735, 95% CI 28-1243, respectively). However, Romeo et al [18] (age range 22-63 years) and Direito et al [41] (age range 8.4-71.7 years) did not find these results (MD 477, 95% CI –230 to 1183 and SMD 0.14, 95% CI –0.01 to 0.29, respectively).

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The possible explanation is that the intervention effects of smartphone, app, or app plus other components are the difference [21,42]. It is necessary to conduct controlled trials between different interventions. In addition, although a significant MVPA increase was not observed in most studies, we cannot ignore the potential health-promoting effects of increased other intensity PA by smartphone interventions. Recent epidemiological evidence indicated the potential benefits of increasing light-intensity PA (LPA), including association with decreased systolic blood pressure, diastolic blood pressure, markers of lipid, and glucose metabolism [43,44]. Therefore, how to improve LPA is also the focus of future research.

At present, only Shin et al's [32] study (10-19 years) focused on children and adolescents, and a significant improvement effect was found on MVPA (SMD 0.34, 95% CI 0.02-0.66). However, Shin et al [32] only included 5 studies, and it is difficult to identify the real smartphone intervention effect because 2 of these 5 studies were multicomponent interventions (including smartphones and other components). Hence, to fill up the research gaps from the previous meta-analysis, this study included more studies published in recent years and determined the actual effect of smartphone-based intervention alone on PA in children and adolescents which may provide additional information and be a valuable contribution to this area of inquiry.

The Intervention of Two Smartphone Technologies and Their Effects

At present, the number of smartphone apps on the Chinese market monitored is 4.49 million, and youth per capita under 10, 10-14, and 15-19 years is as high as 30, 44, and 59, respectively [45]. These show that app technologies are mature enough to provide technical guarantees for the development of different interventions. Indeed, subgroup analysis found that app intervention can significantly improve PA. This finding is similar to previous meta-analyses on the adult population [14,21]. The advantage of app lies in its convenience and novelty. Through the app, you can receive feedback in real time, communicate, and self-monitor, among other possibilities. At present, an increasing number of children and adolescents are searching for health-related information and guiding their fitness via app [46,47]. Therefore, an app-based intervention meets the needs of modern people for health.

Unlike the intervention effect of an app, SMS text messaging intervention has no significant improvement effect on PA. However, 2 systematic reviews are inconsistent with the results of this review. Ludwig et al [48] performed a systematic review of the efficacy of the intervention that uses SMS text messaging to improve PA and found that some studies have potential effects on improving PA in adolescents. Similarly, Feter et al [21] found that SMS text messaging intervention can significantly improve PA in adults. However, interventions in some studies included in these 2 reviews are SMS text messaging plus other components, so it is difficult to discern whether the actual effect comes from SMS text messaging or other interventions. Unfortunately, there are no controlled trials on separate interventions for SMS text messaging–only and SMS text messaging plus other components, which is also an issue that researchers need to study further.

Effects of the Smartphone on Different Age and Study Duration

Our subgroup analyses found that smartphone intervention has a significant effect on improving PA of children. In the studies in this review where the participants are children, the implementation of interventions requires parental assistance. A previous study found that parents play an important role in supporting and managing child-related health behaviors (eg, PA, sedentary behavior) [49]. The assistance of parents is conducive to the implementation of the intervention, which may lead to a positive effect on increasing PA. For adolescents, smartphone intervention has played a role in the intervention to a certain extent. However, adolescence is a transition period from the growth of children to adults, and it is also a stage of emotional fluctuation and frequent physiological changes. Rebellious emotions in the adolescent stage may resist and not cooperate with the implementer, which affects the effectiveness of the intervention and the compliance with the research.

The short-term (≤8 weeks) intervention effects may be attributed to the curiosity of the participants in the early stages of the intervention, and that they are willing to participate in the implementation. Over time, the decline in the interest and compliance of the participants led to the intervention effect not being maintained. A 4-week game app intervention found that the first-week intervention significantly improved PA in children, but the second-week and the fourth-week follow-up had no significant effect [22]. When all the games are unlocked or participants are familiar with the game, the participants are no longer interested in continuing, and the intervention effect of PA cannot be maintained. Therefore, considering the interest and passion of children and adolescents, we should strive to propose a novel strategy along with the design for a long-duration intervention.

Strengths and Limitations

This review has several strengths. First, scientifically rigorous RCT studies were included in the meta-analysis. Second, the included studies are smartphone-alone intervention, excluding studies with other intervention content, so the results can better reflect the intervention effect of smartphone. Lastly, this review conducted a subgroup analysis to explore the potential modifying effect of different factors thoroughly.

Despite these strengths, the review has several limitations. First, there are not enough studies to examine potential modifying effects of LPA, economic levels, and demographic characteristics (eg, gender, body mass index, economic status). Second, the different characteristics of the included studies lead to high heterogeneity. However, we have included the latest Chinese and English literature and conducted a subgroup analysis based on literature characteristics.

Conclusions

The findings of this meta-analysis indicated that interventions based on smartphone may be a promising strategy to increase the number of steps and TPA of children and adolescents, but

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the effect of intervention on MVPA remains to be studied. Currently, app intervention may be a more effective strategy among smartphone intervention technologies. To extend the promise of smartphone intervention, the future needs to design comparative trials among different smartphone technologies (ie, app vs SMS text messaging, app vs app + SMS text messaging, SMS text messaging vs app + SMS text messaging). Moreover, additional studies are needed to determine the effects on different participants, such as for children who are overweight and obese and low-income people.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File , 13 KB - mhealth_v9i2e22601_app1.docx]

Multimedia Appendix 2
Characteristics of Included Studies.
[DOCX File , 15 KB - mhealth_v9i2e22601_app2.docx]

Multimedia Appendix 3
Robustness of the Results.
[PDF File (Adobe PDF File), 148 KB - mhealth_v9i2e22601_app3.pdf]

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Abbreviations

LPA: light-intensity physical activity
mHealth: mobile health
MVPA: moderate-to-vigorous-intensity physical activity
PA: physical activity
PRISMA: preferred reporting items for systematic reviews and meta-analyses
RCT: randomized controlled trial
SMD: standardized mean difference

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TPA: total physical activity
WHO: World Health Organization
WMD: weighted mean difference

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Review

Effectiveness of Disease-Specific mHealth Apps in Patients With Diabetes Mellitus: Scoping Review

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Abstract

Background: According to the World Health Organization, the worldwide prevalence of diabetes mellitus (DM) is increasing dramatically and DM comprises a large part of the global burden of disease. At the same time, the ongoing digitalization that is occurring in society today offers novel possibilities to deal with this challenge, such as the creation of mobile health (mHealth) apps. However, while a great variety of DM-specific mHealth apps exist, the evidence in terms of their clinical effectiveness is still limited.

Objective: The objective of this review was to evaluate the clinical effectiveness of mHealth apps in DM management by analyzing health-related outcomes in patients diagnosed with type 1 DM (T1DM), type 2 DM (T2DM), and gestational DM.

Methods: A scoping review was performed. A systematic literature search was conducted in MEDLINE (PubMed), Cochrane Library, EMBASE, CINAHL, and Web of Science Core Collection databases for studies published between January 2008 and October 2020. The studies were categorized by outcomes and type of DM. In addition, we carried out a meta-analysis to determine the impact of DM-specific mHealth apps on the management of glycated hemoglobin (HbA_{1c}).

Results: In total, 27 studies comprising 2887 patients were included. We analyzed 19 randomized controlled trials, 1 randomized crossover trial, 1 exploratory study, 1 observational study, and 5 pre-post design studies. Overall, there was a clear improvement in HbA_{1c} values in patients diagnosed with T1DM and T2DM. In addition, positive tendencies toward improved self-care and self-efficacy as a result of mHealth app use were found. The meta-analysis revealed an effect size, compared with usual care, of a mean difference of –0.54% (95% CI –0.8 to –0.28) for T2DM and –0.63% (95% CI –0.93 to –0.32) for T1DM.

Conclusions: DM-specific mHealth apps improved the glycemic control by significantly reducing HbA_{1c} values in patients with T1DM and T2DM patients. In general, mHealth apps effectively enhanced DM management. However, further research in terms of clinical effectiveness needs to be done in greater detail.

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KEYWORDS

diabetes mellitus; mobile apps; mHealth apps; medical apps

Introduction

In today's world, digitalization is always advancing and increasingly connecting the real with the virtual world [1]. As that happens, our mutual understanding of what is meant by the term digitalization changes. While at the end of the 20th century, digitalization described the conversion of information from analog to digital storage, more extensive definitions are used today [2,3]. For example, a human-centered definition describes digitalization as a process in which people, as well as their living and working worlds, are transferred to a digital level [4]. Digitalization changes the way we interact with our world and vice versa [2]. Consequently, it is not surprising that

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digitalization also influences the daily lives of patients and health care providers.

Looking back to the 1970s, with the beginning of telematics and telemedicine, the focus was on bridging the distance between patients and health care professionals (HCPs) [2]. However, with the emergence of the internet in the 1990s, new communication channels opened up and the principal use of information and communication technologies became the decisive criterion for digitalization in medicine. The term "electronic health" (eHealth) was created [2,5]. In 2015, the term "digital health" came up in the course of the development and use of new technologies. Digital health includes the use of information and communication technologies to support people in maintaining their health. This is realized by creating opportunities for monitoring, managing, and improving their state of health with the aim of adapting medical care to the needs of the individual [2]. One application of digital health and eHealth is mobile health (mHealth) technologies. mHealth refers to medical and health-promoting methods that are supported by mobile devices such as smartphones and tablets [2,3,5,6]. A smartphone itself can be used as a device to support health, for example via social networking features [3,7]. However, since the launch of smartphone app stores in 2008, it was only a matter of time until apps became a medium for mHealth solutions [3,8,9].

Because the mHealth app market is very heterogeneous and growing so rapidly, there is currently no general mandated definition of mHealth app [10,11]. However, according to the World Health Organization (WHO), mHealth apps are software programs for smartphones and other devices that aim to influence people's physical, mental, and social well-being in a positive way [12]. In general, medical apps must be distinguished from mHealth apps [13,14]. On a side note, if an mHealth app is classified as a medical app, national and international laws, such as the Medical Device Regulation of the European Union (EU 2017/745), must be taken into account. This means that the app has to go through an approval process that includes, for example, risk analyses [14,15]. Therefore, mHealth apps—medical apps in particular—offer the possibility to improve general health care issues and, more specifically, issues related to type 1 (T1DM) and type 2 (T2DM) diabetes mellitus [3,16-18].

Diabetes mellitus (DM) affects millions of people worldwide and its prevalence is rising [19,20]. Affecting approximately 462 million people globally, T2DM makes up a significant part of the global burden [19], but the prevalence of T1DM, gestational DM (GDM), and other forms of DM are rising drastically as well [20-22]. Despite the huge improvements in diabetes technologies, such as glucose monitoring systems and insulin pumps, many people with diabetes do not meet glycemic control targets [23] and would benefit from greater flexibility and more individualized diabetes therapy.

This underlines the urgent need to improve diabetes care in addition to HCP visits, such as by supporting digital diabetes self-management [24,25]. mHealth apps offer novel possibilities, and first steps have been taken in this regard by a small but growing part of the DM community [26-29]. In 2015, DM-specific mHealth apps had been installed approximately 6.7 million times. Since then, the number of installations has increased dramatically, with approximately 15 million installations in 2018 [29] and 46.3 million installations in 2019 [30], which represented approximately 11% of patients with DM diagnoses worldwide in 2019 [30]. Of the mHealth apps that were installed, 35.8% focused on T1DM, 47.6% on T2DM, and 32.0% on GDM [29]. DM-specific mHealth apps exist in great variety and include different features [31]. Possible app features include tracking of blood glucose levels or insulin usage; calculation of insulin dosages; monitoring of diet, body weight, or physical activities; or providing education or information [3,29,30,32-38]. However, the available evidence on the effectiveness of DM-specific mHealth apps is limited [39]. Therefore, this paper aims to give an overview of the clinical effectiveness of DM-specific mHealth apps on different health-related outcomes for T1DM, T2DM, and GDM. Clinical effectiveness is defined as a process measured by improvements in the parameters of a morbid condition (eg, lowering blood glucose) and aims to provide optimal care, including evidence-based practice [40]. From a clinical point of view, it is important to know the effect size that results from modifying the communication level by using mHealth apps. In clinical practice, these effects must be added to the therapeutic effects (eg, from insulin). This is also important in order to be able to give evidence-based recommendations.

Methods

Data Sources and Search Strategy

In October 2020, we conducted a systematic literature search in MEDLINE via PubMed, Cochrane Library, EMBASE, CINAHL, and Web of Science Core Collection in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) strategy [41]. These databases are representative of the entire health-related literature on DM, as they are the five largest databases in this field. The search strategy included the following keywords as Medical Subject Headings or EMBASE Subject Headings terms, as well as title and abstract terms: ("diabetes mellitus") AND ("smartphone" OR "mobile phone" OR "cell phone" OR "iOS" OR "android") AND ("mobile applications" OR "app"). The search strategy in PubMed, for example, was as follows: ("diabetes mellitus"[Mesh]) AND ("Smartphone"[Mesh]) OR ("Cell Phone"[Mesh]) OR ("mobile phone"[Title/Abstract]) OR (ios[Title/Abstract]) OR (android[Title/Abstract]) AND (app[Title/Abstract]) OR ("Mobile Applications"[Mesh]).

In addition, we manually searched reference lists and Google Scholar to identify further papers. The search results were filtered in the databases by year (January 2008 to October 2020) and language (German and English). The studies were screened and selected by two independent reviewers.

Eligibility Criteria

Since this is a scoping review, we have included several study designs and outcomes to summarize the evidence available on the topic. We included primary research studies (randomized controlled trials, exploratory studies, observational studies, and pre- and posttest design studies) and peer-reviewed studies

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published between January 2008 and October 2020. Because English is the worldwide scientific language and the authors are native German, we have taken German and English literature into account.

Studies reporting on the clinical effectiveness of DM-specific mHealth apps in DM management in patients with T1DM, T2DM, and GDM that specified the features of the apps and their health effects were included.

We looked for reported significant changes ($P<.05$) in health-related oucomes such as glycemic control (eg, glycated hemoglobin [HbA_{1c}], and hypo- and hyperglycemia), blood pressure, cholesterol, body weight, self-care, and self-efficacy. Self-care was defined and measured as DM self-management that included items assessing general diet, specific diet, exercise, blood glucose testing, foot care, and smoking using a questionnaire. Self-efficacy is a predisposing factor that be impaired in chronic diseases like DM. Increased self-confidence levels, measured by questionnaires, can set the stage for improved glycemic control [42].

Furthermore, we excluded posters, comments, study protocols, duplicates, and studies focused on DM diagnosis or prevention.

Data Extraction

We extracted the following information about each study: author, year, study design, intervention and control groups, baseline and follow-up HbA_{1c} values, type of DM, sample size, and main findings related to the outcomes of interest.

Data Synthesis and Analysis

We synthesized the studies according to outcomes because the clinical perspective focuses on the improvement of individual outcomes through the intervention. In addition, we conducted a meta-analysis to assess the impact of the interventions on the management of HbA_{1c}.

HbA_{1c} is the most important and most studied clinical outcome related to technological therapy for DM, including mHealth apps. To determine the change in HbA_{1c}, we pooled appropriate studies with intervention groups (using mHealth apps only) and control groups (usual care) and calculated the difference in means, with a 95% confidence interval. We included studies that reported changes in HbA_{1c} as a percentage from baseline to the end of the study for intervention and control groups.

Results

Overview

The database search in October 2020 in the five relevant databases yielded a total of 796 hits. After removing the duplicates, there were 654 citations. Based on the titles and abstracts, we excluded 619 unsuitable papers. The reasons for exclusion can be found in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart (Figure 1). Furthermore, we excluded 8 unsuitable studies based on their full texts. After the additional manual research, which identified 2 papers, there was a total of 27 suitable studies to include in this scoping review. In total, we included 27 papers analyzing 1646 patients in the intervention groups and 1241 in the control groups.

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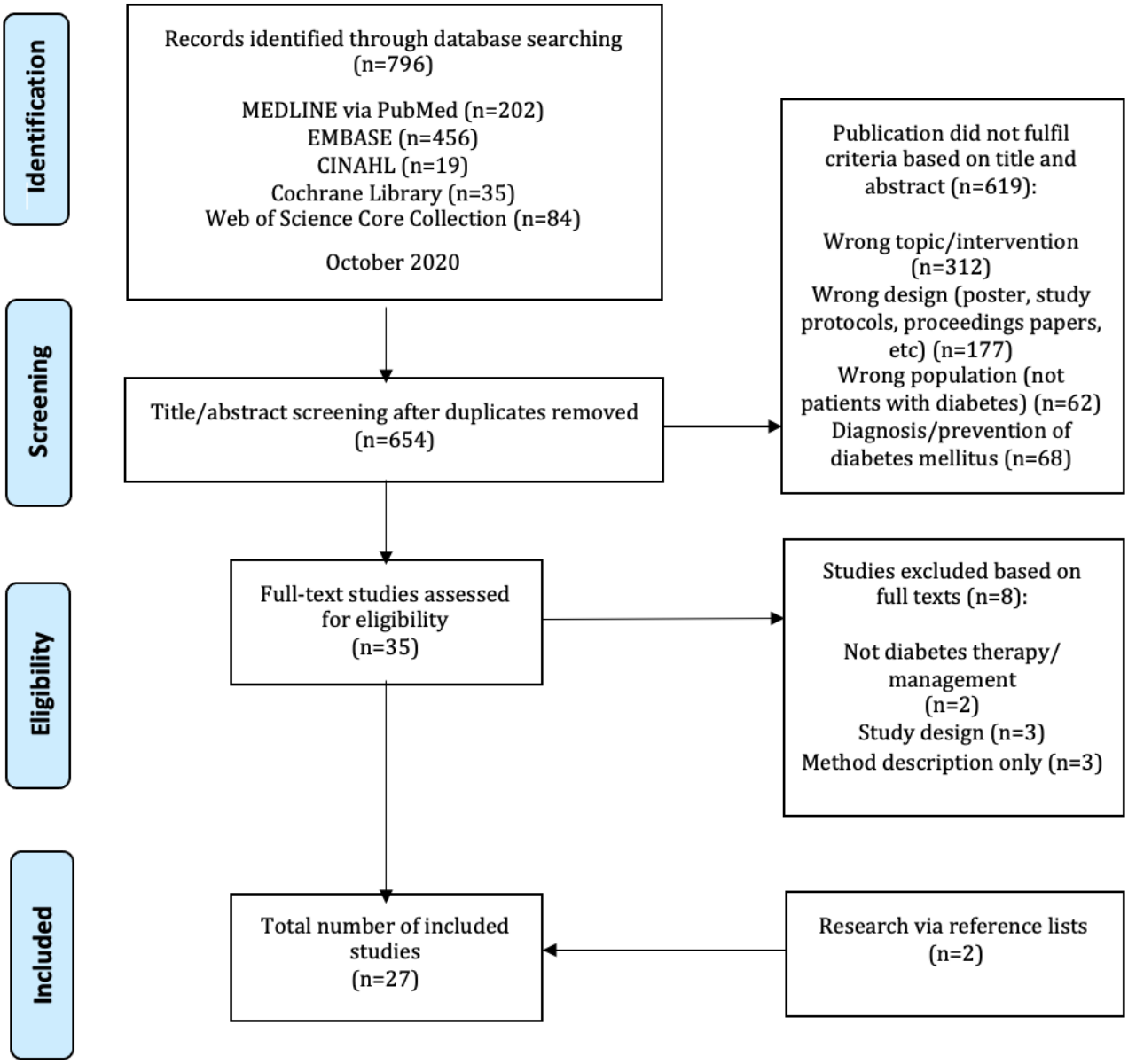
Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart.



Of the 27 papers, 7 were focused on T1DM (308 patients in the intervention groups and 129 patients in the control groups) [43-49], 12 were focused on T2DM (743 patients in the intervention groups and 645 patients in the control groups) [50-61], and 4 were focused on GDM (339 patients in the intervention groups and 343 patients in the control groups) [62-65]. The remaining 4 papers did not specify the type of DM they looked at or included a mix of DM types (256 patients in the intervention groups and 124 patients in the control groups) [66-69]. Multimedia Appendix 1 gives an overview of the included studies. With regard to the study design, we included 19 randomized controlled trials, 1 randomized crossover trial, 1 exploratory study, 1 observational study, and 5 studies that used a pre-post design (1 of which was controlled). Different diabetes mHealth apps were evaluated in each study. As predicted, the apps had a great variability in their features. Some apps included only one feature, such as digital diaries [47,60], feedback on glucose measurements [51], physical activity promotion [53], data transfer to electronic medical records [61], or educational features [52], while other apps combined multiple features. In the following sections, we present the results of the studies sorted by included outcomes.

T1DM Studies

HbA_{1c}

Overall, 264 patients in the intervention groups and 129 patients in the control groups were investigated in the T1DM studies. In 3 of the 7 studies, significant improvements of HbA_{1c} levels within the intervention groups were found (mean difference: –1.1%, $P<.001$ [47]; –0.3%, $P<.001$ [45]; and –0.3%, $P=.04$ [46]), yielding an HbA_{1c} of 7.73% on average. Charpentier et al [48] and Drion et al [43] did not report on significance within groups and Rossi et al [49] did not find significant differences ($P=.27$). Also, 2 studies in which control groups were included reported significant differences between the groups, with better outcomes in the app intervention groups than in the groups receiving usual care ($P<.001$ [47]; –0.67%, $P<.001$ [48]).

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Hypo- and Hyperglycemia

Foltynski et al [44] found a significant 12% difference in 2-hour postprandial time in range (TIR) in favor of the periods with app support (P=.031). However, they did not find significant differences regarding TIR (P=.764), time ≤70 mg/dL (P=.764), and time ≥180 mg/dL (P=.883) [44]. In addition, Tack et al [46] did not find any significant differences in hypoglycemic events (P=.21).

Fasting Blood Glucose

Fasting blood glucose was reported in 1 study (41 patients [49]), but a significant change was not found (P=.09).

Self-Care

Kirwan et al [47] used the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire in their study (36 patients in the intervention group, 36 patients in the control group). On the scales for exercise and blood sugar testing, no significant differences were found (P>.05). On the scale for diet, there were significant differences within groups (3.42 to 4.62 from baseline to end of study in the intervention group, P<.05) but not between groups (1.2 in intervention group versus –0.05 in control group, P>.05) [47].

Self-Efficacy

Kirwan et al [47] used the Diabetes Empowerment Scale–Short Form (DES–SF) to examine self-efficacy, but no significant differences between the groups were found.

T2DM Studies

HbA_{1c}

In total, 743 patients in intervention groups and 645 patients in control groups were investigated in the studies focused on T2DM. Eleven of the studies reported a decrease of HbA_{1c} within the app intervention groups, yielding a mean difference of –0.42% [50-52,54-61], but only 1 study reported a significant change of –1.1% (P<.001) [56]. The proportion changes when differences between intervention and control groups were considered. Of 11 studies that included control groups in their study design, 7 studies reported significant differences (mean difference: –0.78%, –1.51 to –0.35) in favor of the app intervention groups [51,53-58], while 3 studies did not find a significant difference between groups [52,59,60] and 1 study did not report on differences between groups [61]. Moreover, Kim et al [61] found a significant decrease of 0.4% (P<.001) in HbA_{1c} in their subgroup analysis for participants with a high satisfaction level and no significant decrease in participants with a low satisfaction level.

Fasting Blood Glucose

Fasting blood glucose was included in 2 studies (51 patients in the intervention groups and 54 patients in the control groups) [54,57]. Both studies found a significant difference between groups favoring the intervention groups (–28.23 mg/dL, P<.001 [54]; –9.6 mg/dL, P=.019 [57]).

Blood Pressure

None of the 7 studies that reported on blood pressure found significant differences either within or between groups [51-53,55,57,58,61].

Cholesterol

Cholesterol levels were reported in 7 studies (407 patients in the intervention groups and 348 patients in the control groups). Six studies looked at total cholesterol [52,53,55,56,58,61], but only 1 study found a significant change within the intervention group (P=.01), as well as between the groups (P=.009) [56]. High-density lipoprotein (HDL) cholesterol and low-density lipoprotein (LDL) cholesterol were both included in 7 studies [52,53,55-58,61]. Regarding HDL cholesterol, only 1 study found significant differences within groups (P=.002 in the intervention group, P=.004 in the control group) and between groups, showing greater improvement and lower values in the control group (60.67 mg/dL to 54.33 mg/dL in the intervention group versus 60.07 mg/dL to 52.73 mg/dL in the control group; P=.048) [56]. With regard to LDL cholesterol, 1 study reported a significant change within the intervention group (–20.42 mg/dL; P=.007) and between the intervention and control groups (P=.01) [56].

Body Weight

Three studies [52,55,59] observed the body weights of 215 patients in intervention groups and 156 patients in control groups. One study reported a significant difference between the groups (–2.1 kg in the intervention group versus 0.4 kg in the control group; P=.021) [51]. While Holmen et al [59] reported a decrease of body weight in the intervention group, they did not report on the significance. Meanwhile, Kim et al [55] did not report significant differences between the intervention and control groups (P=.531).

Self-Care

Two studies (229 patients in the intervention groups and 224 patients in the control groups) used the SDSCA questionnaire to evaluate self-care [52,54]. Only 1 study reported a significant difference between the groups (P<.001) [54]. The scales for diet and exercise were also included in 2 studies [52,54], but only one of the studies showed significant differences between the groups for both outcomes (P<.001) [54]. No significant differences were reported for the scales for blood sugar testing (P=.509) [52] or smoking (P=.729) [54], which were each included in one study.

Self-Efficacy

Chomutare et al [50] (7 patients) reported improvements in scores on the DES–SF and Health Education Impact Questionnaire (heiQ [70]), but they did not report on significance. Kusnanto et al [56] (15 patients in the intervention group and 15 patients in the control group) used a diabetes management self-efficacy scale consisting of 15 questions and found significant improvements within and between the groups (within groups: 15.48, P<.001 in the intervention group versus 9.6, P<.001 in the control group; between groups: P<.001).

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GDM Studies

HbA_{1c}

Two studies [62,64] (167 patients in the intervention groups and 162 in the control groups) investigated the HbA_{1c} levels in patients with GDM. One of the studies [62] found a significant difference between the groups in favor of the app intervention (–1.3% in the intervention group versus –0.6% in the control group; $P<.001$), while the other study found no significant difference [64].

Hypo- and Hyperglycemia

Significant differences between groups favoring the app intervention groups were found for off-target fasting glucose measurements ($P<.001$ [62,65]), off-target 1-hour glucose measurements ($P<.001$ [65]), and off-target 2-hour glucose measurements ($P<.001$ [62]).

Blood Glucose and Oral Glucose Tolerance Test

Miremberg et al [65] reported a significant difference between the intervention and control groups ($P<.001$), without giving the exact value. Regarding oral glucose tolerance test (OGTT) results, neither Guo et al [62] nor Borgen et al [63] found significant differences in fasting OGTT or 2-hour OGTT.

Self-Care

Two studies [62,65] (124 patients in the intervention groups and 120 patients in the control groups) included the outcome of patient compliance, defined as the ratio between actual blood glucose measurements and instructed measurements ×100. Both studies found significant differences between the groups, favoring the app intervention groups ($P<.001$ [62,65]). In addition, Mackillop et al [64] (103 patients in the intervention group and 102 patients in the control group) reported significant differences in the number of blood glucose readings per day, also favoring the app intervention group ($P<.001$).

Studies With Type of DM not Specified

HbA_{1c}

Gunawardena et al [66] reported a significant decrease of –0.96% ($P<.001$) in HbA_{1c} level within the app intervention group and a significant difference ($P<.001$) between groups in favor of the intervention group. The study by Yu et al [68] did not show a significant difference in HbA_{1c} between the groups ($P>.05$), but a significant difference was reported regarding the proportion of participants reaching the goal of HbA_{1c} ≤7%, with use of the app as the decisive factor ($P<.05$).

Fasting Plasma Glucose

Yu et al [68] reported on fasting plasma glucose (48 patients in the app intervention group and 47 patients in the usual care group), but they found no significant differences between the groups ($P>.05$).

Self-Care

Kim et al [69] (90 patients in the intervention group) reported significant improvements through the intervention regarding the total SDSCA score ($P<.05$), as well as on the scales for diet (0.73, $P<.05$), exercise (1.11, $P<.05$), blood sugar testing (1.93, $P<.05$), and smoking (–0.51, $P<.05$). Jeon and Park [67] (38 patients in the intervention group) used the Information-Motivation-Behavioral skills model as a basis to evaluate their app. They found significant improvements in self-care social motivation ($P=.05$) and self-care behaviors ($P=.02$), but they did not find significant differences in self-care information ($P=.85$), self-care personal motivation ($P=.57$), or self-care behavioral skills ($P=.89$) [67].

Effects on HbA_{1c}

Table 1 shows all of the results according to HbA_{1c} values. Effects based on the comparison of HbA_{1c} levels between the intervention and control groups at the study end points were investigated. Findings are presented in Multimedia Appendix 2. The meta-analysis revealed an effect size, compared with usual care, of a mean difference of –0.54% (95% CI –0.8 to –0.28) for T2DM (8 suitable studies) and –0.63% (95% CI –0.93 to –0.32) for T1DM (2 suitable studies) (Multimedia Appendix 3).

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Table 1. Study results according to glycated hemoglobin (HbA_{1c}) values.

Diabetes type and reference	Study groups	HbA_{1c} (%), mean (SD or 95% CI)		Differences in HbA_{1c} (%): mean (SD or 95% CI), *P* value	
		Baseline	Follow up	Within groups	Between groups
T2DM [a]					
[50]	Intervention	6.97 (0.69)	6.79 (0.68)	NR[b]	N/A[c]
[51]	(A) Intervention; (B) control	(A) 6.86 (1.56); (B) 7.09 (1.51)	NR	(A) –0.40 (–0.67 to –0.14); (B) 0.036 (–0.23 to 0.30)	NR, *P*=.02
[52]	(A) Intervention; (B) control	(A) 8.1 (1.2); (B) 8.3 (1.6)	(A) 8.0 (1.6); (B) 8.2 (1.4)	NR	–0.08 (–0.37 to 0.2), *P*=.56
[53]	(A) Intervention; (B) control	(A) 6.2 (0.6); (B) 6.9 (0.7)	(A) 6.2 (0.7); (B) 7.0 (1.0)	NR	–0.9 (–1.5 to –0.2), *P*=.016
[54]	(A) Intervention; (B) control	(A) 7.10 (1.22); (B) 6.85 (0.93)	(A) 6.84 (0.63); (B) 8.10 (0.10)	(A) NR, *P*=.232; (B) NR, *P*<.001	NR, *P*<.001
[55]	(A) Intervention; (B) control	(A) 7.7 (0.7); (B) 7.8 (0.7)	NR	(A) –0.4 (0.09); (B) –0.06 (0.1)	0.35 (0.14 to 0.55), *P*<.001
[56]	(A) Intervention; (B) control	(A) 8.74 (1.34); (B) 8.18 (1.02)	(A) 7.64 (1.29); (B) 7.91 (0.88)	(A) –1.1, *P*<.001; (B) 0.27, *P*=.208	NR, *P*=.005
[57]	(A) Intervention; (B) control	(A) 7.1 (1.0); (B) 7.0 (0.9)	(A) 6.7 (0.7); (B) 7.1 (1.1)	(A) –0.4; (B) 0.1	NR, *P*=.015
[58]	(A) Usual care; (B) app only; (C) app + web portal; (D) app + web portal + decision support	(A) 9.2 (1.7); (B) 9.3 (1.8); (C) 9.0 (1.8); (D) 9.9 (2.1)	(A) 8.5 (1.8); (B)7.7 (1.0); (C) 7.9 (1.4); (D) 7.9 (1.7)	(A) –0.7 (–2.3 to –1.0); (B) –1.6 (–2.3 to –1.0); (C) –1.2 (–1.8 to –0.5); (D) –1.9 (–2.3 to –1.5)	A vs D: 1.2 (0.5 to 1.9), *P*<.001; A vs B: NR, *P*=.027; A vs C: NR, *P*=.40
[59]	(A) Usual care; (B) app; (C) app + HCP[d] support	(A) 8.4 (7.97 to 8.76); (B) 8.1 (7.72 to 8.53); (C) 8.1 (7.76 to 8.43)	(A) 8.2 (7.77 to 8.61); (B) 7.8 (7.48 to 8.15); (C) 8.0 (7.49 to 8.41)	(A) –0.16 (–0.50 to 0.18); (B) –0.31 (–0.67 to 0.05); (C) –0.15 (–0.58 to 0.29)	A vs. B: –0.22 (–0.75 to 0.32), *P*=.42; A vs C: 0.01 (–0.52 to 0.54), *P*=.097
[60]	(A) Usual care; (B) app; (C) education program; (D) app + education program	(A) 9.2 (1.6); (B) 9.3 (1.6); (C) 9.4 (1.7); (D) 9.2 (1.4)	NR	(A) –0.7; (B) –0.7; (C) –1.1; (D) –1.1	NR, *P*=.771
[61]	(A) Intervention; (B) control	(A) 7.7 (0.7); (B) 7.7 (0.5)	(A) 7.5 (0.7); (B) 7.7 (0.7)	(A) NR, *P*=.077; (B) NR, *P*=.973	NR
T1DM[e]					
[43][f]	(A) Intervention; (B) control	(A) 61 (57 to 65); (B) 62 (57 to 66)	(A) 63 (58 to 67); (B) 63 (57 to 69)	(A) 1 (–1 to 2); (B) 1 (–4 to 6)	–2 (–6 to 5)
[45]	Intervention	8.1 (7.5 to 9.0)	7.8 (6.9 to 8.3)	NR, *P*<.001	N/A
[46]	Intervention	7.9	7.6	NR, *P*=.04	N/A
[47]	(A) Intervention; (B) control	(A) 9.08 (1.18); (B) 8.47 (0.86)	(A) 7.80 (0.75); (B) 8.58 (1.16)	(A) –1.10 (0.74), *P*<.001; (B) 0.07 (0.99), NS[g]	NR, *P*<.001
[48]	(A) Usual care; (B) app only; (C) app + teleconsultations	(A) 8.91 (0.90); (B) 9.19 (1.14); (C) 9.11 (1.14)	(A) 9.10 (1.16); (B) 8.63 (1.07); (C) 8.41 (1.04)	NR	A vs B: 0.67 (0.35 to 0.99), *P*<.001; A vs C: 0.91 (0.60 to 1.21), *P*<.001; B vs C: *P*>.05
[49]	Intervention	7.6 (7.3 to 7.9)	NR	–0.33 (–0.77 to 0.11), *P*=.27	N/A
GDM[h]					
[62]	(A) Intervention; (B) control	(A) 6.0 (0.4); (B) 5.9 (0.3)	(A) 4.7 (0.2); (B) 5.3 (0.3)	NR	NR, *P*<.001

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Diabetes type and reference	Study groups	HbA_{1c} (%), mean (SD or 95% CI)		Differences in HbA_{1c} (%): mean (SD or 95% CI), *P* value	
		Baseline	Follow up	Within groups	Between groups
[64]	(A) Intervention; (B) control	(A) 5.42 (0.34); (B) 5.39 (0.35)	NR	(A) 0.02/day; (B) 0.03/day	–0.01 (–0.05 to 0.03), NS

[a]T2DM: type 2 diabetes mellitus.

[b]NR: not reported.

[c]N/A: not applicable.

[d]HCP: health care professional.

[e]T1DM: type 1 diabetes mellitus.

[f]HbA_{1c} values in this study were reported in mmol/mol.

[g]NS: not significant.

[h]GDM: gestational diabetes mellitus.

Discussion

Principal Results and Comparison With Prior Work

In general, specific mHealth apps clearly improved glycemic control by effectively reducing HbA_{1c} values in patients with T1DM (mean difference: –0.63%, 95% CI –0.93% to –0.32%) and T2DM (mean difference: –0.54%, 95% CI –0.8% to –0.28%). While no significant improvements in blood pressure or cholesterol were found in patients with T2DM, a few studies showed positive tendencies toward improved self-care and self-efficacy with regard to patients with DM in general.

The studies were diverse with respect to the type of DM, study design, number of participants, and app features. Often, different app features were combined or the app was used in conjunction with web portals, feedback from HCPs, or Bluetooth-enabled devices. Because of that, it was not possible to distinguish a relationship between specific app features and health outcomes.

However, some effects were clearly demonstrated from the use of DM-specific mHealth apps in general. We categorized the outcomes included in the studies into HbA_{1c}, hypo- and hyperglycemia, further glycemic control outcomes, blood pressure, cholesterol, body weight, self-care, self-efficacy, and further outcomes.

Nearly all of the studies (22 of 27 studies) included HbA_{1c} level as an outcome, with a total of 2352 patients analyzed. For patients with T1DM, 3 studies reported significant improvements within the intervention groups, with a mean difference of –0.57%, yielding HbA_{1c} levels of 7.73% on average, and 2 studies reported significant differences between groups with a mean difference of –0.73, favoring the intervention groups. Those results are consistent with other reviews. Sun et al [71] reported on 3 studies that showed a significant improvement in HbA_{1c} levels, ranging from –0.50% to –0.58%, in people diagnosed with T1DM. Hou et al [72] reported a significant improvement of –0.49% in HbA_{1c} level but rated the grade of evidence to be low. Moreover, Kitsiou et al [73] investigated the effect of mHealth interventions in general and reported an improvement of –0.3% in HbA_{1c} levels in people with T1DM.

For T2DM, one of the included studies found a significant improvement in HbA_{1c} levels, approximately –1.1%, yielding a mean HbA_{1c} of 7.64% in the intervention group [56], and 7 studies determined a significant difference between intervention and control groups, with a mean difference of –0.78%, favoring the intervention group. Furthermore, Kim et al [61] showed a significant improvement for users who were highly satisfied with the mHealth app. This could be problematic in light of the results of Fu et al [74], who found that patients rated the usability of T2DM-specific apps to be “moderate to catastrophic”. However, Fu et al [74] also reported similar significant improvements in HbA_{1c} values, based on the results of 4 studies, ranging from –1.9% to –0.4% [74]. In addition, they highlighted that people with poor glycemic control (HbA_{1c} >9%) achieved greater reductions and that apps with interactive features (eg, receiving feedback) were especially likely to show highly significant improvements [74]. The importance of receiving feedback, for example from HCPs, was also reported by Hou et al [72]. In their review, they reported that the higher the frequency of HCP feedback was, the greater was the reduction in HbA_{1c} [72]. All in all, they reported a mean difference of –0.57% in HbA_{1c} for patients with T2DM using mHealth apps [72]. In other reviews, such as one by Cui et al [75], a significant mean difference of –0.4% of HbA_{1c} was found between DM-specific mHealth app intervention groups and usual care groups in favor of the intervention groups.

The reported improvements in HbA_{1c} in people with T1DM and T2DM are consistent with the results of the studies that did not specify the type of DM. Of the studies that did not specify the DM type, one study found a significant improvement in HbA_{1c} within the intervention group [66] and the other study found an increase in the proportion of participants with HbA_{1c} <7% [68]. No clear effect on HbA_{1c} could be seen in the studies that focused on patients with GDM because of limited data.

The problem of limited data also applies to the study outcomes of hypo- and hyperglycemia and further glycemic control parameters because the studies included different kinds of outcomes. Thus, no clear conclusions can be drawn from them. Other reviews reported an improvement of glycemic control

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through mHealth app interventions [71,74,75] but mainly based their conclusions on HbA_{1c} improvements.

The outcomes of blood pressure, cholesterol, and body weight were only included in studies focusing on T2DM. No effect could be determined for blood pressure, total cholesterol, or HDL or LDL cholesterol because the studies predominantly reported nonsignificant differences. With regard to body weight, no effects could be determined either because of inconclusive study results. This is consistent with the review by Cui et al [75], which did not report on the effects of T2DM-specific mHealth apps on blood pressure, cholesterol, or body weight.

Although the data on the outcomes of self-care and self-efficacy were also limited for all types of DM, the studies showed a trend toward improvements in both. Other studies reported improved DM self-management skills as well [71,76]. However, Hoppe et al [77] criticized the lack of inclusion of behavior change techniques in DM-specific mHealth apps.

Other than the effects on health-related outcomes, different aspects of DM-specific mHealth apps should be taken into account for further research and development. For example, Höchsmann et al [53] highlighted that not just the content of an app is important but also the way it conveys the content. They created their app as a game and found significant effects on HbA_{1c} level and steps per day as a result of the intervention [53]. In addition, Boels et al [52] reminded us that the different needs of people with DM—for example, if someone requires insulin or not—need to be considered. Also, the age of the patients appears to matter. Hou et al [78] showed in their subgroup analyses that young people with T2DM are more likely to benefit from apps. Moreover, elderly people diagnosed with DM may have special needs, such as a larger font size because of reduced eyesight, and not all apps are able to meet these needs [79]. This goes hand in hand with the conclusion of Meister et al [2] that living in the digital world demands a kind of digital literacy. But despite the widespread use of smartphones, digital literacy barriers are common in vulnerable populations, which could reduce the effectiveness of diabetes technologies [80]. Moreover, a lack of standards and regulations lead to potential health risks, for example via misinformation through an mHealth app [39]. Certified medical apps are more trustworthy and should therefore be preferred. However, in the field of DM, they are still rare, and additional online libraries of high-quality DM-specific mHealth apps should be taken into account for recommendations [28]. In addition, data safety in mHealth apps is a serious concern, as they deal with sensitive data [28,39,81]. These issues need to be addressed in future studies.

Limitations of the Study

Although the results of this paper show some possible improvements achieved by using mHealth apps in the treatment of DM, some limitations need to be addressed. A major limitation is the small sample size, especially regarding GDM. Only 4 studies that focused on GDM were included, and they in turn reported predominantly on different outcomes. Thus, no effects of mHealth app use could be determined for patients with GDM. To resolve this issue, we must increase our knowledge of which outcomes are affected by DM-specific mHealth apps and include these outcomes in further studies. In addition, it appears that for patients with GDM, a separate assessment of mHealth app effectiveness is reasonable because outcomes that are important to patients with GDM do not apply in general to patients with T1DM or T2DM, such as different aspects of pregnancy and childbirth. Another limitation of this paper is that the quality of the included studies was not assessed. Therefore, we cannot judge whether an effect was based on poor study quality.

Conclusions

Overall, this review clearly shows how the use of DM-specific mHealth apps results in improvements in glycemic control by effectively reducing HbA_{1c} levels in patients with T1DM and T2DM. However, a few studies found no significant effects of app use on blood pressure or cholesterol in patients with T2DM. With regard to the other outcomes, only a few suitable studies could be identified. In addition, a handful of studies showed positive tendencies toward improved self-care and self-efficacy as a result of mHealth app use in patients with any type of DM. This suggests a need for further research on the clinical effectiveness of DM-specific mHealth apps.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Overview of included studies.
[DOCX File , 29 KB - mhealth_v9i2e23477_app1.docx]

Multimedia Appendix 2
Results regarding glycated hemoglobin (HbA_{1c}) values.
[DOCX File , 23 KB - mhealth_v9i2e23477_app2.docx]

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Multimedia Appendix 3
Changes in glycated hemoglobin (HbA_{1c}) values (%).
[DOCX File , 19 KB - mhealth_v9i2e23477_app3.docx]

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Abbreviations

DES–SF: Diabetes Empowerment Scale–Short Form
DM: diabetes mellitus
GDM: gestational diabetes mellitus
HCP: health care professional
HDL: high-density lipoprotein
heiQ: Health Education Impact Questionnaire
LDL: low-density lipoprotein
MD: mean difference
mHealth: mobile health
OGTT: oral glucose tolerance test
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SDSCA: Summary of Diabetes Self-Care Activities
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus

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TIR: time in range

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Review

Effectiveness of Mobile Health–Based Exercise Interventions for Patients with Peripheral Artery Disease: Systematic Review and Meta-Analysis

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Abstract

Background: Peripheral artery disease (PAD) affects over 236 million people worldwide, and exercise interventions are commonly used to alleviate symptoms of this condition. However, no previous systematic review has evaluated the effects of mobile health (mHealth)–based exercise interventions for patients with PAD.

Objective: This study aimed to assess the effect of mHealth-based exercise interventions on walking performance, functional status, and quality of life in patients with PAD.

Methods: A systematic review and meta-analysis were conducted. We searched in seven databases to identify randomized controlled trials of patients with PAD published in English up to December 4, 2020. Studies were included if patients participated in mHealth-based exercise interventions and were assessed for walking performance. We analyzed pooled effect size on walking performance, functional status, and quality of life based on the standardized mean differences between groups.

Results: A total of seven studies were selected for the systematic review, and six studies were included in the meta-analysis. The duration of interventions in the included studies was 12 to 48 weeks. In the pooled analysis, when compared with the control groups, the mHealth-based exercise intervention groups were associated with significant improvements in pain-free walking (95% CI 0.13-0.88), maximal walking (95% CI 0.03-0.87), 6-minute walk test (6MWT) distance (95% CI 0.59-1.24), and walking distance (95% CI 0.02-0.49). However, benefits of the interventions on walking speed, stair-climbing ability, and quality of life were not observed.

Conclusions: mHealth-based exercise interventions for patients with PAD were beneficial for improving pain-free walking, maximal walking, and 6MWT distance. We found that exercise interventions using mHealth are an important strategy for improving the exercise effectiveness and adherence rate of patients with PAD. Future studies should consider the use of various and suitable functions of mHealth that can increase the adherence rates and improve the effectiveness of exercise.

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KEYWORDS

peripheral artery disease; mobile health; exercise; adherence; meta-analysis

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Introduction

Peripheral artery disease (PAD) is a major cardiovascular disease characterized by limitations to arterial blood flow in the lower extremities (commonly due to atherosclerosis) and ischemia that can induce walking impairments [1,2]. PAD affects the lower extremities more commonly than the upper extremities and may present as intermittent claudication, atypical leg symptoms, critical limb ischemia, and functional impairments [1,3]. Regardless of the presence of symptoms, however, patients with PAD are at a significant risk of cardiovascular morbidity and mortality [2].

PAD is estimated to affect over 236 million people worldwide, and the prevalence increases steeply with age [4,5]. Given the increases in the pace of population aging in many countries, PAD prevalence can be expected to increase further [5].

Structured exercise programs are an important therapy for patients with PAD and can be administered in the form of supervised exercise therapy (SET) or structured community- or home-based exercise therapy (HBET) [1,3]. SET is directly supervised by health care providers in hospital or outpatient facilities, and HBET is self-exercise under the guidance of health care providers in a personal setting [3]. Structured exercise programs have been found to improve walking performance, functional status, and health-related quality of life (QoL) and also to prevent functional decline and mobility loss [3,6]. However, these benefits are most effective when patients actively and comprehensively participate in the interventions [7,8].

According to previous systematic reviews, 30.3% of the patients who participate in exercise interventions show incomplete adherence, mainly due to a lack of motivation, health reasons, patient choice, and a lack of results [6,9]. Adherence to exercise interventions is directly related to the likelihood of a participant changing or maintaining his/her health behaviors [10]. Therefore, it is necessary to find strategies for improving adherence rates to promote behavior changes.

Data-driven approaches involving the use of mobile devices such as mobile phones and wireless devices in exercise interventions have been shown to be effective for improving health outcomes [10,11]. The mobile health (mHealth) approach facilitates extensive supervision and the monitoring of patients without requiring an increase in human resources [12]. In particular, the provision of interventions based on mHealth technologies allows health care providers to provide real-time advice related to therapy and to monitor symptoms and problems without any restrictions on location [13,14]. Thus, well-designed mHealth-based interventions can be used to provide health education and promote behavior changes and have the potential to improve exercise adherence [10,12].

Previous systematic reviews on patients with PAD have mainly focused on the effects of SET, HBET, and endovascular revascularization [15-20]. In addition, some studies have sought to identify more efficient methods of PAD screening and the factors that influence participation in physical activity [21,22]. However, existing reviews have not evaluated the effects of mHealth-based exercise interventions on patients with PAD. To guide the development of future exercise interventions, there is a need for evidence regarding mHealth-based exercise interventions. Thus, in this study, we conducted a systematic review and meta-analysis with a particular focus on the effects of mHealth-based exercise interventions on walking performance, functional status, and QoL in patients with PAD. In addition, adherence rates in exercise interventions and the applied mHealth functions were investigated.

Methods

The systematic review and meta-analysis were performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Multimedia Appendix 1). The protocol for this study is registered with PROSPERO (registration number: CRD 42020191744).

Systematic Search Strategy

The systematic literature search was designed to identify randomized controlled trials (RCTs) of patients with PAD that were published in the English language in peer-reviewed journals up to December 4, 2020. We performed searches in the following seven databases: PubMed, CINAHL, Cochrane CENTRAL, EMBASE, IEEE Xplore Digital Library, Web of Science, and Scopus. We used a combination of keywords and controlled vocabulary terms such as MeSH and Emtree subject headings using Boolean operators, and this was followed by consultation with a professional medical librarian (Multimedia Appendix 2).

Inclusion and Exclusion Criteria

Studies that met the following inclusion criteria were selected: (1) included adult patients with PAD; (2) conducted mHealth-based exercise interventions, such as with mobile phones, wearable devices, and activity trackers; (3) reported walking performance comparing an mHealth intervention group with a control group; and (4) used an RCT design. We excluded studies with the following criteria: (1) not published in English; and (2) not an original article.

Study Selection

Based on the search strategy, studies were extracted from the seven databases and duplicates were removed. Two authors (MK and EK) independently screened the titles and abstracts of the remaining studies to determine their eligibility for the study based on the inclusion and exclusion criteria. The full texts of the selected studies were subsequently assessed and the final studies to be included in the analysis were selected. Thereafter, we manually searched the reference lists of all included studies for additional relevant studies. In instances where there were disagreements regarding decisions, a third author (CK) participated in discussions until a consensus was reached, and the resultant decision was verified by the fourth author (MC).

Data Extraction

Two authors (MK and EK) independently extracted the data elements from the studies included in the final analysis. The data sheet contained fields for first author, year of publication,

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country, participants, indication, sample size, age of participants, study duration, intervention, comparator, follow-up assessment, and outcomes. If some elements of the desired data were not reported in a study, we contacted the corresponding author of the study in an attempt to obtain these data. When a study included multiple control arms, we utilized the control arm that most closely matched the intervention, such as a group that received advice regarding walking and a group that was administered a light-resistance exercise program.

Quality Assessment

Two authors (MK and EK) independently assessed the risk of bias in accordance with the Cochrane Collaboration's risk of bias tool, which focuses on seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias (which were scored as high, low, or unclear) [23]. In the case of disagreement, a third person (CK) participated in the discussion to resolve the disagreement. The results of the risk of bias assessment were inputted into the software Review Manager (RevMan) version 5.4 (The Cochrane Collaboration, 2020) to visually represent the results.

Data Synthesis and Statistical Analysis

The meta-analysis was conducted to compare the standardized mean difference in walking performance, functional status, and QoL pre- and postintervention in patients who were randomly allocated to mHealth intervention groups or control groups. We analyzed continuous data by computing the mean and SD, and the standardized mean differences (SMDs) of the outcome variables were calculated using Hedges *g*, which was weighted according to the sample sizes in the studies [24]. When an original study did not provide SD values, we calculated them using reported 95% CI, range, and sample size according to the guidelines [24] and estimating formulae [24,25].

The SD values were calculated using the following formulae:

In the meta-analysis, the change-from-baseline value of the outcome variables was used, and if there were no change values, the postintervention values were used for analysis [24]. When such data were not available from the original study, we contacted the corresponding authors to request the relevant data. In a few cases, the data remained unavailable, so we excluded one study from the functional status analysis [26] and two studies from the QoL analysis [26,27] in the meta-analysis.

We assessed heterogeneity using two methods. First, we qualitatively performed a clinical judgment of differences in study populations and the follow-up durations of each study. Second, we performed a quantitative assessment, determining statistical heterogeneity using Cochrane Q (χ^2 test) and I^2 statistics after visual inspection of forest plots [24]. We considered heterogeneity to be substantial if the I^2 value was greater than 75% or if the P value of the χ^2 test was less than 0.1. We utilized a random-effects model to calculate the effect size when the included studies were heterogeneous [24]. We used a fixed-effect model, as the number of studies included was small, which presented a risk that the estimation of variance between the studies would be inaccurate [28].

In the meta-analysis of walking performance, the outcomes measured at baseline and at 12 weeks were used for analysis to reduce the heterogeneity of the study periods. When an original study did not measure outcomes at 12 weeks, we did not include it in the pooled analysis [29]. Four of the five studies used change-from-baseline values [26,27,30,31], and one study used postintervention values because the mean change could not be calculated [32] according to the Cochrane handbook for systematic reviews of interventions [24]. Pain-free walking was measured based on claudication onset time or claudication distance, which was defined as the moment the patient wished to stop walking as a result of claudication [26,27,30,31]. Maximal walking was measured using peak walking time or maximum walking distance, which was defined as the moment the patient was forced to stop walking as a result of reaching maximal claudication level [26,27,30,31]. The 6-minute walk test (6MWT) was used to measure the distance that the participants walked in the hallway for 6 minutes [29,32].

Sensitivity analysis was conducted to assess the influence of one single study being removed on the overall effect size. We did not use funnel plots for assessing publication bias, as the number of studies included was less than 10 [33]. Where statistical pooling was not appropriate, the findings were synthesized narratively. All analyses were conducted using RStudio (version 1.3.1056; RStudio, PBC).

Results

Study Selection

Figure 1 shows our search process and the results obtained through our search strategy in a PRISMA flow chart.

We identified a total of 1488 articles from the search of seven databases. After we eliminated duplicates, 1207 articles remained. Of these remaining articles, a further 1171 were excluded based on screening of their titles and abstracts. Two were included after manual searches, and an additional 31 were excluded after full-text readings. Finally, seven studies met the inclusion criteria and were included in the review, and six of them were included in the meta-analysis. One study was excluded from the meta-analysis because it applied mHealth strategies to the SET group, in contrast to the other studies, which applied mHealth strategies to the HBET group; including this study would have resulted in difficulties merging the effect sizes [34].

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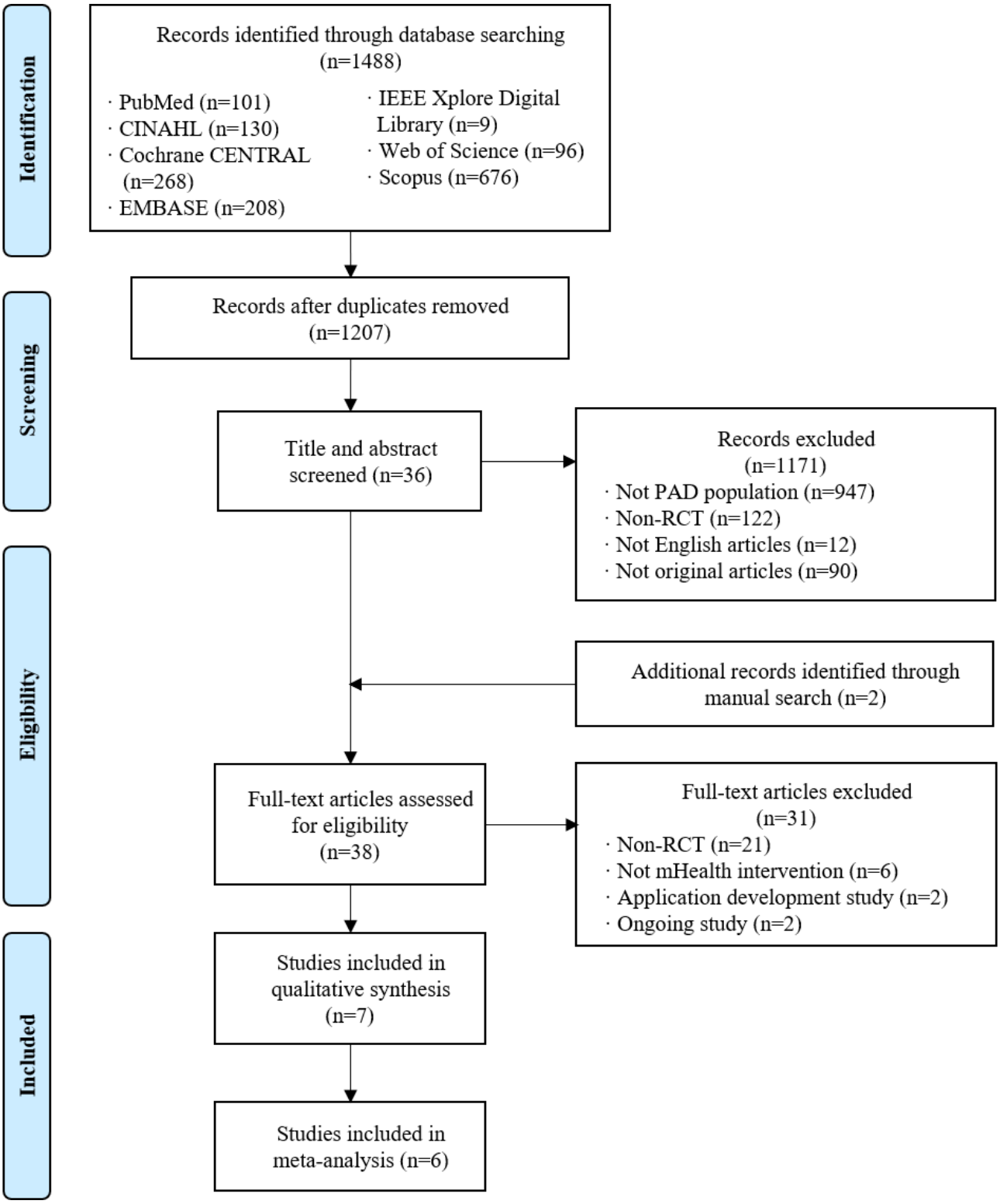
Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow chart of the study selection process. mHealth: mobile health; PAD: peripheral artery disease; RCT: randomized controlled trial.



Study Characteristics

The characteristics of the seven included studies are presented in Table 1.

One study was a pilot RCT [31], and the other studies were RCTs [26,27,29,30,32,34]. Of the studies, five were undertaken in the United States [26,27,29,30,32], one in the United Kingdom [31], and one in the Netherlands [34]. All participants were diagnosed with PAD; five studies included patients with symptomatic PAD [26,27,30,31,34], one study included patients with symptomatic or asymptomatic PAD [29], and one study included patients with asymptomatic PAD [32]. The number of participants varied from 19 to 300, and the mean age of the participants was over 65 years. Of the studies, six applied mHealth strategies in HBET [26,27,29-32] and one study applied mHealth strategies in SET [34]. Regarding the total duration of

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the studies, four studies were performed for 12 weeks [26,27,30,32], one study was performed for 36 weeks [29], and two studies were performed for 48 weeks [31,34].

Table 1. Characteristics of the included studies (N=7).

Study	Country	Indication of participants	Sample size (n)	Age of participants (years), mean (SD)	Study duration (weeks)
[34]	Netherlands	Fontaine stage II	mHealth[a]-based SET[b] group: 90; SET group: 109; control group: 101	mHealth-based SET group: 65.6 (10.5); SET group: 66.1 (9.0); control group: 66.9 (8.6)	48
[31]	United Kingdom	Intermittent calf claudication	mHealth-based HBET[c] group: 20; control group: 17	69.1 (10.4)	48
[30]	United States	Exercise limited by claudication and resting ankle brachial index <0.90	mHealth-based HBET group: 10; control group: 9	69.4 (8.4)	12
[26]	United States	Symptomatic PAD[d]	mHealth-based HBET group: 60; SET group: 60; light-resistance exercise program group: 60	65 (9)	12
[27]	United States	Intermittent claudication	mHealth-based HBET group: 40; SET group: 40; control group: 39	mHealth-based HBET group: 65 (11); SET group: 66 (12); control group: 65 (10)	12
[29]	United States	Regardless of symptoms, ankle brachial index <0.9	mHealth-based HBET group: 97; control group: 101	mHealth-based HBET group: 70.1 (10.6); control group: 70.4 (10.1)	36
[32]	United States	Asymptomatic PAD and resting ankle brachial index <0.9	mHealth-based HBET group: 19; control group: 19	mHealth-based HBET group: 68 (7.5); control group: 68 (10.6)	12

[a]mHealth: mobile health.

[b]SET: supervised exercise therapy.

[c]HBET: home-based exercise therapy.

[d]PAD: peripheral artery disease.

Characteristics of Study Outcomes

All studies included comparators, and they are presented with the intervention methods and outcomes in Table 2.

One study did not administer any intervention to the comparators [29]; four studies provided advice on walking exercises, brochures, a book, or a related video series [27,30,32,34]; one study provided a light-resistance exercise program [26]; and one study did not report any intervention [31]. In all studies, the outcome variables were measured through objective indicators (walking performance), and the subjective indicators of functional status and QoL were measured in five studies [26,27,29,31,34]. Walking performance was measured through a treadmill test or 6MWT at baseline and at the end of the study or at certain time points during the study. In six studies, the results of the walking performance tests showed that the mHealth group significantly improved [26,27,30-32,34]. Functional status was measured using a PAD-specific measure of the self-report Walking Impairment Questionnaire (WIQ). Four studies measured QoL using the 36-Item Short Form Health Survey (SF-36) [26,27,29,34], while one study used the Vascular Quality of Life Questionnaire (VascuQoL) [31]. Four studies showed a significant improvement of functional status and QoL in the mHealth group [26,27,31,34], one study showed no effect [29], and two studies did not measure functional status or QoL [30,32].

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Table 2. Characteristics of the study intervention and outcomes.

Study	Intervention	Comparator	Follow-up assessment	Outcomes
[34]	Referred to a local physical therapist; provided feedback using wearable activity tracker records	Received verbal walking advice and a brochure	Baseline, and 3, 6, 9, and 12 months	ACD[a], FCD[b]: increased significantly in all groups (P<.01); WIQ[c]: total score improved in the SET[d] group (P=.004); SF-36[e]: total score improved in the SET group (P<.001)
[31]	Daily activity goals setting using wearable activity monitor; provided feedback using wearable activity tracker records at each follow-up visit	Not reported	Baseline, and 3, 6, and 12 months	MWD[f]: increased significantly in mHealth[g] group (P=.001); CD[h]: significantly improved in mHealth group (P=.005); VascuQoL[i]: significantly improved in mHealth group (P=.004)
[30]	Provided monthly feedback using wearable activity tracker records; electronic PAD[j] book; weekly emails containing PAD tip; counseling and exercise prescriptions over the telephone	Received a hard copy of the PAD book	Baseline and 12 weeks	COT[k], PWT[l]: increased significantly in mHealth group (P<.06); moderate-high activity minutes: increased significantly in mHealth group (P<.07)
[26]	Provided feedback (including new instructions) and motivation using wearable activity tracker records and logbook	Light-resistance exercise program group: 3 days/week	Baseline, and 1, 4, 8, and 12 weeks	COT, PWT, 6MWT[m]: increased significantly in mHealth group (P<.001); WIQ: increased significantly in mHealth group (P<.05); SF-36: increased significantly in mHealth group (P=.01)
[27]	Provided feedback (including new instructions) and motivation using wearable activity tracker records and logbook	Received verbal walking advice	Baseline, and 1, 2, 4, 6, 8, 10, and 12 weeks	COT, PWT: increased significantly in mHealth group (P<.001); WIQ: increased significantly in mHealth group (P<.05); SF-36: increased significantly in mHealth group (P<.01)
[29]	Provided coaching on exercise goals using wearable activity tracker records over the telephone; group telephone calls to share their successes and challenge experiences (2 calls/month)	Received no study intervention	Baseline, and 4.5 and 9 months	6MWT, WIQ, SF-36: no significant difference in mean change
[32]	Provided interactive wearable activity tracker and its online self-monitoring home page dashboard; bimonthly online video series	Bimonthly online video series	Baseline and 12 weeks	6MWT: increased significantly in mHealth group

[a]ACD: absolute claudication distance.
[b]FCD: functional claudication distance.
[c]WIQ: Walking Impairment Questionnaire.
[d]SET: supervised exercise therapy.
[e]SF-36: 36-Item Short Form Health Survey.
[f]MWD: maximum walking distance.
[g]mHealth: mobile health.
[h]CD: claudication distance.
[i]VascuQoL: Vascular Quality of Life Questionnaire.
[j]PAD: peripheral artery disease.
[k]COT: claudication onset time.
[l]PWT: peak walking time.
[m]6MWT: 6-minute walk test.

Intervention Adherence and mHealth Functions

Table 3 summarizes the attrition and adherence rates, type of mHealth devices used, and applied mHealth functions.

The attrition rate in the mHealth groups ranged from 0% to 28%, and an adherence rate was reported in only two studies (exceeding 80% in both cases) [26,27]. Regarding the use of wearable activity trackers, in five studies the participants wore the trackers on their wrists [26,27,30,31,34], and in other studies they wore them on the ankles [29] or anterior thigh and waist [32]. The common functions applied to mHealth interventions were recording and display. In addition, the reminding/alerting function [31], guiding function [29], and communication function [32] were used.

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Table 3. Summary of attrition and adherence rates, mobile health (mHealth) devices used, and applied mHealth functions.

Study	Attrition rate	Adherence rate	mHealth devices used	mHealth functions
[34]	mHealth-based SET[a] group: 16%; SET group: 15%; control group: 18%	Not reported	Personal Activity Monitor accelerometer (PAM BV)	Recording, display
[31]	mHealth-based HBET[b] group: 20%; control group: 24%	Not reported	Nike+ FuelBand (Nike, Inc)	Recording, display, reminder
[30]	mHealth-based HBET group: 0%; control group: 11%	Not reported	Fitbit Charge device (Fitbit, Inc)	Recording, display
[26]	mHealth-based HBET group: 12%; SET group: 13%; control group: 15%	mHealth-based HBET group: 81%; SET group: 82%	StepWatch3 (Orthoinnovations, Inc)	Recording, display
[27]	mHealth-based HBET group: 28%; SET group: 18%; control group: 23%	mHealth-based HBET group: 83%; SET group: 85%	StepWatch3 (Cyma Inc)	Recording, display
[29]	mHealth-based HBET group: 7%; control group: 7%	Not reported	Fitbit Zip (FitBit, Inc)	Recording, display, guide
[32]	No patients withdrew during the study period	Not reported	Gruve activity tracker (Gruve Solutions; Muve Inc); activPAL (PAL Technologies Ltd); online dashboard	Recording, display, communication (feedback)

[a]SET: supervised exercise therapy.

[b]HBET: home-based exercise therapy.

Quality Assessment of Literature

The risk of bias analysis is shown in Figure 2 (individual studies) and Figure 3 (summary graph). All of the studies were assessed to have a low risk of selection bias. Due to maintaining the blinding of investigators and participants in exercise interventions, six of the seven studies were assessed to have a high risk of performance bias [26,27,30-32,34]. However, both attrition bias and reporting bias were generally assessed as low risk. With the exception of studies that reported that assessors were not blinded due to resource constraints [30,31], detection bias was assessed as unclear [26,27,32] or low risk [29,34].

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Figure 2. Risk of bias: individual studies.

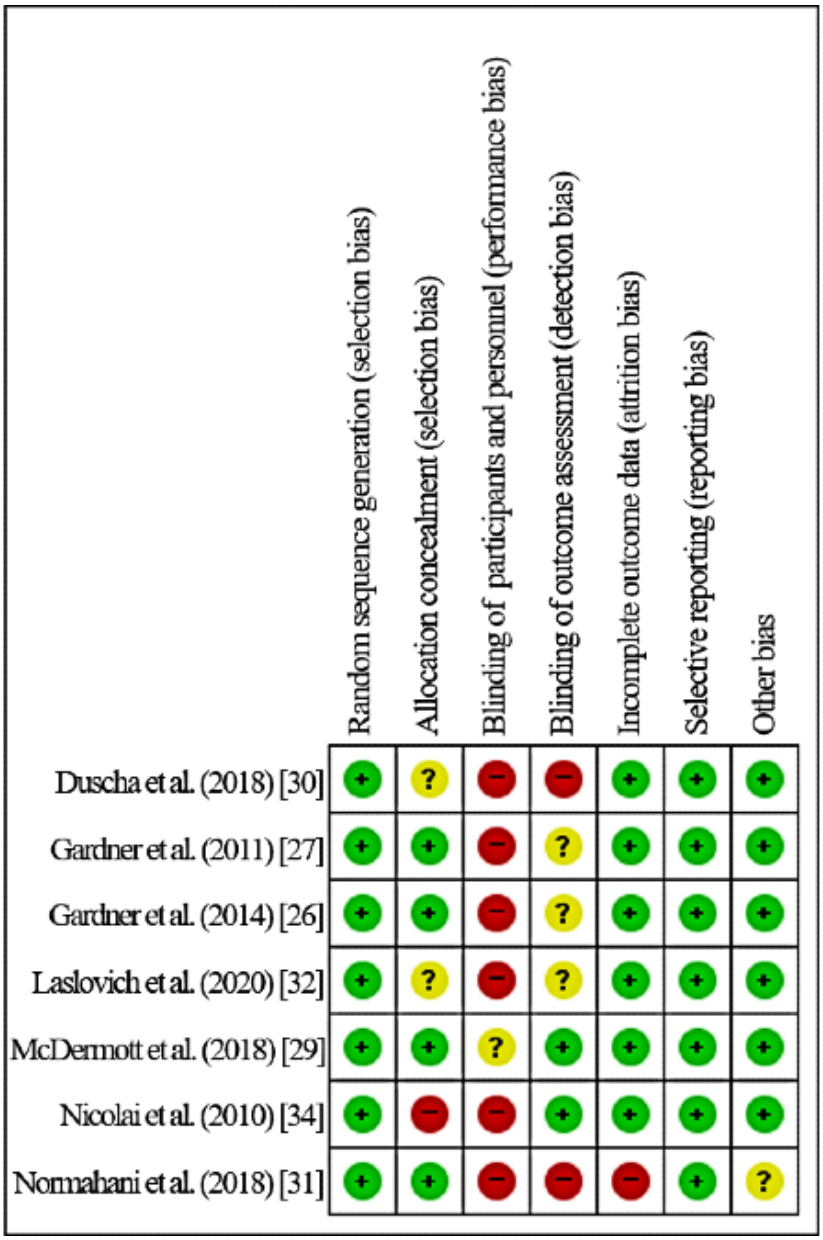
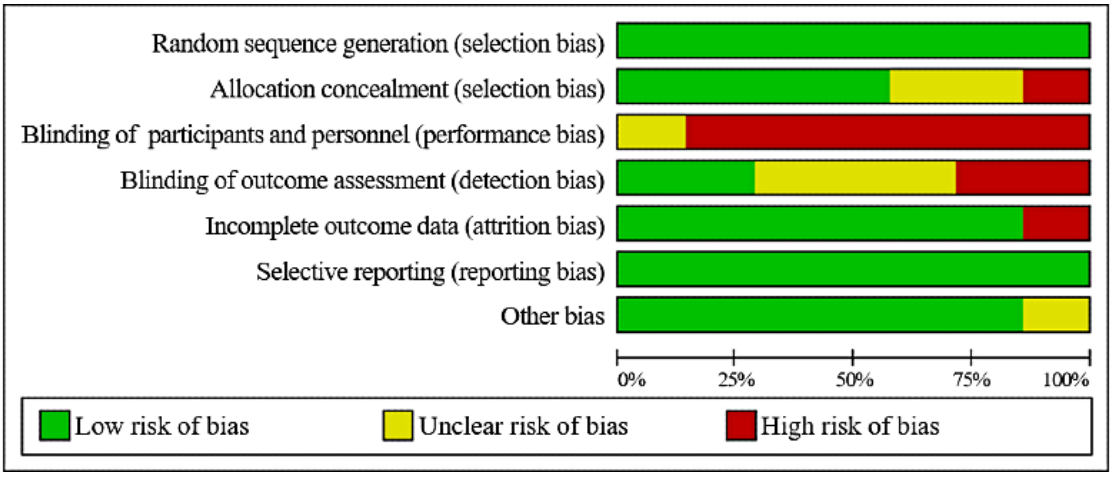


Figure 3. Risk of bias: summary graph.



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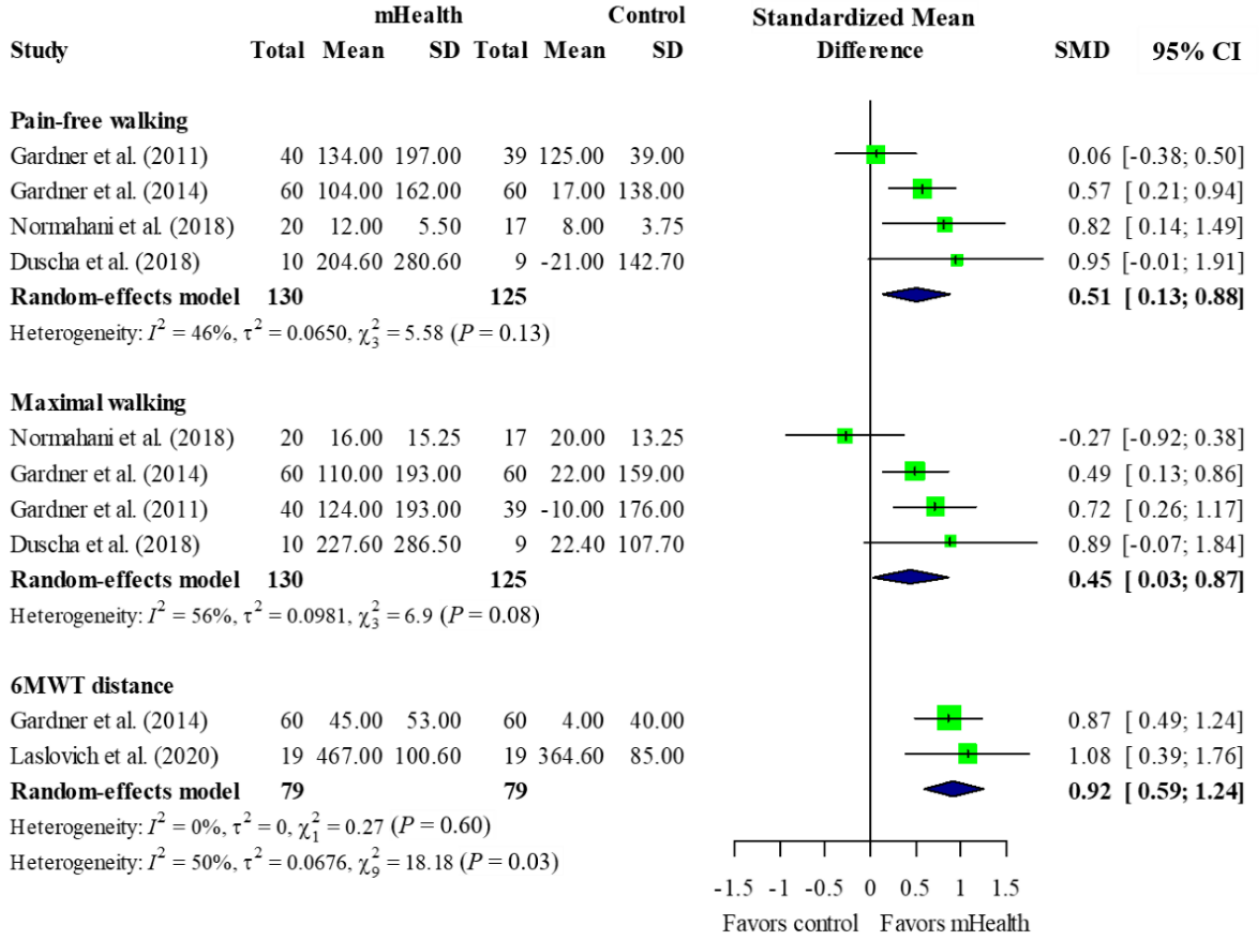
Meta-Analysis Findings: Effects of mHealth Exercise Interventions

Walking Performance

All six studies included in the meta-analysis reported walking performance. A treadmill test [26,27,30,31] and 6MWT [26,29,32] were used. The mHealth intervention groups showed an overall improvement in pain-free walking (SMD: 0.51, 95% CI 0.13-0.88; P=.008), maximal walking (SMD: 0.45, 95% CI 0.03-0.87; P=.04), and 6MWT distance (SMD: 0.92, 95% CI 0.59-1.24; P<.001) when compared with the control groups (Figure 4).

There was heterogeneity when pooling the pain-free walking (χ^2=5.58, P=.13; I^2=46%), maximal walking (χ^2=6.9, P=.08; I^2=56%), and 6MWT (χ^2=0.27, P=.60; I^2=0%) results. There was no significant difference found from omitting one single study using sensitivity analysis (Multimedia Appendix 3).

Figure 4. Forest plot of walking performance (up to the 12-week point). 6MWT: 6-minute walk test; mHealth: mobile health; SMD: standardized mean difference.



Functional Status

Reported functional status, two of which were included in our quantitative synthesis [27,29] (Figure 5).

The two included studies showed that the mHealth intervention groups significantly improved their WIQ distance (SMD: 0.25, 95% CI 0.02-0.49; P=.04) [27,29]. Other elements such as walking speed and stair-climbing ability did not show statistically significant improvements.

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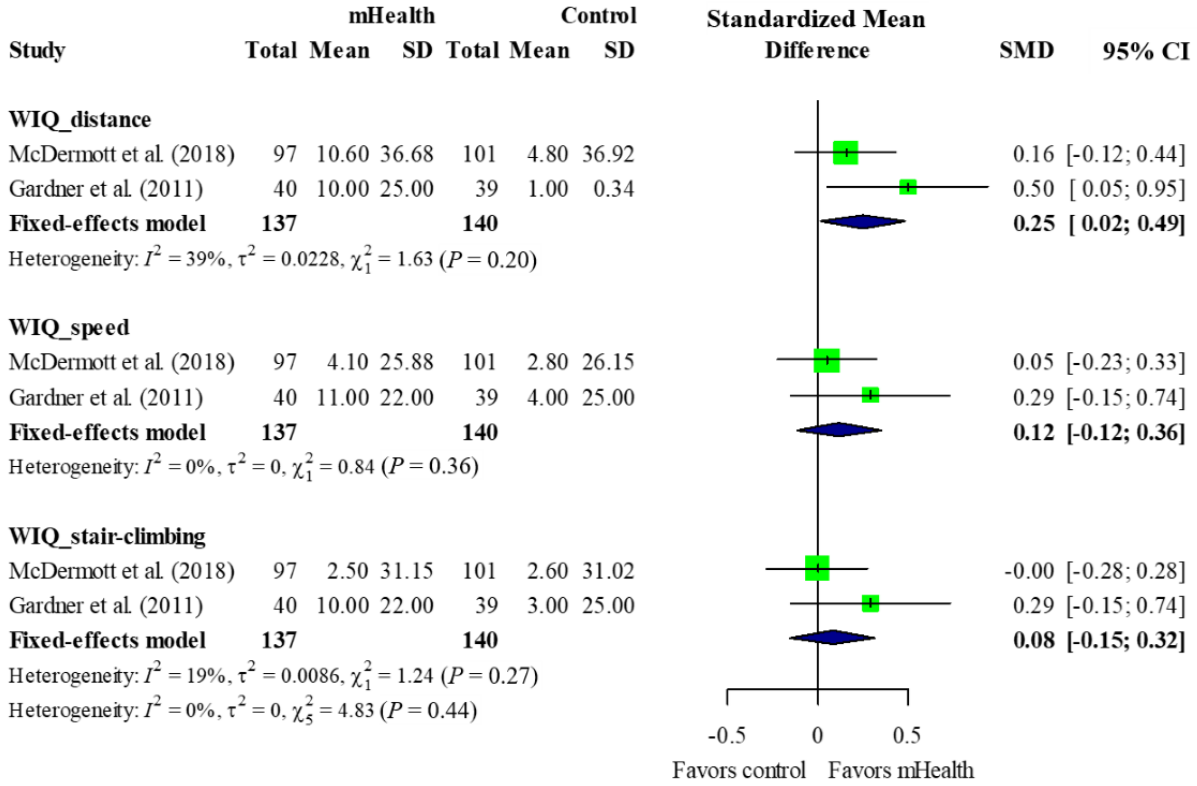
Figure 5. Forest plot of functional status. mHealth: mobile health; SMD: standardized mean difference; WIQ: Walking Impairment Questionnaire.

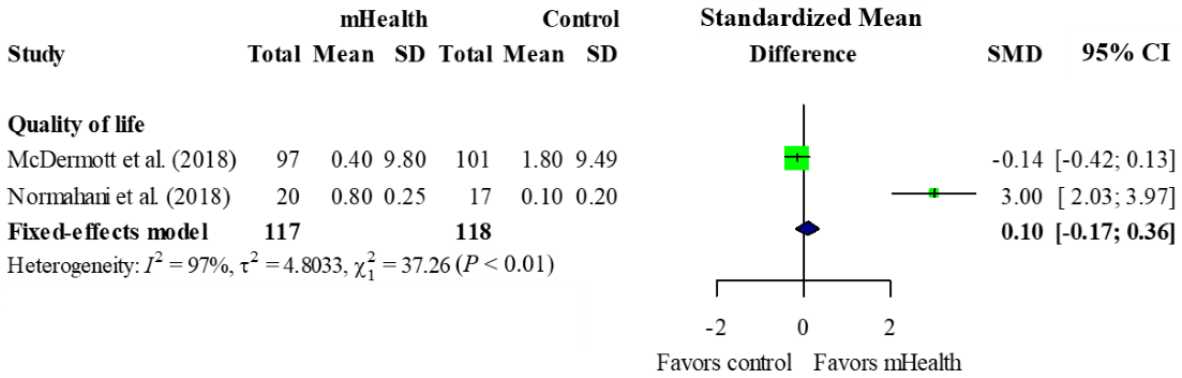


QoL

Four studies reported QoL, two [29,31] of which were included in the meta-analysis (Figure 6).

The two studies included in the meta-analysis measured QoL using VascuQoL [31] and SF-36 [29], respectively. The results showed that the mHealth intervention groups did not show significant improvements in QoL compared with the control groups (P=.48) but showed significant heterogeneity (χ^2=37.3, P<.01; I^2=97%).

Figure 6. Forest plot of quality of life. mHealth: mobile health; SMD: standardized mean difference.



Discussion

Principal Findings

In patients with PAD, effective and structured HBET can be a more accessible and acceptable alternative to SET in terms of burden and cost [3,8]. Therefore, this study is meaningful as the first meta-analysis of the effectiveness of applying mHealth as a strategy to provide structured exercise interventions at home for patients with PAD. In mHealth-based HBET, adherence is important for increasing the beneficial effects of exercise [8]. However, only two studies reported adherence rates [26,27]. This reflects the fact that while adherence in exercise intervention is a precursor and an important predictor for improvement of outcome, it is not always measured [35,36]. The adherence rates in the two above-mentioned studies both exceeded 80%. This is similar to the adherence rates reported in systematic reviews of exercise programs for older adults (65% to 86%) [37], RCTs featuring exercise referral schemes (pooled mean: 80%) [38], and exercise groups for patients with PAD (78%) [7]. Although maintaining high adherence rates is

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difficult in HBET [3], HBET using mHealth technologies such as wearable activity tracking devices seems to maintain high adherence. Future studies should report adherence rates; further, among the various measures of adherence [35,37,38], an appropriate and accurate measure for adherence rates for patients with PAD should be identified and applied.

A total of seven studies were included in our systematic review, and six studies were included in the meta-analysis. The studies included in the meta-analysis all applied mHealth techniques in HBET. During the 12-week interventions, the mHealth group showed significant improvements in pain-free walking, maximal walking, and 6MWT distance when compared with the control group. In one study that was not included in the pooled analysis of walking performance [29], the intervention was performed for 9 months and showed no effects on 6MWT distance in the mHealth group.

The functional status of the patients was measured using the WIQ, which has been validated as a measure of perceived difficulty concerning walking distances and speeds and the ability to climb stairs [39]; significant improvements were seen in walking distance but benefits regarding walking speed and stair-climbing ability were not observed. These results are similar to those of other exercise intervention studies, which reported significant effects on WIQ walking distance and no effects on other outcome measures [40,41].

The mHealth group did not show a significantly improved QoL. In other studies, the effect of mHealth-based interventions on QoL was unclear. Some meta-analyses have reported that mHealth-based interventions did not improve QoL in cancer survivors [42,43], while another study reported improved QoL in patients with coronary heart disease [44]. Therefore, the long-term effect of mHealth interventions on QoL should be investigated further.

Limitations

A major limitation of this study was that the type of mHealth devices used in the reviewed studies was restricted to wearable activity trackers. It is important to monitor activity to promote physical activity in patients with PAD [31]; however, activity trackers may not have a sufficient impact in relation to inducing changes in health behaviors and improving adherence, as they provide a limited range of mHealth functions. Future studies need to investigate the effects of providing patients with PAD with a wider range of mHealth functions such as real-time advice and symptom monitoring [13,14,45], feedback and verification of achievement of individually set goals [6,13,14], and coaching chatbots [46]. In addition, this study was not able to review studies evaluating walking performance beyond 12 weeks, which was a result of the limited durations of the studies. Since all of the studies were based on structured exercise programs with recommended durations of at least 12 weeks [3], there were limited findings for long-term effects. PAD is a chronic disease for which treatment should involve sustained walking exercise; thus, it is important that interventions have effects on the long-term performance of walking exercises [3]. In future studies, the effects of long-term mHealth-based exercise interventions will need to be identified.

Conclusions

This study provides evidence that mHealth-based exercise interventions applied through HBET for patients with PAD improve pain-free walking, maximal walking, 6MWT distance, and walking distance as elements of functional status. In addition, an HBET group that received the mHealth intervention showed an adherence rate similar to the SET group. We found that using mHealth as part of exercise interventions is an important strategy to improve the walking ability and exercise adherence rate of patients with PAD at home or in the community in their daily living environments. Future studies should consider the use of various and suitable functions of mHealth to improve the adherence rate and the effectiveness of exercise interventions.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[DOC File , 68 KB - mhealth_v9i2e24080_app1.doc]

Multimedia Appendix 2
Search strategies.
[DOCX File , 24 KB - mhealth_v9i2e24080_app2.docx]

Multimedia Appendix 3

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Sensitivity analyses of pooled effect estimates.
[DOCX File , 36 KB - mhealth_v9i2e24080_app3.docx]

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Abbreviations

6MWT: 6-minute walk test
HBET: home-based exercise therapy
mHealth: mobile health
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PWT: peak walking time
QoL: quality of life
PAD: peripheral artery disease
RCT: randomized controlled trial
SET: supervised exercise therapy
SF-36: 36-Item Short Form Health Survey
SMD: standardized mean difference
VascuQoL: Vascular Quality of Life Questionnaire
WIQ: Walking Impairment Questionnaire

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Review

mHealth Strategies Related to HIV Postexposure Prophylaxis Knowledge and Access: Systematic Literature Review, Technology Prospecting of Patent Databases, and Systematic Search on App Stores

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Abstract

Background: Globally, the number of HIV cases continue to increase, despite the development of multiple prevention strategies. New cases of HIV have been reported disproportionately more in men who have sex with men and other vulnerable populations. Issues such as internalized and structural homophobia prevent these men from accessing prevention strategies such as postexposure prophylaxis (PEP). Mobile health (mHealth) interventions are known to be one of the newest and preferred options to enhance PEP knowledge and access.

Objective: The aim of this study was to identify and analyze the mobile apps addressing PEP for HIV infections.

Methods: We conducted a descriptive exploratory study in 3 sequential phases: systematic literature review, patent analysis, and systematic search of app stores. For the systematic review, we followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines adapted for an integrative review in the databases of PubMed, Web of Knowledge, Scopus, Cochrane, Embase, Science Direct, Eric, Treasure, and CINAHL. The patent analysis was performed by exploring the databases of the Brazilian National Institute of Industrial Property, the United States Patent and Trademark Office, and the European Patent Office. For the systematic search, we analyzed mHealth apps related to HIV in 2 major app libraries, that is, Google Play Store and App Store. The apps were evaluated by name, characteristics, functions, and availability in iPhone operating system/Android phones.

Results: We analyzed 22 studies, of which 2 were selected for the final stage. Both studies present the use of apps as mHealth strategies aimed at improving the sexual health of men who have sex with men, and they were classified as decision support systems. The search in the patent databases showed only 1 result, which was not related to the topic since it was a drug intervention. In the app libraries, 25 apps were found and analyzed, with 15 (60%) apps available for Android systems but only 3 (12%) addressing PEP. In general, the apps inform about HIV and HIV prevention and treatment, with the focus users being health care providers, people with HIV, or the general population, but they have only limited features available, that is, mainly text, images, and videos. The 3 apps exclusively focusing on PEP were created by researchers from Brazilian universities.

Conclusions: Our review found no connection between the scientific studies, registered patents, and the available apps related to PEP; this finding indicates that these available apps do not have a theoretical or a methodological background in their creation. Thus, since the scientific knowledge on HIV is not translated into technological products, preventing the emergence of new

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infections, especially in the more vulnerable groups, is difficult. In the future, researchers and the community must work in synergy to create more mHealth tools aimed at PEP.

(JMIR Mhealth Uhealth 2021;9(2):e23912) doi:10.2196/23912

KEYWORDS

HIV; eHealth; mHealth; postexposure prophylaxis; PEP; prevention; mobile phone

Introduction

The efforts to globally fight HIV/AIDS have been increasing in the past 30 years since the first HIV global epidemic. There has been a steady global progress in the reduction of AIDS-related deaths over the last decade but a slower progress in the reduction of new HIV infections. However, epidemiological trends have remained consistent over the years, with men who have sex with men being disproportionately more affected by HIV than other populations [1].

In 2014, the UNAIDS (Joint United Nations Program on HIV/AIDS) launched a 90-90-90 target to combat AIDS as a public health threat by 2030, and the joint action of country-led and region-led efforts was required to establish this target for HIV treatment scale-up. The goal was that, by 2020, 90% of all people with HIV will know their HIV-positive status, 90% of all people diagnosed with HIV will have access to antiretroviral treatment, and 90% of all people under treatment will have an undetectable viral load [2]. According to the most recent UNAIDS data, 1.7 million new HIV infections were reported in 2019—more than 3 times the 2020 target. This incidence increased by 690,000 in 2020, indicating that we are very far from ending the HIV global epidemic [1]. A series of new tools complementary to the use of condoms and treatment as a form of prevention has been introduced to achieve the 90-90-90 goals, with emphasis on postexposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP).

PrEP is the daily use of a combination of antiretrovirals (tenofovir plus emtricitabine) to prevent the acquisition of HIV infection. The World Health Organization recommends that people at substantial risk of HIV infection should be offered PrEP as an additional prevention choice as part of comprehensive prevention [1]. PEP is short-term antiretroviral treatment that is one of the key prevention strategies in reducing the likelihood of HIV infection after potential (possible) exposure to the virus, either occupationally or through sexual intercourse, and the success rate of this strategy has been reported to be 89% [3].

PEP is of crucial importance in preventing HIV infections since it can be used even in high-risk situations, for example, during condom tear in sexual intercourse, contact with partners with a high viral or unknown viral load, and even in cases of sexual violence. The main challenge for the consolidation of PEP as one of the main preventive measures against HIV infections is the need for a specific initiation period—2 hours being considered as optimal and up to 72 hours as acceptable. Therefore, this situation is considered as an emergency [3].

The literature points out that, although crucial, data on the use of PEP are still incipient, as they are collected retrospectively instead of systematically [3,4]. Vulnerable populations for infection control are the main potential users of this strategy. However, for this purpose, they need to be properly welcomed into the health care service. There is evidence that serodiscordant couples undergoing treatment are unaware of the option of adhering to PEP for HIV prevention [4] and men who have sex with men do not identify risk situations for exposure to HIV [5].

Mobile health (mHealth) interventions have emerged as a promising tool to support disease self-management among people living with HIV, especially by promoting drug adherence and information sources. mHealth technologies have shown potential in improving patients' communication with their health care providers by offering education and supporting the management of various chronic conditions, including diabetes, cardiovascular disease, and HIV infections. However, for mHealth interventions to be effective, they need to be developed and optimized with the needs of people in mind [6]. Despite this potential, little is known about the usage of this tool to work toward the UNAIDS goals of preventing new infections or improving PEP usage.

In light of the current COVID-19 pandemic, the prevention of HIV infections is facing unprecedented barriers such as shortage of health care professionals and resources and physical distancing from health care services. To overcome this challenge, health care systems and health care professionals are seeking new strategies, particularly eHealth and mHealth strategies, for the prevention of HIV spread [7]. Thus, in this study, we aimed to identify and analyze mobile apps that address PEP.

Methods

Study Design

We conducted a descriptive exploratory study [8] in 3 sequential phases: systematic literature review, patent analysis, and systematic search on app stores. An integrative review is an important resource for evidence-based practices and provides systematic techniques to summarize the literature on a given subject, thereby providing a unique view from different perspectives [9]. As a complement, studies [10] on technology prospecting refer to activities of technology determination focused on technological changes in functional capacity or on when the technologies were created and their innovativeness. This type of study aims at incorporating information into the technology management process, thereby predicting the possible future states of the technology or conditions that affect its contribution to established goals. Therefore, prospecting studies are used to determine the current state of a certain technological area and to generate information about its trajectory, future, and

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market trends, as well as to perceive weaknesses in certain areas [11]. In other words, these studies portray what is being recently done and can be used to point out the gaps that still need to be addressed. Thus, these studies constitute fundamental components to enhance the capacity to guide and subsidize the organization of innovation systems, transcending the business scope toward the academic environment.

Phase 1: Literature Review

To conduct a comprehensive review, we followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines adapted for an integrative review owing to the nature of our objective and the studies related to it. We followed the following steps: (1) identifying the research question, (2) surveying relevant studies, (3) selecting the studies, (4) organizing the data, and (5) collecting, summarizing, and reporting the results [9]. Thus, we defined the mobile apps that were developed to assist in the usage of PEP as the research subject. We then used medical subject heading descriptors to search the PubMed databases through the PubMed portal of the National Library of Medicine, Web of Knowledge, Scopus, Cochrane, Embase, Science Direct, Eric, Treasure, and CINAHL by using a combination of descriptors and keywords. The defined inclusion criteria were primary studies with full text available published until July 2020, in any language. The exclusion criteria were book chapters, doctoral dissertations, master's thesis, and technical reports in the initial search [8]. This research was conducted from June 1, 2020 to June 30, 2020 by a researcher with expertise in HIV prevention and systematic reviews. We used the following descriptors: HIV, Post-Exposure Prophylaxis, and Mobile Phone applications. Boolean operators were used to separate the keywords and descriptors (Table 1).

Table 1. Search strategy in each database and the selected studies.[a]

Database	Search strategy	Retrieved studies (N=22), n
PubMed	("post-exposure prophylaxis"[MeSH Terms] OR ("post-exposure"[All Fields] AND "prophylaxis"[All Fields]) OR "post-exposure prophylaxis"[All Fields] OR ("post"[All Fields] AND "exposure"[All Fields] AND "prophylaxis"[All Fields]) OR "post exposure prophylaxis"[All Fields]) AND ("mobile applications"[MeSH Terms] OR ("mobile"[All Fields] AND "applications"[All Fields]) OR "mobile applications"[All Fields])	5
Scopus	(post-exposure AND prophylaxis AND HIV AND mobile AND applications)	3
Web of Science	("post-exposure prophylaxis"[MeSH Terms] OR ("post-exposure"[All Fields] AND "prophylaxis"[All Fields]) OR "post-exposure prophylaxis"[All Fields] OR ("post"[All Fields] AND "exposure"[All Fields] AND "prophylaxis"[All Fields]) OR "post exposure prophylaxis"[All Fields]) AND ("mobile applications"[MeSH Terms] OR ("mobile"[All Fields] AND "applications"[All Fields]) OR "mobile applications"[All Fields])	1
CINAHL	Post-exposure prophylaxis or PEP or non-occupational post-exposure prophylaxis (nPEP) AND mobile applications	7
Cochrane	Post-exposure prophylaxis AND mobile applications	2
Embase	Post-exposure prophylaxis AND mobile applications	3
Science Direct	("post-exposure prophylaxis"[MeSH Terms] OR ("post-exposure"[All Fields] AND "prophylaxis"[All Fields]) OR "post-exposure prophylaxis"[All Fields] OR ("post"[All Fields] AND "exposure"[All Fields] AND "prophylaxis"[All Fields]) OR "post exposure prophylaxis"[All Fields]) AND ("mobile applications"[MeSH Terms] OR ("mobile"[All Fields] AND "applications"[All Fields]) OR "mobile applications"[All Fields])	1
Eric	Post-exposure prophylaxis AND mobile applications	0
Treasure	HIV AND post-exposure prophylaxis AND mobile applications	0

[a]Source: Direct research.

Two investigators conducted the analyses of the papers and discussed their inclusion during web-based meetings to reach a consensus. The titles and abstracts were read, followed by the application of the inclusion and exclusion criteria. For papers with no abstracts or if the abstracts did not permit paper exclusion or inclusion, the papers were read. The studies were analyzed, evaluating their direct relationship with the research question, along with the method, type of investigation, outcomes, objectives, sample, results, and conclusions. Duplicate studies were excluded. In total, 2 papers were selected (Figure 1).

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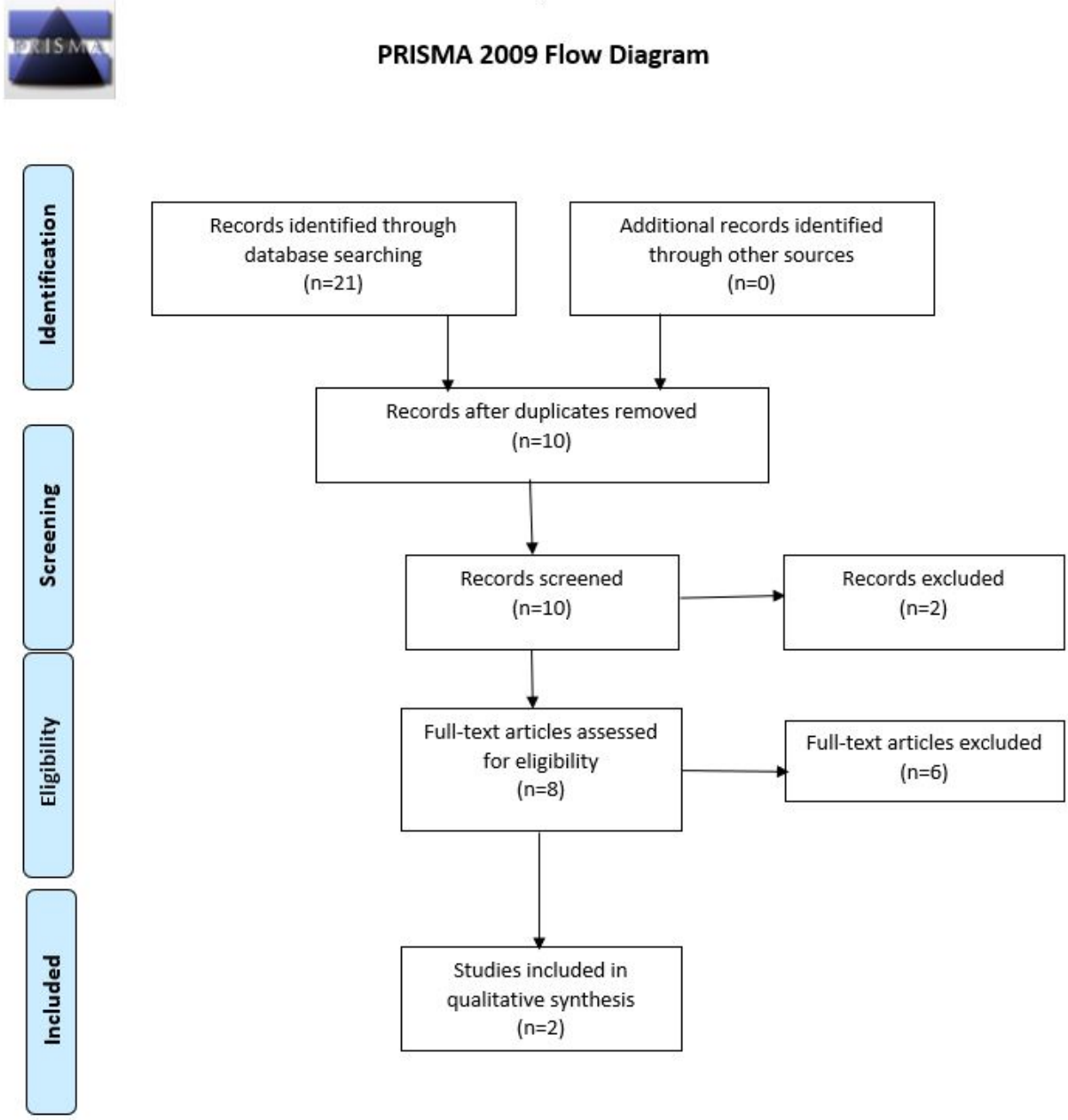
Figure 1. Flow diagram for the selection process following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guideline.



Phase 2: Technology Prospecting of Patent Databases

To execute this stage of the study, we focused on the countries that showed the highest production of mobile apps on PEP (based on the results of the integrative review) to define the patent databases that could be included. The patent databases that were selected were the National Institute of Industrial Property (INPI), which is the official government body responsible for the industrial property rights in Brazil, the United States Patent and Trademark Office (USPTO), which is the federal agency for granting US patents and registering trademarks, and Espacenet, which is the database of the European Patent Office, with documents from more than 90 countries. The duties of INPI include trademark registration, patent grants, technology transfer, and franchising contract registration. The search, retrieval, and export of patents on mobile apps related to PEP for HIV were carried out on July 4, 2020. In this stage, to search the INPI and Espacenet databases, structured search strategies were used with the Boolean operator “and” and the truncation to the right of type “*”. These operators were used in conjunction with the keywords to maximize the possibilities of finding the patent documents on the technology of interest. The keywords used in the searches are described below: “(HIV) AND Post-Exposure Prophylaxis AND Mobile Applications” in the “summary” field in the advanced search engine of the INPI patent database. In the Espacenet Advanced Search Builder, the keywords “HIV AND Post-Exposure Prophylaxis AND Mobile Applications” were used in the “keyword (s) in title or abstract” field. The same keywords but without the truncation features were entered in the USPTO search box.

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Phase 3: App Search

To complement the previous stage, we performed an analysis in 2 major app libraries on July 4, 2020: Google Play Store (for Android apps) and App Store (for Apple). This step enabled us to understand which apps exist, their objectives, functions, who produces them, whether these apps correspond to the published studies (phase 1), and the patents registered (phase 2). For this purpose, we used the following keywords: "HIV Post-Exposure Prophylaxis" in the Google Play Store and "HIV" and "Post-Exposure Prophylaxis" in the App Store. We found 35 apps for Android phones and 4 apps for Apple phones with these keywords. We categorized the selected apps according to the World Health Organization [12] classification for eHealth initiatives: call centers in medical care, free emergency telephone services, emergency apps for public health, mobile telemedicine services, phone reminders, community mobilization for health promotion, treatment compliance initiatives, patient records systems, systems of initiatives for information, apps for patient monitoring, mobile devices for health research, surveillance system, awareness systems, and decision support systems.

Data Analysis

The apps were evaluated by name, characteristics, functions, and availability for the main systems (iPhone operating system or Android) (Table 2). Patent registrations were analyzed descriptively according to the information retrieved from the patent databases, titles, descriptions, and applicants/inventors. This research exempted the evaluation by an ethics committee because it did not involve human beings, according to the determinations of the Brazilian decrees 466/12 and 510/16.

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Table 2. Distribution of the apps according to name, developer, main purpose, hosted platform, and classification.[a]

App	App Developer	Aim of app	Address postexposure prophylaxis (Yes/No)	Target population	Country	Phone operating system	World Health Organization classification
PEPtec	EEUSP Saúde Coletiva	This is an app that assists in the care of people who have experienced situations with a potential risk of HIV infection.	Yes	General population	Brazil	Android	Mobile telemedicine services
PEPusuário	EEUSP Saúde Coletiva	Assist the patient in using postexposure prophylaxis to complete the 28-day recommended measurement.	Yes	People using postexposure prophylaxis	Brazil	Android	Treatment compliance initiatives
HIV Oral PrEP Implementation Tool	Jhpiego Organization	To support the implementation of pre-exposure prophylaxis among a range of populations in different settings.	No	Care providers	United States	Android	Community mobilization for health promotion
Florida HIV/AIDS Hotline	Wellsky	Provides connection to almost 400 related HIV care services in Florida.	No	People living with HIV and general population	United States	Android	Call centers in medical care
PreP4U	HealthHIV	A resource for pre-exposure prophylaxis to prevent HIV information.	No	General population	United States	Android	Systems of initiatives for information
TánaMão	Metasix Tecnologia	This app presents an illustrative questionnaire with simple questions, which can calculate the risk rate of HIV infection.	Yes	General population	Brazil	Android	Awareness systems
EoHIV	GN1 sistemas e publicacoes	Providing information to health workers can enhance self-care and improve adherence to postexposure prophylaxis due to biological exposure.	Yes	Care providers	Brazil	Android	Systems of initiatives for information
AIDSinfo Drug Database	National Library of Medicine at National Institutes of Health	Provides information about antiretroviral drugs	No	Care providers and people living with HIV	United States	Android	Systems of initiatives for information
HIV Dating	MyDatingDirectory	Dating app for people living with HIV	No	People living with HIV	Switzerland	Android	N/A[b]

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App	App Developer	Aim of app	Address postexposure prophylaxis (Yes/No)	Target population	Country	Phone operating system	World Health Organization classification
Nigeria HIV Guideline	Powered by Management Sciences for Health	Provides general and specific guidance for HIV prevention and treatment.	No	Care providers	Nigeria	Android	Systems of initiatives for information
PreParaDXS	Sociedad Española de Farmacia Hospitalaria	Information about HIV and other sexually transmitted infections, HIV testing, pre-exposure prophylaxis, and other prevention methods.	Yes	General population	Spain	Android	Systems of initiatives for information
Beat AIDS - 50+ Tips for HIV prevention	Tipsbook	Provides information about HIV prevention	Yes	General population and people living with HIV	India	Android	Systems of initiatives for information
HIV Instant Test and Guide (2019)	JOE Technologies	Information app	No	General population	United States	Android	Systems of initiatives for information
Life4me+	Life4me.plus fight to AIDS, Hepatitis C, and Tuberculosis	The app automatically remembers testing for sexually transmitted infections, taking pre-exposure HIV prevention medications, and taking antiretroviral drugs for HIV or hepatitis C.	No	General population	Switzerland	Android	Phone reminders
Jilinde	Ubunifu Ltd	To promote oral pre-exposure prophylaxis in Kenya	No	General population	Kenya	Android	Awareness systems
Sintomas do HIV	Dev Galaxy Store	Provides access to the federal government's guidelines for medical practice on HIV/AIDS.	Yes	General population	Brazil	Android	Systems of initiatives for information
2018 BHPS	National Minority AIDS Council, Inc	To inform about the third annual Biomedical HIV Prevention Summit.	No	General population	United States	Android	Systems of initiatives for information
Be-PrEP-ared	Frederik Matthesstraat	To support pre-exposure prophylaxis users in correct usage	No	General population and pre-exposure prophylaxis users	Netherlands	Android	Apps for patient monitoring
HIV and Aids	Focus Medica India Pvt. Ltd	Animated videos about HIV and AIDS	No	General population	India	Android	Systems of initiatives for information

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App	App Developer	Aim of app	Address postexposure prophylaxis (Yes/No)	Target population	Country	Phone operating system	World Health Organization classification
HIV-Rx DDI Check	John Faragon	This app provides an easy-to-use Drug Interaction mobile reference based on the Department of Health and Human Services Guidelines for the Use of Antiretroviral drugs.	No	Care providers	United States	Android	Decision support systems
Guia de teste do HIV	Anadoluapps	Information about HIV	No	General population	Brazil	Android	Systems of initiatives for information
Połączenia	Program Stacja	Information about HIV	No	General population	Poland	Android	Systems of initiatives for information
RIghtTime: RI's Sexual Health app	Rhode Island Department of Health	Offers information, resources, and videos on sexual health topics in the Rhode Island region.	No	General population	United States	Android	Systems of initiatives for information
How to Prevent HIV Infection	NonitaDev	HIV information	No	General population	United States	Android	Systems of initiatives for information
Long Exposure Camera 2	__[c]	Long-exposure photography	No	Not related to HIV content	—	Android	N/A
MSACS	IT Hubtech Solutions	To inform about Maharashtra State AIDS Control Society in India	No	General population	India	Android	Systems of initiatives for information
Pre-exposure prophylaxis	Pomorski Uniwersytet Medyczny w Szczecinie	To inform about HIV, mainly pre-exposure prophylaxis	No	General population and pre-exposure prophylaxis users	Poland	Android	Systems of initiatives for information
Yazi	Oluwatoni Fuwape	To design customized condoms	No	General population	United States	Android	N/A
EDUC@AIDS	Rvs Comunicação e Tecnologia	To inform about HIV	Yes	General population	Brazil	Android	Systems of initiatives for information
Avoid HIV and AIDS	Oualidosdev	To inform about HIV	No	General population	—	Android	Systems of initiatives for information
DIKA	DIKA	To inform about HIV	No	General population	Mozambique	Android	Systems of initiatives for information

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App	App Developer	Aim of app	Address postexposure prophylaxis (Yes/No)	Target population	Country	Phone operating system	World Health Organization classification
Остров	Prometheus Studio	To create a service to increase the availability of peer counselors and support groups for people living with HIV	No	People living with HIV	—	Android	Community mobilization for health promotion
Candowell	Candowell	A social network that connects people, content, and purpose.	No	Not related to HIV	—	Android	N/A
Exposure Calculator	Evan Shortiss	Light exposure calculator	No	Not related to HIV	Spain	Android	N/A
Tratamentos e Doenças	goGOODapp	Inform about general infections	No	General population	—	Android	Systems of initiatives for information
Monthly Prescribing Reference	Haymarket Media	Inform about general drugs, including antiretroviral agents	Not	Care providers	United States	iPhone operating system	Systems of initiatives for information
ABC Medical Notes Pro for Exam	Pocketmednotes.com	Medical guide for medical students	No	Medical students	England	iPhone operating system	Mobile telemedicine services
HIV 3D study	USaMau03	Shows the HIV reference study and 3D digital cell with pins to show parts of the HIV cell structure.	No	Care providers	United States	iPhone operating system	Mobile telemedicine services
HIV Antibody Database	Zentropy Software	Display the sequence, structure, and neutralization data for neutralizing anti-HIV antibodies and some HIV-1 strains. It is meant to be a tool for scientists involved in HIV vaccine research.	No	HIV researchers	United States	iPhone operating system	Decision support systems

[a]Source: Google Play Store (2019) and App Store (2019).

[b]N/A: not applicable.

[c]Not available.

Results

Literature Review

The exhaustive literature review resulted in only 2 studies that guided phases 2 and 3 of our study (Figure 1), and both originated in the United States. We focused on databases used in the United States even for phases 2 and 3 of this study. The 2 studies in the literature review report intervention measures—one being a pilot study for a randomized controlled trial and the second, a full randomized controlled trial. Both studies present the use of apps as mHealth strategies aimed at improving the sexual health of men who have sex with men and can be classified as "decision support systems" by the World Health Organization standards. Still, none of the studies were related to the apps found on Google Play Store and App Store.

Our first finding in the literature review was the system created by Sullivan et al [13], the HealthMindr, which included tools that help in self-assessment, recommend prevention strategies, help in finding and ordering condoms or HIV self-tests, and send reminders for prevention services, condom use, HIV

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testing, and screening for PrEP and PEP. All these features were provided with information that allowed users to choose the best form of prevention that fit their lifestyles. The second finding was the "MyPEEPS" app, a peer-based system developed by Hidalgo et al and Kuhns et al [14,15] that provides educational information about HIV and sexually transmitted infections among young men who have sex with men, and it focused on raising awareness about minority stress (eg, due to sexual identity) and capacity building for condom use, emotional regulation, and negotiating interpersonal and substance-related risk; these skills were delivered through gamifications, scenarios, and role plays through 21 different activities.

Technology Prospecting of Patent Databases

Based on the finding that most studies in the systematic review were developed in the United States of America, a systematized search was executed in the chosen patent bases as described. Only 1 patent was found in the INPI database, but it was unrelated to the subject; it described the patent for an antiviral drug, thereby suggesting the lack of technological innovation efforts in PEP.

Systematic Search on App Stores

In total, 25 apps were retrieved, which were mostly developed for Android systems (21/25, 84%) in the United States (12/25, 48%) or Brazil (7/25, 28%). In general, of the 25 apps on HIV and HIV prevention and treatment, 8 (32%) target health care providers, 7 (28%) target people living with HIV, and 23 (92%) target the general population. The apps mainly consist of text, images, and videos (15/25, 60%). As 11 of the 25 (46%) apps were centered on information, they were classified as "Mobile telemedicine services" and "Systems of initiatives for information" [11]. Only 3 (12%) of them specifically focused on PEP (EoHIV, PEPtec, and PEPusuário), and these 3 apps were created by researchers from Brazilian universities.

EoHIV provides information for health care workers to assist in their self-care and improve adherence to PEP in the face of exposure to biological materials. The main functions of EoHIV are information provision about exposure to HIV, PEP and its side effects, planning about treatment, and provision of a calendar that enables the scheduling of the daily intake of the medication.

The focus of PEPusuário is to improve PEP adherence, thereby assisting the user to complete the 28-day treatment. This app also allows one to document the treatment start time, type of health care professional, and location. Information about the medication, its indications, and the location to access the medication are also available.

PEPtec is an app that assists people who have gone through a potential risk of HIV infection. Its design allows it to be used as a decision-making tool for receiving PEP by health care professionals in different settings such as emergency room, specialty clinic, basic health units, and maternity hospitals.

Discussion

Overview of the Findings

Our study combines a literature review and technological (prospecting and mobile app search) strategies to identify mobile apps for PEP. This analysis of 3 different data sources makes this study innovative in that it seeks to trace a relationship between the creation of scientific knowledge (phase 1) and its translation into technological products (phase 2 and phase 3). The lack of correspondence between the results in the 3 phases shows a gap between the construction of knowledge and its practical application.

The mapping of the mobile apps focused on PEP showed that there are very few initiatives dedicated exclusively for PEP, as most of the apps address HIV infections, with PEP being part of this broader content. The objective and content analyses of this mapping show that these apps are very similar to traditional strategies (booklets and websites) by using little or none of the wide range of tools a smartphone can offer. mHealth information initiatives are defined as services that provide access to health science publications or databases at points of care by using mobile devices. While relatively new to limited-income countries, these mHealth services are established in industrialized countries, where medical professionals are often equipped with advanced mobile devices [12]. Despite this, our data show a new trend since the exclusive PEP apps available in libraries were created in Brazil, a limited-income country. The Unified Health System in Brazil is the largest public health care system in the world, currently providing treatment and care for 150 million people. This system was part of the main HIV care network in 2018, wherein around 580,000 people living with HIV/AIDS received their antiretroviral drugs free of charge [16]. Its integration also extends to the country's teaching and research institutions, which explains the pioneering spirit in the creation of technologies, as we have reported.

As our review shows, even though there are only few apps related to PEP, future efforts should be made not only to create mHealth services but also to ensure that these services are evidence-based and reliable. A recent survey by the World Health Organization found that only 12% of the member states reported evaluating mHealth services and little was known about how to effectively evaluate these services [12]. Mobile telemedicine initiatives include consultations between health care providers and transmission of a patient's health-related data by using mobile devices.

The lack of innovative resources in the apps found can be a limiting factor for their use since they do not consist of attractive and engaging tools. However, one must take into consideration that more advanced mobile telemedicine initiatives require a significantly established infrastructure, fast telecommunication networks (ie, general packet radio services, 3G, 4G), and advanced technology, thereby making it challenging for growth and adoption by low- and middle-income countries [12], which have higher rates of HIV infection [1].

Governments are expressing interest in mHealth as a complementary strategy for strengthening the health care

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systems and for achieving health-related millennium development goals in low- and middle-income countries. This interest has taken the form of a series of mHealth deployments worldwide, which are providing early evidence of the potential for mobile and wireless technologies. mHealth is being applied in maternal and child health and in programs to reduce the burden of diseases linked with poverty, including HIV/AIDS, malaria, and tuberculosis. mHealth apps are being tested in diverse scenarios such as in improving timely access to emergency and general health services and information, managing patient care, reducing drug shortages at health clinics, and in enhancing clinical diagnosis and treatment compliance [12]. Most people using PEP or reporting knowledge of this strategy have already used it or belong to the lesbian, gay, bisexual, and transgender community (which historically has a closer relationship with HIV and its prevention forms), thereby placing a large part of the population in a window of "missed opportunity"—people who may have been candidates for this mHealth strategy but, due to lack of knowledge, could not access the service, especially heterosexual women, who are rarely contemplated by government campaigns on this subject [17].

Minority communities (by gender, sexuality, or ethnicity) are underrepresented in advertising, government, and even peer-to-peer education campaigns [18]. Evidence from a systematic review shows how lesbian, gay, bisexual, transgender, and queer + youth showed good adherence to tools tailored specifically for them. Digital health interventions have the potential to improve health disparities in this population, which in turn, would impact HIV transmission and prevention [19]. mHealth services offered to the public can help reach a larger population. However, when the applicability of the mHealth services is restricted, it becomes less attractive to the user. All the apps found in the literature are aimed and designed for men who have sex with men—a vulnerable population that is dismissed for large public health care or governmental initiatives [20]. Specially, young men who have sex with men are more prone to use eHealth and mHealth tools as ways to manage their own health similar to how they use other apps to tackle daily life issues [21]. However, there is a shortage of apps designed for other populations such as young women or transgender individuals. Evidence has shown that young people from sexual minorities, especially men who have sex with men, who perceive themselves within patterns of risky behavior are more likely to use the internet, especially on their smartphones to seek information about sexual health [22]. The combination of practicality, speed, and privacy make this tool an ideal way to deliver interventions and information. The fact that these individuals are so young is crucial in the strategic thinking of stopping the emergence of new infections; therefore, proper development of several tools based on scientific principles is critical. Despite the widespread promotion of technology-based interventions, evidence supporting their effectiveness in addressing noncommunicable diseases has not reached a consensus yet. Evaluations of apps and web-based programs as ways to deliver health interventions have reported that these technologies are no more effective than paper-based approaches or offer no additional benefit as an adjunct intervention. Although recent systematic reviews of eHealth and mHealth interventions targeting health behaviors provide some evidence of the short-term benefits, the effects are modest and long-term efficacy is yet to be established [21].

One of our main findings is that there is no correspondence between the 3 data sources assessed (scientific databases, patent databases, and mobile app libraries), which indicates that the scientific knowledge discovered and validated does not have the corresponding technology for implementation and most technologies that are available are not supported with appropriate methodological rigor.

Limitations

Our study has the following limitations. First, even though we did a thorough search on the apps, these results did not include all the existing app libraries. However, our data are still relevant because they are obtained from App Store and Google Play Store, which are the 2 main app libraries. Second, it is possible that other apps that address this topic exist but they did not appear in our search because of the specific combination of words. We used the best possible combination to find as many apps as possible with a focus on PEP because of its specific characteristics and unique importance in HIV prevention.

Conclusion

Our study demonstrates the lack of mHealth interventions for PEP. The apps that do exist are still focused on delivering information about HIV, and no initiative has been taken to improve access to further HIV interventions. These apps are deeply focused on the traditional format of compiling and organizing HIV information, without providing support for action. Thus, there is no available approach to prevent the emergence of new infections, especially in the more vulnerable groups (such as young lesbian, gay, bisexual, transgender) that already have high adherence to eHealth and mHealth interventions. Our review found no connection between scientific studies, registered patents, and the available apps, thereby indicating that the available apps do not have a theoretical or a methodological background in their creation. The accuracy and quality of these apps should be explored in future studies. Researchers and the community must work in synergy to create more mHealth tools aimed at PEP.

Acknowledgments

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Authors' Contributions

AQ was responsible for the conception and design of the study, analysis and interpretation of data, and writing of the paper. IM and LL provided the theoretical and methodological background for the study. SD was responsible for ensuring the accuracy and integrity of all aspects of this study. All authors reviewed the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

INPI: National Institute of Industrial Property
mHealth: mobile health
PEP: postexposure prophylaxis
PrEP: pre-exposure prophylaxis
UNAIDS: Joint United Nations Program on HIV/AIDS
USPTO: United States Patent and Trademark Office

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Original Paper

Acceptability, Validity, and Engagement With a Mobile App for Frequent, Continuous Multiyear Assessment of Youth Health Behaviors (mNCANDA): Mixed Methods Study

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Abstract

Background: Longitudinal studies of many health behaviors often rely on infrequent self-report assessments. The measurement of psychoactive substance use among youth is expected to improve with more frequent mobile assessments, which can reduce recall bias. Researchers have used mobile devices for longitudinal research, but studies that last years and assess youth continuously at a fine-grained, temporal level (eg, weekly) are rare. A tailored mobile app (mNCANDA [mobile National Consortium on Alcohol and Neurodevelopment in Adolescence]) and a brief assessment protocol were designed specifically to provide a feasible platform to elicit responses to health behavior assessments in longitudinal studies, including NCANDA (National Consortium on Alcohol and Neurodevelopment in Adolescence).

Objective: This study aimed to determine whether an acceptable mobile app system could provide repeatable and valid assessment of youth's health behaviors in different developmental stages over extended follow-up.

Methods: Participants were recruited (n=534; aged 17-28 years) from a larger longitudinal study of neurodevelopment. Participants used mNCANDA to register reports of their behaviors for up to 18 months. Response rates as a function of time measured using mNCANDA and participant age were modeled using generalized estimating equations to evaluate response rate stability and age effects. Substance use reports captured using mNCANDA were compared with responses from standardized interviews to assess concurrent validity. Reactivity was assessed by evaluating patterns of change in substance use after participants initiated weekly reports via mNCANDA. Quantitative feedback about the app was obtained from the participants. Qualitative interviews were conducted with a subset of participants who used the app for at least one month to obtain feedback on user experience, user-derived explanations of some quantitative results, and suggestions for system improvements.

Results: The mNCANDA protocol adherence was high (mean response rate 82%, SD 27%) and stable over time across all age groups. The median time to complete each assessment was 51 s (mean response time 1.14, SD 1.03 min). Comparisons between mNCANDA and interview self-reports on recent (previous 30 days) alcohol and cannabis use days demonstrate close agreement

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(eg, within 1 day of reported use) for most observations. Models used to identify reactivity failed to detect changes in substance use patterns subsequent to enrolling in mNCANDA app assessments ($P>.39$). Most participants (64/76, 84%) across the age range reported finding the mNCANDA system acceptable. Participants provided recommendations for improving the system (eg, tailoring signaling times).

Conclusions: mNCANDA provides a feasible, multi-year, continuous, fine-grained (eg, weekly) assessment of health behaviors designed to minimize respondent burden and provides acceptable regimes for long-term self-reporting of health behaviors. Fine-grained characterization of variability in behaviors over relatively long periods (eg, up to 18 months) may, through the use of mNCANDA, improve our understanding of the relationship between substance use exposure and neurocognitive development.

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KEYWORDS

mobile applications; young adults; smartphone; health behavior; underage drinking; alcohol drinking; self-report; illicit drugs; mobile phone

Introduction

Background

Obtaining behavioral reports on a mobile technology platform from youth has been widely applied in various substance use research contexts [1-5]. These reports are commonly tied to substance use interventions [6,7]. Mobile apps have also been used in community-based research on substance use [2,8,9]. The high penetration of mobile technology among teens enables this approach to be feasible [10]; however, frequent assessment of substance use in multi-year studies across a broad age group of youths has rarely been employed or evaluated.

More frequent assessment, over shorter reference periods in community-based research with youth, may provide 2 benefits: (1) allow for fine-grain characterization of substance use patterns, which can be complex among community youth [11], and (2) provide additional follow-up at a low cost and with minimal participant and staff burden. These advantages have important implications for large-scale longitudinal studies [12,13], such as NCANDA (National Consortium on Alcohol and Neurodevelopment in Adolescence) [12]. Youth in the NCANDA study have been assessed annually for ≥6 years on neurocognitive functioning, brain structure and function, psychosocial functioning, and various health behaviors and exposures, including substance use [12]. Substance use measures in NCANDA focus on aggregated substance use during the previous month and year during semiannual interviews. NCANDA's investigation of the causal interplay between substance use and neurodevelopment in human youth would benefit from a more fine-grained assessment of substance use patterns during a critical period of on-going brain maturation.

Self-reporting of substance use has provided acceptable reliability and validity in certain contexts [14]. Factors that increase the validity of self-reported substance use include assurance of anonymity and confidentiality [14], computerized self-report (vs interview) [15], and the absence of sanctions tied to self-report of substance use [16,17].

Sources of error that affect the validity of self-reported substance use include the cognitive limits of recall. Specifically, respondents may have difficulty remembering the date in which events occur as the length of reference periods increase [18,19]. In addition, substance use associated with memorable events may be more easily recollected, contributing to bias [18]. Importantly, when the reference period captures more than 7 events, respondents tend to shift away from enumeration and move toward reporting substance use schema, which degrades validity [18,19]. Periods of abstinence or rare events of extreme use may be underweighted in participant reports. Perceived modal use patterns (ie, schema) rather than responses based on each of the particular substance use events during the reporting period will be more likely to become the basis of behavioral reports [14]. This previous work suggests that the assessment of substance use via self-reporting over an extended duration would benefit from the use of frequent reports based on relatively short reference periods. The design of the mNCANDA (mobile National Consortium on Alcohol and Neurodevelopment in Adolescence) app's schedule for survey administration addresses the need to frequently collect self-report of substance use, maximizing assessment yield, given the constraints of cognitive recall and its effect on the validity of self-report.

To optimize long-term acceptability and respondent compliance to the mobile protocol for long-term, frequent assessment in NCANDA, a tailored app (mNCANDA) was developed. The app's interface minimizes the number of actions for the participant to initiate and complete each assessment. For example, some items automatically advance to the next item upon response entry, and participants would be given *one-touch* response grids that allow a response to be selected again with a single touch rather than by typing several digits, scrolling, or dragging (Figure 1). Substance use assessment in mNCANDA is adaptive, meaning that fine-scale (day-to-day) substance use assessment does not begin until participants report more than 1 substance use event a month. In this case, alternative non–substance use–related items (eg, physical activity) are presented in lieu of substance use to equalize the assessment effort across participants. In addition, only commonly used substances (eg, alcohol, cannabis, and nicotine) were explicitly included in item prompts. Other substances were entered as a free response on their first report, but thereafter, those substances were explicitly included in item prompts and tailored to the participant's vernacular. mNCANDA assessments were designed to take under 1 min each to increase compliance, and participants are given most of the day to respond. Together, these features may enhance the research value of mobile app–administered self-reports.

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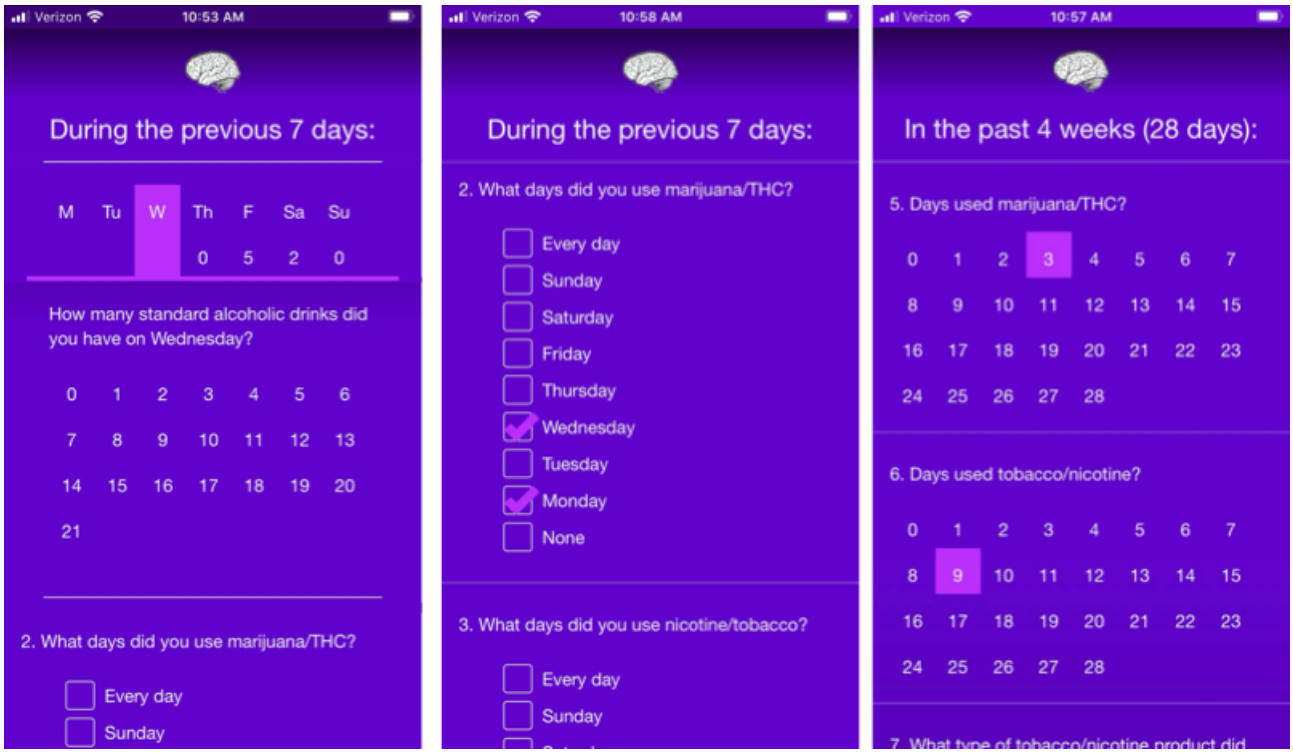
Figure 1. Examples of the mobile National Consortium on Alcohol and Neurodevelopment in Adolescence user interface. In the first panel, users enter the number of drinks they had consumed in each of the previous 7 days, starting with Sunday. This assessment would be issued on a Monday. Upon selecting a number of drinks, the value is entered into the day-by-day list and then automatically advances to the next day of the week until consumption on each day is reported. Users can revise entries by selecting the day. In the second panel, the user selects the day of the week that a substance was used. The last panel is the interface for reporting the frequency of use for 2 substances at a time in the previous 4 weeks, which is part of the core assessments. mNCANDA: mobile National Consortium on Alcohol and Neurodevelopment in Adolescence; NCANDA: National Consortium on Alcohol and Neurodevelopment in Adolescence.



Objectives

This study examined (1) test-retest reliability and concurrent validity of mNCANDA substance use behaviors, focusing on the most prevalent substances (alcohol and cannabis), (2) response rates over extended mobile follow-up assessment, (3) reactivity to the frequent assessment of substance use behaviors over an extended period of self-monitoring, and (4) usability and acceptability of the mNCANDA app, including user suggestions for fine-tuning it. Since the NCANDA project participants span several important development transitions (eg, end of high school and legal drinking age), an overarching study aim is to evaluate the extent to which the results varied as a function of age, which has implications for age-specific refinements of app design and content.

Methods

Recruitment and Eligibility

All participants (N=830) enrolled in the NCANDA project [12] were eligible for enrollment in the mobile app component of the study (mNCANDA), and 534 of these participants enrolled in mNCANDA. Initiation of recruitment to mNCANDA was staggered across the 5 NCANDA study sites (UC San Diego, SRI International, Oregon Health Sciences University, Duke University, and University of Pittsburgh) between April 2019 and June 2020. Recruitment was not complete when this analysis was conducted. Recruitment was limited to regularly scheduled semiannual NCANDA visits. As 3 sites initiated recruitment late and 1 was understaffed during much of the planned recruitment period, not all eligible participants had been invited to participate by the close of the initial evaluation period. The participants' age range was 17-28 years. Tablets were available for participants who did not possess a mobile device. The mobile app protocol was approved by each research project site's institutional review board, and all participants provided informed consent or assent with parental permission. Detailed demographic and substance use characterizations of the NCANDA participants have been previously reported [12].

mNCANDA App

The mNCANDA app (Android and iOS) was engineered to provide participants with a low burden experience to obtain weekly behavioral and substance use exposure reports; the app was installed on participants' personal smartphones. Examples of the interface are shown in Figure 1. No response data were stored locally on the phone or were accessible through the app interface. The software was impacted by a bug that limited participants' ability to complete surveys during 2 assessment windows, which were dropped from the analyses (ie, treated as missing data). The app and protocol were developed in the context of iterative piloting that included both quantitative and qualitative feedback from youth pilot testers (see Mobile App–Related Attitudes and Perceptions: Usability, Acceptability, and Obtrusiveness below).

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mNCANDA Standard Assessment Protocol

mNCANDA issued weekly assessments, in addition to a core substance use assessment every 4 weeks. Weekly assessments were issued on Monday mornings, and the core substance use assessments were given on Sunday mornings. When the participant opened the mNCANDA app, the assessment was automatically loaded and presented questions. Assessment initiation (ie, when questions were seen by the participant) and survey completion times were recorded.

Participants would have approximately 14 h to complete the assessments after the first (morning) signal. If participants did not complete the survey after the first signal, the reminder signals would follow at 3 intervals after the assessment was first issued: 15 min, 5 h, and 6 h. The initial signal and the second reminder came as operating system notifications (banners), whereas the first reminder was delivered as a text message, and the final reminder was an email. Different signaling modes were used to protect against one of the modes failing because of an event such as a change in a handset causing loss of notifications or phone number change resulting in the loss of text signals. Each of these signals allowed the participant to know how much time remained before the assessment window closed.

The mNCANDA weekly assessments covered the following domains: substance use, access to substances, daily activity, stress, socialization, physical activity, use of complementary and alternative medicines, and quality of life. Groups of items were randomly administered each week to help maintain participant interest and engagement with the app, allowing for various developmentally relevant domains to be assessed without a substantial burden on the participant. Weekly substance use questions were granular down to the scale of individual days and were issued only to participants with a history of substance use, as reported in the mNCANDA core assessment. The items were adopted from the standard NCANDA battery and developed or adapted specifically for use on the mNCANDA platform. Items are outlined in Multimedia Appendix 1. Most items were adopted or adapted from several sources to conform to the objectives of the current protocol [20-25]. Content within the mNCANDA weekly assessments varied from week to week; groups of items related to the same domains were randomly issued on a particular week. Each of these question groups was composed of a small set of items (Multimedia Appendix 1). Most assessment events included the administration of 1 question group; 2 groups were issued simultaneously at a target rate of 33% of the assessment events.

The mNCANDA core substance use assessment evaluated substance use frequency (alcohol, nicotine, cannabis, and other drugs) and alcohol intensity during the previous 28 days. Participants entered other drugs as free-response entries. The frequency of substance use was measured in terms of the number of days with use during the reference period. The specific prompts for the items are included in Multimedia Appendix 1.

Participants were given incentives for the submission of mNCANDA assessment responses. The project used 2 incentive systems: threshold and ramped, which were randomly assigned. Incentives in the threshold schedule were US $2 per submission with US $5 to achieve a 90% response rate and an additional US $10 bonus for a 100% response rate during a set 8-week period. By comparison, the ramped schedule increased the incentive (approximately US $0.4) for each consecutive completed assessment in an uninterrupted series of submissions until a ceiling at US $4 was reached. In the ramped schedule, the sequence to determine compensation is restarted upon the participant missing an assessment. Under both systems, participants were presented with an interactive animation of coins showing the amount of their incentive being added to their collection immediately after each submission. The value of future submissions was presented to the participant in conjunction with the animation. The maximum total compensation in the ramped system is pegged to match the maximum under the threshold bonus system.

Reliability and Validity Protocols

A standard core substance use assessment was issued via the app twice on the same day (Sunday) to evaluate the mNCANDA substance use assessment's test-retest reliability. Participants' response windows for the test-retest assessments were 4-h windows with one assessment given in the morning and the other during the afternoon with a minimum 1-h gap between assessments.

To examine concurrent validity, the mNCANDA self-administered self-reports were compared with self-reports obtained from the Customary Drinking and Drug Record (CDDR) [25], an established interview with known psychometric properties, which is used for the assessment of substance use. Approximately one-quarter (139/534, 26%) of participants were randomly selected to be included in the validity component of the study (Figure 2). These participants were then randomly assigned to receive their first mobile app assessment before or after an interviewer-administered CDDR was completed. This interview was scheduled as a standard component of the semiannual assessments issued in the parent study, which alternated between over-the-phone and in-person settings. Participants who were assigned to a particular assessment mode sequence reported substance use using a 30-day reference frame on their first assessment to match the CDDR's reference period. The remainder of the participants used the standard app reference period of 28 days, which allowed for comparison with baseline use in the reactivity analysis.

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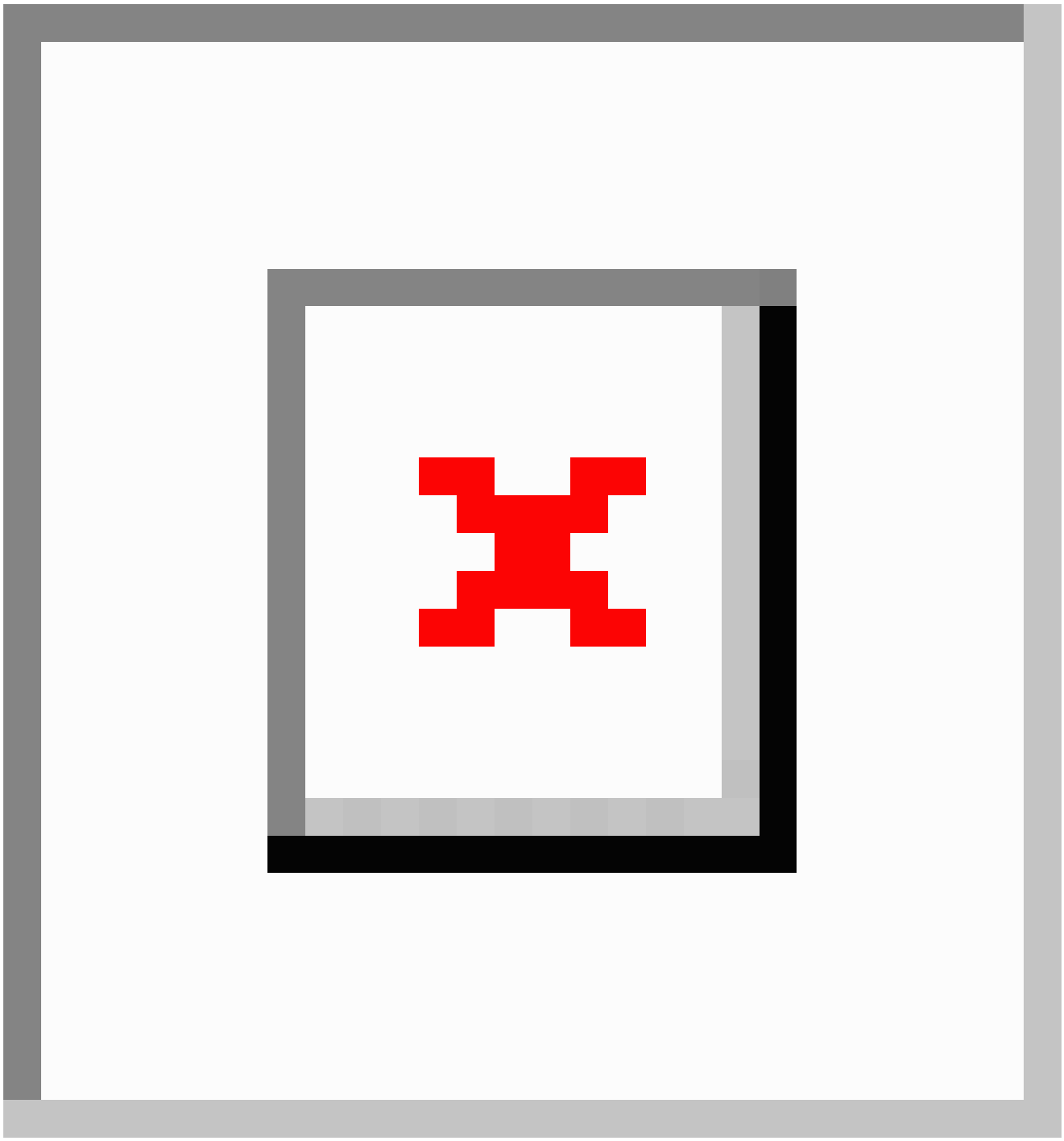
Figure 2. Participant recruitment, study allocation, and treatment allocation flow diagram. All National Consortium on Alcohol and Neurodevelopment in Adolescence (NCANDA) participants were eligible for participation. Recruitment invitations were issued during standard NCANDA interviews. Recruitment, consenting, and initiation of the mobile National Consortium on Alcohol and Neurodevelopment in Adolescence (mNCANDA) app takes approximately 20 min. The mNCANDA evaluation period ended before all participants were invited. mNCANDA: mobile National Consortium on Alcohol and Neurodevelopment in Adolescence; NCANDA: National Consortium on Alcohol and Neurodevelopment in Adolescence.



Reactivity

For participants randomized to the reactivity protocol (Figure 2), reactivity was assessed by evaluating changes in participants' substance use in their initial report. The initial report assessed substance use in the month before enrolling in the mobile app protocol. Thereafter, participants' substance use was assessed every 4 weeks. Reactivity was also addressed with 2 questions presented to the participants as part of the one-time feedback survey (see Mobile App–Related Attitudes and Perceptions: Usability, Acceptability, and Obtrusiveness below). Participants were asked how much they agreed with the statement, "Completing the surveys changes how I think about using alcohol," and a separate statement that referred to "drugs."

Mobile App–Related Attitudes and Perceptions: Usability, Acceptability, and Obtrusiveness

Experiences and attitudes related to the app were evaluated using mixed methods. The specific mixed methods design structure employed was a concurrent nested design with embedded qualitative components within a quantitative investigation. A 20-item web-based, self-administered

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questionnaire was issued to all participants as part of the feedback survey. The feedback survey was issued in 1 bolus. At the time of survey completion, participation in mNCANDA ranged from 2 to 46 weeks (mean 25.4, SD 12.3). For each participant, survey items were randomly selected from a pool of 36 items related to usability, acceptability, obtrusiveness, item clarity, notification systems, incentives, and motivation. Many of the items were modified from or aligned with content found in several previous studies [26-28]. With the paucity of widely adopted instruments holding adequate content validity for each application, it remains common for usability studies to create usability instruments tailored to the specific project [29]. The items in this study assessed agreement with the item prompt on a 5-point Likert scale. In addition, open-ended items were included to provide capacity for interpretation, elaboration, identification of specific issues, and participant-suggested solutions. These open-ended items asked participants to describe why they did not respond to an assessment, the app's features that they appreciated, and how the app and protocol could be improved. Qualitative components of usability investigations are critical for the identification of specific usability strengths and weaknesses [30].

A semistructured qualitative interview was also conducted with 9 participants, exclusively from the San Diego site. Participants were selected through purposeful sampling [31] so that the maximal number of intersections among the 4 participant characteristics was obtained. These characteristics were sex (4 female vs 5 male), age (5 under 21 vs 4 over 21), substance use (4 naïve vs 5 experienced), and mNCANDA response rates (6 high responders vs 3 low responders). Descriptions of participants' experiences using the mNCANDA app were elicited. These semistructured interviews were organized around an interview guide (Multimedia Appendix 2). Interviews were conducted by a research assistant who had previously developed a rapport with the participants while conducting prior interviews. Interview length ranged from approximately 10 to 20 min. Responses were audio recorded, transcribed, coded, and evaluated for the emergence of themes. Coding was conducted by a senior graduate assistant with training in qualitative analysis. Identification of themes was developed in consultations between the first author and the coder, from a grounded theory perspective [31]. Using a complementary mixed methods approach [32,33], the qualitative data were used to give context, elaborate beyond the quantitative response patterns, and screen for critical aspects of the user experience that were absent from the quantitative assessment.

Statistical Analysis

Test-retest reliability was examined using intraclass correlation. Concurrent validity, the extent of agreement between mNCANDA self-reports and the 30-day CDDR of alcohol and cannabis use frequency, was assessed using Bland-Altman plots [34,35] and ordinary least squares regressions with difference scores modeled by the mean of the 2 measures, an indicator for the measurement order, participant age class, and their interactions. Age was categorized as below 18, 18-20, and above 20 years in the statistical models, which is consistent with previous NCANDA age categorization [12] and captures common developmental thresholds. This categorization was a preplanned analytic approach. The exploration of age as a continuous variable was also conducted as a secondary exploratory step, in part motivated by the small numbers of participants in the below-18 years age category by the time the app was deployed and human research protection program review and approval could be obtained.

To examine long-term response rates (ie, engagement) with the mNCANDA app and its correlates (eg, differences in response rates over time by age), generalized estimating equations (GEEs) for binomial outcomes with an autoregressive function for the errors were used. GEEs assume that data are missing completely at random, which is appropriate for these data with monotone missing patterns structured by design. The dependent variable was the completion of the mNCANDA assessment (yes/no). The GEE model included the sequential assessment number (nested within participants), age, and their interaction. GEE models were fit using iteratively reweighted least squares.

Mixed effects Poisson models were used to evaluate assessment reactivity or changes in substance use after initiating the mNCANDA protocol. These models assume that missing values are missing at random. The dependent variable in these models was substance use frequency (alcohol and cannabis). Frequency of use was modeled as a function of the calendar month (to account for seasonal patterns in substance use across the year) and the sequential assessment number (ie, time). An index for participants was included as a random effect. A second set of models extended this base model. This included an indicator variable signifying whether participants self-reported on the feedback survey that they perceived the mNCANDA protocol influenced their substance use. An interaction term between the assessment sequence number and self-reported reactivity items was also included as a step in the hierarchical model building. As participants initiated the protocol on a rolling basis, systematically determined by participants' NCANDA interview schedules, statistical control of temporal patterns in substance use across the year was incorporated into these models by including calendar month as an independent variable. Models were estimated via maximum likelihood. The sets of model parameters added in each step were evaluated using likelihood ratio tests. Analysis of the quantitative survey items consisted of contingency tables for the relationship between age class and response categories using Fisher exact tests.

Results

mNCANDA Sample

At the end of the evaluation period, 72.7% (574/790) of the active NCANDA participants had been approached to participate in the mNCANDA protocol, and most (534/574, 93%) consented and were enrolled. All participants possessed a smartphone. About half (225/534, 42.1%) of the mNCANDA sample was female. At the initiation of the mNCANDA study, participants had a mean age of 21.6 years (SD 2.5), representing the ages of 17 (21/534, 3.9%), 18-20 (187/534, 35%), and 21-28 (326/534, 61%) years. The self-reported race of the mNCANDA sample was 73.6% (393/534) European American, 9.7% (52/534) African American, 7.9% (42/534) Asian, 0.6% (3/534) American Indian, 0.6% (3/534) Pacific Islander, and 7.7%

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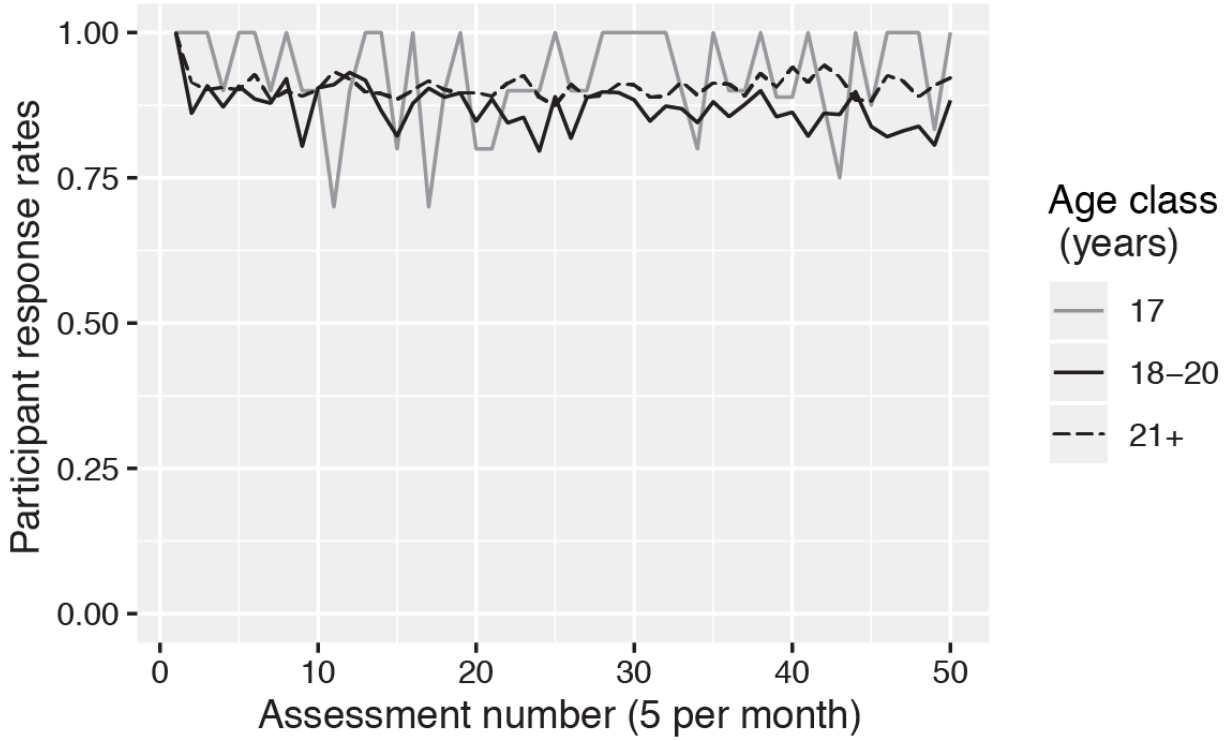
(41/534) mixed or other race or ethnicity; 15.9% (85/534) identified as Hispanic. Compared with the overall pool of NCANDA participants, the enrolled mNCANDA participants were similar to the larger pool based on sex (51% female; Fisher exact test, *P*=.16), age (21.6 years; t_{827} value=0.96; *P*=.36), and race (72% European American, 12% African American, and 8% Asian; Fisher exact test, *P*=.19). Most (422/534, 79%) participants reported some substance use via the mobile app throughout the study. Many (368/534, 68.9%) participants also reported using alcohol in the previous month at the baseline mobile assessment. Fewer participants (198/534, 37.1%) reported using cannabis at the baseline assessment.

Adherence and Time to Complete the mNCANDA Assessment

The median time it took participants to open an mNCANDA assessment, generate responses, and submit survey responses was less than 1 min for most weekly and core assessments ($N_{assessments}$=6113; median 51 s; IQR 0.85 min). The mean response time was 1.14 min (SD 1.03 min).

Participants were assessed continually (ie, at least weekly) with mNCANDA for up to 18.6 months. The mean assessment period was 8.2 months (SD 4.3). The mean response rate was 82% (SD 27%), with 61% (326/534) responding to at least 90% of the study's scheduled assessments. Evidence of an association between age and response rates was absent (*P*>.35). Response rate fluctuations among all age classes predominantly remained above 80% (Figure 3). Evaluation of the temporal patterns of response rates in a GEE model failed to identify temporal trends among any of the age classes (*P*>.20). The strongest age parameter in the GEE models was for the interaction between the assessment number and the 18-to-20-year-old age class (older than 20 years was the reference group; *b*=−.004; SE 0.003).

Figure 3. Mean response rates over time by age class. Assessment number is the sequential index assigned to each participants' series of scheduled assessments.



During the semistructured qualitative interviews, participants indicated that some of the common reasons for missing surveys involved employment, socializing with family and friends, when the assessment notifications were sent, and getting distracted and forgetting to return to the assessment. The self-administered questionnaire also included several noteworthy, isolated responses. These included parental confiscation of the participants' phone, stolen phone, traveling where internet access was limited, and choosing not to respond when the participant was not confident in accurately recalling events. For example, a respondent wrote, "If I don't remember answers to questions, I usually don't answer. Asking me to recall the past month of alcohol use is difficult" (Survey Participant 1). Several respondents also indicated that, on occasion, mobile app "glitches" prevented them from completing an assessment.

A robust theme in the qualitative open-ended responses related to engagement with mNCANDA was the brevity of the assessments. "The questions are easy to understand, there are an appropriate amount of questions, so it doesn't take up too much time," (Survey Participant 2) was characteristic of the explanation that many participants used as a reason for liking the system. "Straightforward," (Survey Participant 3) "simple," (Survey Participant 4) and "it doesn't take much time" (Survey Participant 5) also tie in with a theme identified in the interviews. Interviewees described brevity as one of the reasons they were agreeable to the proposition of continued long-term participation in the mobile study.

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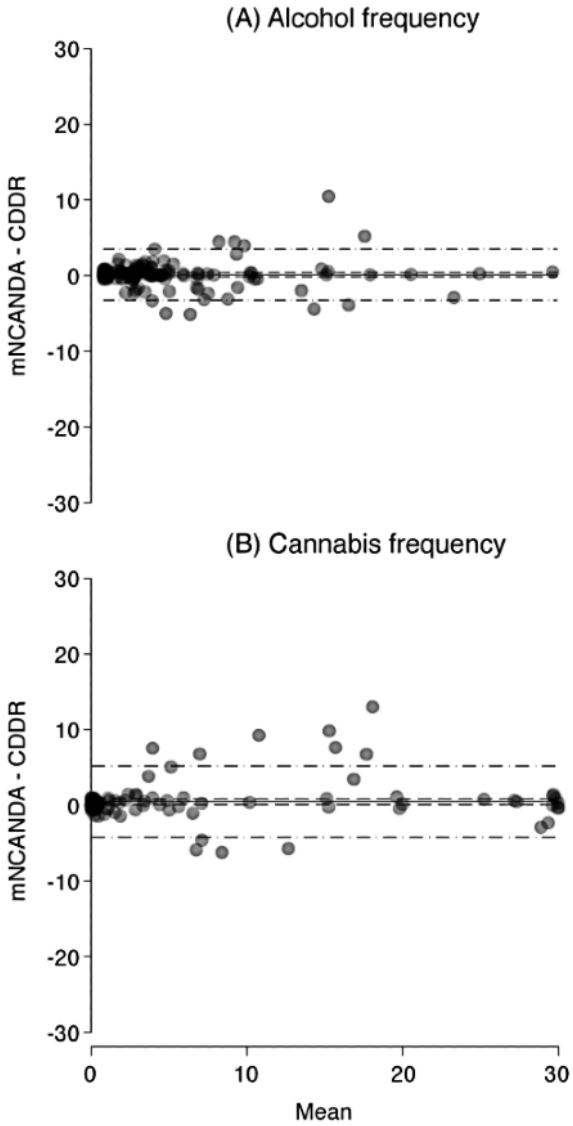
Reliability

Test-retest reliability was found to be high for substance use reports provided via the mobile app. A total of 260 participants (260/338, 76.9% of the active participants at the time) responded to the pair of test-retest assessments. Responses to the 30-day use items for alcohol and cannabis exactly matched for 81.9% (213/260) and 88.1% (229/260) of participants, respectively. The overall correspondence resulted in intraclass correlations of 0.969 (95% CI 0.961-0.977) and 0.987 (95% CI 0.983-0.989) for alcohol and cannabis, respectively.

Concurrent Validity

Comparisons between the mobile app and interview self-report on the recent (previous 30 days) alcohol and cannabis use days showed close agreement for most observations (Figure 4). The mean number of reported alcohol use days was higher by 0.13 (SD 1.7) days on the mobile app relative to the interview report (95% CI −0.17 to 0.42). No associations were detected in the regression model for the difference in the reports related to participants' age, the mean of the 2 reports, and whether the mobile app report was issued before the interview (R^2=2.9%; $F_{10,123}$=0.33; P=.98). The mean number of cannabis use days was 0.48 (SD 2.4) times higher on the mobile app than that reported in the interview (95% CI 0.07-0.88). As with alcohol, no patterns were detected in the regression model predicting differences in cannabis use reports from the participants' age, the mean report, and whether the mobile app report was issued before the interview (R^2=3.7%; $F_{10,123}$=0.48; P=.90). However, the limits of agreement were wider for cannabis than alcohol, with the largest discrepancies favoring greater use days on the mobile app (Figure 4). For both substances, most (92%) responses agreed without deviation at the minimum (0 days) and maximum (30 days). Where there was a deviation at these extremes (for either report), the most common (56%) magnitude of difference in the reports was 1 day of use.

Figure 4. Bland-Altman plot comparing (A) alcohol and (B) cannabis use frequency as reported via mobile National Consortium on Alcohol and Neurodevelopment in Adolescence and in the Customary Drinking and Drug Record. Dashed lines are 95% CIs, and the dash-dot lines are the 95% limits of agreement. Markers are jittered (2%). CDDR: Customary Drinking and Drug Record; mNCANDA: mobile National Consortium on Alcohol and Neurodevelopment in Adolescence.



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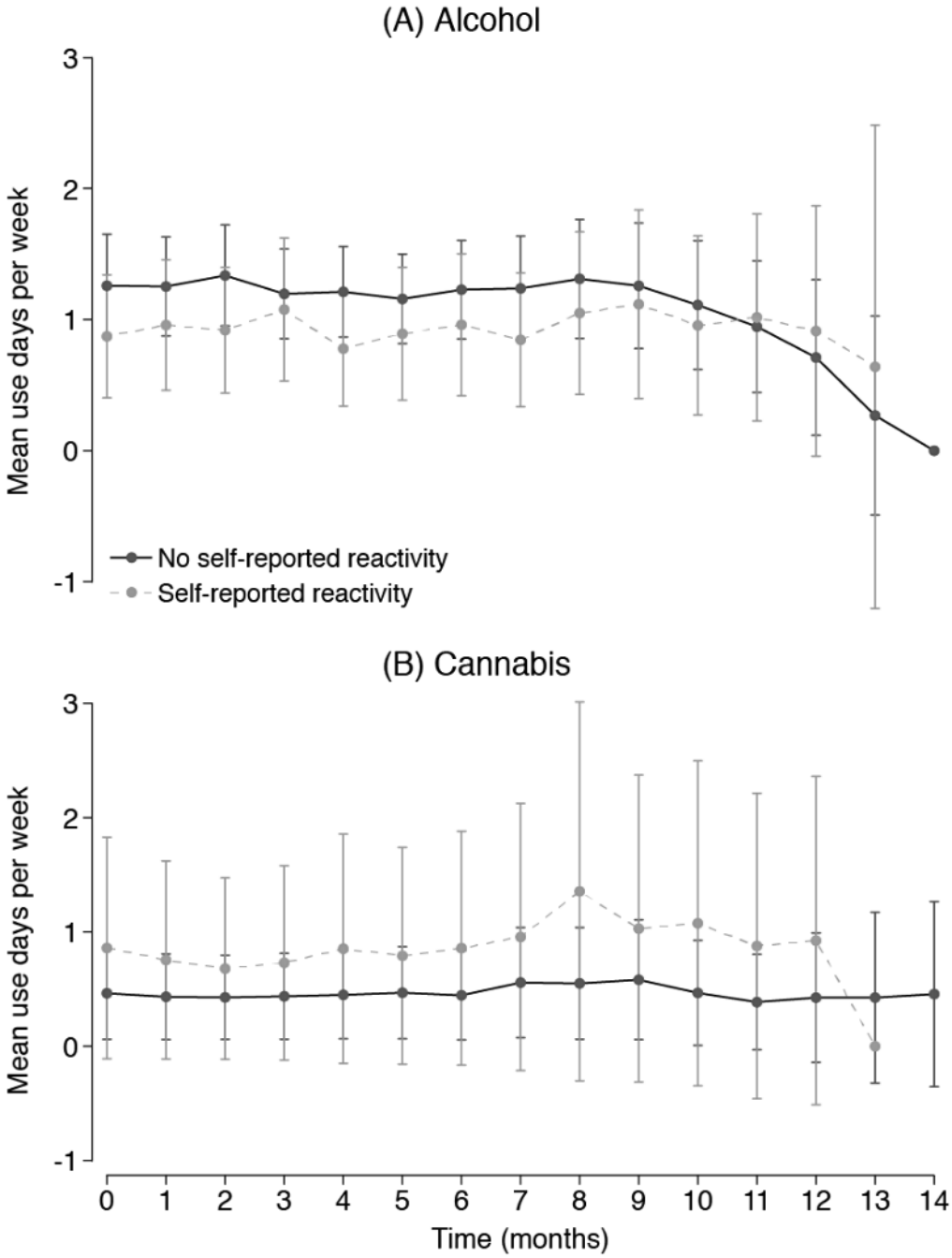
Reactivity

Patterns of change in alcohol or cannabis use were not evident in the assessment of reactive changes in the frequency of substance use (Figure 5). In the reactivity models, there was no resolvable evidence of change over time; time parameters from models for both substances were not statistically significant (likelihood ratio X^2_{14}<15.0; n=395; P>.39). Of the 395 participants randomized to the reactivity evaluation, 165 were also randomized to receive items in the feedback survey asking if the repeated assessments changed the way they thought about their substance use. Among those 165, 38 (23%) reported that the repeated assessments changed how they thought about their substance use (Figure 5). When stratifying participants by self-reported reactivity, differences in trajectories were not evident (Figure 5); the interaction between time and self-reported reactivity was not statistically significant (likelihood ratio X^2_{13}<6.2; P>.93). Furthermore, age and its interaction with time did not show an association with patterns of alcohol or cannabis use (likelihood ratio X^2_{26}<4.1; P>.98).

Figure 5. Days of substance use during 4-week intervals for alcohol and cannabis as a function time since the baseline and self-reported cognitive reactivity to the mobile app after adjustment for the calendar month. Error bars are 95% CIs around marginal means extracted from the mixed effects models. Time 0 assesses the month before the initiation of mobile National Consortium on Alcohol and Neurodevelopment in Adolescence assessments. mNCANDA: mobile National Consortium on Alcohol and Neurodevelopment in Adolescence.



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A theme that emerged in the qualitative interviews was that the participants' perception of their substance use behaviors did not change as a result of using the app. Some participants reported feeling more aware of their behaviors as a result of the app:

> *The questions about how much time I watch [television] or how I spend my leisure time, I tend to notice more of my habits. It hasn't prompted any change, but I am more cognizant but doesn't change anything.* [Interview Participant 2]

> *It made me a little more alert because when I get to the survey, I don't remember if I did this or that. It just made me remember what I am doing more, like how—how much I am drinking or using and just makes me more observant and self-aware, I guess, of what I have been using.* [Interview Participant 9]

Although respondents stated they were more aware of their behaviors, this statement was followed by a denial that changes were made in their substance use patterns. This theme was not universally supported; an interviewed participant stated that they did reduce how much they drank because of the assessments (Interview Participant 5).

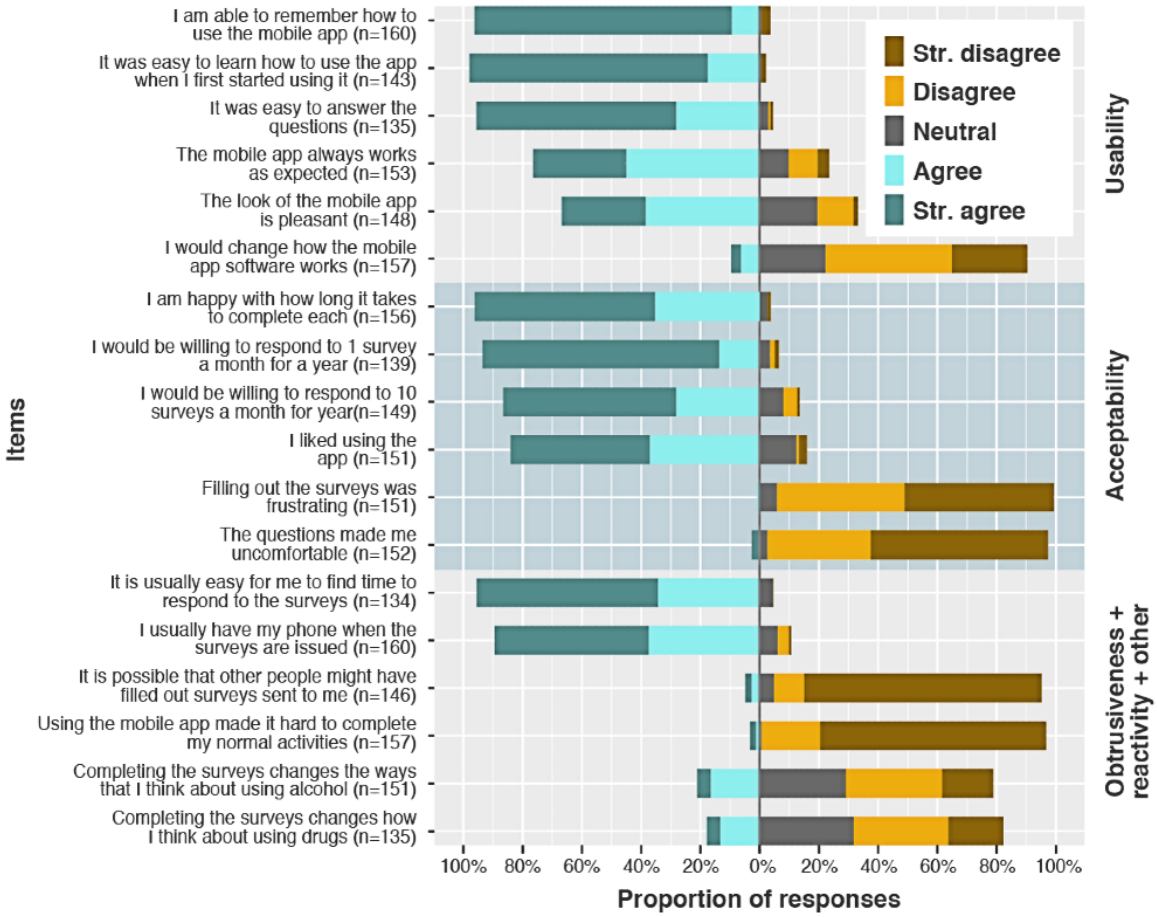
Mobile App–Related Attitudes, Perceptions, and Beliefs

Pooled estimates across age groups are presented in this section. With 2 exceptions, support for differences in response patterns among age groups was not evident (P>.08).

Usability

Most participants rated mNCANDA favorably on the dimensions of usability (Figure 6). More than 67% agreed to each of the positive items related to ease of use (Figure 6). By comparison, 9.6% (15/157) reported a desire for the app to be modified. However, only 3.2% (5/157) strongly agreed with this item. A minority (21/153, 13.7%) indicated that the app did not always work as expected.

Figure 6. Participant responses to the closed-answer questions about perceptions and attitudes related to the mobile National Consortium on Alcohol and Neurodevelopment in Adolescence software and assessment protocol usability, reactivity, and acceptability. mNCANDA: mobile National Consortium on Alcohol and Neurodevelopment in Adolescence.



The simplicity of the mNCANDA app was a theme in the qualitative data. However, multiple participants reported at least one time when the app crashed or glitched, and they were not able to submit or open the survey. A few participants had some suggestions regarding features to improve within the app, such as changing fonts and colors and adding a free-response item to allow for the elaboration of their responses. One of the interviewees stated, "I wish sometimes there was a button where I could explain maybe, like the circumstances of what was going on during that particular week" (Interview Participant 4). Interviewees expressed the recognition that some events may not be easy to categorize because they were unsure how the project administrators wanted unusual situations to be categorized.

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An item related to usability evidenced differential response patterns across age classes assessed, “It was easy to answer the questions” (Fisher exact test, *P*=.03). Very few respondents disagreed with this statement at any age. The difference driving this finding was a greater proportion of 18-to-20-year-olds strongly agreeing (26/32, 79%) rather than agreeing (4/32, 10%). In the other age classes, the ratio of strongly agreeing to agreeing was 2:1.

Acceptability

Most (64/76, 84%) of the participants agreed to the positive acceptability items, including liking the app and willingness to continue with the app for another year (Figure 6). The proportion of participants strongly agreeing to another year of assessments did drop from 80% to 58% when participants were asked about reporting on 1 assessment a month compared with 10 surveys a month. Almost all participants (96%) agreed that they were happy with the length of time that the assessments took to complete.

In addition to the brevity theme, ease of use also emerged as a strong theme in the qualitative interviews. Participants attributed the brevity and ease of answering questions as aspects that increased their willingness to respond to the weekly mobile app assessment on a long-term basis. When asked what it would take for participants to continue using the app, participants stated:

> *honestly, I think what you guys are doing right now is perfect... It has been super easy and... like it isn’t taking time out of my day.* [Interview Participant 6]

> *I do like... how it is set up as is honestly... it seems easy to scroll down and navigate... I think if it stays more or less as is with the notifications and weekly assessments, I think I would be participating moving forward.* [Interview Participant 2]

Obtrusiveness

Almost all (129/134, 96.3%) participants strongly agreed that they could easily find time to complete the assessments. Only 1.9% (3/157) reported that they strongly agreed that the assessment protocol interfered with their normal activities.

Scheduling of Assessments

There were differences by age in responses to the item on the desire to change the days of the week on which assessments were scheduled (Fisher exact test, *P*=.02). For all age classes, few (<8%) participants reported a desire to change the scheduled days; however, differences in the rate of neutral reporting were apparent. The main difference across age was dominated by the large proportion (16/32, 50%) of participants under 21 years, indicating a neutral position on this item, whereas those over 21 years were uncertain only 27% (24/89) of the time. Those aged above 21 years were more likely to report agreeableness with the assessment days than the younger participants (63/89, 71% vs 15/32, 47%).

Item Clarity

Most (70%) participants reported understanding the items as they were presented (Figure 7). Only a minority (17%) reported that they would change some of the questions.

Regarding item clarity, 2 themes emerged in the qualitative data: reference period and relevance. Several participants were unclear if behaviors that occurred on the same day an assessment was issued should be included in the reference period for the behaviors being assessed. The item prompts participants to report behaviors that occurred during the previous 7 days, for example. Another theme was relevance. Participants felt unsure about how to respond to items that were not relevant to their own lives. The examples provided were questions about work and school, which were not seen as relevant to participants not working or not in school, respectively. Certain assessment items were also identified as being difficult for the participants to understand, with a common focus on the items asking participants to identify their social networks. Participants reported that this might be construed in various ways.

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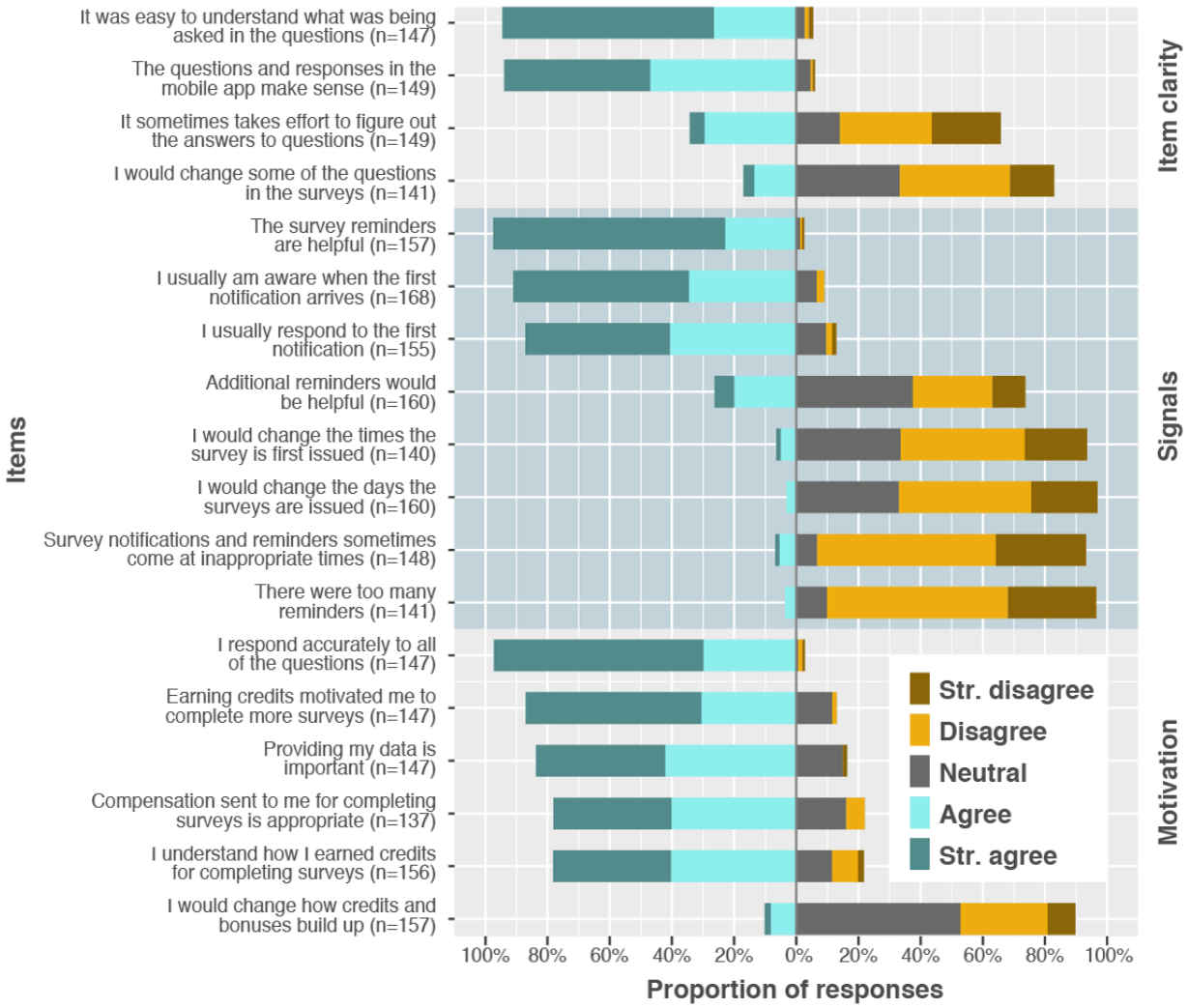
Figure 7. Participant responses to the closed-answer questions about perceptions and attitudes related to the mobile National Consortium on Alcohol and Neurodevelopment in Adolescence item clarity, signals, and motivation to participate. mNCANDA: mobile National Consortium on Alcohol and Neurodevelopment in Adolescence.



Signals and Motivation

Most (152/157, 96.8%) participants strongly agreed that reminder signals were helpful (Figure 7). Very few (6/141, 4.3%) participants indicated that there were too many reminders. There were also patterns of responses across reminder-related items, indicating that most participants were not distressed by the reminder regime (Figure 7). The patterns of responses to items related to motivation indicated that participants responded accurately and attributed the incentive system to at least some of their motivation to complete the surveys (Figure 7).

The qualitative interviews revealed substantial diversity in preference for the timing, form, and nature of the reminder notifications. A participant stated, “I like that they are sent pretty early in the morning...” (Interview Participant 2). Another stated, “I would say that I like noon-ish” (Interview Participant 8). Some participants claimed, “...the text message is most effective...” (Interview Participant 5). Others stated that they liked the app notification “because from there you can automatically click it and go to the app” (Interview Participant 8). A theme that arose in most of the interviews was the desire for the app to issue a final reminder near the end of the reporting window when they had not already responded. For example, a participant suggested, “having second notifications... to remind you... probably like 30 minutes to the deadline” (Interview Participant 6). When interviewees were asked if the number of notifications was intrusive, none thought that they were.

Suggested Improvements for the mNCANDA App

The qualitative data included several themes related to areas for improvement. A strong theme about the system not needing improvement dominated the self-administered open-ended responses. Some respondents suggested changes. One of them was to limit the reference period for behavioral items to the previous week by eliminating items referring to the previous month. Respondents explained that they had more confidence and found it easier to report the previous week’s behaviors. Several respondents asked that the response format be based on a calendar or have it formatted with the date so that individual events could be used to cue and record their activities. A theme

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of user tailoring arose, where users' ability to adjust the timing of survey notifications was seen as a potential benefit to the project.

Discussion

Participant Engagement

Mobile app assessment of substance use has been found to be a highly feasible and valid method among various clinical and nonclinical adult populations [6,7,36-38]. This includes a diverse collection of apps used for alcohol interventions with youth [6,39]. However, these are often of shorter duration (weeks to months) and are aimed at a targeted population seeking assistance [6,7]. Nevertheless, the retention of participants at 80% or higher is inconsistently attained, and response rates exceeding 80% in studies extending beyond a month were not identified [7]. To date, there has been limited research on continuous long-term mobile assessment for substance use among community adolescents and young adults. This population is particularly susceptible to problematic substance use, including high rates of use and substance use–related socioemotional harm [40]. Furthermore, previous studies have used a burst-design methodology, assessing real-time substance use among adolescents and young adults for a short period, usually less than 1 month over longer follow-up [2,8,9,41-43]. Our findings build upon this body of previous work by demonstrating feasibility, acceptability, and validity of smartphone-based measurement of substance use among American community youth 5 times per month over an extended period (eg, up to 18 months).

Impressively, adherence to the assessment protocol throughout the study was, on average, 82%, with 61% (326/534) of the participants responding to at least 90% of the assessments. There was no evidence of bias because of nonresponse over time associated with age. Contrary to our hypotheses, mNCANDA response rates did not decline throughout the extended follow-up. These findings support the use of frequent (eg, weekly), continuous smartphone-based mobile assessment in longitudinal studies of substance use in this high-risk age group. The fine-scale temporal characterization of substance use behaviors can help elucidate differential short- and long-term patterns of use and contextual factors impacting use behaviors over time, with minimal burden to the participant. This is particularly valuable during this developmental period, where substance use is known to fluctuate [2,11]. Low burden measurement approaches, such as mNCANDA, could provide a feasible means to increase the number of longitudinal studies that collect temporally fine-scale behavior data. With the app, the quality of estimated substance exposures over the total course of youth development is expected to be improved; it is expected that respondents will be more likely to enumerate substance use events that are present as salient and retrievable memories, reducing recall biases.

Alcohol consumption assessed in community samples is differentially underreported, particularly by those with lower consumption levels [44,45]. Protocols that allow adjustments to longer reference period reports of drinking frequency based on very recent (yesterday) recall are capable of reducing discrepancies between objective measures (eg, biomarkers) and self-reports [45]. Here, the mNCANDA protocol includes overlapping moderate (last month) and short (each of the last 7 days) reference periods. These reference periods should both reduce bias compared with yearly assessments and provide a fine-scale characterization of youth substance use.

Acceptability and Engagement

This study's high rates of engagement in terms of total participation and response rates are attributable to several factors. First is the simplicity and brevity of the assessments. Only a small number of simple items were presented at a time to the respondent. Most participants found the overall mNCANDA assessment length (~1 min to complete) acceptable. In addition, the user interface was designed to push the user along with a minimum number of user actions. Questions were rotated randomly, which guarded against monotony. Participants were also given an entire day to report; 3 reminders were sent via multiple modes, which was deemed acceptable by most users. The mNCANDA app was designed to reinforce participation by tying survey completion to an animation that appeared upon survey submission (ie, tokens filling the screen) and by providing compensation every 8 weeks (up to US $35) to demonstrate the value of their participation in the project goals. Taking all the mNCANDA app features together, most participants reported they liked the app, which contributed to high completion rates. The high response rates in the mNCANDA study were similar among adolescents, emerging adults, and young adults and maintained through the 18-month follow-up.

The mNCANDA sample was ascertained from a pool of participants who had already participated in a longitudinal study for several years. Retained participants have already invested in the project and may not be representative of the general population. Although the NCANDA participant pool is representative of the catchment areas near each of the study sites on most major demographic dimensions, the participants' parents' education levels are high (53% with at least one parent with education beyond an undergraduate degree) [12]. All participants in the study possessed their own smartphone, which is approaching universal adoption for adolescents [10]. However, adolescents are also exposed to developmental stage-related barriers in phone use, such as temporary parental confiscation of their mobile phone, which can affect timely assessment completion. In addition, the prevalence of smartphones among adolescents is lower in households with lower incomes and educational attainment [10]. In previous studies, access to a mobile device and reliable internet connectivity has been a barrier for some participants [5,46]. In a text messaging–based study, access to unlimited texting and data plans was associated with greater responding among youth from a resource-limited community [3]. A way to address this gap could be by providing rapid cost recovery to participants, which might help make engagement in the research project more equitable. The use of a mobile app that requires low bandwidth, such as mNCANDA, can further alleviate this issue.

Most participants endorsed responses that indicated acceptability of the mNCANDA app and protocol, indicating that they would

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be willing to continue for another year. Very few participants reported being frustrated by the app, even though over 10% reported that the app did not always work as expected, and there were 2 bugs that impacted all app users. The most troubling bug blocked users from downloading an assessment even after having been signaled repeatedly that the assessment was due. In the qualitative assessment, some participants mentioned mobile app glitches as a concern but remained forgiving of the frustrations. When users register for mNCANDA, they are informed that it is an in-house app that is still under development and provided with a way to report bugs.

Attrition and low engagement are general challenges for health-related mobile apps [47]. Usability issues are thought to be gatekeeping barriers to engagement [48]. There is a danger of overengineering and neglecting user preferences and needs [47]. Adoption of formal iterative development cycles can reduce the risks of unexpected usability barriers and optimize acceptability [49,50]. An example of iterated development was reported by Huguet et al [36]. mNCANDA was similarly developed with several development cycles punctuated by quantitative and qualitative feedback. The mNCANDA process used 4 evaluation methods and 2 approaches outlined by Moumane et al [51] to iterate to a version that is highly usable and acceptable. Usability is not a core focus of many research reports about mobile apps related to mental health [52], and many do not include or report the qualitative findings that are critical to guiding the iterations. Qualitative responses have been important in guiding the development of other mobile apps, and reporting of the related qualitative results provides useful lessons for designing future apps [36,46].

Validity and Reliability

The respondents also demonstrated that they were attentive to providing reliable and valid responses. First, very few participants indicated that another person might have completed any of the surveys (there is currently no authentication step as a trade-off for simplicity and speed). The test-retest concordance was extremely high for self-reporting. This demonstrates that the mNCANDA system (ie, the user interface, item construction, and protocols) itself is constructed to promote reliable response entry, elicit attentive responding, and consistency. An additional factor that could explain the response patterns is that the app is being used in the NCANDA project context, which has focused on supporting its participants' interest in maintaining scientific contributions and developing trusted partnerships. The concurrent validity of the mNCANDA responses was also found to be favorable when gauged against the standardized CDDR interview administered as a semistructured substance use assessment [25]. Although there was some variability, respondents provided comparable substance use reports between the 2 measurement techniques, particularly at the extremes, where formulating a response may be easier. Where there were deviations between the reports, they tended to favor greater reporting of substance use using mNCANDA. Although self-administration of substance use assessments has been found to result in greater disclosure [53], this was not expected for the NCANDA project. Social desirability biases are thought to be ameliorated in NCANDA, as participants are specifically enrolled in a substance use study where they are repeatedly asked about recent and lifetime substance use by professional research staff who interview participants regarding the details of their substance use. Overall, repeat testing and concurrent validity for the mNCANDA app were favorable.

Reactivity

Evidence of substantial reactivity to the mNCANDA app measurements was absent. Substance use trends were steady when compared with the period before mNCANDA protocol initiation. Few participants reported conscious changes in their substance use behaviors that they attributed to the repeated self-report measures. Of those who reported that they reflected more about their substance use, there were no detectable changes in substance use after starting to respond to mNCANDA assessments. In a randomized study, Buu et al [54] found reactivity to a long-term repeated assessment of recent substance use was limited to the first week of monitoring, where the frequency of alcohol use increased but quantity decreased. In contrast, self-monitoring is a mechanism leveraged by substance use interventions [55,56]. However, NCANDA is not based on a clinical sample. Substance use is primarily treated as an exposure in the primary aims of the NCANDA project, so reactivity is of a lower concern than it would be in other research contexts. However, the use of mNCANDA increased exposure to harmful levels of substance use, an evaluation of the ethics of continuing to use the app would be warranted. The findings have implications for other youth substance use researchers. Some caution should be exercised when considering the frequent long-term assessment of youth based on the current data because this study is sensitive only to gross changes in substance use frequency. Furthermore, other features of a person's pattern of substance use may have been altered without being detected.

Participant Feedback

The mNCANDA participants provided numerous suggestions for ways to improve the system. Many of the isolated suggestions are being considered for incorporation into the future evolution of the app. Those that formed emergent themes include the request for tailoring the notification-reminder timing for each user. Ensuring that notifications arrive at opportune times rather than during contexts where it would be obtrusive would be a valuable enhancement to long-term assessment. For example, some users indicated that assessment signals arrived when they had been on duty at work, which is most relevant for young adults. In addition, to diminish nonresponse because of oversight, the suggestion to add a final notification near the close of the response window has been incorporated into the system. Allowing individuals to tailor their notification schedule could allow optimal timing of reminders while limiting obtrusiveness; negative affective reactions can be ameliorated by providing the user with greater control of the reminder signals. In the study reported by Huguet et al [36], approximately 40% of participants personalized the times at which they received their signals.

The nonrelevance of items was another theme; 2 approaches were incorporated into the mNCANDA protocol to address participant concern about receiving items that are not relevant for them. The first is item tailoring. For instance, substance naïve respondents do not receive regular assessments of their

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day-to-day substance use as part of the weekly assessments. Most of the items subject to nonrelevance concerns will continue to be issued, but with more regular reminders, a valid response can be provided for all items by all responders. For instance, users who do not have a job can respond that they have worked 0 h in the previous week. Some of our respondents did not recognize a report of 0 h as being an appropriate response, which may be an undetected issue in other behavior studies on North American youth.

Additions to the protocol would need to be balanced against risks to the brevity of the assessments, which was among the strongest themes in the qualitative responses. Applying an additional layer of adaptive sampling could provide a global solution to this issue and the suggestion that substance use assessment be restricted to the past week. Respondents who regularly report high-frequency substances across weekly assessments could be issued additional weekly assessments that allow for continuous temporal coverage in lieu of the core assessments. Currently, core assessments are required to ensure that data are available to provide a continuous temporal characterization of substance use. However, further work would need to be conducted to allow for adjustments to be made because of differential measurement errors that could arise from a system where respondents are reporting at different frequencies. Development, amendments, and mobile app protocols should be made considering respondent burdens and changes to the mean square error of estimation (ie, bias and variance).

Conclusions

Longitudinal studies of health behaviors among youth can be enhanced by using frequent self-reports administered on mobile phones. Youth will elect to participate and adhere to the assessment protocol at a high rate. However, it remains unclear as to how much variation will be observed in various subpopulations, especially in contexts where participants may not feel invested in the study. mNCANDA's acceptability and high retention rate over a relatively long study duration for substance use and health behavior assessment app are based on brief and simple assessments, issued on a platform designed to minimize burden in responding, which incorporates reinforcement components into the app and the protocol. This app could serve an important role in filling gaps in understanding the critical developmental trajectories of substance use.

Acknowledgments

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Conflicts of Interest

RM is a cofounder of KeyWise AI, Inc, and a consultant for NeuroUX. The terms of this arrangement have been reviewed and approved by the University of California San Diego in accordance with its conflicts of interest policies. All other authors have no conflicts to declare.

Multimedia Appendix 1
Mobile National Consortium on Alcohol and Neurodevelopment in Adolescence assessment items.
[DOCX File , 28 KB - mhealth_v9i2e24472_app1.docx]

Multimedia Appendix 2
Qualitative instruments.
[DOCX File , 17 KB - mhealth_v9i2e24472_app2.docx]

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Abbreviations

CDDR: Customary Drinking and Drug Record
GEE: generalized estimating equation
mNCANDA: mobile National Consortium on Alcohol and Neurodevelopment in Adolescence
NCANDA: National Consortium on Alcohol and Neurodevelopment in Adolescence

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Original Paper

Investigator Experiences Using Mobile Technologies in Clinical Research: Qualitative Descriptive Study

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Abstract

Background: The successful adoption of mobile technology for use in clinical trials relies on positive reception from key stakeholders, including clinical investigators; however, little information is known about the perspectives of investigators using mobile technologies in clinical trials.

Objective: The aim of this study was to seek investigators' insights on the advantages and challenges of mobile clinical trials (MCTs); site-level budgetary, training, and other support needs necessary to adequately prepare for and implement MCTs; and the advantages and disadvantages for trial participants using mobile technologies in clinical trials.

Methods: Using a qualitative descriptive study design, we conducted in-depth interviews with investigators involved in the conduct of MCTs. Data were analyzed using applied thematic analysis.

Results: We interviewed 12 investigators who represented a wide variety of clinical specialties and reported using a wide range of mobile technologies. Investigators most commonly cited 3 advantages of MCTs over traditional clinical trials: more streamlined study operations, remote data capture, and improvement in the quality of studies and data collected. Investigators also reported that MCTs can be designed around the convenience of trial participants, and individuals may be more willing to participate in MCTs because they can take part from their homes. In addition, investigators recognized that MCTs can also involve additional burden for participants and described that operational challenges, technology adoption barriers, uncertainties about data quality, and time burden made MCTs more challenging than traditional clinical trials. Investigators stressed that additional training and dedicated staff effort may be needed to select a particular technology for use in a trial, helping trial participants learn and use the technology, and for staff troubleshooting the technology. Investigators also expressed that sharing data collected in real time with investigators and trial participants is an important aspect of MCTs that warrants consideration and potentially additional training and education.

Conclusions: Investigator perspectives can inform the use of mobile technologies in future clinical trials by proactively identifying and addressing potential challenges.

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KEYWORDS

mHealth; mobile technology; mobile clinical trials; digital health; clinical research; mobile devices; digital health technology; mobile applications; clinical trial

Introduction

Digital Health Technologies in Health Care

Health care systems are increasingly using digital health technologies, such as smartphones, tablets, notebook computers, watches, other wearables, and mobile device apps for collecting health data and delivering health care–related services. The use of such technologies, also referred to as mobile technologies, is associated with improved outcomes for many patients [1-6]. For example, smartphone apps have facilitated diet tracking and led to significantly greater weight loss [7], and a game-based module has improved drug adherence, resulting in lower rates of side effects from chemotherapy among patients with breast cancer [8]. As health care systems continue to adopt digital health technologies in the provision of patient care, there is promise of improvement in the delivery of health services to patients in the future.

Digital Health Technologies in Clinical Research

Digital health technologies can also be incorporated into clinical research to potentially improve efficiency, data quality, and data collection. A clear sign of the oncoming shift toward this type of technology comes from the US FDA (Food and Drug Administration), which revised its guidance on software and mobile health (mHealth) technology to encourage innovation in the area of digital health technologies [9]. Although the promise of this technology is garnering enthusiasm from investigators studying issues such as rare diseases [10], high blood pressure [11], and medication adherence [12], information is sparse on how site investigators feel about the potential value and challenges of embedding digital health technologies within clinical trials. Most of the current literature focuses on the acceptability of mHealth apps and the preferences of clinicians and patients for certain features of mobile technologies for specific types of patients [13-15]; for example, the assessment of preferences for an mHealth app to support patients with chronic arthritis [16].

Study Objectives

Recognizing a gap in the evidence base regarding site investigator preferences and barriers, the Clinical Trials Transformation Initiative (CTTI) assessed patient and site investigator perspectives on the use of digital health technologies in clinical research (referred to as mobile technologies at the time of study implementation). CTTI previously published survey findings on trial participant preferences on mobile technologies [17]. Here, we describe site investigator preferences on such technologies. We focused on the following: (1) site investigators' insights on the advantages and challenges of mobile clinical trials (MCTs); (2) site-level budgetary, training, and other support needs necessary to adequately prepare for and implement MCTs; (3) site investigators' insights regarding the advantages and challenges for participants; and (4) suggestions for addressing challenges. We hope that these data will inform the use of digital health technologies in clinical trials for future investigators, particularly to inform investigators' expectations and planning efforts and clinical research sponsors' understanding of the challenges investigators face at the site level.

Methods

CTTI

CTTI is a public-private partnership cofounded by Duke University and the US FDA that seeks to develop and drive adoption of practices to increase the quality and efficiency of clinical trials. CTTI has led several projects on the use of digital health technologies in clinical research [18].

Design and Methods

We conducted a qualitative, descriptive study [19,20] using in-depth interviews with investigators involved in the conduct of MCTs from June 8 to October 11, 2017. Interviews were conducted over the telephone by trained interviewers and were digitally audio recorded with the investigator's permission.

Investigator Selection and Recruitment

We purposefully sampled investigators [21] for participation in this study. They must have had experience in conducting clinical research in the United States (eg, pilot studies, observational studies, phase I-III studies, postmarketing studies, and feasibility studies) that used mobile technology. We did not focus on sampling specific types of mobile technologies; however, investigators must have used the technology to collect data versus for study procedures (eg, for recruitment, retention, or informed consent) or to collect patient-reported data only (eg, accessing internet-based surveys).

Multiple strategies were used to purposefully recruit investigators. First, we contacted sponsors and investigators of MCTs who had previously participated in CTTI interviews on the use of mobile technologies in clinical trials (and who had given permission to be recontacted for CTTI research and projects) and asked if they would be willing to identify site investigators (whom we would then invite for interview participation) or to pass along information about our study to appropriate site investigators. Second, we searched the National Institutes of Health database of privately and publicly funded clinical studies and identified investigators of trials that used mobile technologies. Third, we reviewed articles identified by a CTTI-sponsored systematic review of studies that used mobile technologies to measure clinical endpoints [22] to identify investigators. Finally, the CTTI Mobile Clinical Trials Engaging Patients and Sites project team identified investigators from within their professional networks. Study staff reached out directly to these investigators to screen them for eligibility and, if eligible, to invite them to participate in an interview.

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Data Collection

Demographic information was collected at the beginning of the interview. We explored a range of topics during the interview, including (1) investigators' perceptions of the advantages and disadvantages of MCTs compared with traditional clinical trials for both trial investigators and trial participants and the impact of these advantages and disadvantages on clinical trial activities; (2) how to overcome any disadvantages of using mobile technologies in clinical trials; (3) site support and implementation needs, including budgetary requirements and relevant training for both study staff and trial participants; (4) experiences with investigator and trial participant access to study data; (5) additional Institutional Review Board (IRB) requirements and concerns when using mobile technologies in clinical trials; and (6) guidance for other investigators interested in conducting MCTs. We did not explore perspectives on MCT study designs, the use of mobile technologies for potential participant recruitment or consent, or the incorporation of mobile technologies to enhance patient-reported outcomes.

Data Analysis

We used descriptive statistics to summarize the demographic data and applied thematic analysis [23] to analyze investigators' narratives. All interviews were first transcribed verbatim following a standardized transcription protocol [24]. Investigators' narratives were analyzed using a 2-stage deductive and inductive analysis approach. First, 2 analysts applied deductive structural codes (based on interview topics and organized by research objectives), such as *advantages of MCTs* and *disadvantages of MCTs*, using NVivo 11 [25]. Intercoder agreement was assessed for 25% (3/12) of the transcripts. Any discrepancies in code application were resolved through group discussion; edits were subsequently made to the codebook so that it could be used in the coding of future transcripts, and previously coded transcripts were recoded based on the modified codebook. Second, after the initial deductive coding was complete, coding reports were generated and reviewed by analysts to identify emergent themes; these themes were subsequently coded using NVivo 11 using content codes such as *greater study-related burden on participants* and *challenges of real-time data access for participants*. Summary reports of the content codes were generated and reviewed by analysts. After discussions with analysts, potential themes and the nuances of each theme were examined, and final themes and subthemes were identified based on their salience. Analysts wrote analytical summary reports to describe all themes and subthemes, together with illustrative quotes.

Ethics

The Duke University Health System IRB determined that the research met the requirements for exemption from further IRB review. All investigators received an informational sheet before study participation that explained the study in detail, including its purpose, risks, and benefits.

Results

Study Population

We interviewed 12 site investigators who were diverse in clinical specialties, affiliations, types of clinical trials conducted, and years of experience in conducting both traditional and MCTs. Half of the investigators (6/12, 50%) had experience with observational studies using mobile technologies, whereas more than half (8/12, 67%) had also conducted Phase III trials using mobile technologies (both registrational and nonregistrational). A high percentage of investigators had experience in conducting device acceptability and/or feasibility studies (9/12, 75%) and device validation studies (8/12, 67%; Table 1). In addition, 6 investigators had conducted both industry-funded and investigator-initiated clinical research, 5 had conducted only industry-funded research, and 1 had conducted only investigator-initiated research.

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Table 1. Investigator demographics (N=12).

Demographics	Values, n (%)
Clinical specialty	
Cardiology	2 (15)
Hematology	2 (15)
Psychiatry	2 (15)
Endocrinology	1 (8)
Family medicine	1 (8)
Internal medicine	1 (8)
Internal medicine and gastroenterology	1 (8)
Immunology	1 (8)
Neurology	1 (8)
Oncology	1 (8)
Pharmacy	1 (8)
Affiliation	
Academic institution	7 (58)
Dedicated research site	2 (17)
Other[a]	3 (25)
Years of experience with traditional clinical research	
1-10	5 (42)
11-20	3 (25)
21-30	4 (33)
Types of traditional clinical research[b]	
Phase I	7 (58)
Phase IIa or IIb	9 (75)
Phase III (nonregistrational)	8 (67)
Phase III (registrational)	8 (67)
Observational studies	9 (75)
Other[c]	5 (42)
Years of experience with mobile clinical research	
1-5	6 (50)
6-10	5 (42)
>10	1 (8)
Types of mobile clinical research	
Phase I	4 (33)
Phase IIa or IIb	3 (25)
Phase III (registrational)	6 (50)
Phase III (not registrational)	6 (50)
Observational studies	6 (50)
Device feasibility or acceptability studies	9 (75)
Device validation studies	8 (67)

[a]Investigators reported affiliations with a clinical trial start-up, clinical practice and research entity, and a community-based large multispecialty clinic.
[b]Investigators reported all that applied.

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[c]Investigators reported experience with Phase IV trials, embedded qualitative research, telemedicine, patient registries, and interventional trials in addition to at least one other type of research listed.

Investigators had experience using a wide range of mobile technologies in clinical research. The most frequently reported technologies were continuous glucose monitors (3/12, 25%) and activity or sleep monitors (3/12, 25%). A variety of endpoints were also described. The most frequently reported endpoints were medication compliance (3/12, 25%) and blood sugar levels (3/12, 25%; Table 2).

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Table 2. Investigators' use of technology: type, endpoint, and therapeutic area of investigation (N=12).

Use of technology	Values, n (%)
Type[a]	
Mobile app[b]	7 (58)
Commercial grade activity and sleep monitor	3 (25)
Continuous glucose monitor	3 (25)
ePRO[c] device[d]	3 (25)
Electronic pill bottle	2 (17)
Ingestible sensor with patch	2 (17)
Ambulatory blood pressure monitor	1 (8)
Holter monitor	1 (8)
Implantable cardioverter defibrillator	1 (8)
Mobile spirometer	1 (8)
Tablet-based video monitor	1 (8)
Wearable EKG[e] patch	1 (8)
Wireless weight scale	1 (8)
Endpoint[f]	
Blood sugar	3 (25)
Medication compliance	3 (25)
Blood pressure	2 (17)
Change in heart rate	2 (17)
Heart rhythm	2 (17)
PRO[g]	2 (17)
Steps or activity level	2 (17)
Change in aerobic capacity	1 (8)
Pulmonary artery pressure	1 (8)
Ratio of insulin and glucagon levels	1 (8)
Sleep quality	1 (8)
Spirometry	1 (8)
Visual acuity	1 (8)
Weight	1 (8)
Therapeutic area	
Cardiology	4 (33)
Neurology	4 (33)
Diabetes	3 (25)
Hemophilia	1 (8)
Impact of energy drinks (measure of activity and sleep)	1 (8)
Ophthalmology	1 (8)
Oncology (undergoing chemotherapy)	1 (8)
Pulmonology	1 (8)

[a]Investigators reported all types of mobile technology they used in any of their clinical research studies.

[b]Investigators reported using mobile apps either as a data collection tool or as a hub to receive and send data from a linked mobile device in addition to at least one other listed technology (not including ePRO).

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[c]ePRO: electronic patient-reported outcome.

[d]Investigators reported using patient-reported outcome data in addition to at least one other listed technology (not including mobile apps).

[e]EKG: electrocardiogram.

[f]Investigators reported all study endpoints measured using a mobile technology.

[g]PRO: patient-reported outcome.

Site Investigator Insights on the Advantages and Challenges of MCTs

General Advantages of MCTs Compared With Traditional Trials

Investigators most commonly cited 3 advantages of MCTs compared with traditional clinical trials: (1) more streamlined study operations, including data collection; (2) remote data capture; and (3) improvement in quality of studies and data collected (Table 3).

Table 3. General advantages of mobile clinical trials.

Advantages	Participant examples and descriptions	Participant quotes
More streamlined, simpler study operations and data collection	• More efficient to do continuous follow-up remotely than episodic follow-up in clinic • Less costly to conduct (fewer clinic visits and fewer research coordinators) • Easier to manage more trial participants	• "Typically with traditional clinical trials there is a schedule of in-clinic follow-up, and there are windows within which patients fall in or out of if you get them back at the right time or not. And, it's just a lot more efficient when you can do a lot of this follow-up on a remote basis because it ensures, in many ways, a more continuous follow-up rather than this episodic follow-up. And, makes it easier to get key endpoints assessed within a follow-up window, without the reliance on having patients travel sometimes great distances to get in for a clinic follow-up."
Remote data capture	• Easier to collect a higher volume of data because not restricted to data collection snapshots during clinic visits • Continuous or higher frequency data collection provide more accurate account of trial participants' experiences • Remote monitoring decreases burden on trial participants • Provides greater insights into trial participants' experiences because of real-world data • Can include more endpoints because of higher volume of data	• "Mobile devices can make it easier. They can serve as a really good, valid substitute of what could otherwise be a very cumbersome process. For instance, doing an ambulatory blood pressure monitor, where it's being checked like every 15 minutes for a 24-hour period. It's a little easier than having a patient put their arm in a cuff manually every 15 minutes, right, and checking it. So there are times when your only valid option, the only rational option, is to use a mobile device."
Improvement in quality of studies and data collected	• Designed around trial participants rather than researchers or research sites, which increases the likelihood of generating more applicable real-world study results • Potential to provide better, more objective, higher frequency, and possibly more sensitive assessments of trial participants than traditional trials • Enhanced data quality because of higher frequency data points, less reliance on activity logs • Enhanced ability to deliver quality data—particularly compliance data—to sponsors, which may make it more likely that sponsors will come back to the research site with additional studies • Minimizes geography barrier, which can enhance diversity of participant sample	• "It's easier to make decisions because I've got better quality data. The statistical analysis on the trial should be superior because we've got higher-level data. We're having to throw out fewer data points because of subjective reasons where you're looking at a piece of data and saying, 'That can't possibly be accurate,' but you've got an increased accuracy with the mobile data collection. So there are things like that that make running the research trial easier because of the mobile data collection. But it's more in being able to trust the data and in your analysis of the data."

Investigator-Specific Advantages of MCTs Compared With Traditional Trials

All 12 investigators spoke about their willingness to lead another MCT, with many stating that they believe MCTs are the future of clinical trials. Almost all of these investigators tied their willingness to participate in future MCTs to the perceived benefits of these trials compared with traditional clinical trials, particularly the investigator's role in responding to remote data capture and improvements in the efficiencies of study procedures (Table 4).

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Table 4. Investigator-specific advantages of mobile clinical trials.

Advantages	Participant examples and descriptions	Participant quotes
Remote data capture	• Ability to intervene (ie, communicate with) with trial participants as needed based on real-time data • Enhanced monitoring of trial participants' compliance to study procedures • Better systems for notifications and reminders to enhance compliance • Easier to conduct assessments and make protocol-based management decisions remotely	• "It's of tremendous importance because we are dealing in real-time versus a month later or six months later. And if you see something that's not right you can intervene immediately and take care of it." • "We can do small things to help patients perform better in the study. So we can do things like we use push notifications and reminders as well and so that patients, if they don't do an activity for a day, then they can get a push notification on their study device saying, 'Don't forget to track your symptoms today'... or if they forget to wear a watch overnight to track their sleep, the next morning, we can remind them to wear their watch the next day."
Improvement in efficiency of study procedures	• Ability to more objectively monitor compliance with study procedures and medication adherence • Real-time access to data • Better management of trial participants because of continuous access to data	• "It's really essential because it's what [an investigator] is basing [a] treatment decision upon – having access to the information to do it.… so that they could implement the protocol driven medication changes based on change in pulmonary pressure."

Investigator-Specific Challenges of MCT Compared With Traditional Trials

Investigators reported that operational challenges, time burden, technology adoption barriers, and uncertainties about data quality made MCTs more challenging than a traditional clinical trial (Table 5).

Table 5. Investigator-specific challenges with mobile clinical trials.

Challenges	Participant examples and descriptions	Participant quotes
Operational challenges and time burden	• Additional time required to review higher volumes of data in real time • Additional study procedures necessary such as following up on missing data • Increased time needed for setting up technologies and linking devices to specific users • Large amount of time needed by site staff in maintaining technologies, such as charging and storing devices and troubleshooting problems with malfunctioning devices • Large amounts of data to be managed • Additional time needed for training on the use of various participant databases • Time often not reimbursed	• "Usually the beginning of the study we'll just get a protocol synopsis, so we won't get all of the information. And oftentimes we'll make a decision about whether we take a study on the basis of a protocol synopsis... It might sound like we're going to be collecting this information. And then when you find out how they're going to be collecting it, what type of device they're using, what the burden is on the staff, there can be moans and grunts at an investigator meeting."
Technology adoption barriers by both staff and trial participants	• Difficulties exist among trial participants in using some technologies (eg, feel and comfort of the device, complexity of the participant interface), which can impact compliance • Time needed to train staff and participants on how to use and troubleshoot the technology	• "[Devices] are complicated to use. They are not terribly user friendly... Research trials are harder and now you end up with a patient in a research trial and the device causes that patient to have to drop out of that trial."
Uncertainty about data quality	• Potential for new data biases exists when participants have access to their personal data • The real-world nature of trial is reduced when more study staff must intervene with trial participants to address data quality issues • The clinical meaningfulness of the data is questioned, including how much data should be collected to inform the outcome • Data variation making the analysis plans more complicated • Technical issues may compromise data quality (eg, wireless connectivity in rural areas)	• "[Not allowing participants access to their data is] a plus and a minus. I think you worry that if they see their own data, if it affects what they're doing and bias the studies. You might have people all of a sudden trying to get to a certain number of steps a day or behaving differently because they're monitoring their steps, and so [researchers] avoided that by not having the patients see their data. I think that created some obstacles because then you don't have any real-time confirmation that the data is being transmitted and also the patient doesn't feel like they're getting any benefit out of wearing it." • "Because of a device malfunction, that patient's data has to be thrown out, and that's just terribly unfortunate when that kind of a thing happens."

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Suggestions for Overcoming the Challenges With MCTs

All 12 investigators interviewed had concerns about added site burden in MCTs and made recommendations or observations about ways to minimize these concerns. The most common suggestion for sponsors was to establish and foster collaborative relationships with sites and investigators. One frequently recommended strategy for this was sponsor solicitation of input from sites and investigators about vendors and technology selection. A few investigators also recommended that sponsors provide complete information about the type of device and how technology will be used before any contractual agreements.

Many investigators mentioned the importance of being able to properly address challenges presented by the chosen technology. Investigators commented that appropriate device selection could help prevent challenges, that sponsors should compensate sites appropriately for added staff time involved in device training and troubleshooting, and that sponsor provision of an adequate number of surplus devices would help prevent issues with data loss in the face of device malfunction. In addition, a few investigators highlighted the importance of ensuring that investigators have a thorough understanding of the technology, with one specifying:

> *My recommendation to other investigators would be know your device, know all the nuances of the device...*

Many investigators have emphasized the importance of having systems in place to ensure data integrity when using mobile technologies. One investigator described monitoring data for outliers as a form of quality control on collected data:

> *We do have much more data coming in, so it is easier to sort of identify outliers. Right? So if we're using a wireless scale and every day, we get a measurement of 200 pounds plus or minus a couple of pounds and all of a sudden, we get a measurement of 80 pounds, you can sort of identify some of those outliers as well.*

Site-Level Budgetary, Training, and Other Support Needs

General Needs of MCTs

Technical support was the most frequently mentioned type of assistance needed when implementing a trial using mobile technologies. One investigator also spoke about the utility of technical support when technologies are used in trials in ways that were not initially intended by the manufacturers:

> *We need a lot of support, more so than usual... And typically, we're not using the devices exactly as intended, so for this ECG [electrocardiogram] patch, it's designed to put on in the hospital or in a clinic setting. And we were having the participants do it alone. You have to work with the manufacturers about the educational material, making sure technically it's going to work that way, and what's important and not. And I'd say with all of the manufacturers we've had to work with, it's required a real partnership, not just a vendor kind of, "We're just going to purchase this and use it" type of relationship.*

Budgetary support was also frequently mentioned. Several investigators indicated that they were not adequately prepared to plan for a trial involving mobile technologies from a budgetary perspective, specifically as it related to allotting appropriate funds for staff time required.

Suggestions for Technology Support From Sponsors

Many investigators have suggested that sponsors should provide technical support for activities such as initial setting up of technologies, monitoring of trial participants, data management, and ongoing troubleshooting of technologies. Several also described the need for sponsors to assist with technology-related issues, such as having a call center, or by providing a third-party vendor hired to troubleshoot device-related issues.

Device training was also mentioned by investigators as a provision that should be organized by the sponsor, as was device procurement. One investigator described the sponsor support he received with his MCTs:

> *The sponsors provided training on aspects of device functioning, and how to interrogate the device, and how to access the data through their usually secure web-based portals and so on and so forth. So they provided training on the system. And again, they generally have people in the field who provide troubleshooting; so if there is a problem with not being able to connect to the systems or some other issue, they usually have people in the field that can support the staff in terms of troubleshooting.*

A few investigators suggested that sponsors should conduct a technology assessment to ensure that the best technology is selected or provide more specific information about technologies to be used in the trial when available, such as any potential and past malfunctions and issues associated with devices. In addition, one investigator suggested that sponsors partner with more advanced commercial developers who could better ensure that trial participants would be optimally engaged when interfacing with devices.

A few investigators emphasized fit appropriateness for specific trial participant populations. For example, investigators described selecting technology that is most appropriate for older trial participants who might have less fine motor dexterity in the hands and offering support that was sensitive to the specific needs of certain populations. Another investigator mentioned that sponsors should provide more devices to sites that are historically adept at enrolling trial participants so that backup devices could be issued in the event of a device malfunction without causing any delay in data capture. An investigator said:

> *Things that we could do to have an immediate impact on the conduct of these trials, one, provide more of the devices to well-enrolling sites. If I have more devices and I have a patient with a tech support issue right now, I can swap out the device instantaneously and now take my time at getting this other device analyzed for tech support, but if that's the only device, then it's everyone's brow is sweating. "Are we losing data right now?" "How quickly can we get this fixed?" "The patient's getting upset." "I need to go*

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pick up my kids." So having more devices would absolutely help.

Finally, investigators stressed the importance of sponsors ensuring that technology support was easily accessible throughout the life of a trial, staffed by actual people, and centralized so that each site would not be individually responsible for troubleshooting when trial participants have challenges with technologies.

Suggestions for Budgeting

Many investigators recommended that researchers develop a clear and comprehensive budget that contains adequate compensation for the purchase and storage of devices and staff time spent in training and troubleshooting issues that may arise with technologies. Most of these investigators acknowledged challenges with budget planning, as unforeseen expenses were often mentioned as a common feature of clinical trials that involved mobile technologies. Many investigators recommended budgeting for staff time related to various mobile-specific trial activities, as this was the biggest additional expense when compared with traditional trials. They also recommended budgeting for costs directly related to procuring and managing technologies, including purchasing devices, device repair and storage, device rental, and setup fees associated with certain technologies. A few investigators specifically mentioned flexibility on behalf of sponsors as key to accommodating these types of trials, given how relatively new they are to clinical research. One investigator stated:

I do tend to underbudget because it's hard to take into account all of the eventualities that might occur, and the other thing is, it's hard to justify that. If you're trying to write a budget and you say we have this many hours of this many people, and so forth, and then you can say, in your own head, you can say I'm going to add 50 percent because it never goes as planned, and then it turns out you really should have doubled it. I think sponsors need to understand that... I know they're all focused on trying to get the biggest bang for their buck, but you don't want to underfund the study so that you leave it hobbled and struggling to meet its aims.

Additional Suggestions

Training

Almost all investigators spoke in depth about how to improve training for staff and trial participants. Some investigators suggested that sponsors should allocate more time to training to ensure that site staff are familiar and comfortable with the technologies that trial participants will use. Many mentioned the ideal role that sponsors play in the provision of comprehensive training on devices. One investigator described the various training sponsors had provided in previous trials, including how to share data collected from the device.

The study sponsors provided training on aspects of device functioning and how to integrate the device and how to access the data through their secure web-based portals. Investigators also recommended ways in which future site training on MCTs could be enhanced. Several investigators thought it would be beneficial for training to include more hands-on time with technologies and in-person teaching (vs web-based training). Some also recommended that training should provide device-specific materials that could be referenced throughout the life of the study, with ad hoc access to education and feedback mechanisms related to technology functionality. To enhance the efficiency of device training, some felt that web-based training should be self-paced and optional (vs required) and also indicated that training should be optional for technologies that sites were already familiar with. Investigators felt that training should cover strategies to address device malfunction, study monitoring of real-time data, and suggest ways to improve staff empathy for trial participants. Some also noted that training should aim to provide sponsors, investigators, and study staff with a thorough understanding of technologies before trial initiation.

IRB

Most investigators noted that although their IRBs did not raise any concerns regarding the use of mobile technologies in the research, several said sharing the following information with IRBs would be helpful: data security, including how trial participants will securely share data collected from their device with investigators; participant safety, including how actionable data shared by participants would be monitored by the study team; and certain types of documentation related to the technology, such as proof of investigational device exemption from the FDA (when appropriate).

Site Investigator Insights on the Advantages and Challenges for Trial Participants

Advantages to Trial Participants

Many investigators felt that MCTs can be built around the convenience of trial participants, rather than the investigator, and, therefore, can decrease the burden of trial participation. Investigators also posited that individuals may be more willing to participate in MCTs because they can participate from home, rather than have visits that are clinic based, as in traditional trials. Investigators pointed out that trial participants have direct access to data collected about them, which may enhance engagement throughout the life of a trial (Table 6).

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Table 6. Investigator perspectives on the advantages and challenges of mobile clinical trials for trial participants.

Advantages and challenges	Participant examples and descriptions	Participant quotes
Advantages		
Trial participant access to data	• Potential to drive participant engagement • Increases participant sense of agency • Improves management of disease or health condition	• "Frankly, it's the model of care that I think we should be moving to across the board because it improves patient engagement; it improves patient satisfaction; patients feel like they are regaining some control over their life or their disease."
Decreases burden on trial participants	• Reduces in-person screening • Fewer visits necessitated with remote monitoring	• "It becomes much less of a burden to them…instead of them having to come in at times where they otherwise wouldn't for routine care, or a follow up…all the monitoring, all the communications, everything can occur around their schedule, and at their home, where it's convenient for them."
Data capture and monitoring	• Automated notifications and reminders, thereby improving compliance • Real-time data monitoring allowing trial participants to be reached and receive interventions • Less intrusive for participants	• "That automated process is going to be easier for the patient in the long run... It would be pretty easy for us to show how to do a finger stick blood sugar and just tell the patient, 'You have to do this nine times. Before and after each meal, and then at least one random time.' That kind of thing. Or at least nine times a day... or we could put a continuous glucose monitor in them, which would take us probably half an hour. And [this is] harder for us, but much easier for them."
Challenges		
Additional burdens on trial participants	• Intrusiveness of data capture to daily activities • Technology management and upkeep needed (eg, charging devices) • Education about technology use needed • Additional burden could challenge recruitment and retention	• "It's one more thing they have to manage and either keep on their person or keep nearby. It can be disruptive. If they want to go out to the movies and they're scheduled to have something, some questionnaire that's going to be every night at 7:00 PM they might have to work their schedule around it. There has to be built in relays in these things to allow for patients to have some flexibility. And then any time you add complexity to the picture, it will make a patient less likely to want to do a study."
Technology adoption barriers	• Detrimental impact on participation, data quality, interest, and satisfaction because of cumbersome design and functionality of the technology • Can be difficult for some participants to follow device instructions • Can inhibit potential trial participants from joining the study or using the technology correctly after enrolled because of unfamiliarity with or concern about use (eg, geotracking features) • Can be invasive or uncomfortable	• "I think that if you have a participant who is, for whatever reason, frustrated with the device or having technical problems with the device, that person may actually become less engaged with the study or may even drop out of the study."
Real-time access to data possibly impacting the behaviors of trial participants	• Exposure to data may change the behavior of trial participants • Reactions to inaccurate data may adversely affect the behavior of trial participants (eg, noncompliance reported when the participant had previously been compliant) • Retention could be affected when data show no improvements to health • Trial participants may misinterpret the meaning of the data and could misuse the information in some way	• "I think that's a bit of a disadvantage because it may hinder their mood or their willingness to seek out additional care or continue on what they're doing if they don't see a change in their progression, if these mobile tools are giving them feedback."

Challenges for Trial Participants

Many investigators stated that MCTs pose additional burdens on trial participants (Table 6). Challenges included placing additional burdens on participants, barriers when interfacing with technology, and the potentially negative implications of trial participants being able to access data collected about themselves. Investigators noted that these additional burdens and challenges can lead to greater participant dropout or

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challenges for recruitment, particularly when trial participants are not motivated to accept this added burden.

Suggestions for Reducing the Trial Participant Burden

Nearly all investigators suggested identifying methods to decrease trial participant burden when taking part in MCTs. Investigators recommended that the technologies selected for use in the trial should be as user friendly as possible. One investigator said:

> *Ideally, you make the device and the trial as simple as possible so as little as possible of the burden of understanding the device and how to make it work is on the patient... They put it on, and they wear it, and that's their role.*

Several investigators suggested that all training for trial participants on the use of technologies should be participant centric. Two examples included avoiding assumptions about trial participant preferences and capabilities, and co-designing training with actual participants. Several investigators extended this concept of participant-centricity beyond training and expressed that MCT study designs overall should have a strong focus on being participant centered. For some, this meant patient involvement from the inception of the study and more access to trial developments and results.

In addition, investigators emphasized that device training for trial participants should instruct participants on not only how to use the device but also what type of information is being collected and the significance of that data to the trial being conducted.

Discussion

Principal Findings

We interviewed 12 investigators about the use of mobile technologies in clinical trials, and all the 12 were enthusiastic about the promise of these technologies, indicating their willingness to participate in other MCTs. Investigators described MCTs as the future of clinical research, and many advantages of using mobile technologies were identified, including benefits related to more streamlined study operations, remote data capture, and improvement in the quality of studies and collected data. However, challenges with MCTs were also described, including budgetary issues for both devices and staff time, time burdens for monitoring data and troubleshooting devices, and potential data quality issues and biases. Investigators frequently cited a need for technical support for using technologies in clinical trials and extra training and money in the budget to account for tech-related expenses. To enhance the success of MCTs, sponsors would benefit from establishing and fostering collaborative relationships with sites and investigators and soliciting input about vendors and technologies to be used.

Investigators believed that MCTs have the potential to decrease some types of burden (fewer site visits and remote monitoring) but will increase other types of burden (technology management and upkeep). Although access to real-time data could motivate and engage trial participants, concerns exist about the possibility of data misinterpretation or discouragement of use because of malfunctioning devices. Using simple, user-friendly technologies and providing training to participants is recommended.

Limitations

Although sample sizes with qualitative research are small, the experiences and lessons learned from investigators who have used mobile technologies in clinical research can nonetheless be used to help other investigators consider the use of and prepare for MCTs. Interviews with a different group of investigators could yield different or additional benefits, challenges, and recommendations. For example, investigators using different types of technologies that are more novel and used less frequently among patients and providers might lead to additional considerations and implications for MCTs. Future research should continue to explore and document investigator and participant experiences using mobile technologies in clinical trials.

Conclusions

The benefits of MCTs can best be realized if digital health technologies are used in a way that recognizes and addresses the day-to-day operational considerations at investigative sites. This is accomplished through stakeholder engagement, including site investigators, sponsors, and trial participants as equal partners, from the earliest stages of trial planning. Technology selection, instructing participants on how to use technology, troubleshooting of technologies by study staff, and sharing of information from technologies with investigators and participants are all important aspects of MCTs and may require additional dedicated effort, budgetary considerations, and training. The lessons identified in this paper helped inform CTTI recommendations on the use of digital health technologies in clinical research [26]. These recommendations can help both investigators and clinical research sponsors to proactively identify potential challenges and conduct high-quality MCTs.

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Conflicts of Interest

None declared.

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Abbreviations

CTTI: Clinical Trials Transformation Initiative
FDA: Food and Drug Administration
IRB: Institutional Review Board
MCT: mobile clinical trial
mHealth: mobile health

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Original Paper

Development and Validation of Risk Scores for All-Cause Mortality for a Smartphone-Based "General Health Score" App: Prospective Cohort Study Using the UK Biobank

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Abstract

Background: Given the established links between an individual's behaviors and lifestyle factors and potentially adverse health outcomes, univariate or simple multivariate health metrics and scores have been developed to quantify general health at a given point in time and estimate risk of negative future outcomes. However, these health metrics may be challenging for widespread use and are unlikely to be successful at capturing the broader determinants of health in the general population. Hence, there is a need for a multidimensional yet widely employable and accessible way to obtain a comprehensive health metric.

Objective: The objective of the study was to develop and validate a novel, easily interpretable, points-based health score ("C-Score") derived from metrics measurable using smartphone components and iterations thereof that utilize statistical modeling and machine learning (ML) approaches.

Methods: A literature review was conducted to identify relevant predictor variables for inclusion in the first iteration of a points-based model. This was followed by a prospective cohort study in a UK Biobank population for the purposes of validating the C-Score and developing and comparatively validating variations of the score using statistical and ML models to assess the balance between expediency and ease of interpretability and model complexity. Primary and secondary outcome measures were discrimination of a points-based score for all-cause mortality within 10 years (Harrell c-statistic) and discrimination and calibration of Cox proportional hazards models and ML models that incorporate C-Score values (or raw data inputs) and other predictors to predict the risk of all-cause mortality within 10 years.

Results: The study cohort comprised 420,560 individuals. During a cohort follow-up of 4,526,452 person-years, there were 16,188 deaths from any cause (3.85%). The points-based model had good discrimination (c-statistic=0.66). There was a 31% relative reduction in risk of all-cause mortality per decile of increasing C-Score (hazard ratio of 0.69, 95% CI 0.663-0.675). A Cox model integrating age and C-Score had improved discrimination (8 percentage points; c-statistic=0.74) and good calibration. ML approaches did not offer improved discrimination over statistical modeling.

Conclusions: The novel health metric ("C-Score") has good predictive capabilities for all-cause mortality within 10 years. Embedding the C-Score within a smartphone app may represent a useful tool for democratized, individualized health risk prediction.

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A simple Cox model using C-Score and age balances parsimony and accuracy of risk predictions and could be used to produce absolute risk estimations for app users.

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KEYWORDS

C-Score; mortality; risk score; smartphone; health score; medical informatics; public health; mobile health; development; validation; app; prospective; cohort; machine learning

Introduction

Background

Despite the empirical establishment of strong relationships between given behaviors and lifestyle factors and the development of preventable diseases, individuals may struggle to tangibly conceptualize how their day-to-day behavior affects their long-term health outcomes. A number of mortality risk algorithms or "health metrics" have been developed to quantify general health at a given point in time and estimate risk of negative future outcomes; however, few of these tools are accessible, interpretable, actionable, and easy to calculate [1-3]. Furthermore, their degrees of validation differ [2,3]. The use of univariate measures, while easily calculable and interpretable, may incompletely capture the wider determinants of health, such as psychological well-being.

BMI is often used as a quick means of estimating an individual's relative adiposity and infer the relative likelihood of adverse adiposity-related outcomes [4,5]. Despite its relative ease of calculation, BMI has numerous oft-promulgated limitations, including issues with scalability (two people with the same body proportions but different heights will have divergent BMIs); its ignorance of variation in physical characteristics due to age, sex, or ethnicity [6,7]; its inability to discern between muscle and fat; and its variable strength of relationship to health outcomes [8].

Multivariable risk prediction models can be easily developed using statistical modeling [9,10] or machine learning (ML) [2,11,12] approaches on appropriate data sets and lend themselves to supporting decision making across the manifold aspects of health and disease management or prevention. Indeed, there is a multitude of models published that seek to predict all-cause mortality [1,2]. All-cause mortality is an easily understandable risk trajectory into which the natural histories of many preventable diseases converge and can be manipulated by behavior changes. Therefore, it represents an attractive target for a general health metric or predictive model. However, there are hurdles to the widespread use of such predictive models [13]. Validation of models in the data sets that they were derived from (internal validation) and an assessment of their ability to generalize to independent data sets—preferably in different populations (external validation)—must be achieved prior to widespread use [14,15]. However, even when validated, models tend to remain the preserve of clinicians and may incorporate mathematical analysis of data points that require invasive testing (eg, blood tests), may be nonmodifiable by users (eg, childhood exposures), or are not easily accessible (eg, Townsend deprivation index).

Therefore, an unmet need in public health is the presence of validated health metrics based on models that are not only strongly predictive of outcomes but also accessible, have an understandable/interpretable output, and are parsimonious. Furthermore, should causal mechanisms be clearly established and the metrics validated as "causal prediction models," the focused use of modifiable predictor variables could help demonstrate actionable insights to guide beneficial lifestyle changes. Given the ability of smartphones to utilize inbuilt hardware to capture multimodal data relevant to physiological status, we believe that a smartphone app integrating product design and technological and risk modeling principles could present a novel conduit for risk prediction models focusing on well-established risk factors to enable members of the general public to engage with their health.

Here, the authors describe the development of a novel multivariable health metric, hereon named "C-Score", which seeks to mathematically integrate parameters that can be measured digitally, are almost all modifiable, and are relevant to various domains of health. Three formats of risk score or model were developed: (1) a simple, easy-to-interpret, 0-100 points–based score developed by summation of published literature regarding multiple variables across multiple geographic locations; (2) statistical modeling using Cox proportional hazards methods analyzing C-Score with other predictors such as age; and (3) ML models analyzing C-Score and the same predictor variables as used for statistical modeling. The first was validated, and the latter two were developed and validated using the UK Biobank [16] data.

Objective

This study sought to develop and validate forms of novel risk models for the purposes of a general health metric suitable for embedding into a smartphone app. Given the convergence of multiple key risk factors on the risk of all-cause mortality, as well as morbidity and mortality from leading noncommunicable diseases, the target endpoint chosen for this metric was all-cause mortality.

Methods

The study was planned and conducted in accordance with TRIPOD guidelines [17].

Candidate Explanatory Variables for Models

A comprehensive literature review was conducted using PubMed for candidate predictor variables for all-cause mortality. Search terms included "all-cause mortality," "death," "mortality prediction," and "risk model." In addition, preposited candidate variables were searched alongside "all-cause mortality," such

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as "smoking AND all-cause mortality" and "resting heart rate AND all-cause mortality."

The candidate variables that were identified from the literature review, which was led by clinical and epidemiological acumen regarding biological plausibility, were considered by the authorship panel in terms of their evidence base. They were also considered in terms of the degree to which they are modifiable, their ability to be measured using inbuilt capabilities of commonly available smartphones, and their contributions to engaging user design perspectives. As the intention was to develop an interpretable "general health metric" generated using an explainable underlying model that would be relevant to multiple morbidities rather than mortality alone, candidate variables were reviewed in terms of overlap with leading causes of morbidity and mortality.

Ultimately, eight predictor variables were selected: age, cigarette smoking, alcohol intake, self-rated health, resting heart rate, sleep, cognition (reaction time), and anthropometrics (waist-to-height ratio).

Development of a Points-Based Score (C-Score)

The first risk index ("C-Score") attempted to formulate an easy-to-interpret continuous score that used published evidence from multiple countries focused chiefly on modifiable factors, as opposed to developing a model using a single large database from one geographic location. This approach sought to utilize published hazard ratios or regression coefficients to weight individual parameters, as has been done elsewhere [18,19].

Studies identified using the above search criteria were reviewed by the authorship panel for cohort size, length of follow-up, robustness of statistical analysis, and whether or not hazard ratios for all-cause mortality were reported (and if these were adjusted for age, gender, and/or other confounders).

We opted to include all important variables other than age in the first iteration of the points-based model to ascertain the power of purely dynamic/modifiable characteristics in a risk index.

Hazard ratios were extracted from the studies deemed to be of the highest quality by the authorship panel. These were used as relative "weightings" for a points-based score. The optimal value for each input was set as 0 (lowest risk), with increasing numbers of points assigned for greater diversions away from optimal risk level (these points reflected the literature-extracted hazard ratios). The raw sum of maximal hazard ratios was approximately 25; therefore, the values for all increments of hazard ratios were quadrupled to make a total sum of 100.

The points-based score functions in a penalizing fashion—that is, users "start" with 100 points, and for each health domain, they can sequentially either lose no points (if they optimize that data input) or lose points in accordance with the hazard ratio associated with that level of exposure. For example, users will lose no points for being a never-smoker but will lose more points if they smoke more than 20 cigarettes per day than if they smoke 10 cigarettes per day. As such, the output from the score is a continuous variable—a number between 0 and 100, where 100 is optimal. Table 1 demonstrates the maximum penalty for each subdomain, as informed by extracted hazard ratio data [1,20-25].

Table 1. The range of points allocated to users per data input to C-Score.

C-Score input metric	Domain	Range of points allocated
Resting heart rate (beats per minute)	Cardiovascular fitness	0-7.83
Average hours of sleep per night	Sleep habits	0-10.26
Waist-to-height ratio	Adiposity	0-10.80
Self-rated health (ordinal scale: excellent, good, fair, poor)	Surrogate for existing comorbidity or perception of ill health	0-31.32
Cigarette smoking (status and cigarettes per day)	Tobacco exposure, including past smoking	0-12.96
Alcohol consumption (units/week)	Alcohol intake	0-19.44
Reaction time (ms)	Neurocognition	0-6.75

As the C-Score does not output a percentage risk prediction, it was only assessed for discrimination in predicting all-cause mortality within 10 years. As is evident below, percentage absolute risk assessments are possible if the C-Score is incorporated as a variable in statistical modeling approaches.

App Data Collection Methods and Materials

The raw data points contributing to the C-Score calculation are intended to be obtained using an ad hoc smartphone app (Figure 1). Data inputs for the score include manual entry (eg, age, gender, and alcohol and tobacco consumption), image analyses (eg, waist-to-height ratio), use of phone camera technology (eg, for resting heart rate), and screen-based reaction time testing. Waist-to-height ratio was calculated using camera-based anthropometric measurements (body volume index), which produced the following outputs: waist circumference, hip circumference, body fat percentage, and total body volume. Resting heart rate was collected via a camera-driven photoplethysmogram sensor, which is able to detect the heartbeat when participants position their finger on the camera. Reaction time in the app is measured by asking users to hold their finger on the screen and lift it when the screen changes color; users are asked to repeat the test three times and the average time across the trials is then computed.

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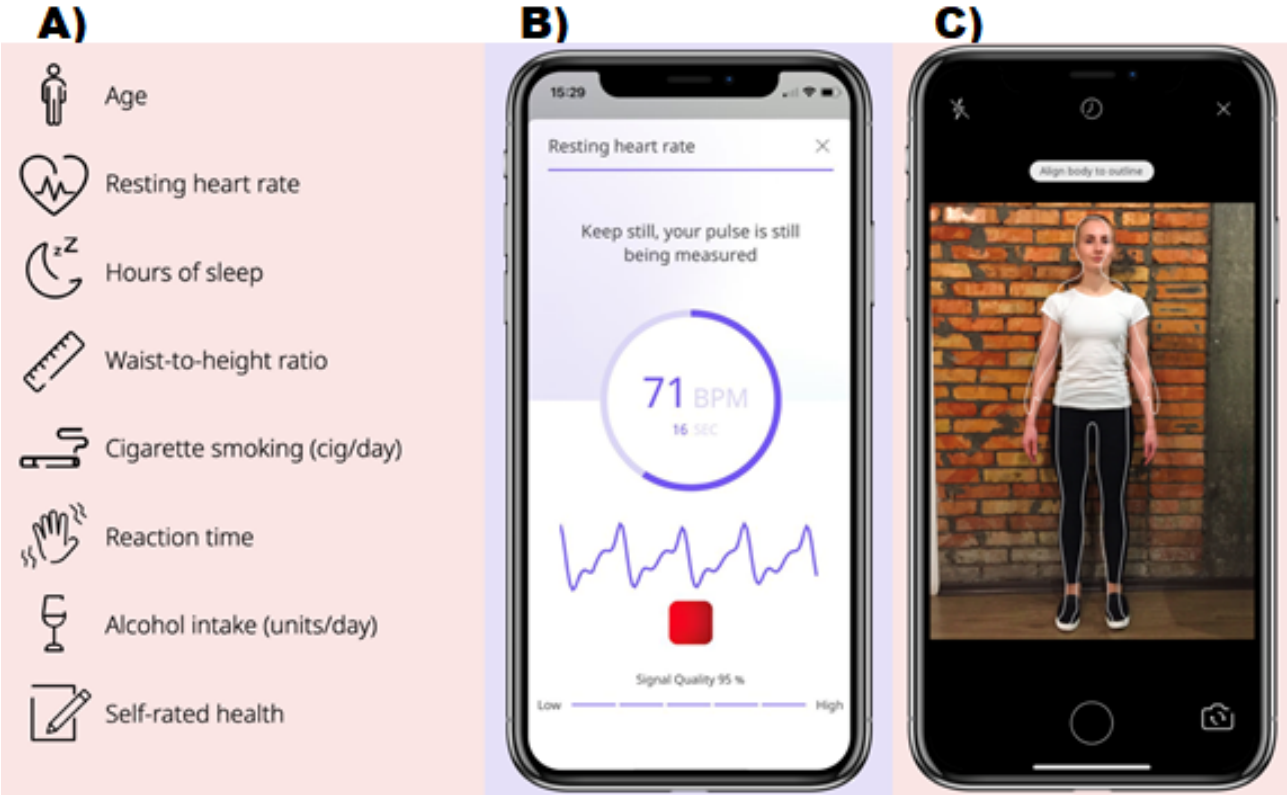
Figure 1. Screenshots of the C-Score mobile app. (A) List of data contributing to the C-Score. (B) Resting heart rate measurement screen. (C) Body scan screen (for waist-to-height ratio).



Study Population

The individual-level data of the UK Biobank were utilized as the study population for the validation of the points-based model and the development and validation of risk models for all-cause mortality that incorporate C-Score inputs (as more complex variants of the initial points-based score). The entirety of the available data set with complete data regarding C-Score inputs was used for our analyses. Briefly, the UK Biobank represents a prospective cohort study where over 500,000 individuals aged 40 to 69 years were recruited between 2006-2010 and followed up thereafter [16]. Participants underwent a robust assessment at baseline, during which multiple questionnaires were completed, anthropometric and other measures were taken, and blood and saliva samples were obtained. In addition to robust phenotyping, all participants have been genotyped, 100,000 are in the process of undergoing whole-body imaging, and 20,000 have completed repeat assessments. Participants' data are linked to multiple other electronic databases, enabling the ascertainment of data regarding date and cause of death. The UK Biobank is an "open" resource accessible to any researcher approved as bona fide by the UK Biobank Access Management Team.

Development of De Novo Models

Whereas C-Score was validated in terms of discrimination using the UK Biobank data, four additional model versions were both generated and validated using data from the UK Biobank, referred to as models 2 to 5. As the continuous "health score" does not predict percentage risks, we used Cox regression to form variants of models that can output such a risk prediction and assess their discrimination and calibration. This opens the possibility of having a user-facing score, with scope for generating individualized percentage-style risk estimates for multiple outcomes of interest, such as all-cause mortality.

Model 2 integrated C-Score and age, whereas model 3 integrated the raw values for all C-Score inputs and age to assess the amount of performance sacrificed by a predetermined weighting system. Model 4 sought to develop "maximally complex" statistical models with interactions to identify the maximum attainable predictive accuracy and also included sex and ethnicity, again to assess the balance between predictive power and expediency of a simple, interpretable score or simple model. These Cox models were developed to predict the risk of death within 10 years of follow-up as a complete case analysis. As the intended smartphone app would require completion of all data fields to generate the health score, a complete case analysis of UK Biobank data offered a form of evaluation that most closely aligned to the intended use of the models. The baseline data values (ie, obtained from the assessment center) were used to calculate C-Scores and also participants' baseline age for the development of the Cox models. Individual follow-up was defined as time elapsed from initial assessment to either death from any cause or censoring (lost to follow-up or reached the end of study date). The end of study date was set as February 9, 2020, which corresponded to the date of data extract download.

Development of ML-Based Models

The approach taken for the development of model 5 was to use supervised ML. The problem was specified as a binary classifier, aiming to assign a label representing whether or not the patient dies 10 years postbaseline. Two commonly used supervised ML

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classifiers were chosen, the K-nearest neighbor (KNN) classifier and the support vector machine (SVM) classifier. As the C-Score was conceptualized as a user-friendly, easily explainable metric, we chose to assess KNN and SVM modeling approaches because their mechanistic underpinnings can be relatively easily relayed to a user, compared with, for example, a neural network or boosting algorithm. Both these algorithms were tuned to select the optimal hyperparameters using 10-fold cross-validation on the training and validation sets (to maximize the area under the receiver operating characteristic curve [AUROC]).

In the UK Biobank cohort, the number of occurrences of the outcome of interest was relatively low (less than 5%). During the SVM and KNN development and evaluation, it became apparent that the outcome sparsity might have had implications for model performance (with initial AUROCs ranging between 0.67 and 0.68 when using a 70:30 "split"). The final model was trained by randomly undersampling the training data (in order to achieve a 50:50 split between the two outcome variables). It is also important to note that these two algorithms are based in feature space, so the weighting of each feature plays a crucial role in the determination of the classification coefficients. As such, it is important to standardize all of the inputs; this was performed by first subtracting the mean and subsequently dividing by the standard deviation for each feature.

We first developed and trained a KNN algorithm to derive a binary label determining the patient's risk of death in the next 10 years. KNNs are a type of classification algorithm based on the premise that similar cases (in feature space) will have similar results. The idea is to classify each new observation based on a metric of "nearness" to all other points and to set its label as the most common label of the K most similar training examples. To use the KNN algorithm, two hyperparameters need to be specified: (1) the value of K (ie, how many training examples will it aggregate to determine the label of the test), and (2) the metric for defining "nearness." For both of these parameters, we tuned our model using 10-fold cross-validation.

The hyperparameters used for defining "nearness" are the two most commonly used distance metrics, namely the Euclidean distance and the Manhattan distance. The other parameter to be tuned was the value of K—values between 5 and 500 were tested. The optimal parameters were determined by maximizing the AUROC using 10-fold cross-validation.

We trained an SVM classifier to optimally separate in feature space between patients. SVMs are a category of classifiers that aim to determine the hyperplane that optimally separates the observations into two sets of data points. The intuitive idea behind the SVM algorithm is to maximize the probability of making a correct prediction by determining the boundary that is the furthest from all of the observations.

Similar to the previous KNN model, considerations in training were taken into account in choosing the hyperparameters. In the case of SVMs, the parameters we chose to optimize were the shape of the separation kernel (linear, polynomial, or radial basis function [RBF]), the C regularization parameter, the degree of the polynomial (only true for polynomial kernels), and the gamma kernel coefficient (for polynomial and RBF kernels). To optimize these parameters, we used 10-fold cross-validation on the training data to maximize the AUROC.

Statistical Analyses and Model Validation

Continuous variables for descriptive statistics are presented as means and standard deviations. Cox models were developed using the entire available data set and then underwent internal validation using bootstrapping with 200 iterations (for discrimination and calibration). Models were tested for proportional hazards assumptions (using log-log plots) and inclusion of restricted cubic splines or logarithms for continuous variables.

Discrimination refers to the ability of a prediction model to distinguish between individuals that experience an outcome of interest and those who do not. Suitable metrics include Harrell c-statistic, which is equivalent to the AUROC for Cox models. A value of 0.5 means that the model is no better than tossing a coin, whereas a value of 1 means perfect prediction.

Calibration refers to the assessment of closeness between predicted and observed risks. This can be assessed by plotting the observed and predicted risks across different levels, such as by tenth of risk. However, "binning" of risk levels is not optimal, and other approaches include linear adaptive spline hazard regression, which interpolates across levels of risk [26]. Therefore, we assessed calibration of the models using smoothed calibration plots to compare predicted and observed risks, which also incorporated bootstrapping to correct for model optimism.

Bootstrap optimism-corrected values for the c-statistic were computed, and calibration plots were formed for models 2 to 4. Initial data handling was performed using Stata v16.0 software (StataCorp LLC), with the statistical analyses handled in R statistical software, notably the rms package. For model 5, algorithms were developed using Python, including the Pandas, NumPy, and Scikit-learn packages; the AUROC is presented.

Ethical Approval

Access to anonymized data for the UK Biobank cohort was granted by the UK Biobank Access Management Team (application number 55668). Ethical approval was granted by the national research ethics committee (REC 16/NW/0274) for the overall UK Biobank cohort.

Results

Study Population Characteristics

In the complete case analysis, there were 420,560 individuals with complete data, including age at baseline assessment and all metrics included in the C-Score. There was a maximum follow-up of 13.9 years, and the total follow-up time for the cohort was 4,526,452 person-years. During this period, there were 16,188 deaths (3.85% of the cohort).

Demographics for the study cohort were as follows: mean age at baseline was 56.58 (SD 8.07) years, mean resting heart rate was 69.84 (SD 11.68) beats/minute, mean waist-to-height ratio was 0.54 (SD 0.075), mean weekly alcohol intake was 14.34 (SD 18.84) units, mean reaction time was 558.03 (SD 117.07) ms, and mean sleep duration was 7.16 (SD 1.26) hours. For

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self-rated health, 68,926 (16.39%) subjects reported "excellent," whereas 245,171 (58.30%), 88,195 (20.97%), and 18,268 (4.34%) subjects reported "good," "fair," and "poor," respectively. There were 230,798 men (55.14%) and 188,601 women (44.86%). Regarding ethnic background, subjects were categorized as "White" (397,763, 94.92%), "mixed" (2480, 0.59%), "Asian or Asian British" (7631, 1.82%), "Black or Black British" (6370, 1.52%), "Chinese" (1293, 0.31%), or "Other" (3524, 0.84%).

Regarding calculated C-Scores, the mean score for participants was 77.25 (SD 12.96; minimum 3.34, maximum 100; Figure 2). Figure 3 displays the risk of death within 10 years according to C-Score decile.

Figure 2. Distribution of C-Score values in the study cohort (N=420,560).

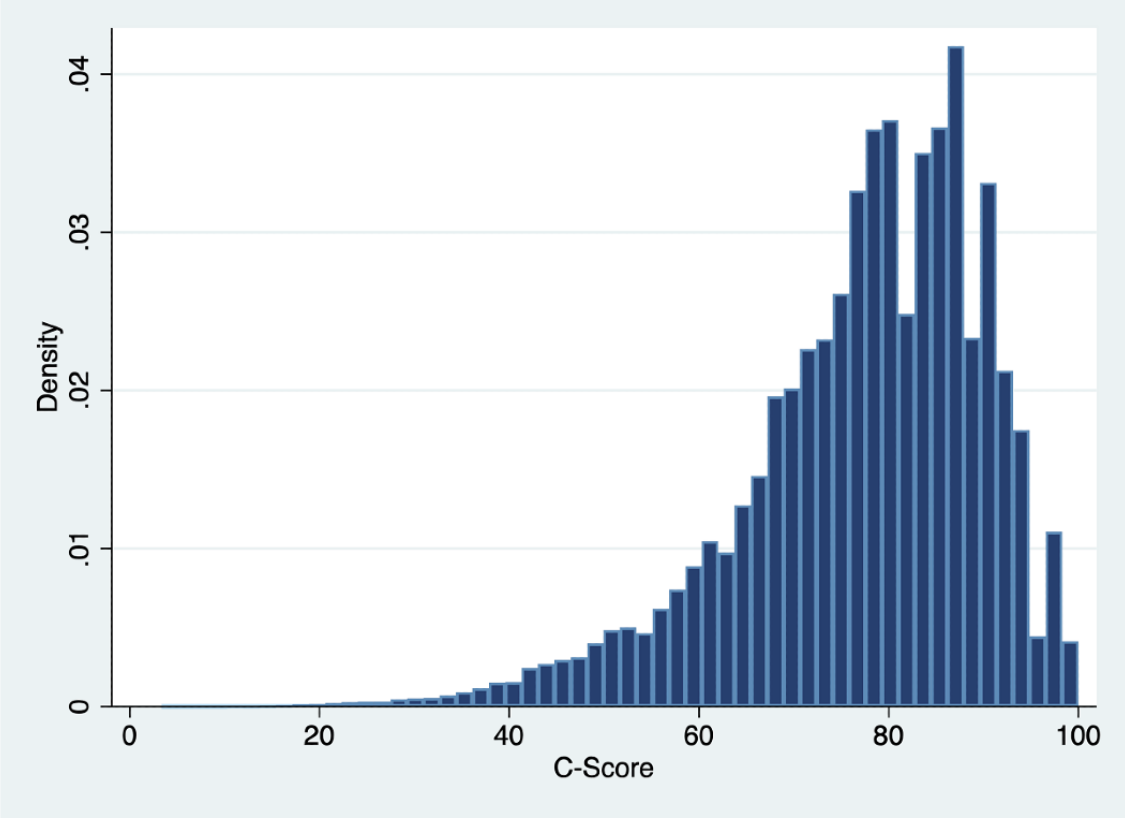
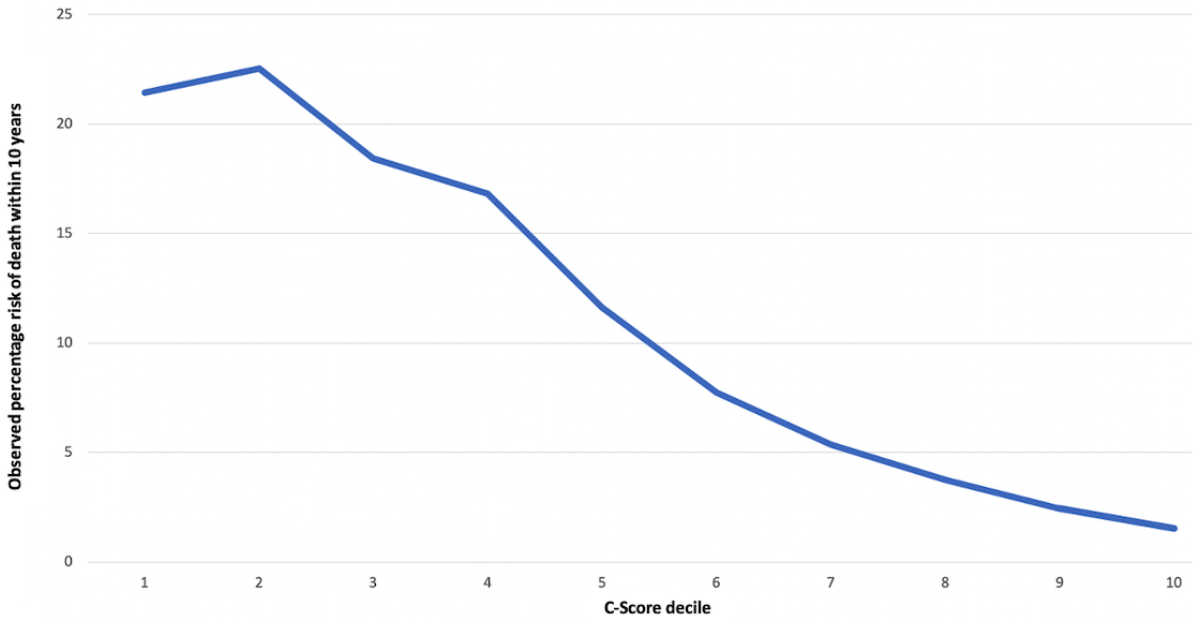


Figure 3. Probability of death within the next 10 years as a function of C-Score decile.



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Discrimination and Calibration

Model 1

The hazard ratio for per-unit increase in C-Score was 0.96 (95% CI 0.960-0.961), suggesting a 4% relative risk reduction per unit improvement. When analyzed in terms of C-Score decile (ie, 10-point brackets of C-Scores), the hazard ratio was 0.69 (95% CI 0.663-0.675), implying a 31% relative risk reduction of all-cause mortality per decile improvement in C-Score. Regarding discrimination, the c-statistic was 0.66.

Model 2

Inclusion of (log)age and C-Score in a Cox model yielded a c-statistic of 0.74 (ie, an increase in discrimination capability of 8 percentage points). The model appeared well-calibrated (Figure 4). Although age is clearly a major predictor of all-cause mortality, the Cox model demonstrated that on the inclusion of age and C-Score, there were significant roles for both: hazard ratio per year increase in age was 1.09 (95% CI 1.091-1.096) and per 10-unit increase in C-Score was 0.67 (95% CI 0.668-0.681). Table 2 demonstrates the coefficients for all Cox models developed.

Figure 4. Calibration plots of predicted versus observed probabilities of all-cause mortality within 10 years for models 2, 3, and 4. The ticks across the upper plot border represent the distribution of predicted risks in the study cohort population. The black line displays apparent calibration and the blue line displays the bias-corrected calibration.

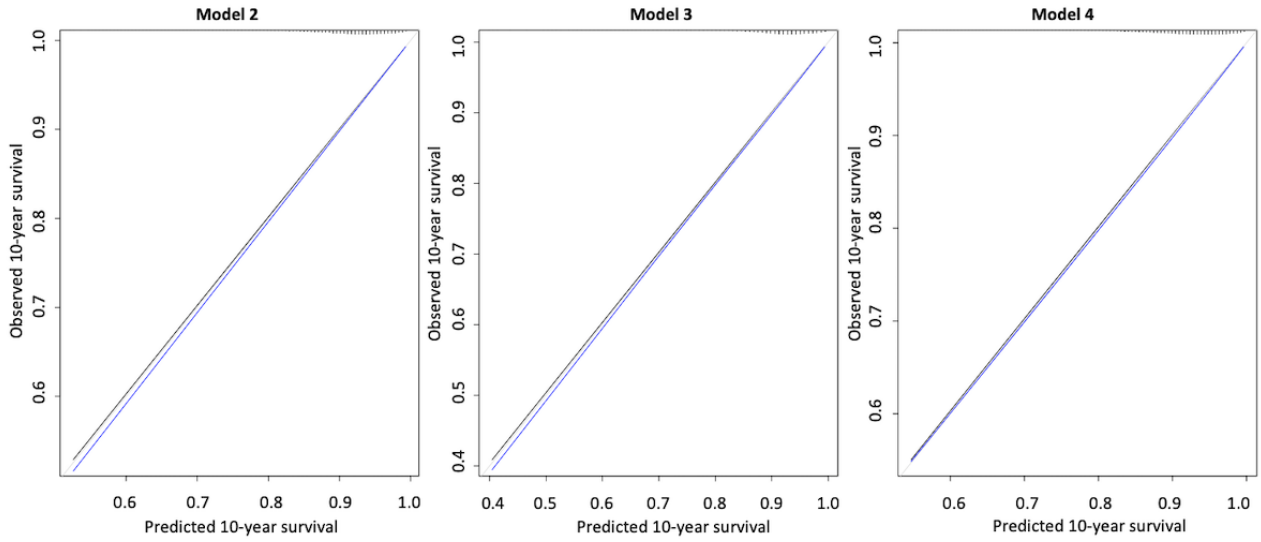

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Table 2. Coefficients from Cox proportional hazards models either examining C-Score alone or alongside additional parameters/interactions or raw data inputs (model 3).

Model and predictor variables	Coefficient (*P* value)	Discrimination (c-statistic)[a]
Cox model with C-Score as sole variate		0.66
C-Score	–.0402 (<.001)	
Model 2		0.74
C-Score	–0.0393 (<.001)	
(log)age	5.0965 (<.001)	
Model 3		0.74
(log)age	3.8622 (<.001)	
Sleep hours	0.0750 (<.001)	
Self-rated health		
Good	0.0964 (.01)	
Fair	0.6310 (<.001)	
Poor	2.5479 (<.001)	
Cigarettes smoked per day	0.0685 (<.001)	
Reaction time	0.0008 (<.001)	
Waist-to-height ratio	1.1679 (<.001)	
Weekly alcohol units	0.0077 (<.001)	
Resting heart rate	0.0133 (<.001)	
Model 4[b]		0.74
C-Score	–0.0874 (<.001)	
(log)age	4.1934 (<.001)	
Ethnic group		
Mixed	–0.6416 (.29)	
Asian/Asian British	0.3550 (.25)	
Black/Black British	–0.2142 (.61)	
Chinese	0.1931 (.88)	
Other	–0.8077 (.10)	
Male sex	0.2132 (.006)	
C-Score[c]		
(log)age	0.0121 (.006)	
Mixed ethnicity	0.0067 (.44)	
Asian/Asian British ethnicity	–0.0094 (.04)	
Black/Black British ethnicity	–0.0005 (.93)	
Chinese ethnicity	–0.0060 (.72)	
“Other” ethnicity	0.0122 (.10)	
Male sex	0.0010 (.33)	

[a]For reference in terms of discrimination, a Cox model using simply the C-Score as the sole variate was fitted to demonstrate the scope for incremental gains in accuracy. For models 3 and 4, the coefficients for the “excellent” self-rated health and White ethnicity are the reference categories, and therefore their coefficients equal 0.

[b]Model 4 is presented prior to backward selection.

[c]Denotes interaction terms.

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Model 3

Using the raw data inputs rather than a preassigned "weighting" plus age yielded a c-statistic of 0.74; therefore, there was no significant improvement in discrimination with a more complex model. The model was also well-calibrated (Figure 4).

Model 4

We also developed a "full model" that included C-Score, age, ethnicity, and sex, as well as interactions between C-Score and the latter three variables. We performed backward elimination to identify the strongest possible performing model via bootstrapping with 200 iterations; selection was based on the Akaike information criterion with a *P* value of 0.01. Herein, the final model that retained C-Score, sex, age, an interaction between C-Score and ethnicity, and an interaction between C-Score and age had an optimism-corrected c-statistic of 0.74 (ie, no improvement with a more complex model).

Model 5

Both of the ML algorithms, KNN and SVM, were applied to a test cohort (n=125,966) in order to predict risk of death in the next 10 years. For the KNN, following 10-fold cross-validation for the tuning of the hyperparameters (we opted to use K=100 and the Manhattan distance metric), the c-statistic on the test data was 0.72. Similar to the KNN algorithm, we tuned the SVM using 10-fold cross-validation on randomly under-sampled training data. This led us to choose C=100, gamma=0.001, and kernel shape as an RBF as the optimal hyperparameters.

Discussion

Principal Findings

Risk prediction models have significant potential for assessing the risk of protean events of interest. However, these models are limited almost exclusively to clinical use, and widely used/easily accessible health metrics, such as BMI, have limitations. Extant multivariable prediction models for all-cause mortality are typically poorly accessible to members of the public and risk limited engagement due to perceived nonmodifiability of covariates or limited ability to understand the mechanisms by which covariates may predict outcomes. Therefore, for the purposes of this initiative, we opted to migrate away from univariate assessments toward a novel, multivariable health metric that is focused on characteristics that span multiple domains of health, is accessible, and can be used by anybody with a smartphone. Our results demonstrate the value of an easy-to-interpret points-based score to infer all-cause mortality risk and mandate consideration of this smartphone-based health index in the prediction of multiple other diseases or conditions. Our results also suggest that a simple Cox model including C-Score and age may provide accurate absolute risk predictions for public health initiatives, such as promoting public understanding of individual health risk or raising awareness of the effects of behaviors on health. Lastly, the results are interesting regarding the power of statistical modeling approaches relative to ML approaches using the same data.

All-cause mortality was selected as a first end point for validation purposes given its ease of comprehension and its close links to multiple modifiable behaviors and/or it often being a consequence of preventable disease. This is an end point that has been robustly examined in the UK Biobank by two other key studies. A study by Weng et al [2] utilized the UK Biobank to derive epidemiological models (ie, Cox) and ML models (ie, random forests and neural networks) to predict premature mortality using a preselected panel of 60 candidate baseline predictor variables encompassing aspects such as sociodemographics, educational attainment, behavior, nutritional intake, lifestyle factors, medication use, and clinical history. In standard Cox modeling, the final included variables were gender; log(age); educational qualifications; ethnicity; previous diagnoses of cancer, coronary heart disease, type 2 diabetes, or chronic obstructive pulmonary disease; smoking history; blood pressure; Townsend deprivation index; and BMI. Variables included in random forests modeling included BMI, forced expiratory volume in the first second of expiration, waist circumference, blood pressure parameters, skin tone, and age. On identifying the optimal neural network parameters using grid-search from 10-fold cross-validation, top risk factor variables included smoking status, age, prior cancer diagnosis, prescription of digoxin, residential air pollution, and Townsend deprivation index. The discrimination of the fully adjusted Cox, random forests, and neural network models were 0.751 (95% CI 0.748-0.767), 0.783 (95% CI 0.776-0.791), and 0.79 (95% CI 0.783-0.797), respectively [10]. While these AUROC values are significantly but marginally higher than those reported with our intended app-based model, they included variables that are, for the most part, nonmodifiable and do not offer clear scope for use by members of the public to not only compute their risk but also be able to act on various components to reduce risk.

Ganna and Ingelsson [1] used the UK Biobank cohort to identify predictors of 5-year all-cause mortality and six cause-specific mortality categories from 655 measurements of demographic variables, the results of which were interestingly packaged as part of an interactive website named Ubble. Ultimately, for all-cause mortality within 5 years, 13 predictors for men and 11 for women in a Cox model achieved discrimination of 0.8 (95% CI 0.77-0.83) and 0.79 (95% CI 0.76-0.83), respectively. Again, although these models attained a significantly but slightly higher discrimination than our model, the majority of parameters included are minimally modifiable (in retrospect, number of children given birth to), have an effect on mortality that is difficult to explain (number of people in the household, numbers of cars or vans owned/used by the household, relationships of people lived with), and emphasize existing health conditions (known diabetic, previous cancer) [1]. While our study did not validate the C-Score as a "causal prediction model," where coefficients have a direct causal interpretation, such further work is underway, and the inclusion of modifiable factors known to have causal implications on health outcomes is encouraging in this regard.

In the era of "big data," a resurgence in the popularity of artificial intelligence and more specifically ML has been seen across a wide array of fields including health care. These novel methodologies have led to some notable results in prediction and diagnostics and so have become a commonly examined tool in medical research. It is, however, important to note that

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ML techniques do not always lead to better results than "classical" statistical methods. Indeed, the results that we observed using two very popular and widely used algorithms, namely KNN and SVM, were comparatively similar or even lower than the results observed using a traditional epidemiological/statistical modeling strategy. ML methodologies rely on the artificial generation of knowledge using machine-guided computational methods instead of human-guided data analysis in order to find a best fit in the data. There are some very strong cases for their use, especially when dealing with wide and complex data sets with multifactorial causation and complex and potentially nonintuitive interactions. However, in this study, we showed that ML is not always the answer and that initial development of an algorithm with few metrics and careful consideration of the input by those with scientific/clinical acumen can yield better results.

Strengths and Limitations

Our work has some strengths and also limitations. Strengths include the use of the UK Biobank, which provided a contemporary, richly phenotyped cohort with linkages to national registries that minimized loss to follow-up, prospectively evaluated risk factors, and enabled accurate ascertainment of outcomes of interest. Another strength was our cognizance of the target users of the app that the model was intended for, which drove us to focus on modifiable risk variables where possible—we were content with sacrificing a small percentage of discriminatory capability without needing to "penalize" intended users for having pre-existing conditions or a certain educational level, or living in areas of heavy air pollution.

Possible limitations of our work include the use of a complete case analysis, which may have introduced bias, and the use of "human intelligence" to prune the possible list of candidate predictor variables, which could have limited the scope for ML to perform optimally. As the overwhelming majority of missing data for the included variables were due to participants "not knowing" the answer or refusing to answer, we considered this to replicate the target end situation, where people will be using the health index or model in an app. We mitigated bias to the best of our abilities throughout the rest of the methodology for the statistical modeling where possible—for example, we used the entire data set for Cox modeling and bootstrapping for validation rather than randomly splitting the data into development and validation sets, which is inefficient and inadvisable [10]. The fact that ML methods did not deliver significant improvements in discrimination is not a formal comparative assessment of statistics versus ML. Indeed, ML is likely best reserved for situations other than trying to optimize the weighting of a small number of variables that humans have preselected, or for situations in which model explainability is less crucial. The validation schemas were different between the approaches, with resampling validation used in statistical modeling and a train-test split used to tune hyperparameters and then assess performance of the ML classifiers. Using the same cross-validation for both hyperparameter tuning and performance assessment on the entire data set is inherently optimistically biased, and while nested cross-validation may be one approach to using all of the data for training and validation, we were unable to do it because of computational limitations. There were also the limitations of data availability and potential selection bias concerning the participants of the UK Biobank. In terms of data availability, the reaction time used at the UK Biobank baseline assessments (2006-2010) was not exactly the same as the reaction test developed for the app: results from a study using the NHANES cohort [23] were used to develop the initial score and inform the reaction time test in the app. However, because the underlying way in which points are allocated for reaction time are based on the relative distribution of time measurements, applying exactly the same cutoff principles (based on standard deviations from the mean) was a pragmatic and suitable way to validate the C-Score in a cohort with a different measurement mechanism. In terms of UK Biobank participants, they tend to be slightly healthier than the general population at large [16,27]. Furthermore, the UK Biobank only recruited individuals between the ages of 40 and 69 years who were generally more affluent and more likely to be of White ethnicity than the general population. Use of the C-Score outside the UK population and in different age groups should follow validation in appropriate local data sets with cognizance of the need for performance evaluation in different ethnic groups, work on which is underway.

Conclusion

In conclusion, we believe that the "general health metric" reported here not only compares well to other work despite using fewer variables but offers several advantages from a population-use perspective, as it offers a holistic review of multiple aspects of health and focuses for the most part on modifiable characteristics that could in time be targets for risk-reducing interventions pending further model evaluation. Our proclivity was not to produce the most powerfully predictive models possible using a prospective data set but rather to develop and validate models that are rational, understandable, and could be engaging within a smartphone app. Given the strong association of many of the included variables on other diseases (and not just all-cause mortality), we believe that a points-based score may be powerful in making inferences regarding current and future health in terms of individual conditions. Even more powerful could be simple statistical models incorporating C-Score and age for each clinical end point of interest. Further work is already underway within our group to assess the capabilities of C-Score and variations thereof across a panel of conditions of interest, as is the embedding of this score system into a mobile app.

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The UK Biobank cohort data are available to researchers as approved by the UK Biobank Access Management Team. Due to commercial sensitivity, we have not presented the complete raw weighting system for deriving the C-Score here; this could be made available by Huma Therapeutics to academic partners seeking to collaborate to externally validate C-Score models in other data sets. The R/Python code used by the investigators for Cox modeling/ML modeling can be provided on request to the authors.

Authors' Contributions

AKC led the design of the study, acquisition and analysis of the data, and manuscript writing. ELL contributed to the design of the study, analysis of the data, and manuscript writing. CPT contributed to the conception of the study, study design, manuscript writing, and critical review. AH contributed to the conception of the study, study design, and critical revision of the manuscript. All other authors contributed to the conception of the study, study design, and critical revision of the manuscript. All authors have approved the final version of the manuscript submitted. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflicts of Interest

AKC is a previous consultant for Huma Therapeutics. DP, SP, ELL, CPT, SSS, MB, AH, TS, DDD, JL, MA, DV, and SJL are employees of Huma Therapeutics.

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Abbreviations

AUROC: area under the receiver operating characteristic curve
KNN: K-nearest neighbor
ML: machine learning
RBF: radial basis function
SVM: support vector machine

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Original Paper

Using a Commercially Available App for the Self-Management of Hypertension: Acceptance and Usability Study in Saudi Arabia

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Abstract

Background: The use of smartphone apps to assist in the self-management of hypertension is becoming increasingly common, but few commercially available apps have the potential to be effective along with adequate security and privacy measures in place. In a previous study, we identified 5 apps that are potentially effective and safe, and based on the preferences of doctors and patients, one (Cora Health) was selected as the most suitable app for use in a Saudi context. However, there is currently no evidence of its usability and acceptance among potential users. Indeed, there has been little research into the usability and acceptance of hypertension apps in general, and less research considers this in the Gulf Region.

Objective: This study aims to evaluate the acceptance and usability of the selected app in the Saudi context.

Methods: This study used a mixed methods approach with 2 studies: a usability test involving patients in a controlled setting performing predefined tasks and a real-world usability study where patients used the app for 4 weeks. In the usability test, participants were asked to think aloud while performing the tasks, and an observer recorded the number of tasks they completed. At the end of the real-world pilot study, participants were interviewed, and the mHealth App Usability Questionnaire was completed. Descriptive statistics were used to analyze quantitative data, and thematic analysis was used to analyze qualitative data.

Results: In total, 10 patients completed study 1. The study found that app usability was moderate and that participants needed some familiarization time before they could use the app proficiently. Some usability issues were revealed, related to app accessibility and navigation, and a few tasks remained uncompleted by most people. A total of 20 patients completed study 2, with a mean age of 51.6 (SD 11.7) years. Study 2 found that the app was generally acceptable and easy to use, with some similar usability issues identified. Participants stressed the importance of practice and training to use it more easily and proficiently. Participants had a good engagement level with 48% retention at the end of study 2, with most participants' engagement being classed as meaningful. The most recorded data were blood pressure, followed by stress and medication, and the most accessed feature was viewing graphs of data trends.

Conclusions: This study shows that a commercially available app can be usable and acceptable in the self-management of hypertension but also found a considerable number of possibilities for improvement, which needs to be considered in future app development. The results show that there is potential for a commercially available app to be used in large-scale studies of hypertension self-management if suggestions for improvements are addressed.

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KEYWORDS

mHealth; mobile phone; hypertension; usability; acceptance; user satisfaction

Introduction

Background

Hypertension is one of the most common chronic diseases in adults and can lead to several serious complications, including stroke, heart disease, and renal failure. The condition affects approximately one billion people globally. In Saudi Arabia, 27.2% of people aged above 30 years have been diagnosed with hypertension [1-5]. Lowering blood pressure (BP) lessens the risk of complications, but many patients with hypertension do not control their BP well [3,5,6]. Self-management is one of the most effective ways to control hypertension. This involves encouraging patients to take control of their condition, for instance, by changing their lifestyle, by becoming more involved in their treatment, and by managing their symptoms and psychosocial and physical effects [7-9]. However, self-management behavior remains to be difficult and is an aspect of treatment with which patients often struggle.

The increase in smartphone use in recent years has led to an increase in health-related apps on these devices. In Saudi Arabia alone, there were an estimated 21.8 million smartphone users in 2018, and as a result, the use of health apps as a means for treating patients has increased [10,11]. Many commercial apps are available, offering a potential way to promote and assist the self-management of hypertension [12-15].

This study focuses on one commercially available app (Cora Health) developed by Swiftware. This app was selected based on the findings of previous studies. Alessa et al [16] conducted a systematic review of apps intended to assist in the self-management of hypertension and found that these are potentially effective in lowering BP, particularly when they have comprehensive functionalities, including self-monitoring, reminders, and educational information or automatic feedback. Most apps were developed specifically for an individual study, and there is still a lack of research evidence supporting the effectiveness and usability of commercially available apps. A recent review of apps actually available in app stores found that only few apps (30/186, 16.1%) had the potential to be effective, very few apps (5/186, 2.6%) had the potential to be effective and with adequate security and privacy safeguard, and none of them claim to have involved users in their development [15]. A subsequent study explored patients' and doctors' preferences toward the 5 apps found to be effective and with adequate security and privacy measures. When participants were asked to rate the apps, the Cora Health app was considered the most suitable. However, there is still no published evidence regarding its usability or effectiveness [15].

Many commercial apps, including the Cora Health app, did not involve users in app development, although many studies have found that participants' acceptance of apps and their perceptions of usefulness and ease of use are all key factors for mobile health (mHealth) adoption [17-19]. Moreover, there is very little research into usability and acceptance in general [15,16] and even less research that specifically examines the Saudi context or the wider Gulf Region. However, Clemmensen et al [20] suggested that usability problems could be influenced by users' cultures, experience, and knowledge. This highlights the importance of assessing a commercially available app's usability, acceptance, and engagement before its effectiveness can be evaluated [21-23]. This study aims to assess the usability and acceptance of the Cora Health app to support the self-management of hypertension in Saudi Arabia, which is the first study in this context. The objectives of this study are as follows: (1) to assess how usable the app is; (2) to assess patients' experience using the app: what barriers to use they see and whether they think it could be improved; and (3) to examine how participants engage with the app. Our central hypothesis was that users would find the app acceptable and usable overall but that they might also identify usability issues or specific preferences and needs, which the app did not meet.

Study Design and Methods

This research used a convergent mixed methods approach to comprehensively assess the app's usability and acceptance [24], conducted via 2 studies: (1) a usability test and (2) a real-world usability and acceptance study.

The qualitative and quantitative data in this research were collected concurrently in both studies and analyzed separately. It was then integrated and synthesized in the interpretation so that the facets of the results could be examined together and compared. Efficient integration of both qualitative and quantitative methods results in a larger knowledge yield than that obtained by treating the 2 strands in isolation [24,25].

Usability is defined as, "the extent to which a product can be used by specific users to achieve specific goals with effectiveness, efficiency and satisfaction in a specific context of use" [26]. Acceptance, for the purpose of the study, includes participants' actual app use, their satisfaction, and attitudes toward using the app and intention or willingness to continue using the app [27].

Participants

The population of this study included Saudi adults with hypertension. Participants for both studies were purposively selected from 1 hospital and 2 primary care centers in Riyadh, Saudi Arabia, based on the predefined inclusion and exclusion criteria [28].

For the usability test, a sample size of 10 eligible participants was used. This is sufficient to discover more than 80% of usability problems [29,30]. For the usability and acceptance study, the target sample size was 20 to 30 eligible people, which is a similar number to previous studies assessing the acceptance and usability of health apps [17,31,32].

The inclusion criteria in both studies were as follows: at least 30 years old; diagnosed with hypertension (stages 1-3) as a primary disease for a minimum of 6 months; able to speak Arabic, give consent, and actively participate in the study; and possess or have access to an iOS-compatible smartphone. The

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exclusion criteria were as follows: having a cognitive impairment that limits the ability to give informed consent or to actively take part in the studies; having prehypertension or hypertension during pregnancy; being unable to read and understand the Arabic language; and (for study 2 only) affected by stage 4 or severe hypertension (≥180/110 mm Hg).

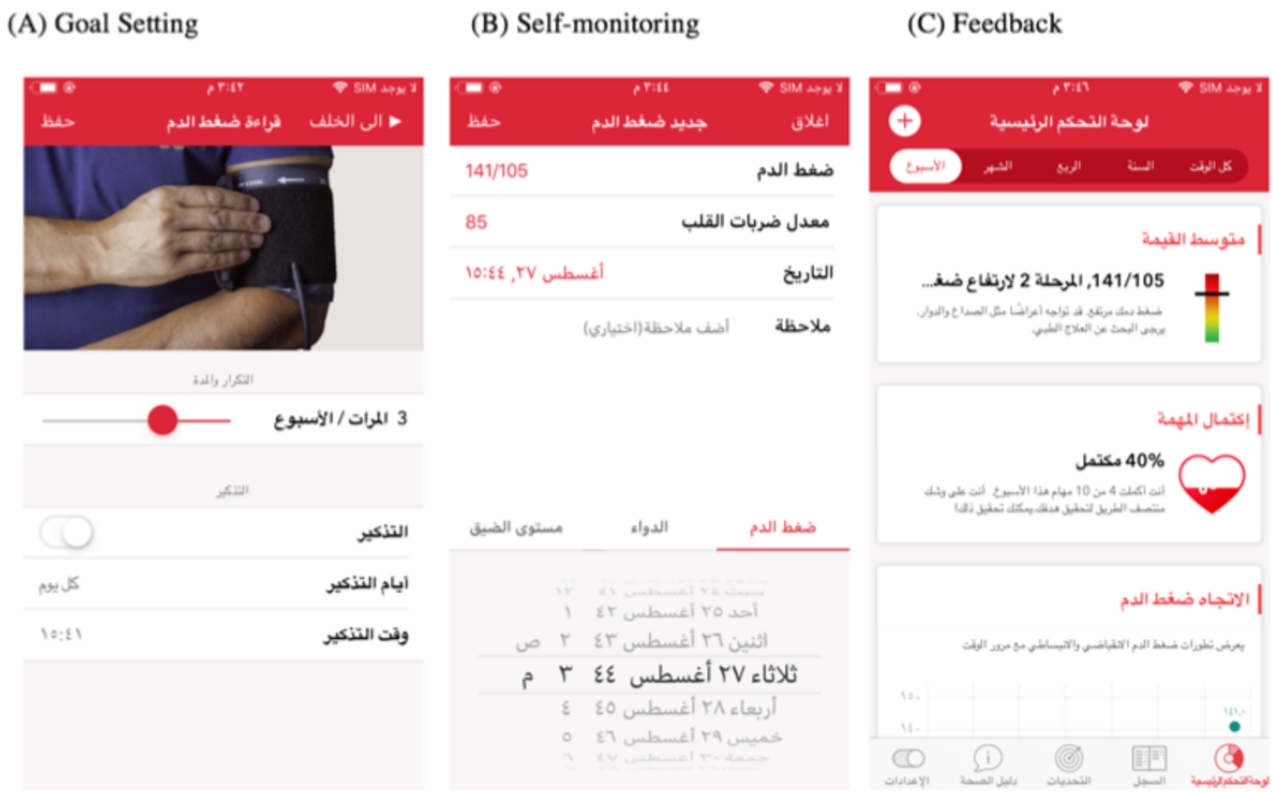
Participant Recruitment

The study was conducted at the largest hospital related to the Ministry of Health and 2 primary care centers related to the hospital. Participants in study 1 were recruited via posters and flyers advertising the study, with recruitment continuing until data saturation was reached, that is, once new participants were no longer revealing new data, information, or usability issues. [33]. For study 2, physicians were approached to recruit participants from among their patients based on the study's eligibility criteria. People who expressed an interest in participating in the studies were provided with a further information sheet and a consent form.

Intervention

Figure 1 shows the app version used runs on the iPhone. The app was translated into Arabic by the researcher and then back into English to check for translation accuracy. Samples of the Arabic version were then sent to a test group of Arabic speakers with hypertension to check its comprehensibility and clarity. Owing to developer constraints, it was not possible to translate the complete app content; some small sections, for example, labels of figures and names of medication, remained in English.

Figure 1. The main functionalities of the app.



The app has 3 main features: monitoring (BP, stress, and medication), setting weekly challenges, and medical information. The BP feature allows users to upload their BP measurements to the device either automatically or manually, displays the readings on graphs, and includes feedback. This app also allows users to enter their distress level and its reasons as well as medication names and doses. The second feature allows users to set weekly challenges, such as monitoring BP. The app also has educational materials that allow patients to learn how to self-manage their chronic conditions.

Methods

Study 1: Usability Testing

The usability of the app was studied using a thinking-out-loud technique, where participants verbalize their thoughts and feelings while using the app and performing a set of predefined tasks. An observer collected first impressions and initial reactions [21]. A pilot of the usability study was undertaken with 2 eligible participants before the commencement of the full study.

The tasks presented to the participants were based on the main functionalities of the app, ensuring that the app was fully tested and used. The tests were audiorecorded to aid analysis. Participants were given multiple attempts to complete the tasks. If the participant was unable to complete a task after several attempts, assistance was offered. Each session lasted approximately 40-60 min and was conducted by the researcher with a facilitator aiding observations and taking notes.

Each session began by briefly introducing the test aim and its procedures and explaining the think-aloud technique and the purpose of the app. The participants were asked to sign a consent form and complete a short questionnaire, including demographic

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questions and smartphone experience. The participants then performed the tasks and vocalized their reactions. The observer recorded the number of tasks participants completed, any requests for assistance, and errors made. The observer also asked questions during the tasks to encourage participants to share their opinions. Finally, the participants were given an opportunity to raise any issues relating to topics that were not covered.

Study 2: Real-World Usability and Acceptance Study

A one-group posttest study was carried out to analyze how the app was used in everyday life as a part of the participants' routines. This study assessed the acceptance and usability of the app by means of a questionnaire, user engagement data, and a post interview after 4 weeks of using the app. Owing to the study aims and methods, patients and investigators were not blinded.

Each participant was asked to sign a consent form and complete a brief demographic questionnaire, including smartphone experience. The app was then downloaded onto the patient's iPhone. Face-to-face training was provided by the researcher, and the instruction manual was provided. Participants were provided with a validated home Omron M7 BP monitoring device [34-36]. Participants could obtain technical support throughout the study from the researcher by email or phone. For quality and safety reasons, patients continued their usual treatment with their physician. At the 4-week follow-up, participants completed the usability questionnaire and were interviewed using a semistructured interview to assess their personal experience, including acceptance of using the app and their views on its usability. The interviews lasted approximately 40 min and were audiorecorded, and concurrent notes were taken. Finally, the BP devices were collected by the researcher.

User Engagement Data

Information on how often participants used the app was automatically (anonymously) recorded. Participants were supplied with a specific link to download the Arabic version created for the study. The engagement data were provided anonymously, where the app did not collect data on a per-user basis due to data privacy regulations. We recorded the number of log-ins, the types and frequencies of data entered, and the number and frequency of features accessed. These are the 3 most common measurements used to assess user engagement with health apps [37]. The study also examined the user's session duration and user engagement over time.

Usability Questionnaire

The mHealth App Usability Questionnaire (MAUQ) was used [38]. The questionnaire was translated into Arabic following the guidance offered by the World Health Organization [39]. The pilot study found this translated questionnaire to have a Cronbach α of .9, a scale level content validity index of 0.98.

Data Analysis

SPSS software (package 19) [40] was used to calculate the descriptive statistics for the quantitative analysis. All qualitative data were transcribed, checked for accuracy, and analyzed using thematic analysis [40,41]. The qualitative analysis followed 6 steps: (1) data familiarization, (2) creation of initial codes, (3) collection of codes into broader themes, (4) specification of themes, (5) review of themes, and (6) writing the report [41].

The thematic analysis was partly deductive and partly inductive. In total, 2 researchers (TA and NA) independently analyzed 20% of transcripts. The researchers then checked for consensus on these coding. This resulted in standardized codes, in which TA was used for the remaining transcripts. Any new codes were added when necessary.

On the basis of the study aims, the initial themes were devised deductively. Additional themes and subthemes were then devised inductively based on users' initial expectations and their experiences of the app. Final themes and subthemes were confirmed through discussion among the authors. Following data analysis, an integration matrix [24,25] was used to compare data from the different methods. The quantitative and qualitative results of the research were integrated and analyzed together, considering any convergences and divergences between these different data. The matrix is given in Multimedia Appendix 1.

Results

Study 1: Usability Testing

Participant Characteristics

The usability study was completed by 10 participants, aged 35 to 69 years, with a mean of 48.8 (SD 11.7) years. In total, 6 participants were female and 4 were male. Overall, 6 participants had a diploma degree (a level of Saudi qualification between high school and bachelor's degree) or higher. Most participants (9/10, 90%) had experience using smartphones for longer than 3 years. Most participants (8/10, 80%) had hypertension for 1 year or more (Table 1).

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Table 1. Characteristics of usability test participants.

Characteristics	Values
Age (years)	
Mean (SD)	48.8 (11.7)
Range	35-69
Age groups (years), n (%)	
30-39	2 (20)
40-49	3 (30)
50-59	2 (20)
≥60	3 (30)
Gender, n (%)	
Male	4 (40)
Female	6 (60)
Time since diagnosed with hypertension (years), n (%)	
<1	2 (20)
1-3	4 (40)
>3	4 (40)
Education level	
Less than high school	3 (30)
High school	1 (10)
Diploma	2 (20)
Undergraduate degree	2 (20)
Postgraduate degree	2 (20)
Smartphone users	
Yes	10 (100)
No	0 (10)

Usability Test Results

The analysis of the usability test transcripts resulted in 2 themes: overall usability and user satisfaction and app content to support self-management.

Overall Usability and User Satisfaction

Users gave numerous positive comments relating to the usability of the Cora Health app interface and were generally satisfied. They described it as *helpful*, *fab*, and *easy to use*, and some asked to continue using the app by downloading the original English version from the app store. Patients felt that using the app would help improve their understanding of hypertension and their management of the condition. More than half of the participants completed all but 2 tasks. Participants often needed assistance while performing tasks, as they were unfamiliar with the app. They would require some time to become familiar with the app before being able to use it proficiently. The theme of overall usability and user satisfaction is separated into the 2 subthemes of app accessibility and user interface issues. Further details of these are presented in Multimedia Appendix 2.

App Content to Support Self-Management

User comments on the app content were generally positive, with participants describing it as "useful in self-managing." Some users liked the information available in the health guide and accompanying the BP feedback. They felt that this would increase their understanding and encourage them to take action to control their BP:

> *I really love the additional explanation. It offers some helpful advice that encourages me to take action because my BP is not normal. It helps me to understand my situation and to do something to control [my BP].* [P2]

Some participants expressed that the tick feature of the app (ticking off completed tasks) would encourage completion of the challenges:

> *it encourages me to do more tasks.* [P4]

Task Completion

Most participants downloaded the app (task 1) without any assistance, except for 3 older participants who required help. However, this difficulty may have been related to the method of downloading the trial version, which is different from a

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typical app. All participants completed both the *Entering Stress Data* task (task 3.2), inserting a tick to mark self-monitoring as completed (task 8), and *indicate how many challenges* are set (task 9), without making any errors or asking for any assistance. Therefore, these tasks had the highest completion rate.

Very few users completed task 7: setting a reminder for self-monitoring BP. Only 20% (2/10) of participants completed this task without errors, whereas 80% (8/10) of participants completed the task with errors. Similarly, in task 10, only 2 participants completed the task without errors, whereas 5 participants (5/10, 50%) completed the task with errors and 3 participants (3/10, 30%) required help.

The remaining tasks were completed by most participants without errors or assistance (60% for tasks 2, 3.1, 4, and 11; 70% for tasks 5 and 6). The full completion, error, and assistance rates are presented in Table 2.

Table 2. Usability test tasks.

Task	Participants who completed the task, n	Participants who made errors, n	Participants who needed an assistance, n
1. Downloading the app and log-in	7	0	3
2. Monitoring and registering BP[a] with the app	6	0	4
3. Recording other data (medication and distress)			
3.1 Enter the medication name and its dose	6	4	0
3.2 Enter the distress level you feel and select any applicable problems	10	0	0
4. Indicate whether the BP average value and see if its normal or not	6	2	2
5. Compare the new measurement of BP data with those measured before	7	1	2
6. Indicate whether the current measured BP is normal or not using the Blood Pressure Scatter Char	7	1	2
7. Set a reminder for self-monitor BP 4 times a week	2	8	0
8. Inserting a tick to mark self-monitoring as completed	10	0	0
9. Indicate how many challenges are set	10	0	0
10. Indicate how many tasks have you completed and how many tasks do you still to need finish	2	5	3
11. Read the information about BP monitors	6	0	4

[a]BP: blood pressure.

Study 2: Real-World Usability and Acceptance Study

Participant Characteristics

In total, 23 participants agreed to participate in this study. A total of 2 participants decided to withdraw after a few days because of their busy schedule. One other participant had to withdraw because of technical issues related to their device. In total, 20 participants (11 males and 9 females) completed the study. They were aged between 33 and 71 years, with a mean of 51.6 (SD 11.7) years. Overall, 80% (16/20) of participants had a diploma degree or higher. Most participants had experience using smartphones for more than 3 years. Most participants (16/20, 80%) had hypertension for 1 year or more (Table 3).

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Table 3. Participant characteristics.

Characteristics	Values
Age (years)	
Mean (SD)	51.6 (11.7)
Range	33-71
Age groups (years), n (%)	
30-39	3 (15)
40-49	6 (30)
50-59	6 (30)
≥60	5 (25)
Gender, n (%)	
Male	11 (55)
Female	9 (45)
Time since diagnosed with hypertension (years), n (%)	
<1	4 (20)
1-3	7 (35)
>3	9 (45)
Education level, n (%)	
Less than high school	4 (20)
High school	0 (0)
Diploma	5 (20)
Undergraduate degree	7 (35)
Postgraduate degree	4 (20)
Smartphone users, n (%)	
Yes	20 (100)
No	0 (0)

Usability Questionnaire

This section presents the results pertaining to the usability of the app and participants' satisfaction (as measured by the MAUQ). Participants perceived the app as a useful tool (mean score 6.3, SD 0.40 on a scale of 1-7). They were also satisfied with the app and its interface (mean score 6.2, SD 0.25) and expressed that the app was easy to use (mean score 6, SD 0.2).

Participants scored high when asked whether the app is a useful tool in helping them to manage their condition effectively (mean score 6.6, SD 0.50). A high score was also given when asked whether the app is useful for receiving health care services such as accessing educational information, tracking their own activities, and performing self-assessment (mean score 6.7, SD 0.47). However, participants scored lower (mean score 5.7, SD 1.49) when asked if they could use the app even when the internet connection was poor or unavailable.

App Engagement Data

Table 4 shows group-level data on participants' engagement with the app over a month, measured by the length of time of each user's session. The average session duration was 1 min and 35 seconds, with around 72.9% (346/474) of users' sessions being in the *meaningful engagement* ranges of 30 to 60 seconds or longer [42].

Figure 2 shows the retention data for study participants, that is, the number of users who continued to use the app. A total of 6 users ceased using the app following the first day's use. From day 1 to day 6, 74% of the participants were active. From day 7 to 18, 70% were active. User retention then gradually decreased to 48% on day 30.

On average, the app was opened 21.4 times per user, totaling 493 times over a month, as shown in Table 5. The most accessed functionality was viewing the Logbook, which allows users to self-monitor their previously entered data. The least accessed functionality was setting behavior goals (*Challenge Created*).

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Table 4. Participant session duration.

Sessions durations	Sessions, n
0 seconds	0
0-3 seconds	38
3-10 seconds	40
10-30 seconds	50
30-60 seconds	96
1-30 minute	141
3-10 minute	93
10-30 minute	16

Figure 2. Participant engagement over time.

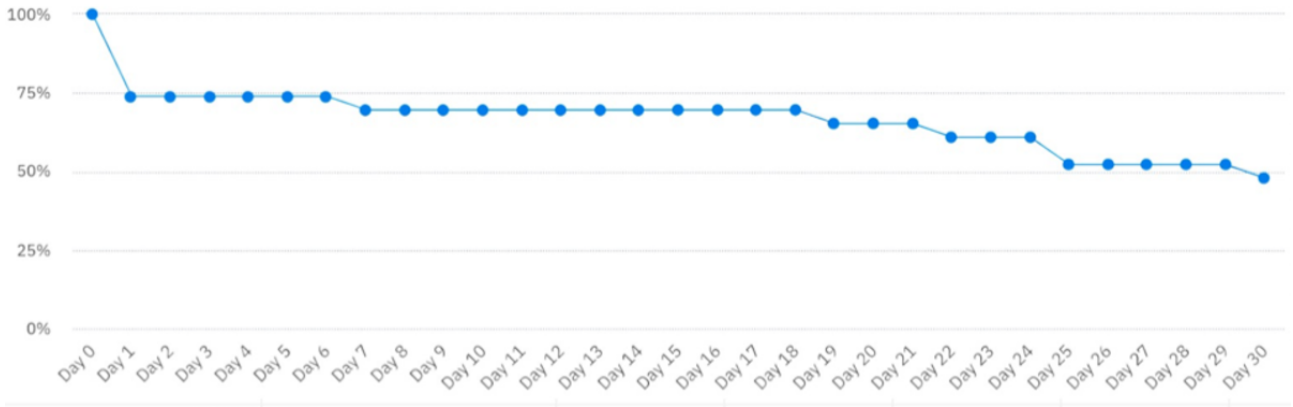

Table 5. App functionalities use.

App section and app functionalities	Participants who used the functionalities, n	Times functionality was used, n	Average per participant
General			
App opened	23	493	21.4
App closed	23	768	33.4
Logbook and dashboard			
Feedback on behavior or outcome of behavior (dashboard viewed)	23	1002	43.6
Self-monitoring of previous data (logbook viewed)	23	1384	60.2
Self-monitoring of blood pressure	21	416	19.8
Self-monitoring of medication	20	234	11.7
Self-monitoring of distress	20	246	12.3
Challenges			
Setting behavior goal	19	72	3.78
Review of behavior goal(s)	21	704	33.52
Task completed	19	721	37.94

The most common self-monitoring behavior was entering BP, followed by stress and medication: each user self-monitored their BP and inputted an average of 19.8 times.

The user engagement data over the month for entering BP, medication, and stress levels and for viewing previously entered data are presented in Multimedia Appendix 3. These graphs clearly show a distinction between a group of users who engage regularly (more than 6 times) and a group with lower engagement figures. The majority of participants engaged regularly with the app. In total, 15 (71.4%) participants recorded data for at least 3 days per week (the level considered sufficient

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for treatment and adherence with self-monitoring [43]). The figures for recording emotion and medication use are lower.

The user engagement data over the month for goal setting (challenges), task completion for each goal, and reviewing behavior goals are presented in Multimedia Appendix 3. Most participants (n=19) set at least one goal, with a number ranging from 1 to 10. Most participants (n=14) set 3 or more different types of goals.

Interview Results

Analysis of interviews resulted in 3 themes: usage of the app, capacity to support self-management, and usability of the app. Some participants' quotations for this section are provided in Multimedia Appendix 4.

Usage of the App

General Satisfaction and Use

Patients were satisfied with the app and saw it as an *enjoyable, interesting, accessible and convenient, useful,and informative* tool in managing hypertension. They generally found it easy to incorporate the app into their routines. Few participants (n=2) felt that the app felt the app required time and effort.

Patients expressed that they would be likely to continue using this app after the study and that they would recommend it to others. They gave several reasons, including that the app offered a single easily accessible location for their data, that it provides a good overview of their BP level, and because of its ease of use and convenience for managing their diseases.

App Functionality Use

Participants used most of the app functionalities. Interviewees reported that the most commonly used app function was self-monitoring BP data, followed by viewing the graphs and lists showing trends over a week or month. They stated that the visual representations were valuable, as was the quick and direct transmission of BP data from a BP monitoring device to the app.

Most people recorded medications and stress and perceived the facility to enter these as a positive feature. They also reported setting different types of challenges, the most common being entering BP and taking medication. Most also set challenges for other activities intended to increase exercise, and a few set challenges to reduce stress.

Hypertension information was generally considered useful, but a few patients stated that information was lacking, or already known, for example, regarding meals (especially Saudi foods), mental health, smoking, or information about pregnancy. Some participants emphasized that it was the overall range of functionalities that made the app valuable and worth using.

External Factors Influencing Use of the App

Participants reported a range of external factors that affected their use of the app. Family was one of the key factors mentioned, as both a motivating and demotivating factor for using the app. Busy lifestyles and other health issues reportedly prevented some participants from undertaking and/or completing additional challenges.

Capacity to Support Self-Management

A Daily Monitoring Tool

The app provides patients with a routine and structured system, helping them to maintain discipline in self-monitoring different types of data. Transmission of BP data by Bluetooth was easier and quicker than conventional recording methods or relying on memory. Presenting data immediately in a graphical view helped patients see trends over time.

Monitoring emotions and indicating the reasons behind them was a positive feature, but it would be good to allow monitoring of the symptoms that patients feel.

An Informative Tool

Participants found the feedback functionalities to provide a clear picture of BP levels and to show the relationship between their challenges completed and their BP level. However, participants would have liked more detail in the feedback on task completion and more tailoring of BP feedback to their individual cases.

A Commitment Tool

Participants expressed that this app increased their commitment and encouraged them to add and achieve more self-management strategies to their routine. Some participants also found that repeated reminders further encouraged them to complete their activities, but showing more written details would encourage them more rather than relying on notification alone. In total, 2 participants felt that it would increase their commitment if they were able to set their own challenges.

A Communication Tool

Participants felt that the app would be a valuable tool to increase patients' participation in their care, for example, by aiding communication and sharing of data at doctors' visits more easily than carrying manual copies. This aspect of the app was considered particularly beneficial for assisting during medical emergencies, with one suggesting that doctors should have real-time access to the app data.

Usability of the App

Overall Usability

Most participants found the app easy to use and reported high levels of confidence. Those who had little experience required some practice to increase their confidence or ability, some being more reliant on the study training and instructions or assistance.

Most participants found it easy to navigate the app and enter data, except when attempting to enter multiple readings at once, which requires the save button to be pressed multiple times. The ability to enter data retrospectively and to edit previously entered data were valued features. However, patients reported some issues with the *tick* feature for marking completed challenges, either because of physical difficulties in using the functionality or being unable to undo *ticks* made in error. To improve this feature, some participants suggested that ticking could be prompted by the app.

App Accessibility

Some participants, particularly older people, had difficulty reading text within the app. They liked the zoom feature in the

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health guide but would like to be able to change the font size elsewhere. Some suggested that the contrast in the BP entry screen could be improved to make buttons easier to find.

Not all words in this version were translated into Arabic (eg, medication names), which was an issue for some participants, as was the default calendar (ie, Gregorian rather than Islamic).

Suggested Improvements

The study results found some aspects of the app that should be considered for improvement. There is a need to increase the app accessibility by (1) translating some words into Arabic (eg, medication names); (2) allowing changing between Islamic and Gregorian calendars; (3) increasing the color contrast in the BP entry screen; and (4) allowing changing font size. Suggested improvements regarding user interfaces include (1) using clear and meaningful terminology (such as health information); (2) making the data entry button more visible; (3) allowing inputting of multiple data at once; (4) adding text in some charts to supplement the color coding; and (5) displaying a message when tasks are marked as complete or making this data visible from the Challenge screen."

There were also some more general recommendations regarding app content. The feedback of BP should be more detailed and tailored for individual cases. The app should allow entering the symptoms that patients feel and allow them to set their own challenges. The *tick* function could be improved if it prompted participants to tick off items they have set reminders for and if it allowed participants to edit a tick when it was made in error.

Discussion

Principal Findings

This study evaluated a commercially available app that was carefully selected on the basis of existing evidence regarding the effectiveness, usability, privacy and security, and preferences of end users and health care professionals. This process resulted in selecting an app that was expected to have the best potential for being usable, acceptable, and effective in general, particularly in the Saudi context. The results presented in this paper do indeed show relatively good usability outcomes but still a considerable number of possibilities for improvement because of users' differing needs, expectations, and preferences that need to be considered [44]. The actual usage data show that even this *best practice* app is not used by all participants and that only some of the functionalities are regularly used. This demonstrates the complexity of *getting it right* when developing smartphone apps and once again emphasizes the importance of acceptability, usability, and effectiveness evaluation, among target users, who are rarely consulted or involved in the commercial app development process, typically only being asked to evaluate once the app is released [45].

The results suggest that the provision of training could be a possible way to mitigate most usability issues and enhance user acceptance. The interview and MAUQ showed that the app is easy to use and generally accepted by participants. Some of these participants commented that training and instructions helped them use it more easily. The usability test, however, found that app usability was only moderate, and participants needed some familiarization time before they could use the app proficiently. A small number of tasks remained uncompleted by most people. Similarly, in the interview and questionnaire, participants reported that it was easy to navigate the app and enter data, whereas the usability test showed that participants faced issues with these aspects. This difference might be a consequence of the usability test being conducted in a controlled setting, in which participants had not received any previous training or practice. This finding appears to be in line with previous evidence indicating that a wide range of different users can use apps given the right training and support [46-48].

The results indicate that commercial apps have the potential to be met with sustained engagement from users. Engagement data showed that users' sessions with the app were similar to other studies using similar apps for other chronic diseases [42]. However, the actual usage data show a higher level of sustained engagement with the app, with a 48% retention rate on day 30, in comparison with another study of self-monitoring apps, which showed a retention of 3.3% [49]. This study also found much higher levels of BP monitoring than some other studies concerning other chronic conditions. Most participants (71.4%) recorded their BP around 3 times or more per week. In contrast, Goyal et al [44] found that only 9% of participants achieved similar levels of engagement (≥3 times). There are several possible explanations for this, with potential implications for future research and app development: doctors asked patients to record BP measurements twice for each reading to ensure accuracy, which could increase the frequency of measuring [43]. This study did not provide patients with a secondary phone, which could have led to higher engagement [44]; the app's feature for transmitting data either automatically or manually could have increased BP measurement. User motivation has been shown to be key to adherence with self-monitoring [22], so this may be another factor.

The study showed that participants in all strands expressed enthusiasm for using an app to support self-management because of its benefits in increasing their understanding and participation. All strands found that the app content (eg, information, etc) was considered a good potential tool to support self-management and to increase participants' understanding and commitment. However, participants' responses in interviews also revealed several concerns or limitations, suggesting that an app alone would not be a sufficient tool for self-management. Some external factors and barriers, for example, family, affected participants' use of the app such as positively or negatively affecting patients' optimism and self-esteem, or easing the stress of using the app to support the self-management of their disease [50]. These factors must also be considered when assessing the benefits of using apps to support the self-management of hypertension.

The usability test and interviews reported similar difficulties with app accessibility, for example, font size and color scheme. Previous research has shown that older people are likely to encounter more difficulties and have lower engagement with these types of technological interventions [51,52]. It is therefore important to assess how engagement levels might differ between younger and older participants and who are most likely to benefit from these interventions, particularly because most patients

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with hypertension are older [52]. Owing to data privacy regulations, the engagement data were collected anonymously in this study, so it is not possible to compare older and younger participants. These older members of the study sample highlighted some issues regarding the accessibility of the app, such as the inability to change font sizes, app presentation, data entry, and the need for help from family members. This suggests that the engagement of these older members of the population might be improved if such accessibility issues were addressed. Understanding and considering older adults' opinions and needs is crucial to help introduce apps to this population and maximize their usability [53].

Participants in this study suggested that sharing their data with health care professionals for ongoing care should be effectively supported. Previous studies have suggested that apps that share health data with health care professionals can aid in treatment, especially in emergencies [54]. Apps that are limited to one specific condition may be less helpful if not properly integrated with health information systems, particularly for patients who have comorbid conditions that might complicate their treatment needs and require a large treatment team [54,55]. However, there are several potential barriers to mHealth integration with existing systems that should be considered [56].

Strength and Limitations

Our study has several strengths. First, it evaluates the selected app, Cora Health, in 2 different situations: in real-life and under controlled settings, integrating different methods (eg, interview, questionnaire, etc) to gain in-depth insight and provide a complete picture of the usability of the app. As the convergent and divergent results from these strands indicate, such a mixed methods approach yields a more detailed picture of the research area. Second, through our analysis, we were able to identify areas where usability was a potential concern. From these findings, we were able to comprehensively establish ways to further refine the app to make it more usable. These conclusions could be extended to other mHealth apps. Third, this is the first study to evaluate the usability and acceptance of a commercially available app for people with hypertension in Saudi Arabia.

However, there are also some limitations to this study. For instance, the study only focused on patients' opinions without considering health care professionals' or experts' opinions, which might have provided different clinical insights. This is because the app did not support any access for health care professionals. The small number of participants and selection bias are likely to have been other limitations: in order to be eligible, participants had to own an iOS-compatible smartphone; and as recruitment for the usability test was conducted via posters and flyers, the sample was therefore self-selecting and may have been biased in favor of highly motivated individuals. For the interviews, participants were recruited via their physicians. The study also used self-selecting and purposive sampling, which may be influenced by errors in judgment or assumptions by the researcher, leading to higher levels of bias and lower reliability. The number of older participants in the study sample was relatively low (8/30, 27%). This may have been a limitation, especially because the majority of patients with hypertension are older people. For these reasons, the generalizability of the study to the general population is somewhat limited. Despite attempts by the researcher and moderator to create a comfortable and welcoming research space, it is possible that the presence of a session moderator in the usability test may have affected user confidence or performance in a way that they may have differed from field use. Similarly, the potential generalizability of these findings beyond the Saudi context may also be limited: it may only be possible to generalize them to similar cultural contexts and to health care settings that are similar to the Saudi Ministry of Health. Finally, this study showed engagement over a 30-day period. As such, it is not possible to draw conclusions as to whether this might be sustained over a longer period. The study was concerned with describing users' engagement rather than examining how this engagement might contribute to achieving certain health outcomes or behavior change, meaning it is also not possible to draw conclusions as to whether this constituted *effective engagement*.

Recommendation for Further Studies

On the basis of the study results, it is important for future studies to investigate whether the levels of engagement recorded in this study could be sustained over the longer term to achieve the desirable outcomes [48,57]. There is also a need to evaluate the effectiveness of the app as well as *effective engagement*, that is, engagement that achieves desired behavior changes [58,59] and compare these results with usual care to reach clinical conclusions. This would require studies with larger numbers of users and longer follow-up periods. Future research should also consider how participant age might influence their engagement and should also examine contexts outside Saudi Arabia. Some issues raised by participants in this study will need to be addressed before the Cora Health app can be maximally effective in large-scale studies. Future studies should undertake a more collaborative approach between app developers and potential users to be mutually beneficial and lead to higher quality apps that can more fully support patients' self-management.

Conclusions

This study showed that a commercially available app can be usable and acceptable for the self-management of hypertension. Participants were generally satisfied and found that the selected app was easy to use and useful in supporting their self-management activities. However, some participants experienced issues with the app's interface that need to be considered in future studies and app development. The results of this study suggest that there is potential for a commercially available app to be used in large-scale studies of the self-management of hypertension if suggestions for improvements are addressed.

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Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Data Integration matrix.
[DOCX File , 130 KB - mhealth_v9i2e24177_app1.docx]

Multimedia Appendix 2
Usability test data.
[DOCX File , 100 KB - mhealth_v9i2e24177_app2.docx]

Multimedia Appendix 3
Engagement data.
[DOCX File , 791 KB - mhealth_v9i2e24177_app3.docx]

Multimedia Appendix 4
Qualitative data.
[DOCX File , 109 KB - mhealth_v9i2e24177_app4.docx]

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Abbreviations

BP: blood pressure
MAUQ: mHealth App Usability Questionnaire
mHealth: mobile health

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Original Paper

An Interactive Voice Response Software to Improve the Quality of Life of People Living With HIV in Uganda: Randomized Controlled Trial

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Abstract

Background: Following the successful scale-up of antiretroviral therapy (ART), the focus is now on ensuring good quality of life (QoL) and sustained viral suppression in people living with HIV. The access to mobile technology in the most burdened countries is increasing rapidly, and therefore, mobile health (mHealth) technologies could be leveraged to improve QoL in people living with HIV. However, data on the impact of mHealth tools on the QoL in people living with HIV are limited to the evaluation of SMS text messaging; these are infeasible in high-illiteracy settings.

Objective: The primary and secondary outcomes were to determine the impact of interactive voice response (IVR) technology on Medical Outcomes Study HIV QoL scores and viral suppression at 12 months, respectively.

Methods: Within the Call for Life study, ART-experienced and ART-naïve people living with HIV commencing ART were randomized (1:1 ratio) to the control (no IVR support) or intervention arm (daily adherence and pre-appointment reminders, health information tips, and option to report symptoms). The software evaluated was Call for Life Uganda, an IVR technology that is based on the Mobile Technology for Community Health open-source software. Eligibility criteria for participation included access to a phone, fluency in local languages, and provision of consent. The differences in differences (DIDs) were computed, adjusting for baseline HIV RNA and CD4.

Results: Overall, 600 participants (413 female, 68.8%) were enrolled and followed-up for 12 months. In the intervention arm of 300 participants, 298 (99.3%) opted for IVR and 2 (0.7%) chose SMS text messaging as the mode of receiving reminders and health tips. At 12 months, there was no overall difference in the QoL between the intervention and control arms (DID=0.0; P=.99) or HIV RNA (DID=0.01; P=.94). At 12 months, 124 of the 256 (48.4%) active participants had picked up at least 50% of the calls. In the active intervention participants, high users (received >75% of reminders) had overall higher QoL compared to low users (received <25% of reminders) (92.2 versus 87.8, P=.02). Similarly, high users also had higher QoL scores in the mental health domain (93.1 versus 86.8, P=.008) and better appointment keeping. Similarly, participants with moderate use (51%-75%) had better viral suppression at 12 months (80/94, 85% versus 11/19, 58%, P=.006).

Conclusions: Overall, there was high uptake and acceptability of the IVR tool. While we found no overall difference in the QoL and viral suppression between study arms, people living with HIV with higher usage of the tool showed greater improvements

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in QoL, viral suppression, and appointment keeping. With the declining resources available to HIV programs and the increasing number of people living with HIV accessing ART, IVR technology could be used to support patient care. The tool may be helpful in situations where physical consultations are infeasible, including the current COVID epidemic.

Trial Registration: ClinicalTrials.gov NCT02953080; https://clinicaltrials.gov/ct2/show/NCT02953080

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KEYWORDS

mHealth; HIV; quality of life; interactive voice response; mobile health; digital health

Introduction

The response to the HIV/AIDS epidemic and the scale-up of antiretroviral therapy (ART) has been successful globally. Over the last decade alone, the number of people living with HIV who are receiving ART increased from 400,000 in 2003 to 24.5 million in 2019 [1]. Although ART improves the quality of life (QoL) in people living with HIV [2,3], studies after ART scale-up continue to report low QoL, even in people living with HIV receiving ART [4]. The World Health Organization (WHO) has highlighted the need for HIV care programs to increase coverage of comprehensive HIV services and ensure good QoL for people living with HIV [5].

The biomedical goal of ART is to stop HIV replication, achieve viral suppression, and ultimately reduce HIV-associated mortality and its transmission. To achieve these goals, people living with HIV need to be highly adherent to ART and remain engaged in care. Ensuring social support and improving knowledge about HIV ART improves the QoL in people living with HIV [3]. Conversely, poor adherence [6] and noncontrolled symptoms [7] are associated with poorer QoL. To this end, HIV care should encourage strict adherence to ART and support symptom surveillance and alleviation to improve the QoL in people living with HIV. However, the provision of continuous adherence support and symptom surveillance is challenging and time-consuming and requires resources. Therefore, there is a need for patient-centered systems that enhance adherence and symptom surveillance but do not burden already-constrained health systems, especially in the low- and middle-income countries (LMICs) with a high burden of HIV.

Following the increasing access to mobile technology in the most-burdened countries [8], mobile health (mHealth) technologies are increasingly leveraged to support people living with HIV. However, there is limited evidence on the impact of mHealth tools on QoL in people living with HIV, especially in LMICs. The majority of mHealth tools evaluated in LMICs have used SMS text messaging interventions with mixed results [9]. The adoption and impact of SMS text messaging interventions are likely to be low in countries with low literacy rates. This study sought to determine the acceptability and impact of an interactive voice response (IVR)–based patient support technology among people living with HIV in Uganda. The IVR technology allows for two-way communication between the software and end user and can be deployed on a simple feature phone. The IVR tool evaluated in this study delivered daily adherence reminders, appointment reminders, and weekly health tips to people living with HIV.

To increase the adoption, replication, and impact of the intervention, we used the criteria and taxonomy suggested by Tabak et al [10] and selected the information, motivation, and behavioral skills (IMB) model of behavioral change [11] as the theory for the intervention (Figure 1). The IMB model was initially developed to understand and change HIV-risky behaviors in developed countries [11]. It has since been widely used in LMICs to assess and improve adherence to ART [12,13]. The model suggests that motivation, skilling, and provision of information on adherence to people living with HIV improve adherence. We hypothesized that IVR-based technology could provide motivational information and reminders to people living with HIV and ultimately improve ART adherence, QoL, and viral suppression. Figure 1 shows the aspects of the IMB model that were adapted to design the intervention used in this study.

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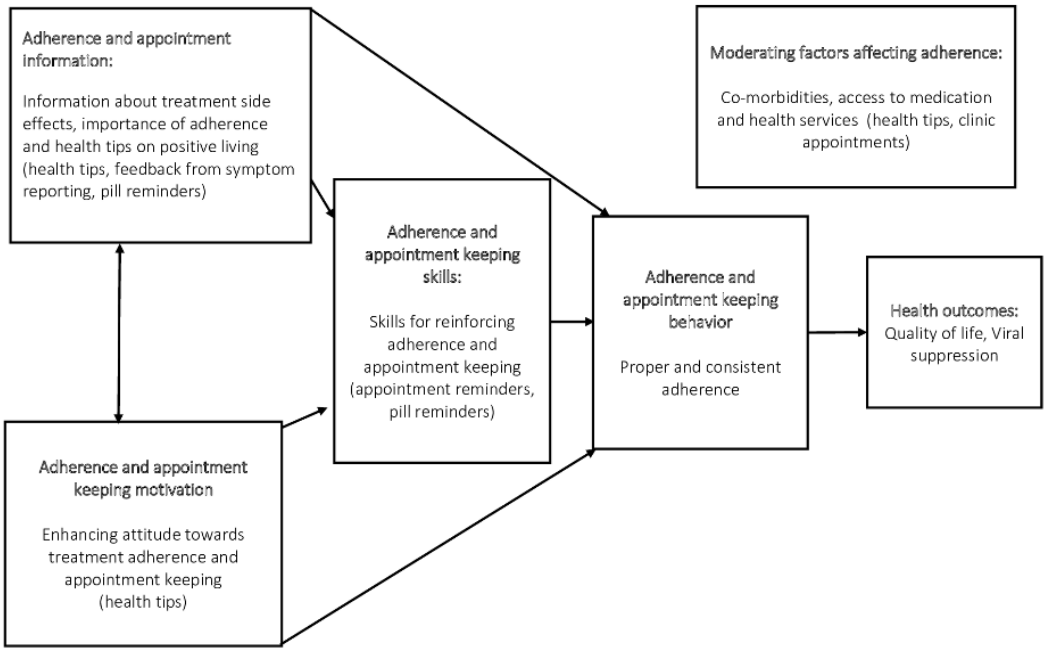
Figure 1. Behavioral change conceptual framework for the study, adapted from the information, motivation, and behavioral skills model [11].



Methods

Study Design

This was an open-label randomized controlled trial (RCT) to evaluate the impact of a patient support tool, Call for Life Uganda (CFL), on QoL and viral suppression in people living with HIV in Uganda. The primary outcome was the difference in the differences in QoL between the study arms at month 12.

Study Settings

The study was conducted at two HIV clinics. The Infectious Diseases Institute (IDI) clinic is a specialist urban HIV clinic located within the National Mulago Hospital complex and serves more than 8000 people living with HIV. Kasangati Health Centre IV is a government-owned clinic in peri-urban Kampala and serves approximately 5000 people living with HIV. At both clinics, comprehensive HIV care and treatment services were provided according to the WHO and national guidelines for HIV treatment [14,15]. Nurse counselors physically provide face-to-face patient adherence support during clinic visits with no option for remote support.

The technology evaluated in this study was CFL, a software that is based on open-source Mobile Technology for Community Health (MoTeCH). MoTeCH was initially developed by the Grameen Foundation and the University of Southern Maine with the support of Janssen, the Pharmaceutical Companies of Johnson & Johnson. Before this study, the software was used in India and Ghana [16,17]. The initial software was called Treatment Advice by Mobile Alerts (TAMA) [17]. Following the adaptation of TAMA for use by people living with HIV in Uganda, the local system was named Call for Life.

Before adoption, user acceptability testing (UAT) was undertaken with study staff (medical and information systems) and the TAMA team based at Janssen Global Public Health. Between October 2015 and August 2016, 103 “expert” people living with HIV who had been attending IDI for over 5 years and who had prior participation in research were enrolled on the TAMA software. The purpose of this exercise was to tailor the software to the needs of people living with HIV and care providers in Uganda and to pilot health tip content. Before adding patients to the system, 6 UAT sessions were held to test inbound and outbound calls, the registration process, and the functioning of the audio files. In December 2015, a focus group discussion was held with 43 people living with HIV registered on TAMA to understand the experiences and challenges users faced. The major challenges experienced during study implementation included internet and system failures and the need for security upgrades (Multimedia Appendix 1). As a result, the system was iteratively upgraded from version 1.0.0 to version 9.3.0, before and during use in the study. The changes aimed at optimizing usability and security, not the intervention delivered, as summarized in Multimedia Appendix 2.

The health tips were developed by an experienced team of HIV clinicians and behavior change specialists in collaboration with Straight Talk Foundation, a local nongovernmental organization that specializes in health messaging and behavior change. The health tips were based on international and national best practices and guidelines for HIV messaging [15,18]. In collaboration with Community Health and Information Network Uganda, a patient advocacy nongovernmental organization, focus group discussions were held in January and February 2016 with people living with HIV not enrolled on the tool to assess the acceptability and clarity of the messages. The discussions also assessed the accuracy of translations to local languages. Overall, there were 330 messages that covered various topics including general information on HIV, antiretroviral therapy and adherence, positive living, sexual and reproductive health, pregnancy, and safe breastfeeding and general health. Multimedia Appendix 3 summarizes the message categories and provides examples of each.

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Study Intervention

The software evaluated in this study is CFL and is compatible with messaging in four languages: English, Luganda, Kiswahili. and Runyankore. The system allows automatic interaction with patients using voice and tone input via a keypad (IVR) or by SMS text messaging using simple phones (GSM-2/feature). CFL was integrated with the patient health information management systems used for HIV care in Uganda, so as to obtain appointment dates and ART regimens. Participants in the intervention arm received the usual standard of care plus daily adherence IVR voice reminders (or SMS text messaging), delivered just before the usual pill-taking time. Intervention participants also received pre-appointment reminders and weekly voice calls offering educational health tips. In addition, intervention participants had an option to call a toll-free line and report symptoms or drug side effects. Such patient-triggered calls could generate alerts that would prompt health care workers to call back within 24 hours. Participants chose the preferred languages, time, and frequency of receiving reminders. For security, both outbound and inbound calls played music until the participant entered a personal identification number (PIN) unique to them. Participants chose their preferred "health topics", from which the system randomly shuffled and randomly played different health tips for each call (Multimedia Appendix 3). Multimedia Appendix 4 shows the call flow diagram for the CFL software. Overall, participants received reminders and had to key in their PIN before listening to the calls. After the reminder was played, the system prompted participants to select additional services they wanted using buttons on the phone keypad. People living with HIV in the control arm received standard of care comprising face-to-face facility appointments but no access to remote adherence, appointment reminders, or symptom reporting.

Quality Assurance and Software Updates

The health care workers accessed the CFL dashboard on the web [19], which required connection to an internet server (thus needing a stable connection to power and internet). Participants did not require smartphones. They received and made calls using any mobile phones, including feature phones. The software allows for the configuration of call times, inputting of mobile phone contacts, PIN setting, and synchronization of data with the patient health information systems.

At baseline, participants in the intervention arm were trained on how to initiate and receive calls. Participants were asked at each appointment if they were experiencing challenges with the IVR calls. Call completion rates were reviewed weekly. Patients with a blocked PIN were contacted by the study medical team within one week to reset the PIN. Throughout the study period, there were 16 upgrades of the CFL software (Multimedia Appendix 2). However, the content delivered by the software did not change throughout the follow-up period, except for health tips; following feedback from the participants, 30 additional messages (16 on nutrition and 14 on cancer) were added.

Sample Size and Power

Based on pre- and post-ART assessments of QoL in people living with HIV in Burkina Faso [7] and Uganda [20], we anticipated a 15-point difference in overall QoL following ART in people living with HIV in the control and intervention arms. We also estimated that there would be an additional 5-point improvement in the QoL in those receiving CFL. Therefore, we expected an overall difference of 5 points in ART-experienced people living with HIV in the intervention versus control arms. For a power of 90% and precision of 0.05, we needed a minimum of 273 patients in each arm (overall 546) to detect a 5-point difference in the QoL in the intervention versus the control arm. The estimated sample size was adjusted for the anticipated attrition of 9% to give a final sample size of 600.

Randomization

Eligible patients were randomized to either the control (standard of care) or intervention arm (1:1 ratio) in this open-label study. Randomization blocks (sizes of 4) were generated by an independent statistician and kept under lock and key at the two sites. The study medical team assigned randomized participants to their final allocated study arms. We interviewed participants in the intervention arm at each visit if they had trouble using the intervention. A detailed trial design can be found in the study protocol (Multimedia Appendix 5).

Study Procedures and Data Collection

Participants were physically evaluated at baseline and months 6 and 12. At each time point, the study team collected data on sociodemographics (age, sex, marital status) and treatment history (ART status, duration on ART, ART regimen, and HIV RNA). Plasma HIV RNA testing was performed on plasma at months 6 and 12 using the Roche COBAS TaqMan v2.0 HIV-1 assay. Viral suppression was defined as less than 50 copies of HIV RNA per mL. QoL was measured using the HIV version of the Medical Outcomes Study (MOS-HIV) [21] because its local language version has been validated in Uganda [22]. The MOS-HIV measures health-related QoL in 11 areas: health perceptions, bodily pain, physical function, role function, social function, mental function, vitality, health distress, cognitive function, QoL, and health transition. The QoL scores on this scale range from 0 to 100, with higher scores implying better health. Overall scores and individual scores for the physical health summary (PHS) and mental health summary (MHS) domains were calculated. Adherence to appointments was defined as attending appointments within 3 working days of the scheduled visit.

The study was terminated before its conclusion, based on guidance by an independent data safety monitoring board (DSMB), after it was found that there was no difference between study arms at 6 months. The study was closed when all participants had completed at least 12 months (follow-up period range: 12-24 months). The study protocol and DSMB allowed all participants who were willing to continue receiving IVR technology support to do so. Throughout the study, treatment-related data were shared with medical teams. Those with detectable HIV RNAs received appropriate treatment that included intensive adherence counseling.

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Study Subjects

ART-naïve and ART-experienced people living with HIV were consecutively screened, and participants were eligible for enrollment if they belonged to any of the following categories: ART-naïve adults or ART-experienced people living with HIV, including key populations (sex workers and men who have sex with men), young adults (18-24 years), pregnant and breastfeeding mothers, and people living with HIV in discordant relationships. People living with HIV were eligible if they were 18 years or older, were willing to comply with study procedures, and had access to and were able to use a cell phone. Participants also spoke English or one of the available local languages and provided informed consent. We excluded people living with HIV with clinical conditions that could interfere with the use of cell phone (for example, deafness, severe cognitive impairment, critical illness), and those who were not receiving the standard first-line (efavirenz, tenofovir disoproxil fumarate, and lamivudine) or second-line (atazanavir or lopinavir with boosted ritonavir plus lamivudine and tenofovir) ART regimens. Participant screening and enrollment were done in person by study medical teams.

Statistical Analysis

The primary endpoint was the difference in the change in the QoL (MOS-HIV) at 12 months among ART-experienced people living with HIV in the intervention and control arms at the two study sites. The secondary outcomes were differences in viral suppression (HIV RNA<50 copies/mL) and appointment keeping. All analyses were conducted using Stata software, version 14 (StataCorp). We compared the changes in the QoL and HIV RNA outcomes using Pearson chi-square or paired *t* test and determined the difference in differences (DID) in the endpoints between intervention and control arms. Analysis of covariance was used to test the interaction effects of categorical variables on the QoL, controlling for the effects of other selected continuous variables, including baseline HIV RNA, CD4, and duration of care. Additionally, we compared the outcomes within the intervention arm according to the intensity of use of the system (proportion of users receiving reminders): low users (<25% calls answered), fairly low users (26%-50% of calls answered), moderate users (51%-75% answered) and high users (>75% calls answered). The results of this analysis are reported as per the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) [23] and are also consistent with the mobile health evidence reporting and assessment guidelines (Multimedia Appendix 6) [24].

Data Security

All study data were double-encrypted by CFL. All clinic data of people living with HIV remained on the local IDI servers as per Uganda data protection guidelines. Communication between the CFL browser and the server was encrypted using 128-bit Secure Sockets Layer. CFL system servers were hosted by Amazon Web Services (AWS) and secured by Amazon virtual private cloud and AWS web firewalls. At the same time, data were protected from virus threats using Bitdefender antivirus technology.

Ethics

The study was approved by the Makerere University School of Medicine Research Ethics Committee (REC# 2015-083) and Uganda National Council of Science and Technology and was registered with ClinicalTrials.gov (NCT02953080) [25]. All study participants provided informed consent before participation. An independent DSMB supervised the study implementation. An interim analysis was planned at 12 months a priori, and the study was to be terminated if there was no difference in the primary outcomes between study arms at 6 months.

Results

Study Population

From August 2016 to August 2017, 1079 participants were screened concurrently at the two study clinics, 715 participants were eligible, and 600 participants were enrolled (Figure 2). The most common reasons for nonenrollment included postponing enrollment to a date beyond the enrollment period—such participants were not enrolled as they returned after the sample size had been accrued (47)—and failing on second-line ART (22). The other reasons for exclusion are shown in Figure 2.

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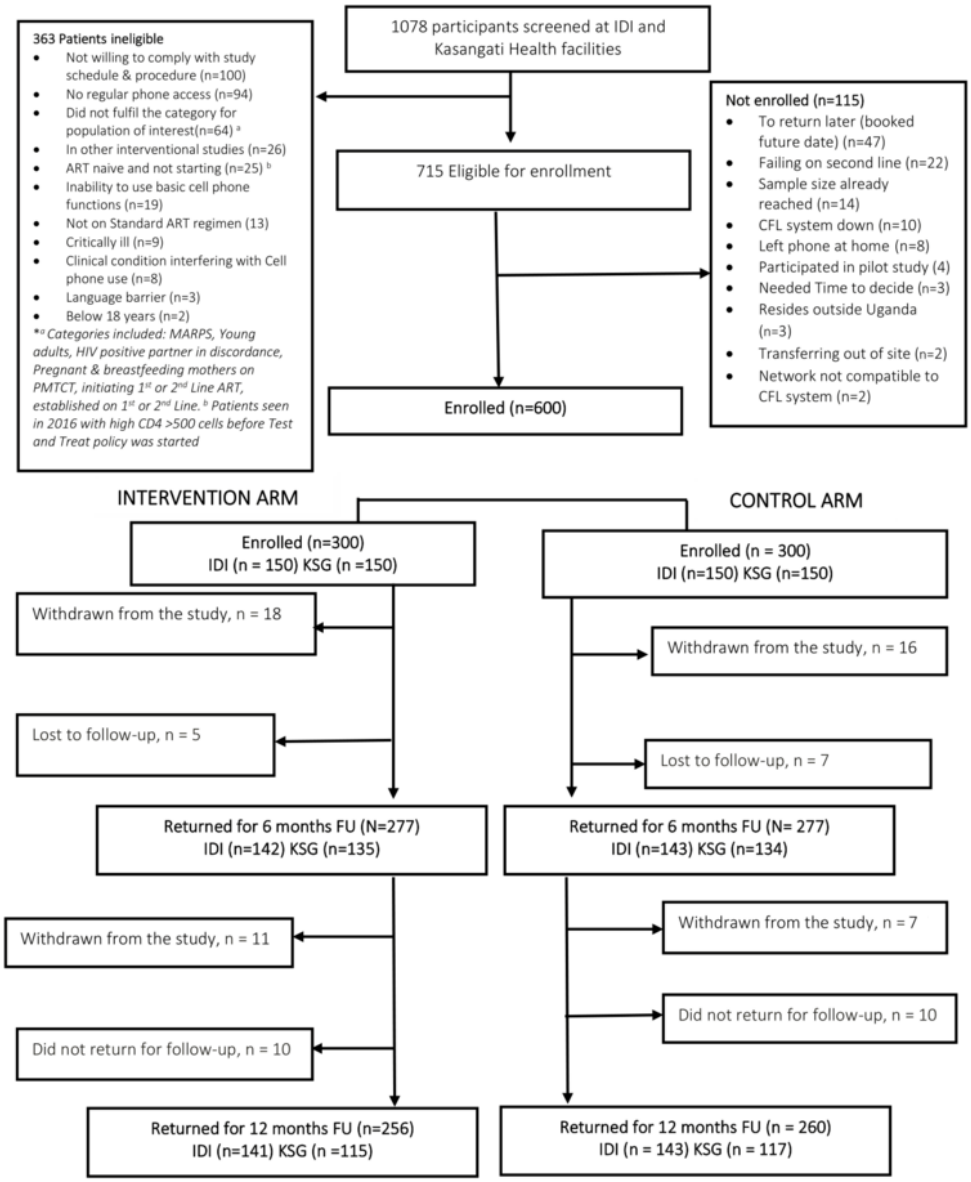
Figure 2. Study enrollment, randomization, and follow-up. ART: antiretroviral therapy; CFL: Call for Life; FU: follow-up; IDI: Infectious Diseases Institute; KSG: Kasangati Health Centre IV; MARPS: most-at-risk populations; PMTCT: prevention of mother-to-child transmission.



Of the 600 enrolled participants (300 in each arm), 554 completed 6 months (277, 92.3% in each arm), and 516 completed 12 months (256, 85.3% and 260, 86.7% in the intervention and control arms, respectively). Of the 600 enrolled participants, 413 (68.8%) were female, 468 (78%) were receiving first-line ART, and 388 (64.7%) had undetectable HIV RNA (Table 1). The median age (IQR) was 32 (25-40) years, one-third (193/600, 32.2%) were in serodiscordant relationships, and 155 (25.8%) were pregnant or breastfeeding.

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Table 1. Characteristics of study participants (N=600).

Characteristic	Total (N=600)	Intervention (n=300)	Standard (n=300)	*P* value[a]
Gender, n (%)				
Female	413 (68.8)	210 (70.0)	203 (67.7)	.54
Male	187 (31.2)	90 (30.0)	97 (32.3)	__[b]
Age (years), n (%)				
16-24	161 (26.8)	82 (27.3)	79 (26.3)	.78
25-35	219 (36.5)	104 (34.7)	115 (38.3)	—
36-50	181 (30.2)	95 (31.7)	86 (28.7)	—
≥50	39 (6.5)	19 (6.3)	20 (6.7)	—
Marital status, n (%)				
Married	449 (74.8)	223 (74.3)	226(75.3)	.78
Not married	151 (25.2)	77 (25.7)	74 (24.7)	—
Education level, n (%)				
None	24 (4.0)	8 (2.7)	16 (5.3)	.32
Primary	231 (38.5)	118 (39.3)	113 (37.7)	—
Secondary	265 (44.2)	137 (45.7)	128 (42.7)	—
Tertiary	80 (13.3)	37 (12.3)	43 (14.3)	—
Alcohol use, n (%)				
Yes	292 (48.7)	147 (49.3)	144 (48.0)	.74
No	308 (51.3)	152(50.7)	156(52.0)	—
ART[c] regimen, n (%)				
First-line	468 (78.0)	230 (76.7)	238 (79.3)	.43
Second-line	132 (22.0)	70 (23.3)	62 (20.7)	—
Duration on ART (years), median (IQR)	2.0 (0.3-3.8)	1.8 (0.3-3.8)	2.1 (0.3-3.7)	.23
Baseline HIV RNA, n (%)				
HIV RNA≥50 copies/mL	212 (35.3)	113 (37.3)	99 (33.0)	.28
HIV RNA<50 copies/mL	388 (64.7)	187 (62.7)	201 (67.0)	—

[a]There were no differences between the two study arms, and *P* was attained using the Pearson chi-square test.

[b]Not available.

[c]ART: antiretroviral therapy.

Change in Quality of Life

The mean overall MOS-HIV QoL scores at baseline in the intervention and control arms were 85.5 and 86.0, respectively, and this increased to 90.3 and 90.7, respectively, at 12 months (DID=0.0, SE 1.03; *F*=0.52, *P*=.47) (Table 2). The change in PHS domain score between baseline and months was also comparable between the two arms (DID=−0.1, SE 1.28; *F*=0.600, *P*=.44). Similarly, there was no overall difference in the change in MHS QoL scores between the two study arms (DID=0.2; *F*=0.860, *P*=.35). Subanalyses did not show any significant difference between arms in any category except when the analysis was stratified by the intensity of the use of the software.

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Table 2. Quality of life scores at baseline and 12 months.

QoL[a] domain and subgroup	Baseline				Follow-up (month 12)				DID[b] analysis		ANCOVA[c] analysis	
	I[d], mean	C[e], mean	Diff[f] (I-C)	*P* value	I, mean	C, mean	Diff (I-C)	*P* value	DID	*P* value	*F*	*P* value
MOS-HIV[g]												
Overall	85.5	86.0	−0.5	.53	90.3	90.7	−0.5	.54	0.0	.99	0.52	.47
IDI[h]	89.3	90.7	−1.5	.04	90.9	92.1	−1.2	.10	0.3	.80	3.14	.08
KSG[i]	80.9	80.1	0.8	.51	89.6	89.1	0.5	.67	−0.3	.87	0.16	.69
Mental health summary score												
Overall	86.6	87.4	−0.8	.30	91.5	92.1	−0.6	.46	0.2	.83	0.86	.35
IDI	90.8	92.2	−1.4	.07	92.3	93.9	−1.6	.04	−0.2	.86	6.26	.01
KSG	81.4	81.4	−0.1	.94	90.5	89.8	0.7	.58	0.8	.66	0.54	.46
Physical health summary score												
Overall	86.7	87.3	−0.6	.52	92.3	93.0	−0.7	.45	−0.1	.93	0.60	.44
IDI	90.3	92.2	−1.9	.06	92.7	94.0	−1.3	.19	0.6	.67	1.24	.27
KSG	82.4	81.4	1.0	.48	91.8	91.7	0.1	.96	−1.0	.64	0.01	.91

[a]QoL: quality of life.

[b]DID: difference in differences; the difference between the differences in QoL scores between the intervention and control arms at baseline and 12 months.

[c]ANCOVA: analysis of covariance.

[d]I: intervention arm.

[e]C: control arm.

[f]Diff: difference between scores at baseline or 12 months.

[g]MOS-HIV: Medical Outcomes Study, HIV version.

[h]IDI: Infectious Diseases Institute.

[i]KSG: Kasangati Health Centre IV.

Change in HIV RNA at 12 Months

At baseline, viral suppression rates in the intervention and control arms were 62.7% (188/300) and 67% (201/300), respectively. At month 12, viral suppression improved to 80.9% (195/241) and 82.6% (213/258) among participants who had data on HIV RNA in the intervention and control arms, respectively. There was no difference between the intervention and control arms regarding the change in the log HIV RNA between baseline and 6 months (DID=0.05, SE 0.137, *P*=.66) and at 12 months (DID=0.01, SE 0.134, *P*=.94). Similarly, there was no difference in the change in log HIV RNA between the two arms (Table 3).

Table 3. Mean percentage scores of HIV RNA log copies/mL by arm and study group.

Time point	HIV RNA (copies/mL)												
	Baseline					Follow-up					DID[a]		
	I, mean[b]	C, mean[c]	Diff[d] (I-C)	SE	*P* value	I, mean	C, mean	Diff I-C)	SE	*P* value	DID	SE	*P* value
6 months	2.04	2.09	−0.05	0.094	.63	1.66	1.66	0.00	0.099	.88	0.05	0.137	.66
12 months	2.02	2.02	0.00	0.094	.95	1.67	1.66	0.01	0.095	.87	0.01	0.134	.94

[a]DID: difference in differences; the difference between the differences in log HIV RNA copies between the intervention and control arms at baseline and 6 and 12 months.

[b]I: intervention arm.

[c]C: control arm.

[d]Diff: difference in the log HIV RNA copies between the I and C arms.

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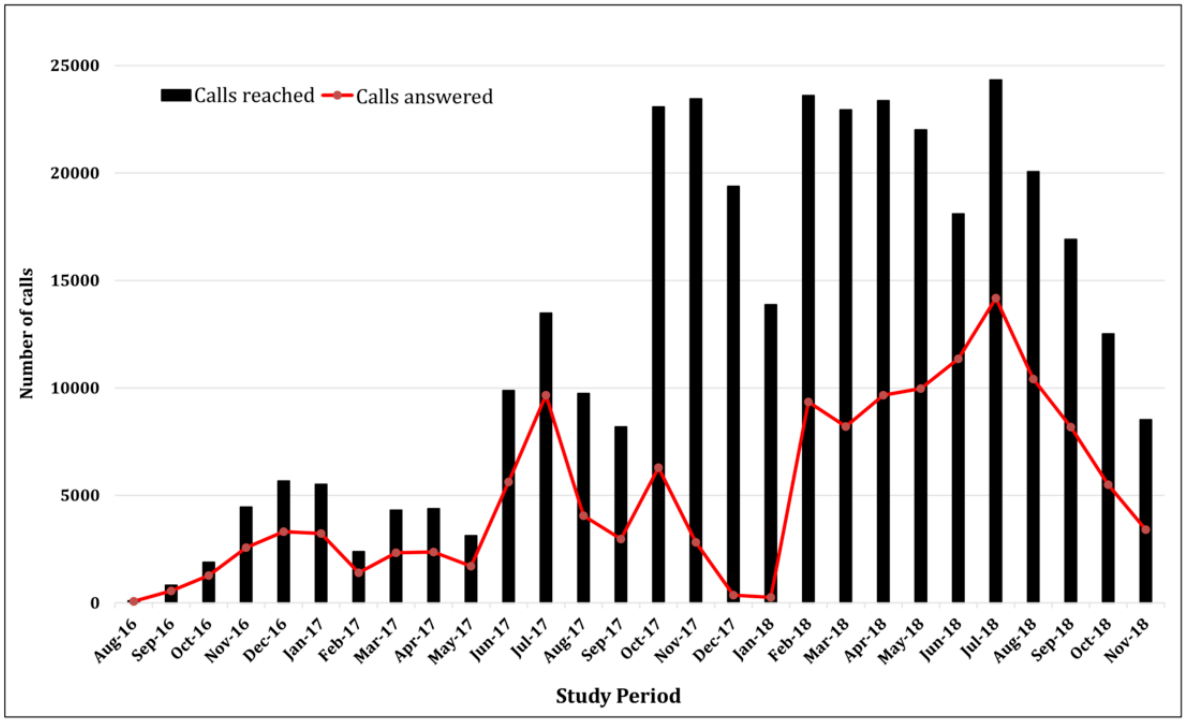
Adherence to Appointments

Overall, there was significantly higher adherence to appointments (*P*=.04) in the participants in the intervention arm at 6 months (200/277, 72.2%), compared to those in the control arm (178/277, 64.3%). However, at 12 months, there was no difference in appointment keeping in the intervention versus the control arm (intervention arm: 178/256, 69.5%; control arm: 178/260, 68.5%; *P*=.79).

Fidelity to Intervention Delivery

At baseline, 298 of the 300 participants (99.7%) in the intervention arm chose IVR, and only 2 selected SMS text messaging. Throughout the study, 346,286 outbound calls were made, of which 182,943 (52.8%) calls were answered and 141,043 (40.7%) were uninterrupted until the end (Figure 3). At 12 months, 25 of the 256 active participants (9.8%) were low users, 107 (41.8%) were moderate users, and 124 (48.4%) were high users.

Figure 3. Number of calls made and successfully completed by the study participants in the intervention arms.



The study was halted between January 20 and February 2, 2018, due to a software failure. There were no confidentiality breaches during this software failure, and a protocol deviation was reported to the institutional review board. Upon fixing the technical failure, participants were interviewed on whether they wanted to re-enroll. Only 1 participant out of 299 patients on the intervention arm declined (due to reasons other than software) to rejoin the study after this time. During the system failure period, all participants received the standard of care.

Outcomes by the Level of Use of the Tool

Among participants in the intervention arm who were active at 12 months, there was a general trend toward better study outcomes in participants with higher use of software compared to low users (received <25% of all reminder calls). The baseline scores were generally similar in the different strata of tool usage (Table 4). At 12 months, overall QoL, as well as the QoL scores in the MHS domain, was higher for participants with high use of the tool than for those with low use (overall QoL score: 92.2 versus 87.8, *P*=.02; MHS scores: 93.1 versus 90.7, *P*=.008). However, there was no statistical difference in the PHS domain scores between higher and low users (94.6 versus 90.7, *P*=.07) (Table 4).

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Table 4. Change in quality of life by utilization of the intervention.

QoL[a] domain, by calls answered (%)	Baseline			6-month follow-up			12-month follow-up		
	Participants, n	QoL scores, mean (SD)	*P* value[b]	Participants, n	QoL scores, mean (SD)	*P* value[b]	Participants, n	QoL scores, mean (SD)	*P* value[b]
MOS-HIV[c]									
0-25	37	85.2 (7.6)	Ref[d]	58	88.5 (7.2)	Ref	25	87.8 (8.2)	Ref
26-50	123	86.1 (8.7)	.57	88	88.5 (7.1)	.96	107	90.8 (5.1)	.04
51-75	108	83.8 (10.9)	.52	92	88.2 (8.8)	.79	99	89.9 (7.0)	.24
76-100	30	90 (7.1)	.02	39	89.4 (5.7)	.54	25	92.2 (3.2)	.02
Mental health score									
0-25	37	86.1 (8.4)	Ref	58	89.5 (7.1)	Ref	25	86.8 (10.3)	Ref
26-50	123	86.7 (9.9)	.76	88	89.9 (6.3)	.73	107	91.9 (5.1)	.001
51-75	108	85.3 (11.6)	.72	92	90.0 (7.7)	.68	99	91.6 (6.1)	.005
76-100	30	90.5 (8.8)	.06	39	91.5 (4.9)	.14	25	93.1 (4.1)	.008
Physical health score									
0-25	37	86.5 (9.6)	Ref	58	90.8 (10.1)	Ref	25	90.7 (8.6)	Ref
26-50	123	88.1 (9.7)	.39	88	90.7 (10.4)	.96	107	92.9 (7.1)	.19
51-75	108	84.1 (13.1)	.34	92	89.2 (12.6)	.41	99	91.4 11.0)	.79
76-100	30	92.1 (7.8)	.02	39	90.3 (8.7)	.77	25	94.6 (5.4)	.07

[a]QoL: quality of life.

[b]The *P* values are attained using one-way analysis of variance.

[c]MOS-HIV: Medical Outcomes Study, HIV version.

[d]Ref: reference group for comparisons.

Compared to low users, viral suppression rates at 12 months were higher in those with higher usage. This was significant for those with moderate usage of the tool (80/94, 85% versus 11/19, 58%; *P*=.006) and in those with fairly low usage (26%-50% usage) (84/103, 81.5% versus 11/19, 57.9%; *P*=.02). However, the difference did not reach significance in those with highest usage in viral suppression (20/25, 80% versus 11/19, 58%; *P*=.11) (Table 5).

Participants with better usage of the tool also generally had higher rates of appointment keeping compared to low users. Compared to the rates in low users (12/25, 48%), appointment keeping was higher in participants with fairly low usage (74/107, 69.2%, *P*=.046), moderate usage (72/99, 73%, *P*=.02), and high usage (20/25, 80%, *P*=.02) (Table 5).

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Table 5. Viral suppression and appointment keeping at 12 months by the level of use of the tool.

Outcome, by calls answered (%)	Month 6		Month 12	
	Participants, n/N (%)[a]	*P* value[b]	Participants, n/N (%)[c]	*P* value[b]
Viral suppression[d]				
0-25	49/57 (86.0)	Ref[e]	11/19 (57.9)	Ref
26-50	64/86 (74.4)	.16	84/103 (81.6)	.02
51-75	74/90 (82.2)	.75	80/94 (85.1)	.006
76-100	32/39 (82.1)	.78	20/25 (80.0)	.11
Appointment adherence				
0-25	39/58 (67.2)	Ref	12/25 (48.0)	Ref
26-50	63/88 (71.6)	.57	74/107 (69.2)	.046
51-75	66/92 (71.7)	.56	72/99 (72.7)	.02
76-100	33/39 (84.6)	.05	20/25 (80.0)	.02

[a]5 missing values at 6 months.

[b]The *P* values are attained using the Pearson chi-square test. Missing values not included in the analysis.

[c]16 missing values at 12 months.

[d]HIV RNA <50 copies/mL.

[e]Ref: reference group for comparisons.

Serious Adverse Events

There were 8 adverse events in each study arm. The adverse events included 7 deaths and 9 hospitalizations. Of the adverse events, 11 were HIV-related, and none were attributed to the use of the tool.

Discussion

Principal Findings

Despite the increasing data from pilot studies in LMICs that support mHealth interventions, very few interventions have involved IVR. Similarly, few studies have assessed the scalability and sustainability of mHealth interventions. In this RCT, we determined the impact of an IVR-based patient-centered tool on the QoL and treatment outcomes of people living with HIV. To our knowledge, this is the largest mHealth intervention trial to evaluate the impact of IVR technology and the only one to offer a choice of IVR and SMS text messaging in Africa. Mobile health technologies that utilize voice calls are ideal for patient support in most LMICs due to high illiteracy rates [26]. Our study did not find any statistical difference in the change in QoL at 12 months in participants enrolled in the intervention and control arms. Similarly, there was no difference in viral suppression rates in the two arms. However, we found an association between improved QoL (overall and MHS) as well as viral suppression and adherence to clinic appointments in participants who had moderate or high use of the tool.

Before this study, studies involving SMS-based interventions had reported no improvement in the QoL in people living with HIV [27]. However, studies involving live phone calls to people living with HIV reported significant improvement in the QoL [28]. The CFL software provided automated IVR calls with improvement in QoL in the users. Therefore, it seems that “live calls” and IVR, which is a prerecorded voice, are more effective than SMS text messaging in improving QoL. Other IVR-based tools have previously reported higher ART adherence rates among patients receiving IVR adherence reminders in people living with HIV in comparable resource-limited settings [17,29]. Qualitative interviews suggested that people living with HIV became attached to the “voice” and felt as if they were better cared for.

Study Limitations

This study has a few limitations. While attempting to increase the generalizability of our study findings, we enrolled a heterogeneous population. Participants included highly ART-experienced people living with HIV as well as those newly diagnosed and initiated on ART. Owing to the successful ART scale-up, people living with HIV commencing ART are increasingly healthier at diagnosis [30,31]. Similarly, ART-experienced people living with HIV may have higher QoL scores. The overall baseline QoL scores in this study were high (86 in each arm), so the study may not have been well powered to detect small differences in QoL or HIV RNA. While viral suppression rates at 12 months had improved in both arms, the heterogeneity of the population limited our ability to show a statistical change in viral suppression. The baseline viral suppression rate was 67%, lower than the rates reported in most HIV programs [32], due to the inclusion of those with detectable viral loads such as ART-naïve people and those failing on first-line therapy. This study was conducted at two different facilities, one urban and the other peri-urban. The QoL of patients attending the peri-urban facility was lower at baseline compared to that of patients attending the urban HIV clinic. This difference narrowed at 12 months. The enrollment of patients at the two facilities introduces heterogeneity in the study population but increases the generalizability of the study

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results. In addition, access to a simple mobile phone was required to access the tool. There is a gender gap in the accessibility of mobile phones in sub-Saharan Africa, where 15% fewer females own a mobile phone, compared to males [33]. We found that 8.7% (94/1078) of those screened had no access to phones; phone ownership was higher than the 70% national coverage [34]. The high mobile phone ownership is attributable to the predominantly urban and educated study population. In key groups, providing a cheap mobile phone (under US $10) may mitigate this. We will explore the feasibility of this approach in our ongoing study with CFL in youths and adolescents with HIV. Additionally, we did not assess the attentiveness of the participants during the whole call, which is a further limitation. Therefore, some participants may have not listened to the entire health tips and reminders. Focus group discussions and in-depth interviews were undertaken to understand the personal, technological, and environmental determinants of tool use, including among young adults [35]. Participants generally responded that the calls reminded them to take their ART, but some did not pick up the call as they felt that just hearing the ringtone was enough of a reminder. The health tip topic for each participant was changed at each appointment, and with 329 tips available, there was considerable new health tip content. Many participants requested to receive health tips on weekends so that they had time to listen to the health tips. The details of the patient preferences for health tips have been described elsewhere [36]. The greatest challenges expressed were PIN code issues and timing of the calls when busy at work, rather than lack of interest in the content.

Acceptability and Use of the Tool

Technology problems could have contributed to the results, as the intervention was halted for 3 weeks. Still, after the tool failure, surprisingly 99.7% (299/300) of participants agreed to come back to the study, so technology failure did not seem to affect long-term uptake. The study population was urban and highly educated, and participants may have had alternative adherence reminders, including self-set phone alarms and email alerts. However, we did not inquire about the existence of alternative adherence reminders. Nevertheless, Musiimenta et al documented the lack of adherence reminders as a crucial barrier to adherence to long-term treatment in patients with tuberculosis in Uganda [37].

The proportion of patients who successfully received calls was relatively stable throughout the study period. This is reassuring given that some studies have reported a decline in the utilization of mobile health interventions over time. Since the conclusion of this RCT, the scale-up of CFL has been successful. More than 3000 people living with HIV at three health facilities in Kampala are receiving IVR-based patient support; over 1,300,000 successful calls have been placed using the tool over four years [38]. This study demonstrated a higher preference for IVR over SMS text messaging. Qualitative work suggested that this was due to the belief that confidentiality was greater with an anonymous call compared to a message flashed on a screen, but also due to comfort in hearing a real human voice [35]. This raises the opportunity of using IVR technology to mitigate high illiteracy rates in resource-limited settings. In India, a study reported a higher preference for IVR compared to SMS text messaging reminders [17,39].

The study showed high acceptability of the tool, and those who engaged with the tool had better outcomes. The call success rates (141,043/346,286, 40.7% of all calls) for daily uptake (calls repeated up to 3 times on each day until picked up) are higher than what has been reported in similar settings (range: 22%-31%) [40,41]. For those with high use of the tool, the QoL scores were higher than for those with low use of the tool. This could either mean that this population is keen to engage with care and any support that is given or that the subset who used the tool did have an improvement in outcomes. In LMICs, with the need to provide differentiated HIV services, CFL and IVR solutions could support differentiated care models. The WHO recommends low-intensity engagement for stable people living with HIV to allow resources for those who have or are at risk of viral failure. Appropriate use of IVR could provide reassurance to health facilities that longer periods between appointments and fewer face-to-face sessions are safe for stable patients. In the prevailing circumstances when most LMICs are under lockdown and most people living with HIV do not have physical support, IVR could provide alternative support. The impact and cost-effectiveness of replacing face-to-face consultations with IVR in the COVID era will be assessed in our ongoing research project.

Conclusion

While this study did not find an overall difference in QoL or viral suppression in people living with HIV, the impact of this software in ART-naïve patients with advanced HIV ought to be determined. The software did not find a significant difference in appointment keeping, but most of the patients were highly experienced. Therefore, the intervention should be evaluated in people living with HIV who are newly engaging in care. This study provides useful information on the feasibility and impact of IVR intervention on QoL of people living with HIV in sub-Saharan Africa. While there was no overall difference in QoL and viral suppression in the two study arms, high-intensity users of the tool showed improvement in QoL and viral suppression. With the declining resources available to HIV programs in Africa and the increasing number of people living with HIV accessing ART, other IVR could be useful to enhance patient support for those that are keen and willing to use the system to support them at home. It could also be used to support people living with HIV who cannot or do not want to attend facilities face-to-face during the COVID epidemic.

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Authors' Contributions

DMB supported data analysis and drafted and revised the manuscript. RPR led the study design, implementation, and data analysis and contributed to manuscript writing and review. ABN and EO led study implementation and data collection, supported analysis, and contributed to manuscript writing and review. BC, ML, EL, RO, NO, and RK contributed to study design and manuscript review. MSN and AK analyzed data and contributed to manuscript writing and review.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Issues identified with TAMA/Call for Life system during the pilot phase.
[DOCX File , 47 KB - mhealth_v9i2e22229_app1.docx]

Multimedia Appendix 2
Version changes and system upgrades of Call for Life Uganda.
[DOCX File , 48 KB - mhealth_v9i2e22229_app2.docx]

Multimedia Appendix 3
Health educational messages (tips) used in the study.
[DOCX File , 47 KB - mhealth_v9i2e22229_app3.docx]

Multimedia Appendix 4
Call flow diagram for Call for Life™ Project.
[DOCX File , 341 KB - mhealth_v9i2e22229_app4.docx]

Multimedia Appendix 5
Call for Life study protocol.
[PDF File (Adobe PDF File), 1939 KB - mhealth_v9i2e22229_app5.pdf]

Multimedia Appendix 6
CONSORT-eHEALTH checklist (V 1.6.1) and compliance with the mHealth evidence reporting and assessment (mERA) guidelines.
[DOCX File , 78 KB - mhealth_v9i2e22229_app6.docx]

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Abbreviations

ART: antiretroviral therapy
CFL: Call for Life
DID: difference in differences
DSMB: data safety monitoring board
HIV: human immunodeficiency virus

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IDI: Infectious Diseases Institute
IMB: information, motivation, and behavioral skills
IVR: interactive voice response
LMICs: low- and middle-income countries
mHealth: mobile health
MHS: mental health summary
MoTeCH: Mobile Technology for Community Health
MOS-HIV: Medical Outcomes Study, HIV version
PHS: physical health summary
PIN: personal identification number
QoL: quality of life
RCT: randomized controlled trial
TAMA: Treatment Advice by Mobile Alerts
UAT: user acceptability testing
WHO: World Health Organization

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Original Paper

Implementation of a Newborn Clinical Decision Support Software (NoviGuide) in a Rural District Hospital in Eastern Uganda: Feasibility and Acceptability Study

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Abstract

Background: Lack of trained health care workers and nonadherence to national guidelines are key barriers to achieving high-quality newborn care in health care facilities in low- and middle-income countries. Traditional didactic approaches addressing these barriers fail to account for high staff turnover rates and result in temporary behavior change. NoviGuide, a clinical decision support software designed to standardize neonatal care through point-of-care assessments, has the potential to align bedside practice to national guidelines in settings lacking subspecialty neonatal providers.

Objective: This study aims to determine the adaptation, adoption, feasibility, acceptability, and sustainability of NoviGuide and its impact on nurse-midwives' knowledge in a rural hospital in eastern Uganda.

Methods: This mixed methods observational study was guided by the Proctor framework. Experts reviewed the clinical content of NoviGuide to ensure fidelity to Uganda guidelines. We enrolled nurses and midwives providing newborn care at Tororo District Hospital, trained them on NoviGuide use, and followed them for 12 months. We assessed adoption, feasibility, acceptability, and sustainability by analyzing NoviGuide use data, comparing it with maternity registry data and administering the System Usability Scale (SUS) and the Center for Health Care Evaluation Provider Satisfaction Questionnaire. We compared the mean knowledge assessment score at baseline, 6 months, and 12 months using a two-tailed *t* test.

Results: Five Ugandan experts suggested two minor changes to NoviGuide: the inclusion of an unsterile birth environment as an indication for empiric antibiotics and the addition of a reminder to follow-up with newborns with temperatures between 37.7°C and 37.9°C. Of the 19 nurse-midwives enrolled in February 2017, 74% (n=14) completed the follow-up in March 2018. The participants entered a total of 1705 assessments of varying newborn characteristics into NoviGuide throughout the day, evening, and night nursing shifts. The SUS score at the end of the study was very high (93.5, above the average of 68). Participants had a positive perception about NoviGuide, reporting that NoviGuide saved time (mean 5, SD 0) and prevented mistakes (mean 5, SD 0), and that they felt more confident in taking care of newborns when they used NoviGuide (mean 5, SD 0). Participants were highly satisfied with NoviGuide (mean 4.86, SD 0.36), although they lacked medical supplies and materials needed to follow NoviGuide recommendations (mean 3.3, SD 1.22). The participants' knowledge scores improved by a mean change of 3.7 (95% CI 2.6-4.8) at 6 months and 6.7 (95% CI 4.6-8.2) at 12 months (P<.001).

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Conclusions: NoviGuide was easily adapted to the Uganda guidelines. Nurse-midwives used NoviGuide frequently and reported high levels of satisfaction despite challenges with medical supplies and high staff turnover. NoviGuide improved knowledge and confidence in newborn care without in-person didactic training. NoviGuide use has the potential to scale up quality newborn care by facilitating adherence to national guidelines.

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KEYWORDS

clinical decision support; neonatology; neonatal mortality; mHealth; mobile phone

Introduction

Background

In 2018, 2.5 million children died in their first 28 days of life worldwide, with the highest neonatal mortality rate observed in sub-Saharan Africa (28 per 1000 live births) [1]. The causes of death in the neonatal period are well known, including complications of prematurity; intrapartum complications; and infections, such as sepsis, pneumonia, and meningitis [2]. Neonatal care protocols, such as those described in the World Health Organization (WHO) Essential Newborn Care guidelines [3], can lead to significant improvements and comprise the core of current global efforts to reduce neonatal mortality [4-7]. However, lack of trained health care workers and nonadherence to national neonatal care clinical guidelines are key barriers to achieving high-quality newborn care in health care facilities in low- and middle-income countries (LMICs) [8]. Implementation of evidence-based protocols in LMICs has been hampered by significant challenges: in-person training does not reliably lead to changes in workplace behavior, medical errors are common, changes in practice are lost quickly without reinforcement, high staff turnover rate, and performance of health care providers is difficult to monitor [9-12].

Traditional approaches to implementing neonatal care clinical guidelines in LMICs are based on lectures, the distribution of educational material, and hands-on training; although these approaches can be effective for focused topics or procedures such as neonatal resuscitation [13,14], they are not well suited to multistep neonatal protocols. A key component of behavior change is immediate and consistent feedback. Health care providers learning neonatal resuscitation receive immediate feedback on their performance through a newborn's second-to-second response to care, whereas the degree to which a provider's care aligns to a complex neonatal protocol, such as an antibiotic prescription guideline, cannot anticipate a similar deliberate practice benefit [15]. In addition, although the performance of a hands-on procedure is relatively constant across diverse patients, the application of complex neonatal protocols requires that health care providers must often account for patient-specific factors and adjust for site-specific constraints [16].

Clinical decision support (CDS) software has the potential to enable health care providers to deliver complex medical protocols as responsive point-of-care assessments [17-21]. CDS aims to achieve desired quality aims through care standardization rather than relying on individual performance, while improving health care provider satisfaction by deploying medical protocols through a validated user interface. A key feature that distinguishes CDS from traditional didactic training is that it does not rely on the health care provider to summon previously learned content at the point-of-care, either from memory or by seeking a resource. Instead, CDS uses patient-specific factors, such as a patient's age, vital signs, and symptoms, and directs health care providers to potentially relevant medical protocols.

NoviGuide

Our team developed NoviGuide (Global Strategies) [22], a tablet-based CDS software, to optimize the facility-based care of newborns in LMICs by transforming complex neonatal disease-specific protocols into comprehensive patient assessments.

NoviGuide has 3 main sections: *Resuscitation*, *My Patient*, and *Learning* (Figure 1). The *Resuscitation* section contains an instructional three-dimensional animation depicting the steps of neonatal resuscitation (Multimedia Appendix 1). The *My Patient* section houses point-of-care CDS algorithms that guide health care providers through the initial assessment and daily care of newborns. The *Learning* section is a standard e-book with additional information on neonatal topics and videos from the Global Health Media Project [23] depicting physical signs, common newborn procedures, and breastfeeding positions. A menu bar includes an *emergency* button to directly access clinical guidance for the treatment of neonatal seizures and abdominal emergencies (Figure 1). We selected algorithms for the emergency section based on the need for rapid guidance and the ability to generate that guidance based solely on the current dosing weight. NoviGuide was created by the nonprofit organization Global Strategies [24] for widespread use in low-resource settings. Global Strategies built the core software and content of NoviGuide and partnered with Plexus Medical Arts [25] to design the resuscitation video. The Global Health Media Project allowed the inclusion of its neonatal and breastfeeding films in the software.

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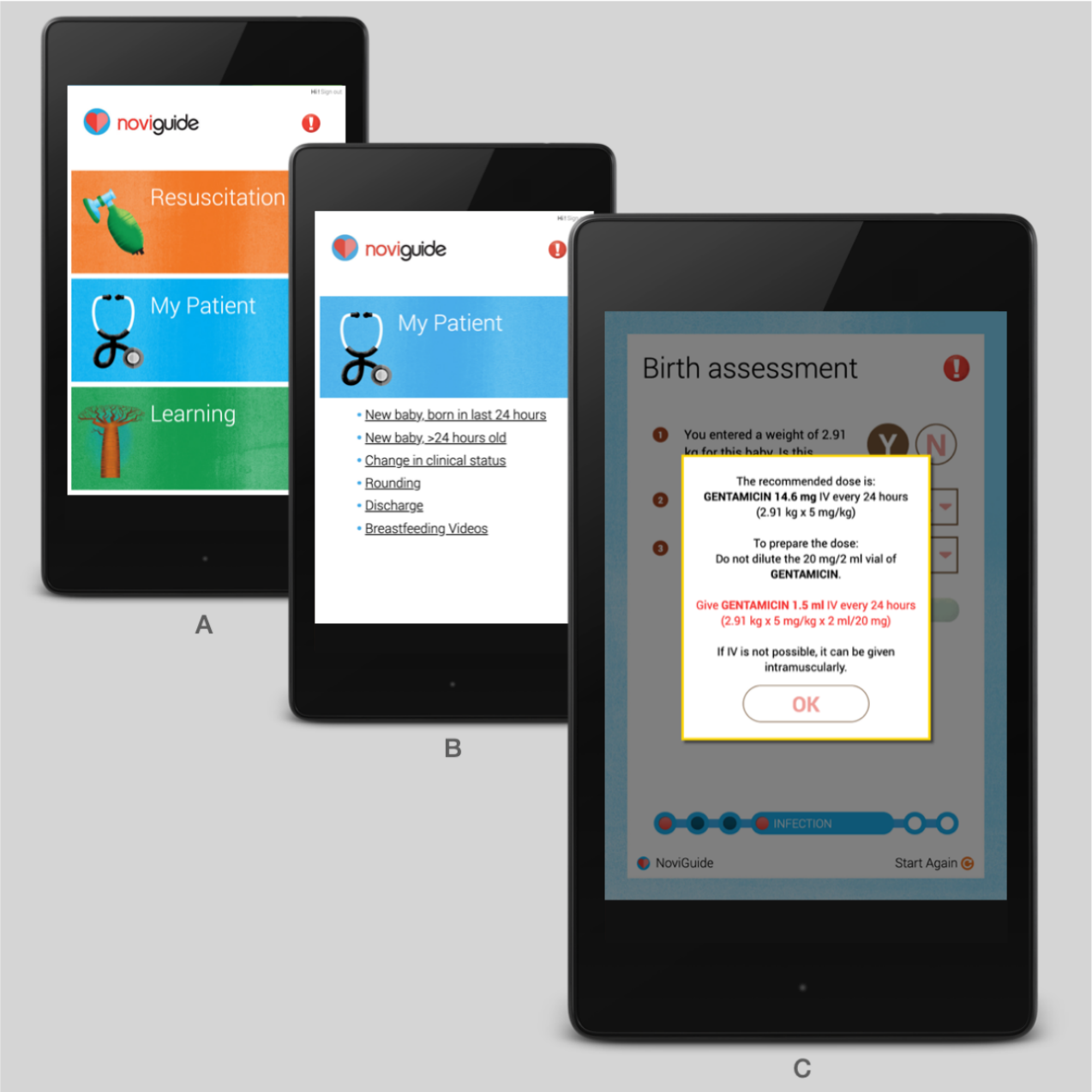
Figure 1. NoviGuide screenshots: Home page, NoviGuide clinical assessments, and Medication dosing instructions pages.



The *My Patient* CDS content includes 4 comprehensive clinical assessments to assist health care providers in the initial assessment; subsequent care; and discharge of well, sick, and preterm newborns. These assessments are named *new baby more than 24 hours old or change in clinical status*, *rounding*, and *discharge* (Figure 1). The assessments provide step-by-step prompts to guide the health care provider to enter data from the physical examination findings and key pieces of medical history (Multimedia Appendix 2). The assessments are dynamic, adding more questions in response to danger signs and alerting users to potential inconsistencies in their responses. NoviGuide then makes case-specific management recommendations derived from national clinical guidelines that are tailored to the newborn's weight, gestational age, day of life, clinical features, and available equipment. The *My Patient* assessments include numerous job facilitators to incentivize use, save time, and decrease medical errors (Multimedia Appendix 2). These job facilitators include preterm feeding calculators, medication and fluid calculators, guidance interpreting vital signs, and the generation of a printable summary. Responses to abnormal vital signs, infection risk stratification for antibiotic use, medication doses, and fluid calculations are provided automatically alongside any equations used to derive the recommendations (Figure 1).

When initiating an assessment, health providers are asked to indicate if the assessment is being completed on a *real baby* or *just practicing* (Multimedia Appendix 2). Users are often prompted to consider actions in NoviGuide's pathways that require resources. In numerous instances, users can indicate if they encounter a resource constraint related to the guidance, and these data are captured. NoviGuide works either offline or when connected to WiFi. All the information contained in the NoviGuide is present in the initial download. When NoviGuide is connected to the internet by Wi-Fi, data are automatically

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synchronized to a cloud-based database. NoviGuide is designed to work on Google Android, iOS, and FireOS platforms.

With this study, our aim is to describe the adaptation, adoption, feasibility, acceptability, and sustainability of NoviGuide use in a rural district hospital in eastern Uganda. We used a mixed methods observational study design among nurses and midwives in the context of newborn care. In addition, we analyzed the impact of NoviGuide use on the knowledge of nurse-midwives. The Proctor framework [26] guided the definition of implementation constructs with respect to the users and the local context.

Methods

Adaptation of NoviGuide to Uganda Clinical Guidelines

With the assistance of the Uganda Pediatrics Association, we recruited a team of 5 Ugandan experts to review the content of NoviGuide over a series of meetings between August and November 2016. The aim was to ensure the fidelity of NoviGuide to the Uganda neonatal care clinical guidelines and to refine the NoviGuide design to suit the Uganda local context [27]. The study team presented an overview and instructions on how to visualize and verify the content, order, and branch-point logic of NoviGuide's decision trees (Table 1). The study team also showed the experts how to evaluate NoviGuide's decision trees using test cases comprising sick and well neonatal scenarios. The study team highlighted specific content in which there are frequent variations in recommendations among national guidelines, including the preparation of medications and various pharmacologic diluents, the management of well-appearing newborns born to mothers with fevers and/or other sepsis risk factors, and the threshold at which a glucose level is considered low. For each clinical area, the experts viewed a series of videos that explained the clinical topic and how it manifests in NoviGuide's *My Patient* assessments. The study team gave each expert a tablet (Amazon Fire HD 8) loaded with NoviGuide version 1.6 to take home and instructed them to make notes of any recommendations. The tablets were returned following this activity. The Ugandan experts met for a second meeting for free discussion of their findings and to achieve consensus on a set of recommendations for Global Strategies.

Table 1. Description of content areas for Ugandan expert panel review.

Area	Description
Content	Verifying that the clinical information is consistent with national protocols. For example, the study team shows the expert panel the temperature threshold where a newborn is considered febrile. The expert panel then votes to confirm or modify.
Order	Verifying that the order of questions in each assessment is consistent with national protocols. For example, confirming that lines of questioning concerning hypoglycemia should precede lines of questioning concerning the initiation of antibiotics.
Branch-point logic	Reviewing how the software responds to user input and verifying that the response is consistent with national protocols. For example, the study team shows the expert panel the alert message a user sees after entering a risk factor for infection. The expert panel then votes to confirm or modify.

Study Setting

We conducted an implementation study from February 2017 to March 2018 at Tororo District Hospital (TDH), a rural government-owned district hospital in eastern Uganda. TDH, a 200-bed facility, serves approximately 517,000 people, the majority of whom live in rural areas [28]. The hospital conducts about 360 births per month and receives sick newborns from the community, surrounding health centers, and private facilities including referrals from across the Kenya-Uganda border. One medical officer is assigned to work in the maternity ward. Nurses and midwives provide the majority of newborn care working in shifts of 2 to 3 providers. In addition, these same nurses and midwives provide care for laboring women and postpartum mothers and conduct all vaginal deliveries in a 6-bed labor suite. TDH has basic newborn care supplies, including bag-valve-masks, warming tables for resuscitation, intravenous (IV) supplies, and a standard country formulary for medications. At the time of the study, TDH did not have a dedicated neonatal care unit. Newborns requiring close nursing attention were cared for on 2 warming tables within the labor suite. Newborns requiring only intermittent IV antibiotic therapy were admitted by the medical team in the general postpartum ward with women requiring postnatal care.

Enrollment and Training of Study Participants and Launch of Study

We screened all the nurses and midwives working in the maternity ward at the TDH and enrolled them into the study in February 2017. Inclusion criteria for nurse-midwives included providing newborn care at TDH, having current licenses to practice, and willingness to participate in the study. In addition, nurse-midwives had to have completed the WHO Integrated Management of Childhood Illnesses modules [29]. Participants exited the study if they were transferred by the hospital administration to another ward within the hospital, ceased employment at the hospital, or withdrew consent.

To recruit participants, we invited all nurse-midwives working at the TDH and their supervisors to attend an organized meeting in the hospital boardroom. The study team provided a brief introduction about the study, including NoviGuide and evaluation methods, and obtained written informed consent from the nurse-midwives who met the eligibility criteria. We asked the nurses and midwives who declined participation for their reasons. The medical superintendent, matron, and wards-in-charge were recruited as key informants in the study development; hospital leadership encouraged but did not mandate or require the use of NoviGuide.

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Following enrollment, the study participants attended a 3-hour training conducted by representatives of Global Strategies on how to use NoviGuide. Following the training, the participants created individual unique usernames and passwords to log in to the tablet and the NoviGuide software. The study team provided 7 tablets (Amazon Fire HD 8 tablet) loaded with NoviGuide in February 2017. The tablets were stored in a lockable wooden cabinet in the nurses' office in the labor suite. During the first week, the study team provided on-site technical support to troubleshoot technical issues. We followed the study participants through March 2018.

Data Collection

At baseline, participants completed a survey that included demographic data (age, sex, and level of education), years of clinical experience, experience using technology, and perceived challenges in caring for newborns at TDH.

The study participants also completed a questionnaire assessing basic knowledge in newborn care, including questions about the management of hypoglycemia, indications for antibiotics, management of the HIV-exposed infant, and the specific order of tasks in neonatal resuscitation. This questionnaire was then repeated at 6 and 12 months with modifications of the question order and variables, such as newborn weights, in the clinical scenarios (Multimedia Appendix 3).

Throughout the study period, the study team connected the tablets to a Wi-Fi network once per day to upload NoviGuide use data, stored in the tablet, onto a secure cloud-based database. NoviGuide use data were linked to the participants' unique study identification number. We compared the total number of assessments entered into the NoviGuide with the total number of births and admissions of newborns at the hospital during the study period. The study team instructed the participants to keep notes on any technical problems encountered during NoviGuide use in a study logbook or contact the study team by SMS, phone, or email for urgent concerns.

At 12 months, the participants completed 2 validated measures of software usability. We used the System Usability Scale (SUS) [30], consisting of 10 standard questions, where a statement is made and the respondent then indicates the degree of agreement or disagreement with the statement in a Likert scale format with responses 1 to 5, where 1 represents strongly disagree and 5 represents strongly agree. We also used a provider satisfaction questionnaire adapted from the Center for Health Care Evaluation Provider Satisfaction Questionnaire (CHCE-PSQ) [31], which has 8 questions and the respondent then indicates the degree of agreement or disagreement with the statement in a Likert scale format with responses 1 to 5. For questions 1 to 4, response 1 represents poor and 5 represents excellent. Whereas for questions 5 to 8, response 1 represents strongly disagree and 5 represents strongly agree. In addition, participants completed an end-of-study questionnaire containing 15 questions assessing perceived acceptability and feasibility of NoviGuide using a Likert scale of 1 to 5, where 1 represents strongly disagree and 5 represents strongly agree (Multimedia Appendix 3).

Analysis

We defined adoption as the measure of the initial uptake or intention to use the NoviGuide and measured it by reviewing the NoviGuide use data for (1) the different assessments made into the NoviGuide and how many of these were completed through to the summary page, (2) the time participants spent during the NoviGuide assessments, (3) NoviGuide use during the different nursing shifts (day, evening, and night), (4) whether participants accessed the NoviGuide's educational videos or reading materials and whether the participants used the NoviGuide for practice or with a real newborn, and (5) total NoviGuide assessments in relation to the total births and admissions at the hospital during the study period.

We defined acceptability as the measure of the participants' satisfaction with the various components of NoviGuide, including content, complexity, navigation, ease of use, and general experience using NoviGuide for newborn care, and measured it by (1) comparing the overall SUS score with an average score of 68, as described by John Brooke [30], and (2) determining the mean scores and SD of the questions in the CHCE-PSQ and end-of-study questionnaire. We calculated the overall SUS score by summing up the score contributions of each question and multiplying it by 2.5.

We defined feasibility as the actual fit and the use of NoviGuide within the rural hospital context and measured it by reviewing the NoviGuide use data for (1) the characteristics of newborns cared for using NoviGuide and (2) whether the study participants indicated resource or health system constraints that could prevent the use of NoviGuide. We also measured feasibility by determining the mean scores and SD of questions 11 to 15 of the end-of-study questionnaire assessing the availability of medical supplies and materials needed to follow NoviGuide recommendations; time to use the NoviGuide; and support from colleagues, supervisors, and hospital administrators.

We defined sustainability as the extent to which NoviGuide use was maintained throughout the study period and the frequency and degree of technical problems preventing NoviGuide use. We measured use over the study period by individual users and collectively, across 100-day interval study periods (day 0-99, 100-199, 200-299, and 300-397).

We measured the impact of NoviGuide use on participant knowledge by comparing the mean knowledge assessment score at baseline with scores at 6 and 12 months using a paired *t* test. We used Stata (version 16, StataCorp) for all statistical analyses. A P value of <.05 was considered significant.

Ethical Review

The University of California San Francisco Committee on Human Research (16-19241), the Makerere University School of Biomedical Sciences (SB-352), and Uganda National Council for Science and Technology (IS 125) approved the study. All study participants provided written informed consent before participation in the study-related activities.

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Results

Adaptation of NoviGuide to Uganda Clinical Guidelines

The study team selected 4 Ugandan neonatologists and 1 Ugandan neonatal nurse as expert reviewers. The experts suggested 2 modifications to the decision trees. First, they recommended that birth in an unsterile environment should be added as a sepsis risk factor and that its presence should prompt a recommendation for empiric antibiotics. Second, they recommended that a specific pop-up message be generated for temperatures between 37.7°C and 37.9°C to alert users that the newborn was *warm* and they suggested that a follow-up temperature measurement be taken. Global Strategies incorporated these modifications into the NoviGuide decision trees.

Participant Characteristics and Follow-Up

The study team screened 13 nurse-midwives and enrolled 12 nurse-midwives in February 2017 (Figure 2). One nurse declined to participate, citing that she was going to be away for further educational studies. Of the 12 participants in the initial enrollment group, 1 had a late start date of May 2017 because of maternity leave, and 5 participants were transferred to either other units within TDH or to other hospitals during the study period. In September 2017, following new hires at the maternity ward, the study team screened and enrolled an additional 7 nurse-midwives as replacements for those who had been transferred from the maternity ward. All 19 (100%) study participants were female, with a mean age of 39 (SD 14) years (Table 2). Of the 19 participants, 11 (58%) reported using a calculator on their phones to calculate medication dosages and fluid rates, 3 (16%) used a handheld calculator, and 5 (26%) performed the calculations mentally. All 19 participants reported that they believed that technology could help them in the care of newborns. Of the 19 enrolled participants, 14 (74%) were followed up with until the end of the study period.

Figure 2. Study flow diagram. TDH: Tororo District Hospital.

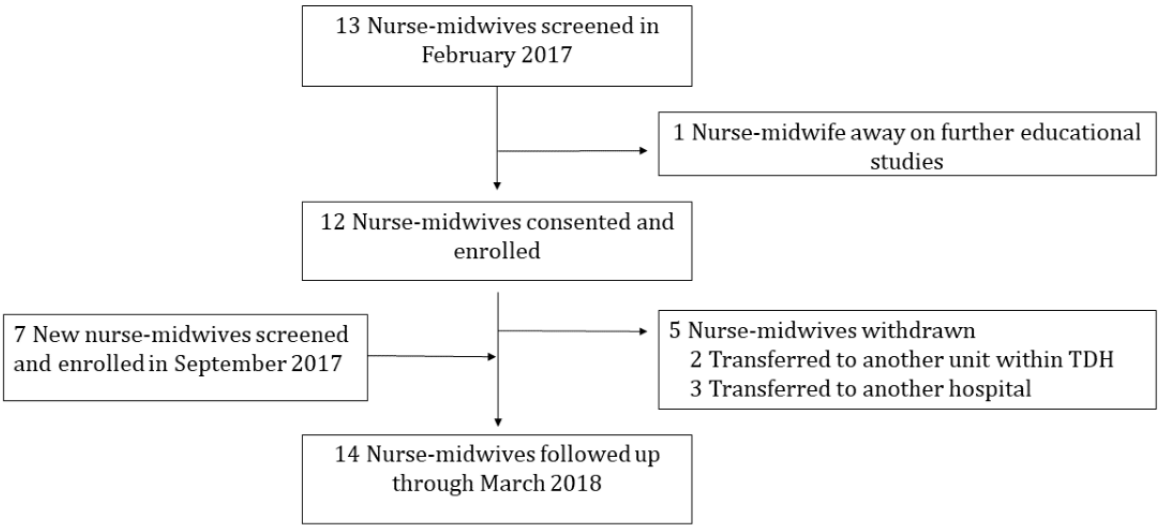

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Table 2. Baseline demographics and participant characteristics (n=19).

Characteristics	Values
Female, n (%)	19 (100)
Age (years), mean (SD)	39 (14)
Highest educational level, n (%)	
Bachelor's	1 (5)
Registered nurse	12 (63)
Certified midwife	6 (32)
Work experience (years), n (%)	
0-2	4 (21)
3-10	5 (26)
11-20	4 (21)
>21	6 (32)
Devices owned personally, n (%)	
None	2 (11)
Home computer or laptop	1 (5)
Tablet	0 (0)
Smartphone	9 (47)
Ordinary phone	9 (47)
How frequently do you access the internet, n (%)	
Never	5 (26)
Rarely or at least once a month	6 (32)
Occasionally	1 (5)
Weekly	3 (16)
Daily at least once a day	4 (21)
Has technology made your life easier, n (%)	
Easier	17 (89)
No difference	2 (11)
Harder	0 (0)
Do you think technology can help you take care of babies, n (%)	
Yes	19 (100)
No	0 (0)
How do you describe yourself, n (%)	
I am the first to try something new	6 (32)
Before I try, I watch others try it and see if it fits my life	13 (68)
I am usually among the last to try something new	0 (0)
How satisfied are you with the care of newborns at the Tororo District Hospital, n (%)	
1 (least satisfied)	1 (13)
2	2 (11)
3	8 (44)
4	2 (11)
5	5 (28)
6	0 (0)
7 (most satisfied)	0 (0)

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Characteristics	Values
How do you currently do the medication and fluid calculations, n (%)	
By handheld calculator	3 (16)
By calculator on the phone	11 (58)
I do them in my head	5 (26)
How do you decide when and which particular medication to give a sick baby, n (%)	
Check the World Health Organization chart at the maternity ward	14 (74)
Consult with the medical doctor	12 (63)
I use my judgment and experience	6 (32)

Adoption

The study participants entered a total of 1705 assessments into NoviGuide over the study period. Of these 1705 assessments, 1412 (82.82%) were completed through to the summary page. The most common completed entries were birth assessments with 65.93% (931/1412) assessments for *new baby born in last 24 hours* and 20.25% (286/1412) assessments for *new baby more than 24 hours old or change in clinical status* (Figure 3), followed by *discharge* 6.51% (92/1412), *rounding* 5.59% (79/1412), seizure emergency 1.48% (21/1412), and abdominal emergency 0.21% (3/1412). Of the 293 uncompleted assessments, 161 (54.9%) were for *new baby born in last 24 hours*, 81 (27.6%) for new baby more than 24 hours old or change in clinical status, 32 (10.9%) for *rounding*, 2 (0.68%) for *discharge*, 15 (5.1%) for seizure emergency, and 2 (0.68%) for abdominal emergency.

The median time for a participant to complete assessments was 2.0 (IQR 1.0-5.0) min for *new baby born in last 24 hours*, 6.0 min (IQR 3.0-13.0) for *new baby more than 24 hours old or change in clinical status*, and 6.0 (IQR 4.0-10.5) min for *rounding*. In total, participants used the *My Patient* section for a total of 161 hours. NoviGuide was used frequently throughout the day, with 839 (49.2%) assessments made during the day shift, 700 (41.1%) during the evening shift, and 166 (9.7%) during the night shift (Table 3).

All but 1 of the 19 study participants recorded entries into the NoviGuide. The mean (range) number of completed assessments per study participant was 90 (0-321). The participant without entries had been transferred to another hospital shortly after enrolling. Of the 1092 assessments of babies born within the last 24 hours, 68.13% (744/1092) were completed by only 26% (5/19) study participants. Participants entered 46 practice cases, denoted by answering “N” (no) to the question, “Are you with a real baby? (Touch N if practicing).”

Data from the maternity register included 4704 admissions from February 1, 2017, to February 20, 2018. Of these, 97.55% (4589/4704) were identified as born at TDH, 2.32% (109/4704) were born outside of TDH, and 0.13% (6/4704) entries did not specify the birth site. Six deaths (0.13%) were recorded in the registry, and 0.64% (30/4704) newborns were transferred to a higher acuity facility. The registry, while noting whether the newborn was born at TDH, does not include the requisite data to determine whether the care encounter occurred immediately postpartum or upon return to the hospital following discharge.

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Figure 3. NoviGuide use by assessment type.

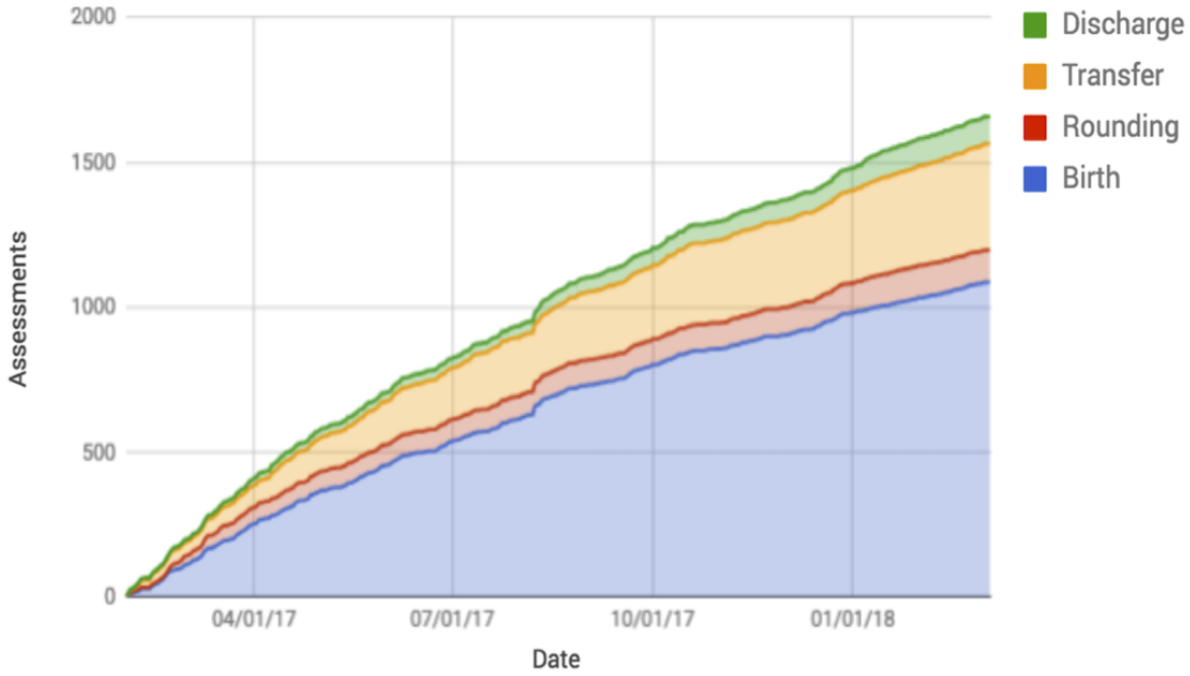

Table 3. NoviGuide use by work shifts and time of day.

Assessment type	Assessments made during the different shifts and time of day			Total
	Day (8 AM to 2:59 PM)	Evening (3 PM to 7:59 PM)	Night (8 PM to 8 AM)	
New baby born in the last 24 hours, n	529	451	112	1092
New baby more than 24 hours old, n	176	151	40	367
Rounding, n	64	44	3	111
Discharge, n	54	33	7	94
Abdominal emergency, n	4	1	0	5
Seizure emergency, n	12	20	4	36
Total (%)	49.2	41.1	9.7	100

Acceptability

The overall SUS score at the end of the study was very high at 93.5 (Table 4) compared with the average score of 68, as described by John Brooke [30]. The mean (SD) scores of all the questions in the CHCE-PSQ were more than 4 (out of a maximum of 5; Table 5). The participants reported high levels of satisfaction with the NoviGuide (mean 4.86, SD 0.36). The participants' perceptions about NoviGuide included the following: NoviGuide saved time (mean 5, SD 0), its information was useful (mean 4.79, SD 0.43), its information was easy to understand (mean 4.5, SD 0.52), the graphics were highly effective (mean 4.07, SD 0.47), and it could improve patient-nurse encounters (mean 5, SD 0).

In the end-of-study questionnaire (Table 5), the participants reported that NoviGuide helped them deliver better care and prevented them from making mistakes and that they felt more confident in taking care of newborns when they used the NoviGuide.

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Table 4. Usability scores.

SUS[a]	Score, mean[b] (SD)	Converted[c]
1. I think that I would like to use the NoviGuide frequently.	5 (0)	4
2. I found the NoviGuide unnecessarily complex.	1.14 (0.36)	3.9
3. I thought the NoviGuide was easy to use.	4.7 (0.46)	3.7
4. I think that I would need the support of a technical person to be able to use NoviGuide.	1.21 (0.43)	3.8
5. I found the various functions in the NoviGuide were well integrated.	4.86 (0.36)	3.9
6. I thought there was too much inconsistency in the NoviGuide.	1.36 (0.74)	3.6
7. I would imagine that most people would learn to use the NoviGuide very quickly.	4.57 (0.65)	3.6
8. I found NoviGuide very cumbersome to use.	1.21 (0.80)	3.8
9. I felt very confident using the NoviGuide.	5 (0)	4
10. I needed to learn a lot of things before I could get going with the NoviGuide.	1.86 (1.23)	3.1
Total converted mean scores × 2.5 (overall SUS score)	N/A[d]	93.5

[a]SUS: System Usability Scale.

[b]1: strongly disagree, 2: somewhat disagree, 3: neutral or no opinion, 4: somewhat agree, and 5: strongly agree.

[c]For items 1, 3, 5, 7, and 9, the converted score is the mean score minus 1. For items 2, 4, 6, 8, and 10, the converted score is 5 minus the mean score.

[d]N/A: not applicable.

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Table 5. Mean scores of the Center for Health Care Evaluation Provider Satisfaction Questionnaire and the end-of-study questionnaire.

Questionnaires	Value, mean (SD)
Center for Health Care Evaluation Provider Satisfaction Questionnaire[a]	
1. How useful is the information provided in the NoviGuide?	4.79 (0.43)
2. How easy is it to understand the information in the NoviGuide?	4.5 (0.52)
3. How effective are the graphics in NoviGuide?	4.07 (0.47)
4. What is your general satisfaction with the NoviGuide?	4.86 (0.36)
5. The NoviGuide could improve patient-nurse encounters	5 (0)
6. The NoviGuide saved me time	5 (0)
7. I would use it regularly in the clinic or hospital	4.71 (0.47)
8. I would recommend that other nurses use this tool	5 (0)
Acceptability: end-of-study questionnaire[b]	
1. The NoviGuide helped me deliver better care to newborns	5 (0)
2. The NoviGuide prevented me from making a mistake while providing care to newborns	5 (0)
3. The NoviGuide improved my documentation on newborns and mothers	4.79 (0.43)
4. I was proud to use the NoviGuide	4.93 (0.27)
5. I feel more confident taking care of newborns when I use the NoviGuide	5 (0)
6. I think that using NoviGuide made a good impression on parents of the newborns I have seen	4.71 (0.61)
7. I think that using NoviGuide made a good impression on other parents in the community	4.43 (0.65)
8. I think that NoviGuide improved newborn care at my hospital	4.93 (0.27)
9. I think that using the NoviGuide to deliver newborn care at other hospitals is a positive idea	5 (0)
10. I think that NoviGuide is an important part of meeting my needs in caring for newborns	5 (0)
Feasibility: end-of-study questionnaire	
11. I had the medical supplies and materials needed to follow NoviGuide recommendations	3.36 (1.22)
12. I had enough time to use the NoviGuide	4.57 (0.65)
13. My colleagues supported my use of the NoviGuide	4.71 (0.47)
14. My supervisor and the hospital administration supported my use of the NoviGuide	4.71 (0.47)
15. Technical support was always available for any difficulties I had with the NoviGuide	4.93 (0.27)

[a]For Center for Health Care Evaluation Provider Satisfaction Questionnaire questions 1 to 4: 1, poor; 2, fair; 3, good; 4, very good; and 5, excellent; and for questions 5 to 8: 1, strongly disagree; 2, somewhat disagree; 3, neutral or no opinion; 4, somewhat agree; and 5, strongly agree.

[b]For the end-of-study questionnaire: 1, strongly disagree; 2, somewhat disagree; 3, neutral or no opinion; 4, somewhat agree; and 5, strongly agree.

Feasibility

Study participants initiated and completed assessments on both well-appearing and ill-appearing newborns with diverse clinical characteristics (Table 6). Of the 1092 assessments for new baby born in last 24 hours, 29.21% (319/1092) were sick appearing, 24.82% (271/1092) had difficulty breathing, 19.51% (213/1092) weighed under 2.5 kg, 12.18% (133/1092) were born preterm, and 38.00% (415/1092) had at least one abnormal vital sign. Of the 367 assessments for new baby more than 24 hours old or change in clinical status, 77.4% (284/367) were sick appearing, 27.5% (101/367) had difficulty breathing, 53.1% (195/367) had at least one abnormal sign, 30.2% (111/367) weighed under 2.5 kg, 16.1% (59/367) were born preterm, and 59.9% (220/367) had antibiotics calculated during the assessment.

Rounding assessments included 6.51% (111/1705) of the total 1705 assessments entered into NoviGuide. Of these, 77.5% (86/111) were for *term baby needing treatment*, 18.0% (20/111) for *preterm baby*, and 4.5% (5/111) for *term baby*.

In a number of instances, participants working in the same maternity ward reported varying resource capabilities. In 738 assessments where participants were guided to check a glucose level, 46.3% (342/738) reported that a glucometer was available and entered a level, whereas 53.7% (396/738) responded *Cannot test*. Of the 264 completed assessments where a newborn had respiratory distress, participants indicated that a regular nasal cannula was available in 98.5% (260/264) assessments, whereas in 1.5% (4/264) assessments, participants indicated that there was no treatment available. Concerning the availability of IV fluids, participants indicated a desire to calculate IV fluid doses

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or rates in 328 assessments but indicated they could not give IV fluids in 20 assessments (6.1%).

In the end-of-study questionnaire, participants responded with a mean score of 3.3 (SD 1.22) when asked whether they had the requisite resources to follow NoviGuide's recommendations (Table 5). The participants' mean scores for the following questions were all above 4.5: (1) Was there enough time to use NoviGuide? (2) Was there support from their colleagues, supervisors, and hospital administration? and (3) Was technical support readily available?

Table 6. Characteristics of newborns entered into NoviGuide.

Newborn characteristics	New baby born in the last 24 hours (n=1092), percent birth assessments, n (%)	New baby more than 24 hours old (n=367), percent birth assessments, n (%)
Sick appearing	319 (29.21)	284 (77.4)
Difficulty in breathing	271 (24.82)	101 (27.5)
Weight under 2.5 kg	213 (19.51)	111 (30.2)
Preterm (<37 weeks)	133 (12.18)	59 (16.1)
Abnormal vital signs[a]	415 (38.00)	195 (53.1)
HIV exposed	55 (5.04)	12 (3.3)
Maternal fever	70 (6.41)	N/A[b]
Foul smelling amniotic fluid	109 (9.98)	N/A
Born in an unsterile environment	51 (4.67)	N/A
Antibiotics calculated during assessment	440 (40.29)	220 (59.9)

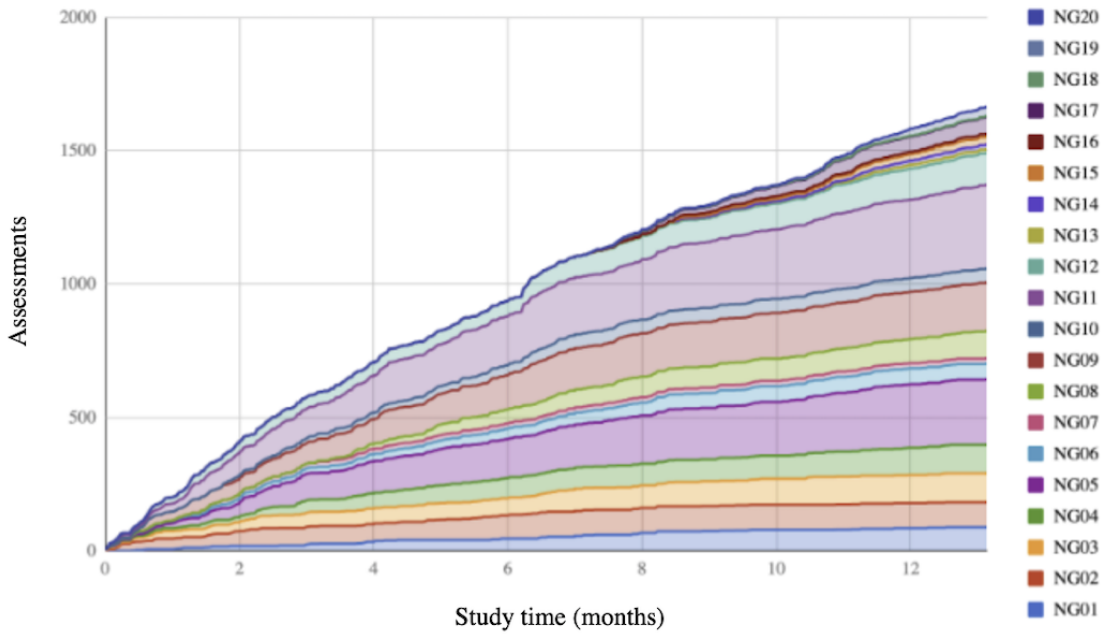
[a]Abnormal vital signs were defined as follows: temperature <36.5°C or >37.9°C, respiratory rate <30 or >60 breaths per minute, or heart rate <100 beats per minute or >160 beats per minute.

[b]N/A: not applicable.

Sustainability

Although NoviGuide continued to be used regularly throughout the study (Figure 4), use declined with time. Study participants made 35.36% (603/1705) assessments on days 0-99 and then 27.74% (473/1705), 18.82% (321/1705), and 18.06% (308/1705) assessments over the subsequent 100-day intervals. There were only 3 instances of minor technical issues; the only technical issue reported was screen freezing, which was easily resolved by either the participant or the study team.

Figure 4. NoviGuide use by user. Individual study participants had unique identification numbers starting with NG, followed by the number, for example, NG01.



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Impact on Participant Knowledge

The results from the knowledge assessment questionnaires demonstrated significant improvement in basic newborn care knowledge over time. Among the 18 participants who were assessed at 6 months, scores increased from a mean of 10.4 to 14.1, reflecting a mean change of 3.7 (95% CI 2.6-4.8; $P<.001$) points. Among the 8 patients who were assessed at 12 months, the mean change from baseline was 6.7 (95% CI 5.07-8.31; $P<.001$).

Discussion

Principal Findings

NoviGuide was easily adapted to Uganda clinical guidelines, and its implementation in a rural district hospital was feasible and acceptable to nurse-midwives caring for newborns. The nurse-midwives used NoviGuide across a range of clinical scenarios, reported high levels of satisfaction with the software, and reported that it significantly improved their knowledge of newborn care. This study adds to the growing evidence that CDS software designed for facility-based health care workers delivering complex inpatient care can increase the use of national clinical guidelines in LMICs [32-35].

There are a number of features that distinguish NoviGuide from previously reported neonatal CDS software designed for LMICs [32,36-38]. NoviGuide converts guideline documents into patient-specific guidance, providing contextual drug dosing and cross-referencing diagnoses with vital sign inputs. Although other CDS apps only provide users with treatment guidance for a pathology the user has selected, NoviGuide not only provides treatment guidance but also prompts users to consider pathologies based on patient-specific inputs. Finally, NoviGuide is not a medical record by design and therefore does not require patient identification inputs. This makes the time required to complete an assessment through NoviGuide significantly shorter.

Ugandan experts suggested only two minor modifications to NoviGuide's decision trees. Although the suggested additions are not explicitly detailed in the Uganda clinical guidelines, they do align with the national strategy to reduce deaths from newborn infections and with general standards of care. The paucity of modifications suggests that NoviGuide was well aligned to the Ugandan local context and suggests that there may be similar ease of adaptation in other countries where national guidelines are based on WHO recommendations on newborn health [36]. This finding has implications for scalability, as it suggests that algorithm templates with a few configurable settings may be acceptable in a wide range of health systems.

A key finding is that nurse-midwives had very high levels of satisfaction with NoviGuide; participants reported that the NoviGuide saved time, that they would recommend it to other nurses, and that they were even proud to use it. These findings highlight the potential of CDS as a delivery system for implementing complex clinical protocols. CDS-enabled functionalities, such as automated drug dose calculations, combined with a streamlined and attractive user interface, may confer a benefit on the user separate from that acquired by adhering to a specific clinical standard. Interestingly, these high levels of satisfaction with the NoviGuide persisted despite evidence that participants did not use it on every baby, there was wide variation in use, and there was an overall decrease in use over time. There are a number of possible explanations for the wide variation in use among participants, including differences in hours worked per individual, role within the ward, and planned absences. It is possible that autonomy in using, or not using, NoviGuide contributed to overall satisfaction with the software; NoviGuide may have been time saving because participants could self-select when they wanted to use it. Regardless, as in previous studies on CDS [20,37,38], our study demonstrates that the deployment of CDS in a way that does not mandate use will not capture all patients.

Participants improved their knowledge scores over the study period, even as they only rarely engaged with the parts of NoviGuide intended for self-directed learning outside of clinical care. This finding suggests that rather than becoming dependent on CDS to the detriment of internalized knowledge, CDS can improve provider knowledge through exposure. The finding that participants visited the self-directed learning section only 14 times over the study period requires additional qualitative investigation. One possibility is that health care providers form an early perception of the software as either a point-of-care software or a continuing education software, but not both.

A potentially important finding was that NoviGuide's use data captured entries where participants working at the same hospital reported that they had different resources to treat patients. This finding has potentially important implications, as it suggests that CDS could be used to identify instances where either an individual or system barrier prevents available resources from being used. The same data, if transmitted frequently, could facilitate the rapid identification of resource gaps, such as the stock out of drugs or malfunction of a previously functioning medical equipment.

Limitations

We acknowledge several limitations of our study. The newborn clinical characteristics entered into NoviGuide were not corroborated by reference to clinical charts or direct observation. Some of the investigators performing this evaluation were the designers of this tool, raising the possibility of bias; additional evaluation of our tool at a later stage in development could be informative. The lack of rolling enrollment may have influenced our adoption measurements, as new staff in the maternity ward began work before being enrolled in the study, resulting in a period where these staff observed NoviGuide in use but could not use it themselves. We also lack data to draw conclusions regarding the resource availability discrepancies identified through NoviGuide use. Specifically, we cannot determine whether these variances corresponded to a lack of provider comfort in using the resource, lack of access, equipment malfunction, or other causes. Finally, the Likert scale, which is commonly used to evaluate software acceptability and feasibility, is an imperfect tool and can result in *response style bias* [39].

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Conclusions

A CDS software for neonatal health care providers can be an alternative method for implementing complex neonatal protocols in LMICs and may improve upon, and complement, the standard didactic approach because of its ability to couple clinical protocols with job aide functionalities. The NoviGuide software was easily adapted to Uganda neonatal care clinical guidelines, was used across a range of clinical scenarios, resulted in high levels of satisfaction, and significantly improved knowledge among nurse-midwives. Although CDS is not a solution for all the training needs of a health care workforce in LMICs, it may be the optimal choice for content that is complex, not easily retained or applied, and for which immediate performance feedback is not possible.

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Authors' Contributions

TR, LB, and JB conceived and designed the study. MM, JA, and KR designed the data collection forms. MM and KR collected, cleaned, and analyzed the data. TR, LB, and MK provided technical and mentorship support for MM, a research fellow with University of California San Francisco PTBi. JB and ED developed NoviGuide. All the coauthors critically revised the manuscript and approved the final draft before submission.

Conflicts of Interest

The following authors work with Global Strategies, the organization that developed NoviGuide: JB as President, ED as Director of Software Design and Development, and JA works as a Program Coordinator. JB, ED, and JA did not participate in the data collection process. TR is a member of the board of directors of Global Strategies and advised in the development of NoviGuide. However, he receives no financial compensation from the organization or is in any other way related to NoviGuide; neither he nor his family members have any potential financial benefit from this manuscript's publication. The remaining authors declare no conflicts of interest.

Multimedia Appendix 1
NoviGuide resuscitation video.
[PPTX File , 32148 KB - mhealth_v9i2e23737_app1.pptx]

Multimedia Appendix 2
NoviGuide step-by-step prompts.
[PPTX File , 43816 KB - mhealth_v9i2e23737_app2.pptx]

Multimedia Appendix 3
System Usability Scale and provider satisfaction questionnaire adapted from the Center for Health Care Evaluation Provider Satisfaction Questionnaire, the end-of-study questionnaire, and the knowledge assessment questionnaire.
[DOC File , 136 KB - mhealth_v9i2e23737_app3.doc]

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Abbreviations

CDS: clinical decision support
CHCE-PSQ: Center for Health Care Evaluation Provider Satisfaction Questionnaire
IV: intravenous
LMIC: low- and middle-income country
PTBi: Preterm Birth Initiative
SUS: System Usability Scale
TDH: Tororo District Hospital
WHO: World Health Organization

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Original Paper

Bed Sensor Technology for Objective Sleep Monitoring Within the Clinical Rehabilitation Setting: Observational Feasibility Study

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Abstract

Background: Since adequate sleep is essential for optimal inpatient rehabilitation, there is an increased interest in sleep assessment. Unobtrusive, contactless, portable bed sensors show great potential for objective sleep analysis.

Objective: The aim of this study was to investigate the feasibility of a bed sensor for continuous sleep monitoring overnight in a clinical rehabilitation center.

Methods: Patients with incomplete spinal cord injury (iSCI) or stroke were monitored overnight for a 1-week period during their in-hospital rehabilitation using the Emfit QS bed sensor. Feasibility was examined based on missing measurement nights, coverage percentages, and missing periods of heart rate (HR) and respiratory rate (RR). Furthermore, descriptive data of sleep-related parameters (nocturnal HR, RR, movement activity, and bed exits) were reported.

Results: In total, 24 participants (12 iSCI, 12 stroke) were measured. Of the 132 nights, 5 (3.8%) missed sensor data due to Wi-Fi (2), slipping away (1), or unknown (2) errors. Coverage percentages of HR and RR were 97% and 93% for iSCI and 99% and 97% for stroke participants. Two-thirds of the missing HR and RR periods had a short duration of ≤120 seconds. Patients with an iSCI had an average nocturnal HR of 72 (SD 13) beats per minute (bpm), RR of 16 (SD 3) cycles per minute (cpm), and movement activity of 239 (SD 116) activity points, and had 86 reported and 84 recorded bed exits. Patients with a stroke had an average nocturnal HR of 61 (SD 8) bpm, RR of 15 (SD 1) cpm, and movement activity of 136 (SD 49) activity points, and 42 reported and 57 recorded bed exits. Patients with an iSCI had significantly higher nocturnal HR (t_{18}=−2.1, P=.04) and movement activity (t_{18}=−1.2, P=.02) compared to stroke patients. Furthermore, there was a difference between self-reported and recorded bed exits per night in 26% and 38% of the nights for iSCI and stroke patients, respectively.

Conclusions: It is feasible to implement the bed sensor for continuous sleep monitoring in the clinical rehabilitation setting. This study provides a good foundation for further bed sensor development addressing sleep types and sleep disorders to optimize care for rehabilitants.

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KEYWORDS

continuous sleep monitoring device; bed sensor technology; mHealth; nocturnal heart rate; nocturnal respiratory rate; nocturnal movement activity; neurological disorders; incomplete spinal cord injury; stroke; inpatient rehabilitation; clinical application

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Introduction

An important aim of rehabilitation therapy for patients with neurological disorders such as stroke or spinal cord injury (SCI; including incomplete SCI [iSCI]) is to develop skills needed for independent living. Although rehabilitation focuses mainly on activities during the day, sleep is also important for rehabilitation. Patients with a stroke or SCI can face sleep disturbances including sleep disorders [1-3]. Up to 60% of patients with stroke or SCI suffer from sleep disorders [1,2], which is high compared to the 24% of people with sleep problems in the general European population [4]. Those sleep disturbances may interfere with their long-term rehabilitation process for a variety of reasons in terms of lowering motivation, energy, and concentration, which are needed to fully participate in the rehabilitation process [3,5]. Sufficient and adequate sleep promotes rehabilitation by gaining physical and psychological energy [3,6]. It also improves implicit learning of motor skills [7] and cognitive performance [8-10], which may result in performance improvements [11]. Furthermore, sleep positively affects patients' daily activity and reduces the risk of diabetes, cardiovascular diseases, and development of metabolic disorders [1,2,8,10,12,13], which in its totality contributes to the quality of life. Hence, sleep is essential for optimal inpatient rehabilitation and long-term health, indicating the importance of sleep assessment.

At the moment, polysomnography (PSG) is considered one of the most comprehensive methods for sleep assessment and therefore the gold standard for the diagnosis of many sleep disorders [14,15]. Unfortunately, PSG is generally experienced as impractical, expensive, and limited in accessibility during inpatient rehabilitation in specialized rehabilitation centers [3,14,16-18]. Subjective measurements, such as self-report questionnaires, are inexpensive and easy to implement [16]. However, they summarize only the perception of the patient and are prone to missing data [19,20]. Therefore, a wide range of sleep technology devices used to assess sleep have been developed [18,21,22]. The main aim of those devices is to be less expensive, less invasive, and more accessible for assessing sleep compared to PSG. These sleep technology devices can be classified into contact (actigraphy, electroencephalography) and contactless (ballistocardiography [BCG], microphone, infrared, video camera, echo-based, or mobile) devices [19,22]. The accuracy and reliability of these devices have been continuously increased with the advances of technology [19]; however, most of them have several disadvantages when applied in a clinical inpatient rehabilitation setting. Disadvantages of contact devices comprise discomfort and disruption of sleep, potential for misplacement, and limited data storage and battery capacity [17,18,22]. Contactless portable devices based on infrared, video camera, echo, or mobile phones have the disadvantages that they might lead to incorrect measurements when there are multiple patients in one room, patients change rooms, or nursing staff visits the patient during the night [17,18,22]. Furthermore, most do not monitor heart rate (HR) and respiratory rate (RR), two vital signs during inpatient rehabilitation [23]. A solution to overcome the aforementioned disadvantages of various sleep measuring methods can possibly be found in the recent development of unobtrusive, contactless, portable sensor–based devices for objective sleep analysis based on BCG. BCG technology consists of a highly sensitive pressure sensor, which can measure HR, RR, and movement activity (body movements), which are parameters used in sleep monitoring [24,25]. Studies have reported nocturnal HR and RR coverage ranging between 83% and 92% [26,27]. In this way, a portable bed sensor based on BCG can measure multiple nights without causing any discomfort over a longer period of time. Furthermore, this bed sensor is not prone to disturbance of its signal by others in comparison to the other contactless devices. Therefore, the portable bed sensor based on BCG has potential to be suitable for sleep monitoring in long stay rehabilitation inpatients such as stroke or SCI [28-30].

To our knowledge, portable bed sensors have not yet been implemented during inpatient rehabilitation, although they could be useful in clinical practice. Only a few studies have included a small number of patients using portable bed sensors under research circumstances in a hospital setting [31-33]. However, human, technological, or environmental issues might come along with implementation of sensors in noncontrolled settings [34-36]. Therefore, the aim of this study was to investigate the feasibility of an unobtrusive, contactless, portable bed sensor for continuous sleep monitoring overnight in a clinical rehabilitation SCI and stroke ward. Feasibility was examined based on missing measurement nights. To examine the ability of the bed sensor to capture sleep-related parameters, the following secondary outcomes were analyzed: coverage percentages of HR and RR, missing HR and RR periods, interruptions of HR and RR signals due to bed exits, and the discrepancy in number of reported and recorded bed exits. Additionally, descriptive data on average nocturnal HR, RR, and movement activity for iSCI and stroke patients were reported. We hypothesized that the bed sensor is feasible in inpatient rehabilitation and is considered feasible if at least 95% of the nights were captured and the total coverage of nocturnal HR and RR was above 80% [26,27,36]. Based on the literature, a higher nocturnal HR for iSCI compared to stroke patients was hypothesized [37,38], which serves as a first indication of group validity of the bed sensor.

Methods

Study Design

This observational cohort study was carried out at the Sint Maartenskliniek (Ubbergen, the Netherlands). This study was part of an overarching study [39], which aimed to develop a sensor-based technological platform to monitor gait and sleep. It was performed in the clinical treatment environment of the rehabilitation department to integrate the intervention in a realistic setting. Interaction between participant and researcher was kept to a minimum to prevent interference with clinical practice. The study was conducted in accordance with the principles of the Declaration of Helsinki (64th World Medical Association General Assembly, Fortaleza, Brazil, October 2013) and approved by the Medical Ethical Research Committee of Arnhem-Nijmegen (4222-2018).

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Participants

Twelve iSCI patients (ASIA [American Spinal Injury Association] scale C/D) and 12 first-ever stroke survivors (Functional Ambulation Category score≥2) were recruited (both sexes, age≥16 years), as they both have relatively long inpatient hospital stay durations. The following criteria had been applied in relation to the overarching project: minimum age of 16 years, not wheelchair-bound, participation in ambulation therapy, no other comorbidities affecting patients' ambulatory function, and no use of an anti-decubitus air bed mattress because of interference with the measurement. Participants who were unable to grant permission to participate in the study due to language issues or cognitive impairment were excluded.

Patients who were already admitted to the inpatient clinical rehabilitation ward of the Sint Maartenskliniek were pre-assessed for eligibility for study participation. The Montreal Cognitive Assessment test score, which was already performed by the responsible rehabilitation physician for usual care, was used to determine if the patient was capable of participating in the study. Eligible patients were asked to voluntarily participate in the study, and participation was not incentivized. After patients were asked to participate, they had time to consider participation before deciding whether or not to participate in the study. There was no intrusion on the patient's rehabilitation process, and patients could follow their normal care program based on their personal needs. Patients were hospitalized for both day and night during weekdays (sometimes during weekends) for several weeks. Written informed consent was obtained from all participants before the start of the measurements.

Instrumentation

A portable bed sensor, the Emfit QS sleep tracker (Emfit Ltd; 542 mm × 70 mm × 1.4 mm), was used. The sensor consists of thin elastic lightweight polymer layers separated by air voids and coated with electrically conductive, permanently polarized layers. The Emfit bed sensor was placed under the bed mattress at the thoracic area of the sleeping patient [40]. Changes in pressure distribution generate a charge on the electrically conductive surfaces of the sensor, which can be measured as a current or a voltage signal [32]. The sensor was compatible with IEEE 802.11b/g/n networks, an international standard local area network protocol, and provides data about HR, RR, and movement activity every 4 seconds. Movement activity was expressed by activity points (AP) in which a higher number of AP corresponds with larger body movements. Small movements with the arm will result in fewer AP compared to whole body movements if sleep position changes. Bed exits were identified by the sensor if no pressure was detected. Bed exits were described by duration and frequency. The Emfit bed sensor needs at least one hour of recording before generating a data file. Data were sent to the Emfit server [41].

The Emfit bed sensor was designed for people who lie in bed with the intention to sleep. As the Emfit bed sensor has not been validated to indicate the moment of sleep onset and offset in iSCI and stroke patients, a sleep questionnaire was filled out manually by the patient himself or herself (or with help of the nursing staff) at the end of every night regarding bedtime, time of awakening, bed exits, and use of sleep medication. Those questions were based on the Pittsburgh Sleep Quality Index referring to "last night" instead of "the last month" [42].

Procedure

After written informed consent, the bed sensor was placed under the bed mattress of the participant by the researcher, and the sleep questionnaires were handed over to the participant. The bed sensor remained under the bed mattress for 1 week. During the weekend, most patients were allowed to stay at home for one or two nights for rehabilitation purposes. If a participant was transferred to a different room, the nurse was responsible for moving the bed sensor. If there were any errors or questions regarding the bed sensor during the measurement week, the researcher visited the patient. Visits by the researcher during the measurement week were considered as interference and registered. At the end of the measurement week, the researcher collected the bed sensor and the questionnaires. Only one researcher (MMSH) was involved in the described procedure and was not blinded to the study outcomes.

Outcome Measures

The primary outcome for feasibility was the percentage of missing measurement nights. A night was considered as missing if data were not available. Furthermore, reasons for missing nights were noted. To examine the ability of the bed sensor to capture sleep-related parameters, the following secondary outcomes were analyzed: coverage percentages of HR and RR, distribution of missing HR and RR periods based on duration, interruptions of HR and RR signals due to bed exits, and the discrepancy in number of reported and recorded bed exits. The coverage percentages are the percentages of timestamps in which HR or RR data were detected by the bed sensor. Because duration of missing data might have clinical impact, the missing HR and RR data periods per night were presented in time categories of <31, 31-60, 61-120, and >120 seconds. Furthermore, the sensor registers a bed exit if no pressure is recorded. As a result of getting in or out bed, HR and RR signals could be interrupted prior to or after a bed exit while the sensor measures pressure. These adjoining time intervals of missing HR and RR signals were calculated and referred to as response time. This response time of HR and RR due to bed exits was not included in previous outcomes but was investigated separately. The discrepancy between the number of bed exits reported by the questionnaire and the number of bed exits recorded by the bed sensor was described. Average nocturnal HR was calculated for each night as beats per minute (bpm), RR as cycles per minute (cpm), and movement activity as AP. Interference by the researcher if a participant or nurse noticed and reported an error was noted. In addition, the number of patients who had to switch rooms and the complaints regarding the usage of the bed sensor were obtained.

Data and Statistical Analysis

The Emfit company provided bed sensor data in CSV files on HR, RR, movement activity, and bed exits, based on their algorithm. A custom MATLAB (R2017b, Version 9.3.0.713579, The MathWorks Inc) script was used for processing and analyzing the sleep period data regarding HR, RR, and

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movement activity recorded by the bed sensor. For analysis of secondary outcomes, measurement nights were only included if bed sensor data and a complete filled out sleep questionnaire corresponding to that night were available. The questionnaire was used to determine the sleep period, time points of sleep onset, and moments of waking up during each night. Missing data periods due to bed exits were excluded from the coverage percentage and missing data calculations. Statistical analyses were performed with SPSS (version 20.0; IBM Corp) and RStudio (version 1.2.5042; RStudio, PBC). The level of statistical significance was set at $P<.05$. Data were tested for normality using the Shapiro-Wilk test. A *t* test was used for normally distributed data, and a Wilcoxon signed rank test (paired) or Mann-Whitney *U* test was used for nonnormally distributed data. For categorical data, a chi-square test was used. Descriptive statistics were presented as mean (SD) if data were normally distributed and as median (range, minimum-maximum) otherwise. The bed sensor was considered feasible if at least 95% of the nights were covered and the total coverage percentage of nocturnal HR and RR was above 80% [36]. All outcome measures were reported for the in-hospital iSCI and stroke patients separately.

Results

In total, 25 participants (12 iSCI, 13 stroke) were included in this study. One stroke participant dropped out on the first day because of the experienced additional cognitive load to participate in the study. Therefore, data of 24 participants were analyzed. No statistical differences in sex, age, premorbid sleep problems, or the use of sleep medication were found between the iSCI and stroke groups (Table 1).

Table 1. Characteristics of participants.

Characteristic	iSCI[a]	Stroke	*P* value	Chi-square (*df*)
Demographics				
Participants, n	12	12	N/A[b]	N/A
Gender (male/female), n	9/3	7/5	.39	0.8 (1)
Age (years), mean (SD)	63.4 (12.9)	68.7 (9.0)	.22	N/A
Days since injury, mean (SD)	83.8 (67.4)	47.0 (25.6)	.09	N/A
Premorbid sleep problems, n	0	0	>.99	0 (1)
Sleep medication, n	2	2	>.99	0 (1)
iSCI characteristics				
ASIA[c] (AIS[d] C/D), n	1/11	N/A	N/A	N/A
SCI level (>T6/<T6), n	7/5	N/A	N/A	N/A
Lesion level (cervical/thoracic/lumbar), n	4/6/2	N/A	N/A	N/A
Stroke characteristics				
Stroke location (left/right), n	N/A	7/5	N/A	N/A
Stroke category (ischemic/hemorrhagic), n	N/A	10/2	N/A	N/A
Stroke type (cortical/subcortical/lacunar), n	N/A	9/1/2	N/A	N/A

[a]iSCI: incomplete spinal cord injury.
[b]N/A: not applicable.
[c]ASIA: American Spinal Injury Association.
[d]AIS: ASIA Impairment Scale.

A total of 67 nights with a median of 5 (range 3-7) per person for iSCI patients and 65 nights with a median of 5.5 (range 5-7) per person for stroke patients were measured, adding up to a total of 132 measurement nights. Of the 132 intended measurement nights, 5 (3.8%) had missing sensor data (3 iSCI, 2 stroke). The reasons for missing sensor data nights were errors with the Wi-Fi connection (2), the sensor slipping away from the bed mattress (1), and unknown reasons (2). Those errors did not interfere with the sleep of the participants, and the participants did not report any hindrance from the bed sensor. Twenty-seven nights were excluded (20.5%) due to incomplete questionnaires making it impossible to detect the sleep period (7 iSCI, 20 stroke). One night (0.8%) of a stroke patient could not be analyzed due to inconsistency regarding end of bedtime between the sensor data and questionnaire. Therefore, a total of 99 (57 iSCI, 42 stroke) measurement nights of 20 patients (11 iSCI, 9 stroke) could be analyzed. The average number of hours of indicated sleep per night was 8 hours and 1 minute (SD 1 hour and 7 minutes) for the iSCI group and 8 hours and 10 minutes (SD 33 minutes) for the stroke group ($t_{18}=0.3$, $P=.74$).

Table 2 shows the coverage percentages, mean numbers of missing data periods per time category, and durations of HR and RR signal interruptions due to bed exits. For the iSCI group, coverage percentages of 97% for HR and 93% for RR were found. Stroke participants had coverage percentages of 99% and 97% for HR and RR, respectively. Two-thirds of the missing

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HR and RR periods had a short duration of less than 121 seconds. The average duration of bed exits per night was 342 (SD 168) seconds for the iSCI group and 257 (SD 121) seconds for the stroke group (t_{16}=−1.2, P=.23). The HR response time (66 seconds; range 0-3972 seconds) to bed exits was significantly shorter compared to the RR response time (163 seconds; range 0-3226 seconds) (z=−9.0, P<.001). Response time before bed exits (0 seconds; range 0-3226 seconds) was significantly shorter than the response time after bed exits (99 seconds; range 0-3972 seconds) (z=−8.4, P<.001).

Table 2. Coverage percentages, mean number of missing data periods per time category (<31, 31-60, 61-120, and >120 s), and response time due to bed exits of nocturnal HR and RR for iSCI and stroke patients recorded by the bed sensor.

Group	Coverage (%), mean (SD)	Missing data periods per night, mean (SD)				Response time due to bed exits (s), mean (SD)	
		<31 s	31-60 s	61-120 s	>120 s	Before	After
iSCI[a]							
HR[b]	96.8 (4.5)	3.1 (2.8)	1.8 (2.1)	1.5 (1.6)	1.4 (2.0)	9.7 (7.5)	141.1 (261.1)
RR[c]	92.5 (4.7)	4.6 (1.9)	2.1 (1.0)	2.3 (0.9)	4.6 (2.4)	87.1 (100.1)	240.8 (294.7)
Stroke							
HR	99.3 (0.6)	2.0 (1.2)	0.8 (0.8)	0.7 (0.5)	0.5 (0.7)	8.4 (8.6)	36.2 (25.3)
RR	96.7 (2.6)	3.1 (1.7)	2.0 (1.5)	1.6 (1.6)	2.4 (2.0)	61.8 (78.9)	103.1 (46.5)

[a]iSCI: incomplete spinal cord injury.

[b]HR: heart rate.

[c]RR: respiratory rate.

Patients with iSCI reported a total of 86 bed exits by questionnaire, of which 84 were recorded by the bed sensor. Stroke patients reported a total of 42 bed exits, whereas 57 bed exits were recorded. There was a difference between self-reported and recorded bed exits per night in 15 of the 57 nights (26%) for iSCI and in 16 of the 42 nights (38%) for stroke patients (Table 3).

Table 3. Difference in reported and recorded bed exits per night for iSCI and stroke patients.

Group	Frequency Δ[a] of reported (questionnaire) and recorded (sensor) bed exits								
	−4	−3	−2	−1	0	+1	+2	+3	+4
iSCI[b]	0	0	1	5	42	9	0	0	0
Stroke	0	0	5	8	26	3	0	0	0

[a]Negative value indicates fewer reported bed exits; positive value indicates more reported bed exits.

[b]iSCI: incomplete spinal cord injury.

The nocturnal HR in iSCI (72 bpm, SD 13 bpm) was significantly higher compared to the stroke group (61 bpm, SD 8 bpm; t_{18}=−2.1, P=.04). Nocturnal RR was 16 (SD 3) cpm and 15 (SD 1) cpm for iSCI and stroke, respectively (t_{18}=−2.4, P=.21). Average nocturnal movement activity was significantly different between iSCI (239 AP, SD 116 AP) and stroke (136 AP, 49 AP) (t_{18}=−1.2, P=.02). The median percentage for movement activity of large movements (>500 AP) was significantly larger in iSCI patients (5.7%, range 1.8%-28.2%) compared to stroke patients (2.8%, range 0.4%-4.9%) (z=2.2, P=.03). Furthermore, no errors were noted, no participants had to switch rooms, and none of the participants had any complaints regarding the usage of the bed sensor.

Discussion

The aim of this study was to investigate the feasibility of an unobtrusive, contactless, portable bed sensor for continuous sleep monitoring overnight in a clinical rehabilitation SCI and stroke ward. Sensor data were available for more than 95% of the measured nights. The bed sensor was able to capture HR and RR with high coverage percentages between 92% and 99%, with only short missing HR and RR periods during the night and some interruptions of the HR and RR signals caused by bed exits. iSCI patients had significantly higher nocturnal HR and movement activity than stroke patients. Moreover, no complaints were mentioned regarding the use of the bed sensor. These findings indicate the feasibility of an unobtrusive, contactless, portable bed sensor for continuous sleep monitoring overnight within a clinical setting.

The 3.8% (5/132) missing measurement nights fell within the 5% boundary for feasibility and are in line with literature regarding missing data of various sensor technologies [36,43,44]. Another important positive finding of this study was the high coverage rates (>92%) of HR and RR in both patient groups. These coverage percentages largely exceeded the set boundary of 80% and are at the upper limit of what has been found in literature; studies found average coverage percentages of 83% [26] and 93% [27] for HR and 87% [26] for RR using unobtrusive, contactless, portable sensors under bed mattresses at home and in sleep centers. A possible explanation for our

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slightly higher coverage percentages might be the exclusion of bed exits and response time due to bed exits. However, patients are not asleep around bed exits, which causes those periods to be clinically less relevant for HR and RR signals. Furthermore, the missing data due to bed exits were mostly short periods of signal interruptions (<31 seconds). Including bed exits in the coverage percentages would reduce the coverage by less than 3%: iSCI HR 94.6% (SD 5.0) and RR 89.6% (SD 6.0), stroke HR 97.9% (SD 1.3) and RR 95.0% (SD 3.0)). Therefore, the clinically relevant nocturnal HR and RR signals could almost entirely be monitored with the bed sensor.

A high coverage of HR and RR is essential to assess HR- and RR-based functional sleep outcomes. Possible interesting HR- and RR-based functional outcomes for clinicians from the bed sensor could be (1) time in bed, (2) sleep latency, (3) sleep efficiency, (4) total time awake, (5) total sleep time, (6) sleep stages (%), and (7) apnea-hypopnea index [1,12,32,45,46]. To determine these functional sleep outcomes, it is important that HR and RR, as well as movement, can properly be measured with the bed sensor. So far, the bed sensor has appeared to be suitable for measurement of HR and RR in laboratory studies with healthy subjects [47-49]. Previous studies found significantly higher HR in low paraplegia SCI patients compared to healthy controls [37] and similar HR in stroke patients and healthy controls [38]. The higher HR in iSCI compared to stroke patients in this study supports higher nocturnal HR in iSCI patients. Although nocturnal RR data in SCI and stroke patients in literature is lacking, nocturnal RR was within the range of a normal population [50]. Studies reporting on nocturnal movement activity are scarce. Based on this study, iSCI patients seem to have a significantly higher percentage of large body movements compared to stroke patients. The abovementioned findings support the bed sensor's ability to discriminate between different groups and is a first indication toward group validity. It suggests that HR, RR, and nocturnal movement activity can be monitored by bed sensors on the rehabilitation ward, but this needs further study and comparison with healthy controls.

Despite the wide range of sleep technology devices, the perfect sleep assessment method does not yet exist: all methods have their advantages and disadvantages [14]. Disadvantages of the portable bed sensor are that the sensor cannot be used in combination with an airflow mattress and that it is designed for sleep detection with intention to sleep. However, in-hospital patients are often inactive due to physical impairments and therefore spend a lot of time in their bed without the intention to sleep, which the sensor cannot distinguish from being asleep. Hence, further validation of the portable bed sensor is needed, and attention must be paid to the overestimation of sleep time, sleep onset, and wake/sleep periods in a greater proportion of the rehabilitation center population [20,46,51].

A limitation of our study was that the data analysis was dependent on completely filled out sleep questionnaires. During our study, we were confronted with a disadvantage of using sleep questionnaires that has been reported previously [14,20]. Patients, especially stroke patients with mild cognitive impairment, did not fill them out regularly and accurately, which was supported by the difference in reported and recorded bed exits. As a consequence, a large proportion (27/132, 20.5%) of measurement nights could not be used in data analysis. In contrast, only 3.8% (5) of the nights were missing due to technical errors. Nonetheless, subjective sleep measures assess more habitual patterns of sleep and sleepiness compared to the objective monitoring of different body functions during sleep [14,16]. Therefore, combining subjective and objective measures of sleep may provide a more comprehensive, continuous evaluation of sleep quality. The bed sensor is a more robust way of sleep monitoring and can complement the subjective sleep assessment in the clinical setting. Therefore, future research should study more extensively the validity of the unobtrusive, contactless, portable bed sensor in immobilized patients within rehabilitation populations, in comparison with healthy controls.

In conclusion, the unobtrusive, contactless, portable bed sensor is a promising and feasible instrument to monitor sleep in the clinical rehabilitation setting. This provides a good foundation for further development of these types of sensors targeting sleep types and sleep disorders.

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Authors' Contributions

MMSH, JHvL, and NLWK contributed to study conceptualization, methodology, formal analysis, writing and preparation of the original draft, and project administration. MMSH and JHvL contributed to investigation, data curation, and visualization. MMSH, JHvL, NLWK, and MV-vdH contributed to resources and the review and editing of the manuscript. NLWK and MV-vdH supervised the study. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AP: activity points
ASIA: American Spinal Injury Association
BCG: ballistocardiography
bpm: beats per minute
cpm: cycles per minute
HR: heart rate
iSCI: incomplete spinal cord injury
PSG: polysomnography
RR: respiratory rate
SCI: spinal cord injury

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Original Paper

Use of a Smartphone Platform to Help With Emergency Management of Acute Ischemic Stroke: Observational Study

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Abstract

Background: To improve the outcomes of acute ischemic stroke (AIS), timely thrombolytic therapy is crucial. Series strategies were recommended to reduce door-to-needle (DTN) time for AIS. Mobile technologies are feasible and have been used in stroke management for various purposes. However, the use of smartphone platforms that integrate series strategies through the entire first aid process to improve emergency management of AIS remains to be verified.

Objective: This study aims to describe the utility and application of a smartphone platform in the emergency management of AIS and report the DTN time for patients with AIS during its 2-year application period. Our results are relevant to digital health management.

Methods: A smartphone platform named “Green” was developed to incorporate the field assessment, hospital recommendation, prehospital notification, real-time communication, clinical records creation, key time-stamping, and quality control to streamline and standardize overall AIS emergency management processes. The emergency medical system (EMS) and all the emergency departments in Beijing have used this platform since 2018. From January 1, 2018, to December 31, 2019, 8457 patients diagnosed with AIS received intravenous tissue-type plasminogen activator therapy. The median DTN time and the proportions of patients with DTN times of ≤60 minutes and ≤45 minutes were reported.

Results: During the 2-year application period of this platform, the median DTN time was 45 minutes, and the proportions of patients with DTN times of ≤60 minutes and ≤45 minutes were 74.6% and 50.5%, respectively. The median DTN time was significantly reduced from 50 minutes in 2018 to 42 minutes in 2019 ($P<.001$). The proportions of patients with DTN times of ≤60 minutes and ≤45 minutes increased from 66.1% and 40.7%, respectively, in 2018 to 80.7% and 57.3%, respectively, in 2019 (both $P<.001$). Sustained improvement in DTN time was seen during all the observed months. The improvement occurred across all facilities, and the variations among hospitals also decreased. The median DTN time for patients transferred by ambulances (43 minutes) was significantly shorter than those who reached hospitals by themselves (47 minutes; $P<.001$).

Conclusions: Sustained reductions in DTN time reflected the improvement in AIS emergency management processes. The use of a smartphone platform integrating recommended strategies throughout all first aid stages is a practical way to help the emergency management of AIS.

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KEYWORDS

acute ischemic stroke; door-to-needle time; smartphone platform; emergency management; smartphone; mHealth; stroke; management; emergency; first aid; utility; digital health

Introduction

Stroke is the second-leading cause of death and disability worldwide [1] and accounts for almost 10% of all deaths [2]. The number of people who remain disabled from stroke has almost doubled during the last 30 years. Ischemic stroke comprises 65% of all strokes [1]. To improve the outcomes of acute ischemic stroke (AIS), timely thrombolytic therapy is crucial [3,4]. For every 15-minute reduction in door-to-needle (DTN) time, there is an associated benefit of a 5.0% reduction in mortality [3]. Due to the importance of rapid treatment, guidelines recommend that DTN time should be capped at 60 minutes for patients with AIS [5]. According to published data, adopting 10 best-practice strategies could reduce DTN time by 15 minutes [4], and implementing an expanded 16 strategies could save 20 minutes [6]. Of these strategies, several can be carried out in the prehospital emergency medical services (EMS) system. Recent guidelines have advised prehospital EMS systems to be integrated into the early management of patients with AIS [7,8].

In the prehospital stage, integrating mobile technologies such as prehospital assessment and prehospital notification for AIS into the EMS system has been reported to be feasible and beneficial [9-12]. For example, the Field Assessment Stroke Triage for Emergency Destination (FAST-ED) app improves the triage of patients with AIS, reduces hospital arrivals times, and maximizes the use of thrombolytic therapy [9]. Mobile technologies have been widely used to improve the management of stroke in different stages for various purposes [13,14]. Nevertheless, reports on the use of smartphone platforms incorporated into the overall emergency management process—from the prehospital stage to subsequent admission for further in-hospital treatment—are limited [15]. We hypothesize that such smartphone platforms could improve prehospital and in-hospital coordination, facilitate and standardize the workflow, and improve emergency management.

In China, stroke has been the leading cause of death, with an increase of 46.8% in disability-adjusted life years (DALYs) in the last 30 years [16]. Like other countries, ischemic stroke (IS) was the major pathological type [17]. To improve the timely therapy for AIS, a series of policies and procedures have been implemented to set up the prehospital emergency care system, establish stroke care units in the emergency department (ED), and enhance coordination between prehospital care and ED in the stroke center [18]. The prehospital EMS was also recommended in the recent Chinese AIS therapy guideline [19]. To standardize and streamline the processes in prehospital and ED stroke care and strengthen prehospital and in-hospital coordination, a smartphone platform named “Green” was developed [20]. Herein, we describe the utility and application of Green in the emergency management of AIS and report the DTN times for patients with AIS during its 2-year application period.

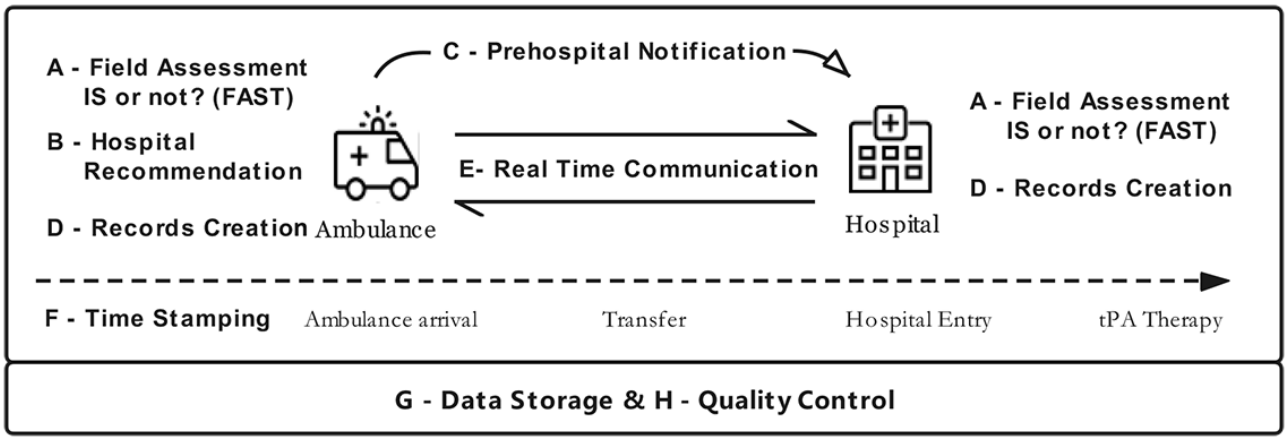
Methods

Workflow for AIS Emergency Management With the Use of Green

Streamlining AIS Emergency Management Processes

Green is a novel medical smartphone app developed jointly by the Beijing Municipal Health Commission and BEIJING ANMED Medical Technology Co Ltd in 2017. From January 2018, it has been freely available to the EMS systems and all eligible hospitals for AIS therapy in Beijing. Paramedics, physicians, and nurses in all stroke first aid facilities, as well as hospital management and quality control groups in Beijing, were trained several times to use this platform. In all, 8 aspects were integrated with the use of this app (Figure 1): (1) field assessment, (2) qualified hospital recommendation, (3) prehospital notification, (4) clinical records creation, (5) real-time communication, (6) time-stamping of events, (7) data storage, and (8) quality control.

Figure 1. Application of the Green App in the workflow for acute ischemic stroke (AIS) prehospital and in-hospital treatment. FAST: Field Assessment Stroke Triage; H: hospital; IS: ischemic stroke; tPA: tissue-type plasminogen activator.



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Field Assessment for Stroke

Once the ambulance receives an emergency call and reaches the patient, paramedics will first assess whether it is a suspected IS according to 3 simple tests: face (does the face droop on one side when the person tries to smile?), arms (is one arm lower when the person tries to raise both arms?), and speech (can the person repeat a simple sentence without slurring?). If any of these signs are observed, paramedics will classify the patient as having a suspected IS. Then, paramedics will input the patient's demographic characteristics and activate the platform. If the patient reaches the hospital by themselves, doctors who receive the suspected IS patient will activate the platform and create relevant clinic records.

Qualified Hospital Recommendation

Once paramedics activate the platform with the demographic information of a suspected patient, the nearest qualified stroke center or hospital will show up on the screen according to the First Aid Treatment Map for Stroke (FATMS) published by Beijing Health and Family Planning Commission. Based on the real-time traffic information, the app can calculate the estimated arrival times from the patient's location to the nearest qualified hospitals on the FATMS. The paramedics will then choose either the nearest qualified hospital or one of the other nearby hospitals according to the patient's preference (if any) and send the patient's information to the hospital while transporting the patient there.

Prehospital Notification to the Receiving Hospital

At the same time, the ED in the selected hospital will be alerted to any new potential stroke case. If the chosen hospital has a spare treatment bed at the time, the ED stroke care team in the hospital will confirm the information, alert the entire therapy team, prepare computed tomography (CT) scans and other resources, and clear a fast pathway for the incoming patient. Meanwhile, paramedics in the ambulance will receive confirmation from the target hospital via the Green app and transfer the patient there accordingly. During the transportation, automated time-stamping of events can be seen from the app for both paramedics in the ambulance and the ED care team in the receiving hospital, as the app incorporates GPS information.

Clinical Records Creation

During transportation, paramedics will initiate the patient's clinical records, including the main complaint, disease onset time, vital signs, blood glucose levels, and electrocardiogram. Prehospital staff will obtain informed consent from patients' relatives for thrombolytic therapy. The ED care team in the receiving hospital has simultaneous access to the clinic records, which are updated in real-time. If the patients reach the hospital by themselves, doctors in the hospital create and complete clinic records for patients in the app. The records are then automatically entered into the electronic clinic records in the chosen hospitals.

Real-Time Communication Between Prehospital and In-Hospital

Real-time communication between medical care professionals in the ambulance and the ED in the receiving hospital can take place during the patient's transportation. Paramedics can conduct several prehospital therapies or prepare under the ED care team's instruction, such as initial emergency care and prehospital informed consent for possible thrombolytic therapy. When each link in the ED care team is in a position to receive the patient, their readiness status is updated through the real-time communication window to facilitate care coordination.

Semi-automated Time-Stamping of Events

Once paramedics activate the platform, the time is automatically recorded. Based on the input disease onset time, the interval time from then on will be automatically shown at the top of the screen until the thrombolytic therapy is completed. During the whole treatment, time records for several key points need to be inputted into the app, including times for images, informed consent, intravenous thrombolysis, endovascular treatment, and revascularization. The stroke care team can easily access the interval time from onset from the app.

Data Storage

The data collection terminal is accessed via HTTPS to implement channel encryption and other measures to ensure terminal communication security. The overall software system information security protection is in compliance with the Regulation of the People's Republic of China on Protecting the Safety of Computer Information Systems, which referred to the Grade III information system. Several security strategies were incorporated into the data storage system, including the protection strategy of partition Fenwick, security access, dynamic perception, lean management, and comprehensive protection. The all-around system protection covers physical, boundary, server, terminal, application, and data protection, including integrity protection, confidentiality protection, and backup and recovery protection, to keep the system data in a safe state without danger and infringement.

Quality Control

Using the time records for the key therapy points, outside quality control parties can compare and analyze the data, rate the IS first aid performance of each hospital and ED, adjust the qualification of IS first aid facilities, and renew the regional FATMS. Quality control groups inside hospitals can use the information to find weak points during the therapy courses, provide suggestions, and improve the AIS first aid performance thereafter. During the 2-year usage of this app, the Beijing Municipal Health Commission and other quality control parties released quality control reports every month to all the stroke first aid facilities, held stroke emergency therapy seminars across hospitals, and helped hospitals improve their ability to administer first aid.

DTN Times for Patients With AIS

All the stroke first aid facilities in Beijing have used the application for 2 years since January 1, 2018. From the records in the platform, the DTN times of patients with AIS were analyzed in this report. DTN time was defined as the time interval between hospital arrival to initiation of intravenous tissue-type plasminogen activator (tPA) therapy. From January 1, 2018, to December 31, 2019, a total of 13,434 patients were diagnosed with AIS in Beijing, and of these, 13,058 (97.2%)

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patients had completed time records for key points during the acute treatment process. Among these 13,058 patients, 8457 (64.8%) received tPA, of whom 3186 (37.7%) arrived at the ED by ambulance (group A) and 5271 (62.3%) arrived by other transportation methods arranged by the family (group B). For group A, emergency management started from the time at which the paramedics reached the patients, whereas for group B, management started from the time of the patients' arrival to the hospital. For group A, all the functions in the Green app (stages 1-8) were involved in the management processes. For group B, several functions related to the EMS system, such as field assessment (stage 1), hospital recommendation (stage 2), prehospital notification (stage 3), and real-time communication (stage 5), were not applied; however, functions such as clinical records creation (stage 4), time-stamping of events (stage 7), and quality control (stage 8) were still applicable. The comparison between DTN times in the 2 groups would likely reflect the effect of management in the prehospital stage and the coordination between the prehospital and in-hospital processes.

Statistical Analyses

The median DTN time and proportions of patients with DTN times of ≤60 minutes and ≤45 minutes were reported for the entire 2-year period, for each year and each month, respectively. The median DTN time for each hospital was calculated, and the standard deviation was used to represent the variation between hospitals. All results were calculated separately for groups A and B. The Mann-Whitney U-test and chi-square test were used to compare differences between the groups. *P* values less than .05 were considered to indicate statistically significant differences. All analyses were conducted using R (version 3.6.0; R Core Team) [21].

Availability of Data and Materials

The statistical code is available upon reasonable request to the corresponding author.

Results

From 2018 to 2019, the median DTN time for patients with AIS who accepted intravenous tPA therapy was 45 minutes (Table 1). The median DTN time in 2019 (42 minutes) was significantly shorter than that in 2018 (50 minutes; *P*<.001; Table 2). As seen in Figure 2, the median DTN time in each month decreased continuously during the 2 years, from 54 minutes in January 2018 to 40 minutes in December 2019 (*P*<.001). The improvement in DTN time was noted in all the IS first aid facilities; the median DTN time in each hospital shifted from the right to the left by more than 8 minutes, and the variation of median DTN times among hospitals also decreased from 19.9 minutes in 2018 to 15.5 minutes in 2019 (Figure 3).

Table 1. Door-to-needle (DTN) times for patients with acute ischemic stroke (AIS) transferred by ambulances vs. those that reached the hospitals by themselves.

DTN times (in minutes)	Overall (n=8457)	Group A[a] (n=3186)	Group B[b] (n=5271)	*P* value
Median (IQR)	45 (29)	43 (30)	47 (28)	<.001
≤60 minutes, n (%)	6314 (74.6)	2457 (77.1)	3857 (73.1)	<.001
≤45 minutes, n (%)	4267 (50.5)	1747 (54.8)	2522 (47.8)	<.001

[a]Group A: AIS patients transferred by ambulances.

[b]Group B: AIS patients who traveled to the hospitals by themselves.

Table 2. Door-to-needle (DTN) times for patients with acute ischemic stroke (AIS) who received intravenous tissue-type plasminogen activator (tPA) therapy in Beijing in 2018 and 2019.

DTN times (in minutes)	Overall	Group A[a]	Group B[b]	*P* value
In 2018				
Sample Size, N	3504	1202	2302	
DTN, median (IQR)	50 (34)	48 (35)	53 (34)	<.001
DTN ≤ 60 minutes, n (%)	2316 (66.1)	846 (70.4)	1470 (63.9)	<.001
DTN ≤ 45 minutes, n (%)	1427 (40.7)	564 (46.9)	863 (37.5)	<.001
In 2019				
Sample Size, N	4953	1984	2969	
DTN, median (IQR)	42 (27)	40 (27)	43 (26)	<.001
DTN ≤ 60 minutes, n (%)	3998 (80.7)	1611 (81.2)	2387 (80.4)	0.51
DTN ≤ 45 minutes, n (%)	2840 (57.3)	1181 (59.5)	1659 (55.9)	0.01

[a]Group A: patients with acute ischemic stroke who were transferred by ambulances.

[b]Group B: patients with acute ischemic stroke who reached hospitals by themselves.

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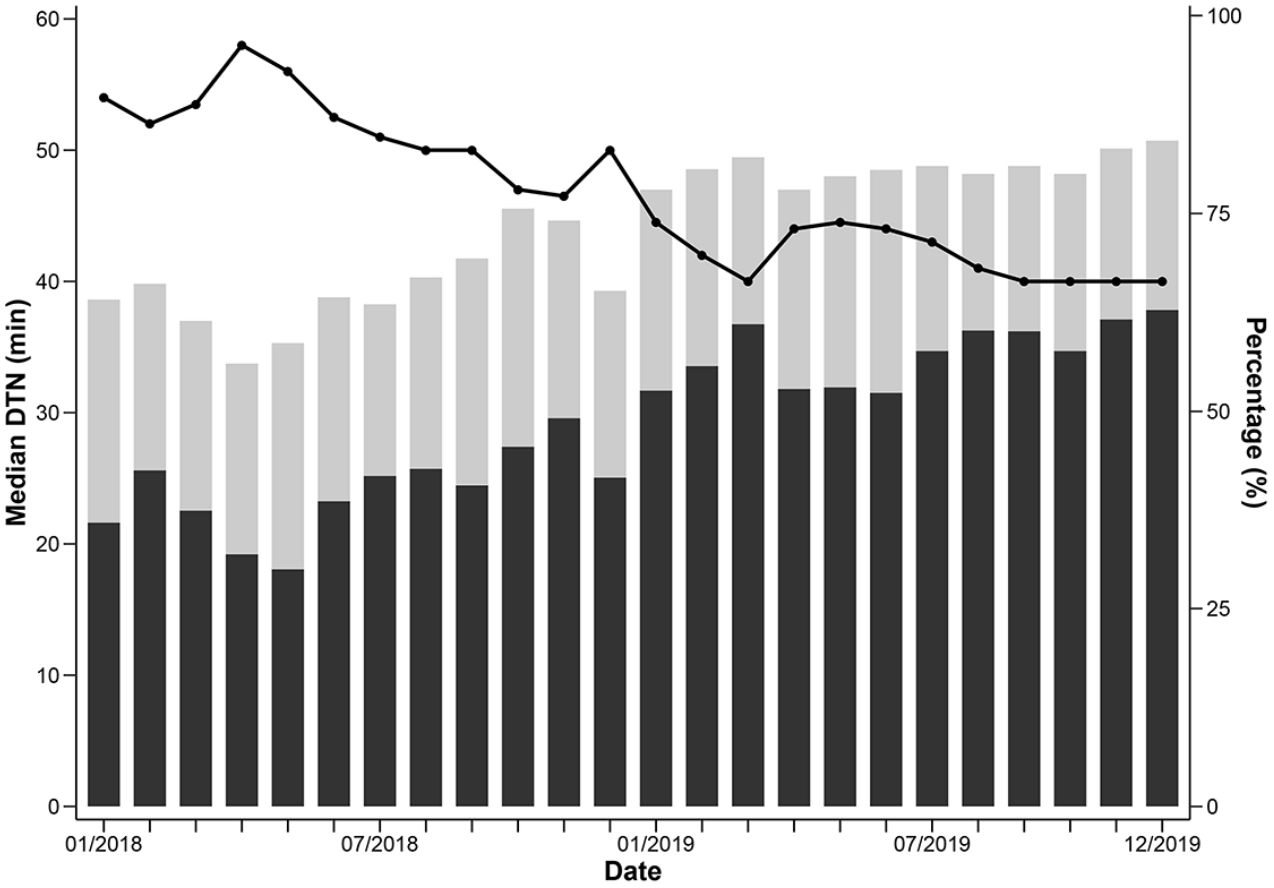
Figure 2. Door-to-needle (DTN) times for patients with acute Achemic stroke (AIS) who received intravenous tissue-type plasminogen activator (tPA) therapy from January 2018 to December 2019. Black bars: proportion of patients with DTN ≤45 minutes; dots and lines: median DTN times; grey bars: proportion of patients with DTN times ≤60 minutes.



Overall, among 8457 patients with AIS traveling to hospitals, 6314 (74.6%) and 4267 (50.5%) patients received intravenous tPA therapy within 60 minutes and 45 minutes, respectively (Table 1). The proportion of patients with DTN times that were ≤60 minutes and ≤45 minutes were 66.1% (2316/3504) and 40.7% (1427/3504) in 2018, respectively, while both proportions increased significantly (both $P<.001$) in 2019 to 80.7% (3998/4953) and 57.3% (2840/4953), respectively (Table 2). Continuous increases in these 2 proportions (DTN ≤60 minutes and ≤45 minutes) for each month was seen during the 2 years, with 64.1% and 35.9% in January 2018 and 84.2% and 62.8% in December 2019 (Figure 2).

The median DTN time for patients who were transferred by ambulance (43 minutes) was significantly shorter than those who reached the hospital by themselves (47 minutes; $P<.001$; Table 1). Accordingly, the proportion of patients both with DTN times of ≤60 minutes and ≤45 minutes were significantly higher in patients transferred by ambulance (both $P<.001$; Table 1). Similar results were seen in both 2018 and 2019 (Table 2). For both groups, the DTN times and proportions with DTN times of ≤60 minutes and ≤45 minutes each month showed continuous improvement (Multimedia Appendix 1).

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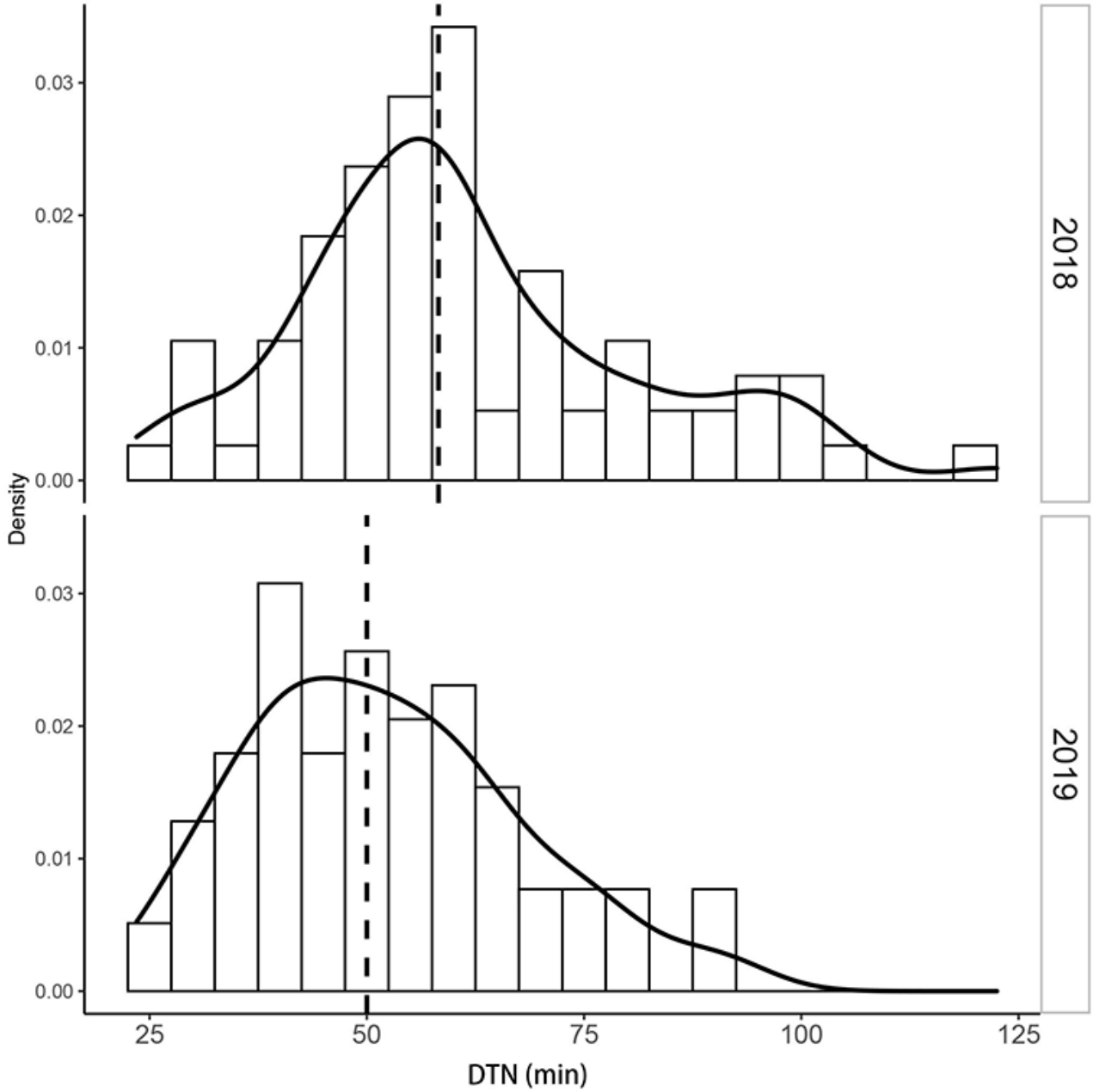
Figure 3. Distribution of door-to-needle (DTN) times among acute ischemic stroke (AIS) first-aid hospitals in Beijing.



Discussion

Principal Results

In this study, we described a smartphone freeware app developed for the emergency management of AIS through the entire first aid process. In the 2 years of use for standardizing the emergency management of AIS, the DTN time decreased significantly, with substantial increases in the proportion of patients with DTN times of ≤60 minutes and ≤45 minutes. Several strategies incorporated in the process accounted for the improvement, including hospital prenotification by EMS, rapid triage protocol, enhanced coordination, communication among providers inside and outside the hospital, key point time trackers, and prompt patient-specific data feedback to the EMS providers and stroke team. These strategies were among the 10 best stroke therapy practice strategies recommended by the American Heart Association/American Stroke Association (AHA/ASA) [22]. According to the results from 71,169 stroke patients, the DTN time decreased by about 15 minutes after implementing the 10 best strategies [4]. Moreover, the DTN time may decrease by about 20 minutes if 16 strategies recommended by AHA/ASA were implemented together [6].

Comparison With Prior Work

Using electronic apps is a feasible way to implement multiple recommended strategies. Reportedly, the Stop Stroke app, which can enhance coordination and communication between the inside and outside of hospitals, improved DTN time by a decrease of 21 minutes [23]. The reasons for the improvement were multifactorial [15]. Similarly, the Green app's use in this study improved DTN time significantly by implementing several management processes. Moreover, the improvement was continuous from the first months after its application to the 24

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months thereafter. According to previous studies, for every 15-minute reduction in DTN time, an associated improved mortality benefit of 5.0% could be obtained [3]. Therefore, significantly improved mortality benefits may be obtained as a result of the continuous improvement in DTN time.

According to our results, an improvement in DTN was seen in all the first aid facilities, along with a significant decrease in the variations among facilities. The variations among facilities were influenced by multiple factors [24]. It was reported that hospital variation accounted for 12.7% of the variability in DTN times [25]. Since January 2018, all the first aid facilities in Beijing began to use this application. The standardized management processes among facilities after applying a unique platform was the major reason for the reductions in the interhospital variations. Moreover, the prompt patient-specific data feedback may have also contributed to the changes. The data feedback system can help different stroke teams identify their specific delays and devise strategies to overcome these barriers [6]. Due to a systematic improvement in all the facilities, further health benefits would be obtained, along with an improvement in the equality for AIS treatment in the whole region.

According to the results, patients who were transferred by ambulances had shorter DTN times than those who went to hospitals by themselves. This result was similar to those reported in previous studies [24]. Prehospital EMS systems and advanced hospital notifications may play significant roles in the differences between both groups. The EMS triage and advanced hospital notification by EMS has been reported to significantly reduce DTN time [6,26]. Moreover, in the standard management processes in our study, paramedics would explain the possibility of intravenous therapy, as well as the potential benefits and side effects of the therapy, to the patient's relatives during the transfer. If possible, pre-informed consent will be signed by relatives. This process can further save time for in-hospital consent. It has been reported that a waiver of written informed consent before tPA administration could save about 0.8 minutes [6]. From 2018 to 2019, there were only about 40% of patients with IS transferred by ambulances. In the future, an improvement in the usage of the prehospital EMS system would further improve the DTN time for patients with AIS.

Limitations

Our study has some limitations. First, because of the lack of information before the study period and the lack of a parallel control group during the study period, we were unable to estimate the magnitude of DTN improvement owing to the processes we implemented. Despite this, continuous reductions in DTN time were observed during the study period, and the reductions happened in all hospitals. The improvement was a combined effect from fast EMS triage, prehospital notification, enhanced coordination, and a prompt feedback process. Further studies should explore to what extent each strategy can influence the outcome. Second, spatial factors may influence the usage and performance of the platform. In this study, the platform was developed and used in Beijing, an overpopulated city with a large number of acute stroke care centers. Compared with peripheric city areas, the performance of the platform may be different because of the current treatment workflow, capacity, and efficiency of the emergency medical system and emergency departments in the hospitals, as well as the traffic conditions and distribution of acute care centers in the city. When more data is available, the performances of the platform in peripheric city areas should be further evaluated. Third, the long-term health and economic benefits should be evaluated when data are available.

Conclusions

A smartphone app was developed to streamline the emergency management of AIS in Beijing since 2018. Sustained reductions in DTN time were observed, reflecting the improvement in management processes. The use of a smartphone platform was a feasible way of integrating recommended strategies to help the emergency management of AIS. Similar measures are recommended in other areas with high AIS risks.

Acknowledgments

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Conflicts of Interest

DL is the CEO of BEIJING ANMED Medical Technology Co Ltd, which participated in developing the Green app. The other authors have no conflicts of interest to declare.

Multimedia Appendix 1
Door-to-needle (DTN) times for patients with acute ischemic stroke (AIS) transferred by ambulances or who reached hospitals by themselves, from January 2018 to December 2019. (A) DTN times for patients with AIS transferred by ambulances; (B): DTN times for patients with AIS who reached hospitals by themselves. Black bars: proportions of patients with DTN ≤ 45 minutes; dots and lines: median DTN times; grey bars: proportions of patients with DTN ≤ 60 minutes.
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Abbreviations

AHA/ASA: American Heart Association/American Stroke Association
AIS: acute ischemic stroke
DTN: door-to-needle
ED: emergency department
EMS: emergency medical system
FATMS: First Aid Treatment Map for Stroke
IS: ischemic stroke
tPA: tissue-type plasminogen activator

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Original Paper

Addressing Implementation Challenges to Digital Care Delivery for Adults With Multiple Chronic Conditions: Stakeholder Feedback in a Randomized Controlled Trial

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Abstract

Background: Digital tools accessed via smartphones can promote chronic condition management, reduce disparities in health care and hospital readmissions, and improve quality of life. However, whether digital care strategies can be implemented successfully on a large scale with traditionally underserved populations remains uncertain.

Objective: As part of a randomized trial comparing care delivery strategies for Medicaid and Medicare-Medicaid beneficiaries with multiple chronic conditions, our stakeholders identified implementation challenges, and we developed stakeholder-driven adaptions to improve a digitally delivered care management strategy (high-tech care).

Methods: We used 4 mechanisms (study support log, Patient Partners Work Group log, case interview log, and implementation meeting minutes) to capture stakeholder feedback about technology-related challenges and solutions from 9 patient partners, 129 participants, and 32 care managers and used these data to develop and implement solutions. To assess the impact, we analyzed high-tech care exit surveys and intervention engagement outcomes (video visits and condition-specific text message check-ins sent at varying intervals) before and after each solution was implemented.

Results: Challenges centered around 2 themes: difficulty using both smartphones and high-tech care components and difficulty using high-tech care components due to connectivity issues. To respond to the first theme's challenges, we devised 3 solutions: tech visits (eg, in-person technology support visits), tech packet (eg, participant-facing technology user guide), and tailored condition-specific text message check-ins. During the first 20 months of implementation, 73 participants received at least one tech visit. We observed a 15% increase in video call completion for participants with data before and after the tech visit (n=25) and a 7% increase in check-in completion for participants with data before and after the tech visit (n=59). Of the 379 participants given a tech packet, 179 completed care during this timeframe and were eligible for an exit survey. Of the survey respondents, 76% (73/96) found the tech packet helpful and 64% (62/96) actively used it during care. To support condition-specific text message check-in completion, we allowed for adaption of day and/or time of the text message with 31 participants changing the time they received check-ins and change in standard biometric settings with 13 physicians requesting personalized settings for participants.

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To respond to the second theme's challenges, tech visits or phone calls were made to demonstrate how to use a smartphone to connect or disconnect from the internet, to schedule video calls, or for condition-specific text message check-ins in a location with broadband/internet.

Conclusions: Having structured stakeholder feedback mechanisms is key to identify challenges and solutions to digital care engagement. Creating flexible and scalable solutions to technology-related challenges will increase equity in accessing digital care and support more effective engagement of chronically ill populations in the use of these digital care tools.

Trial Registration: ClinicalTrials.gov NCT03451630; https://clinicaltrials.gov/ct2/show/NCT03451630.

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KEYWORDS

telehealth tools; smartphones; remote patient monitoring; care management; mobile phone

Introduction

Over the last 10 years, ownership and use of smartphones has more than doubled in the United States, from 35% to 81% of the population [1]. One potential benefit of increased access to smartphones is the reduction in health disparities. As smartphone ownership becomes more equitable across socioeconomic categories [1], the use of smartphones provides an opportunity for traditionally underserved or isolated populations to remain connected to health care professionals despite geographic distance or mobility limitations, to quickly receive up-to-date and accurate health education information, and to monitor changes in health conditions using digital health care strategies [2]. In the context of care management teams, remote monitoring platforms provide the opportunity to scale programs, allowing teams of health care professionals and social workers to reach a higher number of individuals living in medically underserved areas [3].

Digital care tools have a growing evidence base, including evidence supporting the effectiveness of such technologies for patients managing chronic conditions. For example, these tools can support individuals with diabetes in lowering hemoglobin A_{1c} levels, improve quality of life and lower number of hospital readmissions for individuals with heart failure [4], improve symptoms and outcomes for individuals with respiratory conditions [5], support better blood pressure control for individuals with hypertension [6], and reduce symptoms of depression [7]. Increased access to and use of digital care strategies has the potential to increase health systems' ability to achieve the quadruple aim: improving population health, enhancing both patient and provider experience, and reducing costs [8].

Despite increased smartphone use and evidence supporting the benefits of digital care strategies such as remote patient monitoring, biosensors, and wearable devices, barriers to care are ever-present when implementing digital tools on a large scale. Notably, there is a lack of research on the challenges that occur when implementing digital care with traditionally underserved populations and those with high-burden, high-cost medical conditions [9]. A pervasive barrier to the success of digital tools is that individuals may lack confidence in their ability to learn how to use these new tools, which may impact their readiness to engage with such tools [10]. According to recent research on mobile devices and health, over half of Americans are considered to have low digital literacy skills when it comes to using mobile devices [11]. A recent survey of Americans aged above 65 years indicated that although respondents generally had a positive view of technology, they doubted their capacity to learn to use new technology without extra help [12]. In addition, although access to smartphones is becoming more prevalent among all socioeconomic groups, a digital divide still exists in the United States between high- and low-income Americans [13,14], with some research showing that both access and ability may be contributing reasons for why low-income adults may use online health resources less [15,16]. Finally, research has historically focused on remote patient monitoring care effectiveness with older Americans [17] and may not address common challenges faced by younger and other diverse populations.

Overcoming these challenges to realize the full potential of digital care to support the management of chronic conditions and reduce health disparities requires an iterative development approach that includes ongoing consumer and community stakeholder input. We are conducting a large-scale, randomized controlled trial comparing the effectiveness of 3 care management strategies (ie, high-touch, high-tech, and usual care) delivered by a commercial insurance organization for adult Medicaid and Medicare-Medicaid beneficiaries living with multiple chronic conditions. To address the unique needs and challenges experienced by this population and to ensure that our digital interventions are patient-centered and pragmatic, we describe early implementation challenges and our stakeholder-driven process adaptions specific to the digitally delivered chronic disease care management strategy (high-tech care).

Methods

Randomized Controlled Trial Overview

The 3 study comparators are approaches to care delivered by a chronic disease care management program and incorporate fundamental, evidence-based components of integrated care models including interdisciplinary care management [18,19], individualized care plans [18,19], chronic disease self-management education or self-care support [8,18,20-24], and linkages to medical/behavioral health and social services [18,25,26]. High-touch is delivered primarily face-to-face, with telephonic support as needed. High-tech is delivered via a remote care management platform. Both high-touch and

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high-tech participants receive care management for at least 4 months and can continue care for up to 1 year, based on need. Usual care consists of an initial visit and care management for 14 days, which includes connections to condition management support and resources. Care managers receive a weekly worklist denoting individuals who are eligible to be offered participation in the study. To be eligible, individuals must be 21 years or older, have Medicaid or Medicare-Medicaid insurance, have at least 2 chronic conditions, including 1 physical health condition, and have been discharged from a hospital within the past 30 days.

Introducing Participants to the High-tech Care Strategy

All study participants work, one on one, with a care manager (ie, nurse, social worker, and licensed professional counselor) to create individualized care plans [18,19] centered around chronic disease self-management education, self-care support [8,18,20-24], and to form linkages to medical, behavioral health, and social services [18,25,26]. Participants in the high-tech care management strategy have an initial face-to-face appointment with their care manager and are provided with a preconfigured iPhone that allows for care to continue digitally via a remote monitoring platform. We provide iPhones to participants to ensure access to smartphones, and the cost of cellular data is not a barrier to participation. At the initial appointment, the care manager explains 2 key components of the remote monitoring platform that the participant will use on a regular basis: video visits (eg, video conferencing between patients and care managers) and condition-specific text message check-ins. The remote monitoring platform facilitates video conferencing (eg, video visits) between participants and their care manager. Moreover, as our study population has multiple physical and behavioral health conditions, condition-specific check-in questions are sent via text messages to each participant at varying intervals (eg, daily, weekly, or biweekly) based on their condition(s). Check-ins allow care managers to monitor diverse participant needs, symptoms, or condition exacerbations, including specific biometric readings such as pulse, blood glucose level, weight, and blood pressure.

Stakeholder Engagement and Feedback Processes

At the onset of implementation, the study team was acutely aware of the need for continued stakeholder engagement and feedback to promote effective high-tech care implementation. On the basis of the Patient-Centered Outcome Engagement principles [27], we developed 4 mechanisms (Textbox 1) to capture feedback and input from various stakeholder groups. Patients, care managers, and clinical leadership all provided key insights and observations related to technology challenges that care managers or participants experienced during high-tech care implementation. This stakeholder input was collated from the study support log, the case interview log, and the implementation meeting minute log (Textbox 1). Feedback was iteratively reviewed by the study and the clinical team. Stakeholder input was organized by topic and content to understand early stage implementation challenges. Topics were then reviewed by the study team and organized into 2 major thematic categories; themes were reviewed with key stakeholders for validation.

Using information from these 3 feedback mechanisms, we developed solutions to the identified technology-related challenges. Solutions were discussed, refined, and implemented with input from the study team, care managers, and clinical leadership. Solutions were also vetted through the Patient Partners Work Group. A work group of patient partners, who have similar characteristics and lived experiences similar to those experienced by our study population, was established through a collaboration with the National Alliance on Mental Illness Southwestern Pennsylvania's Consumer Action Response Team. Patient partner feedback was tracked in the Patient Partners Work Group log (Textbox 1).

Textbox 1. Mechanisms to capture stakeholder feedback on challenges and/or solutions.

Data source and information collected and provided:

- Study support log
  - Study team created a study-specific, toll-free, hotline staffed during office hours
  - Hotline supports care managers and participants with study-related questions or challenges
- Implementation meeting minutes
  - Study team meets with clinical leadership weekly and meets monthly with all care managers
  - Meetings provide a time and space for care managers and their clinical leadership to voice implementation challenges and to strategize potential solutions
- Case interview log
  - Semistructured interviews were conducted with care managers to identify technology-related challenges, participants experience, and workflow impacts
- Patient Partners Work Group log
  - Study team meets regularly with the work group to discuss high-tech care implementation
  - The work group provides feedback on materials and solutions supporting high-tech care engagement/implementation

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Understanding Process Modifications: Sources of Information

In order to assess a change in participants' abilities to overcome technology-related challenges, we analyzed intervention engagement outcomes that may have been impacted by stakeholder-driven implementation solutions. We reviewed the following 3 sources of engagement data pertaining to care activity from April 23, 2018, to December 31, 2019: (1) the participants' ability to complete a video visit as defined by answering the video call from their care manager, (2) the participants' ability to answer condition-specific text message check-ins, as defined by receiving a check-in via text message and submitting all answers to condition-specific questions, and (3) participant responses to exit survey questions sent via the remote monitoring platform. All pre- and postdata presented are based on the first in-person technology support visit completed by the participant.

Results

Overview

Stakeholders reported challenges centered around 2 major themes: (1) difficulties using basic functionalities of the smartphone and high-tech care components and (2) difficulties using high-tech care components due to cellular reception and internet connectivity issues. Approximately 500 study hotline phone calls, about technology-specific challenges, were made by 129 participants and 32 care managers to the study team, and the calls were tracked in the study support log. Feedback was also provided during clinical leadership meetings (n=82), monthly care management staff meetings (n=16, tracked via implementation meeting minutes), and semistructured interviews with care managers (n=4, tracked via case interview log). For each thematic challenge, we present: (1) specific stakeholder feedback that leads to solution development, (2) the description of the stakeholder-driven solutions as they are a direct result of stakeholder feedback, and (3) changes in participant engagement data after solution implementation.

Theme 1 Challenge: Smartphone and High-tech Care Digital Component Use

With support from care managers and clinical leadership, the study team focused on common functionality challenges experienced by high-tech care participants and devised 3 main solutions: (1) tech visits (technology support visits), (2) a tech packet (participant-facing technology user guide), and (3) tailored condition-specific text message check-in. Table 1 displays stakeholder feedback regarding the participants' experiences when using the smartphone and high-tech care components.

Table 1. Sources of information and solutions: utilizing functionalities of the smartphone and high-tech components.

Data source	Information provided	Informed solution
Case interview log and study support log	1. Care managers concerned about time spent teaching participants basic smartphone functionalities 2. Specific technology challenges faced by participants include screen pressure difficulties, home screen navigation, phone charging, text message access, including opening condition-specific check-ins, and phone volume manipulation	1. Tech visits and tech packet 2. Tech packet
Implementation meeting minutes	1. Clinical leadership interpreted technology-education time concerns as a workflow issue in which care managers had to make up time to ensure participant clinical care needs were met	1. Tech visits and tech packet
Study support log	1. Smartphone factory resets and reconfiguration were time consuming for care managers 2. Smartphone volume manipulation and battery power were 2 participant challenges that resulted in missed high-tech care video visits and condition-specific check-ins 3. Check-in assignments were sometimes automatically scheduled at inconvenient times for participants (ie, work, school or sleeping hours) 4. Biometric check-in settings were automatically standardized for each participant	1. Tech visits and tech packet 2. Tech packet 3. Tailored condition-specific check-ins 4. Tailored condition-specific check-ins

Technology Support Visit (Tech Visit) Solution for Theme 1: Description and Changes in Engagement

Tech visits are structured to allow a study team member to assist participants with time-consuming digital literacy challenges, either at the participant's home or at a community location. Tech visits do not replace initial face-to-face training that care managers provide to high-tech care participants; rather, it is a form of supplemental training to ensure that participants are able to use their smartphone to receive care and to reduce the time care managers spend on high-tech care training during the initial appointment. Participants are selected for tech visits if (1) they have called the study hotline multiple times with issues that could not be completely resolved, (2) a care manager is unable to connect with the member due to technology challenges, and (3) clinical supervisors believe a participant's level of digital literacy requires a substantial amount of care manager's time.

During the first 20 months of implementation, 73 participants received at least one tech visit. Before the tech visit, 23% (17/73) of the participants completed a video call with their care

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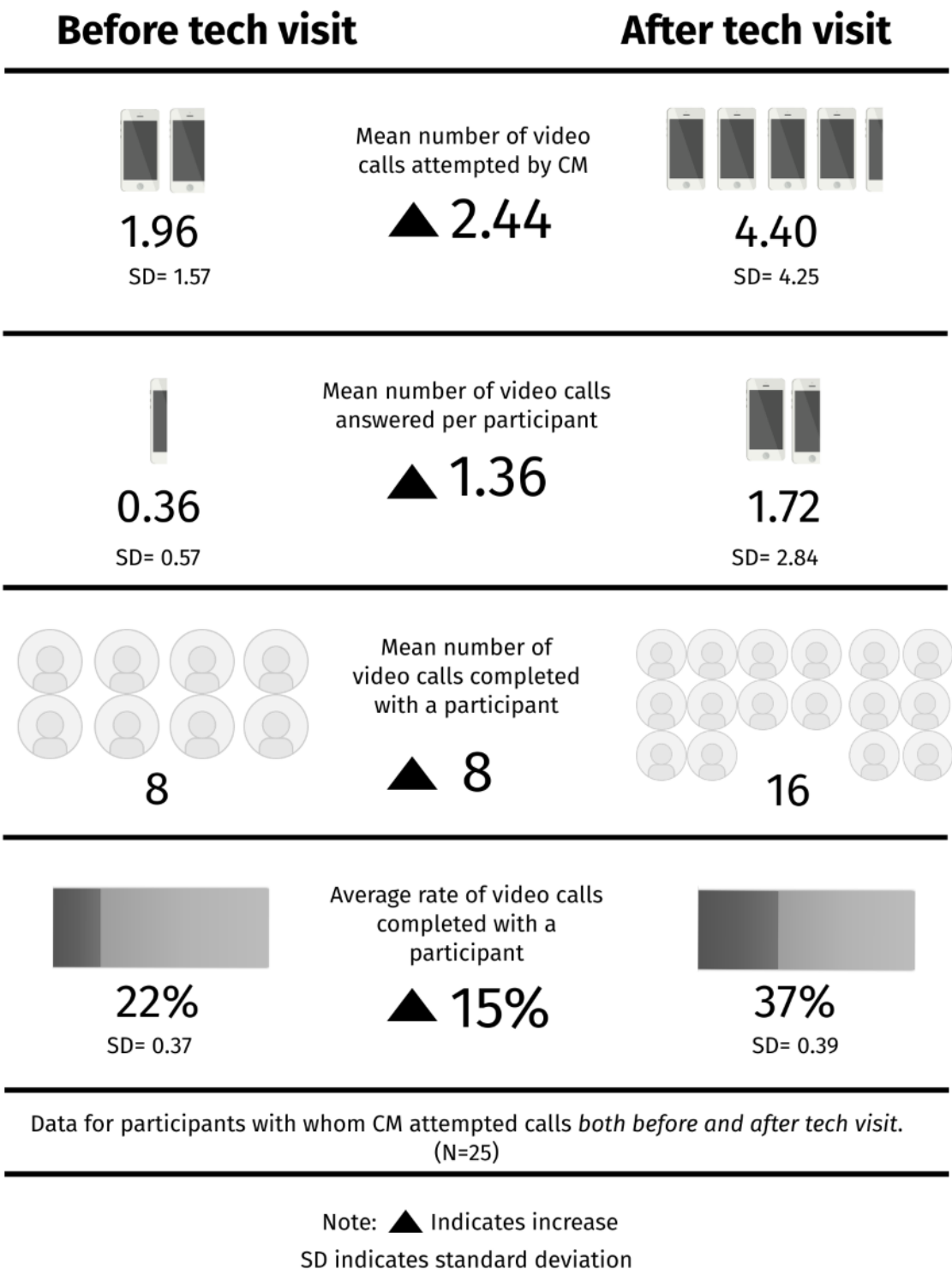
manager. Within 30 days of a tech visit, the average rate for video call completion increased to 51% (n=33). In total, 21 members, who had never been able to connect with their care manager via video calls, before the tech visit completed a video call after receiving the tech support. Of the 73 participants, 25 (34%) had video call data for both before and after the tech visit. For these participants, the average rate of completed calls increased by 15% after the completion of a tech visit (Figure 1).

Figure 1. Video call data for participants with completed pre- and postdata. CM: care manager.



Specific to condition-specific check-ins sent via text message, most participants completed at least one check-in on their own before their first tech visit (60/73, 82%), with an average rate of 36% (n=59). Within 30 days of a tech visit, the average rate for engagement with check-ins increased to 43% (n=59). Two participants completed check-ins after receiving support, who had never completed a check-in prior. Conversely, 15 participants completed check-ins before receiving support but

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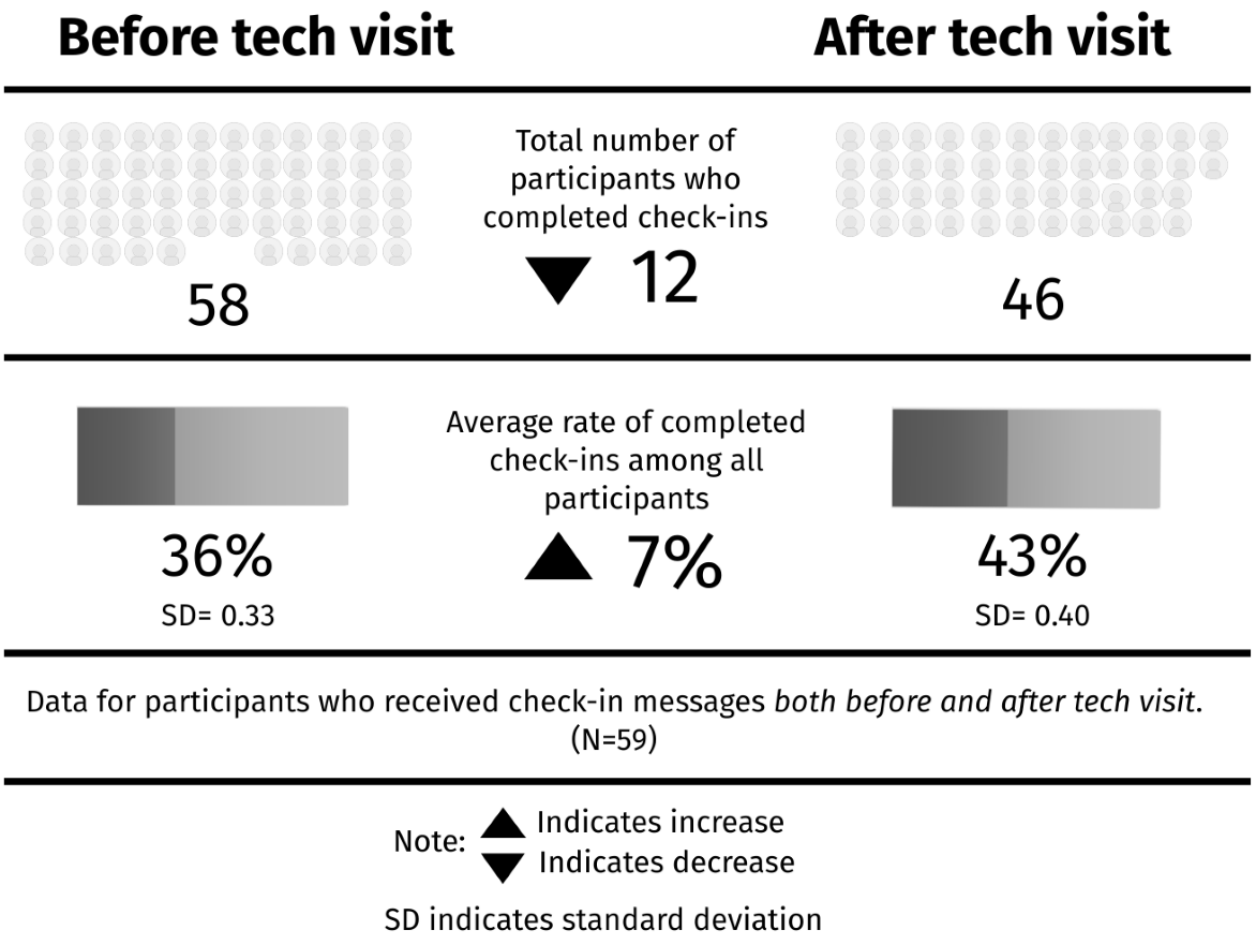
never completed a check-in after the visit. Of the 73 participants, 59 (81%) had check-in data both before and after the tech visit. For these participants, the average rate of completed check-ins increased by 7% after the completion of a tech visit (Figure 2).

Figure 2. Check-in data for participants with completed pre- and postdata.



Participant-Facing Technology User Guide (Tech Packet) Solution for Theme 1: Description and Changes in Engagement

The participant-facing technology user guide (tech packet) is an educational resource for participants learning how to use the smartphone and high-tech care digital components. The tech packet outlines key smartphone functions (ie, how to answer a phone call, how to navigate to the *home screen*, how to open a text message, etc) and high-tech digital care components (ie, how to answer a video call and how to respond to a condition-specific check-in). Care managers give the tech packet to participants during the initial appointment when the participant is randomized into high-tech care; care managers explain the tech packet and have participants practice key functions that they will use throughout their care. Figure 3 shows 2 pages from the tech packet that were developed in response to specific challenges reported in the study support log (Table 1). Feedback from our patient partners, members of the Patient Partners Work Group, was collected over 2-hour-long meetings. Table 2 displays the Patient Partners Work Group feedback on the solution and details on how their feedback was incorporated, and Figure 4 presents a visual example of feedback incorporation. The tech packet is updated regularly based on participant, patient partner, care manager, and clinical leadership feedback.

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Figure 3. Tech packet additions based on study support log.

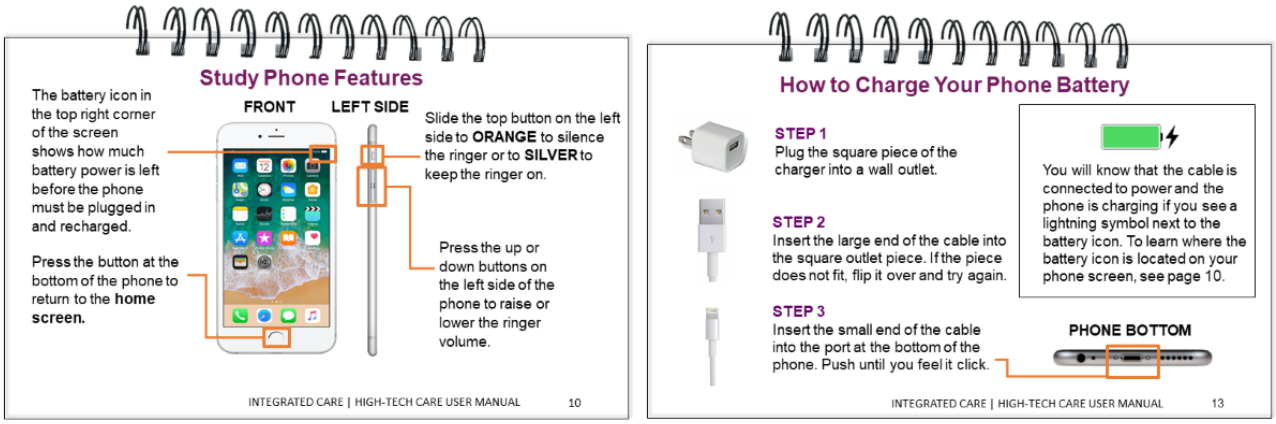

Table 2. Patient Partners Work Group technology user guide feedback.

Work group feedback	Examples of feedback	Feedback incorporated
Use less abbreviations/ jargon as these are difficult to follow	1. App has many meanings to different participants 2. Remote monitoring may have a negative connotation for participants	1. Addition of definitions page and spelling out abbreviations: app to application 2. Replacement of technical jargon: Check-ins with your care manager instead of remote monitoring
Provide an easy *start point* for each section; assume the lowest level of digital literacy when creating the instructions	1. Each section begins on the smartphone home screen, which assumes participants can find the home screen	1. Addition of instructions on how to navigate to home screen at the beginning and end of each section
Dexterity and pressure difficulties may be a concern	1. Press, click, touch, and open were used interchangeably	1. Used touch for screen actions and press for the home screen button to distinguish amount of pressure to be applied
Highlight important contact information associated with care management and study activities	1. Participants may not be able to distinguish who is sending a text message, and some may be concerned about the legitimacy of messages	1. Stated explicitly messages from the remote monitoring platform come from the same phone number each time and make the number visible on all sections 2. Displayed the study hotline number frequently
Participants can be difficult to reach	1. Participants may not be reached during business hours	1. Included a section on how to set up and check a voicemail box

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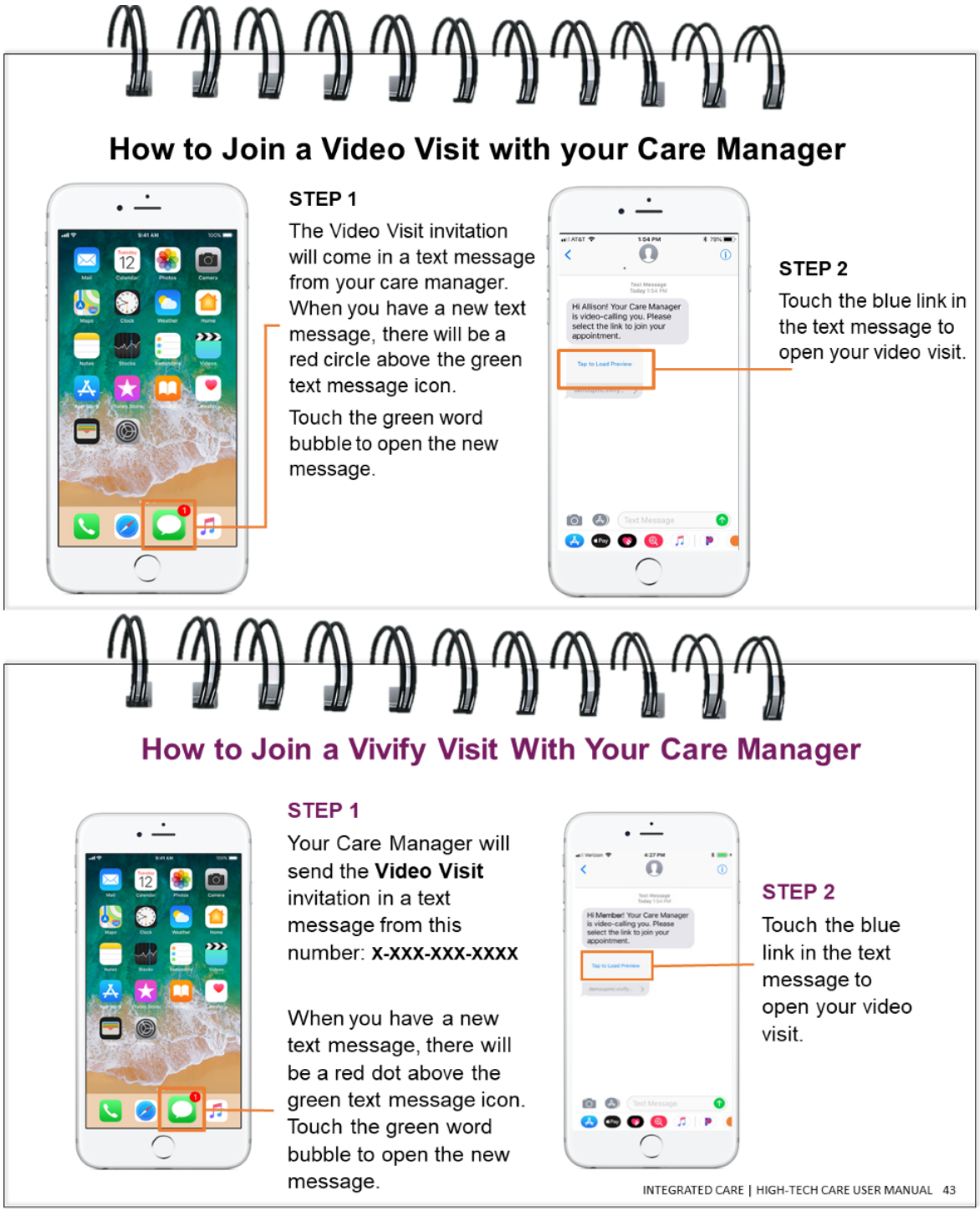
Figure 4. Tech packet updates pre- and postpatient Partners Work Group feedback.



We distributed the tech packets to 379 participants. Of the individuals who received a packet, 179 participants were eligible (eg, completed high-tech care before January 1, 2020) to receive the high-tech care exit survey. Of the 179 participants, 96 responded to the survey; 73 respondents strongly agreed or agreed that the tech packet was useful and 62 actively used the guide at least 1 to 2 times a week during care. See Figure 5 for detailed exit survey results.

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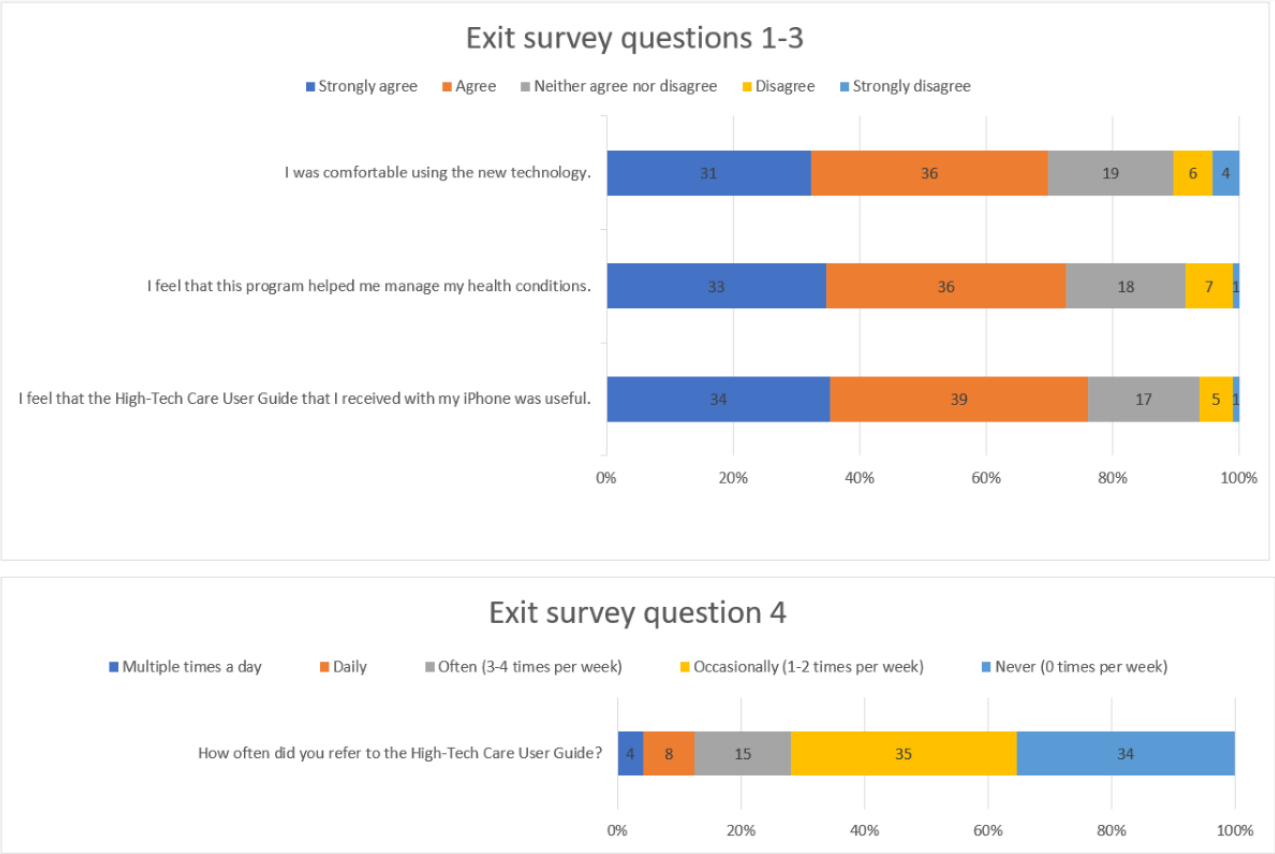
Figure 5. High-tech care exit survey (96/179, 53.6%).



Check-in Tailoring Solution for Theme 1: Description and Impact

Not all challenges presented to the study team were solved through tech visits and the tech packet. To support participants in completing their condition-specific check-ins, the study team adapted their workflow to allow for a modification of when check-ins are assigned (ie, day of the week and time) based on participant preference. In total, 31 participants requested to change the day/time when check-in text messages were to be received. Second, as all biometric check-in settings (eg, normal boundary parameters for pulse, blood glucose level, weight, and blood pressure) were standardized across participants by default, the study team allowed individual check-in settings to be modified based on the agreement of a participant's primary medical provider. For 13 participants, the primary medical provider requested biometric setting changes to reflect the participant's *normal* range; this modification allows care managers to better track if biometric readings fall outside the participant's expected range. Textbox 2 describes specific cases in which check-in assignments or biometric settings were modified.

Textbox 2. Condition-specific check-in tailoring examples.

- Check-in assignments modified based on participant preferences
  - Participant rescheduled their diabetes check-in for the morning, based on when their medical provider had instructed them to check their glucose
  - Participant rescheduled their check-in assignment to the day they are off work
- Biometric settings modified based on provider preferences
  - Primary medical provider verified that the participant takes glucose readings before taking insulin and requested setting alerts to be set at 270 or above
  - Primary medical provider approved to change a participant's blood pressure settings; allowing notification to only send to the care manager when the participant is out of their expected range >170/100 or <90/60

Theme 2 Challenge: Limited Cellular Reception and Internet Connectivity

It was reported, by both care managers and participants themselves, that participants were having difficulties using high-tech care digital components (eg, video visits and condition-specific check-ins) due to limited cellular reception and internet connectivity. Depending on the circumstances, solutions include (1) participant education on how to connect

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a smartphone to the internet, (2) schedule video visits or condition-specific check-ins when the participant is in a location with cellular service or internet, and (3) participant education on how to disconnect from the internet. Table 3 displays the sources of information that led the study team to become aware of the challenge participants experienced with connectivity.

Table 3. Sources of information and solutions: understanding limited cellular reception and intervention connectivity.

Data source	Information provided	Informed solution
Study support log and implementation meeting minutes	• Server error messages reported by participants preventing check-in messages from opening	Education on connecting a smartphone to the internet
Study support log and implementation meeting minutes	• No internet at the home preventing digital tool use • No cellular reception at home prevented digital tool use	Scheduling video visits/check-ins when participant has access to cellular service or internet
Study support log and implementation meeting minutes	• Poor internet service at home chosen as default connection method prevented digital tool use • Poor internet service in community chosen as default connection method prevented digital tool use	Education on disconnecting from the internet

Solutions for Theme 2: Description and Changes in Engagement

Care managers communicate with each participant regarding the best way to provide care, given limited cellular reception and internet connectivity. All 3 connectivity solutions are addressed via a tech visit or phone call. Providing education on connecting a smartphone to the internet is often a solution for participants receiving a *server error* message when attempting to open condition-specific check-ins. Participants were advised to connect to the home internet in case of a bandwidth issue. Scheduling video visits and condition-specific check-ins at specific times affords participants the knowledge that they will have access to cellular service or internet and has been another viable solution. For example, one participant rescheduled their condition-specific check-ins to days of the week when a routine visit was set with family members who have internet access or to business hours as their employer offers internet access. Finally, providing education to participants on how to disconnect from the internet can support video visits or check-in completion. For example, participants are instructed to disconnect weak internet connections, such as home connections or public connections, when they have strong cellular service.

Discussion

Principal Findings

This paper highlights the impact of stakeholder-driven solutions on early implementation challenges specific to a digital care strategy. To support participants in engaging with their smartphone and high-tech care digital components (theme 1 challenge), 3 main solutions were implemented (eg, in-person technology support visits, participant-facing technology user guides, and tailored condition-specific check-ins). For participants who received an in-person technology support visit, we saw an overall increase in engagement with video calls and condition-specific check-ins. For participants who received the participant-facing technology user guide and completed both high-tech care and the exit survey, we found that most used the tech packet while receiving care and or believed it was useful. Finally, condition-specific check-ins were tailored for participants to support engagement and meet their primary medical provider's care goals. To support participants experiencing difficulties engaging in high-tech care due to limited cellular reception or internet connectivity (theme 2 challenges), 3 solutions were devised and implemented as needed to support engagement in the program (eg, education on both connecting and disconnecting a smartphone to the internet, scheduling high-tech care video visits or condition-specific check-ins at times when the participant is in a physical location that allows connectivity to occur).

Our findings suggest that concurrent stakeholder feedback has the potential to increase implementation success; therefore, it is pivotal to provide stakeholders with multiple and continuous avenues for communicating challenges to the study team. Furthermore, the results stress the importance of working collaboratively with stakeholders early in the implementation of digital interventions to design scalable solutions such as educational materials (tech packet) and activities (tech visits and telephonic support) and refine condition-specific check-ins that suit the specific needs of the patient and their primary medical provider. Moreover, although measuring the success of solutions created during implementation is not always preplanned, early results indicate positive changes in participant technology engagement after tech visits are implemented. Our positive trends in engagement highlight the need for earlier identification of patients who require tech visits to promote early engagement, reduce demoralization, and potentially achieve earlier clinical benefits. Understanding the nuanced challenges of delivering interventions and engaging patients—as well as how to create effective solutions—will advance the efficiency and reach of digital care.

Comparison With Prior Work

Current digital care literature focuses on either how tool engagement impacts desired health outcome(s) [6] or defining tool use metrics [28,29]. Processes and solutions to overcome tool utilization barriers are underdeveloped topics in the field that has implications for replication and scaling. One systematic review of digital mental health interventions targeting college students found that of the 89 studies, 45 reported outcomes focused on usability and acceptability (many with low rates of response) and only 2 studies reported on feasibility [30]. It is

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critical to expand knowledge centered on how to design and adapt implementation processes in order for digital care teams to be equipped with the right knowledge and resources to best overcome challenges to digital care provision for chronically ill and low-income populations. Providers delivering care digitally must understand and be able to adequately address patient-specific barriers to using digital care tools before patients can engage in the evidence-based tool functions and work toward improved health outcomes.

Our work is an important addition to the discussion on digital care provision as we provide a systematic framework for how digital care providers can work with stakeholder groups to identify and address care delivery implementation challenges. Although most research on remote patient monitoring focuses on single-diagnosis care for older Americans, our intervention targets adults aged 21 years and older who are managing multiple chronic physical and or behavioral health conditions [6]. Our findings expand knowledge beyond the traditional populations included in digital health research.

Finally, as participants in this research are exclusively eligible for Medicaid, our work promises to reduce health disparities by improving access to digitally delivered evidence-based care management for low-income patients. Supporting consumer adoption of digital health tools is one way to both support patients in their management of chronic conditions and the ethical imperative of reducing health disparities. However, realizing the full potential of digital tools to positively impact health disparities requires continued work on understanding the ways to best support traditionally underserved populations to use digital tools (and how to design those tools and their implementation protocols to meet diverse consumer needs).

Limitations

Although this study contributes novel stakeholder-driven solutions to stakeholder-reported implementation challenges that affect participants' engagement in a digital care intervention, there are several limitations. Data collected via the high-tech care exit survey may be limited due to a nonresponse bias, as participants who completed the survey had to be able to access the check-in and be willing to complete the survey after completing all care goals. However, our current response rate of 54% indicates that this bias may be less salient [31]. In addition, we were not able to control for additional factors such as in-home caregiver support, improvement in health conditions, or time participating in care that may have also impacted a participant's ability to overcome the specific challenges that our solutions were designed to target. However, as our solutions were codesigned with key stakeholders and our ability to review pre- and postsolution data, it is reasonable to assume that our solutions influenced positive trends in high-tech care engagement. We also acknowledge that our provision of a smartphone to all study participants may be perceived as a potential barrier to scalability. However, it is important to understand engagement-related challenges for individuals with varying levels of experience with such technology and provide the same phone to all study participants allows us to understand how heterogeneity in technology comfort/experience manifests over the course of the intervention. For future efforts, care managers can and do support individuals with the procurement of a government-issued smartphone that has similar functionality to the phone provided for this study; thus, our findings related to technology engagement can likely be generalized beyond the scope of this study.

Conclusions

To better understand digital care barriers specific to a patient population or care program, it is critical to develop and employ methods for obtaining feedback from key stakeholders before and during implementation. Key stakeholders may include care providers and implementation teams, digital tool creators, and community organizations that represent the population of interest and patients. Our stakeholder-informed solutions include in-person tech visits, a tech packet detailing how to access and use key technology components, along with the tailoring of digital care components to meet both patient and provider needs. Using high-tech care exit survey responses and remote monitoring engagement data, we measured the impact of our solutions and continued to improve high-tech care delivery. As solutions to challenges develop, detailed tracking of their implementation may positively impact patient engagement with digital tools and ultimately show increased participation in care resulting in improved health outcomes and reductions in health outcome disparities.

Acknowledgments

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Conflicts of Interest

JK has received medication supplies for investigator-initiated trials from Pfizer and Indivior. He received compensation for an educational webinar from Otsuka (condition-specific, not product-focused) within the past 12 months. He receives ongoing compensation for editorial work from the American Association for Geriatric Psychiatry and Physicians Postgraduate Press.

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Abbreviations

PCORI: Patient-Centered Outcomes Research Institute

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Original Paper

Effectiveness of a Mobile Health and Self-Management App for High-Risk Patients With Chronic Obstructive Pulmonary Disease in Daily Clinical Practice: Mixed Methods Evaluation Study

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Abstract

Background: Mobile health and self-management interventions may positively affect behavioral change and reduce hospital admissions for patients with chronic obstructive pulmonary disease (COPD). However, not all patients qualify for these interventions, and systematic, comprehensive information on implementation- and compliance-related aspects of mobile self-management apps is lacking. Due to the tendency to target digital services to patients in stable phases of disease, it is especially relevant to focus on the use of these services in broad clinical practice for patients recently discharged from hospital.

Objective: This study aims to evaluate the effects of a mobile health and self-management app in clinical practice for recently discharged patients with COPD on use of the app, self-management, expectations, and experiences (technology acceptance); patients' and nurses' satisfaction; and hospital readmissions.

Methods: A prototype of the app was pilot tested with 6 patients with COPD. The COPD app consisted of an 8-week program including the Lung Attack Action Plan, education, medication overview, video consultation, and questionnaires (monitored by nurses). In the feasibility study, adult patients with physician-diagnosed COPD, access to a mobile device, and proficiency of the Dutch language were included from a large teaching hospital during hospital admission. Self-management (Partners in Health Scale), technology acceptance (Unified Theory Acceptance and Use of Technology model), and satisfaction were assessed using questionnaires at baseline, after 8 weeks, and 20 weeks. Use was assessed with log data, and readmission rates were extracted from the electronic medical record.

Results: A total of 39 patients were included; 76.4% (133/174) of patients had to be excluded from participation, and 48.9% of those patients (65/133) were excluded because of lack of digital skills, access to a mobile device, or access to the internet. The COPD app was opened most often in the first week (median 6.0; IQR 3.5-10.0), but its use decreased over time. The self-management element knowledge and coping increased significantly over time (P=.04). The COPD app was rated on a scale of 1-10, with an average score by patients of 7.7 (SD 1.7) and by nurses of 6.3 (SD 1.2). Preliminary evidence about the readmission rate showed that 13% (5/39) of patients were readmitted within 30 days; 31% (12/39) of patients were readmitted within 20 weeks, compared with 14.1% (48/340) and 21.8% (74/340) in a preresearch cohort, respectively.

Conclusions: The use of a mobile self-management app after hospital discharge seems to be feasible only for a small number of patients with COPD. Patients were satisfied with the service; however, use decreased over time, and only knowledge and coping changed significantly over time. Therefore, future research on digital self-management interventions in clinical practice should focus on including more difficult subgroups of target populations, a multidisciplinary approach, technology-related aspects (such as acceptability), and fine-tuning its adoption in clinical pathways.

Trial Registration: Clinicaltrials.gov NCT04540562; https://clinicaltrials.gov/ct2/show/NCT04540562.

(JMIR Mhealth Uhealth 2021;9(2):e21977) doi:10.2196/21977

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KEYWORDS

chronic obstructive pulmonary disease; mHealth; self-management; mobile app; mobile phone

Introduction

Background

Chronic obstructive pulmonary disease (COPD) affects over 250 million people worldwide [1] and almost 600,000 people in the Netherlands [2]. In 2020, it is expected to be the third leading cause of death worldwide [3]. COPD is a common disease characterized by persistent respiratory symptoms and airflow limitation due to airway and/or alveolar abnormalities [3]. The most common symptoms are dyspnea, chronic coughing, and sputum production [3-5]. An acute worsening of the symptoms is called an exacerbation [4,6]. Exacerbations lead to additional care [5] and often lead to hospital admission [7], with considerable costs involved [8].

Self-management interventions are also recognized to be important in reducing exacerbations [9] and hospital admissions [10,11], improving quality of life [9-11], and improving patients' control over their health [9]. Self-management skills can be beneficial for patients with COPD to manage their disease on a daily basis [12], for example, for medication use, breathing techniques, physical activity, and symptom recognition [13]. Effing et al [12] defined these interventions for patients with COPD as structured, personalized, and often multi-component, with goals of motivating, engaging, and supporting patients to positively adapt their health behaviors. Relevant features for self-management interventions include smoking cessation, recognition and treatment of exacerbation, increasing physical activity, nutrition advice, and management of dyspnea [14].

Mobile apps are increasingly being used to provide patients with health and self-management interventions, for example, for remote monitoring of patients' health status [15-17], self-report of symptoms or health status [16-18], education [16,19], and digital support or feedback [15,17,18]. This is often combined with feedback from a health care professional or automated via the app [17-19]. Multiple reviews have analyzed the effectiveness of self-management interventions supported by mobile apps for patients with COPD on hospital admissions [15,18], exacerbations [15,16], length of hospital stay [18], behavioral outcomes [15,19], health-related outcomes [15,19], and quality of life [15]. The use of smartphones can be feasible in providing patients with self-management interventions [20,21] and to improve behavioral change [21]. A recent review reported the effects of smartphone interventions on exacerbations and showed that these interventions may decrease exacerbations, compared with usual care [16]. However, the findings remain inconsistent [17] due to heterogeneity among interventions [9,16,17,19,22], target populations [9,22,23], outcomes [9,22,23], and small sample sizes [16]. Further research and analysis on relevant apps for apps to support patients with COPD is necessary [24], as evidence is limited [15].

Until now, much attention has been given to the effects on clinical health outcomes [11,25-27] and hospital services [11,28,29]. Self-management behavior is also found to be important in reducing hospital admissions [30]. Factors affecting use in daily clinical practice, such as patients' satisfaction [31], technology acceptance [32,33], and health care professionals' satisfaction [34], were examined to a lesser extent. It also remains unclear which patients benefit most from these digital interventions [35,36]. It is suggested that it may be beneficial for patients experiencing frequent exacerbations [37]; nevertheless, stable patients with COPD are often the target population [38]. Patients experiencing a hospital admission due to an exacerbation may require a different approach, as they often experience feelings of distress during this time [39]. Additional evidence on this specific subpopulation is still needed [36], especially in combination with mobile health (mHealth) solutions [16]. Health care professionals' involvement is also essential for a successful self-management intervention in clinical practice [13].

Self-management interventions, which are increasingly supported by mobile apps in recent years, may improve disease management in patients with COPD and may decrease hospital admissions. However, not all patients qualify because of reasons such as socioeconomic status, internet access, and skills. Systematic, comprehensive information on implementation- and compliance-related aspects of mobile self-management apps is lacking. Additional evidence about the effectiveness of mobile self-management apps is needed, especially regarding factors affecting the use in clinical practice for high-use patients, such as those recently hospitalized due to an exacerbation.

Objectives

The objective of this study is to evaluate the effects of a mobile health and self-management app (*COPD app*) in clinical practice for patients with COPD, after discharge from the hospital, on app use, self-management, expectations and experiences (technology acceptance), patients' and nurses' satisfaction, and hospital readmissions.

Methods

COPD App

The COPD app consisted of an 8-week health and self-management intervention, including the Lung Attack Action Plan, personalized medication overview, information about COPD, nutrition, physical activity, advantages of smoking cessation, weekly questionnaires monitored by nurses, and video consultation.

Pilot Testing

Pilot testing was used to receive feedback on a prototype of the COPD app. A total of 6 patients, admitted to a large teaching hospital (Rijnstate, Arnhem) for a COPD exacerbation, were provided with a tablet and access to the app. Patients received assignments such as *Can you find and use the Lung Attack Action Plan*, *Can you find and open the questionnaire*, and *Can you find and read the information about nutrition*. We also asked their opinion about the information (eg, if they missed information elements), frequency of notifications they would prefer, the readability, the frequency of new information, and

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their sociodemographic characteristics. Before starting the feasibility study, results from the pilot testing were used to improve the COPD app.

Feasibility Study—Recruitment and Eligibility Criteria

Patients were recruited from a large teaching hospital (Rijnstate, Arnhem). To be eligible, patients must be older than 18 years, diagnosed for COPD by a physician, admitted to the hospital for a COPD exacerbation (generally considered high-risk patients), have access to a smartphone or tablet, have a working internet connection, being able to use a smartphone or tablet, and be proficiency in Dutch language. Patients with cancer or (severe) cognitive or psychiatric conditions were excluded. At least one hospitalization for COPD exacerbation in the year preceding this study was also a criterion for accrual, but it only applied during the first month (of the inclusion period) because the number of eligible patients was too low.

Study Process

Patients were informed about the study by a pulmonary nurse and the researcher during hospital admission. Patients received the study information letter and were asked to sign the informed form. They also received support to download apps. The *Patient Journey App* software (PJA version 4.0) [40] was used for the COPD app and *Facetalk* [41] for video consultation. The apps could be downloaded for free from the Google Play Store and the Apple App Store [41-43].

Intervention

The COPD app provided patients with an 8-week self-management program. The app had 3 views: timeline, information page, and contact page (see Multimedia Appendix 1). The start date was the date of discharge of each patient. The timeline was classified in 8 weeks, and each week included the Lung Attack Action Plan, personalized (daily and extra) medication overview, information and education, and questionnaires. The first week also included a video of a pulmonologist explaining the purpose of the app and additional information about the functionalities of the COPD app. After 8 weeks (until 20 weeks), patients remained accessible to the information in the app, but the questionnaires, medication overview, video consultation, and Lung Attack Action Plan (including contact request) were no longer accessible.

Timeline

The timeline consisted, in all weeks, of 5 elements: (1) *Lung Attack Action Plan*, (2) *Medication Overview*, (3) *Information and Education*, (4) *Questionnaires*, and (5) *Consultations*, in week 4 and 8 (see Multimedia Appendices 1 and 2).

Lung Attack Action Plan

The Lung Attack Action Plan was provided by the Lung Foundation (*Longfonds*) [44] and was digitalized in the COPD app. This action plan could help patients to recognize changes in their symptoms and guide them how to act upon these changes. The action plan consisted of different categories and colors: *I am doing well today* (green), *I feel worse* (yellow), *No improvement after 2 days* (orange), and *The situation is threatening* (red). All levels included advice about symptoms (eg, dyspnea, production of sputum, and coughing), medication, physical activity, and nutrition. Patients could access and use the Lung Attack Action Plan at any time using the COPD app. It was also possible to request contact with a pulmonary nurse after using the Lung Attack Action Plan. The nurse received a notification email and would contact patients within 2 working days.

Medication Overview

Patients had access to an overview of their personal daily and extra medication.

Information and Education

A total of 5 information categories were included in the timeline: the COPD app, the condition COPD, physical activity, nutrition, and advantages of smoking cessation. For each topic, a general page was accessible, including more specific topics. Patients were provided with information, in text and video, about the COPD app (eg, information about the different functionalities), COPD condition (eg, recognizing an exacerbation and accepting your lung condition), nutrition (eg, advice about protein-rich food), physical activity (eg, videos with exercises from a physiotherapist), and smoking cessation (eg, advantages of smoking cessation after 20 min and 1 month).

Questionnaires and Monitoring

Patients were asked to fill out the weekly Clinical COPD Questionnaire (CCQ) and the Hospital Anxiety and Depression Scale (HADS) at weeks 1 and 8, using the app or via email. The results were monitored by nurses. The HADS was used to measure anxiety and depression The HADS is a 14-item screening list that consists of two 7-item subscales. The items are rated on a 4 point Likert scale (range 0-3) [45,46]. The CCQ is a self-administered questionnaire used to assess patients' clinical control. The CCQ is a 10-item scale with 3 domains: functional state, symptoms, and mental state, rated on a 7-point scale (0: no limitation to 6: totally limited). The CCQ score was calculated as the mean of the sum of all items [47]. The first CCQ was completed during hospital admission and repeated weekly. The nurses checked the scores weekly, and if a score was >2 and increased since the previous week, they contacted the patient.

Consultations

A video consultation was planned after 4 weeks with a pulmonary nurse, and a face-to-face consultation was planned after 8 weeks with a nurse practitioner or a pulmonologist. Patients could also request additional video consultations and telephonic consultations using the COPD app.

Information Page

The information page contained an overview of the information elements: Lung Attack Action Plan, the COPD app, condition COPD, nutrition, physical activity, smoking cessation, and information about video consultation. The information elements were presented in a list format, with a search function. See Multimedia Appendices 1 and 3.

Contact Page

The contact page presented 2 elements for patients: (1) the Lung Attack Action Plan and the option to request contact with a

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pulmonary nurse or (2) directly request telephonic contact with a nurse. Nurses received an email and contacted the patients within 2 working days. See Multimedia Appendices 1 and 4.

Outcome Measures

Use of the COPD App

Use of the COPD app is measured with log data. Use is reported as the number and percentage of patients and the number of times, described as page clicks, the app and the information items were opened. The number of times the Lung Attack Action Plan, contact request, and CCQ questionnaires were used is described with absolute and relative numbers.

Patient Satisfaction

Patients completed questionnaires about satisfaction with app use, the information provided, and user-friendliness. This is assessed on a 7-point scale (1: totally disagree to 7: totally agree). Patients were also asked about their overall satisfaction on a scale of 1 to 10 (1: not satisfied at all to 10: very satisfied). See Multimedia Appendix 5 for the questionnaire.

Self-management

The Partners in Health (PIH) scale was used to measure self-management [48,49]. The PIH is a 12-item scale, and the Dutch version consists of 2 subscales: (1) knowledge and coping and (2) recognition and management of symptoms, adherence to treatment. The Cronbach alphas of the subscales were .80 (knowledge and coping) and .72 (recognition and management of symptoms, adherence to treatment). The correlation between the subscales was 0.43. The items are rated on a 9-point Likert scale (0: low self-management and 8: high self-management). The first subscale consists of 7 items, and the second subscale consists of 5 items [49]. The total score for both subscales was calculated by taking the sum of the respective items.

Expectations and Experiences With the COPD App

Questionnaires covering constructs of the Unified Theory of Acceptance and Use of Technology (UTAUT) [50] model were used to measure expectations (baseline) and experiences (weeks 8 and 20) with using the COPD app. The UTAUT consists of 4 constructs that influence behavioral intention and behavior: (1) performance expectancy, (2) effort expectancy, (3) social influence, and (4) facilitating conditions. A total of 8 questions were rated on a 7-point scale (1: totally disagree to 7: totally agree). See Multimedia Appendix 6 for the questionnaires.

Satisfaction of Nurses

After all patients were included and completed the 8-week self-management program, we asked involved pulmonary nurses about their experience with the COPD app, video consultation, experience with monitoring the CCQ scores, and their satisfaction with for example efficiency and time investment.

Hospital Readmissions

A hospital readmission was defined as admission for at least 24 hours. The number of hospital admissions was obtained from the electronic medical record (EMR) after 30 days, 8 weeks, and 20 weeks. This was compared with the readmission rate from the previous year, November 2017 to November 2018.

Other Outcomes

Patients' age, Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage, and comorbidities were extracted from the EMR. Their marital status, education, internet use, smartphone or tablet skills, and need for support using a smartphone or tablet were assessed using a questionnaire.

Data Collection

Use was assessed using log data, extracted from the app software, after 8 and 20 weeks. Patients completed a baseline questionnaire during hospital admission, covering aspects of self-management (PIH), expectations with the COPD app, internet use, smartphone or tablet skills, and sociodemographics. After 8 weeks and 20 weeks, a questionnaire was sent on self-management, experiences with the app, and (overall) satisfaction. After 30 days, 8 weeks, and 20 weeks, the readmission rate was assessed, and data were extracted from the EMR. See Table 1 for an overview of the outcomes and measurement time points.

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Table 1. Outcomes and measurement time points.

Outcome	Measurement instrument	Baseline	30 days	Week 8	Week 20
Use of the COPD app	Log data	__[a]	—	—	—
Self-management	PIH[b] scale	●[c]	X[d]	●	●
Expectations with the COPD[e] app	Questionnaire (UTAUT[f] constructs)	●	X	X	X
Experiences with the COPD app	Questionnaire (UTAUT constructs)	X	X	●	●
Satisfaction (functionalities of the COPD app)	Questionnaire	X	X	●	X
Overall satisfaction	10-point scale	X	X	●	●
Readmissions	EMR[g]	X	●	●	●

[a]—: Weekly assessment from baseline until 20 weeks.

[b]PIH: Partners in Health.

[c]Outcome measurement.

[d]No outcome measurement.

[e]COPD: chronic obstructive pulmonary disease.

[f]UTAUT: Unified Theory of Acceptance and Use of Technology.

[g]EMR: electronic medical record.

Statistical Analysis

Data analysis was performed using IBM SPSS V22.0. Descriptive statistics were used to report the baseline characteristics, app use, expectations and experiences, satisfaction, and number of readmissions. Changes in self-management over time were analyzed using a linear mixed model. Using a linear mixed model allowed for the inclusion of cases with missing data. The relation between app use and self-management was analyzed using linear regression. Normally distributed variables were reported as mean and standard deviation, and non-normally distributed data were reported with medians and interquartile ranges (25th-75th percentiles).

Approval and Ethical Considerations

The study was approved by the local ethical committee *Commissie Mensgebonden Onderzoek Arnhem–Nijmegen*.

Results

Pilot Testing

A total of 6 patients participated in the pilot testing of a prototype of the COPD app: 3 men and 3 women. The age range was 58-78 years. A total of 4 patients used the internet (almost) every day and 2 patients (less than) 1 day per week. Moreover, 3 patients used a smartphone or tablet (almost) every day, 1 patient multiple days per week, and 2 patients never. Furthermore, 3 out of 6 patients perceived their smartphone or tablet skills not good or not bad, 1 bad, and 1 good. In addition, 3 (out of 6) patients did not miss information items in the COPD app.

The information was categorized per day in the prototype, meaning that a new information item was presented daily. During the assignments and observations, we found that it was not easy for patients to find information because the timeline was very long. A total of 4 (out of 6) patients preferred to receive all information items in 1 overview, ordered by information category (eg, nutrition). On the basis of the findings, we categorized the information per category (eg, nutrition, physical activity) instead of per day. To increase ease of use, the 8-week program was classified per week instead of per day. Patients' opinion about the frequency of receiving a notification varied. Therefore, we decided to send a weekly reminder about the Lung Attack Action Plan and a reminder to fill out the weekly CCQ questionnaire.

Feasibility Study—Patient Recruitment

Inclusion took place from November 19, 2018, to December 13, 2019. A total of 174 patients were assessed for eligibility. Moreover, 81 patients did not meet the inclusion criteria because they had no access to a smartphone or tablet (n=41), were not able to use a smartphone or tablet (n=19), no working internet connection (n=5), no proficiency in Dutch language (n=9), cancer, (severe) cognitive disability or psychiatric condition (n=7), or other reasons (n=24 eg, hospital admissions were too short, unclear diagnosis, or no reason was reported). In total, 28 patients declined to participate. Moreover, 2 patients signed the informed consent form, but they were excluded because the COPD app could not be installed on their smartphone or tablet. In total, 39 patients started the intervention. One patient died during the first 8 weeks, and 1 patient died before 20 weeks. Therefore, 39 patients were included in the analysis until 8 weeks, 38 patients were included in the analysis at week 8 and from week 8 to week 20, and 37 patients were included in the analysis at 20 weeks (Figure 1).

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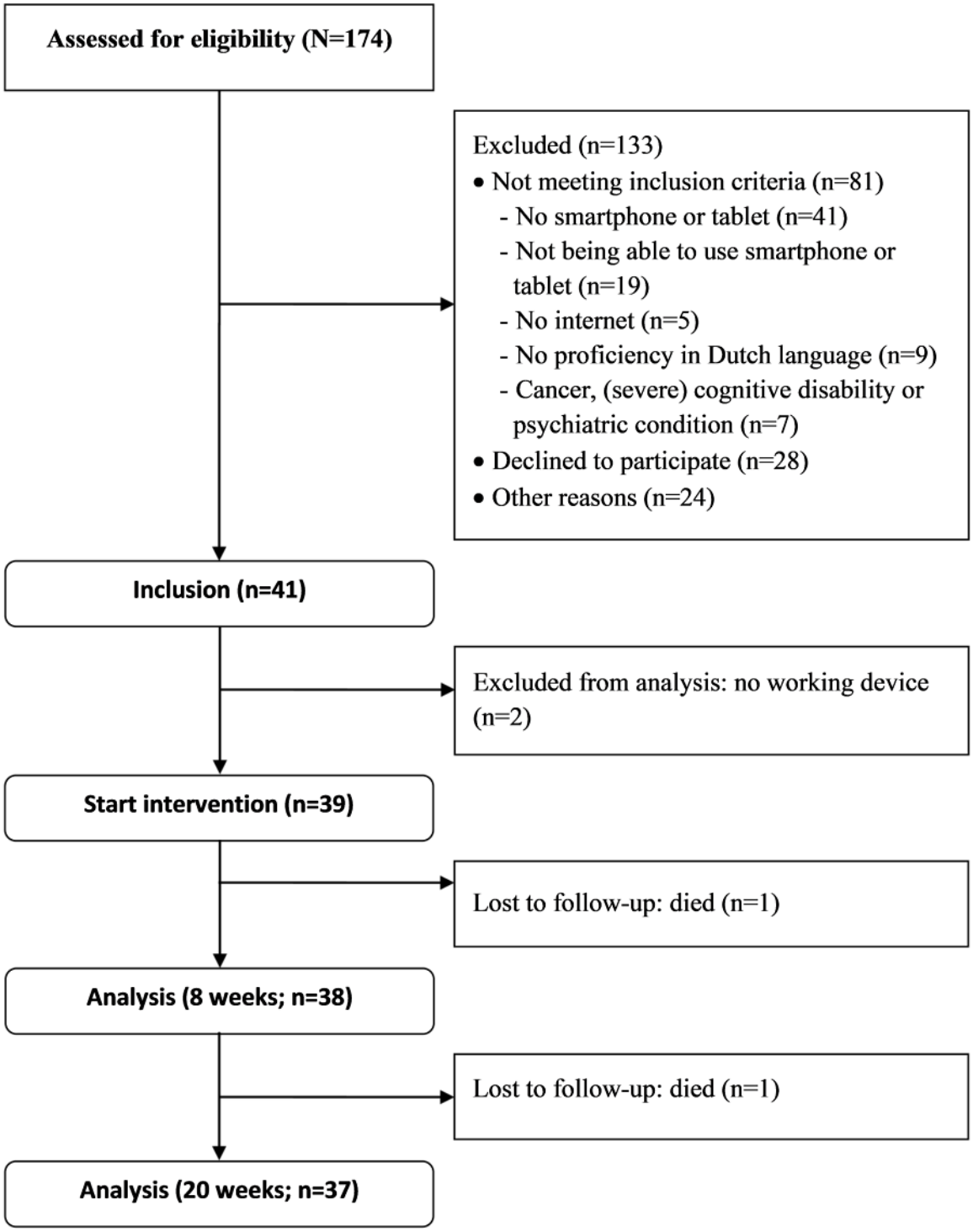
Figure 1. Flow diagram.



Baseline Characteristics

The baseline characteristics of the population included in the feasibility study are presented in Table 2.

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Table 2. Baseline characteristics (N=39).

Baseline characteristics	Patients
Gender, n (%)	
Women	30 (77)
Men	9 (23)
Age (years), mean (SD)	62.2 (6.7)
Severity classification, n (%)[a]	
Moderate (GOLD stage 2)	7 (18)
Very severe (GOLD stage 3+4)	32 (82)
Living with a partner, n (%)[a]	25 (68)
Having children, n (%)[a]	34 (92)
Children living at home, n (%)[a]	10 (30)
Education, n (%)[a]	
Low (primary school)	12 (32)
Middle (high school or vocational education)	22 (60)
High (higher vocational education or university)	3 (8)
Comorbidities, n (%)[a]	
Hypertension	7 (18)
Depression	3 (8)
Diabetes	2 (5)
Asthma	2 (5)
Heart disease	2 (5)
Reuma	2 (5)
Internet use (duration), n (%)[a,b]	
<6 months	2 (5)
6 months to 2 years	2 (5)
>2 years	2 (5)
>3 years	31 (84)
Frequency of internet use, n (%)[a]	
Almost every day	32 (86)
Multiple days a week	3 (8)
About 1 day a week	1 (3)
Never	1 (3)
Smartphone or tablet skills, n (%)[a,b]	
Bad and/or very bad	7 (19)
Not good and/or not bad	16 (44)
Good and/or very good	13 (36)
Expects to need help with smartphone or tablet use, n (%)[a]	21 (58)

[a]Reported as valid percentage.

[b]Does not add up to 100% because of rounding.

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Use

The use of the COPD app, questionnaires, and consultations is described in more detail below and is presented in Table 3.

Table 3. Overview of the use of the chronic obstructive pulmonary disease app functionalities (N=39).

Functionalities	Patients, n (%)
COPD[a] app use	
Week 1	39 (100)
Week 2	33 (85)
Week 3	32 (82)
Week 4-8	31 (79)
CCQ[b] questionnaires	
9 weekly CCQ questionnaires completed	29 (74)
8 weekly CCQ questionnaires completed	3 (8)
7 weekly CCQ questionnaires completed	4 (10)
<7 weekly CCQ questionnaires completed	3 (8)
HADS[c]	
Week 1: questionnaire completed	35 (90)
Week 8: questionnaire completed	33 (85)
Video consultation (week 4)	
Video consultation	17 (44)
Telephonic consultation	13 (33)
No video consultation	9 (23)
Face-to-face consultation (week 8)	
Face-to-face consultation	27 (69)
Telephonic consultation	1 (2)
No face-to-face consultation (canceled)	11 (28)
Lung Attack Action Plan (week 1-8)	
Use Lung Attack Action Plan and request for contact	9 (23)
Contact with a nurse as a result of the use of the Lung Attack Action Plan	9 (100)
Contact page (week 1-8)	
Request for contact using contact page	3 (8)
Contact with a nurse as a result of the use of the contact page	3 (100)

[a]COPD: chronic obstructive pulmonary disease.

[b]CCQ: Clinical COPD Questionnaire.

[c]HADS: Hospital Anxiety and Depression Scale.

COPD App

The use of the COPD app varied widely across patients. The app was opened most often during the first week (median 6.0; IQR 3.5-10.0). However, use decreased over time. The app was opened by the majority of patients during the first 8 weeks, varying from 100% (39/39) in the first week to 79% (31/39) in week 8. Patients read information most frequently during the first week, especially regarding the functionalities in the COPD app (27/39, 69%), physical activity (24/39, 62%), the condition COPD, nutrition, and the Lung Attack Action Plan (22/39, 56%). See Multimedia Appendix 7 for detailed information.

Questionnaires (CCQ and HADS) and Monitoring

In total, 29 patients filled out all the weekly CCQ questionnaires (in total 9 times including baseline), 3 answered the CCQ during 8 weeks, 4 answered the CCQ during 7 weeks, 1 answered the CCQ during 6 weeks, and 2 answered the CCQ during 2 weeks. A total of 35 patients filled out the HADS in week 1 (after discharge) and 33 after 8 weeks. Two patients reported that they did not want to fill out the questionnaires anymore during the study, and 1 patient died 7 weeks after discharge. The monitoring of the scores was used inconsistently, and therefore, the results do not offer a meaningful contribution.

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Consultations

A total of 17 patients attended the planned video consultation 4 weeks after discharge. For 13 other patients, this was replaced by a telephonic consultation because of problems with the video consultation system (eg, technical issues or lack of skills from nurses or patients); 2 patients did not want a video consultation; 1 patient visited the hospital instead; 1 patient's consultation was canceled because of hospital readmission; 1 patient left the digital waiting room because the nurse was too late; 1 patient was not available; and for 3 patients, a reason for cancelation was not reported.

A total of 27 patients attended their face-to-face consultation after approximately 8 weeks. For 11 other patients, the appointment was canceled because patients did not show up (n=5), because of readmission (n=3), two patients canceled the appointment, and 1 patient died. For 1 patient, this consultation was replaced by a telephonic consultation because the patients did not feel fit enough to come to the hospital.

In total, additional contact with a nurse was requested 19 times. A total of 9 patients used the Lung Attack Action Plan 15 times (13 times code yellow and 2 times orange), and 3 patients used the contact form 4 times to request contact with a nurse. See Multimedia Appendix 7 for more details on the use of the Lung Attack Action Plan.

Satisfaction

The COPD app was rated, on a scale of 1 to 10 (1: not satisfied at all to 10: very satisfied), with a 7.7 (SD 1.7) after 8 weeks and 7.0 (SD 2.4) after 20 weeks. Patients thought the app was easy to use and well-structured (26/28, 93%). Almost all patients reported that the Lung Attack Action Plan was easy to find (27/28, 96%) and easy to use (25/27, 93%), and more than half of the patients thought it actually helped them (18/27, 67%). The majority of patients also thought that the information was understandable (27/29, 93%), and all the patients (29/29, 100%) were satisfied with the information about nutrition. According to 33% (9/27) of patients, too much information was available in the COPD app. The majority of patients were satisfied with the video consultations (18/23, 78%) and thought it saved them time (19/29, 66%). See Multimedia Appendix 8 for more detailed information.

Self-management

Knowledge and coping increased significantly over time (P=.04). However, there was no significant change in the recognition and management of symptoms (P=.14). See Multimedia Appendix 9.

Relation Between App Use and Self-management

No relation was not found between use of the app, the number of times the app was opened (mean page clicks during week 1-8), and the self-management elements *knowledge and coping* (P=.75) and *recognition management and adherence* (P=.92).

Expectations and Experiences With the COPD App (Technology Acceptance)

Patients' expectations with the COPD app were relatively high. However, only 2 aspects improved over time. After using the app, more patients thought that it takes no effort to use it and that they had enough skills to use it. However, most aspects related to receiving support using the app decreased over time. See Multimedia Appendix 10 for more detailed information.

Satisfaction of Nurses

The use of the COPD app and monitoring of the weekly questionnaires were evaluated with 3 nurses. They rated the COPD app, on a scale of 1 to 10 (1: not satisfied at all to 10: very satisfied), on average with a 6.3 (SD 1.2) Most of them were satisfied with the app (2/3, 67%) and the information provided (2/3, 67%) and thought that better care was provided using the COPD app (2/3, 67%). However, use of the COPD app did not save time (3/3, 100%). They received a lot of questions from patients (3/3, 100%), and they mentioned that it took them a lot of time to explain it and answer questions (2/3, 67%). They also reported:

> *Unfortunately not applicable for our target population, the app is good.*
>
> *How simple it seemed to use, how difficult it appeared to be for patients.*

Only 1 nurse would recommend the COPD app to more patients. The nurses would not recommend it to their colleagues.

The nurses were less satisfied with monitoring the results of the questionnaires and rated this with a 5.3 (SD 0.58), on a scale of 1 to 10 (1: not satisfied at all to 10: very satisfied). Only 1 nurse thought that monitoring the results of the questionnaires fitted well in their work process. They commented:

> *Plan more time for nurses to monitor the questionnaires.*
>
> *It is often unclear for patients what they have to fill out. Sometimes patients were surprised when they got a call, because they felt good.*

The nurses were less satisfied with the video consultations and mentioned the following:

> *This was very difficult, very unclear for patients, took a lot of time and often a telephonic consultation was needed.*
>
> *Many patients did not understand how to start a video consultation.*

Hospital Readmissions

In total, 39 patients were included in the study. A total of 12 patients (12/39, 31%) were readmitted 22 times during the study period (20 weeks), of which 5 patients (5/39, 13%) were readmitted 1 time in the first 30 days. Within 8 weeks, 8 patients (8/39, 21%) were readmitted 11 times. In the total study period (until 20 weeks), there were 22 readmissions for 12 patients (12/39, 31%). The main reasons for readmissions was COPD exacerbations, and 1 time it was due to a patient's home situation.

In the year preceding the study, from November 2017 to November 2018, 340 patients were admitted 478 times to the hospital. In total, 48 patients (48/340, 14.1%) were readmitted 77 times within 30 days. There were 103 readmissions within

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8 weeks for 61 patients (61/340, 17.9%), and 74 patients (74/340, 21.8%) were readmitted 129 times within 20 weeks.

Discussion

Principal Findings

In this study, a mobile self-management app for high-risk patients with COPD was evaluated in daily clinical practice. The COPD app was opened most often in the first week (median 6.0; IQR 3.5-10.0), but its use decreased over time (median 2.0; IQR 1.0-3.5 in week 8). Information, especially on physical activity (24/39, 62%), was read most often during the first week. The self-management element *knowledge and coping* increased significantly over time (*P*=.04), but a relation with app use was not found (*P*=.75). No significant change was found in *recognition and management of symptoms*, *adherence to treatment* (*P*=.14), or in relation with app use (*P*=. 92). Patients rated the COPD app on average with a 7.7 (SD 1.7) and nurses with a 6.3 (SD 1.2). Preliminary evidence about readmission rate showed that 13% (5/39) of patients were readmitted within 30 days, 21% (8/39) within 8 weeks, and 31% (12/39) within 20 weeks compared with 14.1% (48/340), 17.9% (61/340), and 21.8% (74/340), respectively, in a preresearch cohort.

Comparison With Prior Work

The use of mobile apps itself is not applicable to all patients [51,52]. In total, 37.4% (65/174) of all patients in our study had to be excluded because of lack of access to a mobile device or internet or skills to use it. This is in line with other findings of mHealth use in patients with COPD, in which only a minority owned a smartphone (23%) [53]. Technical issues and low compliance are recognized issues for digital interventions [54], and digital literacy among patients with COPD remains a challenge [52]. As a result of the pilot testing, the app we implemented was already simplified. However, digital literacy may still have been an issue during this study. Therefore, ease of use seems to be an essential element in digital interventions for this patient population [20,27]. A total of 16.1% (28/174) of those possibly qualifying declined to participate, among other things, because it was too much of a burden or effort at the time. Patients may have experienced high levels of distress after experiencing an exacerbation [55], and therefore, they may be less willing to engage in a self-management intervention [38]. Therefore, these interventions are not applicable to all patients who are recently discharged from the hospital [38], as they may still feel (too) sick and/or are not able to focus on the intervention [34]. This emphasizes the importance of timing [39] and tailoring [56] an intervention.

Until now, the effects of self-management interventions on patients recently discharged from the hospital were scarcely evaluated [38] in combination with mobile apps. The direct effects [57] of app supported self-management and health interventions, for example, technology acceptance, self-management, and patients' and nurses' satisfaction are relevant for use in clinical practice. We found that the app was especially used during the first week after discharge. The Lung Attack Action Plan (9/39, 23%) and request for contact using the contact page (3/39, 8%) were used to a limited extent. However, the majority (29/39, 74%) completed the weekly CCQ questionnaires during the whole intervention period and the HADS in week 8 (33/39, 85%). Patients received frequent reminders by email, in the app and sometimes from nurses, to complete the questionnaires. The use of the COPD app and the Lung Attack Action Plan was more optional, rather at patients' own initiative. Receiving feedback can be important [56], and this may explain that the majority of patients completed the questionnaires, but that the use of the COPD app decreased over time. Low frequency of use can also be due to lack of self-management or technological skills [56].

Social support is seen as a facilitator for use [32,52]. The majority of the patients (28/37, 76%) expected to receive enough help using the COPD app. However, only 57% (17/30) of the patients indicated that they had received enough help (Multimedia Appendix 10). Tailored education can also facilitate use [52], but in this COPD app, only the medication overview was really personalized. Although the information items were aimed at high-risk patients with COPD, the information was generic. This might have contributed to the decrease in use. Tailored interventions [56], support [30], and patient engagement during development and implementation [56,58] may be beneficial for improved use.

A positive effect was found on knowledge and coping, which may partly be explained by the selection criteria for this study, as patients with cognitive disability and lack of skills with a mobile device were excluded. In addition, the provision of timely information using a mobile device can positively influence knowledge [59]. Self-management can also be enhanced by involving patients' partners, enhancing self-efficacy, and support from health care professionals [30]. Although positive results on hospital readmissions were found in previous studies [6,18], these findings were inconsistent [15,28,60], which could be due to high methodological heterogeneity [16,19]. In our study, no large difference was observed, possibly due to low numbers. It would be interesting to verify the element of selection bias in view of the large percentage of patients that were excluded from this population.

Patients were satisfied with the COPD app, user-friendliness, and information. However, nurses addressed some concerns, for example, the increased workload and (lack of) integration in the work process. It is common that the degree of satisfaction between patients and health care professionals can differ. In general, patients report more favorable outcomes because mobile interventions are often provided as an extra service in addition to their usual care. For that same reason, health care professionals are generally less satisfied, especially because they often see it as an increase in workload [61]. The nurses in our study addressed concerns about the monitoring of the results of the questionnaires because they experienced a lack of integration in their work processes. Often a common pattern with the introduction of new innovations, this intervention was an addition to their current activities. Another reason might be that nurses had to work with different information technology systems that were not connected to the EMR. Lack of interoperability can be a barrier [58] for use, and this might explain the lack of monitoring of the first phase of the study. This improved after they received the scores in person by email. Health care professionals' adoption is essential to ensure

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success; therefore, they should be involved in the development and implementation process [56].

COPD management requires a multidisciplinary approach that is fragmented [24], and this approach is often not sufficiently supported by information technology [62]. Therefore, future research should focus on self-management interventions with a multidisciplinary approach tailored to individual patients recently discharged from the hospital. Pragmatic trials [63] can be used to determine, at a more rapid pace, which elements of self-management interventions are effective for which subgroups of patients with COPD recently discharged and which characteristics of mHealth solutions are adopted by both patients and health care professionals. Subsequently, a larger controlled study specifically involving this frail subgroup of patients should focus on the effects on clinical outcomes and hospital services use (eg, readmissions).

Limitations

Due to accrual issues, especially related to device availability and internet access, the COPD app was evaluated in a small sample, so we could not reach the power originally calculated for this trial. In addition, nurses found it difficult to comply with the contacting rules, so there were inconsistencies in the follow-up monitoring using the CCQ questionnaires. Some patients were only contacted a limited number of times when they had a high score on the CCQ questionnaire. After approximately 20 patients, we decided to send nurses a notification by email with the scores, and they were asked to take up contact (if necessary). As a consequence of the team setting, only 3 nurses were involved in this study, and we have to be careful about the related outcomes. Preliminary evidence on readmission rates was provided based on an earlier cohort, but this was not a matched exercise. Therefore, definitive conclusions on this aspect cannot be drawn.

Conclusions

The integration and use of a mobile self-management app for recently discharged patients with COPD in clinical practice is affected by multiple factors and is only feasible for a relatively small number of patients after hospital discharge. Patients were very positive about the COPD app; however, its use decreased over time. The findings of this study showed a significant positive change in the self-management element knowledge and coping. Nurses expressed concerns about integration in their work processes and increased workload. Tailored interventions, patient support, and active adoption by professionals are important elements to ensure successful mHealth interventions. Therefore, future research on digital self-management interventions in clinical practice should focus on including more difficult subgroups of target populations, on a multidisciplinary approach, on technology-related aspects (such as acceptability), and on finetuning its adoption in clinical pathways.

Acknowledgments

The authors wish to thank Els Fikkers (nurse practitioner) for her assistance with data collection from the EMR.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Chronic obstructive pulmonary disease (COPD) app.
[PNG File , 881 KB - mhealth_v9i2e21977_app1.png]

Multimedia Appendix 2
Timeline (English translation).
[PDF File (Adobe PDF File), 149 KB - mhealth_v9i2e21977_app2.pdf]

Multimedia Appendix 3
Information page (English translation).
[PDF File (Adobe PDF File), 50 KB - mhealth_v9i2e21977_app3.pdf]

Multimedia Appendix 4
Contact page (English translation).
[PDF File (Adobe PDF File), 251 KB - mhealth_v9i2e21977_app4.pdf]

Multimedia Appendix 5
Questionnaire: Patient Satisfaction.
[PDF File (Adobe PDF File), 37 KB - mhealth_v9i2e21977_app5.pdf]

Multimedia Appendix 6

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Questionnaire: Expectations and Experiences with the COPD app.
[PDF File (Adobe PDF File), 7 KB - mhealth_v9i2e21977_app6.pdf]

Multimedia Appendix 7
Use of the chronic obstructive pulmonary disease (COPD) app.
[PDF File (Adobe PDF File), 200 KB - mhealth_v9i2e21977_app7.pdf]

Multimedia Appendix 8
Patient satisfaction.
[PDF File (Adobe PDF File), 157 KB - mhealth_v9i2e21977_app8.pdf]

Multimedia Appendix 9
Self-management.
[PDF File (Adobe PDF File), 148 KB - mhealth_v9i2e21977_app9.pdf]

Multimedia Appendix 10
Expectations of and experiences with the chronic obstructive pulmonary disease (COPD) app.
[PDF File (Adobe PDF File), 152 KB - mhealth_v9i2e21977_app10.pdf]

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Abbreviations

CCQ: Clinical COPD Questionnaire
COPD: chronic obstructive pulmonary disease
EMR: electronic medical record
HADS: Hospital Anxiety and Depression Scale
mHealth: mobile health
PIH: Partners in Health
UTAUT: Unified Theory of Acceptance and Use of Technology

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Original Paper

Relationships Between Mobile eHealth Literacy, Diabetes Self-care, and Glycemic Outcomes in Taiwanese Patients With Type 2 Diabetes: Cross-sectional Study

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Abstract

Background: Understanding how people with diabetes seek online health information and use health applications is important to ensure these electronic tools are successfully supporting patient self-care. Furthermore, identifying the relationship between patient mobile eHealth literacy (mobile eHL) and diabetes outcomes can have far-reaching utility, for example, in the design of targeted interventions to address mobile eHL limitations. However, only limited studies have explored the impact of mobile eHL in a population with diabetes.

Objective: This study aims to present data about online information-seeking behavior and mobile health (mHealth) app usage, investigate the factors related to mobile eHL in Taiwanese patients with type 2 diabetes, and flesh out the relationship between eHealth literacy (eHL), mobile health literacy (mHL), and health outcomes.

Methods: Subjects were recruited from January 2017 to December 2017 in the outpatient departments of 3 hospitals in Taiwan. A total of 249 Taiwanese patients with diabetes voluntarily completed a cross-sectional survey assessing sociodemographic characteristics; diabetes status; knowledge and skills of computers, the internet, and mobile apps; mobile eHL; and patient outcomes (self-care behaviors, self-rated health, HbA_{1c}). Structural equation modeling analyses examined the model fit of mobile eHL scores and the interrelationships between latent constructs and observable variables.

Results: Of the 249 patients with diabetes, 67% (164/249) reported they had searched for online diabetes information. The participants with smartphones had owned them for an average of 6.5 years and used them for an average of 4.5 (SD 3.81) hours per day. Only 1.6% (4/249) of the patients used health apps. Some demographic factors affecting mobile eHL included age, education, and duration of type 2 diabetes. Mobile eHL was related to self-care behaviors as well as knowledge and skills of computers, the internet, and mobile technology, but only had a weak, indirect effect on self-rated health. The final model had adequate goodness-of-fit indexes: chi-square (83)=149.572, $P<.001$; comparative fit index (CFI)=0.925; root mean square of approximation (RMSEA)=0.057 (90% CI 004-006); chi-square/*df*=1.082. Mobile eHL had a weak, indirect effect on self-rated health through the variables of knowledge with skills.

Conclusions: Our study reveals that although people with diabetes who rated their health conditions as moderate were confident in using mobile eHealth and technology, few adopted these tools in their daily lives. The study found that mobile eHL had a direct effect on self-care behavior as well as knowledge and skills of computers, the internet, and mobile technology, and had an indirect

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effect on health outcomes (glycemic control and self-rated health status). Information about this population's experiences and the role mobile eHL plays in them can spur necessary mobile eHealth patient education.

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KEYWORDS

mHealth literacy; eHealth literacy; diabetes mellitus; self-care behavior; glycemic outcomes

Introduction

Diabetic Population in the Digital Age

Living with diabetes is a stressful condition that requires a great deal of self-care practices. By 2035, more than 1 in 10 adults worldwide will be at risk for developing diabetes [1]. With such a life-altering disease, this population must continuously obtain and process health information to cope. Today, a popular option for disseminating health information is via information technology, on websites accessed from mobile devices and personal computers [2]. In 2019, the rates for individual internet use and mobile internet use were 88% and 85.2%, respectively, according to the Taiwan Network Information Center [3]. The question arises as to whether Taiwanese people with diabetes turn to an online environment for health information or to engage with mobile health (mHealth) apps. Thus, understanding this issue is crucially important, as scholars point out that eHealth and mHealth tools can successfully support patients' self-care [4-7].

eHealth and mHealth Technology

Recent advances in information technology can enhance patient self-care and optimize patient outcomes. One such advancement is eHealth, defined as the delivery of health services and information through electronic technologies [8]. Several web portals have been extensively developed for similar purposes, primarily to optimize patient outcomes [4,6]. Previous reviews have summarized the effectiveness of eHealth programs in regard to better self-management behaviors, adherence to medications and specific dietary recommendations, increased physical activity [4], and cost-effectiveness [9]. Clearly, there is great potential for the utility of eHealth technology to promote patient outcomes.

Mobile technology, an important addition to eHealth, also has great potential to support patient self-care. mHealth is characterized by a focus on mobile telecommunications for a variety of health care services and the implementation of smartphone applications for health purposes [10-12]. The literature shows that mHealth technology could be used to record medication, glycemic monitoring, and healthy food intake to optimize glycemic control [ie, reduction of glycated hemoglobin (HbA_{1c})] [7,13], and ultimately, to prevent diabetic complications [13].

The term mobile eHealth may comprehensively and simultaneously refer to both mHealth and eHealth [14,15], which have more potential together than either technology separately in the future provision of continuing care. Thus, some researchers have made efforts to increase the evidence base for mobile eHealth design and development [16,17]. Unfortunately, these valuable resources can only be helpful if patients have adequate access to them. Research indicates that some barriers still exist, such as limited user engagement [18-20] and technological issues [12,13]. One study [21], reviewing 101 apps, found that most health apps do not adhere to the guideline of mHealth-literate design strategies published by the Institute of Medicine. Due to these issues, patients have not widely embraced mHealth apps, despite their great promise.

eHealth and mHealth Literacy

To overcome these adoption barriers, eHealth and mHealth literacy should be recognized and addressed when planning for these innovations. eHealth literacy can be viewed as an extension of health literacy, the ability to obtain, process, and understand health information [22]. Although the concept of eHealth literacy (eHL) almost resembles health literacy, eHL emphasizes electronic health information rather than traditional information sources (such as pamphlets and printed patient handouts). Finding relevant information online and judging its credibility goes beyond traditional health literacy measures [22,23]. Thus, eHL reflects the complexity inherent in the utility of information technologies for health. These skills are better captured by an eHealth literacy scale [22,24-26].

Another relatively new literacy, mHealth literacy (mHL), is generally viewed as the ability to adopt mobile devices to search, find, understand, appraise, and apply health information when addressing or solving health problems [27]. While the broad definition of mHL seems rather similar to the concept of eHL, the assessment of eHealth literacy cannot fully represent the mHL dimension. To be more precise, eHL does not include the ability to access mHealth apps, download from app stores, and register these apps. In the mHealth field, mHealth literacy is supposed to serve a literacy function, enabling people to properly operate mHealth apps. Unfortunately, the current mHL scale only emphasizes health information seeking and health information appraisal on mobile devices. Thus, this study proposes a mobile eHealth literacy scale by adding a new subscale of mHL items that was modified from the eHL scale of Norman and Skinner [22].

One fundamental challenge facing both eHL and mHL (mobile eHL) is the need to discover how a diverse population could use mobile eHealth technology to acquire health information. Patients with diabetes with lower levels of mobile eHL may not understand or be able to access electronic health information and mobile health apps [28]. To date, research into the combined measurement of eHL and mHL is scant. This lack of data is of great concern to health care providers of vulnerable patients, such as those with diabetes, who should seek reliable information and useful self-care tools [2,15,20,23].

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Relationship Between Mobile eHealth Literacy and Patient Outcomes

There is now a substantial body of literature that examines health literacy effects on disease conditions. Researchers have noted a causal mechanism associating health literacy to health outcomes (ie, utilization of health services, patient-provider interaction, and self-care) [29]. They have identified important pathways and highlighted the complexity involved in patient self-care. Other studies [30,31] demonstrate a logical, linked structure of health literacy, patient characteristics, self-care, and health outcomes. Scholars [31] indicated low to insufficient evidence on the association between health literacy, eHealth literacy, and self-rated health. Similarly, two other systematic reviews offer a comprehensive set of variables to ascertain health literacy skills, patient characteristics, and risk factors associated with clinical outcomes. In sum, these fundamental studies provide a preliminary understanding of health literacy based on an analysis of the literature, but they lack empirical confirmation.

Subsequent studies have sought to confirm these models with empirical findings. For example, one cross-sectional study validated a model that describes how health literacy contributes to physical activity and self-rated health among patients with chronic conditions [32]. Other research reveals that high health literacy has an indirect positive effect that can indirectly facilitate diabetes self-care and improve glycemic control [33]. In brief, health literacy positively relates to health outcomes in chronic diseases.

Evidence of traditional health literacy's capacity to regulate behaviors has been well established, but such evidence in the mobile eHealth field is still limited. As stated by Kim and Xie [23], there is a lack of new health literacy screening tools to identify proper competence in the use of eHealth and mHealth services. A mediation analysis by Schulz et al [25] found that eHealth literacy is weakly associated with health system utilization, though the premise of health literacy resembles eHealth literacy. Additionally, low eHealth literacy is associated with poor quality-of-life outcomes in patients with chronic lung disease [34]. Another research group found that mHealth apps users with heart disease or diabetes have a higher level of eHL [35]. These studies offer valuable insights about eHL but neglect to focus on mobile health literacy.

To sum up, health literacy has not yet been shown to accurately serve the needs of patients with diabetes who rely heavily upon the internet and mobile technology. An eHL measure [22,34] merely reflects internet use without specifically covering mobile apps. Also, the eHL measure has been questioned because it only reflects individuals' perceived performance of online tasks without necessary objective reports [31,36]. Researchers recommend that future studies measure people's internet operation skills in a manner that accurately reflects their eHL [6,36,37]. For this study, self-developed mHL questions and eHL items will be combined to flesh out the scope of mobile eHealth literacy; cross-verification will then be performed by an assessment of knowledge and skills of computer, mobile, and internet competence.

This study is one of the few to date that explores the link between mobile eHL and diabetes outcomes (ie, self-care behavior and glycemic control). As various mobile eHealth programs are particularly attractive for managing chronic conditions [6,13,16,18,38], there are far-reaching benefits to recognizing the relationship between patient literacy and chronic disease outcomes. Thus, identifying the factors linking eHL to behavioral and clinical outcomes in diabetes can contribute to future design projects.

Objective

This study aims to present data about online information-seeking behavior and mHealth apps usage, to analyze the levels of eHealth and mHealth literacy of patients with diabetes, and to flesh out the relationship between eHL, mHL, and health outcomes (self-care behaviors, self-rated health, and HbA_{1c}).

The following 4 hypotheses are examined: Hypothesis 1 posits that higher mobile eHL is associated with (1) greater knowledge and skills of computers, the internet, and mobile technology; (2) increased self-care behaviors; (3) better self-rated health; and (4) lower HbA_{1c}. Hypothesis 2 posits that higher knowledge and skills of computers, the internet, and mobile technology is associated with (1) increased self-care behaviors, (2) better self-rated health, (3) and lower HbA_{1c}. Hypothesis 3 posits that increased self-care behaviors are associated with lower HbA_{1c}, and hypothesis 4 posits that better self-rated health is associated with lower HbA_{1c}.

Methods

Recruitment and Participants

The study employed a cross-sectional survey. A self-administered questionnaire was completed during a 12-month period, from January 16, 2017, to December 15, 2017. Potential participants were referred by endocrinologists or certificated diabetes educators at 3 hospitals in Taiwan. The inclusion criteria included (1) ages 20-65 years, (2) basic reading and writing ability, (3) no vision defects, and (4) a willingness to participate in the research study. Subjects were excluded if they had severe vision loss, communication problems, or if they had alcohol or drug abuse issues.

From the outpatient department of endocrinology and metabolism, 262 patients were recruited. Eligible patients were interviewed in the outpatient department waiting rooms, which are safe, private, and secure. Our researchers introduced the procedure to each participant, including the study's purpose, the method, the time required to complete the questionnaire, and how the data would be used after it was collected. The patients were then administered the questionnaires and skill performance testing and received a gift card worth NT50 (USD $1.50) as an incentive for completing the survey.

Ethics

This study was approved by the institutional review board of the targeted hospitals (IRB# 17MMHIS003e and CGH-OP105003) and was conducted in accordance with CONSORT-EHEALTH (Consolidated Standards of Reporting

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Trials of Electronic and Mobile Health Applications and Online TeleHealth) guidelines (Multimedia Appendix 1) [39]. All respondents were informed that participation was voluntary and that they could leave at any time without reason, and their choice to participate would not affect their care. All who chose to participate gave written consent.

Measurements

Demographics

Demographic items included age, gender, education, health status, duration of diabetes, experience with mobile and internet use, and online health information-seeking habits. Additional measures included validated mobile eHealth literacy and knowledge and skills of mobile app and internet use. The health outcomes as dependent variables included self-rated health, diabetes self-care behavior, and HbA_{1c}.

Mobile eHealth Literacy Questionnaire

The Mobile eHealth Literacy Questionnaire (Multimedia Appendix 2) consisted of 3 parts: (1) an existing scale [22] and self-developed measures in terms of eHealth literacy (8 items), (2) mHealth literacy (8 items), and (3) mobile eHealth preference (4 items). Firstly, eHealth literacy was examined using Norman and Skinner's eHEALS (eHealth Literacy Scale) [22] to measure perceived skills and comfort with using the internet for health information and decision-making. Factorial validity and internal consistency (Cronbach alpha=.94) were reported.

Secondly, our research group used available literature [10,15] to self-develop the mHealth literacy questionnaire by modifying Norman and Skinner's eHEALS [22]. Mobile skills were incorporated into the questionnaire to comprehensively measure all aspects of using internet resources through mobile technology [12]. This part asks questions about perceived skills concerning mobile health apps for self-management. Each item in the 2 subscales is rated on a 5-point Likert scale, in which 1=*strongly disagree* and 5=*strongly agree*. Higher scores indicate higher mHealth literacy.

Thirdly, the mobile eHealth preference was modified from eHEALS [22] and asked each individual their opinion on mHealth and eHealth technology. An example item is “How important is it for you to be able to access health resources on the internet?”

The content validity index for the 3 questionnaire subscales was completed by 6 senior experts (2 metabolism physicians, 2 dietitians, and 2 professors of health informatics) from 3 hospitals and 2 universities in Taiwan. The relevance, clarity, and simplicity of each item were evaluated using the content validity index. All individual items were rated above 3.5 on a 4-point scale. An item-level score of 3 or 4 indicated acceptable content validity [40]. Face validity was carried out with 3 voluntary participants with diabetes. Cronbach alpha for eHL, mHL, and mobile eHL preference scores were .927, .927, and .847, respectively.

Knowledge and Skills of Mobile Technology and the Internet

The knowledge and skills questionnaires examined the use of computers, the internet, and mobile apps, modified from Xie’s study [37]. This questionnaire was designed to offset the disadvantage of the eHL measure, which only reflects people's perceived performance on online tasks and lacks objective measures [36]. The knowledge-related test had 15 items that were each given a score of 1 if answered correctly or 0 if answered incorrectly. An example item is, “Try to find a pictogram meaning a place for downloading apps.”

The second skills-related test has 10 items. Each item scored 1 if operated appropriately and 0 if operated inappropriately; for instance, “Please try to open a browser and connect to a health website” and “Please try to download and use a diabetes app on a mobile device.” The Kuder-Richardson Formula 20 (KR-20) reliability for the knowledge and skills tests was 0.928 and 0.923, respectively. Face validity was carried out with 3 voluntary participants with diabetes.

Self-rated Health

Self-rated health derived by Hornby-Turner et al [41] was measured by asking subjects to respond to 3 questions; for example, “How would you describe your general health?” The reply scores ranged from 1=*very good* to 3=*poor*. Higher scores meant better-perceived health.

Diabetes Self-care Behavior Questionnaire

The 36-item Diabetes Self-care Behaviors questionnaire developed by Parchman et al [42] assesses the degree to which patients follow recommended self-care activities. For example, subjects are asked how frequently they comply with the recommended daily diet in a typical week. Behavior is measured on a 5-point ordinal scale: 0=*never*, 1=*1-3 times per week*, 2=*4-5 times per week*, 3=*more than 5 times per week*, 4=*always*. A higher score indicates more frequent self-care behavior.

Glycated Hemoglobin (HbA_{1c})

Glycated hemoglobin (HbA_{1c}) is a critical index of glycemic control with the ability to reflect average blood glucose over a period of 3 months. The HbA1c data of the study subjects were collected by reviewing the electronic medical records in the enrollment period. The optimal range for HbA_{1c} is below 7.0 mg/dL. A higher level of HbA_{1c} indicates poor glycemic control, which is associated with a higher risk of vascular complications and death [43].

Data Analysis

Data were analyzed using the SPSS statistical software package (version 22.0; IBM Corp). Data analysis included descriptive and exploratory statistical analyses. Pearson correlations evaluated the relations between independent variables and dependent scores. A structural equation model (SEM) was conducted to test the structure of the proposed model and the interrelationships between latent constructs and observable variables.

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Results

Response Rate and Descriptive Statistics

Table 1 presents the demographic characteristics of the patients. Of the 262 participants, 23 were excluded due to incomplete data, and 249 were eligible for the final analysis. The mean age was 44.58 (SD 11.02; range 20-65) years. Of the 249 participants, 164 (65.9%) were men and 85 (34.1%) were women, and 60% (150/249) had an education level of at least college or university. The mean duration of type 2 diabetes was 6.14 (SD 5.6; range 0-26) years, and diabetes duration ranged from 1 to 5 years for 45.7% (112/249) of participants. Of the 249 subjects, 45.8% (115/249) reported their health status was fair. The average HbA_{1c} result was 7.96 (SD 1.89; range 5.3-15.2) mg/dL, and was over 7 mg/dL for 63.1% (157/249) of subjects.

Table 1. Sociodemographic characteristics of the study participants (n=249).

Characteristics	Values
Gender, n (%)	
Male	164 (65.9)
Female	85 (34.1)
Age in years, mean (SD; range)	44.58 (11.02; 20-65)
Education level[a] , n (%)	
High school or less	98 (39.5)
College or university	114 (45.9)
Master or PhD	36 (14.5)
Duration of type 2 diabetes, mean (SD; range)[a]	6.14 (5.60; 0-26)
<1 year, n (%)	29 (11.8)
1-5years, n (%)	112 (45.7)
6-10 years, n (%)	59 (24.1)
>10 years, n (%)	45 (18.3)
Self-rated health, n (%)	
Good	115 (46.2)
Fair	114 (45.8)
Poor	20 (8)
HbA_{1c} (mg/dL), mean (SD; range)	7.96 (1.89; 5.3-15.2)
<7, n (%)	92 (36.9)
≥7, n (%)	157 (63.1)
7.0-8.0, n (%)	72 (28.9)
8.1-9.0, n (%)	31 (12.4)
9.1-10.0, n (%)	20 (8.0)
10.1-15, n (%)	34 (13.7)

[a]Some participant values are missing.

The Use of eHealth, mHealth Technology, and Health Outcomes

Table 2 presents descriptive statistics. The participants were asked about their experience with health information technology, including diabetes information-seeking through the internet and the use of smart devices. Of the 249 participants, 68% (164/249) reported they had searched for online diabetes information. When asked about the information technology tools they owned, 239 of the 249 participants reported owning smartphones, 171 owned computers, and 89 owned a tablet. Regarding their daily usage of smart devices and health applications over the past 30 days, the participants with smartphones (owned, on average, for 6.5 years) used them for a daily average of 4.5 (SD 3.8) hours, while participants with tablet used them for a daily average of 2.2 (SD 2.6) hours. Only 1.6% (4/249) of respondents used health applications.

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Table 2. Participant habits regarding online health information seeking and the use of mHealth apps (n=249).

Characteristics	Values
Search for diabetes information, n (%)	
Have	164 (67.1)
Have not	82 (32.9)
Search for health information (n=134), n (%)	
Have	24 (17.9)
Have not	110 (82.1)
Use of health apps, n (%)	
Use (running app, DM app)	4 (1.6)
Do not use	245 (98.4)
Use of technology in years, mean (SD; range)	
Smartphone (n=239)	6.5 (3.3; 0-20)
Tablet (n=89)	4.9 (3.2; 0-15)
Computer (n=171)	15.9 (6.6; 0-40)
Daily use in hours, mean (SD; range)	
Smartphone (n=239)	4.5 (3.8; 0-20)
Tablet (n=78)	2.2 (2.6; 0-12)
Computer (n=171)	4.8 (3.6; 0-20)

Table 3 presents the means, standard deviations, and Cronbach alpha values for self-rated health, self-care behavior, eHL, mHL, mobile eHL preference, and knowledge and skills of computers, internet, and mobile technology. Most measurements demonstrated good reliability (>0.8), and self-rated health showed moderate reliability (0.546). The overall eHL score averaged 30.16 (SD 5.41) on a scale of 8 to 40, the mHL score averaged 28.86 (SD 6.27) on a scale of 8 to 40, and the mobile eHL preference mean was 14.65 (SD 2.57) on a scale of 4 to 20. The average self-rated health score was 6.70 (SD 1.77), and the average self-care behavior score was 79.30 (SD 26.05).

Table 3. Means, standard deviations, and Cronbach alpha values for self-rated health, self-care behavior, eHealth literacy (eHL), mobile health literacy (mHL), mobile eHL preference, and knowledge and skills of computers, internet, and mobile technology (n=249).

Scale	Mean	SD	Items	Range	Min	Max	Reliability (α)
Moblie eHL							
eHL	30.16	5.41	8	8-40	8	40	.927
mHL	28.86	6.27	8	8-40	8	40	.927
Mobile eHL preference	14.65	2.57	4	4-20	8	20	.847
Knowledge and skills[a]							
Knowledge	13.96	2.66	15	0-15	0	15	.928
Skills	8.54	2.74	10	0-10	0	10	.923
Self-rated health	6.70	1.77	3	0-3	0	3	.546
Self-care behavior	79.30	26.05	36	0-144	17	144	.935

[a]Kuder-Richardson Formula 20 (KR-20) reliability for knowledge and skills of computers, the internet, and mobile technology.

Association and Exploratory Structural Equation Modeling Analyses

The bivariate relationships among the variables are shown in Multimedia Appendix 3. The 3 subscales of mobile eHL are moderately to highly correlated (eHL and mHL, r=0.764, P<.001; eHL and mobile eHL preference, r=0.577, P<.001; mHL and mobile eHL preference, r=0.515, P<.001). The correlations between mobile eHL and self-care behavior are significant (eHL, r=0.157, P=.013; mHL, r=0.188, P=.003; mobile eHL preference, r=0.211, P<.001). Both knowledge and skills of computers, the internet, and mobile technology are also significantly correlated with mobile eHL (*rho*=0.231 to 0.466, P<.001). However, the eHL and mHL literacy scores have significant and negative associations with age (eHL, r=-0.380, P<.001; mHL, r=-0.398, P=.036) and diabetes duration (eHL,

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r=-0.159, *P*=.013; mHL, *r*=-0.135, *P*<.001). The self-care behavior is reversely correlated with hours of smartphone daily use (*r*=-0.139, *P*=.033) but not related to HbA_{1c} or self-rated health. Participants with many hours of smartphone use may have poor self-care behavior. Self-rated health is significantly and negatively associated with HbA_{1c} (*r*=-0.290, *P*<.001). In turn, the results revealed that a higher level of self-rated health was associated with a lower HbA_{1c} level.

An SEM approach was used to explore the structural relationships among the variables. Mobile eHealth literacy, a dependent latent variable, was evaluated through independent latent variables, including eHL, mHL, and mobile eHL preference. The initial structural model is shown in Figure 1. The first model was overly complex and did not achieve a satisfactory fit. Figure 2 presents the pruned model in which some paths were changed. Moreover, a relationship based on mutual influence was proposed between knowledge and skills, and mobile eHL. The refined model had adequate goodness-of-fit indexes: χ^2_{83}=149.572, *P*<.001; comparative fit index (CFI)=0.925; root mean square of approximation (RMSEA)=0.057 (90% CI 004-006); χ^2/df = 1.082. The mobile eHL had a weak indirect effect on self-rated health through the variables of knowledge and skills. The self-rated health score exerted a significant direct effect on HbA_{1c}. However, the result reveals a nonsignificant direct influence on the mobile eHL at HbA_{1c} and self-rated health, and lower-than-expected coefficients for this domain's pathways.

Figure 1. The mobile eHealth literacy (MeHL) model that was first tested. DM: diabetes mellitus; eHL: eHealth literacy; HbA_{1c}: glycated hemoglobin; mHL: mobile health literacy.**P*=.01-.05, ***P*=.001-0.01<.01, ****P*<.001.

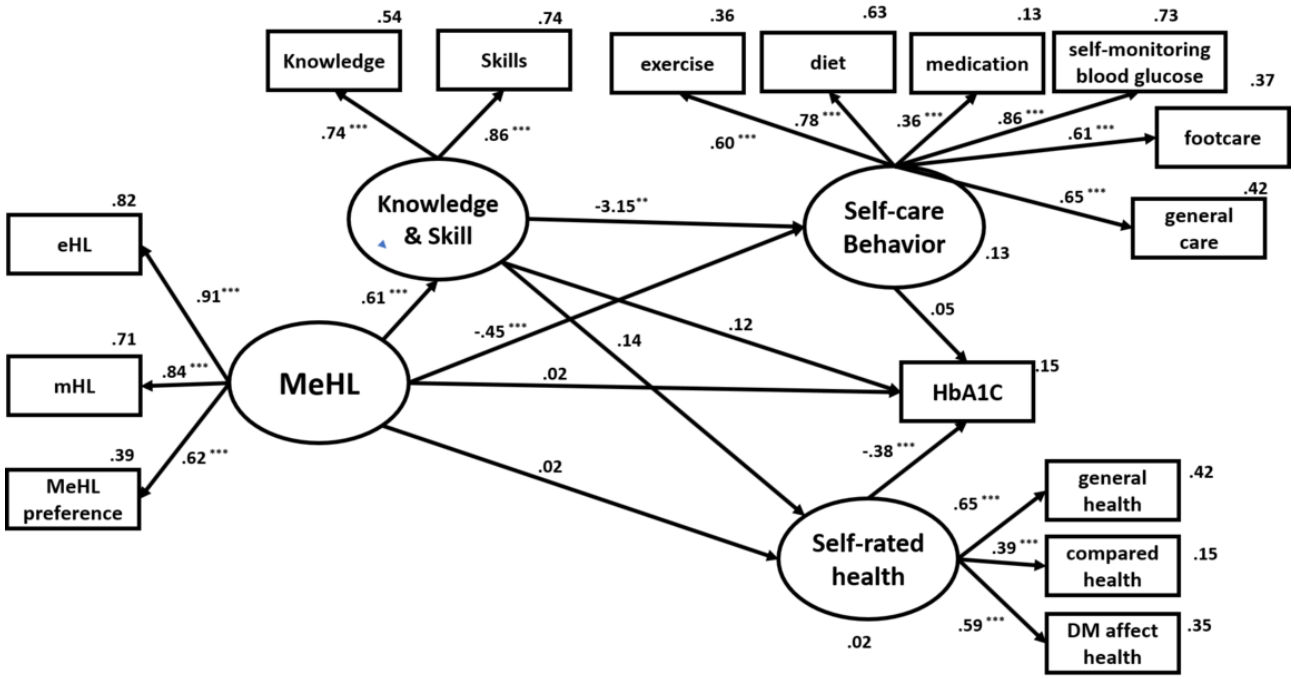

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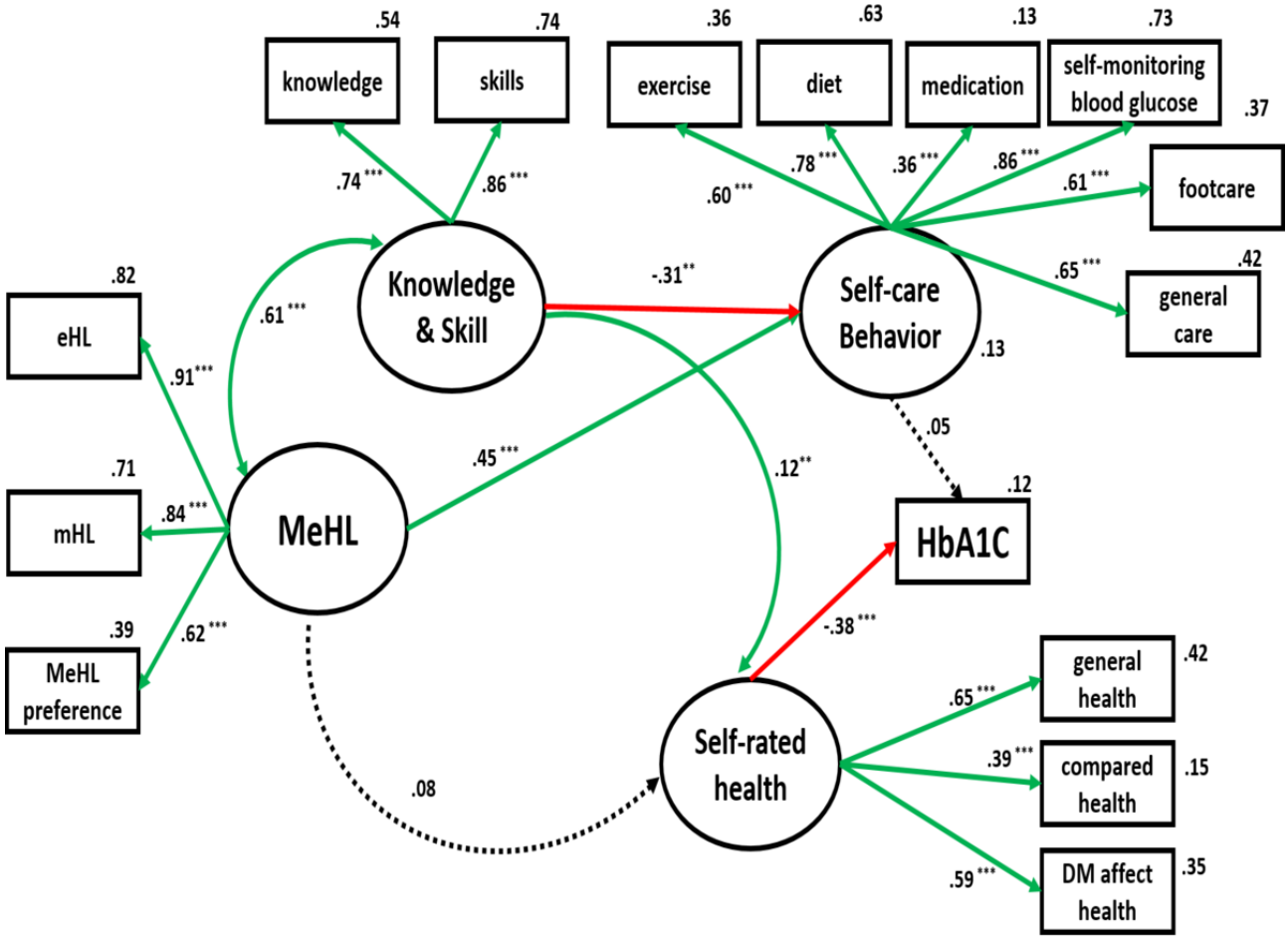
Figure 2. A pruned model of mobile eHealth literacy (MeHL), self-care behavior, and glycemic control. DM: diabetes mellitus; eHL: eHealth literacy; HbA_{1c}: glycated hemoglobin; mHL: mobile health literacy. *P=.01-.05, **P=.001-0.01<.01, ***P<.001.



Discussion

Principal Findings

Firstly, this study conducted a survey that measures mobile eHL and the use of health information technology. Most of the respondents had searched for online diabetes information previously, but only a few respondents had used health apps. Some demographic factors affecting mobile eHL included age, education, and duration of type 2 diabetes. Secondly, this study further examined the link between mobile eHL and health outcomes. Mobile eHL is related to self-care behaviors as well as knowledge and skills of computers, internet, and web mobile technology, but only has a weak, indirect effect on self-rated health. This highlights the value of mobile eHL as a crucial indicator of the ability to embrace health information technology. Finally, the participants with higher mobile eHL were more likely to achieve effective self-care behavior.

The Use of eHealth and mHealth Technology

The respondents reported using their smartphones for an average of 6.5 years, with an average daily use of 4.5 hours. Consistent with previous survey findings [5,28], our findings indicated that over 60% of the participants had looked for diabetes-related information on the internet, but only a very small portion had previously used health apps. Participant education level was high, with 60% of participants having at least a degree from college or university; participants also reported moderate confidence in using mobile eHealth technology. However, a comparison between smartphone use (96%) and mHealth app adoption (1.6%) seems to have a rather large discrepancy in this study. In other words, the mobile eHL results appear to be out of sync with their actual experience. It is possible that the participants were unfamiliar with current health apps. A national survey by Zhang et al [28] found that the awareness rate of diabetes apps was 29.94%, and usage was 15.44%. Another study also noted that many patients were unaware of mHealth apps [18]. These findings suggest that future diabetic populations should be made aware of available mHealth apps.

As expected, the results show that the participants with higher education had a greater level of mobile eHealth literacy, but the duration of type 2 diabetes had an inverse relationship with mobile eHealth literacy. These findings are also consistent with James and Harville's report [5]. Previous studies found [11,18,44] that patients experienced basic computer obstacles and perceived barriers in the use of diabetes apps. To further identify these potential hurdles, the mobile eHL measure proposed in this study can be used as an additional screening tool, serving as a strong proxy for identifying patients who need the most support in using health information and mHealth apps.

Above all, people with diabetes may need a clear reference for which apps to download and use; this reference can come from

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peers with diabetes and health care providers. Although most people use mobile apps daily, this does not necessarily mean that they would be able to employ an mHealth app for handling diabetes. For example, inputting blood glucose data in most diabetes apps requires one to complete several steps, including essential registration involving an email address, personal body weight, height, social security number, password, etc. These digital access and literacy disparity problems might diminish if clinical practitioners were responsible for mobile eHealth education. Also, several approaches might promote mHealth app engagement going forward; for example, social networking app strategies (eg, WhatsApp, Line, or WeChat) can be applied to mHealth apps to increase their popularity and effectiveness. Furthermore, researchers may consider sociodemographic factors such as education and age, which may differently influence people's acceptance of mobile eHealth technology.

SEM Analysis of the Relationship Between Mobile eHealth Literacy and Patient Outcomes

Testing of the hypotheses revealed a positive relationship between mobile eHealth literacy and self-care behavior. Our results are not directly comparable to previous studies on eHL models [16,24,25] since their results did not include mHealth app use literacy. Measures of mHL are relatively few, and its evidence is accumulating in this field.

Hypothesis 1, which states that higher mobile eHL is positively associated with knowledge and skills and increased self-care behaviors, was supported. The result demonstrated that higher mobile eHL only had an indirect connection to better self-rated health status. Similarly, Schulz et al [25] found that eHL was directly related to health information-seeking behavior and only indirectly related to health care system utilization. Critically, the interlocking relationship between mobile eHealth literacy and self-care behaviors can serve to disclose self-care practices. In short, mobile eHL may shape the behavioral responses of the diabetes population.

In more statistical terms, higher mobile eHL cannot be assumed to reduce HbA_{1c} in this study. The research linking eHealth literacy to health outcomes based on cross-sectional data [25,31,45] has mixed results. Another similar concept, health literacy, has neither a direct nor indirect effect on health outcomes (diabetes knowledge and glycemic control); it only has an indirect effect through its association with social support [27]. A recent study of chronic disease indicated that eHealth literacy was correlated to disease-related self-care behaviors [45]. A longitudinal design will provide an opportunity to determine the need to yield more evidence in such a situation.

Hypothesis 2 is just the opposite. Knowledge and skills of computers, the internet, and mobile technology was negatively related to self-care behaviors. Multimedia Appendix 3 shows that spending more time with smartphones was significantly related to poor self-care behaviors. Unfortunately, there are no similar studies to compare with the unexpected result that people with diabetes with higher knowledge and skills about technology will tend to exhibit fewer self-care behaviors. One possible explanation is that those who have higher skills and knowledge of computers, the internet, and web mobile technology may be more immersed in outward-looking technology, leading them, in turn, to pay less attention to self-care activities. Further studies are needed to address this possibility.

Unsurprisingly, the relationship between self-rated health status and glycemic control indicates that higher perceived health status was related to lower HbA_{1c}. However, HbA_{1c} cannot be predicted by self-care behaviors. Our results did not agree with the previous behavior-to-outcomes study [32]. The connections between psychodynamic variables and behavioral variables are complex, perhaps because HbA_{1c} is a 3-month average of glycemic levels, which is a much longer time frame than the other measured variables. More research is needed to elucidate the underlying factors between relationship models, such as adding time considerations.

The bivariate correlation results show more significant relationships than the results of the SEM model. Our results are in line with scholars [46] who have reported a difference between the correlation coefficient and the path coefficient of the SEM model. According to the tracing rule [46], the correlation between any pair of variables equals the sum of the products of the paths or correlations from each tracing. Thus, the significance levels of the variables in our hierarchical model are diminished when weak or negative relationships exist. Benitez et al [47] concluded that it remains indispensable to assess all path coefficients and their significance regardless of whether one performs confirmatory or explanatory research.

Limitations

A possible limitation of this study is that the adult subjects are from the outpatient departments of hospitals in Taiwan. Therefore, the study findings may not be generalized to other populations with diabetes. Other limitations include self-reports and a cross-sectional design, the latter precluding inference on causality. Thirdly, the selection of the participants was not random. Finally, this study did not analyze information on other factors believed to explain the relationship between mobile eHealth literacy and health outcomes in the SEM model.

Despite the above limitations, this study provides some meaningful results. Whereas some paths do not show the correlation between these variables, they do have an impact on the overall model. Many internet use aspects were examined, providing new information about the experiences, opinions, and attitudes of people with diabetes toward computers and the internet. In addition, for the first time, the factors of mobile eHealth literacy among people with diabetes were described and compared. This provides valuable insights into the eHealth literacy and the mHealth app experience of a population with diabetes.

Smart health technology can improve disease conditions. Assessing mobile eHealth literacy can help identify the gaps in knowledge and skills among patients with diabetes. Most patients with diabetes were less likely to use mHealth apps, and their mobile eHealth literacy was found to be moderate. This is a large group that can potentially use diabetes apps after enhancing their literacy. Their eHealth literacy was found to be moderate. Further research should identify more variables that

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mediate the relationship between mobile eHealth literacy and health care outcomes.

Implications

This study's main contribution to the body of knowledge is its enhancement of the mobile eHealth literacy model to understand the relationships of diabetes outcomes. The study highlights the importance of health professionals' awareness of this literacy so that they can appropriately tailor their interventions with patients. Providers can also serve as an educational source of support to enhance patients' health-related internet use abilities and to match suitable health information from the internet to the needs of patients with chronic conditions. The value of using health information technology to provide information for chronic disease self-management may be limited if it does not include support from health care providers.

The mobile mHealth literacy survey tool should be integrated into chronic care delivery, enabling health care providers to measure diabetes technology implementation. This knowledge will help to create a fuller conception of an analytical framework of mobile eHealth literacy.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH V1.6.1.
[PDF File (Adobe PDF File), 3270 KB - mhealth_v9i2e18404_app1.pdf]

Multimedia Appendix 2
Mobile eHealth literacy questionnaire.
[DOCX File , 16 KB - mhealth_v9i2e18404_app2.docx]

Multimedia Appendix 3
Correlation between mobile eHealth literacy (MeHL) variables and patients' outcomes (n=249). eHL: eHealth literacy; HbA_{1c}: glycated hemoglobin; mHL: mobile health literacy.
[DOCX File , 21 KB - mhealth_v9i2e18404_app3.docx]

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Abbreviations

CFI: comparative fit index
eHL: electronic health literacy
HbA_{1c}: glycated hemoglobin
mHL: mobile health literacy
mobile eHL: electronic health literacy and mobile health literacy
RMSEA: root mean square of approximation
SEM: structural equation model

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Original Paper

Effectiveness of the Family Portal Function on the Lilly Connected Care Program (LCCP) for Patients With Type 2 Diabetes: Retrospective Cohort Study With Propensity Score Matching

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Abstract

Background: Diabetes is a major health concern worldwide. Family member engagement in diabetes self-management education programs can improve patients' diabetes management. However, there is limited evidence that the family portal on diabetes management apps is effective in the glycemic control of patients with diabetes.

Objective: We aimed to evaluate the effectiveness of family support through the family portal function on Lilly Connected Care Program (LCCP) platform.

Methods: This retrospective cohort study included patients with type 2 diabetes recruited to the LCCP platform from September 1, 2018, to August 31, 2019. Propensity score matching was used to match family (group A) and non–family (group B) portal use groups with similar baseline characteristics. The patients were followed up with for 12 weeks. The main objectives were differences in mean fasting blood glucose, proportion of patients achieving fasting blood glucose target <7mmol/L, mean postprandial blood glucose, proportion of patients achieving postprandial blood glucose target <10mmol/L, proportion of patients achieving both fasting blood glucose <7mmol/L and postprandial blood glucose <10mmol/L, self-monitoring of blood glucose frequency at week 12 and the number of diabetes education courses patients completed during the 12 weeks. Moreover, logistic regression analysis was used to explore the baseline factors which may be associated with the use of family portal, and odds ratios with 95% confidence intervals were calculated.

Results: A total of 6582 adult patients (aged ≥18 years) with type 2 diabetes who were receiving insulin therapy were enrolled in the study. Overall, 6.1% (402/6582) of the patients chose to engage their family members to use the family portal. Two groups of 394 patients were well-matched regarding baseline characteristics. After matching, mean fasting blood glucose and postprandial blood glucose at week 12 were significantly lower in group A than in group B (fasting blood glucose: 7.12 mmol/L, SD 1.70 vs 7.42 mmol/L, SD 1.88, respectively, P=.02; postprandial blood glucose: 8.56 mmol/L, SD 2.51 vs 9.10 mmol/L, SD 2.69, respectively, P=.002). When comparing group A to group B, the proportion of patients achieving both fasting blood glucose <7mmol and postprandial blood glucose <10mmol/L at week 12 (46.8% vs 39.4%, respectively, P=.04), self-monitoring of blood glucose frequency at week 12 (8.92 times per week, SD 6.77 vs 8.02 times per week, SD 5.97, respectively, P=.05) and number of diabetes education courses completed in 12 weeks (23.00, IQR9.00-38.00 vs 15.00, IQR 4.00-36.00, respectively, P<.001) was higher. Additionally, multivariate logistic regression analysis showed that higher age (OR=0.987, 95% CI 0.978-0.996,

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P=.006) and higher baseline fasting blood glucose (OR=0.914, 95% CI 0.859-0.972, *P*=.004) were correlated with less use of the family portal function, while increased baseline self-monitoring of blood glucose frequency (OR=1.022, 95% CI 1.012-1.032], *P*<.001) as well as increased education courses (OR=1.026, 95% CI 1.015-1.036, *P*<.001) were associated with more use of the family portal function.

Conclusions: Family support through the LCCP family portal is effective for glycemic control and self-management behavior improvement in type 2 diabetes patients.

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KEYWORDS

diabetes management; diabetes mellitus; family support; mobile app; app; self-management; support; online portal; diabetes; cohort

Introduction

Background

Diabetes is a major health concern worldwide [1,2]. In 2013, the prevalence of diabetes in China was 10.4%, representing more than 100 million adults living with diabetes [3]. However, only 39.7% of those treated had ideal glycemic control [4]. Poor glycemic control leads to various complications [5] and brings heavy economic and social burden to the world. The global cost of diabetes was estimated to be up to US $1.31 trillion in 2015 [6].

Diabetes treatment depends on life-long self-management behaviors including maintaining a healthy diet, engaging in regular physical activity, self-monitoring blood glucose, and adhering to prescribed mediation routines [7], which are often inadequate and unsustainable [8]. Diabetes self-management education is critical for patients' self-management behaviors [9]. Because some patients have poor understanding and cooperation, interventions aiming to improve self-management behaviors are not always effectively implemented [10]. Another possible reason for poor self-management behaviors is the lack of diabetes-specific support from social networks, especially family members [11].

Family members can provide patients with financial support, emotional support, supervision and reminders of self-management behaviors, and instrumental support such as administering insulin injections [12,13]. The Chinese culture attaches great importance to the relationship between family members [14]. Confucianism beliefs recognize that everyone is naturally born to, grows up in, and is taken care of within a family [15]. This cultural context makes it so that family members play a key role in diabetes management. Family member engagement in diabetes self-management education programs can improve patients' self-management behaviors, quality of life, and glycemic control [16-18]. Studies have also shown that family-model diabetes self-management education is superior to conventional diabetes education that only involves patients [19,20]. However, family members, especially young members, cannot always participate in diabetes management programs that require onsite visits for long periods of time [11].

Mobile apps can receive and transmit information at any time and any place. With the popularity of smartphones, mobile apps represent a promising technology for supporting diabetes management [21]. Many diabetes management apps provide interhuman communications, blood sugar records, diabetes education, and more [22]. Some diabetes management apps have family portals through which family members can (1) view the blood glucose records of the patient, (2) provide support in diabetes management, and (3) receive diabetes self-management education [23,24]. However, there is limited evidence that the family portals of diabetes management apps are effective in the glycemic control of patients with diabetes, and the characteristics of patients who invite their family members to engage in diabetes management through family portals on diabetes management apps are not very clear.

The Lilly Connected Care Program (LCCP) is a national diabetes care and support program delivered by the LCCP official account on China's largest social app, WeChat. There are more than 60 diabetes education courses created by experts in accordance with the standards of medical care for type 2 diabetes mellitus in China on the LCCP platform. Insulin therapy is the cornerstone of treatment for patients with type 2 diabetes who fail to obtain target glycemic control with oral hypoglycemic agents or for patients who are contraindicated for oral hypoglycemic agents [25]. Our previous study [26] has found that LCCP app-based diabetes education is effective for glycemic control and can improve self-monitoring of blood glucose behavior in patients with type 2 diabetes receiving insulin therapy. Through the family portal function on the LCCP platform, patients can choose to engage family members in their diabetes management.

Objective

The aim of this study is to evaluate the effectiveness of family support through the family portal on the LCCP platform for patients using insulin therapy.

Methods

Research Design and Samples

This retrospective cohort study included patients with diabetes recruited to the LCCP platform from September 1, 2018 to August 31, 2019. Patients with diabetes receiving insulin treatment were encouraged by their doctors to register on the LCCP platform. Patient demographic and disease information, including age, gender, education level, type of diabetes, insulin regimen, and duration of diabetes, were collected after provision of written informed consent. The patients in this study were followed up with for 12 weeks. Eligible samples were adult

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type 2 diabetes patients (aged ≥18 years) with fasting blood glucose and postprandial blood glucose levels recorded using the LCCP platform at least once a week at week 1 and week 12. Patients with type 1 diabetes, patients aged <18 years, and those with missing data on gender, age, education level, type of diabetes, and diabetes duration were excluded from the study.

Intervention

All the patients recruited to the LCCP platform were able to record their blood glucose and take more than 60 diabetes education courses on the LCCP platform. The patients were all informed of the function of the LCCP family portal when recruited and voluntarily chose to engage their family members to use the family portal connected to their private LCCP account. Patient self-monitoring of blood glucose data were automatically sent to the family portal in real time. Family members using the family portal were able to view the patients' blood glucose records and diabetes education course learning records, take the diabetes education courses, and participate in 2-way communications with the patients through the family portal.

Outcome Measurements

Patients recruited to the LCCP platform were all provided with a free intelligent glucometer. Self-monitoring of finger-prick capillary blood glucose was assessed according to the glucose dehydrogenase method using a glucometer (Bionime Biotechnology [Ping Tan] Co, Ltd, Fuzhou City, China). The patients were trained to test their fasting blood glucose and postprandial blood glucose correctly to reduce subject bias. Patient self-monitoring of blood glucose data were automatically transmitted to the LCCP platform through mobile signals. The coefficient of variation of the measurement was below 5%, and the accuracy was in accordance with ISO 15197:2013 [27]. The patients were divided into 2 groups: group A (the family portal use group) and group B (the non–family portal use group). We defined patient baseline fasting blood glucose and postprandial blood glucose as the mean fasting blood glucose and mean postprandial blood glucose at the first week after recruitment. The primary outcomes were differences between group A and group B in mean fasting blood glucose, mean postprandial blood glucose, proportion of patients achieving fasting blood glucose <7 mmol/L, proportion of patients achieving postprandial blood glucose <10 mmol/L, proportion of patients achieving both fasting blood glucose <7 mmol/L and postprandial blood glucose <10 mmol/L, frequency of self-monitoring of blood glucose at week 12, and difference in the number of diabetes education courses that the patients completed in the 12 weeks of the study.

Ethics

All patients provided written informed consent when they were recruited to the LCCP platform. The study conformed to Declaration of Helsinki principles and was approved by the ethics committee of the Second Xiangya Hospital.

Propensity Score Matching

Propensity score matching was used to match group A (the family portal use group) and group B (the non–family portal use group) with similar baseline characteristics. The propensity score was calculated using a multivariable logistic regression model, with the use of family portal as the dependent variable and potential confounding factors as covariates, including age, gender, education level, insulin regimen, duration of diabetes, baseline fasting blood glucose, baseline postprandial blood glucose, and baseline self-monitoring of blood glucose frequency. Because we defined patient baseline blood glucose as the mean blood glucose level in the first week, and as our previous study found that taking the diabetes education courses on the LCCP platform can influence patients' glycemic control, we also included the number of diabetes education courses that the patients completed in the first week as a covariate in the logistic regression model. Matching was performed on a ratio of 1:1 using a nearest-neighbor algorithm with no replacement (Greedy 8-1 digit match algorithm), with a caliper width of 0.02. Once a match was made, patients were not reconsidered for further matching. Standardized mean differences were used to assess comparability of the 2 groups on each confounding variable after matching. A standardized mean difference of less than 10.0% for a given covariate indicates a balance between groups [28,29].

Statistics

Continuous variables with normal or near-normal distributions are presented as means with standard deviations. Variables with nonnormal distributions are presented as medians with IQRs. Categorical variables are presented as the frequency (number of cases, n) and percentage (%) of total study patients. Chi square test was used for categorical variables; t test and paired t test were used for continuous variables with normal distribution before and after matching, respectively; Wilcoxon rank-sum test and Wilcoxon signed-rank test were used for continuous variables with nonnormal distribution before and after matching, respectively. These tests were used to compare baseline characteristics and outcome measurements at week 12 between the 2 groups. The baseline factors which may have been associated with family portal use were explored using univariate and multivariate logistic regression models, and odds ratios with 95% confidence intervals were calculated. Statistical analysis was performed using SAS 9.4 software (SAS Institute, North Carolina, USA) via SAS Enterprise Guide version 7.1. *P* values ≤.05 were considered statistically significant.

Results

Patient Characteristics at Baseline

A total of 6582 adult patients (aged ≥18 years) with type 2 diabetes who were receiving insulin therapy were enrolled in the study. The samples were recruited from 31 provinces across China. Figure 1 shows the patient inclusion flow diagram. Among the total participants, 56.3% (3705/6582) were male. The median age was 53.07 years (IQR 43.81-61.10 years), and the median disease duration was 27.67 months (IQR 1.23-114.17 months). The mean fasting blood glucose at baseline was 7.76 (SD 2.21) mmol/L, and the mean postprandial blood glucose was 9.51 (SD 2.88) mmol/L. The mean frequency of self-monitoring of blood glucose at baseline was 13.63 (SD 9.18) times per week (see Table 1).

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Figure 1. Patient inclusion flow diagram.

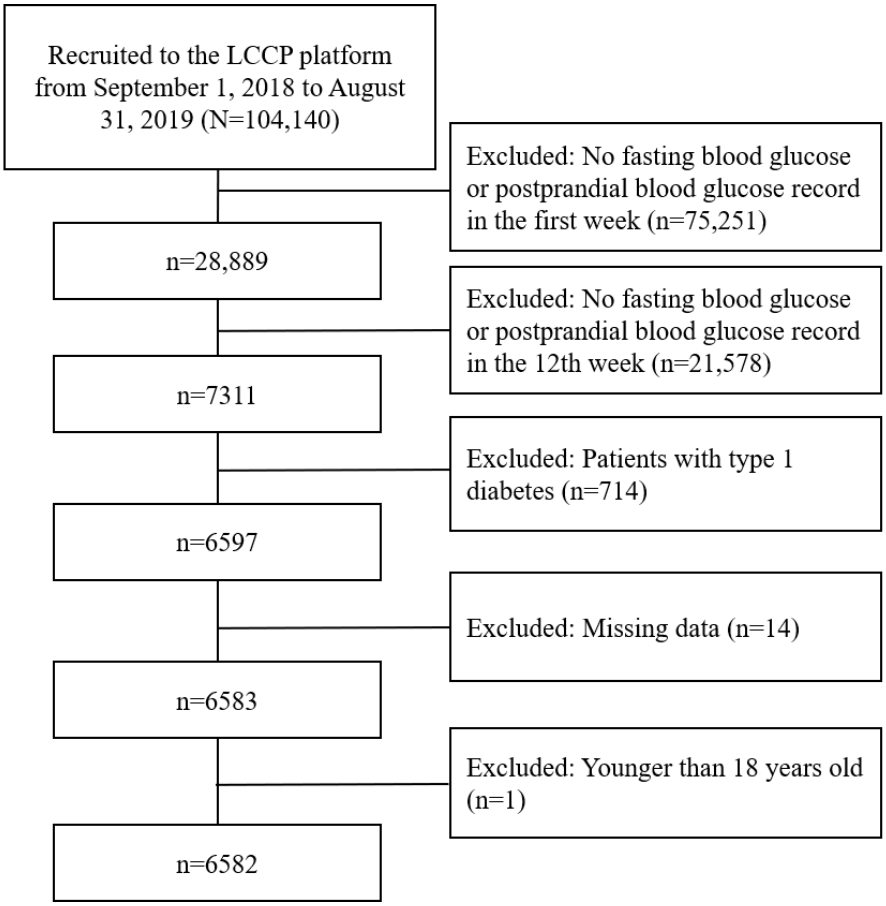

Table 1. Patient characteristics at baseline (N=6582).

Variable	Value[a]
Gender, n (%)	
Male	3705 (56.3)
Female	2877 (43.7)
Education, n (%)	
Junior middle school or below	1830 (27.8)
High school	2165 (32.9)
College or above	2587 (39.9)
Age, mean years (IQR)	53.07 (43.81-61.10)
Baseline fasting blood glucose, mmol/L (SD)	7.76 (2.21)
Baseline postprandial blood glucose, mmol/L (SD)	9.51 (2.88)
Duration of diabetes, months (IQR)	27.67 (1.23-114.17)
Baseline self-monitoring of blood glucose frequency, times per week	13.63 (SD 9.18)
Insulin regimen, n (%)	
Premixed insulin	5240 (79.6)
Fast-acting insulin (with/without long-acting insulin)	1342 (20.4)
Baseline education courses, n (IQR)	2.0 (1.0-5.0)

[a]Continuous variables are presented as means with standard deviations or medians with IQRs, and categorical variables are presented as n (%).

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Comparisons of Baseline Characteristics Between the Family Portal Use Group and Non–Family Portal Use Group After Matching

Overall, 6.1% (402/6582) of the patients chose to engage their family members to use the family portal. With the use of propensity score matching, 394 family portal use patients were matched with 394 non–family portal use patients. After propensity score matching, gender (*P*=.61), age (*P*=.38), education level (*P*=.54), duration of diabetes (*P*=.49), insulin regimen (*P*=.47), fasting blood glucose (*P*=.51), postprandial blood glucose (*P*=.34), self-monitoring of blood glucose frequency (*P*=.75), and the number of diabetes education courses completed (*P*=.44) showed no significant differences at baseline between the 2 groups, and the standardized mean differences were <10.0% for all variables, indicating a good balance between the 2 groups at baseline (see Table 2).

Table 2. Comparisons of baseline characteristics between group A (the family portal use group) and group B (the non–family portal use group) after matching.

Variable[a]	Group A (n=394)	Group B (n=394)	Standardized mean difference, %	*P* value
Gender, n (%)				.61
Male	232 (58.9)	225 (57.1)	3.59	N/A[b]
Female	162 (41.1)	169 (42.9)	3.59	N/A
Education, n (%)				.54
Junior middle school or below	95 (24.1)	82 (20.8)	7.91	N/A
High school	126 (32.0)	133 (33.8)	3.79	N/A
College or above	173 (43.9)	179 (45.4)	3.06	N/A
Age, years (IQR)	50.16 (42.34-58.46)	50.69 (42.20-60.02)	7.62	.38
Baseline fasting blood glucose, mmol/L (SD)	7.44 (1.91)	7.50 (1.88)	2.96	.51
Baseline postprandial blood glucose, mmol/L (SD)	9.40 (2.82)	9.55 (2.84)	5.25	.34
Duration of diabetes, months (IQR)	18.84 (1.10-100.27)	25.92 (1.33-108.20)	4.72	.49
Baseline self-monitoring of blood glucose frequency, times per week (SD)	16.20 (10.30)	16.33 (10.22)	1.29	.75
Insulin regimen, n (%)				.47
Premixed insulin	324 (82.2)	316 (80.2)	5.2	N/A
Fast-acting insulin (with/without long-acting insulin)	70 (17.8)	78 (19.8)	5.2	N/A
Baseline education courses, n (IQR)	3.0 (1.0-9.0)	2.0 (1.0-8.0)	1.83	.44

[a]Continuous variables are presented as means with standard deviations or medians with IQRs, and categorical variables are presented as n (%).

[b]N/A: not applicable.

Effectiveness of LCCP Family Portal

Before matching, compared with the non–family portal use group, the family portal use group had lower fasting blood glucose (7.10 mmol/L, SD 1.70 vs 7.48 mmol/L, SD 2.03, *P*<.001); lower postprandial blood glucose (8.57 mmol/L, SD 2.81 vs 8.97 mmol/L, SD 2.78, *P*=.002); a higher proportion of patients achieving fasting blood glucose target <7mmol/L (52.7% vs 47.4%, *P*=.04), postprandial blood glucose target <10mmol/L (77.6% vs 71.5%, *P*=.009), and both fasting blood glucose <7mmol/L and postprandial blood glucose <10mmol/L (47.5% vs 40.7%, *P*=.008); and higher self-monitoring of blood glucose frequency (8.94 times per week, SD 6.72 vs 8.01 times per week, SD 5.85, *P*=.007) at week 12 and a higher number of diabetes education courses completed in the entire 12 weeks (23.5 courses, IQR 10.0-38.0 vs 13.0 courses, IQR 4.0-33.0, *P*<.001). After controlling for baseline potential confounders using propensity score matching, fasting blood glucose and postprandial blood glucose at week 12 were still significantly lower in the family portal use group than in the non–family portal use group (fasting blood glucose: 7.12 mmol/L, SD 1.70 vs 7.42 mmol/L, SD 1.88, respectively, *P*=.02; postprandial blood glucose: 8.56 mmol/L, SD 2.51, vs 9.10 mmol/L, SD 2.69, respectively, *P*=.002). The proportion of family use group patients achieving both fasting blood glucose <7mmol and postprandial blood glucose <10mmol/L was higher than that of non–family use group patients (46.8% vs 39.4%, respectively, *P*=.04), as was the self-monitoring of blood glucose frequency at week 12 (8.92 times per week, SD 6.77, vs 8.02 times per week, SD 5.92, respectively, *P*=.050) and number of diabetes education courses completed in 12 weeks (23.0 courses, IQR 9.0-38.0, vs 15.00 courses, IQR 4.0-36.0, respectively, *P*<.001) (see Table 3).

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Table 3. Comparison of the outcomes at the 12th week between group A (the family portal use group) and group B (the non–family portal use group) before and after matching.

Outcome[a]	Before matching			After matching		
	Group A (n=402)	Group B (n=6180)	*P* value	Group A (n=394)	Group B (n=394)	*P* value
Fasting blood glucose (12th week), mmol/L (SD)	7.10 (1.70)	7.48 (2.03)	<.001	7.12 (1.70)	7.42 (1.88)	.02
Fasting blood glucose <7 mmol/L (12th week), n (%)	212 (52.7%)	2931 (47.4%)	.04	204 (51.9%)	178 (45.3%)	.07
Postprandial blood glucose (12th week), mmol/L (SD)	8.57 (2.81)	8.97 (2.78)	.002	8.56 (2.51)	9.10 (2.69)	.002
Postprandial blood glucose <10 mmol/L (12th week), n (%)	312 (77.6%)	4417 (71.5%)	.009	304 (77.4%)	287 (73.0%)	.19
Fasting blood glucose <7 mmol/L and postprandial blood glucose <10 mmol/L (12th week), n (%)	191 (47.5%)	2513 (40.7%)	.008	184 (46.8%)	155 (39.4%)	.04
Self-monitoring of blood glucose frequency (12th week), times per week (SD)	8.94 (6.72)	8.01 (5.85)	.007	8.92 (6.77)	8.02 (5.97)	.05
Education courses, n (IQR)	23.5 (10.0-38.0)	13 (4.0-33.0)	<.001	23 (9.0-38.0)	15 (4.0-36.0)	<.001

[a]Continuous variables are presented as means with standard deviations or medians with IQRs, and categorical variables are presented as n (%).

Analysis of Baseline Factors Associated With the Use of Family Portal

To further investigate the baseline factors correlating with the use of family portal, we performed univariate and multivariate model regression analyses. According to the univariate model regression analysis, junior middle school education or below (OR=0.754, *P*=.03), increased age (OR=0.982, *P*<.001), higher baseline fasting blood glucose (OR=0.92, *P*=.002), and longer duration of diabetes (OR=0.999, *P*=.03) were associated with a smaller number of patients using the family portal function, while increased self-monitoring of blood glucose frequency (OR=1.031, *P*<.001) and increased education courses (OR=1.032, *P*<.001) were associated with elevated number of patients using the family portal function (see Table 4). Moreover, multivariate logistic regression analysis showed that higher age (OR=0.987, *P*=.006) and higher baseline fasting blood glucose (OR=0.914, *P*=.004) were independent factors correlating with less use of the family portal function, while increased self-monitoring of blood glucose frequency (OR=1.022, *P*<.001) as well as increased education courses (OR=1.026, *P*<.001) were independent predictive factors for greater use of the family portal function (see Table 4).

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Table 4. Baseline factors associated with the use of family portal according to logistic regression analysis.

Variable	Univariate model OR (95% CI)	*P* value	Multivariate model OR (95% CI)	*P* value
Gender				
Male	1.148 (0.935-1.410)	.19	1.075 (0.873-1.324)	.50
Female	Reference	N/A[a]	Reference	N/A
Education				
Junior middle school or below	0.754 (0.584-0.974)	.03	0.863 (0.664-1.121)	.27
College or above	0.863 (0.682-1.091)	.22	0.938 (0.738-1.191)	.60
High school	Reference	N/A	Reference	N/A
Age	0.982 (0.974-0.990)	<.001	0.987 (0.978-0.996)	.006
Baseline fasting blood glucose	0.920 (0.873-0.969)	.002	0.914 (0.859-0.972)	.004
Baseline postprandial blood glucose	0.985 (0.950-1.021)	.40	1.039 (0.995-1.085)	.08
Duration of diabetes (months)	0.999 (0.997-1.000)	.03	1.000 (0.999-1.001)	.84
Baseline self-monitoring of blood glucose frequency	1.031 (1.022-1.041)	<.001	1.022 (1.012-1.032)	<.001
Insulin regimen				
Premixed insulin	1.016 (0.790-1.306)	.90	1.089 (0.844-1.407)	.51
Fast-acting insulin (with/without long-acting insulin)	Reference	N/A	Reference	N/A
Baseline education courses	1.032 (1.022-1.042)	<.001	1.026 (1.015-1.036)	<.001

[a]NA: not applicable.

Discussion

Principal Findings

We evaluated the effectiveness of family support through the family portal on the LCCP platform for patients receiving insulin therapy and found that the family portal on the LCCP platform was effective for glycemic control. Before propensity score matching, the family portal use group had lower fasting blood glucose, lower postprandial blood glucose, a higher percentage of participants who achieved fasting blood glucose and postprandial blood glucose control targets, separately, and a higher percentage of participants who achieved both fasting blood glucose and postprandial blood glucose control targets at the same time after 12 weeks of intervention compared with the non–family portal used group. However, those choosing to engage their family members in the use of the LCCP family portal might be more active in glycemic control. Thus, we controlled for baseline potential confounders by propensity score matching, including baseline blood glucose, age, gender, duration of diabetes, insulin regimen, and self-monitoring of blood glucose frequency. After matching, the two cohorts were well-matched regarding baseline characteristics, and both fasting blood glucose and postprandial blood glucose at week 12 of the family portal use group were lower and more patients were achieving blood glucose control targets of both fasting blood glucose and postprandial blood glucose at the same time at week 12 as compared to the non–family portal use group. These data indicate that the family portal function on LCCP platform contributes to the glycemic control of diabetes patients receiving insulin therapy.

Studies have shown that family members' support is related to patients' self-management behavior and glycemic control [30]. In our study, family members can take diabetes education courses through the family portal on the LCCP platform. Obtaining more diabetes management knowledge makes it easier for family members to provide regimen-related decision-making and problem-solving support, and family members with more knowledge about diabetes tend to perform more diabetes-specific supportive behaviors [31], including support in meal planning and encouragement of regular physical activity. In addition, we found that the family portal use group took more diabetes education courses on the LCCP platform and had higher self-monitoring of blood glucose frequency at 12 weeks before and after propensity-score matching compared to the non–family portal use group. These could be the possible mechanisms by which the use of the family portal led to glycemic control improvement. Many studies have suggested that diabetes education can improve glycemic control and self-management behaviors of patients [32-35]. Family members can monitor the behavior of patients' diabetes education course learning through the family portal, and the study by McElfish et al [19] has revealed that family-model diabetes self-management education shows better effects than standard diabetes self-management education [19]. The family-model can increase the time of exposure to diabetes self-management education, and increased time of exposure to leads to improved glycemic control in patients [20]. The diabetes education courses on the LCCP platform cover patients' self-care behaviors according to the American Association of Diabetes Educators 7 Standard of Care. Our previous study has also found that patients taking more diabetes education courses on the LCCP platform had better glycemic control [26].

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Self-monitoring of blood glucose is an important part of diabetes self-management in patients receiving insulin therapy; it is useful for patients for adjusting insulin dosage and guiding nutrition therapy and physical activity [36]. The family portal use group had a higher frequency of self-monitoring of blood glucose, possibly because they took more diabetes education courses on the LCCP platform and received telemonitoring from their family members through the family portal. Taking more diabetes education courses could have increased their awareness of the importance of self-monitoring of blood glucose. Previous studies have revealed that diabetes self-management education can improve patients' self-management behaviors, including self-monitoring of blood glucose [9,33]. However, some patients may not attach much importance to self-monitoring of blood glucose [37]. Family members can provide real-time telemonitoring and may be able to remind patients to self-monitor their blood glucose behaviors. Aikens' study [38] has found that integrating support persons into diabetes telemonitoring can improve patients' self-management and medication adherence. This may be particularly helpful for those living out of home and for long-distance family members [39].

Some mobile health solutions now allow patients to invite family members as support persons in disease management. However, few studies have examined characteristics of patients who choose to engage a support person in their healthcare [39]. Our study found that patients with decreased age, lower baseline fasting blood glucose level, higher self-monitoring of blood glucose frequency, and more completed education courses were more likely to use the family portal. Previous studies [40-42] have found that younger patients have a higher usage of diabetes management apps. One study using text messaging to engage family members in diabetes self-management support also found that participants who invited a support person were younger than those who did not [39]. Young patients may be more receptive to new technologies and, as such, may be more inclined to use new technologies with their families in order to manage their diabetes. Otherwise, we observed that lower baseline fasting blood glucose levels were associated with the tendency for participants to invite family members to use the family portal. The reasons for this are not quite clear. A similar negative association of baseline fasting blood glucose with use of mobile app is also observed in another study [43], which infers that the patients with higher fasting blood glucose levels were more reticent to share the high values with their family members, and this fact may explain our results. Moreover, patients with higher self-monitoring of blood glucose frequency may have more initiative in their disease management and raised awareness of their disease after their frequent monitoring; therefore, they may tend to invite family members to participate in their disease management. Additionally, patients who have completed more education courses have obtained more knowledge on diabetes as well as a fuller understanding of the family portal in the LCCP platform compared with those with less education courses; thus, they may be willing to invite their family members to participate in their disease management.

The proportion of patients who invited their family members to participate using the family portal was very low. The possible reasons are as follows: first, although patients were all informed of the function of LCCP family portal, many family members still did not know they were able to view the patients' blood glucose records and diabetes education course learning records by using the family portal connected to their private LCCP account; second, some patients may be unwilling to be monitored by their family members or to bother their family members too much. We may further investigate the possible reasons for the very low usage of the family portal and explore the factors that influence family members to join the family portal on the LCCP platform to improve the app's design.

Although randomized control trials are generally considered to show the most reliable evidence for medical research, they often fail to reflect real-world clinical practice [44,45]. Our study was based on real-world data, and we adjusted the potential confounding factors at baseline by propensity-score matching. Thus, our study can be used as evidence for the efficacy of the family portal function in addition to evidence gathered through randomized controlled trials.

Limitations

Our study has several limitations. First, our observation period was short. The long-term effect of the LCCP family portal needs further investigation, and future studies could use glycosylated hemoglobin as an indicator of blood glucose control. Second, we only investigated the characteristics of patients; the characteristics of family members (such as age, education level, and history of diabetes) were not investigated. In addition, we did not assess the degree of family members' engagement in the LCCP family portal, despite the fact that the degree of engagement could directly influence the intervention effects.

Conclusions

The LCCP family portal is effective for glycemic control and self-management behavior improvement in patients with type 2 diabetes receiving insulin therapy. It is convenient and timesaving for family members to use app-based family portals to provide diabetes management support. The family portal has great potential to be used as a supplement to traditional social support for diabetes management.

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Conflicts of Interest

YXY and XM report being employees of Eli Lilly and Company. The other authors have no competing financial interests or conflicts of interest to disclose.

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Abbreviations

LCCP: Lilly Connected Care Program

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Original Paper

Efficiency of an mHealth App and Chest-Wearable Remote Exercise Monitoring Intervention in Patients With Type 2 Diabetes: A Prospective, Multicenter Randomized Controlled Trial

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Abstract

Background: Exercise has been recommended as a cornerstone for diabetes management. Supervised exercise is more efficient than unsupervised exercise but is less convenient and accessible.

Objective: We aimed to determine the efficiency of exercise using a fitness app and heart rate band to remotely monitor patients with type 2 diabetes in comparison with that of traditional exercise.

Methods: Patients with type 2 diabetes without severe complications or comorbidities were recruited to participate in this multicenter randomized controlled trial and were allocated to either the intervention or control group (1:1 ratio). Participants in both groups were asked to engage in moderate to vigorous physical activity for at least 150 minutes per week; each participant was prescribed individualized exercises. Participants in the intervention group were asked to follow exercise videos on the app and to wear a chest band; heart rate, exercise duration, and exercise intensity were recorded by the app. Participants in the control group self-reported exercise intensity and duration. Cardiopulmonary endurance, body composition, blood glucose level, and insulin level were assessed before and after a 3-month exercise program.

Results: Of the 101 participants who were enrolled, the majority of them (85/101, 84.2%) completed the study. Both groups had similar baseline characteristics, with the exception that participants in the intervention group were slightly younger and less likely to have hypertension. Self-reported exercise duration was longer than app-recorded exercise duration (control: mean 214 minutes/week; intervention: mean 193 minutes/week); in addition, a higher proportion of participants in the control group (29/41, 71%) than in the intervention group (18/44, 41%) met the 150-minute target for moderate to vigorous physical activity. However, compared with the control group, the intervention group had a larger increase in cardiopulmonary endurance (mean difference –2.0 bpm [beats per minute] vs 1.0 bpm; P=.02) and a larger decrease in body fat percentage (mean difference –1.8% vs –0.8%; P=.01). There was no difference in hemoglobin A1c level reduction between the two groups, yet more participants in the intervention group stopped taking their antidiabetic drugs or had their dosages lowered by an endocrinologist, compared with those in the control group. There were no serious adverse events in either group.

Conclusions: This was the first randomized controlled trial in China, to our knowledge, to test the efficiency of exercise using a fitness app and heart rate band to remotely monitor prescribed exercise in patients with type 2 diabetes. The findings of our

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study suggest that exercise programs may be more efficient if participants are remotely monitored with an app and heart rate band than if participants are not monitored.

Trial Registration: Chinese Clinical Trial Register ChiCTR1800015963; http://www.chictr.org.cn/showprojen.aspx?proj=27080

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KEYWORDS

type 2 diabetes; fitness app; heart rate band; exercise monitoring; randomized controlled trial; mobile phone

Introduction

Cardiovascular disease and microvascular complications related to type 2 diabetes are significant causes of premature mortality and morbidity, resulting in a heavy economic burden [1,2]. Lack of physical activity is a risk factor for the development of type 2 diabetes [3], but exercise is effective in both preventing and managing type 2 diabetes [4]; exercise improves blood glucose, reduces cardiovascular risk factors, and improves cardiorespiratory fitness [5]. Therefore, exercise has been recommended as a cornerstone of diabetes management [6,7].

Many factors, including exercise frequency, intensity, duration, type, and volume, have an influence on the efficiency of exercise [8]. Individuals are likely to benefit more from regular exercise that is longer in duration, of greater intensity, or both [9]. Consequently, accurate monitoring and quantification of exercise intensity, duration, and adherence affect exercise efficiency. Supervised exercise, such that the features of exercise and its adherence are monitored by trained staff, is typically performed in specialized facilities. Although unsupervised exercise is more convenient, it may be less efficient. One study [10] found that, compared with participants engaged in unsupervised exercise, those who engaged in supervised aerobic and resistance exercise demonstrated greater improvements in hemoglobin A_{1c} (HbA_{1c}) level, blood pressure, BMI, waist circumference, and other metabolic parameters. The American Diabetes Association recommends supervised exercise, when feasible, for patients with type 2 diabetes [8].

However, the majority of patients with diabetes do not have access to supervised exercise, because it requires trained staff, typically requires specific facilities, and is more expensive than unsupervised exercise. The widespread use of fitness apps and wearable technology in recent years may facilitate the objective monitoring of physical activity. To our knowledge, no studies have examined the efficiency of exercise that is monitored using a fitness app with wearable technology in patients with type 2 diabetes in China. We hypothesized that exercise supervised through remote monitoring using a fitness app and heart rate band would be more efficient than traditional unsupervised exercise in improving cardiopulmonary endurance, body composition, and blood glucose level control in type 2 diabetes patients.

Methods

Study Design

We conducted a prospective, multicenter randomized controlled trial (RCT); the trial was registered with the Chinese Clinical Trial Registry (ChiCTR1800015963). We recruited participants from four tertiary care hospitals—West China Hospital, Chengdu Second People's Hospital, Chengdu First People's Hospital, and Chengdu Branch in Tibet of Huaxi Hospital Affiliated with Sichuan University—in Chengdu, China, through advertising or from endocrinology clinics from September to October 2018. After telephone screening, eligible participants were invited to an orientation session, in which detailed information about the study was provided to potential participants, and informed consent forms were signed by individuals who agreed to participate. Participants aged 18 to 64 years old were included if they met all of the following criteria:

1. Their type 2 diabetes diagnosis was confirmed with an oral glucose tolerance test after recruitment into the study.
2. They had been diagnosed with diabetes 10 years or less prior to the study.
3. They had access to a smartphone that was capable of running the app used in the study.

We used American Diabetes Association criteria for the diagnosis [6], and we chose a limit of 10 years or less since their diabetes diagnosis in order to exclude individuals with advanced diabetes. In addition, individuals with any of the following conditions were excluded:

1. Fasting plasma glucose level greater than 16.7 mmol/L.
2. Recurring hypoglycemia.
3. A history of acute diabetic complications, including diabetic ketoacidosis, hyperosmolar hyperglycemia, and lactic acidosis.
4. A history of severe chronic micro- or macrovascular complications.
5. Diseases that may be exacerbated by exercise or influence exercise efficiency, such as uncontrolled hypertension, hyperthyroidism, osteoarthritis, or hypokalemia.
6. Another medical condition that was judged by the researchers to preclude participation.

The study was approved by the Research Ethics Board of the West China Hospital of Sichuan University.

Randomization

After initial screening and signing informed consent forms, participants were randomly assigned to either the intervention group or the control group. Allocation was performed using four sets of pregenerated randomization schedules that corresponded to the four participating hospital outpatient clinics, with varying block sizes of 2, 4, and 6.

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Procedure

Questionnaires were completed by each participant, and exercise testing was performed on every participant before the start of the exercise programs. The questionnaire was designed to collect information about exercise habits, diet, and lifestyle. Exercise tests that were assessed included resting heart rate measurement, step testing, and muscular endurance. All participants were prescribed a target of 150 minutes per week of moderate to vigorous physical activity based on American College of Sports Medicine guidelines [9] and the information provided by questionnaire responses and from exercise tests. Participants were informed that they would likely see greater improvements if they were able to achieve a target of 300 minutes of moderate to vigorous physical activity or above per week. Both aerobic and resistance exercise, with at least 10 minutes of aerobic exercise each session, were recommended to every participant.

Participants in the intervention group downloaded the R Plus Health app (Recovery Plus Inc), which connected wirelessly to a chest-worn heart rate band (Recovery Plus Inc) to measure exercise frequency, intensity, time, volume, and progression. Although prescribed exercise programs were explained to each participant verbally by the researchers at the start of the study, participants in the intervention group were also sent exercise programs through the app. Individualized exercises were demonstrated with videos on the app. Participants in the intervention group were asked to follow the exercise videos on the app and wear the heart rate band when exercising to determine whether they had reached their target heart rate. The target heart rate (HR_{target}), estimated using the heart rate reserve method, was calculated as follows:

$$HR_{target} = (HR_{max} - HR_{rest}) \times intensity\% \ (40\% \text{ to } 90\%) + HR_{rest}$$

The maximum heart rate (HR_{max}) was estimated as follows:

$$HR_{max} = 220 - age$$

and resting heart rate (HR_{rest}) was measured during initial exercise testing. The app notified the user during exercise as to whether they needed to adjust their workload to achieve the target heart rate, automatically calculated the cumulative time of exercise that reached the target heart rate, and showed the remaining amount of exercise required for that week to meet the target. The user interface of the R Plus Health app is shown in Multimedia Appendix 1, Figures S1-S4.

Participants in the control group self-reported exercise intensity, which they determined using a modified Borg Scale of Perceived Exertion. A diary was given to the participants in the control group to record the exercise duration and intensity, and the information in the diary was collected during monthly follow-ups.

Participants in both groups were followed up by telephone every month. Blood glucose levels were recorded, and endocrinologists reviewed and adjusted medication dosages, if necessary. Participants were followed up for 3 months.

Outcomes

The primary outcomes were body fat percentage and cardiorespiratory endurance. Secondary outcomes were blood glucose level, insulin level, homeostasis model assessment of insulin resistance (HOMA-IR), muscle strength, and cholesterol level. Primary and secondary outcome measures were assessed before and after the exercise programs. Cardiorespiratory endurance was evaluated using a YMCA 3-minute step test. Muscle strength was assessed using the Baseline hydraulic grip handheld dynamometer, model 12-0240 (Fabrication Enterprises, Inc). Body fat percentage was measured using the Lunar iDXA dual-energy x-ray absorptiometer (GE Healthcare). All the tests were conducted before and after the intervention. Both cardiorespiratory and muscle strength assessments were performed by trained researchers at a study hospital site. Safety events and drug adjustments were recorded for both groups.

Statistical Analysis

Statistical analyses were performed using Stata, version 15.1 (StataCorp LLC). Either the chi-square test or the Fisher exact test was used for categorical variables, and *t* tests were used for continuous variables. *P* values of .05 or less were considered statistically significant.

Results

A total of 119 patients were assessed for eligibility, of which 101 individuals met the inclusion criteria and were randomized to either the intervention group (55/101, 54.5%) or the control group (46/101, 45.5%); 85 participants out of 101 (84.2%) completed the study: 44 (52%) from the intervention group and 41 (48%) from the control group. Of the 16 participants out of 101 (15.8%) who did not complete the study, 11 (69%) from the intervention group and 5 (31%) from the control group dropped out of the study (see Figure 1).

Demographic characteristics of the study population are presented in Table 1; the mean age of the participants was 48.2 years (SD 10.4), 76.2% (77/101) were male, and 23.8% (24/101) were female. The mean HbA_{1c} was 7.3% (SD 1.8), the mean BMI was 25.2 kg/m^2 (SD 3.6), and the mean duration since diabetes diagnosis was 46.9 months (SD 41.5). A total of 24.8% (25/101) of the participants had a history of hypertension and 14.9% (15/101) reported having a sedentary lifestyle. With the exception of age and history of hypertension, both groups had similar baseline characteristics. Participants in the intervention group were significantly younger and were less likely to have a history of hypertension.

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Figure 1. Study flow diagram.

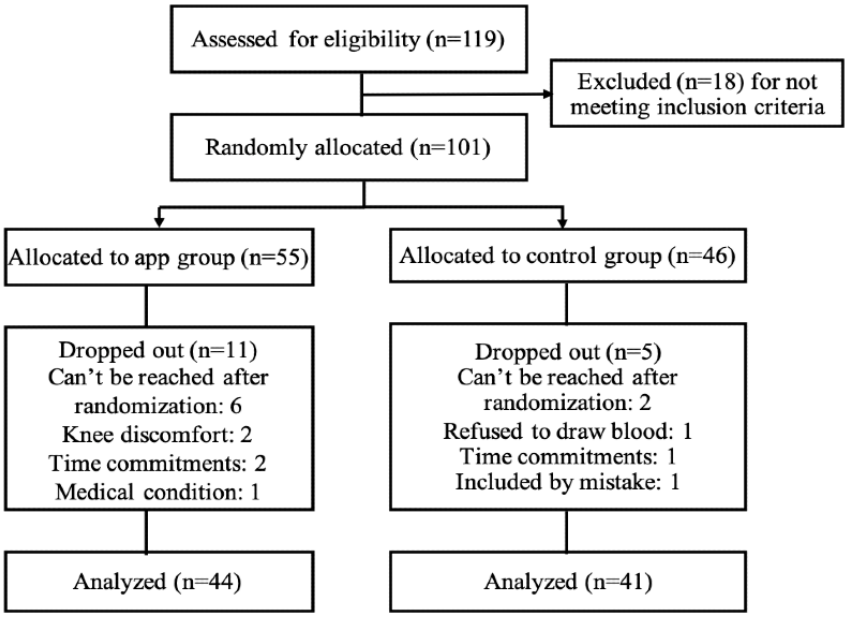

Table 1. Baseline individual characteristics by treatment group.

Characteristic	Total sample (N=101)	Control group (n=46)	Intervention group (n=55)	*P* value
Number of participants, n (%)	101 (100)	46 (45.5)	55 (54.5)	N/A[a]
Age (years), mean (SD)	48.2 (10.4)	51.7 (8.6)	45.3 (11.0)	.001
Female, n (%)	24 (23.8)	12 (26)	12 (22)	.65
Duration since diagnosis (months), mean (SD)	46.9 (41.5)	49.7 (40.6)	44.7 (42.5)	.55
Smoker, n (%)	38 (37.6)	21 (46)	17 (31)	.15
Use alcohol, n (%)	19 (18.8)	11 (24)	8 (15)	.31
Sedentary, n (%)	15 (14.9)	7 (15)	8 (15)	>.99
Family history of diabetes, n (%)	40 (39.6)	18 (39)	22 (40)	>.99
Stressed, n (%)	3 (3.0)	2 (4)	1 (2)	.59
Hypertension, n (%)	25 (24.8)	16 (35)	9 (16)	.04
Weight (kg), mean (SD)	70.5 (13.8)	68.9 (12.9)	71.9 (14.4)	.26
BMI (kg/m^2), mean (SD)	25.2 (3.6)	25.0 (3.1)	25.4 (4.0)	.58
Overweight or obese, n (%)	75 (74.3)	34 (74)	41 (75)	>.99
Waist-to-hip ratio, mean (SD)	0.6 (0.1)	0.6 (0.1)	0.5 (0.1)	.21
Body fat (%), mean (SD)	31.3 (7.7)	31.6 (8.1)	31.0 (7.4)	.69
Hemoglobin A_{1c} (%), mean (SD)	7.3 (1.8)	7.5 (1.8)	7.2 (1.8)	.43
Resting heart rate (bpm[b]), mean (SD)	78.8 (8.9)	79.6 (9.1)	78.0 (8.7)	.37
Step test (bpm), mean (SD)	113.9 (15.6)	113.0 (16.0)	114.7 (15.4)	.60

[a]N/A: not applicable; the *P* value was not calculated for this characteristic.
[b]bpm: beats per minute.

Among participants who completed the study, the self-reported duration of exercise in the control group (214 minutes/week) was longer than the app-recorded duration of exercise in the intervention group (193 minutes/week). Similarly, a higher proportion of participants in the control group (29/41, 71%) than in the intervention group (18/44, 41%) met the 150-minute target for moderate to vigorous physical activity; however, compared with the control group, the intervention group had a significantly larger change in cardiorespiratory endurance (mean difference –2.0 bpm [beats per minute] vs 1.0 bpm; *P*=.02) and a significantly larger decrease in body fat percentage (–1.8% vs –0.8%; *P*=.01) as shown in Table 2. Finally, the intervention group had a greater decrease in BMI (–0.60 kg/m^2 vs –0.32

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kg/m^2); however, the difference was not statistically significant (*P*=.09).

There was no difference in HbA_{1c} level reduction between the two groups (–0.55% and –0.70% in the intervention and control groups, respectively) after exercise intervention. However, 4 participants in the intervention group stopped taking antidiabetic drugs, and 9 participants had their dosages lowered because of well-controlled blood glucose levels, whereas in the control group, 1 participant stopped taking antidiabetic drugs, 2 participants had their dosages lowered, and 5 participants had their dosages increased. There were no significant differences in muscle strength, HOMA-IR, blood cholesterol level, and waist-to-height ratio between the two groups.

There were no severe adverse events in either group. Hypoglycemia occurred 4 times in the intervention group and 8 times in the control group, and muscle pain occurred 8 times in the intervention group and 8 times in the control group.

Table 2. Effect of exercise in type 2 diabetes patients in intervention and control groups.

Exercise measure	Intervention group (n=44)	Control group (n=41)	*P* value
BMI (kg/m^2), median (IQR)	–0.60 (–1.07 to 0.16)	–0.32 (–0.74 to 0.01)	.09
Hemoglobin A_{1c} (%), median (IQR)	–0.55 (–1.53 to –0.07)	–0.70 (–1.40 to 0.40)	.46
Body fat (%), median (IQR)	–1.80 (–2.95 to –0.10)	–0.80 (–1.73 to 0.65)	.01
HOMA-IR[a], median (IQR)	0.07 (–0.51 to 1.06)	–0.17 (–1.48 to 1.29)	.23
HOMA-β[b], median (IQR)	1.44 (–20.70 to 21.18)	3.64 (–19.02 to 42.47)	.52
Resting heart rate (bpm[c]), median (IQR)	2.00 (–3.00 to 10.50)	4.00 (–2.00 to 10.00)	.52
Step test (bpm), median (IQR)	–2.00 (–9.50 to 3.00)	1.00 (–3.00 to 10.00)	.02
Muscle strength (repetitions), mean (SD)	–0.90 (4.60)	–0.78 (4.16)	.91

[a]HOMR-IR: homeostasis model assessment for insulin resistance.

[b]HOMA-β: homeostasis model assessment for β-cell function.

[c]bpm: beats per minute.

Discussion

We found that the majority of participants were able to complete their prescribed exercise program in this study. Although participants in the intervention group demonstrated lower adherence (ie, participated for a shorter duration) than those in the control group, their improvement of cardiorespiratory endurance and decrease in body fat percentage were greater than those of the control group, and more participants in the intervention group stopped taking their antidiabetic drugs or had their dosage of antidiabetic drugs lowered. No severe adverse events were found in either group. These findings suggest that exercise monitored remotely using a fitness app and heart rate band was feasible and efficient among Chinese adults with type 2 diabetes.

There have been many studies showing that exercise interventions improve blood glucose control and other factors, such as weight, body fat mass, cardiorespiratory endurance, and glycemic stability [5,11]; these factors are highly related to long-term cardiovascular diseases and mortality [12,13] in individuals with diabetes. Most studies [5] utilized structured exercise undertaken in specialized facilities with the supervision of trained staff. In such conditions, participants were motivated to adhere to the exercise program by those providing the training, and results cannot be generalized to nonresearch settings where the majority of exercise is unsupervised. Several studies [14,15] have shown that when direct supervision was removed during the maintenance portion of a program, adherence dropped and glycemic control decreased. Studies that compared the efficiency of structured exercise with unstructured exercise found that supervised structured training was more efficient in decreasing HbA_{1c} levels [16]. In our study, exercise performed by the intervention group was monitored using an app and heart rate band. Real-time feedback from the app notified users when to adjust exercise intensity and duration and encouraged exercise adherence. Our results demonstrate that exercise monitored with a fitness app and heart rate band was more efficient than unsupervised exercise in improving cardiorespiratory endurance and decreasing body fat percentage in patients with type 2 diabetes. Because supervised exercise is not accessible for most participants, exercise with remote monitoring using a fitness app and heart rate band can be used as a surrogate.

Mobile app–based interventions for diabetes are widely supported by evidence with high certainty [17]; however, the distribution and efficiency of apps vary by functional design [18,19]. These studies [18,19] recorded exercise duration and intensity by participant self-reporting or objectively using accelerometers. In our study, target heart rate was used to monitor exercise intensity and track exercise duration, which allowed objective assessment of exercise duration and intensity.

Although participants in the intervention group did not have a significantly lower BMI than those in the control group, their decrease in body fat percentage was greater. Previous studies reported a reduction in body fat percentage for their control group that was similar to that of our control group, but a much lower reduction for their intervention group than that of our intervention group [20]. Body fat may be more important than BMI in predicting risk for type 2 diabetes, especially in

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participants with a BMI value in the normal range, and fat mass is an important factor that contributes to insulin resistance, metabolic syndrome, and other cardiovascular risk parameters [21,22]. Therefore, remotely monitored exercise using a fitness app may be a useful method to improve body composition and avoid metabolic consequences.

Our study found similar HbA_{1c} level reductions to those found by another study [23] that tested the efficiency of aerobic and resistance exercise supervised by trained staff in specialized facilities in patients with type 2 diabetes. It should be noted that we allowed the adjustment of antidiabetic drugs in the participants, which may have resulted in the effect of exercise on HbA_{1c} reduction being underestimated. This suggests that remotely monitored exercise and traditional supervised exercise were similarly efficient in terms of reducing blood glucose levels. Because of the convenience and low cost of monitoring with an app and heart rate band, this option may be a better choice for most patients with type 2 diabetes. Although the intervention group did not demonstrate greater HbA_{1c} reductions than those of the control group, more participants had their antidiabetic medication dosage reduced or stopped, which can lead to more patient engagement and lower out-of-pocket costs.

Although there are studies [5,24] showing that exercise improved muscle strength, HOMA-IR, blood cholesterol level, and waist-to-height ratio, our study did not demonstrate that participants in the intervention group had greater improvements in metabolic parameters than those of the control group. Most of these studies had a duration of 16 weeks and had a control group of sedentary participants. The reason that our study did not demonstrate relative improvements in metabolic parameters may be explained by the small sample size, the short duration, and use of an active control group.

In our study, participants in the control group reported longer exercise durations and better adherence to prescribed exercise programs. Many studies [25,26] have already shown that there are discrepancies between self-reported and objective measures of exercise duration and intensity—individuals are prone to overestimate the duration and intensity of exercise in self-reports; therefore, wearable technology can be used to guarantee accurate assessment of these parameters.

Several limitations should be considered when interpreting our study's findings. First, exercise duration and intensity in the control group were self-reported and, thus, may not be reliable. Second, there were slight differences in the mean age and percentage of participants with hypertension between the groups. Participants in the intervention group were slightly younger, and there was a lower percentage with hypertension, possibly because those who were older and had higher cardiovascular risk were more likely to decline to participate. Chance, due to the small sample size in this multicenter RCT, may also have contributed to baseline differences that were observed. Studies have shown that older age is associated with a decrease in exercise capacity [27]. Because participants in the control group were older, it is possible that they may have had decreased exercise capacity, which may have resulted in overestimation of exercise efficiency in the control group. However, participants in the control group reported longer exercise durations and higher adherence to the exercise program, and the age difference between the two groups was minimal. In addition, exercise is as efficient in older patients with type 2 diabetes as it is in those who are younger [24]. Therefore, the age difference between groups may not have an impact on the findings of this study.

To the best of our knowledge, this was the first RCT in China that tested the efficiency of exercise monitored remotely using an app and heart rate band in patients with type 2 diabetes. We found that, despite shorter exercise durations and lower adherence to exercise in the intervention group than those in the control group, participants in the intervention group demonstrated greater improvements in cardiorespiratory endurance and greater reductions in body fat percentage. Both groups had clinically meaningful reductions in HbA_{1c}, and more participants in the intervention group stopped requiring hypoglycemic drugs or had their hypoglycemic drug dosage lowered. These findings suggest that exercise monitored remotely with an app and heart rate band is more efficient than unsupervised exercise in type 2 diabetes patients. Because of the convenience and low cost of the app and wearable technology, it may be used as a surrogate for traditional supervised exercise.

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Authors' Contributions

JL and NT contributed to the design, data analysis, and interpretation of this study. JL drafted the manuscript, and HM and NT critically revised the manuscript. DW, LO, SL, YW, CT, ML, XC, LC, and WZ contributed to the acquisition of the data of this work.

Conflicts of Interest

HM holds stock options for consulting work done for Recovery Plus Clinic. This study was partially funded by Recovery Plus Clinic, Chengdu, China, and the app used in this study was provided by this company.

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Multimedia Appendix 1
Screenshots of the study app's user interface.
[DOCX File , 1532 KB - mhealth_v9i2e23338_app1.docx]

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Abbreviations

bpm: beats per minute
HbA_{1c}: hemoglobin A_{1c}
HOMA-IR: homeostasis model assessment for insulin resistance
HR_{max}: maximum heart rate
HR_{rest}: resting heart rate
HR_{target}: target heart rate
RCT: randomized controlled trial

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Review

Effectiveness of Smartphone-Based Cognitive Behavioral Therapy Among Patients With Major Depression: Systematic Review of Health Implications

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Abstract

Background: Depression is often associated with rapid changes in mood and quality of life that persist for a period of 2 weeks. Despite medical innovations, there are problems in the provision of care. Long waiting times for treatment and high recurrence rates of depression cause enormous costs for health care systems. At the same time, comprehensive limitations in physical, psychological, and social dimensions are observed for patients with depression, which significantly reduce their quality of life. In addition to patient-specific limitations, undersupply and inappropriate health care have been determined. For this reason, new forms of care are discussed. Smartphone-based therapy is considered to have great potential due to its reach and easy accessibility. Low socioeconomic groups, which are always difficult to reach for public health interventions, can now be accessed due to the high dispersion of smartphones. There is still little information about the impact and mechanisms of smartphone-based therapy on depression. In a systematic literature review, the health implications of smartphone-based therapy were presented in comparison with standard care.

Objective: The objective of this review was to identify and summarize the existing evidence regarding smartphone-based cognitive behavioral therapy for patients with depression and to present the health implications of smartphone-based cognitive behavioral therapy of considered endpoints.

Methods: A systematic literature review was conducted to identify relevant studies by means of inclusion and exclusion criteria. For this purpose, the PubMed and Psyndex databases were systematically searched using a search syntax. The endpoints of depressive symptoms, depression-related anxiety, self-efficacy or self-esteem, and quality of life were analyzed. Identified studies were evaluated for study quality and risk of bias. After applying the inclusion and exclusion criteria, 8 studies were identified.

Results: The studies examined in this review reported contradictory results regarding the investigated endpoints. In addition, due to clinical and methodological heterogeneity, it was difficult to derive evident results. All included studies reported effects on depressive symptoms. The other investigated endpoints were only reported by isolated studies. Only 50% (4/8) of the studies reported effects on depression-related anxiety, self-efficacy or self-esteem, and quality of life.

Conclusions: No clear implications of smartphone-based cognitive behavioral therapy could be established. Evidence for the treatment of depression using smartphone-based cognitive behavioral therapy is limited. Additional research projects are needed to demonstrate the effects of smartphone-based cognitive behavioral therapy in the context of evidence-based medicine and to enable its translation into standard care. Participatory technology development might help to address current problems in mobile health intervention studies.

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KEYWORDS

mobile health; depression; cognitive behavioral therapy; systematic review; mobile phone

Introduction

Background

Depression can affect mental and physical health. It is estimated that nearly 322 million people worldwide have depression, and the World Health Organization (WHO) has stated that depression is the single largest factor contributing to global disability [1]. Recently, findings from the Global Burden of Disease study stated that the incidence of depression has increased by approximately 50% in 2017 compared with that in 1990 [2]. Depression is equally prevalent in high-income countries and middle- to low-income countries [3]. In addition, the European Health Interview showed that the European average accounts for approximately 6.6% of people with depression [4]. Due to the widespread prevalence of depression and its rising burden, the social and health policy significance of mental illnesses is increasing [5]. Therefore, depression is a major global public health domain of the 21st century, and its importance is increasing.

Depression is associated with changes in mood and quality of life that persist for a period of 2 weeks [6]. Furthermore, a decline in activity, loss of appetite, or prolonged fatigue is observable. In addition, depression is associated with higher mortality rates, which can be explained by depression-related suicide and an unhealthy lifestyle that can cause diabetes or cardiovascular diseases. Suicide is a major cause of injury and death worldwide [7]. Approximately 15% of patients with depression face suicidal thoughts [8].

In addition to the rising numbers and the increasing burden of disease, mental illnesses have major economic influences. The Federal Statistical Office of Germany reported that in 2019, direct costs of approximately 8.7 billion Euros (US $ 10.5 billion) were caused by depression in Germany. It was estimated that 4.6 billion Euros (US $ 5.5 billion) were spent on the inpatient sector and 3.3 billion Euros (US $ 4.0 billion) were spent on the outpatient sector. This corresponds to approximately 2.6% of the total costs in the health care system [9]. In addition, approximately 42% of early retirements were found to be associated with mental disorders. A health report published by the German insurance company Deutsche Angestellten Krankenkasse ranked mental disorders third in 2019, causing 15.2% of all sick leave days in Germany annually. Only respiratory and musculoskeletal disorders have caused more sick leave days than mental disorders [10,11].

In the past, people with a diagnosis of mental illness faced social consequences such as marginalization, stigmatization, and isolation [12]. However, in recent years, public awareness has increased, and patients with depression should no longer feel the need to conceal their diagnosis. A correct diagnostic classification by the general practitioner and early assessment of treatment needs can significantly contribute to less concealment of diagnoses and public awareness [13].

Even today, people with depression face different barriers to health care access. In contrast to chronic diseases with no reversibility, depression is a treatable disease. Only 25% of depressed patients receive accurate care, and in Germany, approximately 50% are not provided with medical guidelines-oriented care [14]. There are both patient-level and system-level reasons for this undersupply and existing barriers. Patient-level barriers are associated with time, transportation constraints, or a considerable cost. System-level barriers include long waiting lists and a dearth of therapists and doctors, especially in rural areas and low-income countries [15,16]. High-income countries can provide, on average, 72 mental health workers per 100,000 individuals, whereas low-income countries can only provide approximately 2 mental health workers per 100,000 individuals [7].

To overcome these barriers, we need innovative ways to reduce waiting times and increase professional treatment by mental health workers. Due to the increasing use of information and communication technologies, mobile health (mHealth) is considered to have great potential in the health care sector. Especially for rural care concepts, mHealth is a promising tool to improve care in structurally weak areas. Here, the cross-sectoral and interprofessional approach is particularly suitable, as it can lead to a reduction in the care interruptions between outpatient and inpatient sectors [17].

Comparison of e-mental health treatments with traditional face-to-face treatments suggests that technology is not predominantly accepted by patients, although it may still provide solutions to address the patient-level and system-level barriers [18]. Access issues can easily be mitigated using technological innovations. Several studies have demonstrated that telemedicine can be used for remote treatments [19,20]. First-wave technology-based movements such as internet-based cognitive behavioral therapy (CBT) proved their potential in different meta-analyses, which demonstrated both their safety and effectiveness [21,22].

The promising results of treating patients through distance have resulted in considerable interest in transferring internet-based and computerized techniques to smartphone apps. The crucial factor of smartphone-based apps can be seen in their tremendous reach. Patients can also receive therapy whenever they need it most without taking an appointment with their therapist, which often results in long waiting times with possible aggravation of symptoms [23]. Currently, thousands of mental health apps are available in the market, and these apps are designed for a brief frequent use throughout the day [24]. Considering how fast mental health apps are developed and implemented, it is important to address the challenges that these developments yield. We will face 3 major challenges in the future: (1) issues of low engagement with digital mental health tools, (2) lack of sufficient evidence, and (3) poor understanding related to security issues among target groups [25].

There is a lack of evidence for efficacy of smartphone-based interventions, which is essential for integrating new provisions

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into future health care. Although hundreds of mental health apps are available on unregulated app stores, there are only a few proof-of-concept studies and small-scale randomized controlled trials (RCTs) that evaluate the effectiveness of smartphone-based CBTs for depression [26]. Consequently, it is critical to ensure that patients and clinicians have enough information to understand evidence-based digital treatments for depression. Recent meta-analyses have documented positive effects on diabetes [27] and anxiety [28]; however, these effects still need to be measured for depression.

Objectives

Therefore, the aim of this study was to close this existing research desideratum. A systematic review was conducted to examine the effects of smartphone-based CBTs for the treatment of depression. Therefore, the leading research question was as follows: Are smartphone-based CBTs effective for treating depression and do they improve depression-related clinical endpoints?

Methods

Search Strategy

The used literature was determined by a systematic search. A systematic search was conducted in the PubMed and Psyndex databases. Relevant articles on smartphone-based therapy and depression were collected and evaluated. The searched terms were extended by relevant keywords of the articles found and supplemented by Medical Subject Headings (MeSH). Three generic terms were identified for which related terms were collected in English (Table 1). To obtain more results, the words were connected using the Boolean operators *AND* and *OR*. If the identified articles appeared to be relevant, the summaries and available full texts were read. Further articles were found by viewing the source references in the articles read.

Table 1. Search matrix.

Topic	Search terms
Depression	Depression (MeSH[a]); depress; major depression; depressive disorder (MeSH); depressive disorder, major (MeSH); depressive episode; unipolar depression
Cognitive behavioral therapy	Cognitive therapy; behavior therapy (MeSH); cognitive behavioral therapy (MeSH); acceptance and commitment therapy (MeSH), mindfulness
Smartphone-based interventions	Smartphone (MeSH); computers, handheld (MeSH); mHealth; mobile health; smartphone-delivered therapy; smartphone-based therapy; internet-based interventions (MeSH); mobile applications (MeSH)

[a]MeSH: Medical Subject Headings.

The Population, Intervention, Comparison, Outcome, Study Search Strategy

Inclusion and exclusion criteria were developed a priori for the systematic review. For this purpose, the PICOS (population, intervention, comparison, outcome, study) search strategy was used in the context of evidence-based medicine [26,29]. The search strategy was based on population, intervention, comparison, outcome, and study type.

Population

Studies were included if they dealt with people with mild to moderate depression or depressive symptoms. Furthermore, the study participants needed to be aged at least 18 years.

Studies were excluded if they dealt with subpopulations such as children or minority groups (refugees or only specific ethnic communities). Furthermore, studies were excluded when they assessed depression as a comorbidity of other relevant diseases (eg, chronic backpain, diabetes, and cancer). In addition, studies with treatment of other forms of depression such as postpartum depression, severe courses of depression with psychotic events, and schizophrenia were excluded.

Intervention

Studies that focused solely on the provision of CBT via smartphones or tablets or an additional treatment via smartphones or tablets in combination with treatment as usual were included. It was mandatory that the therapy provision be delivered by smartphone or tablet apps.

On the contrary, studies were excluded if they used other therapy delivery formats than smartphone or tablet apps. Studies that merely provided telephone support were excluded. As the aim of this study was to determine the effectiveness of smartphone-delivered therapy formats, computerized therapy formats were excluded. Web-based apps with no smartphone or tablet involvement were also excluded.

Comparison

To include studies in the systematic review, a control group (CG) needed to be present. The CG can be treated as usual, an active control comparison (eg, other treatment apps), or inactive control comparison. Studies that did not provide a CG were excluded.

Outcomes

This systematic review assessed clinical outcome points, which are associated with depression. The following clinical outcomes were assessed: depressive symptoms, depression-related anxiety, self-efficacy or self-esteem, and quality of life. Studies with the abovementioned outcomes as primary or secondary outcomes were included. If the study investigated one of the mentioned endpoints, it was included in the review. Studies that did not consider the investigated endpoints or did not report results were excluded.

Study Design

To provide the highest degree of evidence, RCTs were considered relevant to analyze the stated hypothesis.

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Studies that that had other study designs or lacked a CG were excluded even if they were described as an RCT. Furthermore, owing to the large number of studies conducted in this field, the time interval was limited to consider the most relevant studies. Studies conducted before 2015, indicating a time interval of the last 5 years, were excluded. Studies published in German or English were included.

After a search syntax was developed using the search matrix and the appropriate MeSH terms as part of the systematic literature search, articles were identified in PubMed and Psyndex (Multimedia Appendix 1). The search was last updated in May 2020. The inclusion and exclusion criteria were applied in a 2-stage process. First, the titles and abstracts of the studies were reviewed using the inclusion and exclusion criteria. Duplicates and studies that did not meet the inclusion criteria were excluded. If the studies appeared adequate or an assessment based on the title and abstract was not possible, the full texts were read.

In the second step, the inclusion and exclusion criteria were applied again to the full texts. The full texts that did not meet the inclusion criteria were excluded. In addition to the systematic database search, a hand search was carried out in which further relevant studies were identified according to the inclusion and exclusion criteria. The studies identified by hand search also underwent a 2-stage process.

Quality Assessment

The publications included in the qualitative synthesis were assessed for quality. The instrument described by Hailey et al [30] was used for the quality assessment, which was extended by the method described by Polisena et al [31]. Their approach to the appraisal of study quality relies on the summation of 2 scales dealing with study designs and study performance (Textbox 1 [31]). The authors state that both scales are ordinal, as for each of the 5 study performance attributes, it is hypothesized that they have the same impact on the quality of the study. The scale for study design is also ordinal and values the increasing confidence in the different designs and their relevance for decision making.

Hailey et al [30] distinguished 4 different study designs for quality assessment, which were assigned different scores. RCTs with at least 50 participants per study arm received the highest score. Retrospective, nonrandomized studies received the least number of points. Polisena et al [31] further differentiated the RCTs. Here, half a point was deducted if the randomization was not described correctly or if blinding was not performed or described.

Textbox 1. Instrument to assess the quality of the included studies.

Study category:

- Study design
  - Big randomized controlled trial (RCT; ≥50 participants each intervention arm): 5 points
  - Small RCT (<50 participants each intervention arm): 3 points
  - Prospective nonrandomized trial: 2 points
  - Retrospective nonrandomized trial: 1 point
- If RCT (half a point is deducted if the information is missing)
  - Description of randomization
  - Implementation of blinding
  - Description of blinding
- Study performance (0=no information, 1=information limited, 2=information satisfactory)
  - Patient selection
  - Description of the intervention
  - Specification and analysis of study (intention-to-treat)
  - Patient disposal
  - Outcomes reported
- Resulting quality categories
  - 11.5-15.0 points: high quality (A)
  - 9.5-11.0 points: good quality (B)
  - 7.5-9.0 points: fair to good quality (C)
  - 5.5-7.0 points: poor to fair quality (D)
  - 1.0-5.0 points: poor quality (E)

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A total of 5 study performance attributes were evaluated in the studies. Patient selection, description of the intervention, specification of the analysis, patient dropouts, and reported outcomes were considered. Two points were given when the information was sufficiently presented. A lack of information was rated with zero points. This system allowed to build a score to categorize the studies in terms of quality. The maximum score was 15 points for a study. Studies that achieved a minimum score of 11.5 points were classified in category A, which is the highest quality category. Scores between 9.5 and 11 points were of good quality and corresponded to category B. Quality categories of classes C to E (score below 9) showed fair to poor quality. These studies have considerable limitations that need to be considered when interpreting the results [30].

Risk of Bias Assessment

Although the terms bias and quality are often used as synonymous concepts to evaluate included studies in the systematic reviews, the Cochrane Handbook distinguishes between those terms for the following reasons. First, the key aim of a review is to consider the extent to which the results of the included studies should be considered. Second, a study may have been performed with the highest possible standards but still have an important risk of bias. Third, the risk of bias assessment can be instrumental in overcoming the ambiguity between quality of reporting and the quality of underlying research. Finally, some markers of quality in medical research (eg, ethical approval or performing sample size calculations) are unlikely to have implications for the risk of bias [32]. Therefore, it is necessary to additionally perform a risk of bias assessment, although the quality assessment and the risk of bias assessment might have overlapping issues (eg, evaluation of randomization).

In this systematic review, the risk of bias assessment was used to evaluate the sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, and assessment of outcome data. The Cochrane Handbook for Systematic Reviews of Intervention (Version 5.1.0) was used as a basis for decision making, and the risk of bias assessment was conducted using Review Manager 5.3. (Cochrane Collaboration). By systematically screening the included studies for different biases, either low risk, unclear risk, or high risk evaluations were made.

Results

Overview

A total of 8 studies were included in this systematic review. The process of study selection is further described in Figure 1. After the search syntax was developed and entered in PubMed and Psyndex, 580 studies were identified. A total of 302 records were identified via PubMed, and 277 records were found in Psyndex. One additional record was identified by hand search, systematically reviewing the references of other studies. After duplicates were removed, 450 records were eligible for the first screening. The first screening was done by checking the abstract and title of the studies and evaluating them for suitability. A total of 394 records were excluded, resulting in 56 studies that were included for full-text assessment. From these 56 studies, 48 studies were excluded for different reasons. The main reason for exclusion of studies was an inappropriate intervention (22/48, 46%). This was followed by study protocols (12/48, 25%), an inappropriate population (7/48, 15%), and inappropriate study design (6/48, 13%). One study reported inappropriate outcomes.

The following sections will descriptively present and compare study and patient characteristics at baseline. Subsequently, the studies were analyzed regarding the considered endpoints, namely, depressive symptoms, depression-related anxiety, self-efficacy or self-esteem, and quality of life. The results of the systematic review are presented in Table 2. Multimedia Appendix 2 [16,33-39] presents an overview of the patient characteristics. The results of the regarded endpoints are shown in Multimedia Appendix 3 [16,33-39]. The patient characteristics are presented in Multimedia Appendix 2.

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Figure 1. Process of study selection.

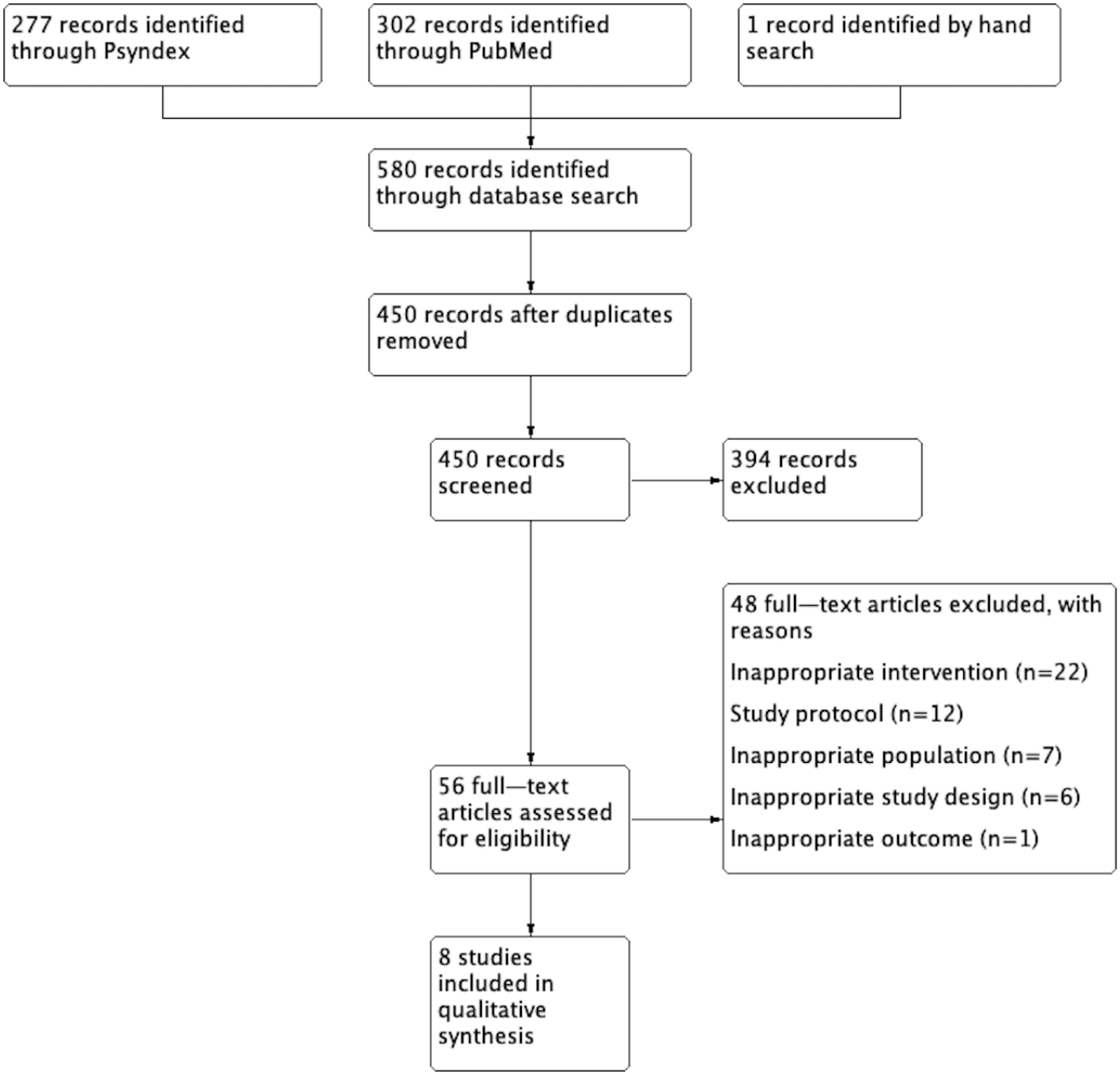

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Table 2. Study characteristics.

Author, year, reference	Country	Evaluation period[a]	Financing	Participants	Intervention	Control	Outcomes	Instruments
Roepke et al, 2015 [35]	United States	6 weeks	Private	283 participants (93 control, 190 intervention) who owned an iPhone and had a CES-D[b] score >16, aged >18 years	Intervention 1: Superbetter CBT[c] app; Intervention 2: general Superbetter self-esteem and acceptance app	Waitlist	• Depression • Anxiety • Life satisfaction • Self-efficacy • Social support • Technology use • Treatment strategies • Daily functioning	• CES-D • GAD-7[d] • SWLS[e] • NGSE[f] • MSPSS[g]
Ly et al, 2015 [37]	Sweden	24 weeks	State	93 participants (47 control, 46 intervention) who owned a smartphone and had a PHQ[h] score of ≥5, aged >18 years	4 face-to-face sessions and apps between the sessions, with behavioral activation components	10 face-to-face behavioral activation sessions	• Depression • Anxiety • Quality of life • Psychological flexibility	• BDI-II[i] • PHQ-9 • BAI[j] • QOLI[k] • AAQ-II[l]
Arean et al, 2016 [16]	United States	12 weeks	State	626 participants (206 control, 420 intervention) who owned a smartphone and had a PHQ-9 score of >5, aged >18 years	Intervention 1: cognitive training app (EVO); Intervention 2: evidence-based psychotherapy app (iPST)	Health tips	• Depression • Disability	• PHQ-9 • SDS[m]
Bakker et al, 2018 [39]	Australia	4 weeks	Not specified	312 participants (78 control, 234 intervention)	Intervention 1: MoodPrism self-monitoring mood tracking app; Intervention 2: MoodMission app for recommendation of CBT strategies; intervention 3: MoodKit CBT-based app	Waitlist	• Depression • Anxiety • Well-being • Emotional self-awareness • Coping self-efficacy • Mental health literacy	• PHQ-9 • GAD-7 • WEMWBS[n] • ESAS-R[o] • CSES[p] • MHLQ[q]
Hur et al, 2018 [38]	South Korea	3 weeks	State	48 participants (24 control, 24 intervention)	Todac scenario-based mobile app	Mood charting app	• Dysfunctionality • Depression • Anxiety • Self-esteem • Quality of life	• DAS[r] • BDI-II • STAI-X2[s] • RSES[t] • QOL[u]
Lüdtke et al, 2018 [36]	Germany	4 weeks	Not specified	90 participants (45 control, 45 intervention) who owned an iPhone, aged >18 years	Be Good to yourself self-help CBT app	Wailtlist	• Depression • Self-Esteem • Quality of life • Willingness to change • Client satisfaction	• PHQ-9 • RSES • WHO-QOL[v] • URICA[w] • CSQ-8[x]
Dahne et al, 2019 [33]	United States	8 weeks	State	52 participants (28 control, 24 intervention) who owned a smartphone and had a PHQ-8 score of >10	Moodivate self-help behavioral activation app	Control 1: MoodKit CBT app; control 2: TAU[y]	• Depression • Feasibility	• PHQ-8 • BDI-II

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Author, year, reference	Country	Evaluation period[a]	Financing	Participants	Intervention	Control	Outcomes	Instruments
Stiles-Shields et al, 2019 [34]	United States	10 weeks	State	30 participants (10 control, 20 intervention)	Intervention 1: Boost Me behavioral activation app Intervention 2: Thought Challenger cognitive therapy app	Waitlist	• Depression • App usability	• PHQ-9 • SUS[z]

[a]Follow-Up Assessment included.
[b]CES-D: Center for Epidemiologic Studies Depression Scale.
[c]CBT: cognitive behavioral therapy.
[d]GAD: Generalized Anxiety Disorder.
[e]SWLS: Satisfaction with Life Scale.
[f]NGSE: New General Self-Efficacy Scale.
[g]MSPSS: Multidimensional Scale of Perceived Social Support.
[h]PHQ: Patient Health Questionnaire.
[i]BDI: Beck Depression Inventory.
[j]BAI: Beck Anxiety Inventory.
[k]QOLI: Quality of Life Inventory.
[l]AAQ-II: Acceptance and Action Questionnaire.
[m]SDS: Sheehan Disability Scale.
[n]WEMWBS: Warwick-Edinburgh Mental Well-being Scale.
[o]ESAS-R: Emotional Self-Awareness Scale-Revised.
[p]CSES: Coping Self-Efficacy Scale.
[q]MHLQ: Mental Health Literacy Questionnaire.
[r]DAS: Dysfunctional Attitude Scale.
[s]STAI: Stat-Trait Anxiety Inventory.
[t]RSES: Rosenberg Self-Esteem Scale.
[u]QOL: Quality of Life.
[v]WHOQOL: World Health Quality of Life.
[w]URICA: University of Rhode Island Change Assessment Scale.
[x]CSQ: Client Satisfaction Questionnaire.
[y]TAU: treatment as usual.
[z]SUS: System Usability Scale.

Description of Study Characteristics

The selected studies were compared in terms of the country of intervention, number of cases, investigation period, and source of funding. Interventions were also presented according to the endpoints, their applied instruments, and the technology used. Finally, the quality of the studies was assessed.

The implementation of the included studies was conducted in different regions of the world. Most of the studies (4/8, 50%) have been conducted in North America. All studies were performed in the United States [16,33-35]. Two studies have been conducted in Northern Europe, with 1 study completed in Germany [36] and 1 in Sweden [34,37]. Two studies evaluated the effectiveness of smartphone-based therapy in South Korea [38] and Australia [39].

The majority of studies (5/8, 63%) reported state funding. Of the 4 identified studies conducted in the United States, 3 were financed by the National Institute of Mental Health [16,33,34]. Two studies did not provide information on research funding [36,39], and 1 study was funded by private donations [35].

The evaluation periods ranged from 3 weeks in the study by Hur et al [38] to 24 weeks in the study by Ly et al [37]. In these evaluation periods, the follow-up assessment was included. Three studies had a shorter or equal evaluation period of 1 month [36,38,39], and in 4 studies, the period was shorter than 3 months [16,33-35].

In total, 1534 patients were evaluated by the 8 included studies. The range of participant numbers was considerably different and varied from 30 to 626 (mean 341, SD 206.2; median 432), when the intervention group (IG) and CG were considered. All studies differentiated between a CG and IG. The number of IGs and CGs differed between the studies. Three studies compared an IG with a CG [36-38]. In addition, 4 studies had more than 1 IG [16,34,35,39], and 1 study was designed with 2 CGs [33]. The number of participants in the IG varied from 20 to 420 (mean 223, SD 145; median 268). Furthermore, the number of

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participants in the CG was considerably lower, ranging from 10 to 206 (mean 118, SD 62.8; median 164).

Although all studies measured depression-related symptoms as outcomes, the instruments to assess the symptoms were different. Patient Health Questionnaire (PHQ-9) and Beck Depression Inventory-II (BDI-II) were the most common instruments. Five studies used the PHQ-9 to assess depression-related symptoms [16,34,36,37,39]. Only Dahne et al [33] used the PHQ-8 to assess symptoms. The reason for using the eighth version of the PHQ instead of the ninth was not further explained by the authors. Three studies measured depression symptoms using the BDI-II [33,37,38], and 1 study evaluated the symptoms by using the Center for Epidemiologic Studies Depression Scale [35].

Depression-related anxiety was measured in 4 studies [16,35,37,38]. Two studies used the Generalized Anxiety Disorder (7-item) Scale [35,39], and 1 study used the State-Trait Anxiety Inventory-X2 [38] and the Beck Anxiety Inventory tools [37].

Self-esteem or self-efficacy was measured differently by 4 studies. Two studies used the Rosenberg Self-Esteem Scale (RSES) to assess self-esteem [36,38]. One study evaluated this outcome using the New General Self-Efficacy Scale [35] and the Coping Self-Efficacy Scale [39]. Both scales had good Cronbach α values between .89 and .96.

Finally, quality of life was only measured in 2 studies. Lüdtke et al [36] used the WHO Quality of Life survey (WHOQOL-BREF), and Ly et al [37] used the Quality-of-Life Inventory. Other measures that were conducted by different studies were client satisfaction, app usability, daily functioning, and psychological flexibility.

The CG, with whom the IG was compared, was considerably different between the studies. Four studies provided a waitlist CG, which provided any form of treatment [34-36,39]. Other treatment strategies (eg, medication, psychotherapy, or coaching) were also allowed. Two studies used an inactive CG by providing health tips [13,16] or asking patients to complete a mood charting app [38]. Ly et al [37] compared IG with 10 face-to-face behavioral activation sessions, indicating an active CG. Patients were supported by therapists, and a treatment that resulted in giving homework and setting individualized aims was also done. Finally, the study by Dahne et al [33] was the only study with 2 CGs. One CG was inactive, providing treatment as usual, and the other CG was active, giving patients access to the CBT app *MoodKit*, which included thought checking, mood tracking, journaling, and activity scheduling.

The interventions performed varied between the studies. Four studies had more than 1 IG, comparing different smartphone apps with each other [16,34,35,39]. Often, a CBT app was compared with a different smartphone-based therapy approach. For example, Arean et al [16] compared the cognitive training app *EVO* with an evidence-based psychotherapy app *iPST*, which is a problem-based therapy approach managing mood in 7 steps. Similar approaches were conducted by Roepke et al [35] and Stiles-Shields et al [34], which compared either a CBT app with a self-esteem acceptance app or behavioral activation app strategies with cognitive restructuring app therapies. The study by Bakker et al [39] was the only study with 3 IGs. The authors compared the self-monitoring app *MoodPrism*; a CBT recommendation app *MoodKit*, which suggested different strategies depending on the reported moods and anxious feelings; and the CBT app *MoodKit*. In contrast, Ly et al [37] applied smartphone-based apps as an additional component to psychotherapy using apps between psychotherapy sessions. Hur et al [38] applied a scenario-based app approach combined with a 3-step quiz in which cognitive distortions were identified and resolved with decatastrophizing approaches, similar to cognitive restructuring. In contrast to other studies, Dahne et al [33] provided a self-help behavioral activation app to treat patients. This self-help approach, which should help patients in their daily routine by providing access to cognitive strategies such as mindfulness-based and social competence skill exercises, was also used by Lüdtke et al [36].

The quality of the identified studies was good to very good (mean 11.43 points, SD 2,16; median 12 points). A total of 5 studies (approximately 63%) were assessed with the highest quality and were categorized as A. One study (approximately 12%) was evaluated with category B, and 2 studies (approximately 25%) were labeled with C. No study could reach the maximum score of 15 points. This may be due to difficulties in blinding in mHealth studies. In contrast to pharmaceutical studies with placebo controls, blinding is difficult to guarantee in mHealth studies. All studies were RCTs. Of these studies, 3 had more than 50 participants in the IG [16,35,39]. The other 5 studies presented less than 50 participants in the IG [33,34,36-38]. Detailed measurements that were performed concerning the study design or study performance are presented in Multimedia Appendix 4.

The performed risk of bias assessment of the included studies revealed different percentages concerning the analyzed biases. Low risks of bias have been found for random sequence generation and allocation concealment. In 75% (6/8) of the studies, a low risk of bias was determined. A total of 88% (7/8) of the studies performed proper allocation concealment, minimizing selection bias. The studies were inconsistent with regard to performance and detection bias. In 63% (5/8) of the studies, a low or high risk of bias could not be determined due to missing information. This was also evident for the detection bias, as the blinding of outcome assessment was often not described. The risk of attrition bias was relatively low in the studies (5/8, 63%). In contrast, the risk of other biases could not be ruled out, as sample sizes, gender biases, or intervention development for only 1 system software (either Android or iOS) could bias the reported effects. Therefore, the percentage of other biases was relatively high, accounting for 62.5% (5/8) of the studies that had a high risk of bias. Comparing the results of the quality assessment by Hailey et al [30] and the risk of bias assessment, a good agreement was found. The overall percentages are shown in Figure 2. Detailed bias characteristics of the included studies can be obtained from Figure 3.

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Figure 2. Risk of bias graph.

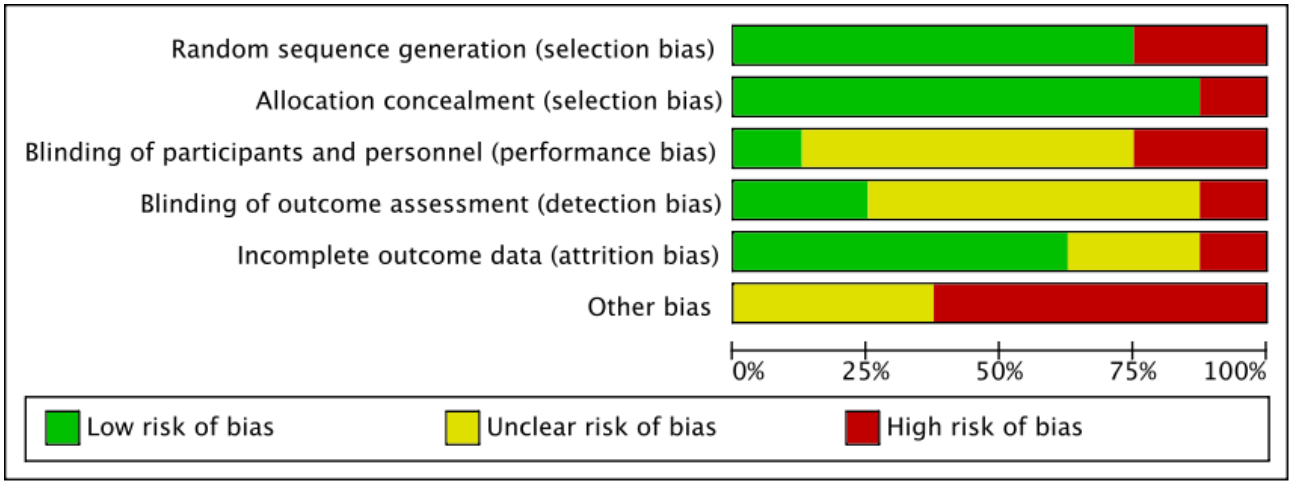
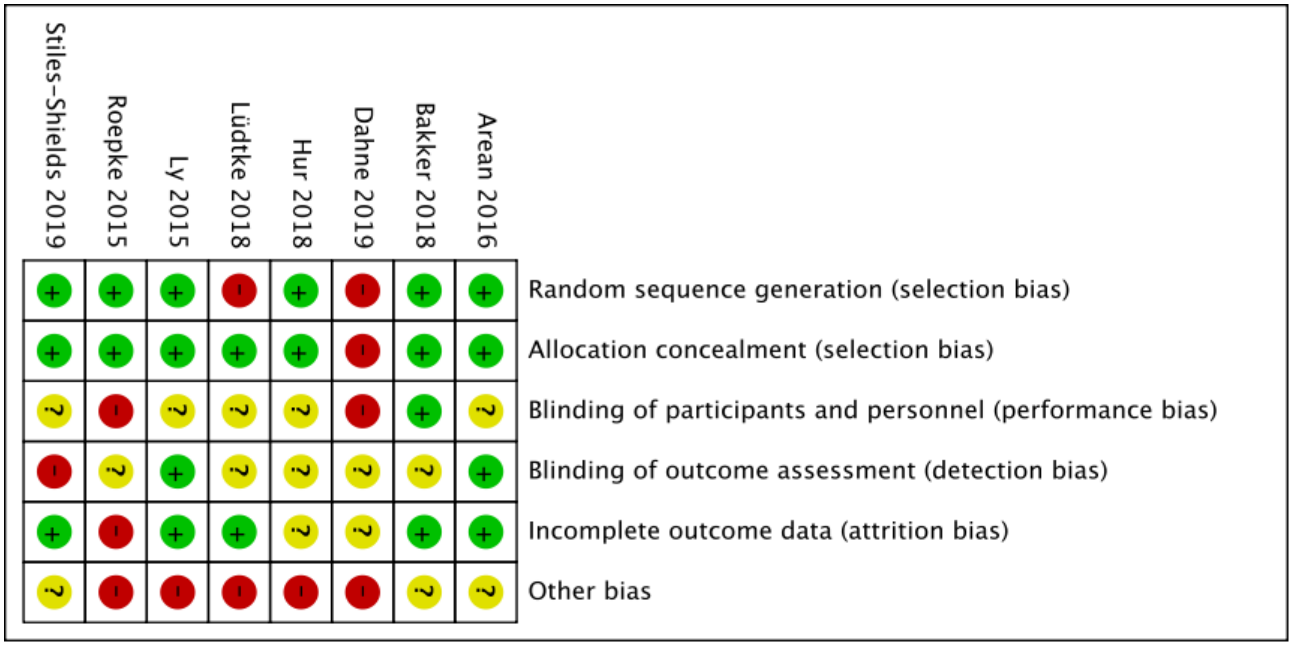


Figure 3. Risk of bias summary.



Description of Patient Characteristics

The overall mean age of the included patients was relatively similar. Only 1 study reported considerably lower ages in the IG and CG [38]. The authors reported the mean age to be 24.76 years (SD 3.70) in the IG and 22.65 years (SD 2.42) in the CG. The overall mean age of the patients in the IG ranged from 24.76 to 43.84 years (mean 35.99, SD 6.35; median 36.85) indicating that the studies observed a relatively young population. The patients in the CG were slightly younger than those in the IG. The lowest age was reported to be 22.65 years, whereas the highest age was reported to be 44.57 years (mean 35.36, SD 7.14; median 33.85). The study by Roepke et al [35] was the only study that reported conventional levels of statistical significance regarding age differences ($F_{2,280}$=2.89; P=.06). The other studies either did not conduct statistical inference or did not report significant differences.

The included studies were highly heterogeneous regarding gender distribution. All studies reported a higher percentage of female patients participating than male patients. This was evident for IG and CG. The most balanced gender distribution for IG was found in the study by Ly et al [37]. They reported that 66% (30/46) were female patients and 35% (16/46) were male patients. The same study also reported the most balanced gender distribution for CG, indicating that 75% (35/47) were female and 26% (12/47) were male. In contrast, other studies had female participant percentages between 80% and 90% [34,36,39].

The observed patients in the included studies were moderately depressed with respect to baseline PHQ-9 values. Only 5 of the 8 studies reported baseline PHQ-9 values [16,34,36,37,39]. The PHQ-9 values ranged from 10.07 to 16.1 in the IG (mean 13.36, SD 2.52; median 13.63) and 8.55 to 16.1 in the CG (mean 13.27, SD 2.95; median 13.64). These mean PHQ-9 values indicate that the observed population had moderate depression [40].

Three studies assessed baseline depression symptoms using the BDI-II [33,37,38]. The results are comparable to the PHQ-9 values, indicating that the patients had moderate depression symptoms [41]. The BDI-II values ranged from 22.65 to 28.96

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in the IG (mean 26.65, SD 3.48; median 28.35) and 25.59 to 32.33 in the CG (mean 28.41, SD 3.5; median 27.32). In contrast to the studies with PHQ-9 measurement, the CG of the studies with BDI-II reported higher values when compared with the IG.

The participants were recruited from the general population. Some studies also recruited patients from outpatient clinics [36,38,39]. Dahne et al [30] recruited patients only from outpatient clinics. Mostly, the recruitment strategies included advertisements on the internet (eg, Craigslist) or social media platforms (eg, Twitter). All studies excluded participants with suicidal thoughts or beliefs. Furthermore, some studies excluded participants who had different doses of antidepressants, comorbidities, alcohol problems, or were already treated by psychotherapy [34,37].

Implications for Depression Symptoms

Data regarding depression symptoms were good. All studies investigated the effects on depression symptoms. However, the reported results of these studies are inconsistent and do not suggest clear implications for depression symptoms.

A total of 5 studies found that there was no significant difference between the IG and CG. Arean et al [16] determined a PHQ-9 score decrease of 0.73 points for the total sample. However, the models revealed no significant difference between the 2 IGs when compared with the CG (β-coefficient −0.01; P=.90). This was also evident in the mildly depressed subgroup analysis. Other subgroup analysis revealed that there was a significant difference for patients with a higher baseline depression at week 12 for the IG that received problem-solving therapy relative to the CG (t_{201}=−2.36; P=.02). Dahne et al [30,33] showed that the between-group mean differences were not significantly different across time points. This was found for IG versus CG 2 (the notations are based on the names used in Table 2; mean difference −3.94; P=.18), IG versus CG 1 (mean difference 1.74; P=.55), and CG 1 versus CG 2 (mean difference −5.69; P=.07). The only significant between-group difference was observed in week 6, in which both IGs reported significantly lower depressive symptoms compared with the treatment as usual condition: IG versus CG 2 (mean difference −7.51; P=.02) and CG 1 versus CG 2 (mean difference −7.68; P=.03). The reported effect sizes were low, estimating Cohen *d* to be 0.33 for IG and 0.44 for CG 1. The study by Hur et al [38] was the only study that estimated the effects between the IG and CG using a nonparametric Wilcoxon rank-sum test. This test also revealed no significant differences between intervention and CG at follow-up (Z=−1.90; P=.06). Other studies conducted an analysis of variance to estimate the differences between intervention and control. Ly et al [37] determined an $F_{1,171.81}$ value of 0.13 for BDI-II and $F_{1,911.85}$=0.11 for PHQ-9, indicating that there was no significant difference between the IG and CG (P=.72 and .74, respectively). These results were supported by Lüdtke et al [36] who estimated an *F* value of 0.173 for PHQ-9 scores with a P value of .68.

Three studies estimated the positive effect of smartphone-based cognitive therapy for depression symptoms. Roepke et al [35] determined depression symptoms using the Center for Epidemiologic Studies Depression Scale and found that IG 1 significantly decreased symptoms relative to the waitlist CG (t_{237}=−2.80; P<.01). In addition, a significant decrease was also found in IG 2, which applied a self-esteem and acceptance app (t_{237}=−3.73; P<.001). When both IGs were compared, there was no significant difference between the groups (t_{237}=0.82; P=.41), indicating that the CBT app was not superior to the self-esteem and acceptance app. The other 2 studies used the PHQ-9 to estimate depression symptoms. Both studies conducted an analysis of variance, which revealed significant differences. Bakker et al [39] compared 3 different interventions with the control condition. Only IG 2 and IG 3, which provided CBT strategies and CBT, showed significant decreases in depression symptoms. The decrease in symptoms was slightly higher in IG 3 (*F*=4.24; P<.05). The analysis of variance of IG 2 also revealed a significant *F* value of 4.39 (P<.05). In addition, the effect sizes were small partial eta–squared=0.035 (IG 3) and partial eta–squared=0.038 (IG 2). In contrast, IG 1 showed no significant effects relative to waitlist CG (*F*=0.78; P>.05). Stiles-Shields et al [34] estimated in a repeated-measures ANOVA (analysis of variance) a higher eta-squared effect size of 0.18 and a significant F_6 value of 2.78 (P=.02), stating that the PHQ-9 scores differed significantly between group assignments. Post hoc analyses revealed that significant differences occurred between the IG 2 and the control condition (P=.03), but no significant differences were found between the behavioral activation app intervention and the other 2 groups (P>.2).

It was evident that the studies that compared a smartphone-based therapy app with a waitlist CG revealed significant differences. With the exception of the study by Lüdtke et al [36], all studies with a waitlist CG showed significant differences. Other studies that had active CGs that applied other smartphone-based therapy formats or support between face-to-face sessions could not establish the superiority of smartphone-based CBT [33,37].

Implications for Anxiety

Of the 8 studies, 4 reported effects on anxiety. Arean et al [16], Dahne et al [33], Stiles-Shields et al [34], and Lüdtke et al [36] reported no results for anxiety. Only 50% (4/8) of the studies reported the desired outcome, and the results are inconsistent. Therefore, a clear implication of smartphone-based CBT cannot be drawn.

Two studies found no significant differences in the reduction of anxiety between the IG and CG. Ly et al [37] tested the reduction of anxiety by conducting an analysis of variance, which revealed a nonsignificant $F_{1,162.05}$ value of 0.34 (P=.56). In addition, the effect sizes were particularly low, estimating Cohen *d* to be 0.03 (95% CI −2.30-2.37). Similar results were found in the study by Bakker et al [39] who used the Generalized Anxiety Disorder Scale (7-item). Although all groups reported a decrease in anxiety, the comparison of the 3 interventions revealed no significant values in the analysis of variance, and the eta-squared effect size was similarly low, ranging from 0.009 to 0.017.

The other 2 studies that reported anxiety as outcomes estimated a significant difference between the groups. Hur et al [38] used

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the State-Trait Anxiety Inventory-X2 tool and reported a Z value of −2.10 at follow-up in a nonparametric Wilcoxon rank-sum test. This was significant with a P value of .035. Both groups showed significantly decreased anxiety symptoms when baseline assessment and follow-up were compared (IG: Z=−2.91; P=.004; CG: Z=−2.51; P=.01). Another study, which reported significant effects of smartphone-based CBT on the reduction of anxiety, found that both IGs significantly declined anxiety relative to the waitlist CG. The *t* test for IG 1 estimated a t_{236} ratio of −2.48, which was highly significant (P=.01). IG 2, using a general version focused on self-esteem and acceptance app, expected a t_{236} ratio of −4.10, which was also highly significant (P<.001). Alternatively, no significant differences were found between both IGs. The estimated difference between the IGs was 1.06, favoring the general version of the intervention (t_{237}=0.82; P=.41). Furthermore, IG 2 revealed a large effect size (Cohen *d* 0.92), whereas IG 1 showed only a small effect size (Cohen *d* 0.43), relative to the waitlist CG [35].

Implications for Self-Efficacy or Self-Esteem

A total of 50% (4/8) of the included studies assessed the effects on self-efficacy or self-esteem. It was evident that different studies had underlying concepts and definitions of the term self-efficacy and self-esteem. Hur et al [38] and Lüdtke et al [36] measured self-esteem using the RSES, which assesses positive and negative feelings about the self as levels of self-esteem. The other 2 studies used various instruments to determine the associated outcomes of self-efficacy or self-esteem. Bakker et al [39] focused on coping abilities connected to self-efficacy and used the Coping Self-Efficacy Scale. However, Roepke et al [35] focused more on general self-efficacy, measuring how much people believe in achieving their goals despite difficulties. Therefore, the New General Self-Efficacy Scale was used.

Studies that used the RSES found no significant increase in self-esteem between the IG and CG. In a nonparametric Wilcoxon rank-sum test, Hur et al [38] estimated a Z value of −0.75, which was not significant (P=.45). Similar to this study, Lüdtke et al [36] conducted an *F* test, which was not significant as well ($F_{1,71}$=1.464; P=.23).

The other 2 studies found significant increases in IG relative to the CG. IG 2 and IG 3 significantly increased self-efficacy (IG 2: *F*=4.86; P<.05; IG 3: *F*=14.95, P<.001). Furthermore, in mediation analyses, self-efficacy was found to be a significant mediator influencing anxiety, well-being, and depressive symptoms (P<.05) [39]. This was also evident in the study by Roepke et al [35]. IG 1 and IG 2 significantly increased self-efficacy relative to the CG at posttest. IG 2, which specifically focused on self-esteem, did not show higher increases in self-esteem relative to IG 1.

To conclude the implications for self-efficacy and self-esteem, inconsistent results were found. Due to the small number of studies and different assessment instruments, the effects of smartphone-based therapy on self-efficacy and self-esteem cannot be clearly shown. Different concepts of self-efficacy and self-esteem are present in the analyzed studies, which may have influenced the results. Furthermore, 1 study showed that self-efficacy was a significant mediator for depression symptoms, anxiety, and well-being.

Implications for Quality of Life

Three studies reported that outcomes for quality of life were increased by smartphone-based CBT. In all studies, it was unclear if quality of life was measured in relation to health, as the studies used the term *Quality of life* instead of *health-related quality of life*. Due to the limited number of studies, it was not possible to draw implications that support the hypothesis of an increase in quality of life by applying smartphone-based CBT.

All 3 studies that directly measured quality of life could not establish significant effects between the IG and CG. Hur et al [38] reported a Z value of 1.19, which was not significant (P=.23). In addition, the analysis of variance of Ly et al [37] was also not significant ($F_{1,165.17}$=1.06; P=.31). This was supported by the results of Lüdtke et al [36], who also did not find significant difference between the groups when analyzing the variance ($F_{1,70}$=0.041; P=.84).

Concepts and definitions of quality of life are quite diverse. Therefore, there were 2 additional studies that reported subareas of quality of life. For example, Bakker et al [39] used the term *well-being* to describe quality of life. The authors showed that there was a significant increase in well-being in patients with depression that used IG 2 and IG 3 relative to the CG (IG 2: *F*=11.0, P<.001; IG 3: *F*=9.47, P<.01). Beyond this, Roepke et al [35] used the term life satisfaction and reported a significant increase in IG 1 and IG 2 (IG 1: t_{236}=3.55, P<.001; IG 2: t_{236}=2.71, P=.01). However, no significant difference was found between the 2 IGs.

Concluding the results of the studies, there are no clear implications concerning quality of life. Three studies that measured quality of life with established instruments [36] found no effects of smartphone-based therapy. Other studies that had a broader definition of life satisfaction or well-being could report effects. However, these aspects only used subareas of the concept of quality of life.

Discussion

Principal Findings

In conclusion, the comparability of the studies is limited due to various factors. This makes it difficult to interpret the obtained results. Due to various approaches to smartphone-based CBT, results differed between the studies. Significant differences were found in gender distributions between the groups, which might have biased the results. In addition, a lack of standardized presentation of the investigated endpoints made it difficult to generate clear implications. Although depression symptoms were mostly assessed with PHQ-9 or BDI-II, other investigated endpoints were assessed with different instruments, which made the comparability difficult. This may be due to the different objectives of the studies. For consistently reported endpoints, such as depression symptoms, the obtained results contradicted each other. Accordingly, no evident results could be found for smartphone-based CBT among patients with depression.

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Limitations

This systematic review has methodological limitations. This concerns the development of the search syntax. For its development, keywords and MeSH terms were used to identify suitable studies. The keywords of the studies were integrated into the search syntax for a larger number of hits. A complete coverage of all relevant keywords could not be guaranteed, which may have led to a bias in the study selection. The strength of this review was the systematic approach and the predefined procedure. To make the search procedure more comprehensible, the search syntax is presented in Multimedia Appendix 1.

Further limitations exist in the selection of studies. Studies were selected from the PubMed and Psyndex databases. Other fee-based databases were not considered and may have led to a selection bias. In addition, the 2 databases can be seen as the most relevant databases for the underlying research question. Furthermore, a selection bias can exist because of language. Only German and English studies were selected.

In total, 8 studies were included in the systematic review. The small number of studies made it difficult to prepare a funnel plot. Therefore, no information can be provided on possible publication biases. In addition, the included studies reported small effect sizes, which do not lead to a large dispersion around the no-effect line.

Finally, the use of the quality assessment tool must be reviewed critically. Owing to the subjective assignment of points to study design and performance, distortion cannot be excluded. To control this, quality assessment was discussed between the 2 reviewers. However, it can be stated that the applied instrument is reliable, as it has already been applied in several telemedical studies. This also accounts for the risk of bias assessment. For orientation, the Cochrane Handbook for Systematic Reviews of Intervention (Version 5.1.0) was used. Imprecise reporting of the included studies may have led to a different assessment of the studies. To control for this judgment, the quality assessment instrument and risk of bias tool were conducted multiple times, and the results were discussed between the 2 reviewers. The vague reporting of the authors was labeled as unclear risk of bias, as shown in Figure 3. However, comparing the quality assessment tool with the risk of bias tool, a concordance can be seen regarding the results.

The small number of included studies can be explained by the selection of study designs. Only RCTs were included to guarantee the highest evidence level. Therefore, this underlying work is a systematic review with a high evidence level. Furthermore, the included studies could report a high quality with a mean score of 11.43 points (median 12 points), indicating that the study design and performance of the RCTs were sufficient.

The content of this review was prepared by a qualitative synthesis of the study results. No statistical analysis of the individual studies was performed with the aid of a forest plot to evaluate the results. As a result, no meta-analysis was performed, which weakens the explanatory power of the results. The results of the review are based on the statistically determined values of the included studies, which were descriptively reported. A high heterogeneity between the studies was the leading argument for not performing a meta-analysis. Although the clinical heterogeneity was medium, the methodological heterogeneity was high. The included studies used different statistical tests to determine the effectiveness of smartphone-based CBTs. Due to the small number of included studies, a subgroup analysis was not considered to be useful. The heterogeneity of studies can further be explained by the research topic. Smartphone-based therapy is a relatively new research topic; therefore, current evidence is limited. CBT, as a profound treatment strategy, has experienced alterations and divisions into smaller treatment sections (eg, mindfulness-based therapy as a component of CBT). These alterations lead to an imprecise use of the definition of CBT. To control this, a sharper inclusion criterion in the beginning might have helped limit clinical and methodological heterogeneity. However, the observed heterogeneity between the studies is not unique to this work because Firth et al [39] determined similar problems with heterogeneity when evaluating the effectiveness of smartphone-based interventions. As children and minorities were excluded, the obtained results were not conclusive for these groups.

Comparison With Prior Work

To place the obtained results in the scientific context, a systematic review and meta-analysis of Firth et al [42] was identified, which showed a significant reduction in depressive symptoms when smartphone-based mental health interventions were applied. In agreement with the results of this review, the authors of the study only found small to medium effect sizes of the intervention. These effect sizes differed when inactive or active CGs were used for comparison. These results cannot be supported by this review, but the statement is limited because a meta-analysis was not conducted. Furthermore, this review had a more detailed approach to mental health interventions. The underlying review assessed the effectiveness of a smartphone-based CBT. However, Firth et al [42] chose a broader approach and included all studies that were classified as a mental health intervention with no scope on specific treatment strategies. This might be a reason why the authors could include 18 studies, whereas this review only found 8 eligible studies. Many studies that were included by Firth et al [42] were excluded in this review for a comprehensible reason. The inclusion of the same studies showed that this review identified the most relevant studies in the research area. Multiple studies that were performed after 2017 were not included by Firth et al [42]. Therefore, this review can be viewed as an update of the effectiveness of smartphone-based therapy among patients with depression. It should also be noted that this review particularly assessed smartphone-based CBT approaches. Another review by Bakker et al [43] formulated evidence-based recommendations, which stated that CBT is a well-researched therapeutic technique for depression. In particular, the effectiveness of computerized CBT was proven by 2 meta-analyses [44,45]. However, recommendations that smartphone-based CBT is effective cannot be supported by this review. The results of this review are inconclusive for the observed endpoints of depression, anxiety, self-efficacy or self-esteem, and quality of life.

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Conclusions

It is apparent that evidence for smartphone-based CBT is limited. Although the economic and public health importance of depression is often mentioned, there is a lack of RCTs with good quality. The effects of smartphone-based apps are insufficiently analyzed. Therefore, there is need for further research. Current research efforts are more focused on determining the feasibility and moderators that are present when applying smartphone-based CBT. These studies fail to determine the effectiveness of technologies that are needed to build the basis for discussions about integrating new treatment methods in reimbursement systems.

The lack of high-quality studies can also be associated with whether effectiveness can only be determined by conducting RCTs. Recently, there has been a rising discussion about alternative study designs that are more flexible than rigor RCT and therefore more suitable for evaluating mHealth technologies [46]. mHealth and other health technologies are more difficult to evaluate than pharmaceutical products. The task of science is to develop new methods and assessment tools that consistently represent the effects of smartphone-based treatments. Efforts toward a standardized reporting of results in the sense of evidence-based medicine would facilitate the comparability and the implementation of systematic reviews and meta-analyses. Actions such as the development of consolidated standards of reporting trials of electronic and mHealth apps and web-based telehealth (CONSORT-EHEALTH) are appreciated and should be recommended for researchers who conduct clinical trials using mHealth technologies [47]. This would facilitate and simplify the execution of systematic reviews to determine evidence-based recommendations for digital health.

For clinical practice, it is crucial to answer the question of how smartphone-based treatment approaches can be integrated into the current routines. Due to legal limitations (eg, ban of remote treatment in Germany), it is clear that these new treatment approaches should add current care and not replace it. A good combination of remote treatment and face-to-face consultation can be considered the gold standard.

Smartphone-based therapy must not interfere with everyday practice or be perceived as disturbing them. Here, technology developers are called upon to develop such a technology for practice. Further training courses for practitioners are of particular importance with regard to the acceptance of smartphone-based therapy.

mHealth interventions often face high attrition rates, which hinders the practical use of those technologies. Therefore, it is of major importance that mHealth interventions are designed with a participatory approach. By integrating users, practitioners, and developers, more effective interventions can be created that are actually used in clinical practice. Concepts such as human-centered design in health technology development should be prioritized to provide digital public health interventions and help patients with a high burden of disease [48,49]. As mHealth interventions rely on user interaction and application, it is important that potential users understand the concepts and applications of smartphone-based therapy. Information and exercises (eg, mood tracking or cognitive behavioral tasks) that are not fully understood by its users lead to attrition. Practitioners or caregivers are seen as being in a position to provide training and introduction and to support the patient in the process of use. In the beginning, this might be a hindering factor for the practitioner to use smartphone-based therapy, but the benefits could be long lasting and establish a shared-decision partnership between the practitioner and the patient. It should be noted that digital competence is always linked to literacy and a certain degree of education. To provide smartphone-based therapy to all population groups, a special focus should be placed on minorities and population groups that face socioeconomical disadvantages. Those population groups need major support and training to ensure that they profit from mHealth interventions.

Fields of action for policy are seen in the development of mHealth structures. In this context, the *GlobalStrategy for Digital Health*, published by the WHO in 2019, can be acclaimed, as their aim is to apply digital health by a vision of health for all. More precisely, the WHO emphasizes that digital health adoption is a decision of the respective country, which requires a unified strategy that integrates leadership, financial, organizational, human, and technological resources. In addition, the use of digital technologies is needed to support equity in terms of access to care by being people-centered, evidence-based, and ethically appropriate [50]. As mHealth competences and socioeconomic determinants are not equally distributed, people with a low socioeconomic status and low competencies need to be supported more. Therefore, policy makers should especially consider those aspects when creating or passing new laws to establish mHealth structures. It is of major importance that digital innovations do not widen the gap of social disparity, which subsequently results in health inequity.

Transparency is an important aspect that empowers patients to make their own decisions [51]. Especially in smartphone-based therapy, it can be seen that the market of apps (eg, Appstore or Android Store) is highly unregulated and policy makers are required to develop regulatory instruments to ensure patients' safety. By regulating the market, technological and scientific innovation can be slowed down. However, it is mandatory that users are able to fully understand whether the app is a medical device or an unregulated app with no evidence-based background [52,53]. Furthermore, the development and functioning of apps is often compared with a blackbox because data use and underlying mechanisms are often hidden by the developers. This hinders transparency, as users should fully understand and know what happens with their data. Open-source projects can be a solution to empower users to understand the mechanisms of mHealth. Through strong involvement of organized interests in health care systems, policy makers must ensure that all involved actors in ensuring care are committed to adhere to the framework conditions. The General Data Protection Regulation of the European Union that increases data protection must also be considered in mHealth interventions [54].

Other areas of responsibility, which need to be addressed by policy makers, include financing issues of mHealth. Although benefits of certain forms of mHealth apps have been proven, the widespread implementation of the technology is failing due

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to financing problems. Financing of innovations as pilot studies is not efficient in the long term. Accordingly, after successful pilot studies, large-scale studies are needed, and the transfer to standard care should be achieved without delay. The obligation of policy makers is to sustainably fund these efforts to modernize and digitalize health care [55].

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Search Syntax.
[DOCX File , 14 KB - mhealth_v9i2e24703_app1.docx]

Multimedia Appendix 2
Patient characteristics.
[DOCX File , 24 KB - mhealth_v9i2e24703_app2.docx]

Multimedia Appendix 3
Study results.
[DOCX File , 14 KB - mhealth_v9i2e24703_app3.docx]

Multimedia Appendix 4
Quality assessment of the included studies.
[DOCX File , 20 KB - mhealth_v9i2e24703_app4.docx]

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Abbreviations

BDI-II: Beck Depression Inventory-II
CBT: cognitive behavioral therapy
CG: control group
IG: intervention group
MeSH: Medical Subject Headings
mHealth: mobile health
PHQ: Patient Health Questionnaire
RCT: randomized controlled trial
RSES: Rosenberg Self-Esteem Scale
WHO: World Health Organization

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Original Paper

mHealth App for Pressure Ulcer Wound Assessment in Patients With Spinal Cord Injury: Clinical Validation Study

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Abstract

Background: Clinical evaluation of a pressure ulcer is based on quantitative and qualitative evaluation. In clinical practice, acetate tracing is the standard technique used to measure wound surface area; however, it is difficult to use in daily practice (because of material availability, data storage issues, and time needed to calculate the surface area). Planimetry techniques developed with mobile health (mHealth) apps can be used to overcome these difficulties.

Objective: The goal of this study was to evaluate the metrological properties of a free-access mHealth app, called imitoMeasure, to assess pressure ulcers.

Methods: This was a noninterventional, validation study. We included patients with spinal cord injury presenting with a pressure ulcer, regardless of its stage or location. We performed wound measurements with a ruler, and we performed acetate tracing using a transparent dressing with a wound measurement grid. Wound evaluation via the mHealth app was conducted twice by the main investigator and also by a coinvestigator to determine validity, intrarater reproducibility, and interrater reproducibility. Bland-Altman plots and intraclass correlation coefficients were used to compute the minimal detectable change percentage.

Results: Overall, 61 different pressure ulcers were included. The validity, intrarater reproducibility, and interrater reproducibility of the mHealth app vs acetate tracing (considered the method of reference) were good, with intraclass correlation coefficients of 0.97 (95% CI 0.93-0.99), 0.99 (95% CI 0.98-0.99), and 0.98 (95% CI 0.96-0.99), respectively, and minimal detectable change percentages between 17% and 35%.

Conclusions: The imitoMeasure app had good validity and reproducibility. It could be an alternative to standard wound assessment methods. Further studies on larger and more diverse wounds are needed.

Trial Registration: ClinicalTrials.gov NCT04402398; http://clinicaltrials.gov/ct2/show/NCT04402398

(JMIR Mhealth Uhealth 2021;9(2):e26443) doi:10.2196/26443

KEYWORDS

mobile app; wound; pressure ulcer; assessment; validity; reliability; app; wound; correlation; access; availability; reproducibility

Introduction

Pressure ulcers are localized damage to the skin and underlying tissue resulting from long-term pressure or pressure in combination with shear or friction [1]. Despite major prevention efforts in hospitals or rehabilitation centers these past decades, pressure ulcers remain a major public health issue. The National Pressure Ulcer Advisory Panel (NPUAP) reports a prevalence of pressure ulcers of 2.3% to 28% in long-term facilities, 10% to 18% in intensive care units, and up to 6% in rehabilitation facilities [2]. Pressure ulcers are of concern in older adults,

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persons with neurological impairments (such as spinal cord injury), persons in intensive care units, and persons in palliative care.

Pressure ulcers have consequences on physical health (increased risk of other complications secondary to immobility, infectious risk, increased malnutrition) but also on mental health (isolation, boredom, depression) and social life (cessation of professional and social activities).

Pressure ulcer care management is based on managing general risk factors (nutrition, prevention, early mobilization) and on local cleansing care and wound dressing; sometimes, surgical debridement is necessary [3].

Care management requires rigorous and regular monitoring of the wound. Wound assessment includes qualitative evaluation (appearance of the wound, borders, perilesional skin, exudates [4]) and quantitative evaluation (volumetric or wound surface). For the latter, a method or reliable tool should facilitate reproducible evaluations from one assessor to the next and be responsive to wound changes, even minimal ones.

The standard method for wound measurement is acetate tracing. It is performed using a transparent acetate paper positioned over a graph dressing to manually calculate the area of the wound. This technique is not often used due to the hygiene risk (contact with the wound) and because it is time consuming. A more rapid estimation of the surface area can be performed with the Kundin method [5]; however, this method is based on the supposition that the wound has an elliptical shape, and thus becomes rather approximate when the wound shape is different. It is also possible to measure the wound using digital planimetry, a method in which the wound's borders are delineated by the clinician using a computerized pen. For example, with the Visitrak system (Smith & Nephew plc), a transparent tracing of the wound is placed on a digital tablet, and its outline is retraced with a digital pen [6]. Its use remains quite rare. Finally, it is also possible to measure wound parameters with standard photography, which enables both qualitative and quantitative evaluation; the main inconvenience of this method is the need for secondary data processing of the image with computer software to obtain surface area (by counting the number of pixels) [5].

Smartphones and digital tablets are now routinely used in clinical practice. Most clinicians own a smartphone and use it for work to access information or to use mobile health (mHealth) apps [7]. This past decade, the development of mHealth apps, especially those for the quantitative evaluation of wounds, has greatly increased. Simply by taking a picture with a smartphone, apps such as MOWA (Healthpath) [8] or Swift Wound (Swift Medical) [9] can compute the dimensions and surface area of the wound. These mHealth apps have several advantages: simultaneous quantitative and qualitative wound evaluation, quick use, and no specific material requirements. The main limitations of these mHealth apps are their access (most require payment) and the lack of evidence regarding their validity for real wounds [10,11].

The objective of this work was to evaluate the metrological properties of a contactless digital planimetry app (imitoMeasure, Imito Ltd) for pressure ulcer measurement (width, length, surface area) in persons with spinal cord injury.

Methods

Study Design

We conducted a noninterventional study between May 2, 2019, and February 7, 2020, at the *Centre Mutualiste Neurologique Propara*, a rehabilitation center specializing in the care management of persons with spinal cord injury, to validate a contactless digital planimetry app (imitoMeasure, Imito Ltd). Each year, approximately 300 patients are seen as outpatients for pressure ulcer monitoring, and 45-50 patients are seen as inpatients for pressure ulcer surgery.

Population and Procedure

Any patient seen for outpatient or inpatient pressure ulcer care management at the *Centre Mutualiste Neurologique Propara* during the study period was screened for inclusion. Inclusion criteria were (1) traumatic or nontraumatic spinal cord injury, regardless of time since injury, injury level, and complete or incomplete nature of the injury and (2) presenting with a Stage 2 to Stage 4 NPUAP pressure ulcer. Exclusion criteria were (1) age <18 years, (2) being an adult patient under legal guardianship, or (3) having a Stage 1 pressure ulcer (since the main objective of this app was to evaluate open wounds).

Data collection and pressure ulcer measurements were performed on the day of the patient's regular consultation for wound evaluation and management. Routine care management of the patient was not modified. If the patient returned several times for the same pressure ulcer, only one measurement was included in the analysis; however, for a given patient, different pressure ulcers could be included.

Potential participants received oral and written information on the study; participating patients provided consent for data use and processing. The research protocol received authorization from the Montpellier University Hospital ethics committee (2019_IRB-MTP_06-02), and the study was registered at ClinicalTrials.gov (NCT04402398).

Data Collected

Anthropometric data (height, weight) were collected along with time since injury, injury level, and American Spinal Injury Association Impairment Scale (AIS) score, which is the spinal cord injury scale of reference to assess severity [12].

Wound Assessment

The duration and location of the wound were recorded. The length and width of the wound were measured with a ruler—the method that is most commonly used [13,14]. Length L was defined as the longest dimension, and width W was defined as the perpendicular measurement. The surface area S was evaluated in two ways: (1) using the Kundin formula [14] to give an approximation of the surface area by considering the wound as an ellipse, $S = L \times W \times 0.785$, and (2) performing acetate wound tracing [15] using Opsite Flexigrid (Smith & Nephew plc) dressings. The wound area on the acetate tracing was calculated manually by the main investigator by counting

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completely filled squares within the wound border and regrouping the partially full squares. This second evaluation method was considered as the technique of reference.

Wound length, width, and surface area were also measured with the imitoMeasure app [16]. The investigators used, according to their preference, an iOS (iPad mini, iPhone) or Android-based device.

To use imitoMeasure, an adhesive calibration marker was placed next to the wound to calibrate the image. The calibration marker is freely accessible with the app and must be printed by the user. The picture was taken with the smartphone, using the app, then the wound borders were manually delineated on the screen (Figure 1). Length, width, and surface area measurements were then automatically calculated.

Figure 1. Image of the wound taken with the imitoMeasure app, with the calibration marker and wound borders manually delineated.

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Description of the Different Evaluations

The objective was to validate the use of the measurement tool in daily clinical practice; therefore, all health care professionals treating pressure ulcers at the *Centre Mutualiste Neurologique Propara* participated in the study. Overall, 12 evaluators, including 7 physicians and 5 nurses performed the assessments; all evaluators were trained to use the imitoMeasure app. For the first evaluation, the evaluator measured the length and width with a ruler, then delineated the wound borders on acetate paper; finally, measurements were taken with the imitoMeasure app. The second evaluator then performed new measurements with the imitoMeasure app (for the interrater reproducibility). The first evaluator then performed another evaluation with the app (intrarater reproducibility). Measures were anonymized and stored in an online medical database (REDCap, Vanderbilt University). The surface area was calculated with the Kundin formula automatically. Each evaluator entered data independently. To optimize the reproducibility of the surface area measurements, the wound tracing measurement was performed independently, by a single blinded investigator, based on the acetate tracings provided.

Sample Size Calculation

In the absence of previously published clinical data on wound evaluations via the mobile app, we followed good practice guidelines for validation studies of measurement tools such as COSMIN criteria [17], considering that a minimum sample of 50 participants was adequate.

Evaluation Criteria and Statistics

The main measure studied for validation was the wound surface area; the surface area measurement obtained via the imitoMeasure app was compared to each method. Measurements (length and width) obtained via the app were also compared to measurements obtained with the ruler. Measurements repeated the same day were used to evaluate inter- and intrarater reproducibility for imitoMeasure wound surface area assessment. Bland-Altman plots [18] were used for validity and reproducibility evaluations. Intraclass correlation coefficients (ICC) for the agreement parameters were computed (ICC 2.1 according to Shrout and Fleiss [19]). The 95% confidence interval of the ICC was calculated via bootstrapped distribution with 1000 replications. The ICC was considered good if >0.75 and excellent if >0.90 [20].

Additional analyses were conducted for reproducibility measures. The standard error of measurement was calculated from the components of the ICC variation [21], and the minimal detectable change (MDC) at 90% was obtained from the standard error. The MDC [22,23], also called smallest detectable change [21], represents the minimal detectable change between 2 measurements in order to be 90% certain that this change does not solely reflect measurement error [24]. If heteroscedasticity was observed from visual analysis of the Bland-Altman plots (ie, increased differences between the measures according to their mean values), the MDC was also expressed as a percentage, which could be interpreted as the minimal detectable change compared to the initial size of the pressure ulcer.

Subgroup analyses were conducted (validity and reproducibility) according to the location of the wound—either on flat (sacrum, flank, iliac crest, tibia, edge of the foot) or curved skin (ischial tuberosity, greater trochanter, calcaneus, occiput, malleolus). Statistical analyses were performed with R software (version 3.6.0 [25]; psy package [26] for ICC, boot package for confidence intervals). Excel (Microsoft Inc) software was used for graphs.

Results

Descriptive Analysis

A total of 61 pressure ulcers for 59 patients were studied (Table 1). Patients were mainly men, with thoracic spinal cord injury and AIS grade A. Most pressure ulcers were located on the ischial tuberosity. Their mean surface area was 7.7 cm^2, ranging from 0.2 cm^2 to 49.2 cm^2 and a median at 4.7 cm^2. The wound evaluations with the mobile app were performed using smartphones (Samsung S5, Samsung S8, iPhone 5S, iPhone 7, Huawei P8 Lite, Altice S70) or tablets (iPad mini 4, iPad Air).

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Table 1. Patient and wound descriptive data.

Characteristic	Value, n (%)
Patient (n=59)	
Sex	
Male	52 (88)
Female	7 (12)
Level of injury	
Cervical	7 (12)
Thoracic	47 (80)
Lumbar	5 (8)
American Spinal Injury Association Impairment Scale	
Grade A	78 (81)
Grade B	6 (10)
Grade C	4 (7)
Grade D	1 (2)
BMI[a]	
<18.5 kg/m^2	3 (7)
18.5-25 kg/m^2	23 (55)
>25 kg/m^2	16 (38)
Wound characteristics (n=61)	
Localization	
Sacrum	12 (20)
Ischial tuberosity	26 (43)
Trochanter	4 (6)
Heel	7 (11)
Other	12 (20)
Age of wound[b]	
<2 weeks	7 (14)
2 weeks to 1 month	8 (16)
1 month to 6 months	17 (35)
6 months to 1 year	8 (16)
>1 year	9 (18)

[a]n=42; data are missing from 17 patients.

[b]n=49; data are missing from 12 patient wounds.

Validity of Wound Measurement via the imitoMeasure mHealth App

The comparison of wound surface area measurements with the imitoMeasure app and those from acetate tracing (the reference method) yielded an ICC of 0.97 (95% CI 0.93-0.99). The Bland-Altman plot for this comparison (Figure 2) showed a systematic bias close to zero (–0.8 cm^2). Differences between measurements did not change with pressure ulcer size.

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Figure 2. Bland-Altman plots: (a) validity (imitoMeasure app vs acetate tracing), (b) intrarater reproducibility, and (c) interrater reproducibility.

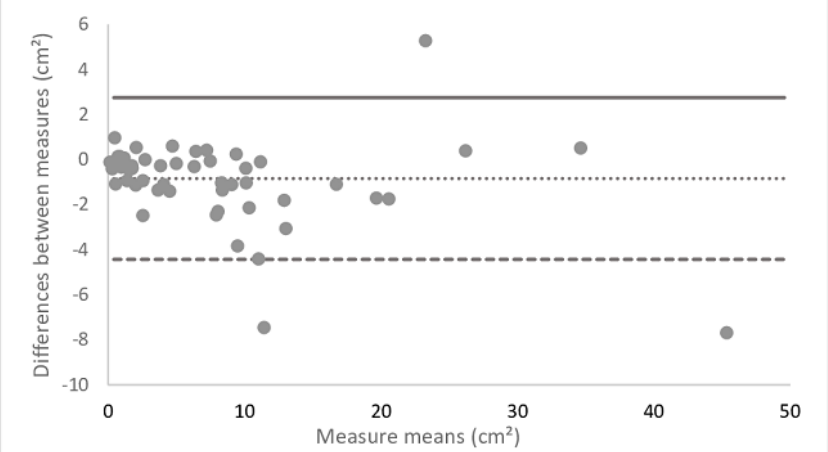

Fig 2a - Surface measurement with imitoMeasure vs. contact tracing

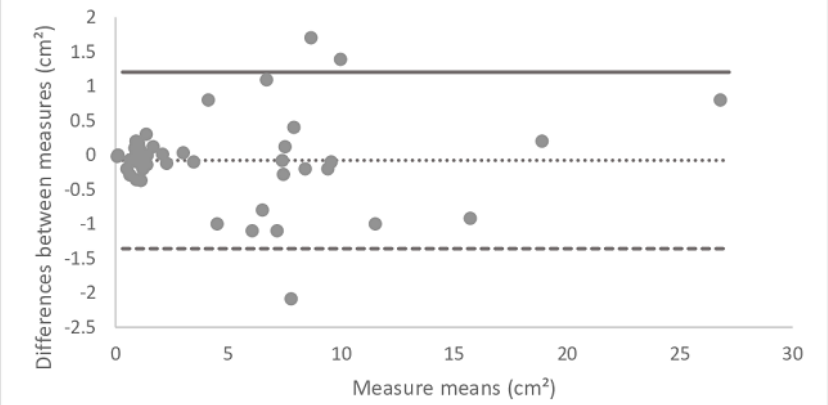

Fig 2b - Intra-rater reliability for imitoMeasure

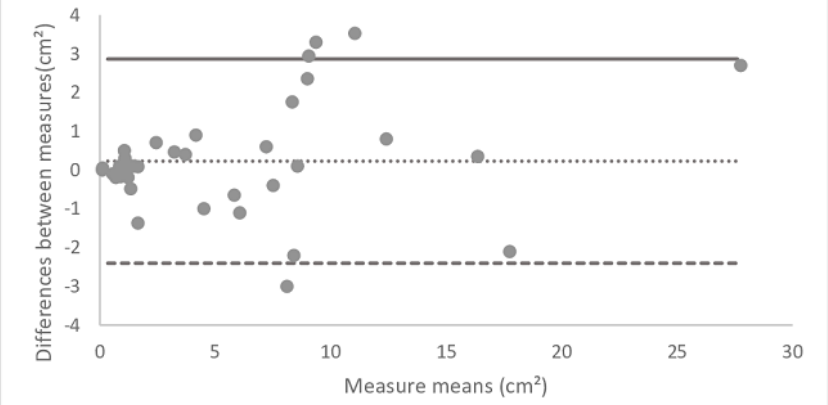

Fig 2c - Inter-rater reliability for imitoMeasure

The comparison between measurements with the imitoMeasure and those using the Kundin method yielded an ICC of 0.96 (95% CI 0.92-0.97). For comparisons of length and width measurements with the imitoMeasure app and those with a ruler, ICCs ranged between 0.95 and 0.97.

Reproducibility of Measures via the imitoMeasure App

For intra- and interrater reproducibility of wound surface area measurements, the Bland-Altman plots showed heteroscedasticity, with differences between increasing measures for larger pressure ulcers.

Intrarater reproducibility ICCs were greater than 0.98 both for dimensions (length and width) and surface area. MDC percentages varied between 15% and 19%. Interrater reproducibility ICCs were greater than 0.97, with MDC percentages ranging from 18% for length to 35% for the surface area (Table 2).

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Table 2. imitoMeaure validity and reproducibility data.

Measure	ICC[a] (95% CI)	SE	MDC[b] cm or cm^2 (%)[c]
Validity			
Acetate tracing vs imitoMeasure (n=60)	0.97 (0.93-0.99)	N/A[d]	N/A
Kundin surface measure vs imitoMeasure (n=61)	0.96 (0.92-0.97)	N/A	N/A
Length ruler vs versus imitoMeasure (n=61)	0.97 (0.94-0.99)	N/A	N/A
Width ruler vs imitoMeasure (n=61)	0.95 (0.90-0.98)	N/A	N/A
Intrarater reproducibility			
Surface area (n=46)	0.99 (0.98-0.998)	0.45	1.05 (17)
Length (n=47)	0.99 (0.98-0.99)	0.21	0.50 (15)
Width (n=47)	0.98 (0.93-0.99)	0.16	0.38 (19)
Interrater reproducibility			
Surface area (n=44)	0.98 (0.96-0.99)	0.93	2.17 (35)
Length (n=44)	0.99 (0.97-0.99)	0.26	0.61 (18)
Width (n=44)	0.97 (0.94-0.99)	0.21	0.48 (24)
Subgroup analysis according to the wound location			
Flat skin			
Validity (n=22)	0.98 (0.95-0.99)	N/A	N/A
Intrarater reproducibility (n=19)	0.99 (0.95-0.999)	0.47	1.10 (16)
Interrater reproducibility (n=16)	0.99 (0.98-0.997)	0.68	1.61 (23)
Curved skin			
Validity (n=38)	0.97 (0.88-0.99)	N/A	N/A
Intrarater reproducibility (n=27)	0.99 (0.98-0.998)	0.43	1.01 (18)
Interrater reproducibility (n=28)	0.97 (0.93-0.98)	1.05	2.45 (43)

[a]ICC: intraclass correlation coefficient.

[b]MDC: minimal detectable change.

[c]Percentage minimal detectable change in relation to the initial measurement.

[d]N/A: not applicable.

Impact of the Wound Location

In subgroups, ICCs remained greater than 0.97, but only MDC values for interrater reproducibility were altered by measurement conditions, with a less reproducibility for pressure ulcer measurements on curved skin (MDC percentage 43%). MDC percentages for intrarater reproducibility were 16% and 18% for wounds on flat and curved skin, respectively.

Discussion

Principal Findings

This study is the first clinical evaluation that follows good practice guidelines for metrological quality [17] to measure pressure ulcers with an mHealth app. For surface area measurements performed via the imitoMeasure app, the validity and reproducibility based on the ICC was excellent (ICC>0.90). The evaluation of reproducibility with standard error and MDC, which is recommended [17,27] but scarcely used in the literature, yielded very satisfactory clinical results in a single rater, but unveiled some variability between raters for the same wound, potentially influenced by measurement conditions and wound location.

The interpretation of reproducibility requires methodological considerations. In fact, reproducibility encompasses 2 dimensions [21]. The so-called reproducibility is the measurement's capacity to differ between 2 different individuals, well reflected by the ICC, which was excellent in our study. However, the ICC is intrinsically affected by interrater variability [21,24] and yields very high values when the sample is heterogeneous, which was the case in our study, with a wide range of pressure ulcer sizes. Thus, it is important to also evaluate the so-called agreement reproducibility, reflecting the similarities between 2 measurements and thus related to measurement error [21,27]. The evaluation of agreement, very rarely used in the literature [5], is now part of the quality criteria in tool validation studies [27], essential for situations wherein it is important to detect slight variations [21], such as wound monitoring. The agreement is sometimes assessed with the coefficient of variation [24,28] but more commonly with standard error and MDC because, as they are expressed in the measurement unit, they are easier to interpret by the clinician

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[21]. Because of ICC limitations, in our results, only standard error and MDC measurements highlighted the impact of changing rater and measure conditions. In previously conducted reproducibility studies [14] on wound measurement tools and techniques, the Pearson R was sometimes used, but it is less recommended than the ICC for reproducibility [27]. When the ICC was calculated for reproducibility, it ranged between 0.70 and 0.99 for traditional methods (acetate tracing, Kundin) [15,29], and it ranged between 0.96 and 0.99 for mHealth app methods [30,31]. Thus, our ICC values are excellent. A few studies gave results on agreement reproducibility, including one for acetate tracing with planimetry analysis (coefficient of variation 7% [32]) and one for a complex instrumental method, stereophotogrammetry (coefficient of variation 6.8% [33]). To our knowledge, no study has previously measured standard error or MDC. To allow for comparison, we calculated a posteriori coefficient of variations for wound surface area measured with the imitoMeasure app and obtained 7.4% for intrarater reproducibility and 15% for interrater reproducibility.

In our study, agreement reproducibility results showed less interrater reproducibility (in percentage MDC) for wounds on curved skin areas (ischial tuberosity, calcaneus, occiput, or malleolus). This is potentially related to planimetry analysis itself. The mHealth app considers that the wound is located on the same plane as the skin marker used to calibrate measures. The surface area measured is the actual projection of the wound onto this plane, thus the approximation value of the measurement widens if the skin is not flat, or if the marker is not positioned correctly. A first step to improve this would be to standardize measurements and have the rater to orient the skin marker to the wound's main plane. Another solution would be to take a video of the wound with the smartphone and a calibration marker to reconstruct a 3D image of the wound surface area before measuring it. This solution would be similar to photogrammetric techniques, using different point of views to assess a wound on curved skin [34].

Strengths

The mHealth app was evaluated in ecological conditions by nurses and physicians experienced in evaluating chronic wounds (experienced using acetate tracing, which was used as the reference). They were familiarized with the app quickly, without any prior training aside from the guidelines given to users by the company and used different mobile devices (iOS or Android-based smartphone or tablets).

Given how quickly one can be familiarized with the app, the time saved during wound assessment, and results from this first validation study, use of the mHealth app could be implemented in clinical practice, taking into account reproducibility limitations during interrater evaluations and for wounds on curved skin surfaces listed above.

Limitations

A standard responsiveness to change study would require longitudinal follow-up [27] with several evaluations per patient, which was not within the scope of this study; however, the MDC assessment gave an indirect evaluation of the tool's responsiveness to change since it allows the determination of the value above which we consider that the wound has changed clinically.

If analyses on the overall population had enough statistic power, subgroups analyses were performed on moderate (between 30 and 49) to small (<30) size samples [17], thus they should be interpreted with caution. Furthermore, reproducibility depended on the size of the wound (Figure 2), and in this study sample, there were few large pressure ulcers. Further validation studies on larger wounds could be useful.

Perspectives for Clinical Practice

In clinical practice, use of the imitoMeasure app has the advantage of bypassing difficulties related to acetate tracing (such as availability of the material, issue of data storage, time to compute the surface area), and it is easily accessible since physicians regularly use their smartphones [35].

Perspectives for Clinical Research

There is a need to evaluate standardization of this app's use in clinical practice to improve interrater reproducibility and to make use of additional technological updates to improve wound measurement on curved skin surfaces. Further studies are needed to evaluate the validity of the mobile app for other clinical indications, such as venous or arterial ulcers, burns, erythematous skin eruptions, or allodynic areas in neuropathic pain. Furthermore, additional studies on pressure ulcers could include NPUAP stage 1 wounds—intact skin with nonblanchable erythema.

With the expansion of digital health in wound monitoring, there is a growing interest for photographic evaluations performed by patients or their families and sent via email to a specialist. A simple picture allows physicians to conduct an acceptable qualitative analysis of the wound, especially to evaluate the infectious risk [36]. Furthermore, most patients are able to send pictures of their wound via a secure email service to a physician, who can then conduct a qualitative clinical interpretation if the quality of the picture is sufficient [37]. The relevance of an mHealth app in the quantitative evaluation of wounds by patients at home to send to a remote physician remains to be defined and could be the topic of further study.

Conclusion

Excellent metrological qualities of the mHealth app imitoMeasure were demonstrated when compared to evaluation methods used in daily practice, in the evaluation of pressure ulcers in persons with spinal cord injury. Further studies, on other types of wound, are needed.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

AIS: American Spinal Injury Association Impairment Scale
ICC: intraclass correlation
MDC: minimal detectable change
mHealth: mobile health
NPUAP: National Pressure Ulcer Advisory Panel

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Original Paper

A Novel User Utility Score for Diabetes Management Using Tailored Mobile Coaching: Secondary Analysis of a Randomized Controlled Trial

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Abstract

Background: Mobile health applications have been developed to support diabetes self-management, but their effectiveness could depend on patient engagement. Therefore, patient engagement must be examined through multifactorial tailored behavioral interventions from an individual perspective.

Objective: This study aims to evaluate the usefulness of a novel user utility score (UUS) as a tool to measure patient engagement by using a mobile health application for diabetes management.

Methods: We conducted a subanalysis of results from a 12-month randomized controlled trial of a tailored mobile coaching (TMC) system among insurance policyholders with type 2 diabetes. UUS was calculated as the sum of the scores for 4 major core components (range 0-8): frequency of self-monitoring blood glucose testing, dietary and exercise records, and message reading rate. We explored the association between UUS for the first 3 months and glycemic control over 12 months. In addition, we investigated the relationship of UUS with blood pressure, lipid profile, and self-report scales assessing diabetes self-management.

Results: We divided 72 participants into 2 groups based on UUS for the first 3 months: UUS:0-4 (n=38) and UUS:5-8 (n=34). There was a significant between-group difference in glycated hemoglobin test (HbA_{1c}) levels for the 12-months study period (*P*=.011). The HbA_{1c} decrement at 12 months in the UUS:5-8 group was greater than that of the UUS:0-4 group [–0.92 (SD 1.24%) vs –0.33 (SD 0.80%); *P*=.049]. After adjusting for confounding factors, UUS was significantly associated with changes in HbA_{1c} at 3, 6, and 12 months; the regression coefficients were –0.113 (SD 0.040; *P*=.006), –0.143 (SD 0.045; *P*=.002), and –0.136 (SD 0.052; *P*=.011), respectively. Change differences in other health outcomes between the 2 groups were not observed throughout a 12-month follow-up.

Conclusions: UUS as a measure of patient engagement was associated with changes in HbA_{1c} over the study period of the TMC system and could be used to predict improved glycemic control in diabetes self-management through mobile health interventions.

Trial Registration: ClinicalTrial.gov NCT03033407; https://clinicaltrials.gov/ct2/show/NCT03033407

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KEYWORDS

type 2 diabetes; mobile applications; diabetes management; patient engagement

Introduction

Background

The rate of diabetes has been steadily increasing over the past few decades [1,2], and its associated complications are major causes of morbidity and mortality [3] that lead to substantial economic loss through direct medical costs [4]. To prevent diabetes complications and decrease economic burden, multifaceted professional interventions are needed [5,6]. Successful treatment of diabetes includes patient self-management such as lifestyle intervention [7,8]. Clinical trials have shown that effective lifestyle modifications can substantially reduce the risk of developing diabetes and improve patient health outcomes [9,10].

Digital health technology-based tools have been developed to assist in diabetes self-management [11]. Due to increasing evidence for the efficacy of digital health tools for improving glycated hemoglobin (HbA_{1c}) levels and other diabetes-related outcomes, both the 2017 National Standards for Diabetes Self-management Education and Support [12] and the 2019 American Diabetes Association Standards of Medical Care [13] recommend including technology-based solutions to deliver diabetes care and education. Mobile platforms and health applications are increasingly being implemented as useful tools for patients and health care providers [14] and play a role in supporting diabetes self-management by sharing data with providers and providing minimal data analysis, interpretation, and guidance to patients [15]. However, the effectiveness of digital health tools to improve diabetes outcomes could depend on patient engagement in the beginning, such as proper blood glucose testing, medication adherence, adoption of a healthy diet and physical activity, and advice-sharing text messages [16]. Patient engagement is increasingly regarded as a crucial factor in diabetes management [17]. Therefore, patient engagement must be examined through multifactorial tailored behavioral interventions because of the variability in self-management capability.

A 12-month randomized clinical trial demonstrating the effectiveness of tailored mobile coaching (TMC) on diabetes management among policyholders with type 2 diabetes was previously reported [18]. TMC is a mobile health care system in which the intensive coaching from health care providers and the self-application of patients are organically connected. The effectiveness of the TMC system can vary depending on patient engagement in diabetes self-management. In this study, we conduct a subanalysis of the TMC study to evaluate the relationship between patient engagement and diabetes-related health outcomes. We developed a novel user utility score (UUS) consisting of 4 major components of blood glucose testing [19], dietary habits [20], exercise [21], and message reading [22] as a tool to measure patient engagement.

Objectives

This study examines the usefulness of UUS as a tool to measure patient engagement by using a mobile health application for diabetes management among policyholders with type 2 diabetes. The primary aim of this paper is to determine whether UUS for the first 3 months results in improved glycemic control over a 12-month follow-up period among policyholders with type 2 diabetes. In addition, we investigate the relationship of UUS with blood pressure, lipid profile, and diabetes self-management.

Methods

Ethics Approval and Consent to Participate

All participants provided written informed consent before any study procedures were started. The trial protocol was reviewed and approved by the institutional review board of Kangbuk Samsung Hospital (KBS12089) and was conducted in accordance with the Helsinki Declaration of 1975.

Study Population and Design

This study was conducted with Korean policyholders with type 2 diabetes recruited from Samsung Fire and Marine Insurance (Seoul, South Korea) from October 2014 to December 2015. This study was an open-label, randomized controlled trial to evaluate the effectiveness of the TMC system provided by Kangbuk Samsung Hospital, Seoul, Korea. Participants were randomly assigned into an intervention group and a control group. During a 6-month assessment period, the intervention group received TMC for diabetes management via a mobile app, whereas the control group maintained their usual diabetes care. After 6 months, the second 6-month period of the study was conducted and included the subjects who agreed to participate. Identification and recruitment of patients have been described in the previous study [18].

We conducted a subanalysis of results from the TMC group over 12 months. During the first 6-month period, 72 participants were assessed, and 54 participants were followed up with in the second 6-month period. There were 18 participants with missing values at 12 months. We analyzed detailed data uploaded to the mobile app Switch (Huraypositive Inc) and developed a novel UUS. Participants who received TMC were divided into 2 groups based on UUS for the first 3 months. We evaluated the relationship between UUS as an index of patient engagement and glycemic control for diabetes management.

Tailored Mobile Coaching (TMC) System and the Switch App

The TMC system is a medical service to support diabetes self-management through bidirectional communication between health care providers and patients by sharing data uploaded to the mobile app Switch without any additional equipment for data transmission or a web portal for users. Users of the mobile app could upload measurement data such as self-monitoring of blood glucose, blood pressure, and body weight, along with their lifestyle, including dietary records, physical activities, and

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medical information. Care managers sent messages to provide appropriate educational information to patients. Participants received regular mobile messages and were allowed to communicate with providers via the Switch app. Care managers analyzed the transmitted records and sent messages on the secured website twice a week. The message content included notifications for behavioral recommendations, diabetes education, and individualized advice. At any time, users could check their data by logging into the Switch app, where they could obtain information on diabetes and other metabolic diseases. Details about the TMC system and Switch app have been described in the previous study [18].

UUS (User Utility Score)

UUS was calculated as the sum of the scores for 4 core components: frequency (days) of self-monitoring of blood glucose testing, dietary and exercise records, and message reading rate (percent). We divided the data of each component for the first 3 months into tertiles: first (T1), second (T2), and third tertiles (T3) that were 0-33, 34-75, and 76-91 days for self-monitoring of blood glucose; 0-3, 4-30, and 31-91 days for dietary records; 0-37, 38-81, and 82-91 days for exercise records; and 0%-73%, 74%-97%, and 98%-100% for message reading rates, respectively. T1, T2, and T3 were scored as 0, 1, and 2 points, respectively, and the range of UUS was 0-8.

To validate UUS accuracy using the current dataset, we used another dataset from an outpatient clinic at Kangbuk Samsung Hospital from June 2012 to March 2013 [23]. The prospective clinical study evaluated the effectiveness of mobile health-based diabetes self-management [23]. The participants from the intervention group (n=39) were used as a sample of the training set. We found that UUS was associated with a change in HbA_{1c} at 6 months; the regression coefficient was –0.078 (SD 0.037; P=.04).

Measurements

The primary outcome was changes in HbA_{1c} over the 12-month study period. The secondary outcomes were diabetes-related health outcomes and diabetes self-management. On the first visit, participants completed a self-administered questionnaire regarding demographic characteristics, social history, and other medical conditions. Smoking and drinking habits were categorized as noncurrent or current. Body mass index (BMI) was calculated as weight in kilograms divided by the square of height in meters. Blood pressure was measured in a seated position after 5 minutes of rest. Blood samples were obtained after overnight fasting to measure HbA_{1c}, total cholesterol, triglycerides, high-density lipoprotein (HDL) cholesterol, and low-density lipoprotein (LDL) cholesterol. The Korean version of the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire [24] and the Korean version of the Appraisal of Diabetes Scale (ADS) [25] were applied to evaluate diabetes self-management. The SDSCA includes items assessing diet (general and specific), exercise, blood glucose testing, foot care, and smoking over the past week; higher scores indicate better self-care behaviors [26]. The ADS is a stable measure of diabetes-related appraisal, with a smaller total score indicating a more positive appraisal [27]. Clinic or laboratory tests were repeated at baseline, 3, 6, and 12 months. A self-administered questionnaire was obtained at baseline and at 6- and 12-month follow-up evaluations.

Statistical Analyses

Participants were divided into 2 groups according to the median value of UUS. The study outcomes of both groups were compared using the Student t test for continuous variables and a chi-square test for categorical variables. Data were expressed as a mean and standard deviation or as a number (proportion). Repeated-measures analyses of variance (ANOVA) were used to monitor differences in HbA_{1c} between the 2 groups over a 12-month period. In cases of missing follow-up visit (12 months) data, the last observation carried forward (LOCF) imputation method was used. Exploratory data analysis is used to investigate changes in HbA_{1c} from baseline at 3, 6, and 12 months for both groups. To assess an association of UUS with changes in HbA_{1c}, multivariable linear regression analyses were used. Model 1 was adjusted for age and sex. Model 2 was adjusted for age, sex, BMI, systolic blood pressure, LDL, HbA_{1c} at baseline, and diabetes duration. Model 3 was adjusted for age, sex, BMI, systolic blood pressure, LDL, HbA_{1c} at baseline, diabetes duration, cigarette smoking, alcohol consumption, and ADS. The Bonferroni correction was then used to perform multiple comparisons between the 3 points of time. To identify the decrease amount in HbA_{1c}, the reduction rate of HbA_{1c} was evaluated. The HbA_{1c} reduction rate was equal to the difference in HbA_{1c} divided by baseline HbA_{1c} value times 100%. Linear regression analysis was performed to test the relationship between the HbA_{1c} reduction rate and UUS. A P value <.05 was considered statistically significant. All data were analyzed using SPSS (version 18.0; IBM Corp).

Prior Presentation and Data Availability

These data were presented at the American Diabetes Association 77th Scientific Session. The data used or analyzed during this study are available from the Samsung Fire and Marine Insurance Company; however, restrictions apply to the availability of these data, which were used under the license of this study. Data are available from the authors upon reasonable request and with the permission of Samsung Fire and Marine Insurance Company.

Results

Participant Characteristics

Participants were divided into 2 groups, UUS:0-4 and UUS:5-8, based on the UUS for the first 3 months. At 3 and 6 months, 72 participants were assessed: 38 participants in the UUS:0-4 group and 34 participants in the UUS:5-8 group. At 12 months, 54 participants were followed up with: 23 participants in the UUS:0-4 group and 31 participants in the UUS:5-8 group. Table 1 shows the baseline characteristics of the 2 groups. There were no significant differences between groups with regard to age, sex, BMI, blood pressure, HbA_{1c}, LDL cholesterol levels, diabetes duration, cigarette smoking, alcohol consumption, and SDSCA and ADS scores. The mean HbA_{1c} level was 8.07% (SD 1.23%; 65 mmol/mol) in the UUS:0-4 group and 8.20% (SD 1.69%; 66 mmol/mol) in the UUS:5-8 group (P=.69).

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Table 1. Baseline characteristics of participants divided into 2 groups based on user utility scores (UUS; n=72).

Characteristic	UUS:0-4 (n=38)	UUS:5-8 (n=34)	*P* value[a]
Age in years, mean (SD)	50.58 (8.52)	52.38 (7.13)	.34
Gender, n (%)			.40
Male	21 (53.8)	21 (63.6)	
Female	17 (46.2)	13 (36.4)	
Body mass index (kg/m^2), mean (SD)	26.34 (3.19)	25.71 (3.42)	.42
Systolic blood pressure (mmHg), mean (SD)	137.29 (16.54)	136.88 (15.50)	.92
Diastolic blood pressure (mmHg), mean (SD)	87.34 (11.74)	86.68 (8.73)	.79
HbA_{1c}[b] %, mean (SD)	8.07 (1.23)	8.20 (1.69)	.69
Total cholesterol (mg/dL), mean (SD)	165.18 (25.22)	175.52 (39.05)	.20
Triglyceride (mg/dL), mean (SD)	153.31 (61.55)	139.73 (60.75)	.35
HDL cholesterol (mg/dL), mean (SD)	46.05 (9.12)	48.85 (13.29)	.30
LDL cholesterol (mg/dL), mean (SD)	88.40 (24.81)	98.54 (34.52)	.17
Current smoker, n (%)	13 (33.3)	6 (18.2)	.15
Current alcohol drinker, n (%)	15 (38.5)	15 (45.5)	.55
Diabetes duration in years, mean (SD)	7.28 (3.71)	7.23 (6.49)	.81
Insulin injection, n (%)	8 (20.5)	8 (24.2)	.70
Antihypertensive medication, n (%)	16 (41)	11 (33.3)	.50
Antidyslipidemic medication, n (%)	24 (61.5)	14 (42.4)	.11
Summary of Diabetes Self-Care Activities (SDSCA) questionnaire, mean (SD)			
Diet total	10.47 (5.47)	11.68 (6.62)	.40
Exercise	5.82 (4.13)	6.26 (3.86)	.64
Blood glucose testing	3.00 (4.23)	4.94 (5.27)	.09
Foot care	3.58 (3.94)	3.09 (3.53)	.58
Appraisal of Diabetes Scale (ADS) total, mean (SD)	19.76 (4.27)	19.18 (4.54)	.57

[a]*P* values were derived from the Student *t* test or Pearson chi-square test.
[b]HbA_{1c}: glycated hemoglobin.

UUS and Changes in HbA_{1c}

Figure 1 depicts mean HbA_{1c} levels for the 12-month study period in the UUS:0-4 group and UUS:5-8 group. Significant differences were observed in the improvement of HbA_{1c} within each group (P<.001) and between groups (P=.011) by repeated-measures ANOVA. The UUS:5-8 group was significantly reduced compared with the UUS:0-4 group at 3, 6, and 12 months in intention-to-treat analyses (LOCF). Table 2 shows changes in HbA_{1c} levels from baseline at 3, 6, and 12 months for both groups. At 12 months, the mean change in HbA_{1c} was –0.92 (SD 1.24%) [–10.1 (SD 13.6) mmol/mol] in the UUS:5-8 group, compared with –0.33 (SD 0.80%) [–3.63 (SD 8.8) mmol/mol] in the UUS:0-4 group (P=.049). Reductions in mean HbA_{1c} levels were greater in the UUS:5-8 group than in the UUS:0-4 group at 3 months [–1.0 (SD 1.40%) vs –0.37 (SD 0.73%); P=.02] and at 6 months [–0.99 (SD 1.09%) vs –0.32 (SD 1.08%); P=.01].

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Figure 1. Glycated hemoglobin (HbA_{1c}) levels for the 12-month study period in the UUS:0-4 group and UUS:5-8 group. Repeated-measures ANOVA revealed significant differences between the groups over 12 months (*P*=.011). The last observation carried forward (LOCF) imputation method was used. UUS: user utility score.

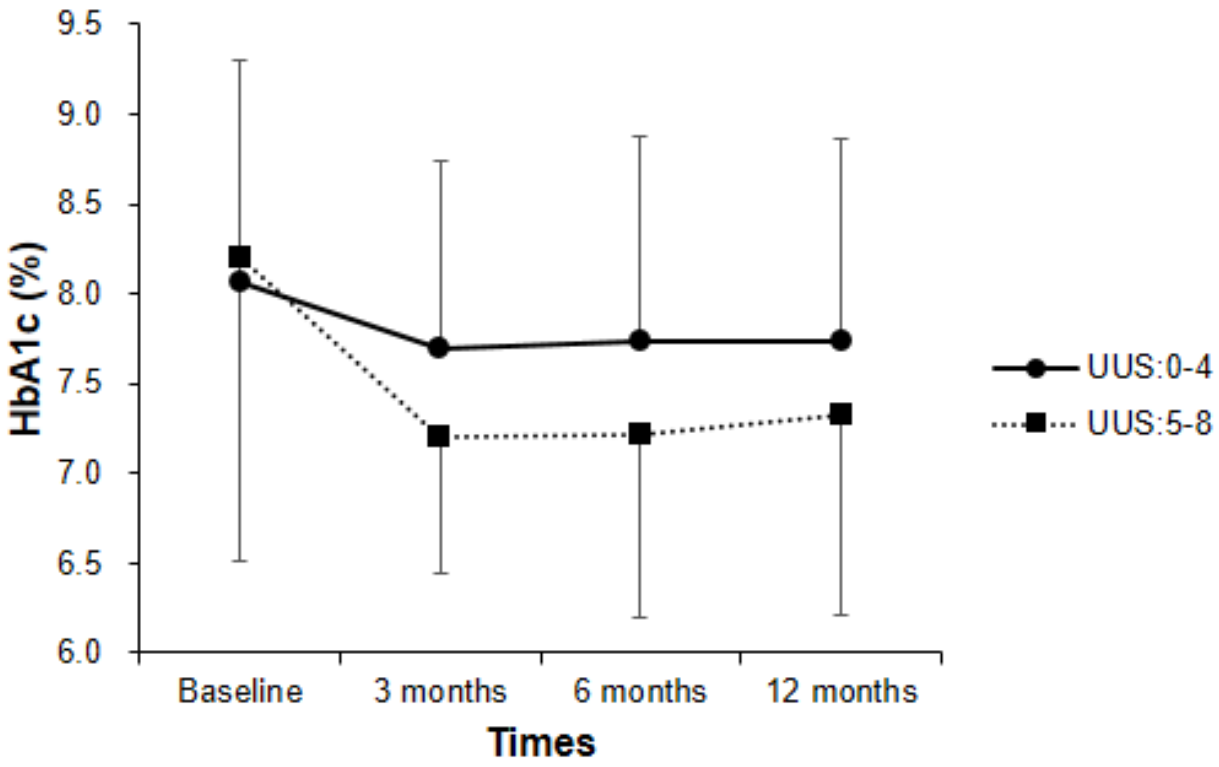

Table 2. Changes from baseline in glycated hemoglobin (HbA_{1c}) at 3, 6, and 12 months in the UUS:0-4 group and UUS:5-8 group.

HbA_{1c} at each time point	UUS[a]:0-4	UUS:5-8	*P* value[b]
3 months from baseline (n=72)			
Participants, n (%)	38 (53)	34 (47)	
HbA_{1c} %, mean (SD)	–0.37 (0.73)	–1.0 (1.40)	.018
6 months from baseline (n=72)			
Participants, n (%)	38 (53)	34 (47)	
HbA_{1c} %, mean (SD)	–0.32 (1.08)	–0.99 (1.09)	.013
12 months from baseline (n=54)			
Participants, n (%)	23 (43)	31 (57)	
HbA_{1c} %, mean (SD)	–0.33 (0.80)	–0.92 (1.24)	.049

[a]UUS: user utility score.

[b]*P* values were derived from the Student *t*-test.

Table 3 shows the association of UUS for the first 3 months with changes in HbA_{1c} at 3, 6, and 12 months. Simple linear regression analysis revealed a significant association of UUS with changes in HbA_{1c} at 3, 6, and 12 months in the LOCF analysis. In multivariable linear regression analyses, after adjustment for age, sex, BMI, systolic blood pressure, LDL cholesterol, HbA_{1c} at baseline, diabetes duration, cigarette smoking, alcohol consumption, and ADS score (model 3), UUS was significantly associated with changes in HbA_{1c} at 3, 6, and 12 months; the regression coefficients were –0.113 (SD 0.040; *P*=.006), –0.143 (SD 0.045; *P*=.002), and –0.136 (SD 0.052; *P*=.011), respectively. In model 3, the result was still significant under the Bonferroni adjustment for multiple comparisons between 3 points of time. In addition, UUS was inversely associated with reduction rates of HbA_{1c} at 3, 6, and 12 months; the regression coefficients were –2.70 (SD 1.24; *P*=.03), –3.35 (SD 1.37; *P*=.02), and –3.19 (SD 1.59; *P*=.049), respectively (Table 4).

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Table 3. Association of user utility score (UUS) with change in glycated hemoglobin (HbA_{1c}) by multivariable linear regression analyses.

UUS	3 months from baseline		6 months from baseline		12 months from baseline[a]	
	β (SE[b])	*P* value[c]	β (SE)	*P* value	β (SE)	*P* value
Crude	–0.121 (0.055)	.031	–0.125 (0.054)	.023	–0.124 (0.048)	.011
Model 1[d]	–0.119 (0.057)	.042	–0.127 (0.057)	.028	–0.128 (0.050)	.012
Model 2[e]	–0.100 (0.037)	.009	–0.109 (0.043)	.014	–0.108 (0.051)	.038
Model 3[f]	–0.113 (0.040)	.006	–0.143 (0.045)	.002	–0.136 (0.052)	.011

[a]The last observation carried forward (LOCF) imputation method was used.

[b]SE: standard error.

[c]*P* values in multiple regression models are significant at *P*<.05. *P* values after Bonferroni correction are significant at *P*<.016.

[d]Model 1 was adjusted for age and sex.

[e]Model 2 was adjusted for age, sex, BMI, systolic blood pressure, LDL cholesterol, HbA_{1c} at baseline, and diabetes duration.

[f]Model 3 was adjusted for age, sex, BMI, systolic blood pressure, LDL cholesterol, HbA_{1c} at baseline, diabetes duration, cigarette smoking, alcohol consumption, and the Appraisal of Diabetes Scale (ADS) score.

Table 4. Association of user utility score (UUS) with glycated hemoglobin (HbA_{1c}) reduction rate by linear regression analyses.

UUS at each time point	β (SE[a])	*P* value[b]
3 months from baseline	–2.70 (1.24)	.033
6 months from baseline	–3.35 (1.37)	.017
12 months from baseline[c]	–3.19 (1.59)	.049

[a]SE: standard error.

[b]Regression coefficients (β) and *P* values were derived from linear regression analysis.

[c]The last observation carried forward (LOCF) imputation method was used.

UUS and Health Outcomes

Table 5 shows changes in health outcomes from baseline at 3, 6, and 12 months in the UUS:0-4 group and UUS:5-8 group. At 3 months, HDL cholesterol levels between the UUS:0-4 and UUS:5-8 groups were –2.03 (SD 7.02) mg/dL and 1.48 (SD 7.33) mg/dL, respectively (*P*=.04). There were no significant differences in the changes in BMI, systolic blood pressure, HDL cholesterol, and SDSCA and ADS scores, after Bonferroni adjustment, between the 2 groups at 3, 6, and 12 months. There was a suggestion that the high UUS was more beneficial for HDL cholesterol, with the *P* value indicating a significant difference on the basis of the conventional threshold for significance but not the Bonferroni-adjusted threshold.

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Table 5. Changes in biochemical parameters and questionnaires over 12 months in the UUS:0-4 group and UUS:5-8 group.

Variable, mean (SD)	3 months from baseline (n=72)			6 months from baseline (n=72)			12 months from baseline (n=54)		
	UUS:0-4 (n=38)	UUS:5-8 (n=34)	*P* value[a]	UUS:0-4 (n=38)	UUS:5-8 (n=34)	*P* value	UUS:0-4 (n=23)	UUS:5-8 (n=31)	*P* value
Body mass index, kg/m^2	–0.25 (0.67)	–0.42 (0.85)	.36	–0.41 (0.82)	–0.32 (0.93)	.68	0.01 (0.92)	0.04 (1.16)	.89
Systolic blood pressure, mmHg	–15.45 (16.82)	–14.38 (16.14)	.79	–17.29 (16.27)	–16.29 (14.15)	.78	–8.01 (16.77)	–7.32 (13.82)	.87
Diastolic blood pressure, mmHg	–7.34 (10.37)	–7.26 (8.87)	.97	–9.84 (10.22)	–6.82 (8.46)	.18	–1.91 (9.65)	–2.97 (7.61)	.66
Total cholesterol, mg/dL	3.56 (32.44)	10.82 (26.50)	.31	–1.15 (31.80)	3.79 (32.15)	.52	6.30 (43.66)	–1.74 (38.18)	.53
Triglyceride, mg/dL	3.87 (72.91)	–17.76 (42.42)	.14	–5.03 (78.00)	–8.30 (51.79)	.84	25.39 (90.86)	–6.65 (60.32)	.14
HDL cholesterol, mg/dL	–2.03 (7.02)	1.48 (7.33)	.04	0.28 (6.48)	2.61 (7.37)	.16	0.43 (7.09)	4.61 (8.55)	.06
LDL cholesterol, mg/dL	4.75 (29.84)	12.78 (24.80)	.22	–0.49 (28.75)	2.85 (28.82)	.63	1.33 (38.63)	–5.07 (35.29)	.53
Summary of Diabetes Self-care Activities (SDSCA) questionnaire, mean (SD)									
Diet total	N/A[b]	N/A	N/A	1.24 (7.05)	1.47 (7.82)	.894	2.23 (6.87)	1.35 (5.35)	.61
Exercise	N/A	N/A	N/A	0.56 (3.79)	0.74 (3.06)	.83	0.58 (2.69)	1.36 (3.14)	.34
Blood glucose testing	N/A	N/A	N/A	2.29 (5.56)	4.15 (6.11)	.38	0.32 (4.94)	1.13 (5.92)	.60
Foot care	N/A	N/A	N/A	3.66 (5.23)	2.79 (5.47)	.50	3.59 (5.79)	2.97 (4.35)	.66
Appraisal of Diabetes Scale (ADS) total	N/A	N/A	N/A	–0.79 (4.82)	–1.5 (4.97)	.54	–1.41 (4.55)	–1.81 (3.75)	.73

[a]*P* values were derived from the Student *t* test.

[b]N/A: not applicable.

Discussion

Principal Findings

In this study, we found that UUS for the first 3 months was associated with changes in HbA_{1c} during a 12-month follow-up period. When we divided participants into 2 groups based on UUS for the first 3 months, the high UUS group resulted in greater decreases in HbA_{1c} over 12 months compared with the low UUS group. Multivariable linear regression analyses revealed that UUS for the first 3 months was significantly inversely associated with changes in HbA_{1c} at 3, 6, and 12 months. These results indicated that initial active engagement for the first 3 months with a mobile health application was associated with improved glycemic control over the whole study period.

Patient engagement with a mobile health application could be a significant factor contributing to diabetes self-management [28,29]. Research showed that initial engagement with a mobile health application is closely related to long-term engagement [30]. We previously reported that initial active engagement was significantly correlated with improved glycemic control [31]. In this study, UUS gradually decreased over 12 months but was consistently higher in the initial high UUS group than in the low UUS group. In addition, more participants were lost to follow-up in the low UUS group (15/38, 39%) than in the high UUS group (3/34, 9%) at 12 months. High UUS in the beginning was critical. We found that initial active engagement could predict improved glycemic control during a 12-month follow-up period. Therefore, initial strategies to enhance patient engagement from the beginning in the low UUS group are necessary.

We developed the UUS as a tool to measure user utility by analyzing and scoring uploaded data, including blood glucose testing, dietary and exercise records, and message reading. The results of this study reinforce findings from previous mobile health investigations that have shown the benefits of lifestyle interventions with appropriate blood glucose testing, adoption of a healthy diet and physical activity, and reading of text messages on diabetes outcomes [31-36]. Meanwhile, patient engagement is related to other factors such as medications, foot care, and changes in weight [37]. To quantify patient engagement, scoring systems should take into account that each factor in UUS varies in priority and importance. Our findings will act as a cornerstone for other studies exploring effective UUS components and the optimal threshold of each component for predicting improved health outcomes.

In addition, we found no difference in baseline HbA_{1c}, BMI, blood pressure, HDL cholesterol, LDL cholesterol, SDSCA, and ADS to assess diabetes self-management between groups divided according to UUS. There was no relationship of UUS with blood pressure, lipid profile, or diabetes self-management.

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Although the high UUS group achieved greater improvement in HDL cholesterol at 3 months than the low UUS group, this difference was not statistically significant. Regular exercise increases HDL cholesterol levels [38,39], and so it would be interesting to evaluate the association between patient engagement and HDL cholesterol. Further randomized controlled trials are needed to investigate the relationship between patient engagement and health outcomes among patients with type 2 diabetes. However, UUS was not related to cardiovascular risk factors such as LDL, blood pressure, and BMI. The results support the concept that UUS could be a useful tool for predicting improved glycemic control in diabetes management using the TMC system.

Chronic diseases such as diabetes that require ongoing medical care can benefit from the integration of digital health technology-based tools [16]. Digital health technology in diabetes care offers the opportunity to track and visualize data regarding parameters such as blood glucose testing, dietary habits, physical activity, and text messages and has been promoted to support self-management and facilitate lifestyle changes [11,40,41]. We found that UUS with behavioral components was correlated with changes in HbA_{1c} in a 12-month follow-up evaluation (r=–0.136, *P*=.01). According to the SDSCA, the frequency of blood glucose testing was higher in patients with a high UUS score than in those with a low UUS score (*P*=.09). This seems to be the most important contributing factor to the results of this study. Interestingly, however, individual components of UUS were not correlated with changes in HbA_{1c}. This study did not show that patient engagement was not associated with each individual behavioral component.

Patient engagement assessment tools could be useful for evaluating their own diabetes self-management [42]. Remmers et al [43] examined the association of patient activation measure (PAM) scores with health outcomes among patients with diabetes and found that PAM scores could be used to identify patients at risk for poorer health outcomes. Previous studies that found differences between patients who engage and those who do not engage in digital health interventions demonstrated the importance of patient engagement to glycemic control [39]. Our results support the idea that although digital technology will not provide a solution for everyone, the use of mobile health technology tools, when applied appropriately, could improve the health outcomes of patients with diabetes [44]. Moreover, long-term management is critical because people usually participate actively in the beginning, but their interest disappears. We suggest that the optimal use of UUS should be individualized based on the clinical needs of individual patients and the requirements of care providers. Further investigation regarding how to motivate participants toward engaging in this digital health system is needed.

Limitations

There were several limitations to the study. First, although the relationship between UUS and glycemic control was statistically significant, the post-hoc analysis study design was one limitation. It is important to adjust for confounding variables, potentially influencing patient outcomes. The use of digital health tools may be influenced by education level and social deprivation, among other factors. Although these variables were not included as covariates in the model, any response bias is likely minimal. Second, UUS consisted of only 4 behavioral components and was calculated retrospectively. However, we used a holdout set for validation and introduced UUS to project user participation and effects on glycemic control. Finally, the study had a small sample size, and values for 25% (18/72) of participants were missing at 12 months. Regression analysis of the association between UUS and HbA_{1c} was performed using the LOCF approach to examine trends over time, rather than focusing simply on the endpoint. This imputation might lead to biased results. However, for the comparison of HbA_{1c} between the UUS groups, data were analyzed without applying LOCF, which revealed a significant group difference. Larger prospective long-term studies are needed to assess the UUS's utility in a real-world setting.

Conclusions

In this study, we developed the UUS as a patient engagement measure with behavioral components from an individual perspective. UUS in the beginning was associated with changes in HbA_{1c} over the study period of the TMC system and could be a useful tool for predicting improved glycemic control in diabetes self-management through mobile health interventions. Our results provide insight into the importance of patient engagement in mobile diabetes intervention, and further studies to explore the optimal measure of patient engagement for diabetes management are needed.

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Authors' Contributions

MKL and DYL contributed to the study design and data analysis. MKL drafted and edited the manuscript. CYP provided supervision and revised the manuscript. MKL, DYL, HYA, and CYP participated in the analytic discussion of the results. All authors have read and approved the final manuscript.

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Conflicts of Interest

None declared.

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Abbreviations

ADS: Appraisal of Diabetes Scale
BMI: body mass index
HbA_{1c}: glycated hemoglobin
HDL: high-density lipoprotein
LDL: low-density lipoprotein
LOCF: last observation carried forward
PAM: patient activation measure
SDSCA: Summary of Diabetes Self-Care Activities questionnaire
TMC: tailored mobile coaching
UUS: user utility score

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Original Paper

Acceptability of a Mobile Health Behavior Change Intervention for Cancer Survivors With Obesity or Overweight: Nested Mixed Methods Study Within a Randomized Controlled Trial

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Abstract

Background: A significant proportion of cancer survivors have overweight or obesity. Although this has negative implications for health, weight management is not a standard component of oncology aftercare. Mobile health (mHealth) technology, in combination with behavior change techniques (BCTs), has the potential to support positive lifestyle changes. Few studies have been carried out with cancer survivors; therefore, the acceptability of these tools and techniques requires further investigation.

Objective: The aim of this study is to examine the acceptability of a behavior change intervention using mHealth for cancer survivors with a BMI of 25 or more and to gather constructive feedback from participants.

Methods: The intervention consisted of educational sessions and an 8-week physical activity goal setting intervention delivered using mobile technology (ie, Fitbit activity monitor plus SMS contact). In the context of a two-arm randomized controlled trial, semistructured interviews were conducted to assess the retrospective acceptability of the intervention from the perspective of the recipients. The theoretical framework for the acceptability of health care interventions was used to inform a topic guide. The interviews were transcribed and analyzed using thematic analysis. A quantitative survey was also conducted to determine the acceptability of the intervention. A total of 13 participants were interviewed, and 36 participants completed the quantitative survey.

Results: The results strongly support the acceptability of the intervention. The majority of the survey respondents held a positive attitude toward the intervention (35/36, 97%). In qualitative reports, many of the intervention components were enjoyed and the mHealth components (ie, Fitbit and goal setting through text message contact) were rated especially positively. Responses were mixed as to whether the burden of participating in the intervention was high (6/36, 17%) or low (5/36, 14%). Participants perceived the intervention as having high efficacy in improving health and well-being (34/36, 94%). Most respondents said that they understood how the intervention works (35/36, 97%), and qualitative data show that participants' understanding of the aim of the intervention was broader than weight management and focused more on moving on psychologically from cancer.

Conclusions: On the basis of the coherence of responses with theorized aspects of intervention acceptability, we are confident that this intervention using mHealth and BCTs is acceptable to cancer survivors with obesity or overweight. Participants made several recommendations concerning the additional provision of social support. Future studies are needed to assess the feasibility of delivery in clinical practice and the acceptability of the intervention to those delivering the intervention.

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KEYWORDS

mHealth; self-management; text messaging; activity tracker; exercise; diet; overweight; obesity; cancer survivors; qualitative research; mobile phone

Introduction

Background

Over the last 20 years, cancer has increased worldwide [1]. Reassuringly, the survival rates are also increasing [2,3]. However, a significant proportion of cancer survivors have overweight or obesity [4]. Oncologic treatment side effects, such as loss of muscular strength, fatigue, and physical inactivity, contribute to weight management issues during cancer and survivorship [5]. Overweight and obesity are associated with all-cause mortality, increased risk for cancer development, and increased risk of development of secondary cancer or subsequent primary cancer in cancer survivors [6-8]. Healthy lifestyle behaviors, such as regular exercise and healthy diet, have the potential to reduce treatment-associated morbidity and mortality in cancer survivors [9]. Therefore, interventions that support cancer survivors' management of lifestyle behaviors are imperative.

Mobile health (mHealth) involves the use of mobile technologies, such as smartphones, tablets, apps, and wearable activity trackers, to improve health care, health outcomes, and public health. mHealth has been associated with significant reductions in weight and BMI [10] and positive health behavior changes [11,12]. Therefore, mHealth tools have the potential to meet the need for interventions that support weight and lifestyle management and, at the same time, are low resource and cost effective. At the same time, it is critical that the design of mHealth interventions is based on theory and evidence [13]. Evidence from systematic reviews suggests that using behavior change techniques (BCTs) significantly increases the success of weight management programs [14]. Interventions, including a greater number of BCTs, were associated with greater changes in health behaviors [15]. This was also the case for digital interventions [16]. Although there are a good number of lifestyle interventions for cancer survivors using BCTs [14], there are fewer mHealth interventions that have adopted this evidence-based approach to development, in the sense that very few have included relevant BCTs [17,18].

Interventions that are evidence based and effective may not be deemed acceptable to the prospective recipients. Acceptability is a key construct in intervention evaluation and is explicitly recommended in the UK Medical Research Council and National Institute of Health Research guidance on evaluating complex interventions [19]. Acceptability is often inferred from behavioral measures (eg, uptake, adherence, and retention), with fewer studies using explicit measures of acceptability or gathering feedback through postintervention interviews or focus groups [20]. Sekhon et al [21] proposed a theoretical framework to advance the systematic assessment of the acceptability of health care interventions. They defined acceptability as a "multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention" [21]. The framework takes into account constructs, such as the participant's attitude toward the intervention, the burden of participating, and the participant's understanding of the intervention and how it is intended to work (a full description is given in Textbox 1). This method of assessment comprising multiple constructs offers a more fine-grained approach to detecting the source of acceptability issues that can be used to improve future interventions [20].

Textbox 1. Definitions of the constructs in the theoretical framework of acceptability of health care interventions.

Constructs of acceptability:

- Affective attitude: How an individual feels about the intervention
- Burden: The perceived amount of effort that is required to participate in the intervention
- Ethicality: The extent to which the intervention has good fit with an individual's value system
- Intervention coherence: The extent to which the participant understands the intervention and how it works
- Opportunity costs: The extent to which benefits, profits, or values must be given up to engage in the intervention
- Perceived effectiveness: The extent to which the intervention is perceived to be likely to achieve its purpose
- Self - efficacy: The participant's confidence that they can perform the behaviors required to participate in the intervention

Qualitative methods add significant value to trial research [22,23], contributing feedback that would not otherwise be captured. For successful uptake and implementation, it is important that the content, design, and delivery of interventions are considered acceptable to the target group [24]. In the area of mHealth, many studies have focused on the usability of technologies rather than the acceptability of interventions that use mobile technology. Some studies have supported the acceptability of mHealth solutions for people living with and beyond cancer [25-28]. However, acceptability is often operationalized behaviorally as adherence and engagement with technology. Few studies in this area have moved beyond behavioral measures or adopted a broader qualitative approach to understanding acceptability [29,30]. Therefore, we currently

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lack a robust understanding of the acceptability of mHealth behavior change interventions for cancer survivors with obesity or overweight. This study is the first to apply the theoretical framework of acceptability [21] to systematically assess the acceptability of an mHealth intervention for this high-risk group.

Aim

This study aims to examine the acceptability of the Moving On intervention to its recipients and to obtain constructive feedback on the intervention and participants' recommendations for improving the intervention content or delivery. The actual trial of the intervention was completed before this study. Full details of the trial protocol are reported elsewhere [31], and this paper presents the results of the mixed methods analysis of the retrospective acceptability of the intervention.

Methods

The Moving on Study Protocol

The Moving On study is a 2-arm parallel randomized controlled trial (RCT) of an intervention for cancer survivors with a BMI of 25 or more (International Standard Randomized Controlled Trial Number (ISRCTN): 18676721). Participants were assessed for clinical outcomes (ie, anthropometric measurements and functional exercise capacity), psychological outcomes (eg, quality of life), and behavioral outcomes (ie, dietary behavior and physical activity) at baseline (T0), at postintervention (12 weeks later: T1), and at the 24-week follow-up (T2).

The intervention uses mHealth in combination with BCTs to increase physical activity and improve diet, thereby improving health and well-being outcomes. This is a complex intervention targeting individuals' self-management of lifestyle behavior, which is described in detail elsewhere [31]. In short, the intervention had 2 components.

1. A 4-hour lifestyle education and information session (week 1) was delivered by health care professionals (3 physiotherapists, 1 dietician, and 1 clinical psychologist). The physiotherapists demonstrated a series of daily strengthening exercises and recommended schedules for moderate-intensity physical activity. The dietician advised participants to; reduce their calorific intake, reduce red meat, processed meat, salt, and sugar intake; and increase fruit, vegetable, and fiber intake. The clinical psychologist offered practical strategies for problem solving, identifying barriers to change, and preventing relapse. The BCTs included in this session were *goal setting (outcome), provide information on consequences of behavior to the individual, demonstration of the behavior, problem solving, goal setting (behavior)*, and *action planning.*
2. An 8-week physical activity goal setting intervention (weeks 4-12) was delivered using mobile technology (ie, Fitbit activity monitor plus SMS contact). Participants received weekly messages with feedback on their average daily step count and a goal to increase their step count by 10% in the following week. The BCTs included in the personalized goal setting intervention were *self-monitoring* of behavior, *feedback* on behavior, *goal setting (behavior), graded tasks, social reward*, and *review behavior goal(s).*

The design of this intervention is well matched with the National Institute for Health and Care Excellence guidelines for weight management of people with obesity [32]. They identify multicomponent interventions as the treatment of choice, which should include effective behavior change strategies aimed at increasing physical activity or decreasing inactivity, improving dietary behavior and quality of diet, and reducing energy intake.

Study Design

This study was a mixed methods study nested within an RCT. In the context of the RCT, postintervention semistructured interviews were conducted, and a brief quantitative survey was administered to assess the retrospective acceptability of the intervention from the perspective of the recipients. Response rates and retention rates for the full trial were also used as indicators of the acceptability of the intervention. The design of this study was approved by the Research Ethics Committee of the National University of Ireland, Galway, and by the Research Ethics Committee at Letterkenny University Hospital.

Study Setting

The Moving On study was a nonblinded RCT implemented in the oncology outpatient department at Letterkenny University Hospital in County Donegal, Ireland. Participants were cancer survivors with a BMI of 25 or more who had completed active cancer treatment. For this study examining the acceptability of the Moving On intervention, only participants randomized to receive the intervention were eligible for participation.

Recruitment

At the 24-week follow-up, all participants in the intervention condition were asked to complete a 5-item survey to provide feedback on the intervention. For the qualitative component, all participants in the intervention condition were included and invited to participate in the qualitative study. No exclusion criteria were applied. An invitation to participate was included with their appointment letter for the final 24-week assessment of the intervention. One week before the final assessment, the invitation letter was followed up with an SMS to the group. The participants were asked to contact the research team if they were interested in participating in the qualitative study. Interviews were conducted with all volunteers who were available to be interviewed at their 24-week assessment (ie, 12 weeks postintervention). Written consent was obtained from 13 participants. The sample size was primarily determined by the size of the participant pool (ie, the intervention group) and the availability of participants. Within the context of this study, the data collected were judged by the research team to be adequate in both amount and variety to answer the research question. The participants did not receive any compensation.

Qualitative Methodology

Thematic analysis was conducted using the essentialist or realist approach (ie, reporting experiences, meaning, and the reality of participants). This is a semantic-level analysis that looks for explicit meanings in data [33]. All interviews were individual and face-to-face and were conducted in the study setting. The semistructured interview topic guide was based on the theoretical framework of acceptability of health care interventions (Textbox 1) [21]. The following constructs were

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deemed the most relevant and used to inform the topic guide: affective attitude, burden, intervention coherence, perceived effectiveness, and self-efficacy. Participants were also asked about their motives for participating in the study and to provide feedback and recommendations for improving the Moving On intervention. The topic guide is included in Multimedia Appendix 1.

Quantitative Methodology

A 5-item self-report measure of acceptability was created for this study, corresponding to the 5 constructs of the theoretical framework of acceptability of health care interventions used to inform the qualitative topic guide. Using a 5-point Likert scale, participants in the intervention were asked to rate their satisfaction with the intervention (affective attitude), the amount of effort required to participate (burden), the extent to which they understand the intervention and how it is intended to work (intervention coherence), the perceived effectiveness of the intervention, and their confidence in performing the behaviors required to participate (self-efficacy). Response rates and retention rates for the trial were used as behavioral indicators of the acceptability of the intervention.

Data Analysis

Descriptive statistics were used to analyze the quantitative data using IBM (International Business Machines corporation) SPSS Statistics 24. Interviews were audio recorded and transcribed professionally. Transcripts were imported into NVivo 12 for analysis. Following the procedure outlined by Braun and Clarke [33], the transcripts were initially read by the primary coder (JG) several times to become familiar with the data. JG and JM independently coded 2 transcripts and agreed upon initial codes. The remaining transcripts were coded by JG. The analysis followed a deductive approach guided by the theoretical framework of acceptability. Transcripts were read in full and coded line by line to identify units of meaning relevant or interesting to answering the research question. These initial codes were then grouped together into the 5 domains described in the theoretical framework of acceptability and into a theme reflecting recommendations to improve the intervention by a multidisciplinary team (JG, JM, JR, MK, JW, and AG). Finally, members of the research team with practice-based experience (JR and MK) reviewed all the transcripts in relation to the themes identified. After analyzing all the transcripts, the analytic team was satisfied that no further interviews were necessary as the codes and themes identified were sufficient to develop a thorough understanding of the acceptability of the intervention and, therefore, meet the aims of the study [34]. The rigor of this study was enhanced by the secondary coding carried out by a multidisciplinary team of 6 such that each transcript was reviewed by at least three team members.

Results

Participants

A total of 13 participants (2 males) were interviewed, and 36 participants completed the quantitative survey. Participant characteristics are described in Tables 1 and 2.

Table 1. Characteristics of the 13 participants interviewed in this study.

Participant ID	Gender	Age (years)	Years since diagnosis	Weight changes at 24-week follow-up (kg)
001	Female	50	>5	−12.4
002	Female	51	>5	−10.6
003	Female	66	2-5	−7.4
004	Female	53	2-5	−7.2
005	Female	53	2-5	−6
006	Female	66	>5	−4.8
007	Male	54	2-5	−3.2
008	Female	67	>5	−0.80
009	Female	58	>5	−0.20
010	Female	68	2-5	−0.00
011	Female	38	<2	+1.5
012	Male	60	2-5	+3.0
013	Female	43	>5	+11.6

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Table 2. Descriptive characteristics of participants in this mixed-methods study and in the intervention group of the full trial.

Participant characteristics	Qualitative interview (n=13)	Quantitative survey (n=36)	RCT[a] (n=53)
Age (years), mean (SD); range	55.92 (9.03); 38-68	56.55 (6.40); 41-68	55.61 (8.05); 30-68
Male, n (%)	2 (15)	7 (19)	12 (28)
Years since diagnosis, mean (SD); range	5.38 (3.42); 1-12	5.78 (3.52); 1-15	6.59 (3.13); 1-15
Weight change in kilogram at 24-week follow-up, mean (SD); range	−2.81 (6.36); −12.4 to +11.60	−2.15 (3.57); −12.4 to +11.60	−1.74 (4.48); −12.4 to +11.60

[a]RCT: randomized controlled trial.

Qualitative Findings on Acceptability

In opening the semistructured interviews, participants were asked about their motives for participating in the trial. Participants were clear that interventions to improve the health and well-being of cancer survivors were both acceptable and necessary. One participant had felt "very traumatised" by the experience (010). Other participants reported living with and beyond cancer as "very difficult" (012) and felt isolated because people who have not had cancer "don't...really understand" (007) what they have been through and what they continue to deal with. They emphasized the desire for continuing support during survivorship. They also described ongoing health and psychological issues and having intrusive thoughts and concerns about these issues:

> *After cancer it can be a very lonely place. After you go through your treatment and you go through because you are getting great help and great encouragement during the process but when you come out the other end it can be very lonely, daunting kind of a place because every ache and pain you get you might just go in the one direction...you do need that support.* [003]

Findings on the perceived acceptability of the Moving On intervention, developed through deductive analysis guided by the theoretical framework of acceptability, are presented under Theme 1: Acceptability, with 5 subthemes relating to the 5 aspects of the framework applied in this analysis. Theme 2 describes participants' recommendations for improving the Moving On intervention.

Theme 1: Acceptability

Affective Attitude: How an Individual Feels About the Intervention

Participants held a positive attitude toward the intervention. They described feeling "delighted" (010) and feeling "glad" (007) and "grateful" (003) that they had taken part in the intervention. However, one participant described feeling "absolutely gutted" and "like I'd failed" when they had not lost weight. As a result, she reported feeling "quite isolated" (009):

> *I truly appreciate it...I don't know where I would be only for it.* [003]

In relation to the mHealth components, 2 participants said they loved their Fitbit and others described it as "absolutely great" (003) and "very beneficial" (013):

> *The Fitbit was fantastic... It didn't control me, but it was a tool that gave me the information I needed to adjust.* [002]

The text messages were a source of comfort, "that someone is there for you...caring for you" (006). On the other hand, 3 of the interviewees mentioned some negative or mixed feelings toward weekly text messages. The participant quoted above (002), who had felt empowered by Fitbit, felt that being prescribed a daily step count goal took away her self-control. Two other participants interpreted the encouragements to be more physically active as meaning they were not trying hard enough already and described feeling "angry" and "annoyed" (009) as a result:

> *At one stage I remember being angry, it was saying "you could do better."* [010]

Attendance at the half-day lifestyle information and education session was described as "really good" (003) "very useful, very informative" (012). One participant saw it as a good opportunity to talk with other people who have been through the same experience of having cancer:

> *I think that is a good starter to launch you on your effort to try to improve. Yea, I would say that was the best part for me.* [012]

Burden: The Perceived Amount of Effort That is Required to Participate in the Intervention

Only 3 participants described participation as a lot of effort, and the remaining participants described it as limited effort and manageable, especially given their motivation to take part. One woman felt that for her survival she needed a "big, big healthy change," and therefore, "big effort was required" (010):

> *No I don't think it took a lot of effort. I felt very committed to it and I felt I wanted to do it.* [003]

Some wondered whether the burden of participating might be higher in the earlier stages of cancer survivorship. The majority of respondents said that changing their dietary behavior was the most difficult aspect of the intervention. Although the majority of participants saw improving diet as the most difficult aspect, increasing physical activity was deemed more time consuming. Participants reflected on external factors that made behavioral changes more challenging, specifically illness among family members and poor weather conditions. They also highlighted times when health behaviors were more difficult to maintain (ie, the weekend and during summer).

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Intervention Coherence: The Extent to Which the Participant Understands the Intervention and How it Works

Weight reduction was an important outcome of the trial; however, only 5 participants referred to weight in their responses. For many participants, the primary aim of the intervention was to provide motivation. For others, the intervention was synonymous with motivation:

> *If I hadn't got the motivation, the programme, I don't know where I would be now you know...in terms of quality of life.* [010]

Aims such as improving mental health and well-being, fitness, eating better, living healthier, and increasing energy have been described. They also identified much broader aims, such as "moving forward" (006) and "getting your life back" (004). In relation to cancer survivorship, participants spoke about goals such as getting "back on track after treatment" (011), "easing back into life" (002), and preventing recurrence:

> *The goal of the programme in my head was to encourage people to be fitter and eat better to avoid illness [recurring] ultimately.* [005]

Participants recognized education as a key function of the intervention:

> *I think it's really to make you aware, it builds your awareness and educates... I've learned a lot.* [009]

The mHealth intervention was perceived to work through a combination of self-monitoring and monitoring by the research team. Seeing progress, having a goal, having it recorded, receiving positive feedback, and being watched were highlighted by participants as mechanisms of health behavior change:

> *I suppose just having a target you know. And knowing I guess that if you did push it, it was being recorded and was coming back to you to say, "well done," you know a bit of enthusiasm.* [005]

A number of participants considered the baseline and follow-up assessments as part of the intervention and discussed them in reference to how the intervention works, particularly in relation to their level of motivation leading up to the assessments:

> *I do think the little interviews and check-ups here really do keep you focused that little bit.* [013]

Perceived Effectiveness: The Extent to Which the Intervention is Perceived as Likely to Achieve its Purpose

Although some of the participants interviewed lost a significant amount of weight over the 6-month study (3.2-12.4 kg), weight loss did not feature strongly in their descriptions of the effects of the intervention. The majority of participants mentioned feeling physically fitter, having more energy, sleeping better, and feeling less fatigued:

> *My goal was to lose weight and get fitter and now I have achieved that.* [001]

Almost all participants mentioned some emotional and psychological improvement, such as, feeling "good – physically, mentally, spiritually...so happy" (003), "mentally a lot better...calmer" (013), and more "productive" (005):

> *Certainly the mood swings are not as hectic...I have come out the other end feeling way more positive than I would have been. I would have been an emotional wreck last year.* [013]

There were also changes related to self and self-image. One woman who lost a lot of weight now felt more confident and noticed a change in her behavior:

> *Before I would have just stayed in the background...now I put myself forward to do things.* [001]

For one woman, the intervention was the first step in reclaiming her old self and how she used to look before cancer:

> *With being sick, and with everything that happened, I didn't feel me, so this sort of put me on the first step to start losing weight, and getting more to looking like myself, by the time I lost a bit of weight, I had some hair got, and you know, standing looking in the mirror thinking "this is what you used to look like...6 months ago I didn't look like this".* [004]

Self-Efficacy: The Participant's Confidence That They Can Perform the Behaviors Required to Participate in the Intervention

Responses were evenly mixed in relation to how confident participants were that they would be able to perform the behavior required to participate in the intervention (ie, improve their diet and increase physical activity). Participants described these changes as something that they wanted to do but needed motivation. Others were not sure of their capability at the outset of the intervention; however, their confidence grew over time:

> *What seemed like a problem at the beginning of the journey you have so many solutions to it by the end of the journey.* [003]

The text messages and goals were the support most commonly referred to as helpful for promoting self-efficacy. Participants also discussed the different sources of social support they received throughout the intervention from staff, friends, family, and other participants:

> *Well I got support from home too. I got support from here [the hospital]... People at work supported you too because they started to join ya. They were starting getting Fitbit and walking and things...I got a lot of support from everybody.* [001]

Participants spoke about having trust in the health information and behavior change advice because of its source, which was the local hospital cancer team and the behavioral science research team. This provided them with confidence in changing their behavior:

> *The fact that it is linked into the hospital is very helpful and very reassuring.* [003]

Quantitative Findings on Acceptability

Recruitment and Retention Rates

The high response rate for the full trial (123/159, 77.4%) and high retention rate (53/62, 85%) of participants in the

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intervention arm support the acceptability of the intervention. Of those who declined to participate in the trial, 77% (28/36) were not interested, 14% (5/36) declined for health reasons, and 8% (3/36) declined because of practical constraints (eg, childcare responsibilities). Of those who dropped out of the intervention arm of the trial (9/62, 15%), 7 participants were lost after the baseline assessment because of rescheduling of the lifestyle information and education session at short notice because of adverse weather conditions. One participant passed away (unrelated to the trial) between the 12- and 24-week assessments, and one participant did not attend the 24-week follow-up assessment.

Acceptability Survey

All 53 participants in the intervention condition who attended their 24-week follow-up assessment were asked to complete an additional 5-item survey to provide feedback on the intervention, and 68% (36/53) of participants completed the survey. Results show that 97% (35/36) of the participants surveyed were satisfied or very satisfied, indicating a positive affective attitude toward the intervention. The same proportion of participants reported that the intervention had a high coherence (35/36, 97%). Furthermore, 94% (34/36) of respondents believed that the intervention was effective in improving health and well-being outcomes. There was more variability in responses to questions of burden, with a similar proportion of participants reporting that the intervention required a great deal of effort (6/36, 17%) as those reporting it required very little effort (5/36, 14%). There was also some variability regarding participants' self-efficacy; however, 83% (30/36) of the participants reported being confident that they performed the behaviors necessary for the intervention. All results are presented in Multimedia Appendix 2.

Theme 2: Recommendations for Improving the Moving on Intervention

When asked how the intervention could be improved, a number of participants wanted more frequent contacts and easier access to clinicians. Although participants wanted more contact, many spoke of the availability of support from staff if required. This was especially valuable posttreatment when people reported feeling isolated and concerned about their health. One participant felt it would be useful to have another session at the end of the intervention to get remotivated:

> *I made all these changes and they're not working...I'd like to have spoken to somebody about that.* [009]

Some participants wanted less information presented during the lifestyle information and education session, whereas others wanted more information. For instance, one participant wanted more education on diet and portion size. Another recommended dietary reminders or ongoing goal setting in relation to healthy eating. One participant recommended providing more training on how to use Fitbit. In relation to the goal setting SMS, 2 participants recommended having more SMS over a longer duration, perhaps in declining frequency. Another participant recommended that SMS text messages be delivered on a fixed schedule (ie, on the same time and day each week).

Participants recommended a range of strategies to increase opportunities for interaction and social support among the participants, for example, a longer time frame for the lifestyle information and education session for people to get to know one another and a group debrief at the end. One participant recommended including peer support that could take the form of an online support group and that participants may actually get involved in delivering elements of the intervention (ie, goal setting). Another participant recommended assigning people a walking partner so they could motivate each other and a half-day session at the midway point where participants could discuss their progress, or lack thereof, with the aim of reigniting their motivation.

Discussion

Principal Findings

The results are consistent with constructs from the theoretical framework of acceptability of health care interventions [21], suggesting high acceptability of the intervention. Overall, the mixed methods results indicate that the majority of participants were satisfied and had a positive attitude toward the intervention, with high perceived effectiveness and high coherence. Most participants were confident that they could perform the required behaviors for the intervention, and qualitative data showed that the design of the intervention helped build self-efficacy in performing health behaviors. In both quantitative and qualitative responses, there was greater individual variability in participants' determinations of the intervention's level of burden and participants' sense of self-efficacy. The high response rate and low rate of attrition in the trial support these qualitative and quantitative findings. Therefore, we are confident that this intervention using mHealth and BCTs to improve health and well-being outcomes is acceptable to recipients. The findings of this study are consistent with research using quantitative and qualitative methods that have found that mobile and digital health solutions are acceptable to people living with and beyond cancer [25,27,28,30] and studies supporting the acceptability of health behavior change interventions more broadly [35,36].

Participants reported a high level of satisfaction with the intervention. Most participants held a positive attitude toward the intervention and enjoyed many of its elements. In particular, mHealth components were rated positively. In terms of intervention coherence, participants' understanding of the aim of the intervention was less focused on weight management and more focused on *moving on* psychologically from cancer. The intervention was perceived to have high efficacy, and the participants described the effects in different areas, especially physical health and fitness, mental health and well-being, and self and self-image. Although weight loss was an important outcome of the intervention, it is noteworthy that weight loss did not feature strongly in participants' responses in terms of the effects of the intervention. This may be linked to the finding that many participants judged the goal of the intervention to be much broader than weight loss. Discordance between patient and provider priorities with regard to health goals and treatment outcomes has been previously observed in the management of cancer and other chronic conditions [37-39]. This highlights

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the importance of patient-centered care [40], along with the person-centered design of health care interventions [41]. There was a variety of responses in terms of the level of burden posed by participating in the intervention and participants' confidence that they could perform expected behaviors. The low level of attrition implies that participating in the intervention itself was not particularly onerous or burdensome; however, the qualitative responses reveal how challenging health behavior change is on a personal level. This is evident in the low success rate of behavioral weight loss interventions [42]. mHealth tools may support health behavior change [43,44]; however, these tools alone do not necessarily increase self-efficacy or reduce the burden of changing well-established dietary and physical activity behaviors.

Participants were generally very positive about the content and delivery of the intervention. Most of the recommendations for improving the Moving On intervention focused on increasing the frequency, duration, and scope of the existing intervention components. For example, the goal setting intervention focused on increasing physical activity, and participants recommended that we extend this goal setting to dietary behavior. This is not unexpected, given reports that dietary behavior change was deemed the most difficult aspect of the intervention, and perhaps, this was because of them receiving less behavioral support in this respect. Clinical guidelines for obesity management recommend that interventions target both physical activity and diet [32,45]. Interventions using goal setting have typically focused on either diet or physical activity, rather than targeting both simultaneously [46]. However, goal setting has been used in interventions focusing on dietary behavior change with positive effects [47]. Participants recommended longer and additional lifestyle information and education sessions, with more time to interact with health care professionals and more goal setting SMS over a longer duration in declining frequency. There are a limited number of mHealth interventions using BCTs with cancer survivors; however, one previous study found that behavioral prompts sent by email in declining frequency over 12 weeks significantly increased physical activity in survivors of breast cancer [18].

It is clear from the feedback that participants also wanted more opportunities for social interaction and support from other participants during the intervention. This is consistent with the findings of another study on breast cancer survivors and their preferences for wearable activity trackers. Their recommendations were to incorporate online and in-person peer support and doctor monitoring [29]. Social support is a common component of psychosocial interventions aimed at improving emotional adjustment in people with cancer [48,49]. The Moving On intervention aimed to improve health and well-being outcomes by improving health behavior. However, the findings presented here highlight the broader issues that cancer survivors face. Participants' recommendations for increased social support are in keeping with participants' descriptions of the cancer experience as lonely and isolating. Together, these findings suggest that this mHealth behavior change intervention, although acceptable for self-management of lifestyle behavior, may not be sufficient to meet the full range of physical and psychological health needs of people living beyond cancer. Future research will be needed to determine whether the addition of social support components to the Moving On intervention has an incremental benefit on the effectiveness of the intervention.

Qualitative research can inform the development of future trials and interventions. Participants' responses raised important questions about the ideal timing of the Moving On intervention. Some felt the burden of participating would be higher in the earlier stages of cancer survivorship when fatigue and treatment effects were most pronounced [50]. At the same time, others described feeling lost and afraid when their acute cancer treatment was complete and their follow-up would be an outpatient visit every 6-12 months, supporting the idea that this may be a good time to intervene. Participants also identified times when behavior change was more difficult, opening up the potential for adapting the mHealth intervention as a just-in-time intervention [51]. These are complex, technologically advanced interventions that provide real-time behavioral support, for example, when the participant has an opportunity to engage in a health behavior or is likely to experience a trigger for unhealthy behavior. A recent review found that these interventions are acceptable to participants and are often used in combination with the same BCTs as in this study (ie, goal setting, prompts, feedback, and action planning) [52].

Qualitative findings can also inform the interpretation of the results of RCTs. The assessment of study outcomes at baseline, at 12 weeks, and at 24 weeks were not coded as BCTs; however, based on the results of this study, they may have been important motivators of behavior change. It is possible that future iterations of the intervention that do not include assessment of clinical, psychological, and behavioral outcomes would be less effective. Our intention was that the goal setting intervention would motivate participants to increase their activity level. However, these qualitative results suggest that participants' motivation was influenced by multiple factors, including self-monitoring their activity via Fitbit, an awareness of being monitored by the research team, accumulating self-efficacy, encouraging interactions with staff (at the lifestyle information and education session and SMS contact), and attending assessments.

Although not an explicit focus of this study, a small number of issues relevant to fidelity were described by participants during the interviews. Some participants spoke of being enrolled in other programs (eg, mindfulness courses and sports clubs), and although this was not discouraged, it was not measured or controlled for. Another participant revealed that he had broken his Fitbit and started using a different service (MyFitnessPal) without informing the research team. Other participants used the Fitbit app in ways they had been explicitly asked not to (ie, for food logging and calorie counting). Fidelity is an important aspect of evaluating complex interventions [53] and may be relevant to the acceptability of an intervention, but it was not measured explicitly in the trial and would be useful to consider in future testing of similar interventions.

Acceptability is an aspect of feasibility. However, future studies are needed to assess the feasibility of delivering this intervention in clinical practice. Although the intervention was perceived as low burden by participants, the burden of delivering the intervention in routine care may be high for clinical staff. There

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is significant promise of and potential for mHealth to limit the burden on the health care system [13]. However, the findings of this study suggest that in addition to mHealth solutions, cancer survivors want additional and extended support from their health care providers in relation to self-management of lifestyle behavior. In many clinical contexts, this may be challenging; however, this program could be facilitated external to the hospital setting, and advancements in digital health technology make this more of a possibility than ever before.

Limitations

This study used qualitative research to assess the retrospective acceptability of the Moving On intervention. The *person-based approach* recommends in-depth qualitative research at the planning and development stage to enhance the acceptability and feasibility of interventions [41]. Unfortunately, participants' perspectives were not considered during the design phase of the intervention. Reassuringly, the results of this study suggest that the Moving On intervention was seen as acceptable by those who participated in it. Relative to other qualitative studies in health research [54], the sample size was limited. At the same time, a sizable portion of the intervention group was interviewed (13/53, 24%). Furthermore, there was a limited number of male participants; however, this is reflective of the composition of the sample in the full trial. With regard to acceptability, the qualitative responses were consistent with the quantitative data with a larger sample size of 36 (representing 36/53, 68% of the intervention group). This concordance provides further support for our judgment that the number of interviews was sufficient to meet the goals of the analysis. Finally, this study focused on the acceptability of the intervention to those receiving the intervention only. It would be equally interesting and important to assess the acceptability of the intervention to those responsible for delivering it.

Conclusions

This study provides insight into the experiences of participants enrolled in the Moving On intervention. This mixed methods analysis identified that the intervention was acceptable to the participants. Participants spoke of cancer survivorship as lonely and isolating, and they wanted more social support and peer interaction to be incorporated into the intervention. Overall, participants were very positive about the intervention in terms of both content and delivery. As it was acceptable and was perceived as having the broad goal of *moving on* psychologically, if found to be effective, the intervention could be offered to individuals following completion of their active cancer treatment as part of standard care to promote the health and well-being of survivors.

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Authors' Contributions

JW, JR, and MK conceived the study. JW and JR were the grant holders. JM, JG, and OH developed the semistructured topic guide and quantitative measure of acceptability. OH conducted the interviews. JG and JM analyzed the data. JG and AG wrote the first draft of the manuscript. All the authors have approved the manuscript for submission.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Semistructured interview topic guide.
[DOC File , 150 KB - mhealth_v9i2e18288_app1.doc]

Multimedia Appendix 2
Results of quantitative survey of acceptability.
[DOCX File , 14 KB - mhealth_v9i2e18288_app2.docx]

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Abbreviations

BCT: behavior change technique
mHealth: mobile health
RCT: randomized controlled trial

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Original Paper

eHealth Intervention to Improve Health Habits in the Adolescent Population: Mixed Methods Study

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Abstract

Background: Technology has provided a new way of life for the adolescent population. Indeed, strategies aimed at improving health-related behaviors through digital platforms can offer promising results. However, since it has been shown that peers are capable of modifying behaviors related to food and physical exercise, it is important to study whether digital interventions based on peer influence are capable of improving the weight status of adolescents.

Objective: The purpose of this study was to assess the effectiveness of an eHealth app in an adolescent population in terms of improvements in their age- and sex-adjusted BMI percentiles. Other goals of the study were to examine the social relationships of adolescents pre- and postintervention, and to identify the group leaders and study their profiles, eating and physical activity habits, and use of the web app.

Methods: The BMI percentiles were calculated in accordance with the reference guidelines of the World Health Organization. Participants' diets and levels of physical activity were assessed using the Mediterranean Diet Quality Index (KIDMED) questionnaire and the Physical Activity Questionnaire for Adolescents (PAQ-A), respectively. The variables related to social networks were analyzed using the social network analysis (SNA) methodology. In this respect, peer relationships that were considered reciprocal friendships were used to compute the "degree" measure, which was used as an indicative parameter of centrality.

Results: The sample population comprised 210 individuals in the intervention group (IG) and 91 individuals in the control group (CG). A participation rate of 60.1% (301/501) was obtained. After checking for homogeneity between the IG and the CG, it was found that adolescents in the IG at BMI percentiles both below and above the 50th percentile (P50) modified their BMI to approach this reference value (with a significance of $P<.001$ among individuals with an initial BMI below the P50 and $P=.04$ for those with an initial BMI above the P50). The diet was also improved in the IG compared with the CG ($P<.001$). After verifying that the social network had increased postintervention, it was seen that the group leaders (according to the degree SNA measure) were also leaders in physical activity performed ($P=.002$) and use of the app.

Conclusions: The eHealth app was able to modify behaviors related to P50 compliance and exert a positive influence in relation to diet and physical exercise. Digital interventions in the adolescent population, based on the improvement in behaviors related to healthy habits and optimizing the social network, can offer promising results that help in the fight against obesity.

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KEYWORDS

adolescent behaviors; BMI; diet; healthy habits; intervention; leader; physical activity; social network analysis; adolescent; social network; behavior

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Introduction

The current trend toward rising BMIs among children and adolescents reflects a standstill in high-income countries and an increase in cases of overweight and obesity in lower-middle-income countries [1]. It is estimated that by 2025, 268 million children worldwide between the ages of 5 and 17 years could be overweight, including 91 million children who meet the criteria for obesity [2]. The World Health Organization (WHO) recognizes that social changes have modified factors related to diet and physical exercise, resulting in an energy imbalance that leads to overweight and obesity [3]. In fact, among all the determining factors that can influence diet and physical activity in the adolescent population, peers can encourage healthy or unhealthy behaviors [4].

Indeed, diet and physical exercise play a role in the conditions of overweight and obesity. In relation to diet, good adherence to the Mediterranean diet has many health benefits [5]. In fact, it is recommended that both Mediterranean and non–Mediterranean countries adhere to the principles of this type of diet to combat obesity and other chronic diseases [6,7]. The problem we currently face is that children and adolescents in European Mediterranean countries tend to neglect the Mediterranean diet pattern because of sociodemographic and lifestyle changes [8], among other causes. In Spain, for example, recent studies have shown that 64.3% of children between ages 6 and 17 years have low or medium adherence to the Mediterranean diet [9].

The same applies to physical activity. Although the benefits of exercise are widely recognized, 55.4% of Spanish children and adolescents do not comply with international recommendations on physical activity [10]. On the other hand, it has been recognized that putting an end to the obesity epidemic requires consideration of the environmental factors that play a role in the problem rather than focusing strictly on the individual as being solely responsible [11]. In fact, the broader the attack strategy, the better the results are expected to be. For example, interventions applied at the school level and focused on food and exercise in combination are considered promising in the fight against obesity [12]. Recent trends show an emerging number of technology-based, adolescent-focused interventions to improve health outcomes for multiple related behaviors—in particular, interventions through web-based platforms focused on health education that propose the fulfilment of certain proposed objectives and invite self-management, succeed in fostering parental involvement, and improve diet and physical activity behaviors [13].

In this context of applying technology to improve the diets and physical activity levels of adolescents, the social environment can be used to facilitate mechanisms of influence and social support and/or the provision of resources between individuals. To achieve this relational perspective, the social network analysis (SNA) paradigm has been applied to analyze the social environment from a structural point of view [14]. There are a number of significant studies that apply the SNA methodology to interventions in obesity and its associated factors. For example, health behavior change in favor of more physical activity could be promoted if we adapt a specific intervention to the characteristics of young people (according to their gender) and their social network [15]. Another option is to identify and work with the “leaders” among peer groups to influence their peers, offering them training so that they can propagate the desired change in behavior through their social network [16]. Several studies are currently being conducted that are trying to shed light on the ways in which interventions based on social networks can be implemented to increase their effectiveness, as it is a field of research with many avenues to explore [17]. Although it has been shown that the mechanism of influence exists by which a health behavior can spread among the individuals in a network, it is not clear how that mechanism works (eg, contagion, acceptance of group norms, imitation, etc) nor how the intervention should be designed to facilitate it [18].

In an attempt to optimize the adolescent social network, while focusing our efforts on improving healthy habits in the adolescent population, we created an eHealth web app with a responsive design called “SanoYFeliz” (ie, Healthy and Happy), which is accessible from anywhere with an internet connection. SanoYFeliz is only available in Spanish, although the English version is being developed for use in a possible international project in the future. This eHealth app, which was developed in the school environment and offers the possibility of parental participation, was based on support from peer networks and provides a system of virtual rewards for the achievement of objectives. As such, SanoYFeliz could be an enormously useful tool in the improvement of behaviors related to eating and physical activity habits. The proposed objectives of this study were (1) to assess the effectiveness of the eHealth app in the adolescent population in terms of age- and gender-adjusted BMI percentiles; (2) to study the social relationships of the adolescents pre- and postintervention; and (3) to identify the group leaders and study their profiles, eating and physical activity habits, and use of the web app.

Methods

Study Design

The study employed a pre-post experimental design using the technique of intentional or convenience sampling and ran for 14 weeks between October 2019 and January 2020. This study is part of the “Acquisition of healthy routines in the adolescent population with a tendency to obesity, through an automated coaching platform based on social networks and Semantic Web” project, funded by the Junta de Castilla y León (The Castilla y Leon Regional Council) in Spain. Before this intervention was conducted, a pilot study was carried out with the participation of 95 adolescents belonging to a single school in order to detect possible defects and resolve them.

Permissions

Because this research was conducted in a population of minors, informed parental/guardian consent was requested prior to adolescent participation. Adolescent consent was implicit if they agreed to participate in the intervention; no adolescent was forced to participate. Given the educational context in which this study was developed, permission was obtained from the

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Department of Education of the Junta de Castilla y León. It was also approved by the Ethics Committee of the University of León (ETICA-ULE-028-2018).

Participants

The population under study was adolescents in their first and second year of compulsory secondary education from three educational centers in the province of León, Spain. After receiving authorization from the directors of the educational centers, a total population of 340 students was assigned to the intervention group (IG; 168 students in their first year and 172 students in their second year) and 171 students to the control group (CG; 90 students in their first year and 81 students in their second year). In total, 124 students in the IG and 80 students in the CG were excluded from the study for not having the informed consent form signed by their parents. Therefore, the IG comprised 216 adolescents (119 in their first year and 97 in their second year) and the CG comprised 91 adolescents (48 in their first year and 43 in their second year). However, the final sample size of the IG was 210 students, as 6 individuals could not participate because of school absence for medical reasons. The criteria for selecting the CG and IG were based on the need for the samples not to be contaminated. As there were two schools in León and one in Ponferrada, it was decided that one of the schools in León would be the CG. In this way we ensured that there was no communication between students in the same school.

eHealth App Development

The eHealth app, SanoYFeliz, was available to all of the adolescents participating in the study. Students were introduced to the app at the beginning of the intervention and were provided with several video tutorials explaining the different functionalities of the app. They were always supervised by the eHealth app administrators and researchers in this project, so that there was no conflict with or abuse toward any of their schoolmates. The adolescents were reminded of their total freedom to use the app without further interference. However, it is important to emphasize that the physical education teacher motivated them to use the app on a weekly basis. Also, since parents are an important source of influence for adolescents [19], it was suggested that participants involve their parents in some of the activities they performed on the app. Although more details about the app can be found in the paper presented at HEALTHINF 2020 [20], some of its functionalities include the ability to create a personal profile and network of contacts online, communicate with friends, and create healthy events and attend them. The app also provides personalized healthy eating and physical exercise tips, and rewards users virtually through “bienStars“ (“healthyStars”) to motivate their participation.

This eHealth app was designed using a variety of behavior change techniques, such as social support (through comments and “likes” that users can send to others), offering information and recommendations (through short messages), or gambling with virtual rewards (through “healthyStars” points) [21].

Functionalities of the App Accessible by the CG Versus the IG

The 91 participants in the CG were part of the 14-week intervention, but they only had access to the public part of the eHealth app (ie, the part of the app that could be accessed from any device by any anonymous user) (Figure 1). The CG could not access the social part of the app (ie, the part where they could request contact or use the chat), create events, access the nutrition or physical activity tips, or receive virtual rewards. On the other hand, the IG was able to create a username and password and use all of the aforementioned features. Users of the app who have access to the restricted area (ie, the IG) can make use of all of the functionalities of the app, including the following:

- access to the social network: add friends, comment on different walls, give likes to publications, create events, and get points in the reward system (healthyStars; Figure 2); and
- personalized notifications: the app sends personalized notifications and advice about nutrition and physical activity. This is accomplished by using push notifications, which are available on smartphones, tablets, and web browsers, as well as sending emails.

Meanwhile, visitors to the website (ie, the CG) can only view the front page and project information and access the blog that contains articles on nutrition and physical activity of approximately 1000 words.

It should be noted that the students in the IG had access to the eHealth app on a daily basis, including all of the functionalities, while students in the CG could only access the public part mentioned above (no access to the social networks, personalized notifications, reward systems, etc).

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Figure 1. Screenshot of SanoYFeliz showing the public interface (left and right panels) and the account menu of a user (center panel).

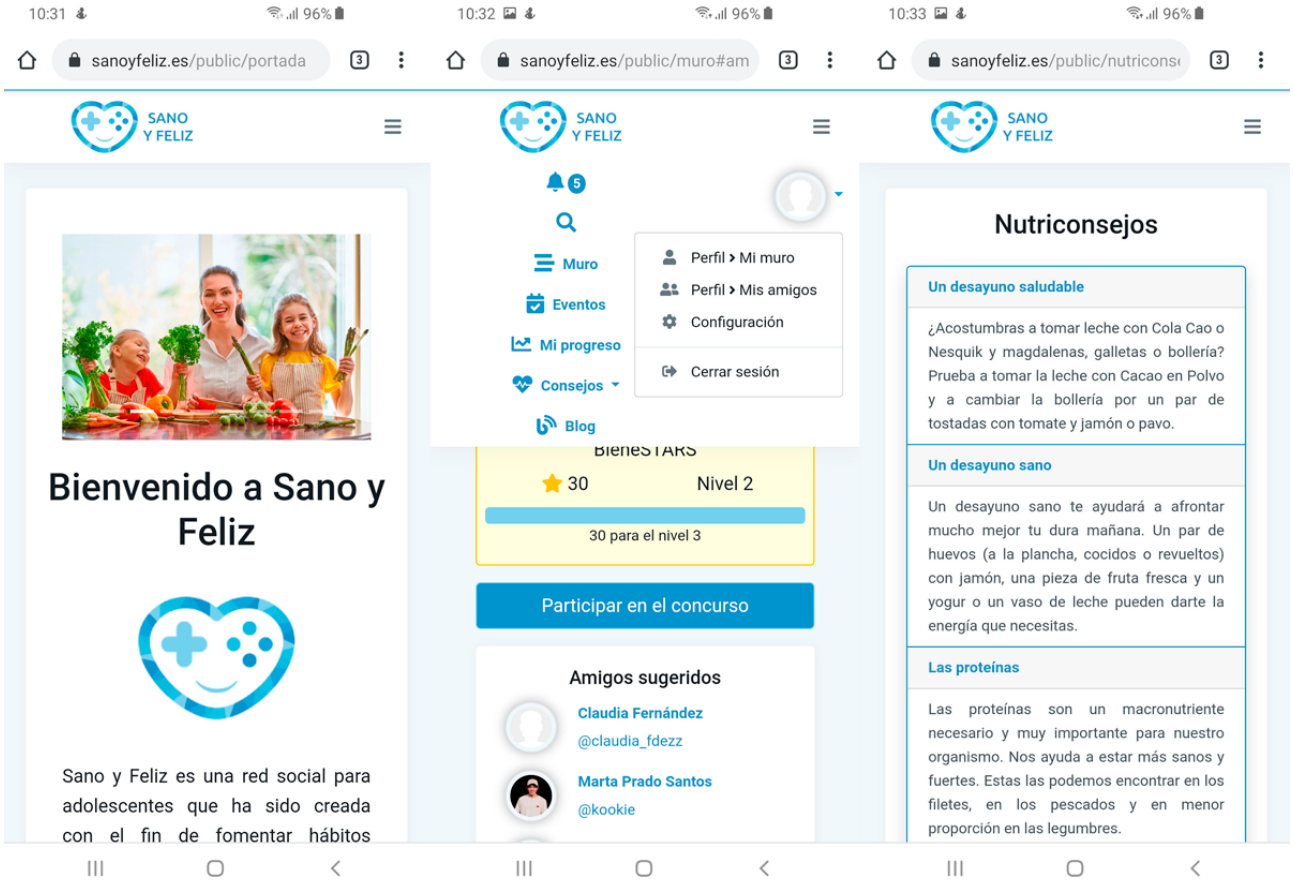

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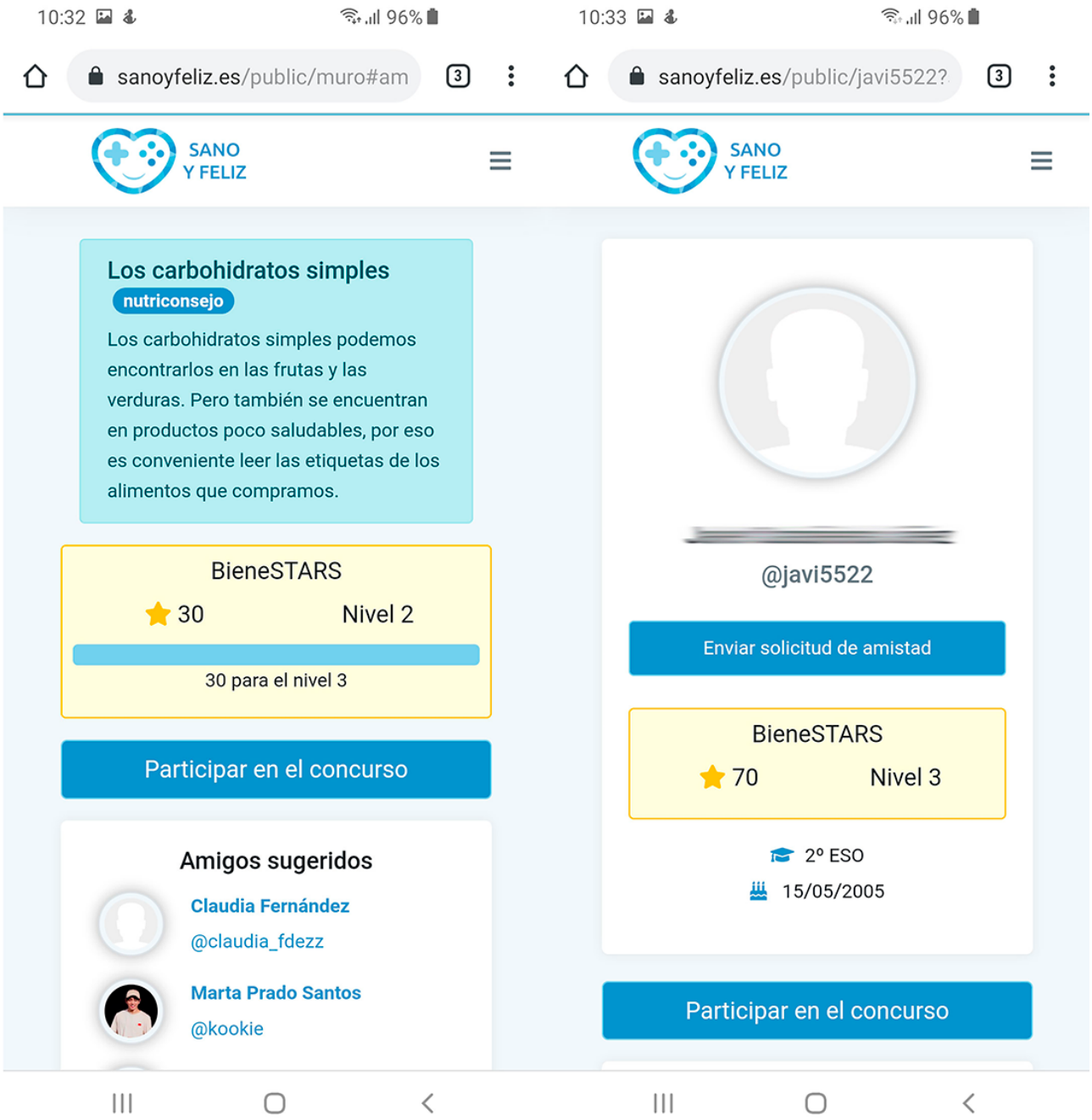
Figure 2. Screenshot of app showing healthyStars as a wall section (left panel) and in a user profile (right panel).



Measuring Instruments and Variables

Anthropometric Variables

The anthropometric measurements collected at the beginning and end of the intervention were height and weight. Since the goal of the app was for adolescents to manage their own health, these data were self-referred, and parents could collaborate with their children when weighing and measuring themselves. A set of video tutorials was provided for clarification and to make the activity possible. With the height and weight data, the BMI was calculated, and the BMI percentile was determined according to age and gender, as per WHO guidelines [22]. In order to meet one of the proposed study objectives, a new dichotomous variable called the "percentile alteration" was created. This reflected whether individuals' BMIs had approached the 50th percentile (P50) at the end of the intervention. That is, if at the beginning of the intervention their BMI was at a percentile below or above the P50, and at the end of the intervention their BMI was at a percentile closer to the P50, they were considered to have improved their weight status.

The BMI percentile was chosen to compare the evolution of adolescents pre- and postintervention, as it is a widely used measure in studies of the pediatric population [23-25]. In addition, it is an objective measure that allows us to know whether adolescents have progressed in the intervention rather than to simply compare those who are underweight, overweight, and obese. To check whether the BMI percentile had improved after the intervention, a partition was applied to this variable,

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dividing it into 2, according to age and gender: (1) individuals at a BMI percentile below the P50, and (2) individuals at a BMI percentile above the P50. According to this partitioning, individuals with BMIs above the P50 in the initial stage would improve their weight status if they managed to reach a lower percentile, while individuals with BMIs below the P50 in the initial stage would improve their weight status if they managed to reach a higher percentile by the end of the intervention.

Eating Habit Variable

The questionnaire used to assess adherence to the Mediterranean diet was the Mediterranean Diet Quality Index (KIDMED) [26]. The KIDMED questionnaire has been the most widely used scoring system to estimate adherence to the Mediterranean diet in children and adolescents [27]. By means of 16 dichotomous questions, a total score of between 0 and 12 points can be obtained by which adherence to the Mediterranean diet can be classified, ranging from poor adherence to an optimal level of adherence (the higher the score, the better the quality of the diet). It was considered as a quantitative variable. The internal consistency of the scale in the study sample was high (Cronbach α=.71).

Physical Activity Variable

The level of physical activity was assessed by means of the Physical Activity Questionnaire for Adolescents (PAQ-A), which has been validated for the Spanish adolescent population between 12 and 17 years of age [28] and consists of 8 questions relating to the type and amount of physical exercise performed during the last 7 days. The total score ranges from 1 to 5 points, and the interpretation is that the higher the score, the more physical activity was performed. It was considered as a quantitative variable. The internal consistency of the scale in the study sample was high (Cronbach α=.76).

Structural Variables

Based on the methodology of the SNA, the "degree" (one of the measures that describe the centrality of the individual within the network) was studied and related to the variables corresponding to physical activity and diet and use of the app. "Degree" is defined as the number of reciprocal connections that the student has [29] (ie, I am your friend and you are my friend). In this study, the term "friendship" was applied when two people claimed to be friends with each other using the definition suggested by authors such as Damon et al [30]: "friendship is a reciprocal relationship that must be affirmed or recognized by both parties." The degree was obtained from both the initial network and the network generated at the end of the intervention, with the aim of studying the adolescents' social relations pre- and postintervention. In response to the statement, "From the following list, point out your closest friends," students were able to choose any classmates in their class with no limit to the quantity within the same course.

Furthermore, it was also necessary to identity the "leaders." Various studies on the application of the SNA paradigm to health interventions have attempted to identify these individuals, as they can act as facilitating agents for the dissemination of healthy behavior on the network following different strategies [31]. It was decided to use the degree as a centrality indicator. The dichotomous variable "opinion leader by degree" was then created. To identify the leaders, 15% of the individuals with higher degree values were chosen, following the recommendations of Valente [31], and individuals with the same score as the last of those included in the 15%, if any, were also included.

Variables Related to Use of the eHealth App

In order to study the activity of adolescents during their use of the eHealth app, a set of variables were used from the data collected from the interaction of the participants:

- number of entries;
- number of responses;
- number of likes;
- number of "healthyStars;" and
- number of interactions.

Statistical Analysis

The data were anonymized with the tool described by Benítez et al [32]. SPSS software (version 24.0; IBM Corp) was used for the statistical processing of the data obtained. For the analysis of descriptive data, frequencies and percentages were used for the qualitative variables, and the mean and standard deviation were used for the quantitative variables. A chi-square test was performed to verify whether there was a relationship between the groups, and the Student *t* test was used to compare mean scores between the groups. A repeated-measures analysis of variance (RM-ANOVA) was carried out to check the differences for time, group, and group-by-time interactions. UCINET software (version 6.679 [33]) was used for the calculation of the SNA measurements. The tests performed to study the normality of the distribution were the Kolmogorov-Smirnov test (for populations of more than 55 individuals) and the Shapiro-Wilk test (for populations of less than or equal to 55 individuals). The level of statistical significance was set at 0.05.

Results

Homogeneity of the CG and IG

Before starting the statistical analysis, the homogeneity of both groups was checked in order to compare them and to ensure that differences observed in the study results between the groups were indeed the consequence of having used the app. An analysis of variance was performed in which age, BMI percentile according to age and gender, and both the KIDMED and PAQ-A scores were considered as dependent variables. Belonging to the CG or the IG was considered as an independent variable. As shown in Table 1, both groups were homogeneous. In the case of gender, the CG was composed of 52.7% (48/91) males versus 54.8% (115/210) males in the IG, with no significant differences (*P*=.75).

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Table 1. Measures used to verify the homogeneity in the control group (CG) and the intervention group (IG).

Measure	CG, mean (SD)	IG, mean (SD)	*P* value
Age	12.77 (0.62)	12.75 (0.72)	.76
Age-adjusted BMI percentile	57.13 (29.16)	50.18 (30.18)	.07
KIDMED[a] score	7.31 (3.24)	7.27 (2.48)	.92
PAQ-A[b] score	2.98 (0.90)	2.77 (0.90)	.09

[a]KIDMED: Mediterranean Diet Quality Index.

[b]PAQ-A: Physical Activity Questionnaire for Adolescents.

Difference Between the IG and the CG

An RM-ANOVA was performed to compare whether the pre-post intervention variation in the means of the four factors (changes in BMI percentile for individuals with BMIs below the P50 and those with BMIs above the P50, in PAQ-A score, and in KIDMED score) was significant, taking as a condition the group they belonged to (CG or IG).

Based on this analysis, it was determined that the changes in all of the study variables in both groups, along with the intervention time, were significantly different. The results obtained are shown in Table 2.

Only the effect of time on the complete study sample did not show significant pre-post intervention differences in changes in the adolescents with BMIs below the P50 (F_1=0.041, P=.84), but there were significant differences in the interaction of whether they belonged to the IG or the GC.

Table 2. Statistical changes in variables by time and by interaction between the control group (CG) and the intervention group (IG).

Source	CG, mean (SD)		IG, mean (SD)		Sphericity assumed	F_1, time	*P* value, time	F_1, interaction	*P* value, interaction
	Pre[a]	Post[b]	Pre	Post					
Initial age-adjusted BMI percentile									
<P50[c]	26.53 (12.61)	24.19 (15.56)	24.05 (13.92)	26.25 (15.31)	218.644	0.041	.84	4.029	.047
>P50	78.09 (15.31)	77.49 (15.87)	77.31 (14.35)	71.37 (18.77)	506.456	16.488	<.001	11.060	.001
PAQ-A[d] score	2.98 (0.90)	2.06 (1.53)	2.77 (0.95)	2.39 (1.45)	8.776	60.291	<.001	9.921	.002
KIDMED[e] score	7.31 (3.24)	7.47 (2.70)	7.27 (2.48)	8.11 (2.50)	14.389	10.271	.001	4.629	.03

[a]Pre: preintervention.

[b]Post: postintervention.

[c]P50: 50th percentile.

[d]PAQ-A: Physical Activity Questionnaire for Adolescents.

[e]KIDMED: Mediterranean Diet Quality Index.

Individual Study of the Results Obtained in the CG and IG

Using RM-ANOVA analysis, together with the study of the means obtained pre- and postintervention in each group, the improvement or worsening of each of the variables in each of the groups was analyzed.

In relation to variable 1 (age-adjusted BMI percentile for individuals with initial BMIs below the P50), there was a worsening in the CG, from a mean percentile of 26.53 (SD 12.61) to 24.19 (SD 15.56), while improvements were seen in the IG, from a mean percentile of 24.05 (SD 13.92) to 26.25 (SD 15.31); this difference between the groups was significant (F_1=4.029, P=.047). With respect to variable 2 (age-adjusted BMI percentile for individuals with initial BMIs above the P50), improvements were observed in the CG, from a mean percentile of 78.09 (SD 15.31) to 77.49 (SD 15.87), and also in the IG, from a mean percentile of 77.31 (SD 14.35) to 71.37 (SD 18.77), with a significantly greater improvement in the IG (F_1=11.060, P=.001).

After analyzing the PAQ-A scores, a worsening was observed in the CG, from 2.98 (SD 0.90) to 2.06 (SD 1.53), and also in the IG, from 2.77 (SD 0.95) to 2.39 (SD 1.45), but the worsening was significantly higher in the CG (F_1=9.921, P=.002).

Finally, the KIDMED score improved in the CG, from 7.31 (SD 3.24) to 7.47 (SD 2.70), and in the IG, from 7.27 (SD 2.48) to 8.11 (SD 2.50), with the improvement in the IG being significantly greater (F_1=4.629, P=.03).

In summary, the results showed significant improvements in the IG in all study variables, except PAQ-A score, where a worsening was detected, although it was significantly less than

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the worsening observed in the PAQ-A scores in the CG. It was also shown that the CG significantly worsened in the P50 approach variables in the age-adjusted BMI percentile for the group of individuals with BMIs below the P50 as well as in PAQ-A, while the P50 approach variables in the age-adjusted BMI percentile for the group of individuals with BMIs above the P50 and KIDMED scores improved, but to a significantly lesser extent than the improvement found in the IG.

SNA Study

To carry out the SNA study, the four networks generated in the IG were analyzed:

- network 1: first-year students in the first school;
- network 2: second-year students in the first school;
- network 3: first-year students in the second school; and
- network 4: second-year students in the second school.

As can be seen in Table 3, the number of established reciprocal relationships (degree) increased significantly after use of the app. The distribution was not normal for any of the measures.

Table 3. Degree of the participants pre- and postintervention in the four networks generated in the intervention group.

	Degree, mean (SD)		
Network	Preintervention	Postintervention	*P* value
Network 1[a]	7.66 (8.86)	11.39 (8.74)	<.001
Network 2[b]	5.52 (3.90)	7.64 (4.40)	<.001
Network 3[c]	4.55 (3.87)	8.70 (4.54)	<.001
Network 4[d]	3.37 (2.89)	5.68 (3.51)	<.001

[a]First-year students in the first school.

[b]Second-year students in the first school.

[c]First-year students in the second school.

[d]Second-year students in the second school.

Regarding the analysis of leaders by degree (15% of the sample with the highest values), the study of the distribution was not normal for any of the measures. The Wilcoxon test was used to analyze whether leaders were predominantly male or female and overweight or not, and whether the PAQ-A and KIDMED scores were higher in groups with leaders (leadership group [LG]) than in the rest of the sample (no leadership group [NLG]). No significance was found for gender (59.4% [19/32] male in the LG vs 53.9% [96/178] male in the NLG; *P*=.57), overweight (9.4% [3/32] in LG vs 11.2% [20/178] in NLG; *P*>.99), or KIDMED score (*P*=0.14). On the other hand, regarding the PAQ-A score, significant differences were obtained between the LG (3.33, SD 0.87) and the NLG (2.22, SD 1.47) (*P*=.002). In the analysis of app use by the leaders in comparison with the rest of the study sample, it was seen that the leaders used the app significantly more (Table 4).

Table 4. Analysis of the activity in "SanoYFeliz" of leaders in comparison with the other adolescents in the study sample.

Activity	Leadership group, mean (SD)	No leadership group, mean (SD)	*P* value
Interactions	12.66 (7.82)	8.49 (10.86)	.045
Entries	4.25 (5.01)	1.39 (3.56)	<.001
Responses	1.94 (3.82)	0.54 (1.72)	<.001
Likes	3.44 (4.32)	0.95 (3.02)	<.001
HealthyStars	47.66 (48.51)	28.51 (34.06)	.008

Discussion

Principal Results

On analysis, it was found that use of the app helped users to achieve BMIs that were closer to the P50, both for the group of individuals with BMIs above the P50 and for those with BMIs below the P50. In this regard, many of the interventions for improving physical activity and eating habits in children and adolescents use the BMI value, age- and gender-adjusted BMI, z-score value, or age- and gender-adjusted percentile as a measure of effectiveness. In fact, these measures were the ones used to compare the effectiveness of interventions in two of the most comprehensive systematic reviews conducted to date on this type of intervention [29,34]. On the other hand, the explanation that we found for the greater significance of the group with BMIs above the P50 relates to the motivation of obese adolescents to live healthier lives. In fact, Silva et al [35] showed in their research that among the multiple motivational factors that an obese adolescent may have to lose weight, the desire for better health was especially important.

We were also able to see how the feeding in the IG improved significantly, something that did not happen in the CG. Similarly, the physical activity scores improved slightly in the IG but worsened significantly in the CG. These results indicate

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that the eHealth app, apart from being beneficial in helping adolescents reach an age-adjusted BMI percentile close to the average value, can also exert a positive influence on adolescents' behavior in relation to physical activity and diet.

In relation to the network leader and his or her relationship to healthy habits, this study found that being a leader and being physically active were significantly related. Since people with a high degree of centrality are a powerful channel of information, our study showed how leaders influenced their peers by increasing the physical activity levels of the rest of the students in the class. Our results are consistent with the literature, stating that friends have a great capacity to influence each other. Schofield et al [36] suggested that friendship, if reciprocal as was the case in our study, could exert a greater degree of influence when modifying a behavior related to physical activity. Similarly, Jago et al [37] found that in the case of boys, best friends influenced the physical activity that was performed, while in the case of girls, those who played sports with their best friends reported higher levels of activity. Macdonald-Wallis et al [38] went further and found not only that best friends and closest peers influenced adolescents' schoolwork, but also that a correlation exists between the behavior of young people with more friendship distance (ie, skipping a degree of friendship by corresponding with the friends of one's friends). In this regard, since our postintervention results reflect that the level of physical activity increased in the IG, we can affirm that these leaders have effectively influenced the rest of their peers in the performance of physical activity. Therefore, the intervention was effective not only in bringing the adolescents' BMI percentiles closer to P50 but also in modifying physical activity–related behavior, in turn weaving a support network among peers.

Also, the group leaders used the website app significantly more than the other adolescents in the study. In this sense, the variables "number of entries," "number of healthyStars," and "number of interactions" can be used as indicators of the level of participation and commitment to the use of the app, similar to what was observed by Tong et al [39]. Similarly, the "number of responses" and "number of likes" can be considered as a measure of the social support provided by each adolescent [40].

Limitations

The research team is aware of the limitations of this study. One of the limitations is the fact that anthropometric measurements are self-referential. In this sense, although there are studies that reflect an underestimation of weight [41], there are other studies that defend that these data can be close to those measured by health professionals [42]. The lack of a longitudinal study to verify that these results can be perpetuated over time is also considered a limitation. Since this eHealth app is in an experimental phase, we can still improve it and measure it in later years if it proves to be as successful as expected. Another point to take into account is the cataloguing of leadership according to "degree," as the literature also recommends measuring "indegree" (nominations of friends received), "closeness" (closeness to other members of the network), and "betweenness" (capacity to mediate) to estimate leadership, without there being a clear consensus as to which of these measures is better for each specific case [43].

Conclusions

In conclusion, it can be stated that the app was effective in helping its users bring their BMIs closer to the P50 for age and gender. Likewise, it is capable of modifying related behaviors or at least modelling them. On the other hand, the capacity of leaders to collaborate with these changes and to promote certain habits has been demonstrated. The eHealth app based on social networks can help in the fight against excess weight in the teenage population.

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Conflicts of Interest

None declared.

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Abbreviations

CG: control group
IG: intervention group
KIDMED: Mediterranean Diet Quality Index
LG: leadership group
NLG: no leadership group
P50: 50th percentile
PAQ-A: Physical Activity Questionnaire for Adolescents
RM-ANOVA: repeated-measures analysis of variance
SNA: social network analysis
WHO: World Health Organization

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Original Paper

Effect of an mHealth Intervention on Hepatitis C Testing Uptake Among People With Opioid Use Disorder: Randomized Controlled Trial

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Abstract

Background: The growing epidemic of opioid use disorder (OUD) and associated injection drug use has resulted in a surge of new hepatitis C virus (HCV) infections. Approximately half of the people with HCV infection are unaware of their HCV status. Improving HCV awareness and increasing screening among people with OUD are critical. Addiction-Comprehensive Health Enhancement Support System (A-CHESS) is an evidence-based, smartphone-delivered relapse prevention system that has been implemented among people with OUD who are receiving medications for addiction treatment (MAT) to improve long-term recovery.

Objective: We incorporated HCV-related content and functionality into A-CHESS to characterize the HCV care continuum among people in early remission and receiving MAT for OUD and to determine whether incorporating such content and functionality into A-CHESS increases HCV testing.

Methods: HCV intervention content, including dissemination of educational information, private messages tailored to individuals' stage of HCV care, and a public discussion forum, was implemented into the A-CHESS platform. Between April 2016 and April 2020, 416 participants with OUD were enrolled in this study. Participants were randomly assigned to receive MAT alone (control arm) or MAT+A-CHESS (experimental arm). Quarterly telephone interviews were conducted from baseline to month 24 to assess risk behaviors and HCV testing history. Cox proportional hazards regression was used to assess whether participants who used A-CHESS were tested for HCV (either antibody [Ab] or RNA testing) at a higher rate than those in the control arm. To assess the effect of A-CHESS on subsets of participants at the highest risk for HCV, additional analyses were performed to examine the effect of the intervention among participants who injected drugs and shared injection equipment.

Results: Overall, 44.2% (184/416) of the study participants were HCV Ab positive, 30.3% (126/416) were HCV Ab negative, and 25.5% (106/416) were considered untested at baseline. At month 24, there was no overall difference in HCV testing uptake between the intervention and control participants. However, among the subset of 109 participants who engaged in injection drug use, there was a slight trend toward increased HCV testing uptake among those who used A-CHESS (89% vs 85%; hazard ratio: 1.34; 95% CI 0.87-2.05; P=.18), and a stronger trend was observed when focusing on the subset of 32 participants who reported sharing injection equipment (87% vs 56%; hazard ratio: 2.92; 95% CI 0.959-8.86; P=.06).

Conclusions: Incorporating HCV prevention and care information into A-CHESS may increase the uptake of HCV testing while preventing opioid relapse when implemented among populations who engage in high-risk behaviors such as sharing

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contaminated injection equipment. However, more studies that are powered to detect differences in HCV testing among high-risk groups are needed.

Trial Registration: ClinicalTrials.gov NCT02712034; https://clinicaltrials.gov/ct2/show/NCT02712034

International Registered Report Identifier (IRRID): RR2-10.2196/12620

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KEYWORDS

intravenous injections; mHealth; hepatitis C virus; opioid use disorder; mobile phone

Introduction

Prescription and illicit opioid addiction are a growing public health problem in the United States [1]. In 2016, an estimated 2.1 million people had an opioid use disorder (OUD) [2], and more than 47,000 people died from overdosing on opioids [3], killing more Americans each day than motor vehicle car crashes [4]. The growing opioid epidemic and associated injection drug use have also resulted in a surge of new hepatitis C virus (HCV) infections [5-7]. With injection drug use being the primary risk factor for transmission and the leading cause of incidence [8], HCV infection is now the most common chronic blood-borne infection in the United States, surpassing all other nationally notifiable infectious diseases combined [9]. From 2004 to 2014, the incidence rate of acute HCV infection increased by 400%, and admission for opioid injection increased by 622% among young Americans [7].

Effective medications are available for the treatment of both OUD and HCV infection. Medications for Addiction Treatment (MAT) are Food and Drug Administration–approved, evidence-based prescription medications used to assist people in recovery from opioid addiction by relieving withdrawal symptoms and physiological cravings [10]. Despite the availability of these effective treatments for OUD, uptake remains low [11]. Moreover, highly effective, well-tolerated, direct-acting antiviral agents are now available for the treatment of HCV, which provide a sustained virologic response (SVR, ie, a cure) in more than 90% of treated patients in as little as 8 weeks [12-14]. These medications provide hope for eliminating HCV; however, only a small proportion of infected individuals have received treatment [15]. One study that examined HCV treatment uptake among patients who received MAT found that among those aware of their infection, only 14% had received HCV treatment [16]. Exacerbating this problem is the fact that approximately half of the HCV-infected individuals are unaware of their infection [17]. Expanding both addiction and HCV screening, treatment, and prevention services are urgently needed in response to the record number of new HCV infections driven by the opioid crisis.

Addiction treatment regimens vary considerably depending on the substances used, comorbidities, severity of substance use disorder, and individual preferences. However, the most effective treatments for individuals with OUD uniformly include a combination of MAT, counseling, and access to other behavioral health services and social supports [18-20]. The Addiction-Comprehensive Health Enhancement Support System (A-CHESS), developed at the University of Wisconsin, is a smartphone app designed to improve recovery from addiction by offering a bundle of services that address the various challenges often encountered during recovery. A-CHESS provides communication with peers and addiction experts, reminders and alerts to encourage therapeutic goals, educational material, and other support services to patients. In an effort to improve long-term recovery from OUD, our research team conducted a randomized controlled trial (RCT) that paired A-CHESS with MAT [21].

MAT alone is associated with an estimated 50% reduction in the risk of acquiring HCV [22]. Combining MAT with harm reduction information and services may further reduce one's chances of acquiring HCV. A systematic review that examined the effect of combining MAT with high-coverage needle and syringe programs found an estimated 74% reduction in HCV infection [22]. Our research team previously designed and pilot tested a computerized intervention to reduce risky injection practices and improve screening for HCV among people who inject drugs [23]. The results from this pilot study suggest that the intervention may reduce the harms of sharing of injection equipment and increase HCV screening [24]. We integrated content and functionality from this computerized intervention into A-CHESS to provide people with OUD who are receiving MAT and addiction counseling access to tailored HCV prevention and care resources.

Methods

Overall Objectives

The primary goal of the RCT was to assess whether A-CHESS can prevent relapse among people with OUD who are in early remission and receiving MAT. Individuals with diagnosed OUD of at least moderate severity who were receiving addiction treatment at 3 centers in Massachusetts and Wisconsin were randomly assigned in a 1:1 ratio to receive either MAT alone (control arm) or MAT+A-CHESS (experimental arm). A web-based tool was used to generate a sequence of random assignments in blocks of 16 subjects, stratified on recruitment site, gender, and type of MAT. Each assignment was associated with a unique study ID number. The electronic randomization lists were managed by the project director and stored in a secure location in the center's shared drive. When subjects completed baseline, they received the next available assignment and study ID on the appropriate randomization list, the group assignment was recorded in Research Electronic Data Capture (REDCap) [25], and the site coordinator was informed by phone or email.

We developed and implemented HCV intervention content within the A-CHESS platform to simultaneously evaluate

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whether A-CHESS improves secondary outcomes related to the HCV care continuum. The objectives of this study were to characterize the HCV care continuum among people in recovery for OUD and to determine whether incorporating HCV-related content and functionality into the A-CHESS system increases HCV testing. Participants were followed for 24 months.

Overview of the A-CHESS System

A-CHESS contains multiple services designed to address several types of challenges facing people with addiction. Key A-CHESS services include a call for help function, cognitive behavioral therapy boosters, a GPS location tracker for avoiding high-risk locations and finding 12-step meeting locations, games, and audio- and video-based relaxation recording, tailored coping support, and coach-monitored discussion groups. A-CHESS provides a platform for people with OUDs to interact with peers and trained counselors, obtain educational information, and provide participant-level data. These existing features were used to collect data on participants' HCV risk behaviors and history of HCV care and deliver behavior change interventions tailored to patients' self-reported stage of HCV care. The study design, recruitment, eligibility, screening process, and addiction-related services incorporated into A-CHESS have been described in the RCT's published protocol [21].

HCV Intervention Content and Functionality

The HCV intervention content included dissemination of educational information, private messages tailored to individuals' stage of HCV care, and a public discussion forum. The educational content is housed within the *Information* tab of A-CHESS and provides answers to HCV-related frequently asked questions and links to factsheets developed by the Centers for Disease Control and Prevention. HCV screening and treatment resources in the individual's community are provided, along with news articles and videos related to the co-occurring epidemics of opioid injection and infectious diseases.

The private messaging feature of A-CHESS is used by study personnel to send tailored messages related to filling gaps in the HCV care continuum. Private messaging conversations began by delivering participants in each HCV stage of care a standardized message pertaining to their current stage of care. Subsequent messages were then guided by each individual's unique response but toward the same goal of helping each individual advance appropriately along the HCV care continuum.

A discussion board, named *Staying Healthy*, was also developed, which provides a forum for participants to ask infectious disease–related questions, share HCV treatment experiences, and discuss barriers to testing and treatment. HCV research staff also engage in these conversations to remind A-CHESS users of the importance of being tested for HCV, encourage healthy behaviors, and stimulate discussion related to such topics. A detailed description of the HCV intervention components and functionality has been previously described [26].

Data Collection

For 2 years, study participants in both the intervention and control arms completed telephone interviews with 1 of 2 study coordinators at baseline and at quarterly intervals (months 4, 8, 12, 16, 20, and 24). At each of these time points, data were collected on illicit opioid use, other nonprescribed substance use, quality of life, retention in treatment, health service use, injection drug use risk behaviors, and HIV and HCV outcomes. Participants were asked whether they had been tested for HCV, the type of test they received (antibody [Ab] test or RNA test), and the date and result of their last test, and if positive, linkage to care and HCV treatment initiation or completion were assessed. A text field, labeled *the comment field*, was available on all surveys for interviewers to enter comments pertaining to the individual's HCV stage of care if they shared additional details. For example, interviewers use the comment field to record whether the individual was approximating the date of their last HCV test or whether they expressed uncertainty regarding the type of testing they had received. Each phone interview lasted approximately 20 to 30 min. Surveys were identified by a study ID and stored in REDCap [25].

Characterizing the HCV Care Continuum

To characterize the HCV care continuum for this study population at baseline, participants were assigned 1 of 7 mutually exclusive stages of HCV care using the criteria specified in Table 1 from the baseline survey. These stages take into consideration the type of test received (Ab or RNA test), test result (positive or negative), and how long ago they were tested.

At each quarterly follow-up interview, their stage of HCV care was updated to one of the stages in Table 2 if their survey answers met the specified criteria.

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Table 1. Criteria for assigning hepatitis C virus stages of care at baseline: Addiction-Comprehensive Health Enhancement Support System Study, 2016-2020.

HCV[a] stage of care	Criteria for assigning stage of care based on baseline survey answers
HCV untested	If they (1) have never been tested for HCV, (2) do not know whether they have ever been tested, (3) do not know the result of their last HCV test, or (4) it has been over a year since their last HCV RNA negative test[b]
HCV Ab[c]−	If they tested HCV Ab negative in the past year
HCV Ab+ no RNA test	If they ever tested HCV Ab positive and have not received an RNA confirmatory test
HCV Ab+ RNA− (ie, "cleared")	If they ever tested HCV Ab positive, tested RNA negative in the past year, and have never received HCV antiviral therapy
HCV Ab+ RNA+	If their last RNA test was positive and they have either (1) never received HCV antiviral therapy or (2) received HCV antiviral therapy in the past and either experienced treatment failure or were reinfected
Currently on treatment	If they are currently receiving HCV antiviral therapy
Achieved SVR[d] (ie, "cured")	If they received HCV antiviral therapy and have been told by a medical professional that they were successfully cured of HCV

[a]HCV: hepatitis C virus.

[b]Note about criteria (4): if an individual tested RNA negative, spontaneously cleared the virus without treatment, or was cured with treatment over 1 year ago and had not received an RNA negative test in the past year, they were considered HCV untested. This logic was chosen to ensure that the HCV intervention delivered recommendations for retesting to these participants.

[c]Ab: antibody.

[d]SVR: sustained virologic response.

Table 2. Criteria for updating hepatitis C virus stages of care at months 4, 8, 12, 16, 20, and 24: Addiction-Comprehensive Health Enhancement Support System Study, 2016-2020.

HCV[a] stage of care	Criteria for updating HCV stage of care
HCV Ab−	If they were previously considered HCV untested and have tested HCV Ab[b] negative since the last survey
HCV Ab+ no RNA test	If they tested HCV Ab positive since the last survey and have not received an RNA confirmatory test
HCV Ab+ RNA− (ie, "cleared")	If they ever tested HCV Ab positive, tested HCV RNA negative since the last survey, and have not received HCV antiviral therapy
HCV Ab+ RNA+	If they tested HCV RNA positive since their last survey and have not received HCV antiviral therapy since the RNA positive test
Currently on treatment	If they are currently receiving HCV antiviral therapy
Achieved SVR[c] (ie, "cured")	If they received HCV antiviral therapy and have been told by a medical professional that they were successfully cured of HCV

[a]HCV: hepatitis C virus.

[b]Ab: antibody.

[c]SVR: sustained virologic response.

If none of the conditions in Table 2 were met at the follow-up interview, the individual's HCV stage remained the same as it was in the previous interview. If interviewers provided any comments in the *comment field* indicating the participant should have been in a stage of HCV care different than this logic assigned, the stage was manually altered accordingly. We have characterized the HCV care continuum for this population by reporting the number of participants in each stage of HCV care at all 7 time points.

Measures and Statistical Analysis

Baseline descriptive characteristics were assessed to describe the study population in terms of age, age of first opioid use, gender, race or ethnicity, educational attainment, employment status, marital status, HIV comorbidity, mental health conditions, prescribed MAT, and HCV status. Differences in baseline sociodemographic characteristics between the intervention and control groups were assessed using Pearson chi-square or Fisher exact tests for categorical variables and the two-sample unpaired *t* test or Wilcoxon rank-sum test for continuous variables.

The primary outcome of interest was days to any HCV test (Ab or RNA test), which was calculated as the number of days between the date of study enrollment and the first reported Ab or RNA HCV test. Cox proportional hazards regression was used to compare the time to HCV testing uptake between the

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intervention and control arms. Participants with no reported HCV test who were lost to follow-up were censored at the time of their last quarterly interview, and those who did not receive an HCV test and completed the 24-month interview were administratively censored. As injection drug use is the primary risk behavior driving HCV transmission, 2 additional Cox proportional hazard models were used to assess the effect of A-CHESS on subsets of participants at the highest risk for HCV, including (1) participants who injected drugs and (2) participants who shared injection equipment with another person. Participants were determined to have injected drugs or shared injection equipment if they reported previously (past 4 months) conducting the behavior on the survey, or any survey before, in which they reported HCV testing or were censored. As individuals' HCV stage of care likely influenced whether they received follow-up testing and how quickly, all analyses adjusted for baseline stage of HCV care, using the stages defined in Table 1. Kaplan-Meier survival curves were created for each risk group to visualize differences in time to HCV testing between intervention and control participants. An intention-to-treat approach was used.

For each time point, we also describe the mean number of days in the previous 4 months that participants in the intervention group used the A-CHESS app. To determine whether engagement with the A-CHESS app was different for higher-risk participants, we conducted negative binomial regression analyses, with cluster robust standard errors to adjust for the nonindependence of observations within persons over time, to compare app use (ie, the number of days they used the app in the 4 months before each survey) between (1) those who injected drugs and those who did not and (2) those who shared injection equipment and those who did not.

All analyses were conducted using Stata version 16 (StataCorp), and statistical significance was determined using $\alpha \leq .05$.

Results

Demographic Characteristics

Between April 2016 and April 2018, 416 participants enrolled in the A-CHESS study and completed the baseline survey; 207 were randomly assigned to the control arm and 209 were assigned to receive A-CHESS. Follow-up was completed for the following number of participants: 382.7% (44/416) at month 4, 79.3% (330/416) at month 8, 72.6%, (302/416) at month 12, 70.4% (293/416) at month 16, 61.8% (257/416) at month 20, and 63.9% (266/416) at month 24. There were no significant differences between the initial sample of 416 participants and the final sample of 266 participants (Multimedia Appendix 1).

The baseline descriptive characteristics of the sample are displayed in Table 3. The sample comprised 85.8% (357/416) of non-Hispanic White people and 54.8% (228/416) male participants. The mean age of the participants was 37 (SD 10) years. Of the 416 study participants, 285 (68.5%) had a high school diploma, General Educational Development, or higher degree, and 101 (24.3%) reported being currently employed for wages. Mental health illnesses affected 70.4% (293/416) of the participants, with the most common diagnoses being depression (218/416, 52.4%), anxiety (215/416, 51.7%), posttraumatic stress disorder (121/416, 29.1%), and bipolar or manic depression (108/416, 26.0%). Overall, 0.01% (4/416) of the participants were HIV positive.

The majority of the sample (302/416, 72.6%) was receiving methadone at the time of enrollment, and heroin was the most commonly used opioid. The average age of participants at first opioid use was 21 (SD 7) years, and 39.4% (164/416) of the participants reported that regular opioid use began through a doctor's prescription. Of the 95 participants who reported using a needle and syringe to inject drugs in the month before study enrollment, 22% (21/95) reported someone else had used their needle after they had used it and 10% (9/95) of the participants reported using a needle after someone else had already used it. There were no significant differences in baseline characteristics between those assigned to the 2 study arms.

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Table 3. Baseline characteristics, by intervention group (N=416): Addiction-Comprehensive Health Enhancement Support System Study, 2016-2020.

Characteristics	Category	Control (n=207)	Intervention (n=209)	*P* value
Enrollment site, n (%)				
Wisconsin	N/A[a]	2 (1)	0 (0)	—[b]
Massachusetts Clinic 1	N/A	5 (2.4)	4 (1.9)	—
Massachusetts Clinic 2	N/A	200 (96.6)	204 (97.6)	—
Age (years), mean (SD)	N/A	37.0 (9.9)	37.4 (10.2)	.73
Age of first opioid use (years), mean (SD)	N/A	21.1 (7.5)	20.5 (6.9)	.45
Gender, n (%)				
Male	N/A	114 (55.1)	114 (54.5)	.91
Female	N/A	93 (44.9)	95 (45.5)	—
Race, n (%)				
White	N/A	190 (91.8)	200 (95.7)	.10
Non-White	N/A	17 (8.2)	9 (4.3)	—
Ethnicity, n (%)				
Non-Hispanic or Latino	N/A	190 (91.8)	187 (89.5)	.46
Hispanic or Latino	N/A	17 (8.2)	21 (10)	—
Highest education level, n (%)				
Less than high school	N/A	63 (30.4)	68 (32.5)	.75
High school diploma or General Educational Development	N/A	86 (41.5)	76 (36.4)	—
Some college or 2-year degree	N/A	50 (24.2)	56 (26.8)	—
4-year college degree or more	N/A	8 (3.9)	9 (4.3)	—
Currently employed, n (%)	Yes	45 (21.7)	56 (26.8)	.23
Marital status, n (%)				
Single	N/A	82 (39.6)	96 (45.9)	.19
Has a spouse or partner	N/A	125 (60.4)	113 (54.1)	—
Diagnosed with HIV, n (%)	Yes	2 (1)	2 (1)	>.99
Diagnosed with mental health illness other than substance use disorder, n (%)	Yes	142 (68.6)	151 (72.2)	.41
Current medications for addiction treatment, n (%)				
Vivitrol	N/A	12 (5.8)	12 (5.7)	>.99
Suboxone	N/A	44 (21.3)	46 (22)	—
Methadone	N/A	151 (72.9)	151 (72.2)	—
HCV[c] status, n (%)				
HCV Untested	N/A	51 (24.6)	58 (27.8)	.56
HCV Ab[d] positive	N/A	87 (42)	91 (43.5)	—
HCV Ab negative	N/A	69 (33.3)	60 (28.7)	—
Injected drugs, n (%)	Yes	45 (21.7)	50 (23.9)	.60
Shared injection equipment, n (%)	Yes	8 (3.9)	16 (7.7)	.10

[a]N/A: not applicable.

[b]*P* value was not calculated when n=0.

[c]HCV: hepatitis C virus.

[d]Ab: antibody.

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A-CHESS Use

The use of A-CHESS decreased over time. Among participants in the intervention arm who completed the 4-month survey, the mean number of days between baseline and month 4 that A-CHESS was used was 30 days. The mean number of days A-CHESS was used between further time points were as follows: 19 days between months 4 and 8, 17 days between months 8 and 12, 15 days between months 12 and 16, 7 days between months 16 and 20, and 3 days between months 20 and 24. There was no significant difference in the mean number of days A-CHESS was used between (1) those who injected drugs and those who did not (odds ratio [OR] 1.06, 95% CI 0.875-1.37; *P*=.43) and (2) those who shared injection equipment and those who did not (OR 1.08, 95% CI 0.767-1.52; *P*=.66).

Characterizing the HCV Care Continuum

The number of participants in each stage of the HCV care continuum at all time points is presented in Table 4 (Multimedia Appendix 2 visually presents these results for the selected stages). Overall, 25.5% (106/416) of the study population was considered HCV untested, 30.3% (126/416) were HCV Ab negative, and 44.2% (184/416) were HCV Ab positive at baseline. From baseline to month 24, there was a trend toward a more favorable HCV care continuum overall. The proportion of participants untested at each quarterly interview appeared to decrease over time, from 25.5% (106/416) at baseline to 3.4% (9/266) at month 24. Similarly, the proportion of HCV Ab-positive participants who had not received an RNA test appeared to decrease over time, from 5.3% (22/416) at baseline to 2.3% (6/266) at month 24, and the proportion of participants achieving SVR appeared to increase over time, from 7.5% (31/416) to 18.4% (49/266). In addition, as HCV untested participants underwent HCV testing throughout the duration of the study, the proportion of participants considered HCV Ab-negative increased over time, from 30.3% (126/416) at baseline to 48.9% (130/416) at month 24. There were no significant differences in the number of participants in each stage of HCV care when comparing those who used A-CHESS with those in the control group over time (Multimedia Appendix 3).

Table 4. Number of participants in each stage of the hepatitis C virus care continuum at baseline and each follow-up: Addiction-Comprehensive Health Enhancement Support System Study, 2016-2020.

HCV[a] stage of care	Value n (%)						
	Baseline (n=416)	Month 4 (n=344)	Month 8 (n=330)	Month 12 (n=302)	Month 16 (n=293)	Month 20 (n=257)	Month 24 (n=266)
HCV untested	106 (25.5)	72 (20.9)	59 (17.9)	45 (14.9)	31 (10.6)	17 (6.6)	9 (3.4)
HCV Ab[b]−	126 (30.3)	111 (32.3)	118 (35.8)	122 (40.4)	129 (44)	115 (44.7)	130 (48.9)
HCV Ab+ no RNA test	22 (5.3)	10 (2.9)	6 (1.8)	1 (0.3)	0 (0)	3 (1.2)	6 (2.3)
HCV Ab+ RNA− (ie, “cleared”)	26 (6.3)	26 (7.6)	25 (7.6)	22 (7.3)	26 (8.9)	25 (9.7)	27 (10.2)
HCV Ab+ RNA+	103 (24.8)	85 (24.7)	72 (21.8)	64 (21.2)	55 (18.8)	49 (19.1)	43 (16.2)
Currently on treatment	2 (0.5)	10 (2.9)	9 (2.7)	4 (1.3)	5 (1.7)	3 (1.2)	2 (0.8)
Achieved SVR[c] (ie, “cured”)	31 (7.5)	30 (8.7)	41 (12.4)	44 (14.6)	47 (16)	45 (17.5)	49 (18.4)

[a]HCV: hepatitis C virus.

[b]Ab: antibody.

[c]SVR: sustained virologic response.

Effect of A-CHESS on HCV Testing

Among the 364 participants who completed at least one follow-up interview by month 12, 66.2% (241/364) had received any (Ab or RNA) HCV test. By month 24, 86.3% (314/364) had been tested for HCV. There was no difference in receipt of an HCV test between intervention and control participants overall, where 66.0% (122/185) and 66.5% (119/179) received testing by month 12, and 85.4% (158/185) and 87.2% (156/179) received testing by month 24, respectively. Kaplan-Meier curves demonstrating the time to HCV testing among all study participants, by randomization group, are presented in Figure 1.

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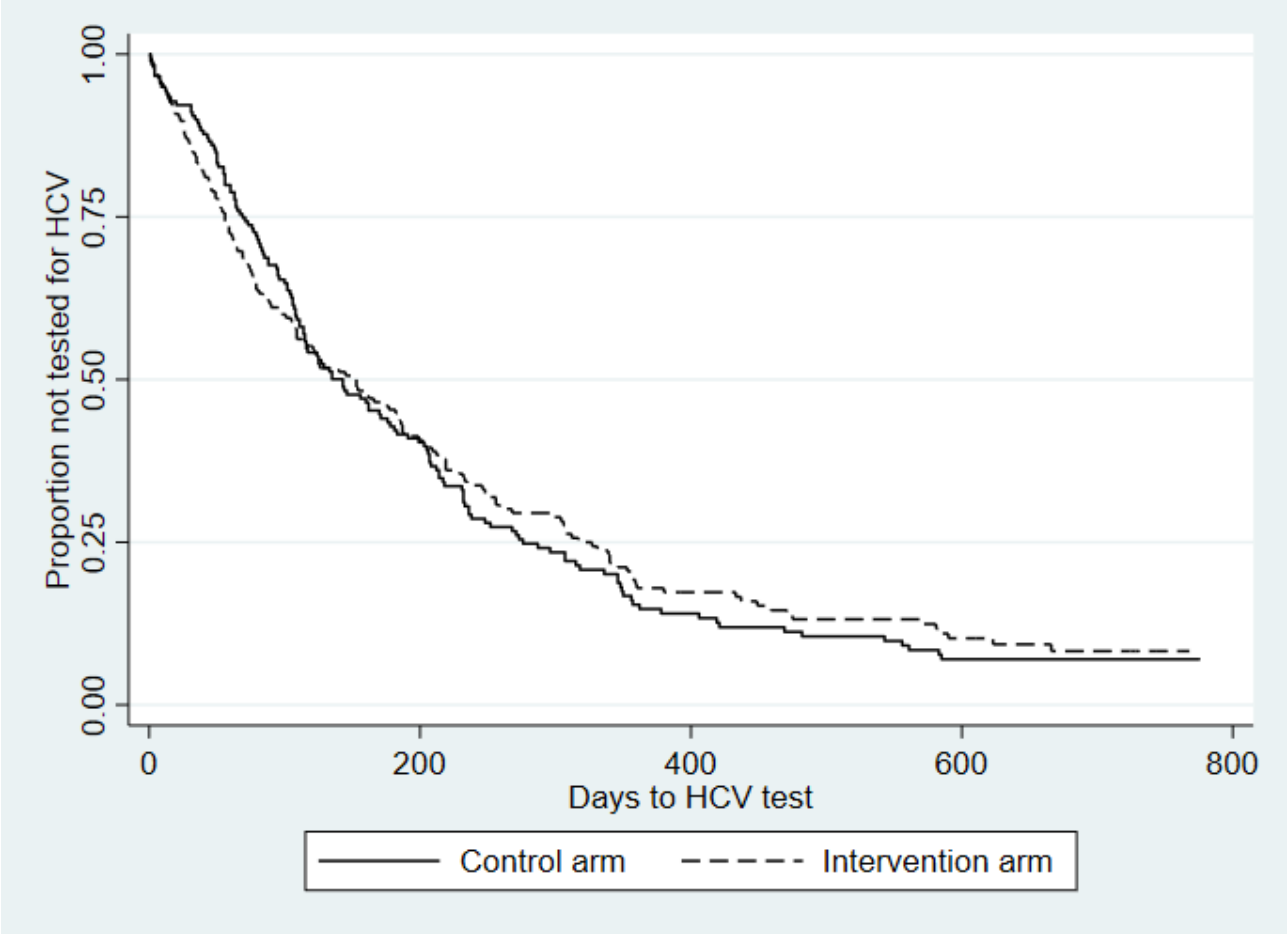
Figure 1. Time to hepatitis C virus test among all study participants, by randomization group: Addiction-Comprehensive Health Enhancement Support System Study, 2016-2020. Hazard ratio: 1.01; 95% CI 0.807-1.26; *P*=.95; n=364. HCV: hepatitis C virus.



Of the 364 study participants who completed at least one follow-up interview, 34.1% (124/364) were considered to have injected drugs in the 4 months before either the baseline or any follow-up survey (70/185, 37.8%, in the intervention arm and 54/179, 30.2%, in the control arm). Of the 124 participants, 15 were excluded from the analysis because they did not report the risk of injecting drugs before undergoing HCV testing. Among the 109 participants who injected drugs and were included in the analysis (63 in the intervention arm and 46 in the control arm), 89% (56/63) of the participants in the intervention arm received an HCV test after injection reporting compared with 85% (39/46) in the control arm. Although not statistically significant, there is a trend toward an increased rate of HCV testing among intervention participants. Compared with those in the control group who injected drugs, the rate of HCV testing among those who injected drugs and used A-CHESS was 1.34 times higher (hazard ratio: 1.34; 95% CI 0.87-2.05; *P*=.18; Figure 2).

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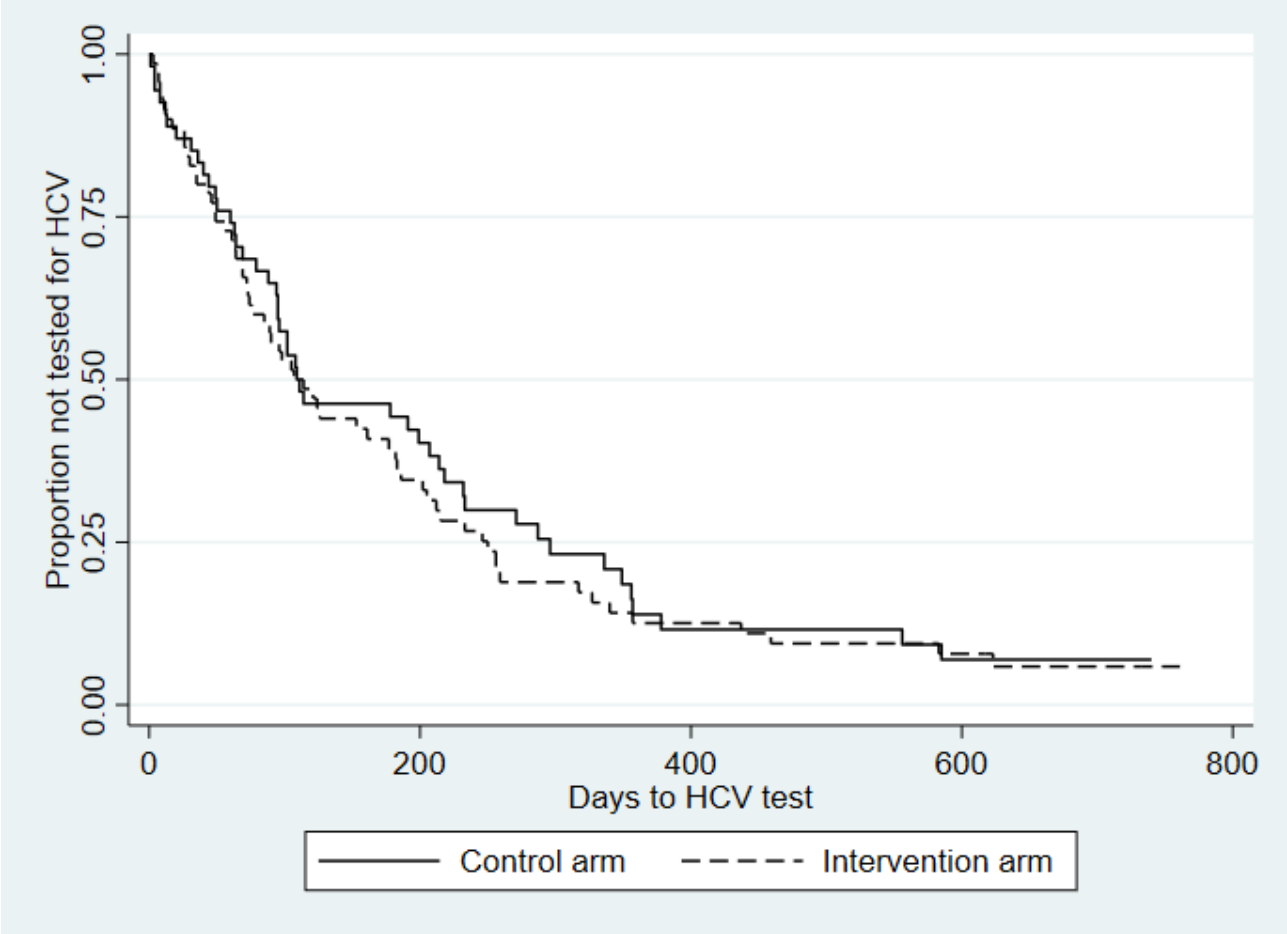
Figure 2. Time to hepatitis C virus test among people who injected drugs, by randomization group: Addiction-Comprehensive Health Enhancement Support System Study, 2016-2020. Hazard ratio: 1.34; 95% CI 0.87-2.05; *P*=.18; n=109. HCV: hepatitis C virus.



Of the 364 study participants who completed at least one follow-up interview, 11.5% (42/364) were considered to have shared injection equipment with another person in the 4 months before either the baseline or any follow-up survey (28/185, 15.1%, in the intervention arm and 14/179, 7.8%, in the control arm). Of the 42 participants, 10 were excluded from the analysis because they did not report the risk of sharing injection equipment before undergoing HCV testing. Among the 32 participants who shared injection equipment and were included in the analysis (23 in the intervention arm and 9 in the control arm), 87% (20/23) of the participants in the intervention arm received an HCV test after reporting sharing, compared with 56% (5/9) in the control arm. Further approaching statistical significance, the rate of HCV testing among those who shared equipment and used A-CHESS was 2.92 times higher than the rate among those in the control group who shared equipment (hazard ratio: 2.92; 95% CI 0.959-8.86; *P*=.06; Figure 3).

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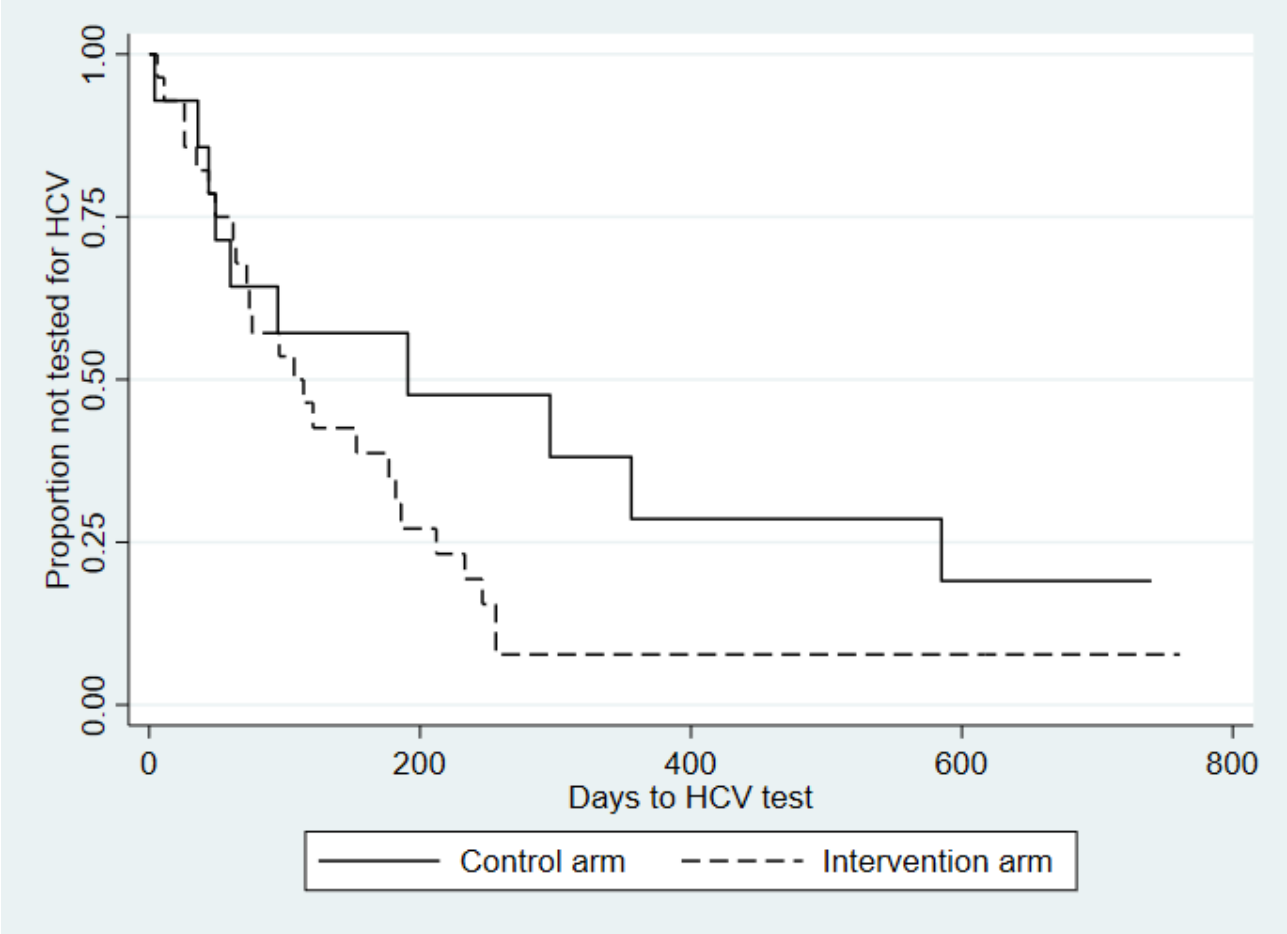
Figure 3. Time to hepatitis C virus test among people who shared injection equipment, by randomization group: Addiction-Comprehensive Health Enhancement Support System Study, 2016-2020. Hazard ratio: 2.92; 95% CI 0.959-8.86; *P*=.06; n=32. HCV: hepatitis C virus.



Discussion

Principal Findings

The goal of this study was to understand the HCV care continuum for people with OUD who are in early remission and receiving MAT and to determine whether implementing HCV-related content and functionality into the evidence-based A-CHESS system may improve HCV outcomes for this population. We found that 44.2% (184/416) of the participants were HCV Ab positive at baseline, indicating that nearly half of the study population had been exposed to the virus at some point before study enrollment. An overall improvement in the HCV care continuum between baseline and month 24 was observed, where a smaller proportion of participants were untested and a higher proportion had tested HCV negative and achieved SVR. These trends appeared among both intervention and control participants, suggesting that there may be external factors influencing changes in the HCV care continuum.

Among the entire study population, we did not observe a difference in HCV testing uptake between those who used A-CHESS and those who did not. However, when focusing on the subset who engaged in injection drug use, there was a slight trend toward increased HCV testing uptake among those who used A-CHESS (89% vs 85%), and a stronger trend was observed when focusing on those who reported sharing injection equipment with another person (87% vs 56%). These results suggest that A-CHESS may increase HCV testing rates if targeted at those with the highest risk of infection: those who share contaminated injection equipment. The intervention likely had no effect on HCV testing uptake among people who had not injected drugs because those participants are at a significantly lower risk of contracting HCV. Future studies that are powered to detect differences in HCV testing among these highest-risk groups are needed.

Limitations

A limitation of this study was that the surveys asked if people injected drugs *in the 30 days before the survey* and shared injection equipment *in the 4 months before the survey*. The fact that these surveys did not ask whether individuals *ever* injected drugs or *ever* shared injection equipment, coupled with the fact that more participants were HCV Ab positive at baseline (n=184) than those who reported injecting drugs (n=124), suggests that we underestimated the number of participants who engaged in these behaviors and who may be at high risk for HCV. In addition, the number of people achieving subsequent steps of the HCV care continuum (eg, linkage to care, and treatment initiation) in this study, particularly among high-risk participants such as those who share injection equipment, limited our ability to test the effect of A-CHESS on these important stages of care.

The logic used to assign participants an HCV stage of care at each time point (Tables 1 and 2) allowed us to best characterize the HCV care continuum after each quarterly interview;

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however, this logic does have limitations because of the complex nature of the disease. Staging the disease in this manner did not allow us to estimate reinfection or HCV treatment failure experiences. In addition, this logic allows participants to advance to the latest stage, achieving SVR, during the study period if they had received treatment before the study but had not undergone RNA testing in the year before enrollment and then received an RNA negative test during the study period. Further analysis is required to estimate how many participants were cured during the study versus before the study.

Our team experiences enrollment challenges at 2 of the 3 addiction treatment centers, primarily because of limited staffing. Owing to these enrollment challenges, 97% of participants were recruited from 1 center in the state of Massachusetts, limiting the generalizability of this study. The primary treatment center is located in an urbanized area with a population size of approximately 89,000 residents [27], where HCV testing services may be more accessible than in rural communities. As suburban and rural communities have been disproportionately affected by the opioid crisis [28-30] and many HCV outbreaks concentrated in rural communities have been detected [31-33], understanding how A-CHESS serves communities with fewer resources for prevention and treatment is needed. Furthermore, only 2 participants were recruited in the state of Wisconsin. These participants may face unique barriers and facilitators to HCV testing compared with residents of Massachusetts; however, the results described in this paper did not change when the 2 Wisconsin residents were excluded.

Another limitation of this study is the use of self-report. The ability of HCV to spontaneously clear without antiviral therapy and the varying levels of clinical testing (eg, HCV Ab, HCV RNA, and tests to evaluate liver damage) complicates the disease, making it difficult for laypersons to understand their exact HCV stage of care. Prior studies have identified significant gaps in knowledge of HCV among people who inject drugs, particularly with respect to transmission risks, symptoms and clinical markers, and treatment options [34-36]. This study would have been strengthened if serologic confirmation of HCV could have been obtained. Likewise, participants often had difficulty remembering the exact date of their last HCV test. Consequently, most test dates were estimated.

Strengths

As mobile health (mHealth) innovations continue to emerge and evolve, the opportunity to address complex, comorbid health conditions on a larger scale grows. To our knowledge, this is the first study to combine an addiction intervention with an HCV intervention to simultaneously address opioid dependence, risky injection behaviors, and HCV infection among people with OUD using a single mHealth app. In addition to the novelty of this intervention, many aspects of the design and analysis strengthened this study. By randomizing participants to the intervention and control arms, the chances of bias because of confounding factors and selection bias have been reduced. In addition, the intention-to-treat analysis maintains the advantages of random assignment and accounts for the fact that some participants assigned to the A-CHESS intervention may have used the app minimally or not at all.

Conclusions

The prevalence of OUD and associated HCV infections has escalated in the United States. Advancements in mHealth technology offer the opportunity to provide information and services for the treatment of both OUD and HCV infection simultaneously. When implemented among populations who engage in high-risk behaviors such as sharing injection equipment, the HCV-enhanced A-CHESS intervention may increase awareness of HCV infection while preventing opioid relapse; however, studies that are powered to detect differences in HCV testing among high-risk groups are needed.

Conflicts of Interest

DG has a shareholder interest in CHESS Mobile Health, a small business that develops web-based health care technology for patients and family members. All other authors declare that they have no competing interests.

Multimedia Appendix 1
A comparison of baseline characteristics between the initial sample (N=416) and the final sample (n=266).
[DOCX File , 16 KB - mhealth_v9i2e23080_app1.docx]

Multimedia Appendix 2
Percentage of individuals in each hepatitis C virus stage of care at baseline and each follow-up: Addiction-Comprehensive Health Enhancement Support System Study, 2016-2020. Ab: antibody; HCV: hepatitis C virus; SVR: sustained virologic response.
[PNG File , 15 KB - mhealth_v9i2e23080_app2.png]

Multimedia Appendix 3
The hepatitis C virus care continuums for intervention and control groups at each time point.
[DOCX File , 16 KB - mhealth_v9i2e23080_app3.docx]

Multimedia Appendix 4
CONSORT-EHEALTH checklist (V 1.6.1).

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[PDF File (Adobe PDF File), 1120 KB - mhealth_v9i2e23080_app4.pdf]

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Abbreviations

Ab: antibody
A-CHESS: Addiction-Comprehensive Health Enhancement Support System
HCV: hepatitis C virus
MAT: medications for addiction treatment
mHealth: mobile health
OR: odds ratio
OUD: opioid use disorder
RCT: randomized controlled trial
SVR: sustained virologic response

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Original Paper

Privacy Concerns About Health Information Disclosure in Mobile Health: Questionnaire Study Investigating the Moderation Effect of Social Support

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Abstract

Background: Mobile health (mHealth) provides a new opportunity for disease prediction and patient health self-management. However, privacy problems in mHealth have drawn significant attention to patients' online health information disclosure and to the possibility that privacy concerns may hinder mHealth development.

Objective: Privacy calculus theory (PCT) has been widely used to understand personal information disclosure behaviors with the basic assumption of a rational and linear decision-making process. However, cognitive behavior processes are complex and mutual. In an attempt to gain a fuller understanding of information disclosure behavior, we further optimize a PCT-based information disclosure model by identifying the mutual relationship between costs (privacy concerns) and benefits. Social support, which has been proven to be a distinct and significant disclosure benefit of mHealth, was chosen as the representative benefit of information disclosure.

Methods: We examine a structural equation model that incorporates privacy concerns, health information disclosure intention in mHealth, and social support from mHealth, all at the individual level.

Results: A validated questionnaire was completed by 253 randomly selected participants. The result indicated that perceived health information sensitivity positively enhances patients' privacy concern (beta path coefficient 0.505, $P<.001$), and higher privacy concern levels will decrease their health information disclosure intention (beta path coefficient –0.338, $P<.001$). Various individual characteristics influence perceived health information sensitivity in different ways. One dimension of social support, informational support, negatively moderates the effect of the relationship between perceived health information sensitivity and privacy concerns (beta path coefficient –0.171, $P=.092$) and the effect of the relationship between privacy concerns and health information disclosure intention (beta path coefficient –0.105, $P=.092$). However, another dimension, emotional support, has no direct moderation effect on the relationship between privacy concerns and health information disclosure intention.

Conclusions: The results indicate that social support can be regarded as a disutility reducer. That is, on the one hand, it reduces patients' privacy concerns; on the other hand, it also reduces the negative impact of privacy concerns on information disclosure intention. Moreover, the moderation effect of social support is partially supported. Informational support, one dimension of social support, is significant (beta path coefficient –0.171, $P=.092$), while the other dimension, emotional support, is not significant (beta path coefficient –0.137, $P=.146$), in mHealth. Furthermore, the results are different among patients with different individual characteristics. This study also provides specific theoretical and practical implications to enhance the development of mHealth.

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KEYWORDS

mobile health; privacy concern; disclosure benefit; health information disclosure intention

Introduction

Background

Mobile health (mHealth), which is a new type of medical service supported by the internet, medical sensors, wireless devices, and information communication technology [1], is snowballing and adding value to health care activities. The global mHealth market is projected to grow at a rate of 36.5% between 2016 and 2022, and would ultimately reach a size of US$ 22.31 billion by 2022 [2]. Through mHealth technology (e.g., mobile apps and wearable devices), health care-related information, knowledge, and consultations can be delivered to patients at any time, which is helpful for disease prediction and self-management behaviors [3].

Although mHealth offers a great potential advantage for improving public wellness, there are still some barriers (such as insufficient patient information disclosure and untimely information upload) that prevent it from being fully used. Some prior studies have worked on these problems and pointed out the factors which may lead to the barriers [4], such as unreasonable IT design [5], insufficient incentive mechanism [6], and unreliable health advice [7]. Among the factors, privacy concerns, which stem from the anxiety that personal information may be used without permission, are proposed to be the biggest barrier related to health information disclosure behaviors [8-13].

Theoretical Foundations

Privacy calculus theory (PCT) adopts an economics perspective to gain an understanding of patients' decisions about health information disclosure [14,15]. According to PCT, consumers conduct a cost–benefit analysis when deciding to disclose personal information in a digital context [16,17]. PCT proposes that patients are rational and make decisions by weighing costs and benefits. If the cost is higher than the benefit, patients usually choose to avoid the risk; otherwise, they will disclose personal information online. PCT can be calculated using the formula U (X) = benefit - cost or UD = F (B, C), where UD is the total calculation utility of decision D.

In mHealth, decision D is whether the patient chooses to disclose personal health information. F is a functional form; C is the opposite of vector B and includes elements that have a negative impact on UD, such as privacy concerns and information leaks. B represents the benefits arising from health information disclosure, such as obtaining necessary medical advice and useful treatment. B enhances the utility of decision D.

Social support, which is exchanged through social connections and interpersonal contacts, is treated as one of the most important benefits of online health activities [18,19]. According to the social support theory, supportive interactions, along with social support itself, protect patients from the health consequences of stress, increase adherence to treatments, and enhance recovery [20,21]. When patients are under health pressure, they need 3 types of social support from others: emotional support, informational support, and substantial support [22]. In mHealth, patients can share their medical experiences and obtain social support from other users [23]. Studies have indicated that of the 3 types of social support, mHealth is especially capable of providing informational support (such as recommendations and suggestions from similar patients or physicians) and emotional support (expressions of emotional care, such as understanding, caring, compassion, and sympathy) [24,25]. While mHealth does offer other benefits such as entertainment or financial returns (eg, gifts or discount vouchers) [26], within the PCT formula, social support is the strongest potential benefit related to patients' information disclosure decisions in mHealth.

Individuals with different characteristics (such as personality and experience) could have different perceptions of the costs and benefits of health information disclosure. Personality may play a role by directly affecting the risk/cost perception of disclosing private information. For example, for patients who are strong in self-protection and self-sensing, privacy leaks may be crucial concerns [27]. By contrast, patients who prefer personalized services would obtain greater perceived benefits from the disclosure of personal information [28], which may moderate their attitudes toward privacy concerns and information disclosure.

Objectives

The basic assumption of PCT is that privacy-related decision making is a rational and linear proceeding. However, in real life, people's cognitive behavior processes are complex and mutual. Information disclosure benefits may have a nonlinear relationship with privacy concerns, and this relationship may affect patients' health information disclosure intention or even influence their privacy concerns. That is, when facing different levels of benefits (eg, social support), patients' privacy concerns may have different negative impacts on their information disclosure behaviors. To better understand patients' mHealth usage and their privacy concerns regarding health information disclosure behaviors, this study takes a PCT-based approach to optimizing the cognitive behavior of patients by identifying the mutual relationship between costs (privacy concerns) and benefits (social support). Therefore, we study the interaction effect of privacy concerns and social support on individual patients' willingness to disclose health information in mHealth.

Hypotheses and Research Model

Privacy Concern and Health Information Disclosure Intention

Previous studies have accumulated considerable knowledge about the relationship between users' privacy concerns and the ultimate use of their personal information. [29]. In the e-commerce field, Yoo et al [30] argued that privacy concern is inversely related to consumers' engagement behaviors. In the context of health care activities, Tang et al [31] focused on the negative impacts of privacy concern on the adoption of electronic medical records, stressing that users' privacy concerns are one of the main barriers to system adoption. Kam and

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Chismar [32] argued that disclosure of health information is influenced by 3 factors: patients' perceived privacy, environmental complexity, and the value of personal information content and feedback. Simon et al [33] also pointed out that privacy concern is one of the main factors affecting users' attitudes toward the exchange of health information. Thus, based on the literature, we hypothesize that:

H1: Privacy concern has a negative impact on patients' intention to disclose health information.

Individual Characteristics and Privacy Concern

Perceived health information sensitivity [34,35] is the individual characteristic evaluated for its relationship with health information disclosure, and it reflects user preferences for information provision. For instance, Wang and Petrison [36] pointed out that when individuals give and obtain information from others, the perceived information sensitivity of the givers affects the probability that the receivers will actually obtain the information. We believe that patients with higher perceived health information sensitivity will make hasty judgments about disclosing health information. Thus, we hypothesize that:

H2: Higher perceived health information sensitivity is positively associated with privacy concern.

It is widely believed that information sensitivity varies from one individual to another [37]. Some studies have pointed out that perceived information sensitivity is mainly related to individual physiological characteristics and external characteristics [35,38]. Physiological characteristics can include disposition, social demographic variables, and personality [39-41]. Compared with dispositions and social demographic variables, personality is more likely to change over time [42]. Therefore, in the rapidly developing mHealth research context, we opt to use personality to represent personal physiological characteristics. Specifically, we use Goldberg's 5 personality traits (extroversion, agreeableness, emotional instability, conscientiousness, and intellect), which have been widely applied in online behavior studies [43,44], to measure personality [45].

Extroversion refers to an individual's attitude toward others, including traits such as talkativeness, boldness, determination, and sociability [46]. Extroverts are satisfied by communication with others, and they need more communication than introverts. In order to adapt to their higher communication needs, extroverts generally have lower information sensitivity [47]. Therefore, patients with high extroversion may be highly likely to share health information in an mHealth context.

Agreeableness refers to the traits associated with an individual's affinity and co-production with their communities [48]. An agreeable person can be described as warm, harmonious, and cooperative. Empirical studies point out that people who are agreeable are more upset by deviant behavior [49]. Therefore, people who show agreeableness may be more sensitive about health information collection behaviors in mHealth. That is, patients with high agreeableness are more likely to have higher health information sensitivity than others.

Emotional instability is characteristic of a person who is often more prone than others to anxiety, depression, stress, and vulnerability [50]. In general, such a person may experience more negative emotions and is likely to be wary of dangerous situations [51]. Patients with higher emotional instability are inclined to be more nervous about disclosing their health information, as they perceive that it may put them in dangerous situations.

Conscientious people are considered vigilant and insightful, reflecting their degree of determination and expectations [52]. Academic terms used to describe conscientious people include organized, reliable, thorough, and rigorous. DeNeve and Cooper [53] argue that conscientious people are more likely to be rigorous in their work and life. Conscientious people orient their behavior toward the prevention of risk and loss [54]. Because health information is important and may cause damage to life when it is violated, conscientious patients are more sensitive to the exposure of medical and health information.

Intellectual people can be described as being imaginative, talented, wise, and logical [50,55]. Research shows that people with intellect-oriented personality traits can better reduce the risks they face and have little concern about information sensitivity [56]. Such people can reasonably analyze the current situations and take appropriate measures to avoid loss. Similarly, when using mHealth, intellectual patients are likely to be more confident in handling personal health information and thus are less sensitive to health information.

Therefore, we hypothesize that:

H3a: Extroversion has a negative impact on perceived health information sensitivity.

H3b: Agreeableness has a positive impact on perceived health information sensitivity.

H3c: Emotional instability has a positive impact on perceived health information sensitivity.

H3d: Conscientiousness has a positive impact on perceived health information sensitivity.

H3e: Intellect has a negative impact on perceived health information sensitivity.

In terms of individual external characteristics, the external environment (eg, life, economic, cultural, and legal context) influences individuals' sensitivity to privacy information [39]. In addition, many scholars have pointed out that past adverse events can affect people's information sensitivity [34,57]. In practice, adverse events also reflect the different influences of the external environment on individuals' characteristics. Moreover, in the novel environment of mHealth, patients who have experienced privacy invasion will be better able to make judgments and construct their sensitivity level regarding health information. Therefore, past experience of privacy invasion is used to explore the relationship between individual external characteristics and perceived health information sensitivity.

To create a hypothesis along these lines, we consider that, as per Pavlou and Gefen [58], previous negative experiences create a lasting effect of increased sensitivity in risk evaluation.

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Consequently, these users will be anxious that similar services may have a high possibility of violating their psychological contracts. Therefore, experiences of privacy invasions will increase their sense of privacy sensitivity. In other words, the more an individual has been subjected to privacy invasion in the past, the higher their sensitivity toward privacy invasion would be now. Thus, we hypothesize that:

H4: Past experience of privacy invasion is positively associated with perceived health information sensitivity.

The Moderation Effect of Social Support

The social exchange theory emphasizes that a person will benefit other persons when he/she receives support from the social network [18]. In mHealth, both informational and emotional support can be provided through online consultations, patient groups, and shared articles.

Informational support, such as advice and assistance, can provide problem-centered solutions that allow the recipient to try to take action against the illness. In the mHealth context, informational support benefits users through professional information services, such as doctor advice or professional health care knowledge. Beneficiaries of such support are also more likely to exchange and share information and experiences in order to help each other. Extensive studies have affirmed the decisive role of informational support [59]. Wilson et al [60] pointed out that perceived informational support makes patients feel healthy.

Meanwhile, emotional support, such as compassion and concern, can help patients manage the negative effects associated with illness [61,62]. This emotional support is also available in the mHealth context, where a consultation with a doctor or communication with other patient may provide emotional encouragement and support in addition to informational support. A user who receives emotional support from the doctors or other patients will then feel obliged to reciprocate. This interactive mechanism encourages users to share their information and knowledge. Liang et al [63] proposed that both informational and emotional support have a positive impact on users' personal information disclosure.

Overall, then, social support helps patients in mHealth through mutual aid and strengthening their capability for self-assistance. Some empirical research has found that even though many users are extremely sensitive to privacy when facing material or emotional rewards, they would nonetheless overlook their privacy concerns and disclose personal information in exchange for rewards [26]. In other words, individuals' decisions about disclosure are not based on rational and linear trade-offs, but are irrational. Specifically, when a patient chooses to use mHealth, they are likely to fully accept the benefits of mHealth care (such as informational and emotional support), which weakens their privacy concerns about information disclosure. When patients receive more social support, although their privacy concerns are not reduced, the influence of privacy concerns on their intention to disclose health information will be reduced. That is, social support and privacy concerns have a reverse interaction effect on patients' intention to disclose health information. Specifically, it can be assumed that:

H5m: Informational support has a negative moderation effect on privacy concerns and online health information disclosure intention.

H5n: Emotional support has a negative moderation effect on privacy concerns and online health information disclosure intention.

Research on the effect of individual characteristics on privacy concerns shows that it changes in different situations [64]. Different potential benefits may have different effects on individual characteristics and privacy concerns [12]. For example, studies have shown that a patient with a personality highly characterized by extroversion or intellect may be much more curious about knowledge and eager to be recognized [39], so informational support may reduce his/her privacy concerns. By contrast, patients with high emotional instability or conscientiousness may find emotional support more important in the mHealth context [65], and it may eliminate their privacy concerns about information disclosure. Moreover, social support is proven to help to assuage privacy concerns of those who experience privacy invasion [66]. Therefore, social support may have a moderation effect on the relationship between individual characteristics and privacy concerns. That is, it can be assumed that social support and individual characteristics have a reverse interaction with patients' privacy concerns.

H6m: Informational support has a negative moderation effect on the relationship between perceived health information sensitivity and privacy concerns.

H6n: Emotional support has a negative moderation effect on the relationship between perceived health information sensitivity and privacy concerns.

Based on the above hypotheses, this study models the impact of the interaction between benefits and costs on mHealth patients' health information disclosure intention (Figure 1).

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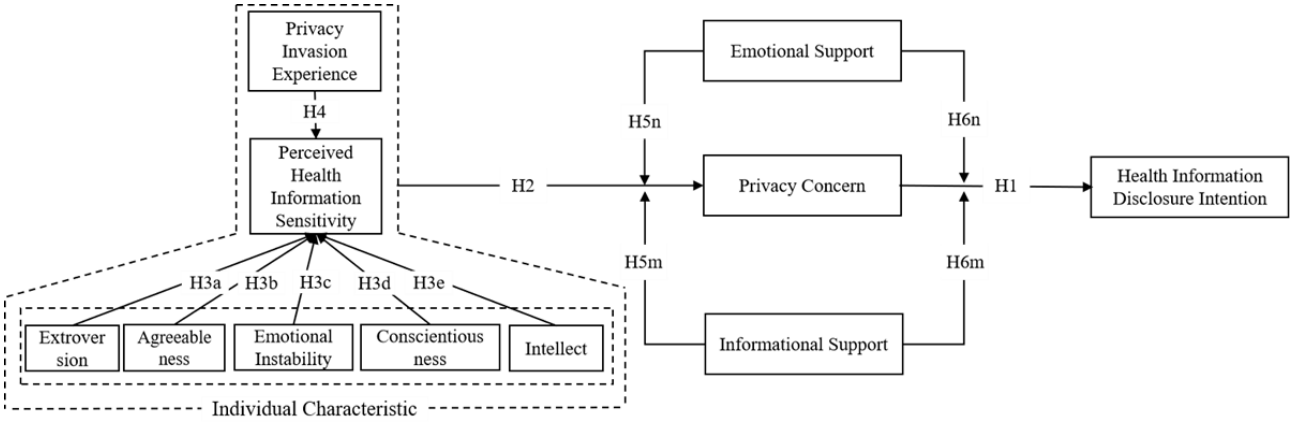
Figure 1. The conceptual model.



Methods

Study Approach

The overall approach was determined by the conceptual model, which sheds new light on 2 main issues: (1) the interaction effect between social support and privacy concerns regarding health information disclosure and (2) the differential impact of individual characteristics. To further analyze the conceptual model and test the proposed hypotheses, structural equation modeling (SEM) and specifically partial least square path modeling (PLS) are used. This is because PLS can analyze the complex relationships between multiple variables, and the results are reliable based on traditional factor analysis techniques [67]. A PLS analysis consists of 2 stages: all items combined weighted composites and regression analysis [68].

The data were collected using an online survey on a digital platform [69]. Participants were those who had experience using mHealth. If the candidate had not used any mHealth apps, the survey would stop; if the candidate has ever used an mHealth platform, he/she continued the survey. If the participant attempted to leave an answer blank, the questionnaire would not move on until they responded.

Many researchers agree that the determining sample size in SEM is uncertain. Schreiber et al [70] suggest that the ratio of observations to estimated parameters can be as low as 10 to 1. Thus, 110 is the minimum required sample size. We also conducted a priori sample size calculations for the minimum sample size required based on the number of latent and observed variables in the design [71]. The results showed that at a probability level of .05, a minimum size of 153 was required. Of our initial sample of 311 copies of the questionnaires retrieved, 58 were deemed unusable because they were incomplete or inconsistent. In the end, 253 valid questionnaires were obtained, and the effective rate of the questionnaire was 81.3% (253/311) . The final research model was tested by using SmartPLS version 3.0 (SmartPLS GmbH) [68], which is widely used, flexible, and efficient.

Instrument Development and Data Collection

Before the main study, we conducted a pilot study to pretest the validity and reliability of the questionnaire before the large-scale survey. We surveyed 100 students who had used the mHealth platform, and of the resulting questionnaires, 88 were valid. Based on this pilot analysis, some of the misleading statements (cultural differences arising during the translation process) were revised. We also determined that if the factor load is less than 0.7 [72], the item would be removed. All factor loading scores were above the recommended threshold of 0.70, except for AG2, IS1, PC3, and PHI1.

The questionnaire consists of 3 parts. The first part concerns whether the candidate has had the experience of disclosing his or her health information on the website or had previously used an mHealth app. If the answer is no, his/her participation in the survey will immediately be stopped. This ensures that the questionnaire is well targeted and the data source is reliable. The second part introduces mHealth. The third part mainly gathers the respondents' demographic information and past health history. In order to ensure construct validity, we used questionnaire items from existing studies (Table 1) and conducted reliability and validity checks (Multimedia Appendix 1).

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Table 1. Measurement scales.

Domain and code	Items	Source
Health Information Disclosure Intention		[73]
HID1	I am very likely to disclose my health information online.	
HID2	I feel good that the website uses my health information.	
HID3	It is okay to share my personal information with the health care platform.	
HID4	I do not feel uncomfortable about sharing my personal information with the health care platform.	
Privacy Concern		[30]
PC1	I am concerned about the potential loss caused by privacy invasion.	
PC2	I worry that others may view my personal health information.	
PC3	Compared with other subjects on my mind, PHI[a] is essential.	
PC4	Compared to others (e.g., friends, relatives, and colleagues), I am more sensitive about the way websites handle my PHI.	
Personality: Extroversion		[74]
EX1	Being the center of attention.	
EX2	Talking to a lot of different people at parties.	
EX3	Not talking a lot.	
Personality: Intellect		[74]
IN1	Having a vivid imagination.	
IN2	Having excellent ideas.	
IN3	Being quick to understand things.	
Personality: Conscientiousness		[74]
CO1	Not paying attention to details.	
CO2	Being always ready for the future.	
CO3	Having a rigorous work attitude.	
Personality: Neuroticism		[74]
EI1	Worrying about things.	
EI2	Changing my moods frequently	
EI3	Being easily irritated.	
Personality: Agreeableness		[74]
AG1	Sympathizing with the feelings of others.	
AG2	I am always glad to help others.	
AG3	Making people feel at ease.	
Experience of Privacy Invasion (When it comes to the privacy invasion of health information online, your feeling can be described as)		[73]
EPI1	Definitely victimized	
EPI2	Definitely bad experiences	
EPI3	Definitely feeling an invasion of privacy	
Perceived Disease Severity		[73]
DS1	I seldom experience major pain and discomfort for an extended period of time.	
DS2	When it comes to chronic conditions, I believe that my condition is severe.	
DS3	In general, I believe that the state of my health is excellent.	
Emotional Support		[63]
ENS1	When faced with health difficulties, some people sympathize with me.	

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Domain and code	Items	Source
ENS2	When faced with health difficulties, some people comfort and encourage me.	
ENS3	When faced with health difficulties, some people pay attention to my private feelings.	
ENS4	When faced with health difficulties, some people show interest and concern about my well-being.	
Informational Support		[63]
INS1	When faced with health difficulties, some people do offer suggestions when I need help.	
INS2	When faced with health difficulties, some people on online health community (mHealth) would provide information to help me overcome my problems.	
INS3	When faced with health difficulties, some people on online health community (mHealth) would help me to discover the cause of my difficulties and provide me with suggestions	
Perceived Health Information Sensitivity (What level of perceived health information sensitivity do I have)		[73]
IS1	Medication	
IS2	State of my health at present	
IS3	Fitness at present	
IS4	Medical history	

[a]PHI: personal health information.

Data Statistics

By collecting and comparing the survey data, we found that people aged 30-49 accounted for more than 50% of respondents (148/253, 58.4%). From the perspective of educational experience, participants with a college education or above accounted for more than 90% of the total number of participants (241/253, 95.2%). Most participants had used the internet for more than 5 years and have had experience with mHealth. The demographics of participants are generally representative of the mHealth user population. These characteristics are also consistent with previous studies [75], indicating that the sample we collected is relatively comprehensive and representative. See Table 2 for demographic statistics. Those who used mHealth apps were more likely to be younger and have more education compared with those who have never used mobile apps or health apps [76]. This may because mHealth is a relatively new IT, and new IT is more easily adopted by younger and well-educated users. The data statistics show that the sample for our study is quite representative.

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Table 2. Demographics of questionnaire respondents.

Variable and its definition	Number of samples, n	Sample frequency, %
Age, years		
Less than 20 years old	1	0.51
21-30	104	44.1
31-40	127	49.74
41-50	21	5.64
More than 51	0	0.00
Education		
Primary school	0	0.00
Secondary school	12	2.05
College degree	25	8.72
University degree	162	72.82
Graduate degree	41	13.85
Postgraduate level	13	2.56
Internet experience, years		
<1	0	0.00
2-4	21	8.21
5-7	64	25.13
8-10	93	34.87
>10	75	31.79
Mobile health experience, years		
<1	52	18.97
2-3	131	56.92
4-5	53	20.51
6-7	16	3.08
>7	1	0.51
Annual frequency of illness		
Less than 1	50	17.95
2-3 times	136	59.49
4-6 times	56	18.97
7-10 times	11	3.08
More than 10 times	1	0.51

Results

Based on the reliability and validity of the questionnaire described above, we tested the hypothesis by structural modeling. The validation process was performed in 2 steps: one for the basic model (Table 3) and the other for the moderation effects (Table 4).

The beta path coefficients show that the direct effect of perceived health information sensitivity positively affects individuals' privacy concerns (beta path coefficient 0.505, $P<.001$), and higher privacy concern levels decrease the health information disclosure intention. Various aspects of personal dispositions influence perceived health information sensitivity in different ways. Agreeableness, emotional instability, and conscientiousness positively enhance perceived health information sensitivity, as hypothesized. However, this is not the case with extroversion and intellect. Previous online privacy invasion has a significant impact on perceived health information sensitivity (beta path coefficient 0.171, $P=.033$), as hypothesized. Prior experience with the website also has a positive influence on trust and on the intention to disclose health information online (Figure 2). Age, education level, digital literacy (mobile usage and mHealth usage), and illness frequency were controlled for in our SEM regression model. These demographics have been identified in the existing literature as determinants of privacy concerns [77,78].

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Table 3. Main results.

Hypothesis	Path coefficients	t_{460} value[a]	*P* value	R^2
H1	–0.338	6.306	<.001	0.321
Age	0.125	1.828	.068	
Education	0.047	0.624	.533	
Mobile usage	–0.062	0.765	.445	
mHealth[b] usage	0.236	2.533	.012	
Illness frequency	–0.745	0.895	.372	
H2	0.505	7.851	<.001	0.294
Age	–0.087	1.377	.169	
Education	0.007	0.112	.911	
Mobile usage	0.099	1.644	.101	
mHealth usage	–0.177	2.650	.008	
Illness frequency	–0.564	1.896	.060	
H3				0.173
H3a	0.152	0.881	.379	
H3b	0.113	1.696	.090	
H3c	0.190	2.563	.011	
H3d	0.167	1.733	.084	
H3e	–0.043	0.404	.686	
H4	0.171	2.134	.033	0.173
Age	–0.125	1.704	.089	
Education	0.086	1.156	.248	
Mobile usage	0.072	0.897	.370	
mHealth usage	–0.095	1.258	.209	
Illness frequency	–1.479	1.534	.127	

[a]One-sample test for null hypothesis and 2-tailed.
[b]mHealth: mobile health.

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Table 4. Results of the moderation model.

Hypothesis	Coefficients	t_{480} value[a]	*P* value
H1	–0.287	4.927	<.001
H5m	–0.105	1.686	.092
Age	0.058	1.312	.190
Education	0.076	1.185	.236
Mobile usage	–0.103	1.488	.137
mHealth[b] usage	0.180	2.623	.009
Illness frequency	–0.258	1.335	.184
R^2	0.337		
H1	–0.285	4.830	<.001
H5n	–0.060	0.891	.373
Age	0.058	1.312	.190
Education	0.076	1.185	.236
Mobile usage	–0.103	1.488	.137
mHealth usage	0.180	2.623	.009
Illness frequency	–8.256	1.326	.187
R^2	0.325		
H2	0.483	6.926	<.001
H6m	–0.171	1.690	.092
Age	0.095	1.456	.146
Education	0.068	1.038	.300
Mobile usage	–0.109	1.508	.132
mHealth usage	0.180	2.646	.008
Illness frequency	–2.756	2.358	.197
R^2	0.324		
H2	0.489	7.108	<.001
H6n	–0.137	1.455	.146
Age	–0.094	1.568	.117
Education	0.023	0.393	.694
Mobile usage	0.104	1.738	.083
mHealth usage	–0.190	2.728	.007
Illness frequency	–4.958	1.449	.149
R^2	0.314		

[a]One-sample test for null hypothesis and 2-tailed.

[b]mHealth: mobile health.

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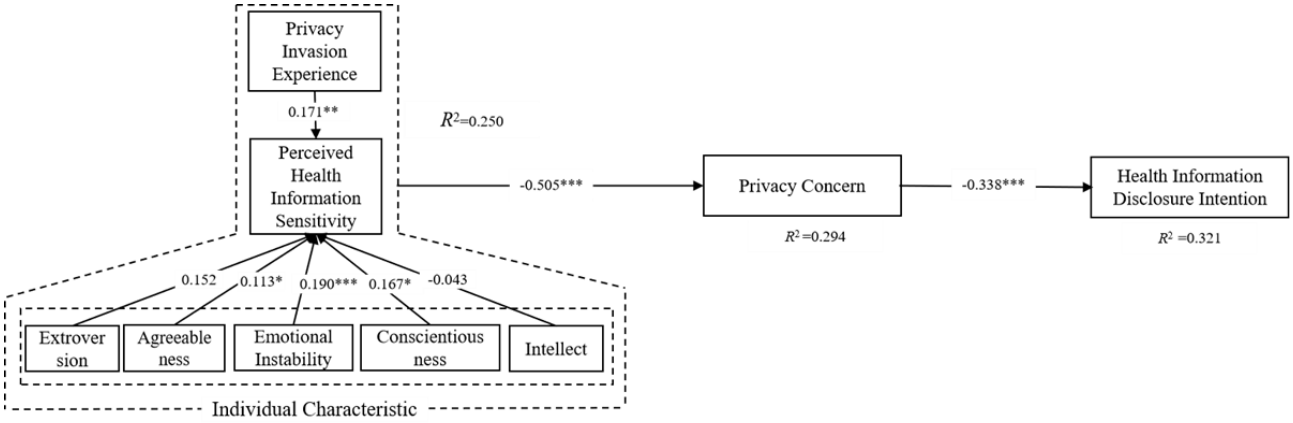
Figure 2. The estimated results of the basic model. Note: *** is significant at the .01 confidence level; ** is significant at the .05 confidence level; * is significant at the .1 confidence level.



The moderation effect model mainly included 2 moderation variables of the original basic model: the emotional support and the informational support obtained through mHealth (Table 4). We find that informational support reduces the positive effect between perceived health information sensitivity and privacy concerns (beta path coefficient –0.171, *P*=.092). Furthermore, informational support will have a negative moderation effect on the relationship between privacy concerns and health information disclosure (beta path coefficient –0.105, *P*=.092). Although the *P* value is at the .1 level, the negative effect of information support on the privacy concerns is a valuable finding that supports the hypotheses [79]. However, we find that emotional support has no direct moderation effect on either privacy concerns or health information disclosure intention. Our summary in Figure 3 shows that our original hypotheses are generally supported (H1a and H1e are not significantly supported; beta path coefficient 0.152, *P*=.379 and–0.043, *P*=.686, respectively), and the moderation effects of emotional support [H5n and H6n] are also not significantly supported (beta path coefficient 0.060, *P*=.373 and –0.137, *P*=.146, respectively) in this situation.

In summary, all the paths are significant at levels greater than .1. The model fits (R^2) show an acceptable level of explanatory power. As much as 9 of the 12 hypotheses are supported, with the exceptions being H3a, H3e, and H6n (Table 5).

Figure 3. The estimated model with moderation effect. Note: *** is significant at the .01 confidence level; ** is significant at the .05 confidence level; * is significant at the .1 confidence level.

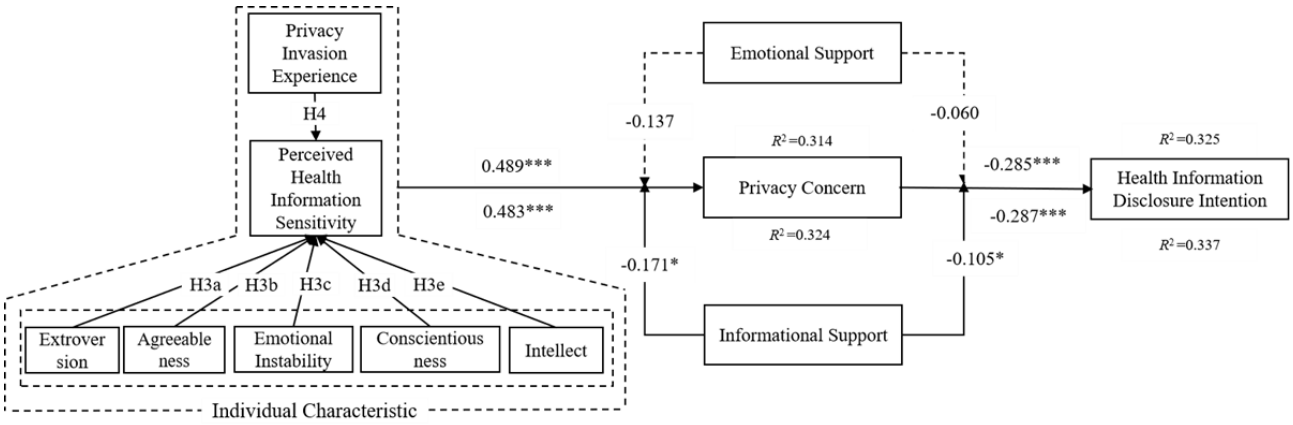


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Table 5. Summary of results.

Hypotheses	Content	Results
H1	Privacy concern has a negative impact on health information disclosure intention.	S[a]
H2	Higher perceived health information sensitivity is positively associated with privacy concern.	S
H3a	Extroversion has a negative impact on perceived health information sensitivity.	NS[b]
H3b	Agreeableness has a positive impact on perceived health information sensitivity.	S
H3c	Emotional instability has a positive impact on perceived health information sensitivity.	S
H3d	Conscientiousness has a positive impact on perceived health information sensitivity.	S
H3e	Intellect has a negative impact on perceived health information sensitivity.	NS
H4	Experience of privacy invasion is positively associated with perceived health information sensitivity.	S
H5m	Informational support has a negative moderation effect on the relationship between perceived health information sensitivity and privacy concern.	S
H5n	Emotional support has a negative moderation effect on the relationship between perceived health information sensitivity and privacy concern.	NS
H6m	Informational support has a negative moderation effect on privacy concern and online health information disclosure intentions.	S
H6n	Emotional support has a negative moderation effect on privacy concern and online health information disclosure intentions.	NS

[a]S: supported.

[b]NS: not supported.

Discussion

Principal Findings

This study empirically analyzes mHealth patients' intentions to disclose health information. Two interesting perspectives are studied: the effect of individual characteristics and the moderation effect of benefits and costs.

Effect of Individual Characteristics

Three relevant features (health information privacy sensitivity, personality traits, and prior privacy invasion experience) of individual characteristics are considered. Specifically, personality affects health information sensitivity in different ways. Hypotheses related to emotional instability are strongly supported, which indicates that those who are emotionally unstable tend to be nervous and frightened to disclose their medical information. Conscientious people are also likely to have higher medical information sensitivity. This may be because people with these personality traits have a higher level of risk awareness than others and tend to identify potential risks and possible negative results. In addition, previous privacy violation experiences enhance individuals' information sensitivity and increase the negative utility of privacy concerns. In other words, people who have experienced malicious violations of personal privacy (regardless of whether this is related to health information or other information) will be extremely cautious. These results are consistent with well-known studies in the information systems field, such as Junglas et al's [80] research in the context of location-based services, Sumner et al's [81] study of Facebook activity, and also Abdelhamid et al's [29] research on sharing personal health information.

One unexpected finding was that the personality factors we hypothesized would have a negative effect on perceived health information sensitivity (ie, extroversion and intellect) had no significant effect (beta path coefficient 0.152, P=.379 and –0.043, P=.686, respectively). Our results show that although extroverts are more open and prefer to disclose private information face-to-face, they are evidently less active in mHealth. Similarly, there is no significant effect between intellect and perceived health information sensitivity (beta path coefficient –0.043, P=.686). The finding that personality traits linked to different communication styles may have different effects is a remarkable result. It may be explained by the fact that if privacy is violated, online information can easily become widespread, which can easily have social consequences [82]. It is possible that for patients with personalities driven by intellect or extroversion, these risks make it especially difficult to reduce perceived health information sensitivity. Previous studies have yielded similar findings [83,84]. For instance, work by Bansal et al [73] indicates that a person with a high intellect trait has a strong sense of control when faced with a privacy crisis.

Interaction Effect of Social Support

Social support has been assumed to be an important factor in improving the acceptance of telemedicine, but this assumption needs more empirical testing [85]. To fill this research gap, our results prove that in mHealth, social support can be regarded as a disutility reducer. That is, on the one hand, it alleviates patients' privacy concerns; on the other hand, it also reduces the negative impact of privacy concerns on information disclosure intention.

Our empirical results indicate that informational support has a negative moderation effect on the relationship between privacy concern and health information disclosure intention, and it has a negative moderation effect on the relationship between health information sensitivity and privacy concerns. In other words, useful informational support encourages users to actively participate in sharing personal health information, reducing psychological and mental barriers to privacy concerns.

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On the contrary, online emotional support has no significant moderation effect on privacy concerns and health information disclosure intention (beta path coefficient –0.060, *P*=.373). In other words, users will not share their information even if they receive some emotional encouragement. The literature has already proven the important role of emotional support in disease recovery [86], and it is a motivator for using mHealth [87]. However, the benefits of emotional support are not enough for it to change users' health information sharing behaviors in mHealth. This may be explained by studies that show that people trust systems more than people [88]. In other words, it is considered safer to disclose shared health information to a system for informational support than to share the health information with other patients for emotional support.

Theoretical and Practical Implications

Several studies have found that privacy concerns (as disclosure cost) and social support (as the benefit) have a significant impact on information disclosure intention [28,89,90]. However, the interaction between costs and benefits has received little attention. This study set out to assess the importance of the interaction effect in the context of mHealth. This research addresses the following 2 areas: (1) The interaction effect between the cost (privacy concerns) and benefits (social support) on health information disclosure intention and (2) the role of emotional support, which has been assumed to play a critical role in mHealth [18]. Our findings challenge this assumption, as they show informational support to have a conducive effect on health information disclosure intention, while emotional support has no significant effect (beta path coefficient –0.060, *P*=.373). Emotional support is an important benefit of participating in mHealth, and its impact is even higher than that of informational support. However, its ability to change patient's willingness to disclose health information is limited, as it is relatively less significant than informational support (beta path coefficient –0.171, *P*=.092; –0.137, *P*=.146). Our results have important implications for mHealth providers, as they show that social support, especially informational support, is effective in prompting patients using mHealth to share their health information. However, emotional support has not been fully utilized, and its role in mHealth therefore needs more attention.

Limitations and Future Research Directions

There are several limitations to our study. First, according to the previous literature, there are several variables that may be related to patients' privacy concern, such as personality tendencies, current physical conditions, context of use (eg, different health status, locations, and times), and so on. However, we limited our variables to 3 that have been widely studied in the literature (ie, personality, experience of privacy invasion, and perception of sensitive health information) in order to focus on the moderation effects between privacy concern and social support. In future studies, more variables can be included in our model, which would result in broader insight into online health information disclosure.

Second, mHealth platforms in China have been specially designed to incorporate social support in such a way that it can be provided from both professional doctors' and patients' perspectives, which thus allows this paper to obtain a unique data set on social support. However, the literature has already shown that culture plays an important role in privacy calculus, especially in the way in which culture and individual characteristics combine to influence patients' perceptions and decisions [91]. Therefore, in future studies, testing this model within different cultures would illuminate how the results are influenced by cultural differences. It is also worth further studying whether the platform's social support function, which is specifically designed for the Chinese cultural context (in which government policies support doctors in providing online consultations and social support) can serve as a reference for the development of mHealth platforms worldwide.

Third, the mechanisms of online emotional support in an mHealth context should be studied. Our results indicate that while informational support plays a significant role in addressing privacy concerns, emotional support has less effectiveness. Emotional support can enhance engagement in online communities [59], but in the face of privacy concerns, this finding may be invalid because emotional support fails to establish trust on health information. Future studies may explore how trust affects emotional support and health information disclosure in mHealth.

Conclusion

In this paper, we used an SEM approach to study patients' health information disclosure intentions in an mHealth context. While most studies to date have considered disclosure costs and benefits independently, we simulated patients' online disclosure behaviors by examining the interactive effects of privacy concerns and social support. Individual characteristics were also included in our model to help us reach a further understanding of the combined effects. Our results offer several insights into the driving forces behind patients' disclosure intentions related to health information, and they demonstrate the usefulness and value of mHealth. Finally, this study may stimulate additional research to further enrich the understanding of health information disclosure in mHealth.

Acknowledgments

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Conflicts of Interest

None declared.

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Multimedia Appendix 1
Reliability and Validity.
[DOCX File , 37 KB - mhealth_v9i2e19594_app1.docx]

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Abbreviations

mHealth: mobile health
PCT: privacy calculus theory
PLS: partial least square path modeling
SEM: structural equation modeling

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Original Paper

Examining an Integrative Cognitive Model of Predicting Health App Use: Longitudinal Observational Study

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Abstract

Background: Specifying the determinants of using health apps has been an important research topic for health scholars as health apps have proliferated during the past decade. Socioeconomic status (SES) has been revealed as a significant determinant of using health apps, but the cognitive mechanisms underlying the relationship between SES and health app use are unknown.

Objective: This study aims to examine the cognitive mechanisms underlying the relationships between SES and use of health apps, applying the integrative model of behavioral prediction (IM). The model hypothesizes the indirect influences of SES on intentions to use health apps, which in turn predict actual use of health apps. The relationships between SES and intentions to use health apps were assumed to be mediated by proximal variables (attitudes, perceived behavioral control [PBC], injunctive norms, and descriptive norms).

Methods: We conducted path analyses using data from a two-wave opt-in panel survey of Korean adults who knew about health apps. The number of respondents was 605 at baseline and 440 at follow-up. We compared our model with two alternative theoretical models based on modified IM to further clarify the roles of determinants of health app use.

Results: Attitudes (β=.220, *P*<.001), PBC (β=.461, *P*<.001), and injunctive norms (β=.186, *P*<.001) were positively associated with intentions to use health apps, which, in turn, were positively related to actual use of health apps (β=.106, *P*=.03). Income was positively associated with intentions to use health apps, and this relationship was mediated by attitudes (B=0.012, 95% CI 0.001-0.023) and PBC (B=0.026, 95% CI 0.004-0.048). Education was positively associated with descriptive norms (β=.078, *P*=.03), but descriptive norms were not significantly related to intentions to use health apps. We also found that PBC interacted with attitudes (B=0.043, SE 0.022, *P*=.046) and jointly influenced intentions to use health apps, whereas the results did not support direct influences of education, income, and PBC on health app use.

Conclusions: We found that PBC over using health apps may be the most important factor in predicting health app use. This suggests the necessity of designing and promoting health apps in a user-friendly way. Our findings also imply that socioeconomic inequalities in using health apps may be reduced by increasing positive attitudes toward, and boosting PBC over, health app use among individuals with low income.

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KEYWORDS

mHealth; health apps; digital divide; integrative model of behavioral prediction; path analysis

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Introduction

Overview

Health-related apps (health apps) are software on mobile devices providing various health care services [1,2]. Health apps have been considered new communication technologies that may substantially affect public health [1]. As of 2019, it has been estimated that 54.2% of US adults have health apps [3]; use of health apps can promote prohealth behaviors such as healthy eating [4-6] and weight loss [7,8], though effectiveness of each app may vary [9]. To assess the public health impacts of health apps, scholars have explored predictors of health app use.

Several pioneering studies have reported that demographic factors, including education and income, which are widely used indicators of socioeconomic status (SES), are positively associated with use of health apps [10-13]. Furthermore, some studies examined the roles of SES and cognitive factors as potential determinants of health app use [11,14]. Nevertheless, they did not theorize how SES and cognitive factors are related to each other in predicting health app use. As a result, it is still largely unknown why people with higher SES are more apt to use health apps than those with lower SES.

To address this issue, we propose a comprehensive model of predicting health app use that utilizes the integrative model of behavioral prediction (IM). This theory has been frequently adopted by health researchers to explain the cognitive mechanisms underlying people's health-related behaviors (eg, safe sex, cancer screening, quitting smoking) [15,16]. We test our model with data from a two-wave panel survey of South Korean adults. Last but not least, to further investigate the relationships between determinants of behaviors in IM, we compare our model with other competing models based on modified IM.

Applying IM to the Context of Health App Use

IM succeeds the theory of reasoned action [17] and the theory of planned behavior [18]; all three theories posit that behavioral intention is the primary determinant of a behavior [15,16]. Then, IM theorizes the roles of two different types of variables in predicting behaviors: proximal and distal variables. Only proximal variables directly affect intentions; the influences of distal variables on intentions are mediated by proximal variables.

IM claims that intentions can be sufficiently explained with three proximal variables: (1) attitudes (overall favorableness) toward a behavior, (2) subjective norms regarding a behavior, consisting of injunctive norms (perceptions of what is approved or disapproved by close others) and descriptive norms (perceptions about prevalence of a behavior among close others) on a behavior, and (3) perceived behavioral control (PBC) over a behavior (self-evaluated capability in performing a behavior) [16]. Adopting this argument, we posit hypotheses as follows:

H1-H3: Attitudes toward (H1), subjective norms regarding (H2), and PBC over (H3) health app use will be positively associated with intentions to use health apps, which, in turn, will be associated with increased health app use.

However, resources available for those who attempt to change people's health-related behaviors are limited. Specifying the proximal variable that most strongly influences a target behavior is necessary to find the most efficient way of affecting it [16]. When it comes to health apps, app developers can devise better promotion strategies and improve the design of their apps more efficiently than they do without such knowledge. For instance, if app developers know that PBC is the strongest determinant of adopting and using health apps, and if the developers have a tight budget, they will want to focus on making apps easy to use. This would be the most cost-efficient way of developing the apps. Hence, we pose the following research question:

RQ1: Which proximal variable will most strongly predict intentions to use health apps?

Applying IM to Investigate Digital Divide in Using Health Apps

Next, IM categorizes all potential determinants of behaviors other than the proximal variables as distal variables. The relationships between distal variables and intentions are hypothesized to be fully mediated by the proximal variables [16]. Thus, SES is conceptualized as a distal variable in IM. Why, then, does this study concentrate on the relationship between SES and health app use?

Investigating whether and how SES relates to health app use is important in order to know how to reduce the *digital divide* in using the apps. The digital divide refers to inequalities in accessing and utilizing information and communication technologies (ICT) across different social groups [19-22]; this has been revealed as a substantial cause of health disparities [23-25]. Evidence has supported the digital divide in using health apps due to SES [10-13].

Given that cognitive approaches have contributed to understanding the diffusion of ICT [26,27], theorizing the cognitive mechanisms behind the digital divide in using health apps is important to find effective ways of diminishing it.

Nevertheless, former studies have not asked how SES is associated with cognitive factors in predicting health app use. For example, Chae (2018) juxtaposed education and income with cognitive factors in predicting health app use but did not theorize the relationship between SES and cognitive factors [11]; Mackert et al (2016) controlled for demographics when testing the potential connection between health information literacy (ie, cognitive capacity for processing health information) and use of health ICT including health apps [14]. In sum, we propose the following hypothesis:

H4: Individuals' SES (education and income) will be positively associated with intentions to use health apps through the mediation of proximal variables.

Moreover, in the following research question, we specify the proximal variable that most strongly mediates the influences of SES on behavioral intentions. This will show what will be the most efficient way of decreasing the gaps in use of health apps across people with different SES:

RQ2: Which proximal variable will most strongly mediate the effects of SES on intentions to use health apps?

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Revisiting the Roles of Distal Variables and PBC in IM

Though IM is considered well-established, there are three ongoing controversies regarding the roles of distal variables and PBC in the model [16]. This study will test those competing arguments in the context of health app use.

First, a handful of health studies have found evidence supporting significant *direct* influences of distal variables on behavioral intentions and actual behaviors [28-30]. Those findings confront two fundamental assumptions of IM: (1) indirect relationships between distal variables and intentions and (2) behavioral intention as the primary determinant of behavior. Given those prior findings, we revisit the role of distal variables in the context of health app use as follows:

RQ3: Will SES be directly associated with intentions to use health apps or actual use of health apps?

Next, the original IM argues that the influence of PBC on behaviors is fully mediated by intentions, and it has been consistently supported by evidence [16,31]. However, a few researchers have suggested that PBC may be directly related to behaviors, bypassing the mediation of intentions, to the extent that PBC may reflect actual control over behaviors [31]. Some health studies have reported evidence supporting this competing argument [32-35]. To examine these potential direct influences of PBC on behaviors in the context of health apps, we propose the following research question:

RQ4: Will PBC be directly associated with actual use of health apps?

Lastly, it has been proposed that PBC may moderate the attitudes-intentions and subjective norms–intentions relationships [31,36-38]. The logic of this hypothesis is that positive attitudes and subjective norms may not translate into a behavior when people do not feel that they have sufficient control over (not) conducting the behavior [31,38]. This issue has not been addressed in the context of health apps, and findings from health studies have been mixed. For instance, PBC significantly moderated only attitudes-intentions relationships in the context of prostate-specific antigen testing, whereas only norms-intentions relationships were significantly moderated by PBC in the context of performing regular exercise [37]. Given these mixed findings and the lack of studies addressing this issue in the health app context, we ask the following question:

RQ5: Will PBC moderate attitudes-intentions and subjective norms–intentions relationships in the context of health app use?

Methods

Survey Data

This study is a part of a larger health communication research project conducted in South Korea. A two-wave opt-in panel survey of Korean adults was collected by a survey company (Embrain). 1718 respondents participated in the baseline survey in February 2016 (completion rate=1718/2415=71.1%). 1304 of those respondents cooperated with a follow-up survey in April 2016 (attrition rate=414/1718=24.1%). The final sample size decreased to 605 at baseline and 440 at follow-up because we included only those who answered “yes” for the following filter question: “Do you know about health apps? Health app refers to health-related software installed on a smartphone or tablet PC to help users to manage their health behaviors.”

If we had provided a brief explanation about health apps, we could have measured proximal variables and intentions even among the respondents who did not know about the apps. However, measures based on very little knowledge have been considered “tentative”; those should be distinguished from “real” views based on good knowledge about the topic [39]. We adopted the filtered sample that allowed us to focus on those real views about health apps; this increased the validity of our measures and findings [39-41].

When it comes to demographic characteristics, the full (N=1718) and filtered (N=605) samples significantly differed only in years of education (full sample mean 14.97 years, 95% CI 14.86-15.08; filtered sample mean 15.30 years, 95% CI 15.13-15.47). The selected baseline (N=605) and follow-up (N=440) respondents were not significantly different with regard to demographic characteristics. For descriptive statistics, see Table 1.

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Table 1. Descriptive statistics of variables.

Characteristic	Baseline (n=605)	Follow-up (n=440)
Age (years), mean (SD)	39.00 (10.94)	40.42 (10.81)
Male sex, n (%)	292 (48.3)	210 (47.7)
Employment status (employed), n (%)	431 (71.2)	326 (74.1)
Marital status (married), n (%)	365 (60.3)	284 (64.5)
Years of education, mean (SD)	15.30 (2.14)	15.32 (2.22)
Monthly household income (US $)[a], mean (SD)	3910.59 (1627.45)	3920.45 (1600.84)
Body mass index	23.10 (3.15)	23.16 (3.02)
Perceived health status[b], mean (SD)	3.41 (0.75)	3.40 (0.75)
Other source use[c], mean (SD)	2.64 (0.50)	2.66 (0.50)
Attitudes[d], mean (SD)	5.01 (0.98)	—[e]
Injunctive norms[f], mean (SD)	2.69 (0.65)	—
Descriptive norms[g], mean (SD)	2.01 (0.70)	—
Perceived behavioral control[h], mean (SD)	3.41 (1.01)	—
Intentions to use health apps[i], mean (SD)	3.32 (1.07)	—
Types of health apps in use[j], mean (SD)	2.01 (1.25)	1.80 (1.57)
Frequency of health app use[k], mean (SD)	2.83 (2.47)	2.50 (2.54)
Health app use (composite measure)[l], mean (SD)	0.00 (1.56)	0.00 (1.65)

[a]Income was measured on an 8-point scale: 1=US $990 or lower to 8=US $7000 or higher. We averaged household income after recoding the response options into a ratio variable (eg, 2=US $1000 to $1990 was recoded as US $1500).

[b]1=very bad to 5=very good.

[c]Mean of seven items tapping use of health information sources other than health apps. 1=never, 4=frequently.

[d]Mean of two attitudes items. 1=very negative, 7=very positive.

[e]Not available.

[f]1=strongly disagree (low norms), 4=strongly agree (high norms).

[g]1=none of them (low norms), 4=everyone (high norms).

[h]1=no confidence, 5=completely confident.

[i]1=extremely low, 5=extremely high.

[j]Sum of 14 items of a certain type of health app use. 0=no (no use), 1=yes (use).

[k]0=never to 7=everyday.

[l]Sum of the standardized values of frequency of health app use and the number of types of health apps in use.

Measures

We created survey items capturing IM-related variables in the context of health apps, following the guidelines from Fishbein and Ajzen (2010) [16]. Moreover, we developed a composite measure of health app use following prior studies' measure creation procedures [42,43].

Distal Variables (Baseline)

We adopted education and income as proxies of SES. For education, we asked respondents their highest level of schooling completed (1=elementary school not completed to 8=doctorate). The response options were recoded into years usually required to finish a given type of education in the nation. Income was captured employing an 8-point scale (1=US $990 or lower to 8=US $7000 or higher) and then recoded using the midpoint of each option (eg, 2=US $1000 to $1990 was recoded as US $1500) [44-47].

Proximal Variables (Baseline)

To measure attitudes toward using health apps, we averaged participants' answers to the following two 7-point semantic differential scale items (r=0.81): "Using mobile health apps in the next two months would be…" (1=very bad to 7=very good; 1=very unenjoyable to 7=very enjoyable).

We measured injunctive norms by asking respondents about their agreement with the following sentence: "Most people important to me think I should use health apps in the next two months (1=strongly disagree to 4=strongly agree)." Descriptive norms regarding health app use were captured by asking for respondents' perceptions of how many people important to them had employed health apps in the past two months (1=none of

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them to 4=everyone). As the correlation between the two norms was only 0.28, they were treated as separate variables in the analyses.

PBC was measured by asking how sure respondents were that they could use health apps on most days in the next two months if they wanted to (1=very unsure to 5=very sure).

Intentions to Use Health Apps (Baseline)

To capture intentions to use health apps, we asked participants to report their likelihood of using health apps in the next two months (1=very unlikely to 5=very likely).

Health App Use (Baseline & Follow-up)

A composite scale of health app use was constructed by summing the standardized values of the two variables: the frequency of health app use and the number of types of health apps in use (r=0.21 at baseline and 0.37 at follow-up). Each reflects the depth and breadth of health app use. The frequency was captured by asking participants about how often they used any health app (0=not at all to 7=all 7 days a week). The other was measured with an additive index of 14 dichotomous items (0=no, 1=yes; the number of users at baseline in parentheses): (a) exercise & fitness (539); (b) healthy diet (145); (c) weight control (141); (d) blood pressure (66); (e) blood sugar (31); (f) menstruation (132); (g) pregnancy (17); (h) baby care (30); (i) medication (12); (j) health information & news (93); (k) mental health (35); (l) sleep (69); (m) quit smoking (20); and (n) beauty (28).

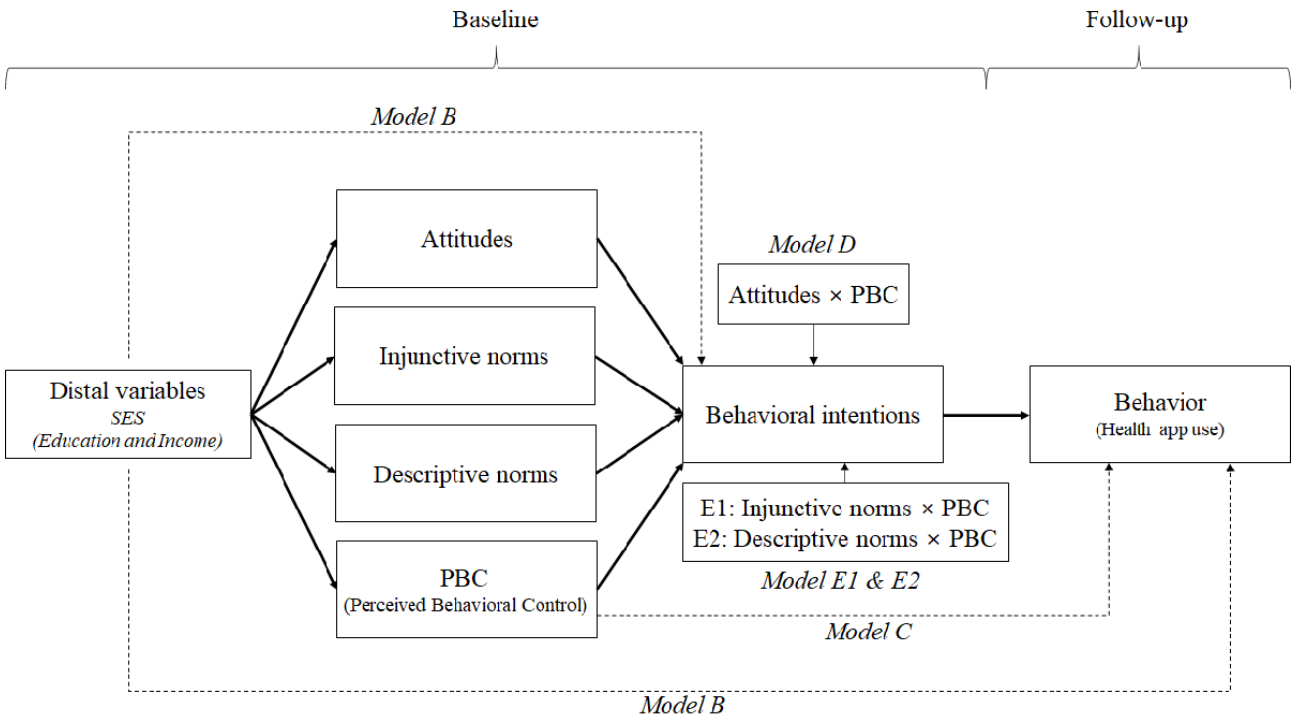
Control Variables (Baseline)

We measured demographic variables (age, sex, marital status, employment status, education, and monthly household income) and health-related variables (body mass index, perceived health status). Additionally, we captured use of health information sources other than health apps (hereafter, other source use) by averaging how often respondents obtained health information from the following seven sources (1=never to 4=frequently): printed media, TV, social media, health websites, general websites, friends, and health professionals.

Analysis Strategy

We performed path analyses via Mplus 8.3 (Muthén & Muthén). Throughout all analyses, we controlled for all potential confounders described above and health app use at baseline (ie, past behavior). To evaluate model fit, we used a root mean square error of approximation (RMSEA), a comparative fit index (CFI), and a standardized root mean square residual (SRMR): RMSEA≤0.05, CFI≥0.95, and SRMR≤0.08 indicated a well-fitting model [48]. We employed the maximum likelihood with robust standard errors (MLR) method to test direct and interaction effects and bootstrapping (5000 samples) to examine indirect effects. Indirect relationships were considered significant when the bias-corrected 95% CI of unstandardized coefficients did not contain 0 [48]. We adopted the full information maximum likelihood method to handle missing values (aka, FIML and Direct ML). Figure 1 is a graphical illustration of the analysis strategy.

Figure 1. Conceptual framework of the analytic procedure. Bolded solid lines represent paths included in the basic model (Model A). Dashed lines represent paths added to the basic model in each competing model. None of the additional paths were adopted in the final model (Model A). Thin solid lines represent interaction relations added to each of Models D, E1, and E2. SES: socioeconomic status.



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The Original IM-based Model

We began by fitting an original IM-based model (hereafter, Model A). In Model A, health app use at follow-up was directly predicted only by intentions at baseline; the associations between intentions and the distal variables (education and income) were fully mediated by proximal variables. We estimated direct and indirect path coefficients to test original IM-based hypotheses (H1 to H4); to compare the relative importance of proximal variables (RQ1 and RQ2), the differences between certain pairs of coefficients were examined with the χ^2 difference test. For bivariate correlations of variables in Model A, see Table 2.

Table 2. Bivariate correlations of variables in Model A (best-fitting model).

Variable	Education	Income	Attitudes	IN[a]	DN[b]	PBC[c]	Intentions	App use (B)[d]	App use (F)[e]
Education									
r	1.000	0.157	0.083	0.052	0.094	0.021	0.086	0.078	0.090
P value	__[f]	<.001	.04	.20	.02	.61	.03	.06	.06
Income									
r	0.157	1.000	0.151	0.087	0.078	0.137	0.097	0.122	0.097
P value	<.001	—	<.001	.03	.05	<.001	.02	.003	.04
Attitudes									
r	0.083	0.151	1.000	0.482	0.227	0.582	0.584	0.396	0.268
P value	.04	<.001	—	<.001	<.001	<.001	<.001	<.001	<.001
IN									
r	0.052	0.087	0.482	1.000	0.275	0.460	0.511	0.321	0.290
P value	.20	.03	<.001	—	<.001	<.001	<.001	<.001	<.001
DN									
r	0.094	0.078	0.227	0.275	1.000	0.208	0.224	0.184	0.137
P value	.02	.05	<.001	<.001	—	<.001	<.001	<.001	.004
PBC									
r	0.021	0.137	0.582	0.460	0.208	1.000	0.680	0.500	0.336
P value	.61	<.001	<.001	<.001	<.001	—	<.001	<.001	<.001
Intentions									
r	0.086	0.097	0.584	0.511	0.224	0.680	1.000	0.581	0.368
P value	.03	.02	<.001	<.001	<.001	<.001	—	<.001	<.001
App use (B)									
r	0.078	0.122	0.396	0.321	0.184	0.500	0.581	1.000	0.514
P value	.06	.003	<.001	<.001	<.001	<.001	<.001	—	<.001
App use (F)									
r	0.090	0.097	0.268	0.290	0.137	0.336	0.368	0.514	1.000
P value	.06	.04	<.001	<.001	.004	<.001	<.001	<.001	—

[a]IN: injunctive norms.
[b]DN: descriptive norms.
[c]PBC: perceived behavioral control.
[d]B: baseline.
[e]F: follow-up.
[f]Not applicable.

Model Comparisons

To address the theoretical controversies about IM, we first created Model B by modifying Model A to include direct links of distal variables (ie, education and income) with intentions and health app use. We compared Models A and B via the χ^2 difference test (RQ3). Notably, since we used χ^2 values from MLR estimations, the values were first adjusted using the scaling correction factors and then employed for the difference tests. The model fitting the data better was selected and then compared

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with Model C, constructed by allowing the selected model (Model A or B) to have a direct association between PBC and health app use (RQ4). The better-fitting model in the last comparison was chosen as the final model.

Moderating Roles of PBC

To assess the potential moderating roles of PBC (RQ5), we added three mean-centered interaction terms to the final model one at a time ("Attitudes × PBC," "Injunctive norms × PBC," and "Descriptive norms × PBC"; Models D, E1, and E2, respectively). We checked the significance of the interaction in each model.

Results

The Original IM-based Model

Model A fit the data well (Table 3). We found that intentions at baseline predicted health app use at follow-up (B=0.164, SE 0.075, β=.106, *P*=.03). The effects of attitudes (B=0.241, SE 0.039, β=.220, *P*<.001) (H1), injunctive norms (B=0.307, SE 0.063, β=.186, *P*<.001) (H2), and PBC (B=0.491, SE 0.046, β=.461, *P*<.001) (H3) on intentions were significant, whereas descriptive norms showed no significant association with intentions (B=0.041, SE 0.046, β=.027, *P*=.38) (H2). Accordingly, the indirect effects of attitudes (B=0.040, 95% CI 0.002-0.077) (H1), injunctive norms (B=0.050, 95% CI 0.001-0.102) (H2), and PBC (B=0.081, 95% CI 0.007-0.154) (H3) on follow-up health app use were significant, while the indirect effects of descriptive norms on health app use were not (B=0.007, 95% CI −0.010 to 0.023) (H2). PBC was more strongly related to intentions than were attitudes ($\chi^2_{diff,1}$=11.3, *P*<.001) and injunctive norms ($\chi^2_{diff,1}$=4.2, *P*=.04). However, the attitudes-intentions relationship was not significantly different from the injunctive norms–intentions relationship ($\chi^2_{diff,1}$=0.6, *P*=.43) (RQ1). In sum, H1 and H3 were supported and H2 was partially supported; PBC was revealed as the strongest proximal determinant of intentions to use health apps (RQ1).

Table 3. Measures of fit for six models.

Models[a]	Chi-square (*df*)[b]	RMSEA[c] (90% CI)	CFI[d]	SRMR[e]
Model A	69.2 (35)	0.040 (0.026-0.054)	0.975	0.027
Model B	63.1 (31)	0.041 (0.027-0.056)	0.976	0.025
Model C	67.7 (34)	0.040 (0.026-0.055)	0.975	0.026
Model D	74.7 (37)	0.041 (0.027-0.054)	0.988	0.027
Model E1	70.4 (37)	0.039 (0.024-0.052)	0.975	0.025
Model E2	70.3 (37)	0.039 (0.024-0.052)	0.975	0.025

[a]Model A: the original IM model; Model B: Model A with direct paths of distal variables on intentions and behavior; Model C: Model A with a direct path of perceived behavioral control (PBC) on behavior; Model D: Model A with an interaction term "Attitudes × PBC"; Model E1: Model A with an interaction term "Injunctive norms × PBC"; Model E2: Model A with an interaction term "Descriptive norms × PBC". Model A was the best-fitting model according to the step-by-step comparisons (step 1: Model A vs Model B; step 2: Model A vs Model C), therefore used for estimating coefficients. Model D, E1 and E2 are employed only for interaction tests.

[b]All χ^2 test results were significant (*P*<.001).

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

[d]CFI: comparative fit index.

[e]SRMR: standardized root mean square residual.

Education was positively associated with descriptive norms (B=0.026, SE 0.012, β=.078, *P*=.03), while income was positively related to attitudes (B=0.050, SE 0.022, β=.096, *P*=.02) and PBC (B=0.053, SE 0.022, β=.100, *P*=.02). The indirect associations between income and intentions through the mediation of attitudes (B=0.012, 95% CI 0.001-0.023) and PBC (B=0.026, 95% CI 0.004-0.048) were significant. However, the indirect relationships between education and intentions through the mediation of descriptive norms were not significant (B=0.001, 95% CI −0.002 to 0.004) (H4). There was no significant difference between the income-attitudes relationship and the income-PBC relationship ($\chi^2_{diff,1}$=0.0, *P*=.88) (RQ2). Overall, we found some evidence supporting H4; the importance of proximal variables in predicting intentions to use health apps was not statistically different.

Model Comparisons

Model A turned out to be the best-fitting model, although Models B and C also fit the data well (Table 3). In the first round of comparison (Model A vs Model B), we found that Model B did not explain the data significantly better than Model A ($\chi^2_{diff,4}$=6.1, *P*=.19). That is, direct effects of distal variables on health app use were not supported (RQ3). The winning model, Model A, was further compared with Model C. Still, Model C did not fit the data significantly better than Model A ($\chi^2_{diff,1}$=1.4, *P*=.24). In other words, there was no evidence for direct associations of PBC with health app use (RQ4).

Moderating Roles of PBC

All models (Models D, E1, and E2) fit the data well (Table 3). The interaction between attitudes and PBC (B=0.043, SE 0.022, *P*=.046) was significant, while neither injunctive norms (B=0.012, SE 0.036, *P*=.75) nor descriptive norms (B=−0.032,

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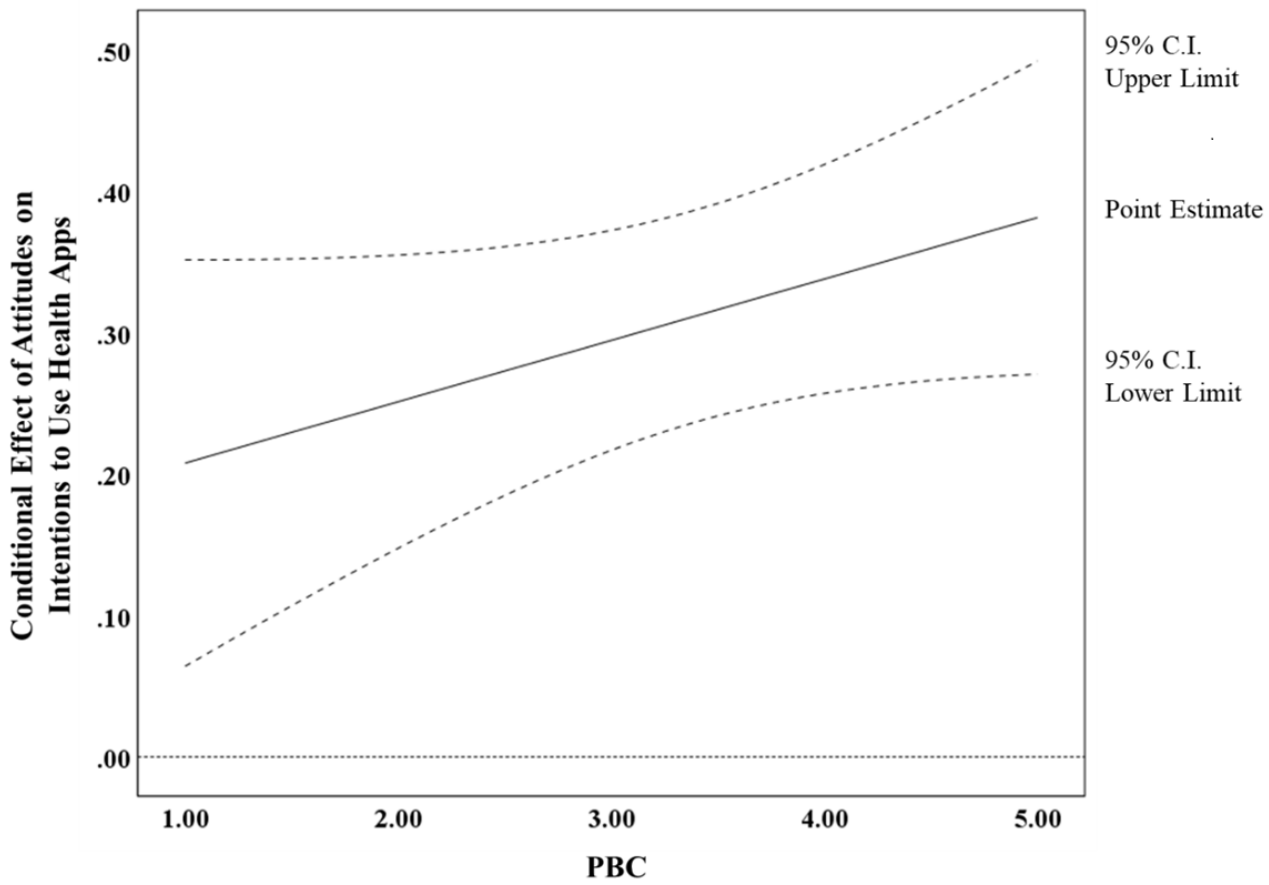
SE 0.047, *P*=.49) significantly interacted with PBC in predicting intentions. The results from the Johnson-Neyman technique [49] showed that the 95% CI of the conditional effect of attitudes on intentions was always above 0 (Figure 2). That is, at any range of PBC, the influence of attitudes on intentions was significantly larger for people with higher PBC than for those with lower PBC (RQ5).

Figure 2. Conditional effect of attitudes on intentions to use health apps as a function of perceived behavioral control from the Johnson-Neyman technique. The 95% CI of the conditional effect of attitudes on intentions to use health apps is always above 0, which means that the effect of attitudes is significantly positive for any value of PBC. PBC: perceived behavioral control.



Discussion

As expected, attitudes, PBC, and injunctive norms were associated with intentions, which, in turn, were related to health app use. In contrast, descriptive norms were not significantly related to intentions; thus, they did not affect health app use. PBC positively interacted with attitudes and jointly influenced intention. The association between income and intention was mediated by attitudes and PBC; education was associated with descriptive norms, but the indirect relationship between education and intention was not significant.

Several limitations of this study should be discussed. First, as our data do not represent the Korean adult population, the generalizability of our findings may be restricted. Second, we used single-item questions to measure norms and PBC; future studies should consider employing multiple-item measures. Third, we cannot eliminate the concern of reverse causality because distal and proximal variables and intentions were measured at baseline. Fourth, our health app use measure cannot distinguish people using one app frequently from those who use many apps, but less frequently. However, our measure may better capture the actual pattern of health app use than binary measures (ie, use or no use) adopted in prior studies [11-14,50]. Lastly, future studies may need to control for factors possibly related to both a distal variable and health app use, such as health literacy, which may correlate to SES and health app use.

The theoretical implications of the findings should be highlighted. First, PBC was most strongly associated with intentions. This finding is inconsistent with a well-known argument that subjective norms are the most powerful predictors of behavioral intentions in collectivist cultures, including Korean, while attitudes are key determinants of intentions in individualistic cultures [51]. The relatively low penetration rate of health apps in Korea may explain this discrepancy [52,53].

PBC positively moderated the effects of attitudes on intentions; this has been repeatedly reported in other contexts [36,37,54]. In contrast, the effects of subjective norms on intentions were not moderated by PBC. This finding is not consistent with the prior evidence from Western countries [36,37,54,55]. Perhaps, as subjective norms are more robustly related to behavioral intentions in collectivist cultures than they are in individualistic

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cultures [51], the relationship might be stable regardless of PBC among Koreans.

We detected significant indirect effects of income on intentions to use health apps. The positive indirect effects of income on intentions mediated by attitudes and PBC were consistent with the key propositions of the diffusion of innovation theory [21]. It argues that individuals with high SES are more likely to be early adopters of technological innovations than people with low SES are, because the former are (1) financially and intellectually more capable of employing new technologies (ie, higher PBC) and (b) more open-minded to use those technologies than are the latter (ie, higher positive attitudes).

The findings of this study also have the following practical implications: First, this study underscores the importance of PBC in designing and promoting health app use. We discovered that PBC was the strongest determinant of intentions to use health apps and moderated the influences of attitudes on intentions. To boost PBC, an app should be designed and promoted in a user-friendly way (eg, using plain and easy-to-read language; providing easy-to-follow guidelines) so that potential users will not experience difficulties in using the app. Second, this study suggests that, to reduce the digital divide in health app use, public health professionals should instill in low-income individuals beliefs about expected positive outcomes from, and confidence in, using health apps. This strategy would thereby form favorable attitudes toward and greater PBC over health app use. Health apps are frequently monetized; thus, they are designed to target people with high SES to maximize their developers' profits [56,57]; given our findings, this trend is particularly worrisome because it can maintain or even worsen inequalities in public health outcomes.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

CFI: comparative fit index
ICT: information and communication technology
IM: integrative model of behavioral prediction
MLR: maximum likelihood with robust standard errors
PBC: perceived behavioral control
RMSEA: root mean square error of approximation
SES: socioeconomic status
SRMR: standardized root mean square residual

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Original Paper

Digital Medicine Community Perspectives and Challenges: Survey Study

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Abstract

Background: The field of digital medicine has seen rapid growth over the past decade. With this unfettered growth, challenges surrounding interoperability have emerged as a critical barrier to translating digital medicine into practice. In order to understand how to mitigate challenges in digital medicine research and practice, this community must understand the landscape of digital medicine professionals, which digital medicine tools are being used and how, and user perspectives on current challenges in the field of digital medicine.

Objective: The primary objective of this study is to provide information to the digital medicine community that is working to establish frameworks and best practices for interoperability in digital medicine. We sought to learn about the background of digital medicine professionals and determine which sensors and file types are being used most commonly in digital medicine research. We also sought to understand perspectives on digital medicine interoperability.

Methods: We used a web-based survey to query a total of 56 digital medicine professionals from May 1, 2020, to July 10, 2020, on their educational and work experience, the sensors, file types, and toolkits they use professionally, and their perspectives on interoperability in digital medicine.

Results: We determined that the digital medicine community comes from diverse educational backgrounds and uses a variety of sensors and file types. Sensors measuring physical activity and the cardiovascular system are the most frequently used, and smartphones continue to be the dominant source of digital health information collection in the digital medicine community. We show that there is not a general consensus on file types in digital medicine, and data are currently handled in multiple ways. There is consensus that interoperability is a critical impediment in digital medicine, with 93% (52) of survey respondents in agreement. However, only 36% (20) of respondents currently use tools for interoperability in digital medicine. We identified three key interoperability needs to be met: integration with electronic health records, implementation of standard data schemas, and standard and verifiable methods for digital medicine research. We show that digital medicine professionals are eager to adopt new tools to solve interoperability problems, and we suggest tools to support digital medicine interoperability.

Conclusions: Understanding the digital medicine community, the sensors and file types they use, and their perspectives on interoperability will enable the development and implementation of solutions that fill critical interoperability gaps in digital medicine. The challenges to interoperability outlined by this study will drive the next steps in creating an interoperable digital medicine community. Establishing best practices to address these challenges and employing platforms for digital medicine interoperability will be essential to furthering the field of digital medicine.

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KEYWORDS

digital medicine; digital health; interoperability; mHealth; wearables; sensors

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Introduction

Digital medicine is defined as the use of technologies as tools for measurement and intervention in the service of human health [1]. Here we will focus on the use of mobile health (mHealth) and wearable sensors for digital medicine applications, which are growing rapidly in importance for health care applications, particularly during the COVID-19 pandemic. The field of digital medicine has seen rapid growth over the last decade [2]. This growth has resulted from a combination of health care costs and utilization at an all-time high [3] and the consistent improvements in mHealth and wearable technology that have resulted in their wide prevalence and accessibility [4-6].

While the field of digital medicine has seen rapid growth, many challenges remain: standards, best practices, and oversight methodology are still under development [7], sensors and devices used in digital medicine are constantly evolving and are often not validated [8], and a lack of interoperability results in a fragmented, inconvenient, and sometimes impossible adoption of digital medicine into medical practice [9-11]. In order to understand how to mitigate these challenges, it is critical to understand who is using and developing digital medicine tools, which tools are most utilized, and what common perspectives are on current challenges in the field.

Few data are available regarding the landscape of the digital medicine community and the challenges researchers in digital medicine are currently facing. In this study, we surveyed 56 digital medicine professionals to understand the topography of digital medicine, including the background and perspectives of digital medicine professionals, which sensors and file types are being utilized most commonly in digital medicine research, and perspectives on interoperability in digital medicine. The primary objective of this study is to provide information to the digital medicine community that is working to establish frameworks and best practices for interoperability in digital medicine.

Methods

An open, web-based survey was conducted from May 1, 2020, to July 10, 2020. The survey was conducted using Google Forms, and usability was tested internally prior to survey deployment. The survey consisted of 19 questions over 4 pages. The survey (Multimedia Appendix 1) was disseminated via monthly email newsletter and Slack to the Digital Medicine professional society (DiMe; approximate reach of 1250 digital medicine professionals), via email to 10 subject matter experts who disseminated the survey in their networks, and via social media (Multimedia Appendix 2). A total of 22 tweets and retweets were tweeted on Twitter, deploying the survey to networks totaling more than 1500 individuals. This survey protocol was approved by the Duke University Campus Institutional Review Board (#2020-0450). All participants provided consent and were provided the survey duration and purpose of the study prior to the survey. No personal information was collected or stored. There were no incentives offered to complete the survey. Survey completion after consent was 100%. All respondents (56 participants) were asked questions on background and perspectives on interoperability challenges. If participants checked that they were involved in digital medicine research, research and development (R&D), or both, we asked additional questions on sensors and file types they use (40 participants). Participants were able to review their survey answers prior to submission.

PubMed literature review was conducted on July 14, 2020, with keywords listed in Multimedia Appendix 3. Results were limited to the time span of 2010-2020.

Results

Who Makes Up the Field of Digital Medicine?

We found that our sample of the field of digital medicine is made up of people with diverse backgrounds (Figure 1). The most common educational backgrounds and current roles among the 56 survey respondents include data science/analytics/machine learning (18), business/entrepreneurship (17), and medicine (practitioners) (16). However, backgrounds were diverse and included nutrition, psychology, economics, design, marketing, and theatre. The sector breakdown for digital medicine professionals in this survey was industry (25, 45%), academia (17, 30%), medical institution (5, 9%), startup/freelance (4, 7%), government (3, 5%), and nonprofit (2, 4%) (Figure 1A). Just over half (52%, 29) of survey respondents hold a doctorate as their terminal degree, and 39% (22) hold a master's degree as their terminal degree (Figure 1B).

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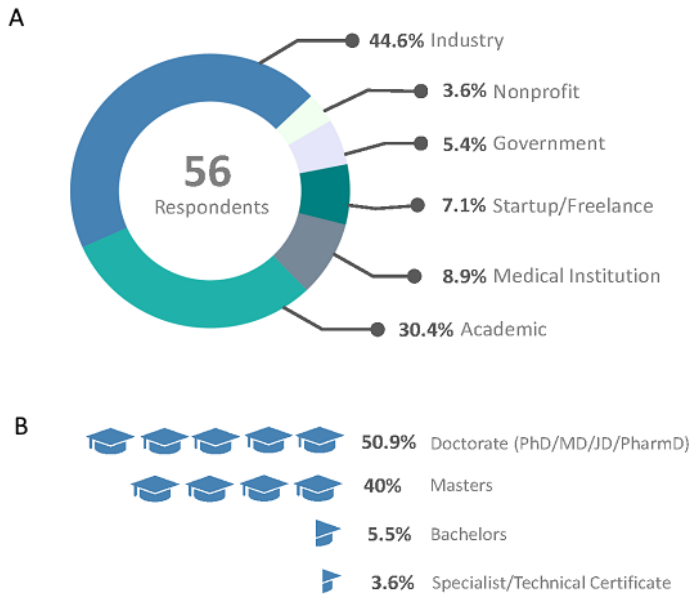
Figure 1. Characteristics of surveyed professionals in the field of digital medicine. (A) Sector breakdown. (B) Terminal degrees.



Which Sensors Do Digital Medicine Researchers Use?

Respondents who were active participants in digital medicine research and R&D at the time of the survey (n=40) answered with a wide variety of responses to the question "Which sensors and devices do you regularly work with?" A total of 153 sensors were reported to be used by these 40 researchers (mean 3.6, median 3 sensors or devices per respondent; Figure 2). Of these 153 sensors, 143 sensors were associated with a particular measurement modality: 39.2% (56) monitored the cardiovascular system, 35.7% (51) measured physical activity, 8.4% (12) measured physiological temperature, 4.9% (7) measured electrodermal activity, 4.9% (7) monitored behavior, adherence, or location, 4.2% (6) monitored brain activity, 2.1% (3) monitored respiration or oxygen consumption, and 0.7% (1) of sensors were reported as proprietary (Figure 2B). The top three reported devices or sensors used by survey respondents include smartphone (iPhone or Android) (8), Apple Watch (7), and Fitbit (7).

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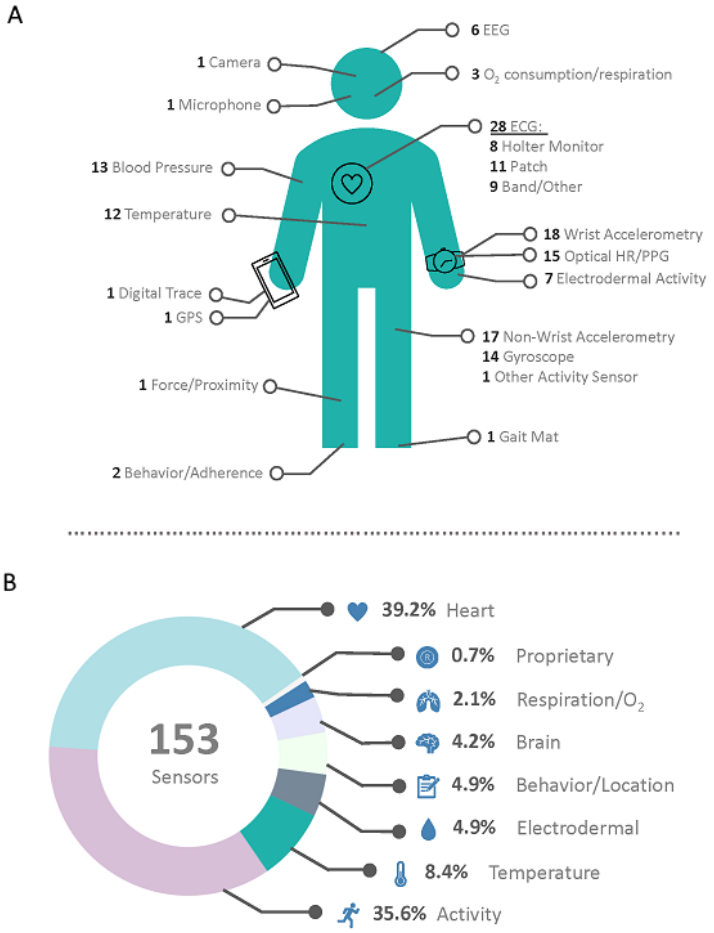
Figure 2. Sensors used by researchers in digital medicine. (A) Types of devices and sensors reported. (B) Measurement modalities of reported devices and sensors. ECG: electrocardiogram; EEG: electroencephalogram; HR: heart rate; PPG: photoplethysmogram.



The results of the survey are consistent with the literature: studies indexed in PubMed in the last decade include electrocardiogram (number of articles [n]=59,114), photoplethysmogram (n=2819), accelerometer (n=11,430), electrodermal activity (n=729), temperature sensor (n=11,980), gyroscope (n=1417), and pulse oximetry (n=7638). Smartphones (n=12,485) are also popular tools for medical research. Fitbit was found to be the most common smartwatch cited in PubMed-indexed research (n=624), followed by Garmin (n=141) and Apple Watch (n=136).

Which Data Formats Are Most Commonly Used in Digital Medicine Research?

The most commonly used data formats among survey respondents include comma-separated values (.csv), JavaScript Object Notation (JSON), and Microsoft XML spreadsheets (.xls/.xlsx) (Figure 3). The most popular file type for both raw files (data sourced directly from the device or company database) and processed files was .csv. While JSON was used more frequently in raw file types, .xls/.xlsx was more frequently the file type researchers reported to use for analysis (Figure 3). Interestingly, there was more diversity among raw file formats (n=114) than file types that researchers map to for analysis (n=79). For raw file formats, respondents listed a mean of 2.75 file types and a median of 2.5 file types. For analysis file formats, respondents listed a mean of 2 file types and median of 2 file types.

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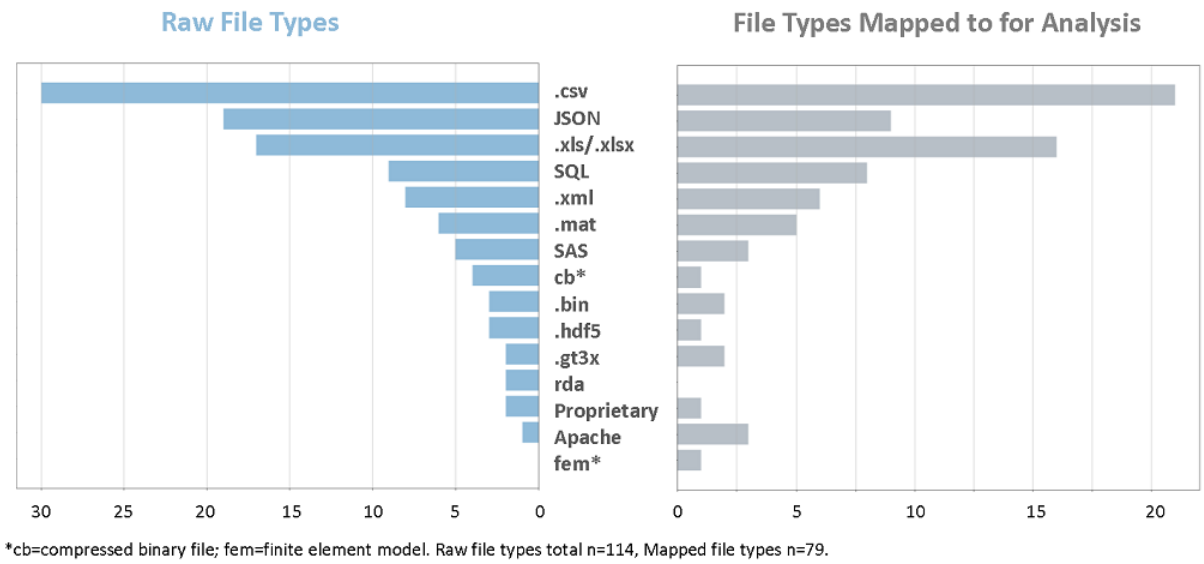
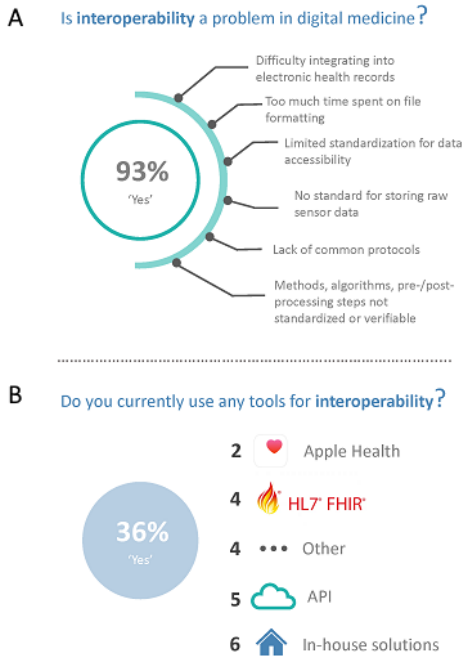
Figure 3. Data formats most commonly used in digital medicine research.



Interoperability in Digital Medicine

Of the 56 survey respondents, 93% (52) agreed that interoperability is a problem in digital medicine (Figure 4A). The most cited challenges in digital medicine interoperability include integration with electronic health records, lack of standard data schemas, and lack of standard and verifiable methods for digital medicine research.

Figure 4. Interoperability in digital medicine. (A) Challenges in digital medicine interoperability. (B) Tools used for interoperability. API: application programming interface; FHIR: Fast Healthcare Interoperability Resources; HL7: Health Level Seven.



While nearly all respondents (52, 93%) believe interoperability is a problem in digital medicine, only 36% (20) currently use tools for interoperability. Those tools for interoperability include Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR), Apple Health, general application programming interfaces (APIs), the Medisafe platform, Epic, Protege, and in-house solutions (Figure 4B).

When asked if they would utilize a platform for standardizing and validating digital medicine algorithms, methodologies, and analyses, 100% (53) of respondents said "Yes" (27, 51%) or "Maybe" (26, 49%). Reasons for use, as described by survey respondents, included that open science increases efficiency and improves reproducibility, work quality, and readability, and that such a platform would allow for direct comparisons of

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analytical results. Considerations for using this type of platform included understanding data security and potential risks.

When asked whether they would use a platform mapping raw data files to a standard format, 84% (47) of respondents said "Yes" (13, 23%) or "Maybe" (34, 61%). Considerations for using this platform included understanding compatibility with electronic health record systems, whether this platform would save time, and whether the resulting file types aligned with the desired file types for analysis.

Discussion

Overview

In a survey of 56 digital medicine professionals, we sought to better understand the digital medicine community. Key challenges in the field of digital medicine include the following: standards, best practices, and oversight methodology are still under development [7]; sensors and devices used in digital medicine are constantly evolving and are often not validated [8]; and a lack of interoperability discourages adoption of digital medicine into medical practice [9-11]. To understand how these challenges can be mitigated, we explored which sensors are most commonly used in digital medicine research, which file types are most commonly used by the digital medicine community, and perspectives in the field regarding challenges in interoperability.

Diversity of the Digital Medicine Community Sets Us Apart

We showed great diversity of backgrounds and current roles in the digital medicine community. We hope that this diversity will be encouraging to those looking to join the digital medicine community who may come from "nontraditional" backgrounds. The diversity of backgrounds in the digital medicine community is one of our most important assets for developing a common language, strong frameworks, and best practices. This diversity in thought and experience has resulted in a uniquely heterogeneous set of voices and perspectives contributing to community standards and best practices in research and application [1,7,12-14].

Digital Medicine Research Is Largely Multimodal

Of the 40 digital medicine researchers in the survey, they regularly work with a total of 153 sensors, indicating that many researchers are using a number of sensors in their research. These sensors are largely used to monitor the cardiovascular system (electrocardiogram, photoplethysmogram, blood pressure) and participant activity (accelerometry, gyroscope, gait map). Literature review of PubMed-indexed studies showed similar results: researchers are primarily employing sensors measuring physical activity and the cardiovascular system in their work. Many are also using temperature, electrodermal activity, or electroencephalogram sensors in their research. Overall, smartphones continue to be the dominant source of digital health information collection in the digital medicine community.

There Is Not a Consensus on File Types in Digital Medicine

In order to inform teams working to establish common data schemas and file types, we examined file types that are commonly used in digital medicine. There are 15 unique file types used by digital medicine researchers, either as raw files or as file types mapped to for analysis. While the .csv file type is the most commonly used, there are other commonly used file types, including JSON and .xls/.xlsx. There was more diversity among raw file formats (n=114) than file types researchers map data to for analysis (n=79), and respondents are averaging 2.75 raw file types versus a mean of 2 file types for analysis, indicating that while researchers may receive raw data in a number of file formats, they are mapping them to a smaller subset of file types for analysis. We show that there is not a general consensus on file types in digital medicine and data is currently handled in multiple ways (both as raw files and as files mapped for analysis). Noteworthy is the low number of proprietary file types, indicating that the digital medicine community is largely using accessible file types that could be mapped to a standard, interoperable format.

Interoperability Remains a Critical Challenge in Digital Medicine

Nearly all digital medicine professionals surveyed (52/56, 93%) agree that interoperability is a problem in digital medicine. Literature points to this lack of interoperability being a critical barrier to using digital medicine in clinical practice, causing fragmented, inconvenient, and sometimes impossible clinical adoption of digital medicine [9-11]. While many specific challenges to digital medicine interoperability were revealed in this study, the most cited challenges include integration with electronic health records, lack of standard data schemas, and a lack of standard and verifiable methods for digital medicine research. These three areas should be the focus of future directions in developing standards, frameworks, and best practices for interoperability in digital medicine.

Despite agreeing that interoperability is a problem facing the digital medicine community, only 36% (20) of respondents currently use existing tools for interoperability. Generally employed tools used in the community include HL7 FHIR, Apple Health, unspecified APIs, and in-house solutions. A large proportion of those declaring that they use interoperability tools use in-house solutions, which addresses a key problem in the current field of digital medicine—siloed solutions that are not generalizable and are adopted by only a small number of digital medicine professionals.

One of the critical interoperability needs identified is the development of standard data schemas. When asked whether they would use a platform mapping raw data files to a standard format, respondents identified considerations that would have to be made to use this platform: they would need to understand compatibility with electronic health record systems and whether this platform would save time. The most cited consideration for using a platform mapping raw data files is the standard format that data would be mapped to. We identified that there is a strong preference for .csv and .xls/.xlsx filetypes for data analysis among respondents. When developing standard data schemas

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for the field of digital medicine, it is important to consider the most commonly used file formats and how standard formats could map from and between these popular file formats. Open mHealth, currently the leading mobile health data interoperability standard, maps data to a common JSON data structure [15].

Other critical interoperability needs included standard and verifiable methods for digital medicine research, including preprocessing and postprocessing, algorithms, models, and analyses. When asked if they would use a platform for standardizing and validating digital medicine algorithms, methodologies, and analyses, respondents identified considerations for using this platform, which include understanding data security, potential risks, and extensibility. MD2K Cerebral Cortex provides a complete software platform that allows for data collection and analysis with interactive web dashboards [16]. Recently, we identified a need for an open-source, crowdsourced software platform where digital medicine researchers could share and compare methods, algorithms, and processing methods. To address this need, we have developed the Digital Biomarker Discovery Pipeline (DBDP) [3]. Future directions for the digital medicine community include addressing and implementing solutions to the critical interoperability needs in digital medicine: integration with electronic health records, standard data schemas, and standard and verifiable methods for digital medicine research.

This study was limited in the small sample size and the short time frame of the survey; thus, extending this work will be necessary to further understanding of the challenges facing the digital medicine community as research in mHealth and wearables expands.

In conclusion, understanding the digital medicine community, the sensors and file types commonly used, and perspectives on interoperability will enable the development and implementation of solutions to the critical interoperability needs in digital medicine. As the digital medicine community builds tools, platforms, and resources for mobile health and wearable sensor data, this study can be leveraged to meet real needs and address existing technology gaps. The challenges to interoperability outlined by this study will drive the next steps in creating an interoperable digital medicine community. Establishing best practices to address these challenges and employing platforms for digital medicine interoperability will be essential to furthering the field of digital medicine.

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Authors' Contributions

BB was involved in concept development, survey development and deployment, analysis, manuscript preparation, and figure development. JPD was involved in concept development, survey deployment, and manuscript preparation. IS was involved with manuscript editing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Web-based survey.
[PDF File (Adobe PDF File), 466 KB - mhealth_v9i2e24570_app1.pdf]

Multimedia Appendix 2
Recruitment blurb for distribution of survey via email, Slack, and social media.
[PDF File (Adobe PDF File), 75 KB - mhealth_v9i2e24570_app2.pdf]

Multimedia Appendix 3
PubMed literature review was conducted on July 14, 2020, with the following keywords. Results were limited to the time span 2010-2020 to account for newer technologies.
[DOCX File , 14 KB - mhealth_v9i2e24570_app3.docx]

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Abbreviations

API: application programming interface
.csv: comma-separated values
DiMe: Digital Medicine professional society
FHIR: Fast Healthcare Interoperability Resources
HL7: Health Level Seven
JSON: JavaScript Object Notation
mHealth: mobile health
R&D: research and development
.xls/.xlsx: Microsoft XML spreadsheets

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Original Paper

Implementation of Online Hospitals and Factors Influencing the Adoption of Mobile Medical Services in China: Cross-Sectional Survey Study

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Abstract

Background: Online hospitals are part of an innovative model that allows China to explore telemedicine services based on national conditions with large populations, uneven distribution of medical resources, and lack of quality medical resources, especially among residents needing to be protected from COVID-19 infection.

Objective: In this study, we built a hypothesis model based on the Unified Theory of Acceptance and Use of Technology (UTAUT) in order to analyze the factors that may influence patients' willingness to use mobile medical services. This research was designed to assist in the development of mobile medical services. Residents who do not live in urban areas and cannot access medical assistance would greatly benefit from this research, as they could immediately go to the online hospital when needed.

Methods: A cross-sectional study based at the West China Hospital, Sichuan University, was conducted in July 2020. A total of 407 respondents, 18 to 59 years old, in Western China were recruited by convenience sampling. We also conducted an empirical test for the hypothesis model and applied structural equation modeling to estimate the significance of path coefficients so that we could better understand the influencing factors.

Results: Out of 407 respondents, 95 (23.3%) were aware of online hospitals, while 312 (76.7%) indicated that they have never heard of online hospitals before. Gender (P=.048) and education level (P=.04) affected people's willingness to use online hospitals, and both of these factors promoted the use of online hospitals (odds ratio [OR] 2.844, 95% CI 1.010-8.003, and OR 2.187, 95% CI 1.031-4.636, respectively). According to structural equation modeling, the results of the path coefficient analysis indicated that performance expectancy, effort expectancy, and facilitating conditions have positive effects on patients' willingness to use online hospitals.

Conclusions: The goal of our research was to determine the factors that influence patients' awareness and willingness to use online hospitals. Currently, the public's awareness and usage of online hospitals is low. In fact, effort expectancy was the most important factor that influenced the use of online hospitals; being female and having a high education also played positive roles toward the use of mobile medical services.

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KEYWORDS

COVID-19; online hospital; mobile medical service; Unified Theory of Acceptance and Use of Technology; UTAUT

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Introduction

Background

With the advent of the *internet plus* era, information technology (IT) has brought great convenience to people's production and lives. At the same time, it has provided new ideas for medical service reform, and remote, mobile medical services have emerged [1]. As the largest developing country, China has a large population, an aging population, uneven distribution of medical resources, and lack of high-quality medical resources. Faced with increasing demand for medical and health services, around the year 2000, the Chinese government actively explored the application of internet IT to carry out innovative diagnoses and treatments based on the conditions seen nationwide. In this context, online hospitals have appeared, along with the emergence and spread of COVID-19, and were vigorously promoted to divert patients from hospitals and to reduce the risk of cross-infection in hospitals. The operation of online hospitals relies on offline physical medical institutions to provide patients with online follow-up services for common and chronic diseases through devices connected to the internet. Patients use mobile terminals to communicate with doctors online in the form of pictures, texts, voice messages, or videos [2]. Studies have shown that mobile medical services need to consider the public's acceptance of these services; more attention should be paid to public awareness and experience during the adoption process in order to increase willingness to adopt services and increase utilization of services by users [3]. For one thing, online hospitals in China have just started to be implemented; as a result, some patients have little understanding of online hospitals. In addition, because of their traditional medical thinking, some patients have misunderstandings that lead them to believe that online hospitals are not reliable. Whether mobile medical services can be popularized and applied has become the focus of current research [4,5]. In order to explore patients' willingness to use mobile medical services and their influencing factors, this study examines Chinese patients' perspectives of online hospitals and builds a model of their willingness to use these services, based on the Unified Theory of Acceptance and Use of Technology. In this study, we discuss patients' willingness to use mobile medical services of online hospitals and their influencing factors in order to provide strong evidence for the study of patients' acceptance behavior of mobile medical services; in addition, using mobile medical methods to provide online diagnoses and treatment services for common and chronic diseases can be a reference point and offer suggestions for the global response to the COVID-19 outbreak.

Literature Review and Hypotheses Development

In the field of IT, users' technology adoption behavior has always attracted much attention. There are many models and theories that can be used to study user behavior, such as the technology acceptance model, the rational behavior theory, the planned behavior theory, and the UTAUT. The UTAUT is a self-rational action theory based on the technology acceptance model by Venkatesh and Davis and others [6,7]. This model is based on four structures: performance expectation, effort expectation, social influence, and convenience to explain the intention and behavior of individuals using technology [7]. Existing literature studies have shown that the UTAUT model provides better and more complete explanations about users' technology adoption behavior than other technology acceptance models. This model not only promotes previous research results but it retains their simple structure. Therefore, it currently has the best predictive ability [8,9]. This model has been widely used in different fields of medical care. Research has confirmed that the UTAUT model is also acceptable in the field of health care mobile technology [10]. Phichitchaisopa and Naenna found that factors such as effort expectation, performance expectation, and facilitating conditions have a significant impact on the adoption of mobile health [11]. Cimperman et al used the UTAUT model to study mobile health factors in the elderly. They also found that performance expectation, effort expectation, social influence, technical anxiety, and other factors had a significant impact on users' behavioral intentions [12]. Most of the relevant research in the field of mobile health, by both domestic and foreign scholars, focuses on product functions and use effects of mobile medical equipment and mobile health apps [13,14]; however, we have found no research on the willingness to use mobile online medical services. Moreover, mobile medical services of online hospitals are different from other mobile health care support applications. In their initial stage of promotion and operation, we should pay attention to the public's expectations of, and willingness to use, these services [15,16]. Through the extension and application of the UTAUT model, we aim to determine the factors influencing willingness to use these services and the relationship between them; our research will fill this gap in the field of mobile medicine.

Hypothetical Model Construction

Due to the special attributes of telemedicine, there will be some risk factors in the use process; for example, the mobile medical platform uploads patient information to the information system, patients and doctors need to communicate in a virtual environment, etc. The way these risks are perceived by the patient will affect their willingness to use the mobile medical platform [17]. Based on this and on the information system selected to adopt the UTAUT model, the *perceived risk* variable was added, which was used to analyze the patients' perception of the risk of diagnosis and treatment via the internet. Finally, the hypothesis regarding patients' willingness to accept medical treatment from online hospitals was formed. This study is based on the scales that have been researched and applied by scholars, both domestic and foreign, combined with the participation by online hospital patients. Through induction and summary, we have defined the model variables; the measurement items and model construction of each research variable in the model have also been proposed, as seen in Table 1 [18-27].

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Table 1. Construct definitions and model assumptions.

Model variable	Definition	Model assumptions	References
Performance expectancy	Refers to the patients' judgment of the benefit of mobile medical services	Performance expectancy has a positive impact on the patients' willingness to use online hospitals	Venkatesh et al [18] Hoque and Sorwar [19] Hoque et al [20]
Effort expectancy	Refers to the patients' judgment of the ease of acceptance and use of mobile medical services	Effort expectancy has a positive impact on the patients' willingness to use online hospitals	Xue et al [21] Alalwan et al [22] Shareef et al [23]
Social influence	Refers to the external influence that patients perceive when using the online hospital app	Social influence has a positive impact on the patients' willingness to use online hospitals	Nguyen et al [24] Hoque and Sorwar [19]
Perceived risk	Refers to the patients' perception of possible adverse consequences through online hospital visits	Perceived risk has a negative impact on the patients' willingness to use online hospitals	Kim and Park [25] Hsieh [26]
Facilitating conditions	Refers to whether the existing online hospital platform, technology, service-supporting measures, and personal equipment are sufficient to support mobile medical services	Facilitating conditions have a positive impact on the patients' willingness to use online hospitals	Cilliers et al [27]

Methods

Participants

The average number of daily outpatients at the West China Hospital, Sichuan University, is about 16,000. Based on the fact that crowd gathering should be avoided during the COVID-19 pandemic, and considering the low awareness and utilization rates of online hospitals, the research team used convenience sampling to recruit survey subjects. Recruitment began on July 4, 2020, when questionnaires were distributed by specially trained investigators at the nurse stations of the West China Hospital, Sichuan University. The target group participants filled out the paper questionnaire on a voluntary basis or filled out the electronic questionnaire by scanning the code on their mobile phones. The questionnaires were answered anonymously and were collected on the spot. Inclusion criteria for participants included the following: (1) were between 18 and 59 years old; (2) were able to fill out the questionnaire independently, with clear consciousness and no obvious cognitive impairment; and (3) volunteered to participate in this study. Exclusion criteria included the following: (1) had a mental disorder and could not communicate normally and (2) refused to participate in this investigation.

Design and Material

This is a cross-sectional study investigating patients' willingness to use an online hospital platform. The research setting was a large general hospital in Western China. Internet diagnosis and treatment services involved in this study are closely related to internet use. A previous survey about online hospital participation by the elderly administered by our team found that most elderly people were not proficient in using mobile phone apps and had some difficulties operating mobile phones; the children of most of these participants helped them operate mobile phones and use the apps Therefore, this survey was mainly aimed at a sample of young and middle-aged participants.

Procedure

Using the questionnaire survey method, the researchers designed their own questionnaires under the guidance of experts based on the UTAUT model, combined with the characteristics of online hospital operations. To ensure the validity of the questionnaire content, all measurement items were modified based on relevant domestic and foreign documents; see Multimedia Appendix 1 for details. The questionnaire used a 5-point Likert scale, ranging from 1 (completely disagree) to 5 (completely agree); the respondents chose the options that best suited their actual situations. Before the formal issuance of the questionnaire, the researchers conducted a presurvey; they selected 20 patients for the presurvey, modified the items in the questionnaire that were difficult to understand, and generated ambiguity. Finally, 31 of the most representative items of the questionnaire were selected. The data were collected from completed questionnaires and sorted using EpiData, version 3.1 (EpiData Association); the questionnaire data were statistically analyzed using SPSS Statistics for Macintosh, version 24.0 (IBM Corp), and SPSS Amos, version 24.0 (IBM Corp). The statistical methods were verified by descriptive analysis, reliability and validity tests, analysis of variance, and structural equation modeling, as needed.

Results

General Statistical Description

In this study, a total of 412 questionnaires were collected, of which 407 were valid, with an effective rate of 98.8%. The ratio of men to women in the survey was 1:1.19, including 319 young people out of 407 participants (78.4%) and 88 middle-aged people (21.6%). Among the survey respondents, 23.3% (95/407) knew about online hospitals, while 76.7% (312/407) said they did not know about, or had not heard of, online hospitals. A total of 95.3% (388/407) of the respondents expressed their support for, and had acceptable attitudes toward, the internet diagnosis and treatment model after being introduced to it by the researchers; see Table 2 for details.

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Table 2. Participants characteristics.

Characteristic	Value (N=407), n (%)
Gender	
Male	186 (45.7)
Female	221 (54.3)
Age (years)	
18-44	319 (78.4)
45-59	88 (21.6)
Education level	
Less than high school	16 (3.9)
High school graduate	98 (24.1)
Bachelor's degree	193 (47.4)
Master's or doctoral degree	100 (24.6)
Professional background	
Official	131 (32.2)
Company employee	137 (33.7)
Migrant worker	10 (2.5)
Farmer	7 (1.7)
Other	122 (30.0)
Monthly income (RMB; US $1=RMB 6.4790)	
0-2000	40 (9.8)
2001-5000	114 (28.0)
5001-8000	127 (31.2)
8001-10,000	68 (16.7)
>10,000	58 (14.3)

Reliability and Validity Test

This study used Cronbach α to measure the reliability of the questionnaire. The lowest value of Cronbach α for this questionnaire was .764 and the highest value was .900, indicating that the measurement scale had good reliability. In order to test the discriminant validity of variables in the model, we used SPSS Amos, version 24.0, to conduct confirmatory factor analysis on performance expectation, effort expectation, social impact, perceived risk, contributing factors, and willingness to use the platform. The indicators were as follows: adjusted goodness-of-fit index (AGFI)=0.858, goodness-of-fit index (GFI)=0.893, comparative fit index (CFI)=0.935, root mean square error of approximation (RMSEA)=0.063, composite reliability (CR)>0.7, and average variance extracted (AVE)>0.5. It can be seen that the goodness of fit of the model was good; that is, the variables had good discriminant validity (see Tables 3 and 4).

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Table 3. Results of the questionnaire reliability analysis.

Dimension and item number	Correlation matrix between items				Corrected item's total correlation	Cronbach α if item deleted	Cronbach α of the dimension
Performance expectancy (PE)							.784
PE.1	1				0.538	.895	N/A[a]
PE.2	0.715	1			0.647	.893	N/A
PE.3	0.413	0.448	1		0.452	.898	N/A
PE.4	0.403	0.489	0.614	1	0.598	.894	N/A
Effort expectancy (EE)							.764
EE.1	1				0.690	.891	N/A
EE.2	0.576	1			0.673	.892	N/A
Social influence (SI)							.802
SI.1	1				0.550	.895	N/A
SI.2	0.629	1			0.572	.894	N/A
SI.3	0.566	0.660	1		0.502	.896	N/A
SI.4	0.415	0.429	0.382	1	0.699	.891	N/A
Facilitating conditions (FC)							.875
FC.1	1				0.701	.891	N/A
FC.2	0.638	1			0.663	.892	N/A
FC.3	0.581	0.659	1		0.651	.893	N/A
FC.4	0.630	0.586	0.727	1	0.675	.892	N/A
Perceived risk (PR)							.841
PR.1	1				0.234	.903	N/A
PR.2	0.600	1			0.225	.904	N/A
PR.3	0.525	0.633	1		0.227	.904	N/A
PR.4	0.473	0.558	0.646	1	0.140	.909	N/A
Behavioral intention (BI)							.879
BI.1	1				0.666	.892	N/A
BI.2	0.662	1			0.631	.893	N/A
BI.3	0.629	0.734	1		0.625	.893	N/A
Total scale							.900

[a]N/A: not applicable; Cronbach α in this column was calculated for each dimension, not for each item.

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Table 4. Results of the questionnaire validity analysis.

Dimension and item number	Standardized factor load	Composite reliability	Average variance extracted[a]
Performance expectancy (PE)			0.693
PE.1	0.684	0.899	N/A[b]
PE.2	0.832		N/A
PE.3	0.933		N/A
PE.4	0.862		N/A
Effort expectancy (EE)			0.522
EE.1	0.625	0.710	N/A
EE.2	0.695		N/A
Social influence (SI)			0.681
SI.1	0.868	0.864	N/A
SI.2	0.845		N/A
SI.3	0.758		N/A
Perceived risk (PR)			0.550
PR.1	0.867	0.826	N/A
PR.2	0.804		N/A
PR.3	0.541		N/A
PR.4	0.714		N/A
Facilitating conditions (FC)			0.617
FC.1	0.780	0.828	N/A
FC.2	0.695		N/A
FC.3	0.872		N/A
Behavioral intention (BI)			0.567
BI.1	0.568	0.793	N/A
BI.2	0.829		N/A
BI.3	0.831		N/A

[a]The fitting indices were as follows: χ^2/df=2.1, adjusted goodness-of-fit index (AGFI)=0.858, goodness-of-fit index (GFI)=0.893, comparative fit index (CFI)=0.935, and root mean square error of approximation (RMSEA)=0.063.

[b]N/A: not applicable; average variance extracted was calculated for each dimension, not for each item.

Structural Equation Model Verification

Structural equation modeling is a statistical method used to analyze the relationship between variables. According to the degree of consistency between the theoretical model and the actual data, the theoretical model is evaluated to achieve the goals of quantitative research on actual problems. This method overcomes the shortcomings of SPSS software's widely used multiple regression analysis method. It not only explains the relationship between variables but also allows the existence of measurement error of the variables. It can realize the estimation of factor structure and relationship as well as the simultaneous estimation of the degree of model fitting. In this study, the structural equation model analysis software SPSS Amos, version 24.0, was used to draw the structural equation model analysis diagram (see Figure 1); the model verification of the parameters of the initial hypothetical model was carried out to analyze the relationship between the variables and their influence mechanisms (see Table 5). From the significance of the model path coefficient, it can be seen that Hypothesis 1, Hypothesis 2, and Hypothesis 5 are valid, while the assumptions of Hypothesis 3 and Hypothesis 4 are not valid. That is to say, performance expectation, effort expectation, and contributing factors have significant effects on patients' willingness to use mobile medical services. However, social influence and perceived risk do not have significant effects on patients' willingness to use mobile medical services. In order to ensure the rigor of the model's logic, the two insignificant paths mentioned above were deleted, the revised model was obtained, and the SPSS Amos, version 24.0, program was run again to verify each parameter. The corrected significance level of each path coefficient was less than 0.001, and the model-fitting indexes were as follows: χ^2/df=3.5, CFI=0.899, AGFI=0.900, and RMSEA=0.092. These values indicate that the revised model fit was acceptable.

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According to the estimation result of the model path coefficient and the analysis result of the adjustment effect, we finally determined the following: performance expectation, effort expectation, and contributing factors are the three main factors influencing patients' use of online hospitals and they play a positive role.

Figure 1. Results of the structural equation model analysis. Note, e1 to e31 are residuals, which are not explained in the hypothesis equation. The number on each arrow indicates the factor load of the latent variable on the observed variable: the larger the factor load, the better. If the value is greater than .40 and less than 1, the contribution is qualified.

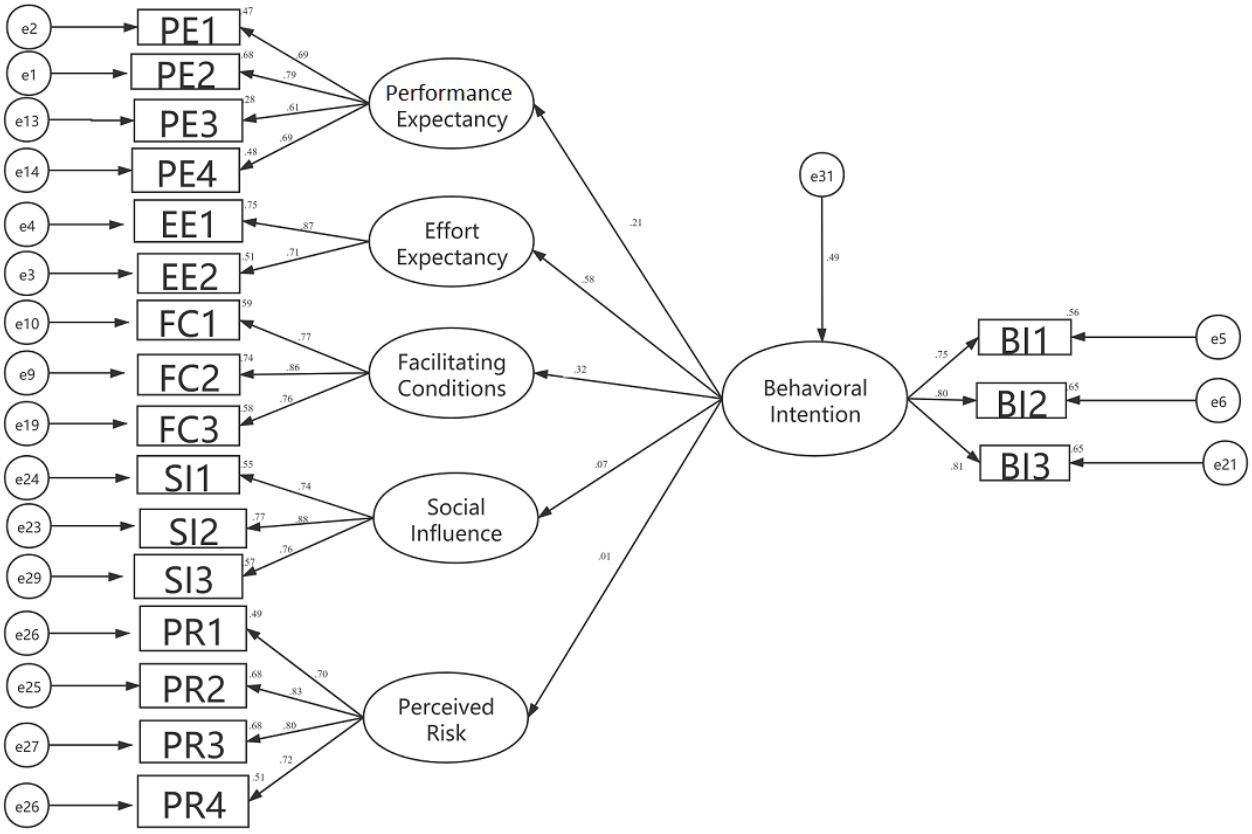

Table 5. Verification of the path coefficients of the initial hypothesis model.

Hypothesis (H)	Path	Estimate	SE	Composite reliability	*P* value	Results
H1	PE[a]→BI[b]	0.21	0.063	2.587	.01	Established
H2	EE[c]→BI	0.58	0.076	6.290	<.001	Established
H3	SI[d]→BI	0.07	0.045	1.217	.22	Not established
H4	PR[e]→BI	0.01	0.031	0.286	.78	Not established
H5	FC[f]→BI	0.32	0.055	4.414	<.001	Established

[a]PE: performance expectancy.
[b]BI: behavioral intention.
[c]EE: effort expectancy.
[d]SI: social influence.
[e]PR: perceived risk.
[f]FC: facilitating conditions.

The Relationship Between Different Demographic Characteristics and Willingness to Use Online Hospitals

Structural equation modeling and hypothesis tests were applied in this research. A *P* value less than .05 is considered statistically significant. To measure the relationship between gender, age, education level, income, and willingness to use online hospitals, we conducted a separate test by establishing a logistic regression model, and the result is summarized in Table 6. Here, we took *male* gender and *less than high school* education level as the reference group and transformed behavioral intention into a

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binary variable (0: reject; 1: accept). We found that gender (*P*=.048) and education level (*P*=.04) affected the willingness to use online hospitals, and both of them promoted the use of online hospitals (odds ratio [OR] 2.844, 95% CI 1.010-8.003, and OR 2.187, 95% CI 1.031-4.636, respectively) as shown in Table 6. In other words, female participants' willingness to use online hospitals was 2.844 times that of male participants, while willingness to use online hospitals increased 2.187 times (ie, OR 2.187, 95% CI 1.031-4.636) with each level of education.

Table 6. Variables in the equation.

Variable	B	SE	Wald value	*P* value	Odds ratio (95% CI)
Gender	1.045	0.528	3.918	.048	2.844 (1.010-8.003)
Age	–0.262	0.444	0.349	.56	0.769 (0.323-1.836)
Education	0.782	0.383	4.162	.04	2.187 (1.031-4.636)
Income	–0.128	0.219	0.343	.56	0.880 (0.573-1.351)

Discussion

Principal Findings

A total of 407 young and middle-aged patients at a hospital in Western China were surveyed regarding their willingness to use an online hospital. This study analyzed the factors, and their relationships, that influenced patients' use of online hospitals and provided some prior information and a theoretical basis upon which other researchers can carry out similar research. The results show that the public's awareness and usage of online hospitals was low. According to the estimation results of the model path coefficient and the analysis of the adjustment effect, we determined the following: performance expectancy, effort expectancy, and facilitating conditions were the three main factors that affected patients' willingness to use an online hospital. They all had a positive impact on behavioral intention. It can also be seen from the path coefficient results in Table 5 that effort expectancy is the most important factor. This may indicate that the user's effort expectancy shows the user's ability to accept new things to a certain extent. When users encounter unfamiliar content when operating within the online hospital platform, their efforts will inspire them to try and learn new things, so as to make better use of online hospitals. From Table 5, we can see that performance expectancy had a positive impact on behavioral intention, which shows that perceived ease of use of mobile medical platforms and the usefulness of mobile medical services may have a positive effect on patients' willingness to use online hospitals [28]. Furthermore, facilitating conditions also had a positive impact on behavioral intention, which shows that some external promotion effects, such as medical staff recommendations and guidance, government policy support, and policies that benefit people, will probably increase the willingness of patients to use online hospital mobile medical services. In addition, gender and education level were personal factors that influenced patients' willingness to use mobile medical services. It can be seen from the OR value in Table 6 that women were more likely to accept mobile medical services of online hospitals than were men; the acceptability by women was 2.844 times that of men. Meanwhile, the higher the education level that a patient had, the more adventurous the patient became. The acceptance increased 2.187 times with each increase in education level. People with higher education levels may be more willing to try this new type of technology platform. Throughout the whole process, it was indicated that certain patient attributes may influence people's decisions. Further research is needed to explore these relationships more deeply.

Research Impact

The current outbreak of COVID-19 is still spreading all over the world, which poses great threats to the safety and health of people around the world. Medical systems in all countries are facing great amounts of pressure and challenges. This study has several implications for both researchers and practitioners of mobile medicine and provides a reference for the response to the COVID-19 pandemic. Online hospitals constitute a new mode of telemedicine. Members of the public are limited by traditional modes of medical thinking and their awareness is relatively low. Most of them hold a conservative wait-and-see attitude. There will be a certain resistance to this in the early stages. Medical habits and thinking styles require a transformation process [29]. To change the public's resistance to change, the government and medical institutions need to continue to increase the promotion of mobile medical services. It will be important to pay attention to improving public eHealth literacy [30], especially among middle-aged and elderly groups who know little about new technologies and have relatively low levels of education. Differentiated promotion in different age groups will be important, focusing on the interaction between patient groups. At the same time, it is necessary to fully standardize the management of mobile medical practitioners; strictly control the quality of mobile medical services; conduct daily monitoring and scoring of doctors' qualification reviews, prejob training, medical quality, service attitudes, and patient satisfaction; and establish multidimensional online assessment standards and scientific management of every aspect of mobile medical service. In this regard, government departments should play a leading role. We can learn from the experience of developed countries with regard to the supervision of mobile medical services [31,32]. It will be important to accelerate the improvement of relevant legislation and regulatory policies and to formulate mobile medical service quality standards, industry regulations, and information security standards in order to promote the long-term development of online hospitals.

Research Limitations

Since this study recruited a cross-sectional sample of young and middle-aged participants in Western China, it may not truly reflect the willingness of the entire Chinese population or groups in other regions to adopt mobile medical services. In addition,

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this study found that social influence and perceived risk have no significant impact on patients' willingness to use online hospitals. This is inconsistent with the results of other studies on the willingness to adopt other mobile health technologies. Further research is needed to re-examine social influence and perceived risk. At the same time, mobile medical services are under continuous development in China, and the relevant research has not yet formed a relatively complete research framework.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Measurement items of research variables.
[DOCX File , 14 KB - mhealth_v9i2e25960_app1.docx]

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Abbreviations

AGFI: adjusted goodness-of-fit index
AVE: average variance extracted
CFI: comparative fit index
CR: composite reliability
GFI: goodness-of-fit index
IT: information technology
OR: odds ratio
RMSEA: root mean square error of approximation
UTAUT: Unified Theory of Acceptance and Use of Technology

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Original Paper

WeChat as a Platform for Baduanjin Intervention in Patients With Stable Chronic Obstructive Pulmonary Disease in China: Retrospective Randomized Controlled Trial

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Abstract

Background: Pulmonary rehabilitation is a crucial part of the nonpharmacological treatment of stable chronic obstructive pulmonary disease (COPD), but management remains problematic. WeChat could serve as a useful tool in patient management. Baduanjin is a popular exercise in China that is usually applied in pulmonary rehabilitation, which has been confirmed to be effective in improving lung function and life quality.

Objective: This study aimed to explore the efficiency of WeChat in the management of Baduanjin exercise in COPD patients.

Methods: A total of 200 patients from the respiratory department of Putuo Hospital participated in the Baduanjin rehabilitation project from September 2018 to October 2019, and were randomly assigned to the WeChat and control groups and followed up using the WeChat platform or telephone for 12 weeks. The frequency of Baduanjin exercise, lung function (percentage of forced expiratory volume in 1 second predicted, FEV1% predicted), and COPD assessment test (CAT) scores were collected and compared between the two groups. The number of message exchanges and a satisfaction survey on the WeChat platform were used to assess the feasibility of WeChat management outside the hospital.

Results: The Baduanjin exercise frequency significantly differed between the control group and WeChat group (F=33.82, P<.001) and across various time points (F=214.87, P<.001). After the follow-up on WeChat, there were fewer patients not performing Baduanjin exercise. The FEV1% predicted value significantly differed before and after Baduanjin exercise in the control group (Z=−3.686, P<.001) and the WeChat group (Z=−6.985, P<.001). A significant difference in the FEV1% predicted value was observed after Baduanjin exercise between the two groups (Z=−3.679, P<.001). The CAT score significantly differed before and after Baduanjin exercise in the control group (Z=−4.937, P<.001) and the WeChat group (Z=−5.246, P<.001). A significant difference in the CAT score was observed after Baduanjin exercise between the two groups (Z=−5.246, P<.001). The number of completed Baduanjin exercises, lung function, and CAT scores in active patients were higher than those in nonactive patients. All satisfaction survey items were scored with more than 4 points. Among the items, the highest score (mean 4.54, SD 0.77) was for continued WeChat management, followed by the effective management of Baduanjin exercise (mean 4.46, SD 0.87). The patients in the WeChat group showed much higher enthusiasm for and compliance with Baduanjin exercise, resulting

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in better life quality and lung function. The patients were very satisfied with the WeChat management because of the obvious curative effect and home feeling.

Conclusions: The WeChat platform provided a feasible, effective, and sustainable management plan for Baduanjin rehabilitation.

Trial Registration: Chinese Clinical Trial Registry ChiCTR1900028248; http://www.chictr.org.cn/showprojen.aspx?proj=46995

(JMIR Mhealth Uhealth 2021;9(2):e23548) doi:10.2196/23548

KEYWORDS

WeChat management; chronic obstructive pulmonary disease; Baduanjin rehabilitation

Introduction

Chronic obstructive pulmonary disease (COPD) is a chronic disease characterized by persistent respiratory symptoms and airflow limitation. COPD develops progressively and is related to an abnormal inflammatory response to harmful gases or particles [1]. COPD, ischemic heart disease, cerebrovascular disease, and cancer are the four major causes of human death. The prevention and treatment of COPD have introduced substantial economic burdens for families and countries [2]. The currently used drugs cannot prevent the progression of COPD. The incidence is approximately 13.6% among persons older than 40 years in China [3], and patients usually have a low quality of life with a high disability rate. As a chronic disease, COPD is prone to acute exacerbation [4]. The goals of COPD treatment are to reduce the symptoms, reduce the frequency and severity of exacerbations, and improve the health status and exercise tolerance [5]. Except for hospitalization during acute exacerbation, most patients need to perform self-care at home for many years. Therefore, the management of stable patients is especially important [6]. However, most COPD patients lack disease-related knowledge. Although medical staff members provide disease health knowledge education using different modes, such as education during hospitalization, owing to differences in patient awareness of the disease, education level, compliance, and other factors, many patients cannot effectively manage themselves [7]. It is difficult to meet the needs of the increasing morbidity of COPD and satisfy the increasing expectation of a quality life with the existing medical and health service model in China. Therefore, it is necessary to explore a new management model for stable COPD patients [8].

Pulmonary rehabilitation for COPD has been given more attention in recent years. Pulmonary rehabilitation has been demonstrated to improve the symptoms of dyspnea, improve exercise endurance, reduce the number of in-hospital days, and reduce the frequency of acute exacerbation [9]. Baduanjin, as a traditional aerobics exercise, is listed as the 97th sports item officially launched by the State General Administration of Sport in 2003 and has been widely promoted in China. Baduanjin involves the following eight components: (1) pushing up the heavens, (2) drawing the bow, (3) separating heaven and earth, (4) shaking the heavenly pillar, (5) punching with an angry gaze, (6) shaking the head and swaying the buttocks to extinguish fire in the heart, (7) touching the toes and bending back, and (8) bouncing on the toes. Baduanjin has been applied in lung rehabilitation for many years in China. Previous studies have confirmed that Baduanjin has a strong clinical effect on lung rehabilitation in COPD patients [10]. Thus, Baduanjin has become an exercise prescription for COPD [11]. However, owing to the lack of effective management, pulmonary rehabilitation, including Baduanjin, has not been practiced widely and continuously, and the benefit for patients is limited. In addition, there is a lack of consistency in the length of the research period among many published studies [12].

With the key position of home-based physical activity, long-term management becomes critical. With the rapid development of computer technology, network technology, and multimedia technology, new media have become convenient, fast, interactive, and wide-spread platforms for information dissemination. WeChat is the mainstream instant communication platform in China [13]. The “2018 WeChat Annual Data Report” reported that 1.01 billion users logged on to WeChat daily in 2018. The function of the platform is quite strong but is very easy to operate. Various message forms, such as text, picture, voice, and video, could be presented in communication. WeChat has rapidly developed into a comprehensive information platform integrating communication, information, entertainment, search, e-commerce, office collaboration, and corporate customer service. It is reasonable to apply new technology in medical areas. The “Internet Medical” model is very suitable for China’s current situation, that is, a large population with a shortage of medical resources [14]. WeChat has been gradually used in medical education and the follow-up of patients, and it has produced successful outcomes [15,16].

Because the benefits disappear over time if activity and other good behaviors are not continued, COPD patients should be offered consistent guidance. The telephone has been used for follow-up in early studies but can no longer meet the requirements [17]. New technologies, such as WeChat, could be applied for more effective management. Thus, we established a new system for continuous management from inside the hospital to outside the hospital under the WeChat platform. In the hospital, patients are provided disease knowledge and educated regarding the skills of pulmonary rehabilitation, such as Baduanjin, diet nutrition, correct drug use, etc [18,19]. After discharge, all patients are placed under management using the WeChat platform.

As Baduanjin requires long-term persistence by COPD patients, consistent encouragement from medical staff is essential. In this study, the established WeChat platform was applied to manage Baduanjin exercise in patients with stable COPD, and the results are encouraging.

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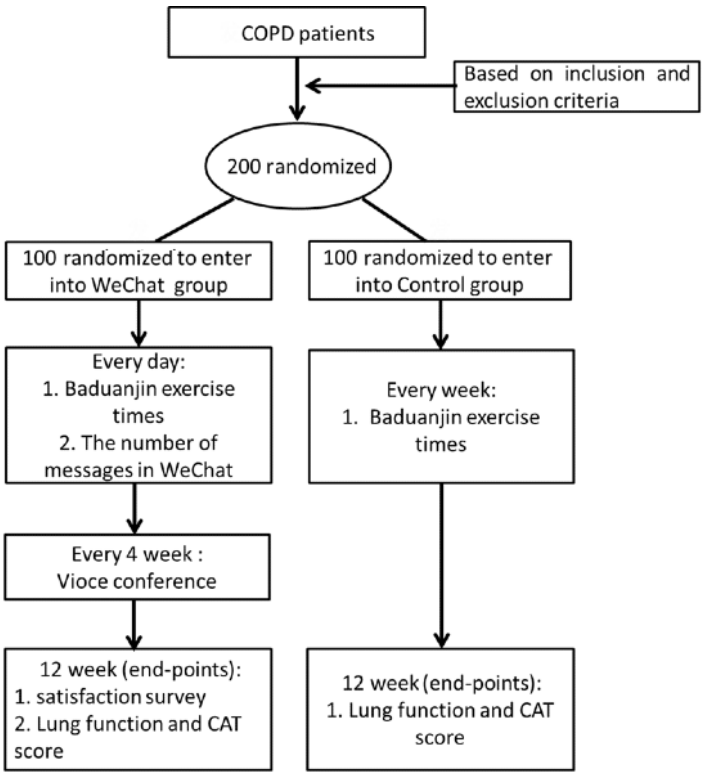
Methods

Research Design and Flow Chart

This study was a parallel controlled study conducted from September 2018 to October 2019 in Shanghai, China. Two hundred stable COPD patients were included, and the participants were randomly divided into the following two groups (1:1 ratio): the WeChat intervention group and routine nursing control group (Figure 1). The research plan was approved by the ethics committee of Putuo Hospital (grant number: PTEC-A-2018-25-1).

Figure 1. Flowchart of the research design. CAT: chronic obstructive pulmonary disease assessment test; COPD: chronic obstructive pulmonary disease.



Procedures of Baduanjin Exercise

The rehabilitation therapist instructed the patients to perform Baduanjin exercise until they could accomplish proficiency according to the Baduanjin video (produced by the State Sports General Administration in 2003). All patients were asked to perform the exercise two to four times a day for no less than 5 days per week.

Establishment of the WeChat Platform

A WeChat platform team with six members was established. The head nurse of the ward served as the team leader and was responsible for the operation and guidance of the entire project. Two nurse supervisors were responsible for teaching the patients and their families how to use the platform, providing all educational documents to the patients at the appropriate time, maintaining contact with the patients, and urging the patients to perform Baduanjin exercise. Two physicians were responsible for evaluating the patients' condition and devising the medical plan. One technician in the pulmonary function room was responsible for evaluating the lung function of all patients, collecting the data, and performing statistical analyses of the data. The team members cooperated very well, and the platform was operated effectively. The patients very actively participated in the communication. Responses to all questions were obtained from the medical staff in a timely manner.

Participants

All patients with stable COPD were discharged from the respiratory medicine ward of a large general hospital. All candidates first completed a brief screening questionnaire. Patients who met the inclusion criteria were invited to participate in the study and received more detailed information regarding the study. After providing written informed consent, all qualified patients were divided into the WeChat group and control group.

The inclusion criteria were as follows: (1) 50 to 80 years of age regardless of gender; (2) confirmed clinical diagnosis of stable COPD according to the standard of GOLD 2018 [20]; (3) informed consent (patients and families); (4) ability to use WeChat proficiently (patients and primary caregivers); and (5) ability to perform Baduanjin independently.

The exclusion criteria were as follows: (1) severe heart, liver, and kidney diseases, tumors, or other conditions that may affect the observation; (2) life expectancy less than 1 year; and (3) history of conducting physical exercise for a long time (≥3 times/week, ≥20 minutes/time, persisting for more than 12 months) [21].

Pulmonary function (percentage forced expiratory volume in 1 second [FEV1%]) was the outcome index. Based on previous studies showing FEV1% improvement in clinical trials [22], the mean and SD of FEV1% in the control group were 57.09 and 22.53, respectively, while the mean and SD of FEV1% in

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the experimental group were 60.24 and 20.15, respectively. The alpha level was set to .05, the power was 80%, and the participant dropout rate was 20%. A sample size of 192 patients (96 per group) was required for the primary analysis. Thus, we recruited 200 patients in the trial (100 in the WeChat group and 100 in the control group).

Randomization and Masking

Using the method of block randomization, 200 research patients were randomly assigned to the WeChat and control groups. The block size was defined as four, and there were six sequential arrangements and combinations. Excel (Microsoft Corp) randomly generated 50 (1 50) numbers that did not repeat. Then, the numbers were divided by six to obtain the remainder, and six combinations were matched according to the remainder. A random block group table was then completed. After the research patients were included, the random block table was assigned to a group. By the nature of the trial design, neither the research staff nor the participants were blinded to the intervention.

Intervention Method

Control Group

Handbooks were distributed to the participants, and they included the following: (1) a Baduanjin video (produced by the State Sports General Administration in 2003); (2) Baduanjin notes; (3) information regarding COPD disease; (4) the importance of pulmonary rehabilitation; (5) nutrition and diet suggestions; and (6) prevention of acute exacerbation of COPD. The patients were asked to comply with medical advice, including performing Baduanjin exercise at home and being followed up by telephone once a week. The chronic obstructive pulmonary disease assessment test (CAT) questionnaire and lung function evaluation were performed before and after the study using a spirometer.

WeChat Group

The participants also received the necessary education on WeChat. All education materials, including text, pictures, videos, and voice messages, were sent to the patients as an electric document via WeChat and individuals as needed. The patients were supervised while performing Baduanjin and maintaining healthy behaviors.

A WeChat voice conference was held every 4 weeks for 40 minutes. The medical staff were required to be online, and they held a seminar regarding common problems that the patients usually discussed and answered questions.

The feedback information was as follows: (1) dyspnea status; (2) discomfort status; (3) appetite status; (4) number of Baduanjin exercises completed every day (the patients in the WeChat group submitted their information online every day); (5) completion of the satisfaction survey by all patients at the end of the 12th week; and (6) the CAT questionnaire and lung function evaluation before and after the study.

Quality Control

A designated attending physician supervised the project every month and evaluated the progress.

Outcome Measures

Baseline Assessment

The general demographic data included the patients' gender, age, smoking status, disease course, lung function, classification of airflow limitation severity, comorbidities, and combined COPD assessment according to GOLD 2018.

Data Collection and Evaluation at the Endpoint

The Baduanjin exercise frequency was collected each week in WeChat and once a week by telephone. At the end of the study, the lung function evaluation, quality of life evaluation (CAT), personal activity evaluation, and satisfaction survey were completed by all participants.

Lung Function and CAT

All patients underwent a spirometric analysis before and after the trial. Given the noninvasive and simple characteristics of lung function tests, they are generally adopted in clinical practice for early diagnosis and prognostic evaluations. Lung function tests can effectively reflect the pathological changes in the airway and their degree, and provide reliable results of the presence and severity of spirometric abnormalities. The CAT score is a reliable and effective indicator used to assess the living conditions and quality of life of COPD patients. The CAT questionnaire is very simple, can be completed by patients in 2 to 3 minutes, and includes eight items, including daily living ability and physical health. Compared with the St. George's Respiratory Questionnaire (SGRQ), the content is greatly reduced, but the required indicators are comprehensive and can more intuitively reflect changes in patient health. Related studies have shown that the lung function of patients with COPD is correlated with the CAT score [23] and that the CAT score has good repeatability [24]. Thus, the CAT score is a good evaluation of stable COPD.

Activation of the Platform

We recorded the number of messages exchanged on the WeChat platform. The communication included text/graphics, voice, pictures, videos, etc. The activity on the platform and the degree of concern regarding the disease were evaluated.

Assessment of Satisfaction With the WeChat Platform Management

A self-designed questionnaire was used to evaluate the satisfaction of the participants at the end of the trial. In total, the following eight items were assessed: effective management of Baduanjin exercise, practical information, convenient communication and interaction, smooth platform operation, simple operation process, continued WeChat management, effective COPD rehabilitation management, and service attitude of the medical staff. A 5-point Likert scale was used with scores ranging from 1 to 5 points (1, strongly disagree; 2, disagree; 3, uncertain; 4, agree; and 5, strongly agree) [25]. A higher score was associated with better COPD patient experience and service evaluation of the WeChat platform and better effectiveness of the WeChat management of Baduanjin exercise.

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Statistical Analysis

The baseline data were based on continuous measurement data and categorized count data. The measurement data are expressed as mean (SD) or median (IQR). The count data are characterized as frequencies. Two-tailed *t* tests (mean and SD) or chi-squared tests were used to analyze the normally distributed data. A nonparametric test was used to analyze the nonnormally distributed data (median and IQR).

To analyze the results, repeated measures analysis of variance, a simple effect model, and two-sample *t* tests were used. To determine the within-group differences and between-group differences, the 95% CIs were calculated for the continuous measures. The statistical analysis was performed using SPSS 22.0 software (IBM Corp), and $P<.05$ was considered statistically significant.

Results

Sample Characteristics

Based on the inclusion and exclusion criteria, we screened 200 patients and completed baseline assessments before randomization to the trial of 100 patients in each group. Of the 200 patients, 67 were female and 133 were male. The ratio of male and female patients assigned to the two groups was not different. The mean age was 68.16 years (WeChat group, 69.43 years; control group, 68.87 years), and the mean course of COPD was 4.46 years (WeChat group, 4.50 years; control group, 4.31 years). Most patients had severe COPD, accounting for 73% (146/200) of cases (WeChat group, 72% [72/100]; control group, 74% [74/100]). Patients with moderate and very severe COPD accounted for 11.5% (23/200) of cases (WeChat group, 12% [12/100]; control group, 11% [11/100]) and 15.5% (31/200) of cases (WeChat group, 16% [16/100]; control group, 15% [15/100]), respectively. We also assessed the number of acute exacerbations and current smokers in both groups. Patients who had acute exacerbation at least once in the past year accounted for 31% (31/100) of cases in the control group and 35% (35/100) of cases in the WeChat group. The proportion of current smokers in the control group (34% [34/100]) was comparable to that in the WeChat group (37% [37/100]). According to statistical analysis, the baseline characteristics were balanced in both groups (Table 1).

Table 1. Baseline characteristics of the participants in the WeChat and control groups.

Baseline characteristics	Control group (n=100)	WeChat group (n=100)	*P* value
Gender (female/male), n	32/68	35/65	.76
Age (years), mean (SD)	68.87 (5.33)	69.43 (7.38)	.54
Course (years), mean (SD)	4.31 (2.07)	4.50 (2.46)	.56
Acute exacerbation[a], n (%)	31 (31%)	35 (35%)	.65
Current smoker, n (%)	34 (34%)	37 (37%)	.77
Severity, n			.95
Moderate	11	12	
Severe	74	72	
Very severe	15	16	

[a]Acute exacerbation: at least once in the past year.

Comparison of the Baduanjin Exercise Frequency Between the Control and WeChat Groups

A repeated measures analysis of variance was performed to analyze the data from the two groups. The data did not conform to the sphericity test ($P<.001$). The analysis of the multivariate test revealed that in the within-group comparisons in both the control and WeChat groups, the Baduanjin exercise frequency significantly differed across various time points ($F=214.87$, $df=11$, $P<.001$). This finding indicates that in both the control and WeChat groups, Baduanjin management was effective. Additionally, in the between-group comparisons, the different groups (control group vs WeChat group) showed a significant difference in the time points ($F=33.82$, $df=1$, $P<.001$) (Multimedia Appendix 1, Figure 2).

Further analysis by a simple effects model showed a difference within and between the groups. The Baduanjin exercise frequencies in the control and WeChat groups (1 week to 4 weeks) increased from week 1 to week 4 and then maintained a plateau until the end of the project. In the within-group comparisons, there were statistically significant differences at each time point in weeks 1 to 3 compared with week 4, but no difference was observed between weeks 5 and 12 and week 4. According to the between-group comparison results, significant differences were found between the WeChat and control groups at the same time points (all $P<.001$). We found that WeChat management was more effective for performing Baduanjin exercise (Multimedia Appendix 1, Figure 2).

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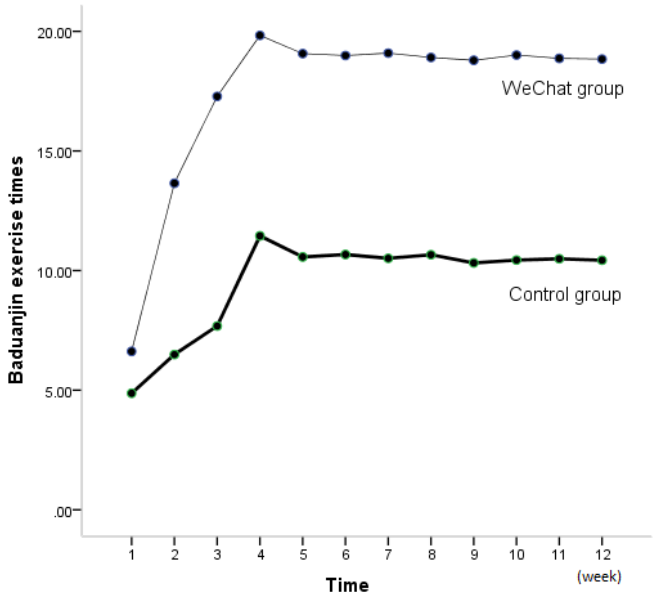
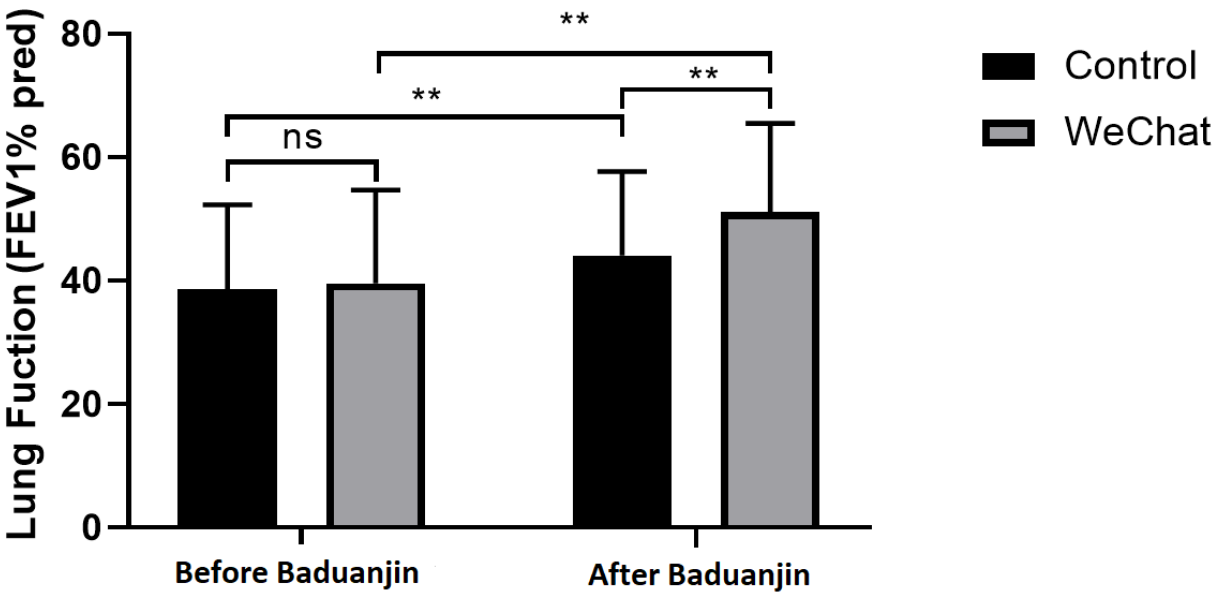
Figure 2. Comparison of Baduanjin exercise frequency per week (mean) between the WeChat group and control group (all *P*<.001).



Lung Function Assessment

The FEV1% predicted value significantly differed before and after the trial in both the control group (*Z*=−3.686, *P*<.001) and WeChat group (*Z*=−6.985, *P*<.001), and the FEV1% predicted value in both groups improved after Baduanjin exercise. A significant difference was found in the FEV1% predicted values after Baduanjin exercise between the two groups (*Z*=−3.679, *P*<.001), and no difference was observed before the trial (Multimedia Appendix 2, Figure 3). The results demonstrate that Baduanjin exercise was more effective in the WeChat group.

Figure 3. Lung function before and after Baduanjin exercise. FEV1% pred: percentage of forced expiratory volume in 1 second predicted; ns: not significant. ***P*<.001.



CAT Score Evaluation

All patients completed the questionnaire independently. We found that the CAT score significantly differed before and after the exercise in the control group (*Z*=−4.937, *P*<.001) and the WeChat group (*Z*=−5.246, *P*<.001). The life quality of the patients in both groups improved after Baduanjin exercise (Figure 4). No statistically significant difference was found in the CAT score between the two groups before the study (*Z*=−1.407, *P*=.30), and a significant difference was found after the exercise (*Z*=−5.246, *P*<.001). These results demonstrate greater improvement in the life quality of patients in the WeChat group after the exercise (Multimedia Appendix 3, Figure 4).

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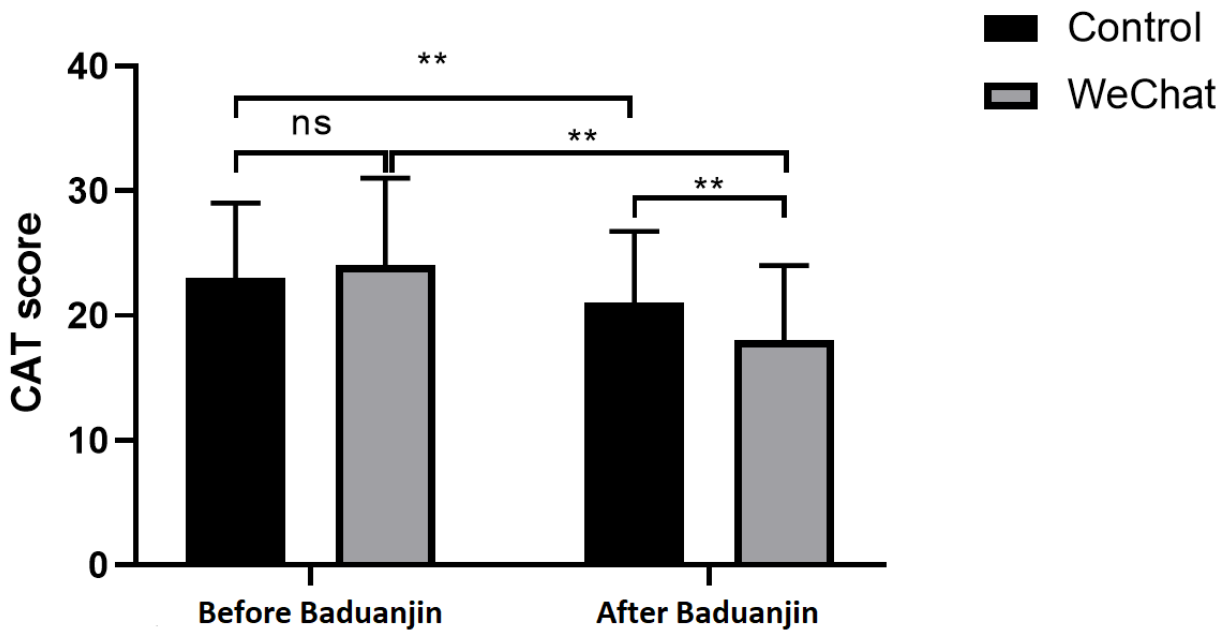
Figure 4. Chronic obstructive pulmonary disease assessment test (CAT) score before and after Baduanjin exercise. ns: not significant. **P<.001.



Activity and Interaction on the WeChat Platform

Communication in the WeChat group was mainly conducted via text/graphics, with 13,911 items, followed by voice messages, with a total of 1317 items. Text/graphics and voice accounted for the main methods of message exchange. Pictures and videos were also used; however, the frequency was relatively low (Table 2).

Table 2. Distribution of different message forms present on the WeChat platform.

Message form	1-4 weeks, n	5-8 weeks, n	9-12 weeks, n	Total (N=16,100), n (%)
Text/graphics	4680	4601	4630	13,911 (86.40%)
Voice	388	428	501	1317 (8.18%)
Picture	173	200	289	662 (4.11%)
Video	52	54	77	183 (1.14%)
Other files	10	7	10	27 (0.17%)

All messages could be divided into the following three groups: information provided by the medical team, medical staff-patient interaction communication, and patient-patient interaction communication. The frequency of the provided information was relatively fixed. Medical staff-patient interaction was relatively frequent during the first 2 weeks but was less frequent thereafter. However, patient-patient interaction gradually increased, indicating that a COPD family was established. Interestingly, we found that the patients interacted and encouraged each other. The platform became a common home for all WeChat participants.

We divided the WeChat group into active patients and nonactive patients based on the number of messages exchanged. Those with more than two messages per day were considered active patients, and those with one or fewer messages were considered inactive patients. Eighty-six patients were more active in the group. The number of completed Baduanjin exercises, lung function, and CAT scores of these active patients were higher than those of the nonactive patients (Figure 5). The amount of information exchanged by the WeChat group reflected the activity of the WeChat management platform, indicating that COPD patients actively participated in the management of the disease and received better outcomes.

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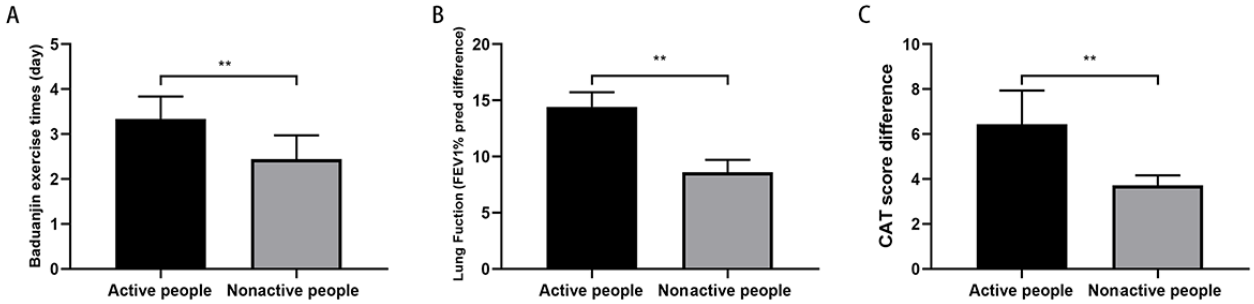
Figure 5. Comparison of outcomes between active patients and nonactive patients. (A) Daily exercise frequency; (B) Difference in lung function before and after Baduanjin exercise; and (C) Difference in the chronic obstructive pulmonary disease assessment test (CAT) score before and after Baduanjin exercise. FEV1% pred: percentage of forced expiratory volume in 1 second predicted.**P<.001.



Evaluation of the Satisfaction With the WeChat Platform

According to the score of the 5-point Likert scale, items that received more than 4 points were as follows: continued WeChat management, effective Baduanjin exercise management, practical information content, convenient communication and interaction, smooth platform operation, simple operation process, service attitude of the medical staff, and COPD rehabilitation. The results indicated that the COPD patients were satisfied with the management of the WeChat platform. Among these items, the highest score was for continued WeChat management (mean 4.54, SD 0.77), followed by effective management of Baduanjin exercise (mean 4.46, SD 0.87), indicating the feasibility, sustainability, and effectiveness of disease management with the WeChat platform (Table 3).

Table 3. Satisfaction scores of the WeChat platform.

Contents	Agreement (N=50)[a]					Score, mean (SD)
	Strongly agree, n (%)	Agree, n (%)	Uncertain, n (%)	Disagree, n (%)	Strongly disagree, n (%)	
Continued WeChat management	28 (56%)	21 (42%)	1 (2%)	0 (0%)	0 (0%)	4.54 (0.77)
Effective Baduanjin exercise management	26 (52%)	21 (42%)	3 (6%)	0 (0%)	0 (0%)	4.46 (0.87)
Practical information content	22 (44%)	28 (56%)	0 (0%)	0 (0%)	0 (0%)	4.44 (0.71)
Convenient communication and interaction	24 (48%)	23 (46%)	3 (6%)	0 (0%)	0 (0%)	4.42 (0.86)
Smooth platform operation	21 (42%)	28 (56%)	1 (2%)	0 (0%)	0 (0%)	4.40 (0.76)
Simple operation process	21 (42%)	28 (56%)	1 (2%)	0 (0%)	0 (0%)	4.40 (0.76)
Service attitude of the medical staff	24 (48%)	20 (40%)	6 (12%)	0 (0%)	0 (0%)	4.36 (0.98)
COPD[b] rehabilitation	22 (44%)	22 (44%)	6 (12%)	0 (0%)	0 (0%)	4.30 (0.97)

[a]Strongly agree, 5 points; agree, 4 points; uncertain, 3 points; disagree, 2 points; strongly disagree, 1 point.

[b]COPD: chronic obstructive pulmonary disease.

Discussion

Principal Findings

The main purpose of this study was to test the feasibility and efficiency of WeChat in the management of Baduanjin exercise in COPD patients. The results of this study suggest that the management of Baduanjin exercise with the WeChat platform improves the enthusiasm and compliance of patients. The frequency of Baduanjin exercise using the WeChat-based intervention was 0 to 21 times (mean 18.84) to 0 to 13 times (mean 10.43) per person per week compared with traditional interventions at 12 weeks. The Baduanjin exercise frequency in the WeChat group was markedly higher than that in the control group. Under the management of WeChat, some patients did not perform Baduanjin exercise. However, after the follow-up on WeChat, the number of patients with a Baduanjin exercise frequency of 0 decreased (Figure 6). Therefore, Baduanjin exercise management based on the WeChat platform improved the enthusiasm and compliance of patients. These results are consistent with the beneficial effect of compliance using WeChat management in other clinical populations [26].

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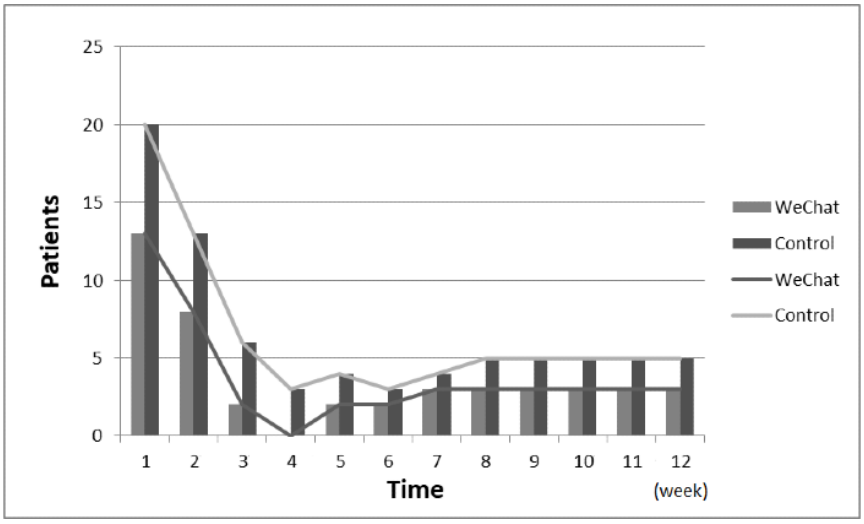
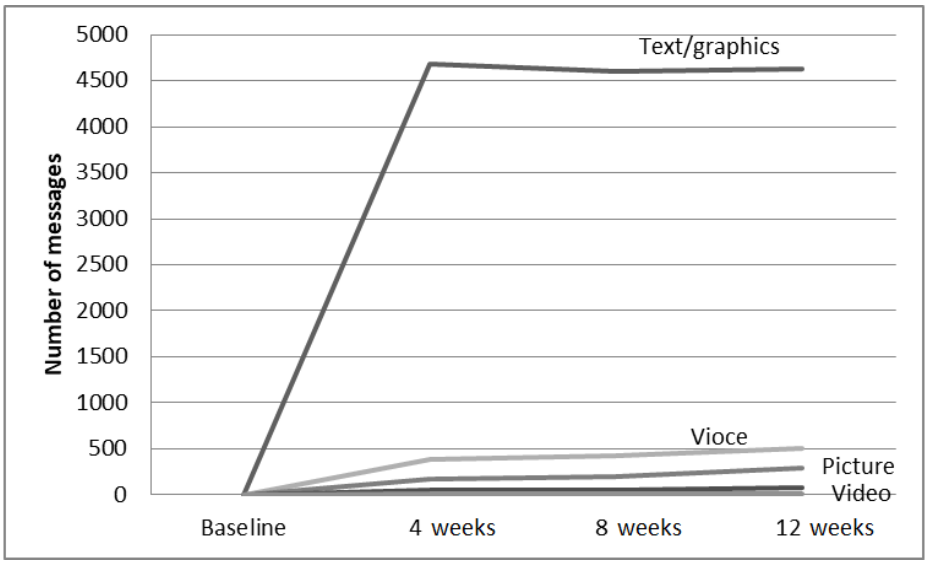
Figure 6. Number of patients with a Baduanjin exercise frequency of 0 (per week) in the WeChat group and control group.



Based on the WeChat platform, communication between medical staff and patients increased, and the effectiveness of Baduanjin lung rehabilitation improved. Studies have shown that the frequency of the use of the platform is crucial for the effectiveness of the intervention [27]. Our results indicate that the total number of messages exchanged gradually increased and reached a peak at approximately 4 weeks; thereafter, the number maintained a plateau. Interaction with text/graphics exhibited the most obvious increase (Figure 7). We also found that active participants had better outcomes. The interaction between patients increased, and mutual exchange, sharing, and supervision promoted more enthusiasm among the patients. The role of the team was always favorable.

Figure 7. Trend of messages exchanged on WeChat.



All participants completed the satisfaction survey, and a high score was obtained in the WeChat group. Based on the questionnaire responses, we found that continuing WeChat management and Baduanjin exercise management were the top two ranked items. The other items also achieved relatively high scores. Thus, the patients expected to continue WeChat management, and the WeChat management of Baduanjin exercise is feasible.

Early hospital follow-up, coaching, COPD action plans and management programs, telemedicine, pulmonary rehabilitation, and other interventions require more research. Improvement in management is an effective strategy for improving patient recovery [28]. A recent study also noted that reducing readmission could improve prognosis [29]. Although the management of COPD patients has been studied since the 1960s [30], the situation of management is not optimistic. Many problems are associated with COPD management, and a key problem is lung rehabilitation [31]. Currently, published data lack sufficient evidence for the identification of an effective pathway to improve the symptoms of COPD by management. Therefore, better ways to achieve management must be explored [32].

With the development of the internet, major communication platforms have begun to be applied in health care. Social media platforms, such as Twitter and Facebook, have been steadily applied in medical education [33,34]. Facebook has been used to study many aspects of health care, and it provides a convenient and easily accessible way to collect unsolicited and

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observational patient data [35]. An analysis of the content of COPD group chats on Facebook showed that COPD Facebook group members share specific disease-related experiences and request information regarding select self-management topics. This information can be used to improve the quality of self-management support provided to members of popular COPD Facebook groups [36]. WeChat is also gradually being used in medical teaching and the clinic, but the clinical application needs improvement [37]. Clinical studies based on the WeChat platform, such as cough variant asthma and promoting weight loss, have achieved good results [38]. The internet could also help patients with COPD understand the disease and manage the condition by themselves [39].

Limitations

This study has some limitations. First, the study period was quite short (approximately 12 weeks), which may have affected the judgement of compliance, but our study is ongoing, and more data will be reported in the future. Second, the number of participants in this study was relatively small, although the sample size was calculated statistically. However, because of the complexity of clinical trials and the uncontrollability of patients, a larger number of patients could supply more intact information. Third, as the original data were obtained from patient reports, inaccurate reports could not be fully excluded. Thus, there is a problem of credibility in patient reports using WeChat management. Finally, our study only explored the effectiveness of Baduanjin rehabilitation training under WeChat platform management. More projects in self-management supported by the WeChat platform could be fully studied in the future.

Conclusions

In this study, a new management platform involving WeChat from the in-hospital period to the out-of-hospital period was established for patients. Pulmonary rehabilitation using Baduanjin exercise for COPD patients was applied using this platform. This online rehabilitation training model met the patients' requirements as this platform was convenient, easy to understand, and time saving. Information is shared in a timely manner, and seamless communication is maintained with patients. Additionally, the compliance and enthusiasm of the patients were much higher. Baduanjin exercise based on WeChat platform management was effective in improving the life quality and lung function of COPD patients. Patient management based on WeChat is effective, feasible, and sustainable.

Acknowledgments

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Conflicts of Interest

None declared.

Editorial Notice

This randomized study was only retrospectively registered by the authors due to technical issues and the limitation of time. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials because the risk of bias appears low and the study was considered formative, guiding the development of the application. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Multimedia Appendix 1
Effects of the WeChat intervention on Baduanjin exercise times.
[DOCX File , 15 KB - mhealth_v9i2e23548_app1.docx]

Multimedia Appendix 2
Lung function in the WeChat group and control group.
[DOCX File , 15 KB - mhealth_v9i2e23548_app2.docx]

Multimedia Appendix 3
Chronic obstructive pulmonary disease assessment test score in the WeChat group and control group.
[DOCX File , 15 KB - mhealth_v9i2e23548_app3.docx]

Multimedia Appendix 4
CONSORT-eHEALTH checklist.

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[PDF File (Adobe PDF File), 92 KB - mhealth_v9i2e23548_app4.pdf]

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Abbreviations

CAT: chronic obstructive pulmonary disease assessment test
COPD: chronic obstructive pulmonary disease
FEV1%: percentage of forced expiratory volume in 1 second

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Original Paper

Simple Smartphone-Based Assessment of Gait Characteristics in Parkinson Disease: Validation Study

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Abstract

Background: Parkinson disease (PD) is a common movement disorder. Patients with PD have multiple gait impairments that result in an increased risk of falls and diminished quality of life. Therefore, gait measurement is important for the management of PD.

Objective: We previously developed a smartphone-based dual-task gait assessment that was validated in healthy adults. The aim of this study was to test the validity of this gait assessment in people with PD, and to examine the association between app-derived gait metrics and the clinical and functional characteristics of PD.

Methods: Fifty-two participants with clinically diagnosed PD completed assessments of walking, Movement Disorder Society Unified Parkinson Disease Rating Scale III (UPDRS III), Montreal Cognitive Assessment (MoCA), Hamilton Anxiety (HAM-A), and Hamilton Depression (HAM-D) rating scale tests. Participants followed multimedia instructions provided by the app to complete two 20-meter trials each of walking normally (single task) and walking while performing a serial subtraction dual task (dual task). Gait data were simultaneously collected with the app and gold-standard wearable motion sensors. Stride times and stride time variability were derived from the acceleration and angular velocity signal acquired from the internal motion sensor of the phone and from the wearable sensor system.

Results: High correlations were observed between the stride time and stride time variability derived from the app and from the gold-standard system (r=0.98-0.99, P<.001), revealing excellent validity of the app-based gait assessment in PD. Compared with those from the single-task condition, the stride time ($F_{1,103}$=14.1, P<.001) and stride time variability ($F_{1,103}$=6.8, P=.008) in the dual-task condition were significantly greater. Participants who walked with greater stride time variability exhibited a greater UPDRS III total score (single task: β=.39, P<.001; dual task: β=.37, P=.01), HAM-A (single-task: β=.49, P=.007; dual-task: β=.48, P=.009), and HAM-D (single task: β=.44, P=.01; dual task: β=.49, P=.009). Moreover, those with greater dual-task stride time variability (β=.48, P=.001) or dual-task cost of stride time variability (β=.44, P=.004) exhibited lower MoCA scores.

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Conclusions: A smartphone-based gait assessment can be used to provide meaningful metrics of single- and dual-task gait that are associated with disease severity and functional outcomes in individuals with PD.

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KEYWORDS

smartphone; gait; stride time (variability); validity; Parkinson disease

Introduction

Parkinson disease (PD) is a common neurodegenerative disease associated with numerous movement disorders and symptoms. One of the most significant disorders of PD is abnormal gait [1], which includes slowed walking speed, increased variability in stride timing (ie, stride time variability), and festination. These gait abnormalities have been linked to disease severity [2], and are on the causal pathway to an increased risk of falls [3], mortality, and morbidity [4]. As such, the functional status of patients suffering from PD, including gait, needs to be carefully assessed and considered for appropriate disease management.

Considerable effort has focused on the measurement of gait and mobility. Clinical rating scales [5,6] or stopwatch-based measurements (eg, timed-up-and-go test [7]) have been widely used to characterize gait in PD. However, these types of assessments are limited by subjective bias from clinicians, often have poor reliability, and are often insensitive to subtle pathological changes in PD. Recently, more advanced technologies have been developed to measure gait using specialized equipment such as wearable sensor systems or motion capture systems. This instrumented type of measurement can provide sophisticated and objective gait analysis with excellent reliability. For example, Mancini and colleagues [8] showed that using six wearable motion sensors consisting of a gyroscope, accelerometer, and digital compass attached on the left and right wrists, chest, lumber, and left and right shanks can accurately measure the temporal and spatial metrics of gait in multiple cohorts. However, such assessments are typically limited to clinical and laboratory settings, and require in-person contact with trained study personnel to reliably administer protocols and standardized instructions [9,10]. Moreover, such instrumented techniques do not afford regular gait assessments in large numbers of people due to the testing constraints, especially for those who are unable to utilize personal or public transportation and for those who live far from clinical centers or hospitals. Therefore, novel, easy-to-use, cost-effective, and scalable approaches for gait measurement in PD are needed.

With progress in smartphone technology, the inertial measurement unit (IMU) of smartphones—which consists of a 3D accelerometer, 3D gyroscope, and digital compass—has been utilized to capture movement associated with gait. Several studies have shown that the IMU of smartphones can accurately and reliably measure motion of the body in younger and older adults, as well as in those with PD [11-16]. For example, Ellis et al [15] showed that using the IMU of Apple iPod Touch secured on the navel can reliably and accurately measure gait in participants with and without PD. However, these approaches require the phone to be tightly secured to one part of the body and the studies were limited to assessments in laboratory environments with the need of trained study personnel to appropriately secure the phone using specialized equipment and to verbally provide standardized instructions to the participants.

Our team recently created a smartphone-based app enabling automatically guided assessment of gait when walking normally (ie, single task) and while performing a serial-subtraction cognitive task simultaneously (ie, dual task). The app was designed to provide standardized multimedia instructions to the user throughout the test to minimize the need for trained study personnel to administer the tests. Moreover, the assessment is completed with the phone placed in the user's pants pocket, thereby removing the need for additional equipment to secure the phone to the body with a predetermined orientation. We previously demonstrated the validity and reliability of this app-based approach to measure gait characteristics in healthy adults [17]. The aim of this study was to determine the validity of using this app-based approach to gait assessment in people with PD, and to establish the association between app-derived gait metrics (eg, stride time, stride time variability) and the performance of several clinical characteristics in patients suffering from PD.

Methods

Participants

Fifty-two patients diagnosed with idiopathic PD by clinicians of the Department of Movement Disorders at Beijing Tiantan Hospital (Beijing, China) completed this study. All participants provided written informed consent as approved by the Beijing Tiantan Hospital Institutional Review Board. The inclusion criteria were: (1) aged between 25 and 80 years, (2) clinically diagnosed with PD using the 2015 Movement Disorder Society diagnosis criteria [1], and (3) the ability to walk for 1 minute without ambulatory or personal assistance. The exclusion criteria were: (1) presence of other overt neurological diseases such as dementia or stroke; (2) orthopedic impairments, history or presence of ulceration, amputation, or other painful symptoms in the lower extremities associated with impairment in gait; (3) self-reported diabetes mellitus or cardiovascular disease that may further alter gait; (4) drug or alcohol abuse; or (5) inability to understand the study procedure.

Smartphone App

The app was designed for use on the iPhone iOS platform. The goal of the app was to recreate standard laboratory-based assessments of standing and walking for use in the laboratory, clinics, and other nonlaboratory remote environments. Here, we focused on the functionality of the app to measure gait in participants with PD. The full description of the app, as well as the validity and reliability of the gait assessment in healthy

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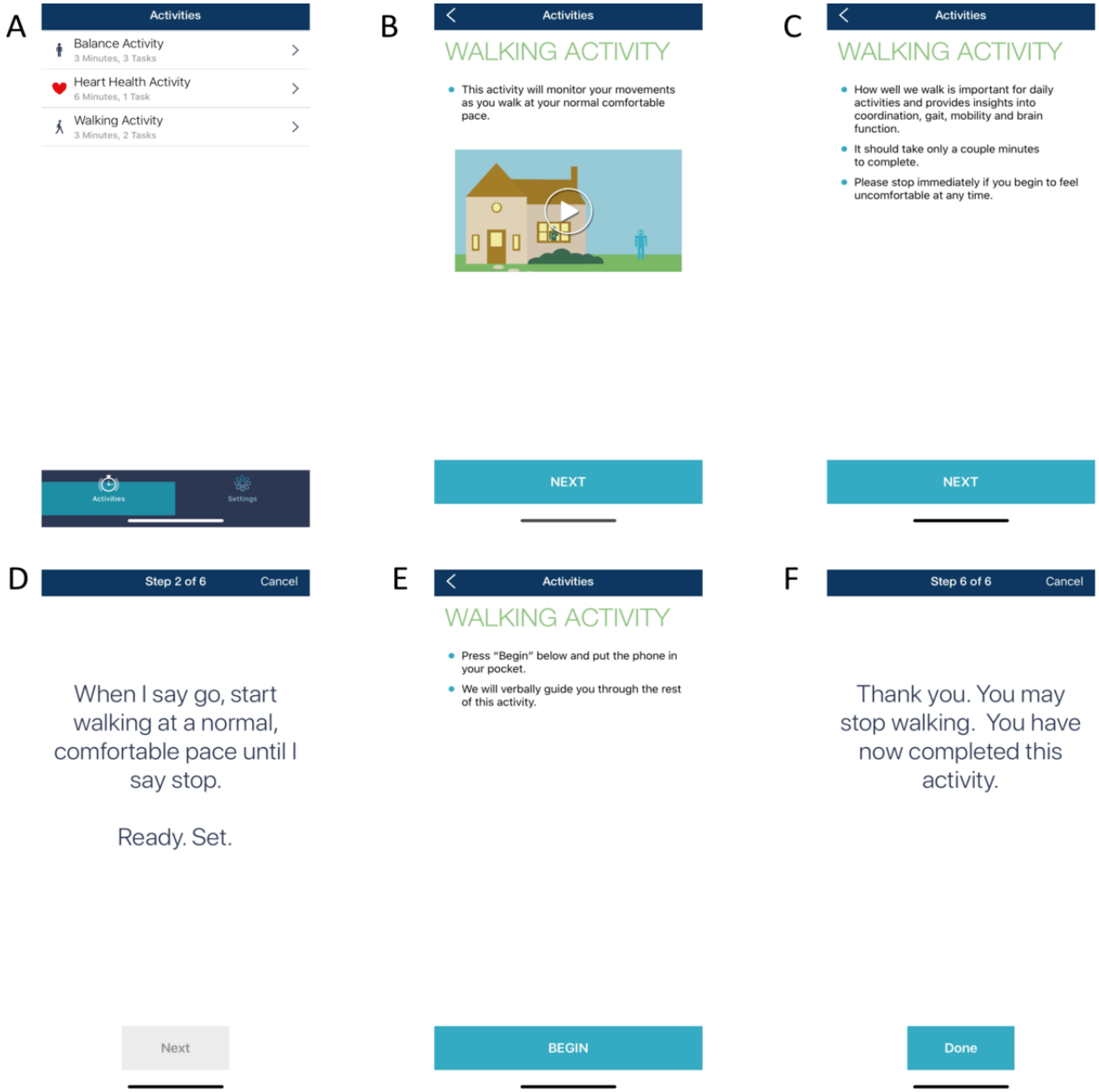
adults, has been previously reported [17]. The previous validation study demonstrated that the app and customized-designed analytic approach can effectively quantify the stride time and stride time variability of gait during both single- and dual-task walking conditions as accurately as gold-standard laboratory instrumentation. The app-based assessment starts with an animated movie that provides a general overview of the assessment (developed by Wondros Inc, Los Angeles, CA), followed by several on-screen text step-by-step instructions. After watching the animation and reading the text instructions, participants press "Begin" and are instructed to place the phone into the pocket of their pants or shorts. The phone speaker then provides voice instructions and cues, guiding the participant through a 45-second trial of single-task walking and dual-task walking at their preferred speed (Figure 1). The dual-task walking involved asking the users to perform a verbalized serial subtraction of threes from a randomly generated 3-digit starting number when walking at their preferred speed. A 30-second rest between each trial was provided. Trial start and end "beep" cues triggered acquisition of the accelerometer, gyroscope, and compass data to the phone's internal storage capacity. These data were automatically uploaded via Wi-Fi or a cellular service to a cloud-based data server immediately following the test for offline analyses [17] (Figure 1).

Figure 1. Screenshots of the smartphone gait and balance assessment app. The app, consisting of automatic animated, text, and voice instructions to users can measure the standing balance, 6-minute walking, and 45-second single- and dual-task walking performance (A). Before the walking test starts, users must first watch a comprehensive animation to introduce the testing procedure (B). Then, users must read several screens of text instruction (C). After reading the instruction, they press "begin" (D) and place the phone into the pocket of their pants to initiate the test. They then complete the walking trials following voice cues (including the message shown in panel E and the random 3-digit number provided in the dual-task condition). After pressing "Done" (F), the motion data of walking captured by the smartphone are automatically uploaded to a cloud-based server for storage and offline analysis.



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Study Procedures

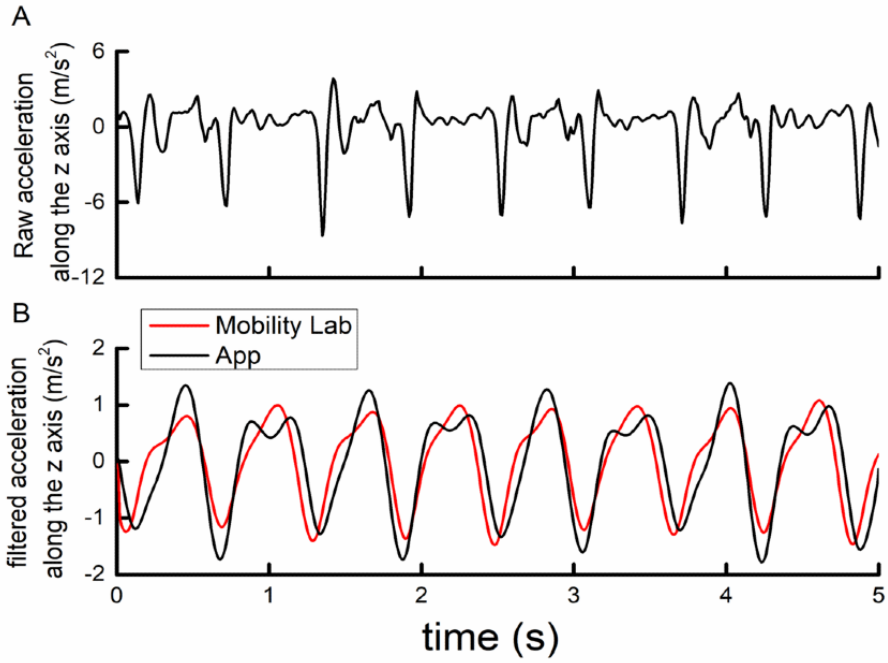
Setting and Design

All assessments were completed in the neurological clinics of Tiantan Hospital. All participants completed the tests in "medication-off" state, as defined by withholding their levodopa medication for at least 8 hours. The functional tests and clinical rating scales were completed before the walking assessment for all participants. Participants were given sufficient rest (at least 10 minutes) between each test to eliminate the effects of fatigue on test performance.

Walking Assessment

The walking assessment was completed along a straight 10-meter hallway of the hospital. Participants were instructed to wear comfortable shoes and pants or shorts with pockets. Each participant completed the app assessment twice, with each assessment entailing one trial of single-task walking and one trial of dual-task walking at the participant's preferred speed. During each trial, participants were asked to walk down the 10-meter hallway, turn 180 degrees, and walk back to the start. Therefore, the total length of straight walking in each trial was 20 meters. The trial order was randomized within each pair of trials. Participants utilized the app instructions to initiate and complete each trial. Study personnel oversaw the safety of participants without providing specific instructions. To assess the validity of gait metrics derived from the app, the Mobility Lab system (APDM, Seattle, WA), a widely used gold-standard and commercialized system of gait measurement, was also used to assess gait kinematics of each trial (Figure 2) [8]. This system consisted of three sensors: one secured over the lumbar back and two others secured to the top of each foot with Velcro straps.

Figure 2. Example of raw (A) and filtered smartphone- (black) and Mobility Lab (red)–recorded acceleration signals (B) along the Earth coordinate system vertical axis during straight walking for 5 seconds.



Unified Parkinson Disease Rating Scale Part III

The Unified Parkinson Disease Rating Scale III (UPDRS III) was completed to assess PD severity. The UPDRS III assesses multiple aspects of function, including mental and mood function, motor control, activities of daily living, and complications of therapy. The total score of UPDRS III, ranging from 0 to 28, was used in the analysis, with greater scores reflecting more severe PD.

Montreal Cognitive Assessment

The Montreal Cognitive Assessment (MoCA) was used to examine global cognitive function, including visuospatial, executive function, attention/working memory, episodic memory, and language. The MoCA total score, which ranges from 0 to 30, was used for analysis, with lower scores reflecting worse cognitive function.

Hamilton Anxiety and Depression Rating Scales

Participants completed the Hamilton Anxiety (HAM-A) [18] and Hamilton Depression (HAM-D) [19] scales to assess their mood. HAM-A consists of 14 items assessing symptoms related to anxiety and HAM-D consists of 21 items (17 of them used in this study) assessing symptoms related to depression. Each item of HAM-A was scored between 0 (ie, not present) and 4 (severe), with a total range of 0 to 56. Nine items in HAM-D were scored between 0 and 4 and the other eight were scored between 0 and 2, with a range between 0 and 52. The total scores of HAM-A and HAM-D were used in the subsequent analysis, with greater scores reflecting more severe anxiety or depression.

Analysis of Gait Metrics

The pipeline of signal processing and data analysis was described in our previous paper [17]. Briefly, kinematic data related to gait (ie, the acceleration and angular velocity time series) were captured by the accelerometer and gyroscope within

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the IMU of the smartphone and from the IMUs within the Mobility Lab sensors at a sampling frequency of 100 Hz. The raw 3D acceleration and angular velocity time series captured by the app were then each transformed from the device coordinate to an Earth-based coordinate system using the quaternion rotation matrix [20]. By doing so, the *Z*-axis was thus approximately vertical to the ground, regardless of the orientation of the phone placed in the pocket (Figure 2A). Each rotated time series was then filtered using a low-pass Butterworth filter with a cut-off frequency of 3 Hz. These filtered time series, containing peaks that oscillated with different amplitudes, aligned with the time series recorded by the Mobility Lab system very well (Figure 2B). Turns of 180 degrees were automatically detected and removed from the analysis as described previously [17], so that gait was only analyzed during periods of straight-line walking. We then identified each heel strike and toe-off of the phone-side leg, which we previously determined to correspond with the trough nadir following each relatively high peak and the trough nadir following each relatively low peak [17].

Finally, stride time and stride time variability were calculated for each trial. Stride time is typically defined as the time between two consecutive heel strikes of one foot, and thus relates to one complete gait cycle. Stride time variability is defined using the ratio of the SD of the stride times to the mean stride time within each walking trial. Longer stride time and greater stride time variability within a given walking condition (ie, single or dual task) have each been associated with aging [21], incidence of movement disorders (including PD) [22], the development of falls [3], and even the likelihood of future cognitive decline [23]. We also calculated the dual-task "costs" to stride time and stride time variability as the percent change of each metric from the single- to dual-task walking condition. A greater dual-task cost reflected a greater dual-task decrement in walking performance. The averaged stride time, stride time variability, and dual-task cost across two trials for each participant were then used in the following analyses.

Similar gait metrics were derived from the Mobility Lab data using the software platform provided with the system.

Statistical Analysis

Statistical analyses were performed using JMP Pro 14 software (SAS Institute, Cary, NC). The significance level was set to $P<.05$ for all analyses.

We examined the validity of app-derived stride time and stride time variability by assessing the correlation between app-derived metrics and the corresponding metrics derived from the Mobility Lab system using Pearson correlation analysis. The validity in single- and dual-task walking conditions was examined in separate models. We also calculated the absolute difference between the metrics measured by the app and by Mobility Lab. In addition, we examined the effects of task condition on stride time and stride time variability in separate two-way analysis of variance (ANOVA) models. The model factor was the task condition (ie, single and dual task), and the dependent variables were the stride time and stride time variability in each model, respectively. Each of these ANOVA models was adjusted for age, sex, and years of formal education.

Linear regression models were then used to examine the relationships between gait metrics measured by the app and scores of the UPDRS III, MoCA, HAM-A, and HAM-D scales. Age, sex, and years of formal education were included as covariates in each model.

Results

Participant Characteristics

Participants ranged in age from 40 to 83 years. No adverse events or safety issues were reported during the study. Each participant successfully completed the walking trials following the instructions provided by the app with no difficulty. Table 1 shows the demographic, clinical, and functional characteristics, and app-measured gait metrics of participants. Compared to the single-task condition, the stride time ($F_{1,103}$=14.1, $P<.001$) and stride time variability ($F_{1,103}$=6.8, P=.008) of gait in the dual-task condition were significantly larger, indicating significant "interference" from the concurrent serial subtraction task on locomotor control. Each of these results was independent of covariance associated with age, sex, and education ($F_{1,103}<1.3$, $P>.66$).

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Table 1. Participants characteristics (N=52).

Demographics and gait metrics	Value
Female, n (%)	19 (37)
Age (years), mean (SD)	63 (10)
Education (years), mean (SD)	11 (3)
Height (m), mean (SD)	1.7 (0.9)
Body mass (kg), mean (SD)	70 (21)
Duration of Parkinson disease (years), mean (SD)	6.4 (3.8)
UPDRS III[a]	38.3 (15.1)
MoCA[b], mean (SD)	22 (4)
HAM-A[c], mean (SD)	11.8 (4)
HAM-D[d], mean (SD)	11.1 (5.1)
Stride time, mean (SD)	
single task (s)	1.09 (0.08)
dual task (s)	1.17 (0.12)
DTC[e] (%)	2.7 (6)
Stride time variability[f], mean (SD)	
single task (%)	40 (22)
dual task (%)	63 (19)
DTC (%)	5.1 (39.4)

[a]UPDRS III: Unified Parkinson Disease Rating Scale III.
[b]MoCA: Montreal Cognitive Assessment.
[c]HAM-A: Hamilton Anxiety Scale.
[d]HAM-D: Hamilton Depression Scale.
[e]DTC: dual task cost.
[f]Ratio of the SD to the mean of stride time.

Validity and Variability of App-Derived Stride Time

The average number of identified strides during the 20-meter straight-walking trials was 9.5 (SD 1.5). The absolute difference between the app and Mobility Lab measures was quite small (Table 2). Pearson correlation analysis revealed that app-derived stride time was strongly correlated with that derived from Mobility Lab under both the single-task (r=0.99, P<.001) and dual-task (r=0.99, P<.001) conditions (Figure 3A). Moreover, the app-derived stride time variability was strongly correlated with that derived from Mobility Lab in both single-task (r=0.99, P<.001) and dual-task (r=0.98, P<.001) conditions (Figure 3B). Taken together, the stride time and stride time variability derived from the app demonstrated excellent validity as compared with those derived from Mobility Lab for gait assessment in people with PD.

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Figure 3. Correlation between stride time (A) and stride time variability (B) as measured by the app (x-axis) and the Mobility Lab system (y-axis) for each participant.

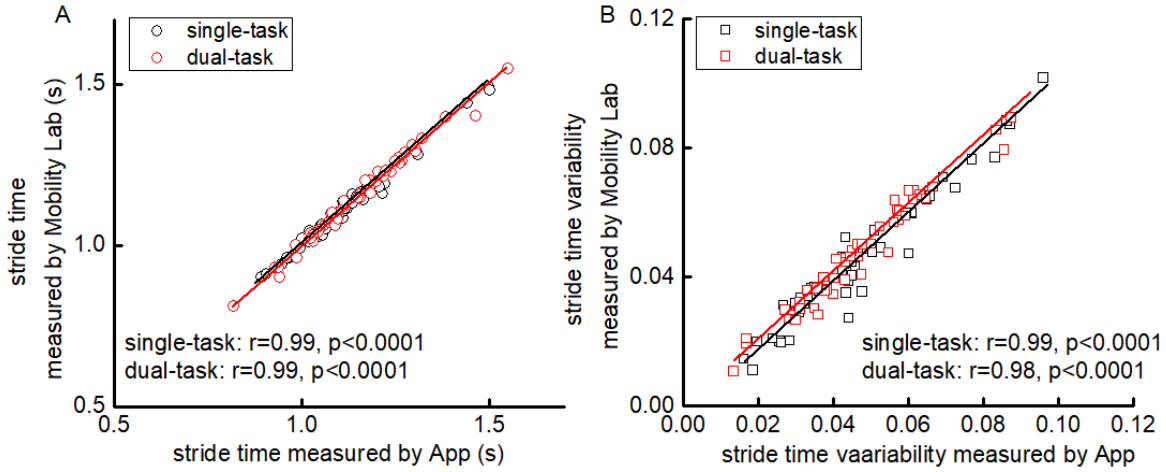


Table 2. Absolute difference between gait metrics derived from the app and Mobility Lab data.

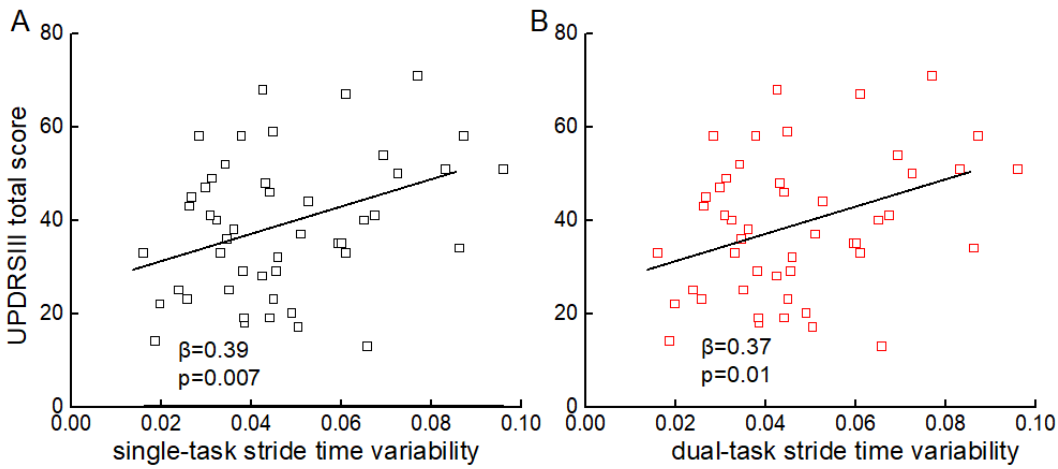
Condition	Stride time (seconds), mean (SD)	Stride time variation (seconds), mean (SD)
Single task	0.01 (0.008)	0.003 (0.003)
Dual task	0.01 (0.009)	0.002 (0.002)

Relationship of App-Derived Gait Metrics With Clinical and Functional Status

UPDRS-III

Linear regression models adjusted for age, sex, and duration of formal education demonstrated that the stride time variability of both single-task (β=.39, *P*<.001) and dual-task (β=.37, *P*=.01) walking was significantly correlated with the UPDRS-III total score (Figure 4). Participants with greater stride time variability tended to exhibit more severe PD as measured by the UPDRS III. No significant correlations were observed between other gait metrics (stride time in either condition, dual-task cost to stride time or stride time variability) and the UPDRS-III score (β=.12 to.21, *P*=.18 to .34).

Figure 4. Association between single- (A) and dual-task (B) stride time variability and total score of Unified Parkinson Disease Rating Scale III (UPDRS III).



MoCA

Linear regression models revealed that the stride time variability of dual-task walking (β=.48, *P*=.001) and the dual-task cost to stride time variability (β=.44, *P*=.004) were each correlated with the MoCA score. Participants with greater stride time variability in dual-task walking or greater dual-task cost had lower MoCA scores (ie, worse cognitive function). No such association was observed between other gait metrics and this measure of global cognitive function (β=.06 to .12, *P*=.42 to .53).

HAM-A and HAM-D

Stride time variability of both single- and dual-task walking was significantly correlated with HAM-A (single task: β=.49, *P*=.007; dual task: β=.48, *P*=.009) and HAM-D (single task:

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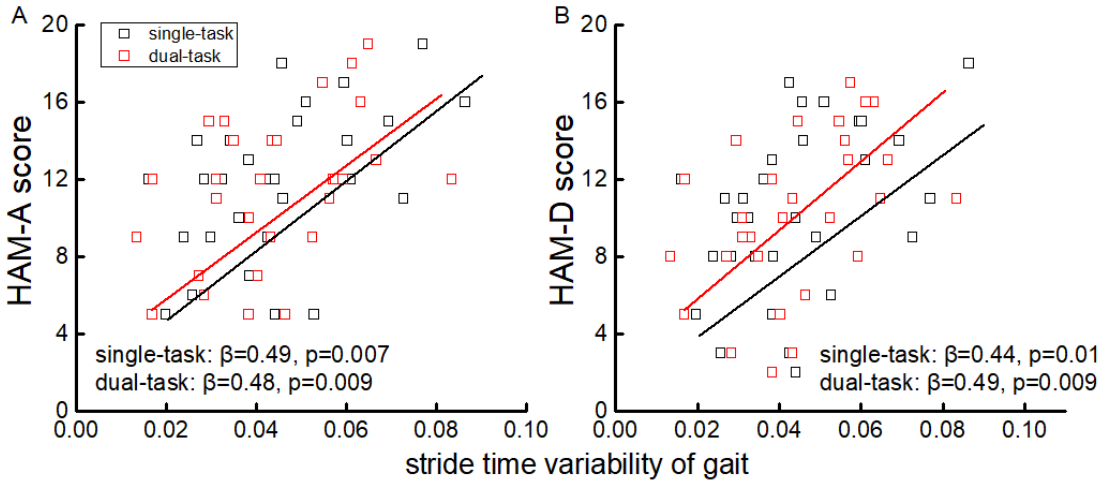
β=.44, *P*=.01; dual task: β=.49, *P*=.009). In each case, participants with greater stride time variability reported worse anxiety and more severe depressive symptoms (Figure 5).

Figure 5. Association between single- and dual- task stride time variability and the score of the Hamilton Anxiety (HAM-A) (A) and Hamilton Depression (HAM-D) (B) scales. Greater scores reflect a worse mood status.



Discussion

This study provides a proof of concept that patients with PD can use a smartphone app by themselves to accurately assess gait during both single-task and cognitive dual-task walking conditions, with the phone placed in the front pocket of the pants or shorts. Moreover, gait metrics derived from app data, particularly under the dual-task condition, were associated with several important functional and clinical rating scales in PD. Such information may thus be used to help assess PD severity, its functional impact, and potentially the effectiveness of medication or other clinical interventions within this vulnerable population.

Typically, gait assessments are performed with low frequency (ie, only during in-person clinical visits, or only before and after a study intervention). However, recent studies have demonstrated that even within an individual, the characteristics of walking vary considerably within and between days. Such variance in function has been associated with multiple important outcomes [24-28]. For example, Leach et al [27] demonstrated that older adults with greater day-to-day variance in standing balance had lower cognitive function. Albrecht et al [28] reported that a single measurement of walking performance may cause misinterpretation of functional status in patients with multiple sclerosis due to the high day-to-day variance in gait. It is thus important to characterize gait with sufficiently high frequency. In-person assessments that require specialized equipment and trained personnel to administer tests do not lend themselves well to high-frequency monitoring [29-32]. The smartphone app-based gait measurement used in this study does not require specialized equipment beyond a smartphone and does not need trained personnel to administer the test. It also automatically uploads and stores acquired data via Wi-Fi or a cellular service, and is thus highly portable. Taken together, the app may therefore serve as an easy-to-use, widely accessible, and cost-effective tool for high-frequency assessment of gait within both laboratory and nonlaboratory settings.

Walking in everyday life often requires simultaneous performance of additional cognitive tasks such as speaking to others, thinking of questions, or reading signs in the environment. This dual tasking disrupts the performance of one or both tasks. Consistent with previous studies [17,33], we observed that in people with PD, gait is more unstable (ie, greater stride time variability) when dual tasking as compared to when walking quietly, revealing that the performance of the concurrent cognitive serial-subtraction task alters locomotor control. Mounting evidence has shown that walking performance in the dual-task condition can be used to characterize an individual's capacity of cognitive-motor control, and can predict both fall risk and the incidence of dementia in older adults [34,35]. Consistent with these results, we observed that the stride time variability of gait in the dual-task condition and the dual-task cost to this metric were cross-sectionally associated with the severity of PD as assessed by the total score of UPDRS-III, the general cognitive function as measured by the MoCA score, and mood problems (ie, anxiety and depression as assessed by the HAM-A and HAM-D rating scales, respectively) in this cohort. Recent research efforts have provided evidence that gait and other movement disorders in PD, including freezing of gait (FOG), are not only motor issues, but arise in part because of deficits in cognitive functioning [36-40]. For example, Amboni and colleagues [39] observed that compared to those without FOG, participants with PD and FOG had significantly poorer performance of cognitive tasks, including frontal assessment battery, verbal fluency, and the 10-point clock test [39]. Therefore, the assessment of dual-task gait in PD promises to help the characterization of cognitive-motor functioning as it relates to gait and mobility in this population.

This study demonstrated the feasibility of using a smartphone app for gait assessment in PD, as well as the validity of app-derived gait metrics within this population. Several participants in this study had mild-to-moderate cognitive impairment as assessed by the MoCA (the mean score was 22)

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and all of the participants successfully completed the test without any reported difficulties. Future development and testing is nevertheless needed to optimize the design of the app for use in patients with PD that have more severe cognitive impairment, as well as for those with other comorbidities (eg, diabetes mellitus, cardiovascular disease, chronic pain), and those with limited vision, hearing loss, tremor, or other issues that may hinder the ability to interact with the smartphone. In this study, the association between gait metrics and functional characteristics was assessed cross-sectionally, and gait metrics were only assessed in person within the clinical setting. Future work is thus warranted to establish the usefulness of regular, smartphone-based gait assessments captured from remote settings (ie, patient homes). Work focused on remote assessment is of particular importance during the current COVID-19 pandemic as it promises to help maintain quality of care while reducing the spread of infectious disease. The usefulness of the app is also likely to be further optimized by validating other clinically meaningful metrics of gait (eg, gait speed and the asymmetry of gait); characterizing gait during turning [41]; detecting FOG, festination, or other movement abnormalities that may occur during walking; enabling the passive monitoring of gait throughout the day; and implementing other types of cognitive tasks (eg, auditory wording task [42]) into the dual-task walking paradigm.

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Conflicts of Interest

None declared.

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Abbreviations

ANOVA: analysis of variance
FOG: freezing of gait
HAM-A: Hamilton Anxiety Scale
HAM-D: Hamilton Depression Scale
IMU: inertial measurement unit
MoCA: Montreal Cognitive Assessment
PD: Parkinson disease
UPDRS III: Unified Parkinson Disease Rating Scale III

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Original Paper

Malay Version of the mHealth App Usability Questionnaire (M-MAUQ): Translation, Adaptation, and Validation Study

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Abstract

Background: Mobile health (mHealth) apps play an important role in delivering education, providing advice on treatment, and monitoring patients' health. Good usability of mHealth apps is essential to achieve the objectives of mHealth apps efficiently. To date, there are questionnaires available to assess the general system usability but not explicitly tailored to precisely assess the usability of mHealth apps. Hence, the mHealth App Usability Questionnaire (MAUQ) was developed with 4 versions according to the type of app (interactive or standalone) and according to the target user (patient or provider). Standalone MAUQ for patients comprises 3 subscales, which are ease of use, interface and satisfaction, and usefulness.

Objective: This study aimed to translate and validate the English version of MAUQ (standalone for patients) into a Malay version of MAUQ (M-MAUQ) for mHealth app research and usage in future in Malaysia.

Methods: Forward and backward translation and harmonization of M-MAUQ were conducted by Malay native speakers who also spoke English as their second language. The process began with a forward translation by 2 independent translators followed by harmonization to produce an initial translated version of M-MAUQ. Next, the forward translation was continued by another 2 translators who had never seen the original MAUQ. Lastly, harmonization was conducted among the committee members to resolve any ambiguity and inconsistency in the words and sentences of the items derived with the prefinal adapted questionnaire. Subsequently, content and face validations were performed with 10 experts and 10 target users, respectively. Modified kappa statistic was used to determine the interrater agreement among the raters. The reliability of the M-MAUQ was assessed by 51 healthy young adult mobile phone users. Participants needed to install the MyFitnessPal app and use it for 2 days for familiarization before completing the designated task and answer the M-MAUQ. The MyFitnessPal app was selected because it is one among the most popular installed mHealth apps globally available for iPhone and Android users and represents a standalone mHealth app.

Results: The content validity index for the relevancy and clarity of M-MAUQ were determined to be 0.983 and 0.944, respectively, which indicated good relevancy and clarity. The face validity index for understandability was 0.961, which indicated that users understood the M-MAUQ. The kappa statistic for every item in M-MAUQ indicated excellent agreement between the raters (κ ranging from 0.76 to 1.09). The Cronbach α for 18 items was .946, which also indicated good reliability in assessing the usability of the mHealth app.

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Conclusions: The M-MAUQ fulfilled the validation criteria as it revealed good reliability and validity similar to the original version. M-MAUQ can be used to assess the usability of mHealth apps in Malay in the future.

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KEYWORDS

mHealth app; questionnaire validation; questionnaire translation; Malay MAUQ; usability; mHealth; education; usability; Malay language; Malay; questionnaire; mobile phone

Introduction

Mobile health (mHealth) plays a vital role in delivering health education and disease management advice and in monitoring patients' health in many ways [1,2]. mHealth development is beneficial not only for populations with diseases but also for active individuals, athletes, and older adults [3-6]. The 2 main factors that influence the effective use of mHealth apps for self-care are perceived usefulness and ease of use [7]. Well-designed mHealth apps have proved their cost-effectiveness by educating and empowering patients as well as by improving the medication adherence of patients [8-10]. However, reviews have shown that there is insufficient evidence for the quality of mHealth apps.

The target users of mHealth apps can be categorized into either patients or health care providers. mHealth apps for patients are specifically designed for those who intend to manage their health, for example, health behaviors, while mHealth apps for health care providers are developed for delivering health care services, for example, medication prescription, laboratory orders, consultation, and patient education [11]. Some terms need to be customizable in the usability questionnaire to represent specific target users of mHealth devices. In addition to categorization according to target users, mHealth apps can be categorized according to interactive functions, that is, interactive mHealth app or standalone mHealth app [11]. Interactive mHealth apps enable users to send and receive information from their health care providers. Patient-provider communication can be synchronous or asynchronous. Standalone mHealth apps contain reminders or progress charts that collect health or activity information; however, the data are not shared with the health care providers immediately. Therefore, there are limited interactions in standalone mHealth apps [11].

Any mobile app should be designed with good usability or the app should be easy to use without errors and be able to achieve its objectives effectively. The characteristics of good usability are (1) efficiency: the comprehensiveness of a product enables users to achieve their goals, (2) satisfaction: users have positive feedback about the product, (3) learnability: the product is easy to learn, (4) memorability: the usage mechanism of the product or the system is easy to remember even after the users have not been using it for a while, and (5) low error rate: low errors can prevent disasters [12,13]. However, the above usability characteristics are not specific to mHealth apps because of several phone issues, for example, small screen or screen overload [14].

A new usability model has been proposed to enhance the framework within the context of mobile apps and it is called PACMAD (People At the Centre of Mobile App Development) [15]. This model identifies 3 factors that should be considered when evaluating usability: (1) user, (2) task, and (3) context of use that can affect the overall usability of a mobile app [15]. The added element of "cognitive load" in PACMAD assesses the user ability to perform additional tasks, for example, exercise while using the mobile device [15]. Therefore, usability should be based on effectiveness, efficiency, satisfaction, learnability, memorability, and cognitive load with very minimal errors [15].

Several usability scales have been evaluated based on the importance of usability in developing mobile apps. The mobile app rating scale and the user version of the mobile app rating scale include some usability components to assess the quality of mobile apps [16,17]. However, they does not assess the usability by the end user and they have a broader scope [16,17]. Taking this into consideration, mobile apps that are intended for health purposes (mHealth apps) should be assessed with a more appropriate usability questionnaire. Therefore, a new usability scale called the mHealth App Usability Questionnaire (MAUQ) was developed [18]. This MAUQ can assess the ease of use, interface, satisfaction, and the usefulness of mHealth apps to the end users (either patients or health care providers) and the type of interaction between the patients and health care providers (standalone or interactive).

To the best of our knowledge, only 1 study has reported the usability of a Malay-translated mobile app [19]. However, the questionnaire used was the system usability scale questionnaire, which caters to general software systems. As more health interventions using mobile apps are being developed, this study aims to translate and validate a Malay version of MAUQ for future mHealth app research and usage.

Methods

Overview of the Questionnaire

The English version of MAUQ was developed and validated by Zhou and his team [11]. The aim of MAUQ was to assess the usability of mHealth apps among patients and health care providers. MAUQ has 4 versions assessing the type of app (interactive or standalone) and the target users of the app (patient or health care provider). For this study, "MAUQ standalone used by the patient" was used. The patient refers to a person who uses an mHealth app to maintain, improve, or manage his/her health. The questionnaire consists of 3 subscales, which are ease of use (5 items), interface and satisfaction (7 items), and usefulness (6 items). Participants rate each of the items using a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). The usability of the app is determined by the total and average of all statements—the higher the overall

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average, the better the usability of the app. However, if the average score is lower than 4, it means that the usability of the app is not good. MAUQ standalone used by patients had strong internal consistency with an overall Cronbach α value of .914 [18]. This study was conducted from April to August 2020.

Translation and Adaptation Process

The original MAUQ standalone questionnaire was translated into Malay using the guidelines for health care translation and cross-cultural adaptation to achieve equivalence between the original and the translated version [20]. First, the forward translation process (from English to Malay) was conducted by 2 independent certified translators who knew the Malaysian culture and linguistics; 1 translator was specialized in the computer science field while the other was specialized in health sciences. Thus, 2 independent documents (F1 and F2) were produced. Second, the documents (F1 and F2) underwent harmonization. In this process, a third translator was appointed (in this step, we used a Malay language teacher with teaching experience of more than 5 years) to identify any ambiguities and discrepancies in the words, sentences, grammar, and meaning by comparing between F1 and F2 and between the original MAUQ and both F1 and F2. The discrepancies and ambiguities were discussed and resolved through consensus decision making by the third translator, the first 2 translators, and 2 members of the research team (NM and AJ) to produce an initial translated version of the MAUQ document (H1). Third, the translated version of the MAUQ (H1) was given to 2 independent native Malay speakers who spoke English as their second language. One was the content expert of the build instrument (computer science lecturer) while the other one did not know the instrument construct (English language teacher). Both had never seen the original version of MAUQ. They produced 2 independent documents of the back-translated version of MAUQ (B1 and B2). Fourth, a committee was approached to compare the documents with the original MAUQ. This committee comprised of 2 researchers (NM and AJ), translators in the first and third steps, and the original developer of MAUQ. The discussion among the committee members was conducted through emails and web-based meetings using the Google meet platform. Any ambiguity and inconsistency in the cultural meaning and expression of the words and sentences of the items and answer format were addressed and resolved through consensus among committee members to derive the prefinal adapted questionnaire. This adapted questionnaire was called the Malay version of the mHealth Usability Questionnaire (M-MAUQ).

Validation of the Questionnaire

The M-MAUQ underwent a process of validation that consisted of content validity, face validity, and reliability (internal consistency). Content validation aimed to evaluate the relevancy of the items in each domain and the clarity of the translated item to assess the usability of mobile apps related to health. The 10 experts who conducted content validation of the M-MAUQ were 4 mobile app developers, 3 PhD senior lecturers in computer science and information technology, and 3 health-related practitioners. They were asked to give a score of 1 (item not relevant/clear) to 4 (item very relevant/clear). The establishment of content validity was represented by the content validity index value in the form of item-level content validity index and overall-scale content validity index. Before content validity index was calculated, scores of 3 and 4 were recategorized as 1 (relevant/clear) and scores of 1 and 2 as 0 (not relevant /not clear). Next, the number of experts in agreement (relevant/clear) was divided by the total number of experts. The items that had content validity index of at least 0.79 indicated that the item was relevant to the domain, clear, and comprehensible to the target users [21].

Face validation testing, which aims to assess the clarity and comprehensibility of the translated items, was conducted by 10 target users. The users were asked to give scores from 1 (item not understandable) to 4 (item very understandable) based on the understandability of the translated items in M-MAUQ. Scores of 3 and 4 were recategorized as 1 (understandable) and scores of 1 and 2 as 0 (not understandable). The face validity index was computed by calculating the scale average. They highlighted the words that they could not understand. The interrater agreement among the 10 experts and the 10 target users was determined using the modified kappa statistic. The probability of chance agreement (Pc) was first determined for each item using the following formula:

$$Pc = [(N!/A!)\ (N–A)!] * 0.5^N$$

In this formula, N is the number of raters (experts/target user) and A is the number of experts/target users who agree that the item was clear or relevant or understandable [21]. Next, kappa was determined using the following formula:

$$\kappa = (\text{item-level content validity index} – Pc) / (1 – Pc)$$

The kappa formula was computed using Microsoft Excel, with a value above 0.74 considered as excellent, 0.60 to 0.74 as good, and 0.54 to 0.59 as fair [21]. For reliability testing, a sample size of 38 participants was calculated, with an expected Cronbach α of .80 and an expected precision of 0.1 at 95% CI [22]. With an expected dropout rate of 20% taken into account, the final sample size calculated was 48 [22].

Participants were recruited among students in the International Islamic University of Malaysia, Kuantan Campus through invitation using the WhatsApp group by student representatives. The student representative contact was obtained with his/her permission from the department administrative office. Participants interested in joining the study were given a link to a new WhatsApp group where further instructions were provided. A web-based consent form and the flow of the study were shared to the WhatsApp group. Participants who agreed to join had to complete the web-based informed consent form. The inclusion criteria of the participants were (1) no known medical illness and (2) owned a smartphone. They were asked to install the MyFitnessPal app on their mobile phone and use it multiple times for 2 days before the session in order to be familiar with the features. The MyFitnessPal app was selected for the usability study because it is among the most popular installed mHealth apps globally; it has been used in most studies and is available for Android and iPhone users [23,24]. Moreover, the MyFitnessPal app is considered a standalone mHealth app.

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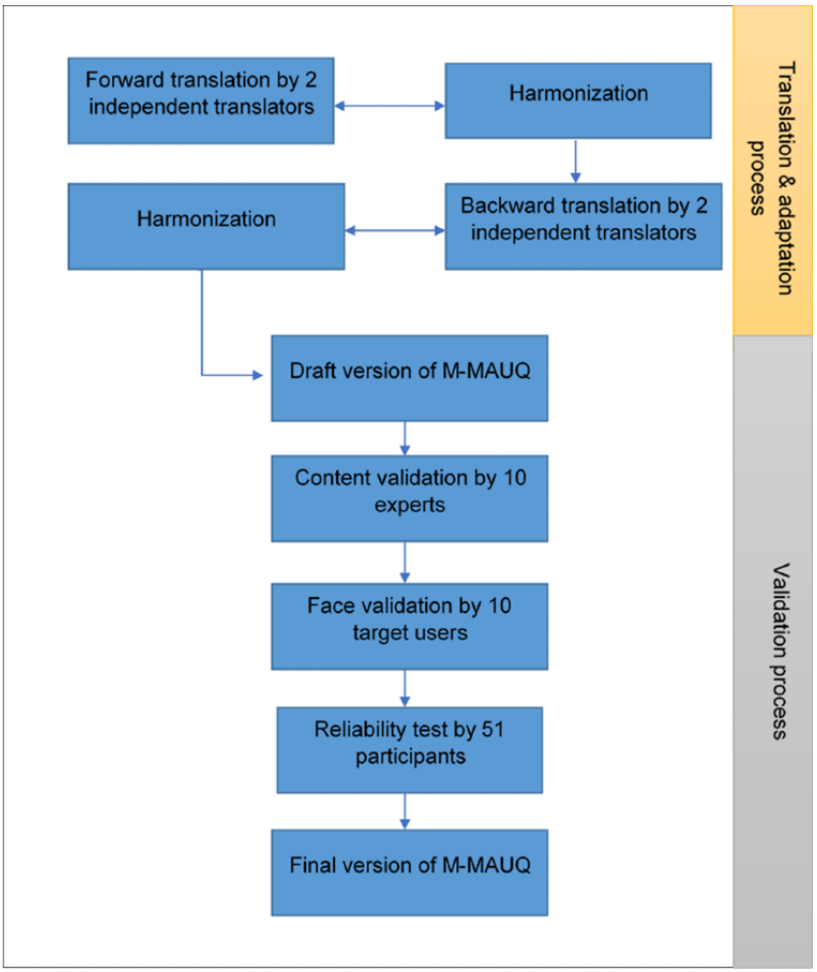
A general introduction and a brief demo of the MyFitnessPal app was provided on the Google meet platform. When using the MyFitnessPal app, participants were asked to finish the following tasks: (1) create own profile and determine their weight goals, (2) identify their remaining calories for that day, which included calorie goals, calories in (food), and calories out (exercise), (3) use diary features to add new records about food eaten and water consumed on that day and view the total nutrient intake (macronutrient and micronutrient), and (4) explore health-related and nutrition-related articles, recipes, and plan features. After finishing the tasks, participants were asked to answer the M-MAUQ. Web-based data were collected due to the current COVID-19 pandemic, because mass gathering was not recommended. The internal consistency of M-MAUQ was evaluated by calculating the Cronbach α value for the entire questionnaire and its subscale. Higher α value suggests greater internal reliability and more than .70 is acceptable as good internal reliability [25].

The validation tests performed on M-MAUQ were conducted using a web-based Google form, where the link was sent to each participant via personal WhatsApp (for the content and face validity test) or group WhatsApp (for the reliability test) to facilitate data collection. Figure 1 illustrates the overview of the flow of the translation and adaptation process, together with the validity process. All statistical analyses were performed using SPSS statistics version 23 (IBM Corp). This study obtained ethical approval from the UKM Research Ethics Committee (Ref No. UKM PPI/111/8/ JEP-2019-008) and was funded by the National Sports Institute of Malaysia (Grant code: NN-2018-093).

Figure 1. The flow of translation, cross-cultural adaptation, and validation process for the Malay version of the mHealth App Usability Questionnaire (M-MAUQ).



Results

The content validity index for the relevancy (Table 1) and clarity (Table 2) of M-MAUQ was calculated to be 0.983 and 0.944, respectively. Meanwhile, the face validity index (Table 3) for understandability was calculated to be 0.961. The content validity index and face validity index scores above 0.79 indicate that the items in the questionnaire are relevant for domain, clarity, and understandability for the target user [26]. The modified kappa agreement for every item in M-MAUQ demonstrated excellent agreement (κ=0.76-1.09).

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Table 1. Content validity index of item relevancy and modified kappa agreement by 10 experts.

Items	Rating of 3 or 4 (n)	Rating of 1 or 2 (n)	Item-level content validity index[a]	Probability of chance occurrence[b]	Modified kappa[c]	Interpretation
1	10	0	1.000	0.001	1.000	Excellent
2	10	0	1.000	0.001	1.000	Excellent
3	10	0	1.000	0.001	1.000	Excellent
4	9	1	0.900	0.010	0.899	Excellent
5	10	0	1.000	0.001	1.000	Excellent
6	10	0	1.000	0.001	1.000	Excellent
7	10	0	1.000	0.001	1.000	Excellent
8	10	0	1.000	0.001	1.000	Excellent
9	10	0	1.000	0.001	1.000	Excellent
10	9	1	0.900	0.010	0.899	Excellent
11	10	0	1.000	0.001	1.000	Excellent
12	10	0	1.000	0.001	1.000	Excellent
13	10	0	1.000	0.001	1.000	Excellent
14	10	0	1.000	0.001	1.000	Excellent
15	10	0	1.000	0.001	1.000	Excellent
16	10	0	1.000	0.001	1.000	Excellent
17	9	1	0.900	0.010	0.899	Excellent
18	10	0	1.000	0.001	1.000	Excellent

[a]Overall-scale content validity index=0.983.

[b]Computed using the formula: $Pc = [(N!/A!)(N–A)!] * 0.5^N$, where Pc=probability of chance occurrence, N=number of experts, and A=number of experts who agree the items are relevant.

[c]Computed using the formula: κ = (item-level content validity index – Pc) / (1–Pc), where Pc=probability of chance occurrence. The interpretation criteria for kappa were as follows: Excellent=$\kappa>0.7$, Good=$0.6\leq\kappa\leq0.74$, and Fair=$0.40\leq\kappa\leq0.59$.

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Table 2. Content validity index of item clarity and modified kappa agreement by 10 experts.

Items	Rating of 3 or 4 (n)	Rating of 1 or 2 (n)	Item-level content validity index[a]	Probability of chance occurrence[b]	Modified kappa[c]	Interpretation
1	10	0	1.000	0.001	1.000	Excellent
2	10	0	1.000	0.001	1.000	Excellent
3	8	2	0.800	0.176	0.757	Excellent
4	10	0	1.000	0.001	1.000	Excellent
5	10	0	1.000	0.001	1.000	Excellent
6	9	1	0.900	0.010	0.899	Excellent
7	10	0	1.000	0.001	1.000	Excellent
8	8	2	0.800	0.176	0.757	Excellent
9	7	3	0.700	4.219	1.093	Excellent
10	9	1	0.900	0.010	0.899	Excellent
11	10	0	1.000	0.001	1.000	Excellent
12	10	0	1.000	0.001	1.000	Excellent
13	10	0	1.000	0.001	1.000	Excellent
14	10	0	1.000	0.001	1.000	Excellent
15	10	0	1.000	0.001	1.000	Excellent
16	10	0	1.000	0.001	1.000	Excellent
17	10	0	1.000	0.001	1.000	Excellent
18	9	1	0.900	0.010	0.899	Excellent

[a]Overall-scale content validity index=0.944.

[b]Computed using the formula: $Pc = [(N!/A!)(N–A)!] * 0.5^N$, where Pc=probability of chance occurrence, N=number of experts, and A=number of experts who agree the items are relevant.

[c]Computed using the formula: κ = (item-level content validity index – Pc) / (1–Pc), where Pc=probability of chance occurrence. The interpretation criteria for kappa were as follows: Excellent=$\kappa>0.7$, Good=$0.6\leq\kappa\leq0.74$, and Fair=$0.40\leq\kappa\leq0.59$.

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Table 3. Face validity index of item understandability and modified kappa agreement by 10 target users.

Items	Understand (rating of 3 or 4) (n)	Not understand (rating of 1 or 2) (n)	Item-level face validity index[a]	Probability of chance occurrence[b]	Modified kappa[c]	Interpretation
1	10	0	1.000	0.001	1.000	Excellent
2	10	0	1.000	0.001	1.000	Excellent
3	8	2	0.800	0.176	0.757	Excellent
4	9	1	0.900	0.010	0.899	Excellent
5	10	0	1.000	0.001	1.000	Excellent
6	8	2	0.800	0.176	0.757	Excellent
7	10	0	1.000	0.001	1.000	Excellent
8	10	0	1.000	0.001	1.000	Excellent
9	10	0	1.000	0.001	1.000	Excellent
10	8	2	0.800	0.176	0.757	Excellent
11	10	0	1.000	0.001	1.000	Excellent
12	10	0	1.000	0.001	1.000	Excellent
13	10	0	1.000	0.001	1.000	Excellent
14	10	0	1.000	0.001	1.000	Excellent
15	10	0	1.000	0.001	1.000	Excellent
16	10	0	1.000	0.001	1.000	Excellent
17	10	0	1.000	0.001	1.000	Excellent
18	10	0	1.000	0.001	1.000	Excellent

[a]Face validity index average for 18 items (understandability)=0.961.

[b]Computed using the formula: $Pc = [(N!/A!)\ (N–A)!] * 0.5^N$, where Pc=probability of chance occurrence, N=number of experts, and A=number of experts who agree the items are relevant.

[c]Computed using the formula: κ = (item-level content validity index – Pc) / (1–Pc), where Pc=probability of chance occurrence. The interpretation criteria for kappa were as follows: Excellent=$\kappa>0.7$, Good=$0.6\leq\kappa\leq0.74$, and Fair=$0.40\leq\kappa\leq0.59$.

Of the 59 participants, 51 (the calculated sample size was 48) signed the web-based consent form and completed the questionnaire for the reliability study. The age of the participants ranged from 22 years to 25 years, and all of them were students (females, 47/51, 92%). The mean usability score for MyFitnessPal using M-MAUQ was 0.802 (SD 0.104), which indicated good usability. The Cronbach α values for total, subscale ease of use (Q1-Q5), subscale interface and satisfaction (Q6-Q12), and subscale usefulness (Q13-Q18) were .946, .893, .942, and .742, respectively. The value of Cronbach α if an item was deleted (refer to Table 4) remained highly consistent without significant difference, indicating good internal reliability of the developed questionnaire. The final M-MAUQ can be viewed in Multimedia Appendix 1.

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Table 4. The internal consistency of the item total statistics.

Item	Scale mean if item deleted	Scale variance if item deleted	Corrected item total correlation	Cronbach α if item deleted
Q1	95.31	156.660	0.789	.941
Q2	95.12	161.866	0.761	.942
Q3	95.37	158.558	0.674	.943
Q4	95.39	160.323	0.706	.942
Q5	95.49	158.135	0.650	.944
Q6	95.41	158.487	0.795	.941
Q7	95.29	159.812	0.776	.941
Q8	95.06	160.856	0.794	.941
Q9	95.41	158.407	0.751	.941
Q10	95.31	156.900	0.825	.940
Q11	95.57	155.370	0.849	.939
Q12	95.27	159.723	0.868	.940
Q13	95.18	160.868	0.745	.942
Q14	95.10	162.570	0.759	.942
Q15	95.31	162.500	0.727	.942
Q16	95.47	161.454	0.655	.943
Q17	97.35	180.113	–0.057	.961
Q18	95.24	165.304	0.703	.943

Discussion

This study described the translation, adaptation, and validation of the English version of MAUQ into the Malay version. The results of our study revealed a high level of content validity and face validity for M-MAUQ (standalone for patients). The content validity index was high for all individual items (item-level content validity index >0.900) and for overall score (scale content validity index >0.944) in term of relevancy and clarity, which exceeded the recommended benchmark of 0.79 [21]. Moreover, our kappa statistic indicated excellent agreement between expert raters for content validity and among user raters for face validity (κ>0.77). This study also had high reliability for the total domains of M-MAUQ, with Cronbach α>.90.

A questionnaire is one of the well-known methods for usability testing [27], but developing a new one might require concerted effort by the members of a research team, extra cost, and a lot of time [19]. Thus, adaptation of established, appropriate, and available questionnaires with documented validity in other languages is recommended [19]. Appropriate translation and adaptation of an instrument are essential for ensuring the equivalence between the original and translated versions translated according to the accepted standards and at the same time being culturally and conceptually appropriate [28]. Literal translation might cause misunderstanding of the questions posed since it does not anticipate the cultural sensitivity or the cultural influence of the question. Regardless of the presence of a multi-ethnic community in Malaysia, Bahasa Malaysia or Malay is the national language, which justifies validating a Malay-translated version for MAUQ [29]. In this study, we translated, culturally adapted, and validated an 18-item questionnaire called the M-MAUQ. This study adheres to the comprehensive and detailed guidelines for the translation, adaptation, and validation process documented by Sousa and Rojjanasrirat [20], which was adopted by Marzuki et al [19]. Translating some technical words such as navigation and interphase were challenging since these words were more familiar in English than in Malay. Moreover, a direct translation of the words of “social setting” from the questionnaire might raise questions from the user regarding the meaning. Thus, the involvement of certified translators who are experts in the translated and original language is essential. Harmonization among experts is essential to ensure that the user has understood the sentence correctly. A few examples were added to make the questions more clear and discussions were held with the original authors of MAUQ to ensure the consistency of each item in both languages.

Validation is an essential process for assuring that the measures in the translated version of the questionnaire are equivalent to those of the construct of the original version. Numerous studies have established content validity by using content validity index to quantify the validity of the questionnaire [27]. Content validity index is used primarily by researchers because it is simple to measure, is understandable, provides details for each item, and can be used to modify or delete instrument items [21]. Meanwhile, face validity focused more on the appearance and the understandability of the questionnaire by the target user. The validation process involved both experts and target users to ensure that different opinions from the 2 groups could be collected and discussed, and a consensus could be reached [21]. Modified kappa informed the agreement properties among the

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raters [30], and high scores in both content validity index and face validity index suggest that M-MAUQ had been translated accurately and adopted appropriately by our local users.

The internal consistency of the questionnaire is one of the reliability components. Internal consistency was determined by calculating the Cronbach α coefficient that represents the extent to which the items are measuring the same things [31,32]. The results of the reliability of M-MAUQ were comparable to those of the English MAUQ, which was tested among 128 participants in the Greater Pittsburgh area and the Cronbach α coefficients for the 3 subscales ranged from .717 to .908 [11].

This study utilized the web-based data collection method owing to the current COVID-19 pandemic, wherein mass gathering is not encouraged. Participants were gathered through virtual meetings using the Google meet platform. Although virtual meetings offer few advantages such as flexible time schedules and flexibility in attending the meeting from each one's own comfort zone, some limitations were identified. Technical issues such as sudden internet breakdown or slowdown could have led to communication breakdown. However, participants who had problems with internet connection were contacted later in separate virtual meetings. The other limitations were as follows. First, the convenient sampling method was used, wherein participants were recruited from 1 university in the state of Pahang, Malaysia, thereby making it difficult to generalize the findings of this study to a wider population in Malaysia. Second, this research only focused on healthy young adults and the findings may not be generalizable to older adults or anyone with health-related issues. Third, additional reliability steps of test-retest would be beneficial for measuring the stability of respondent attributes.

In conclusion, our study shows that M-MAUQ has excellent validity and reliability. M-MAUQ can be used to assess the usability of mHealth apps among healthy young adults who are native Malay speakers. We suggest conducting a criterion validation study for future research [33,34] as this would be able to predict an outcome for another measure or domain of the M-MAUQ. Moreover, this questionnaire can be added in the future usability rating scale, as suggested in the Good Practice Guidelines on Health Apps and Smart Devices [35].

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Authors' Contributions

The concept for this study was designed by NM, NSS, and AJ. Data were collected by NM, AHAR, and AJ. The data were then analyzed by NM and AJ. Data interpretation and manuscript preparation were undertaken by NM, NSS, AJ, SMS. Several drafts were reviewed and commented on by NSS, SMS, AHAR, NS, and MIM.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Actual Malay version of the mHealth App Usability Questionnaire (M-MAUQ).
[PDF File (Adobe PDF File), 15 KB - mhealth_v9i2e24457_app1.pdf]

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Abbreviations

MAUQ: mHealth app usability questionnaire
mHealth: mobile health
M-MAUQ: Malay version of the mHealth app usability questionnaire
PACMAD: People at the Centre of Mobile App Development

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Original Paper

Induction of Efficacy Expectancies in an Ambulatory Smartphone-Based Digital Placebo Mental Health Intervention: Randomized Controlled Trial

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Abstract

Background: There is certain evidence on the efficacy of smartphone-based mental health interventions. However, the mechanisms of action remain unclear. Placebo effects contribute to the efficacy of face-to-face mental health interventions and may also be a potential mechanism of action in smartphone-based interventions.

Objective: This study aimed to investigate whether different types of efficacy expectancies as potential factors underlying placebo effects could be successfully induced in a smartphone-based digital placebo mental health intervention, ostensibly targeting mood and stress.

Methods: We conducted a randomized, controlled, single-blinded, superiority trial with a multi-arm parallel design. Participants underwent an Android smartphone-based digital placebo mental health intervention for 20 days. We induced prospective efficacy expectancies via initial instructions on the purpose of the intervention and retrospective efficacy expectancies via feedback on the success of the intervention at days 1, 4, 7, 10, and 13. A total of 132 healthy participants were randomized to a prospective expectancy–only condition (n=33), a retrospective expectancy–only condition (n=33), a combined expectancy condition (n=34), or a control condition (n=32). As the endpoint, we assessed changes in efficacy expectancies with the Credibility Expectancy Questionnaire, before the intervention and on days 1, 7, 14, and 20. For statistical analyses, we used a random effects model for the intention-to-treat sample, with intervention day as time variable and condition as two factors: prospective expectancy (yes vs no) and retrospective expectancy (yes vs no), allowed to vary over participant and intervention day.

Results: Credibility (β=−1.63; 95% CI −2.37 to −0.89; P<.001) and expectancy (β=−0.77; 95% CI −1.49 to −0.05; P=.04) decreased across the intervention days. For credibility and expectancy, we found significant three-way interactions: intervention day×prospective expectancy×retrospective expectancy (credibility: β=2.05; 95% CI 0.60-3.50; P=.006; expectancy: β=1.55; 95% CI 0.14-2.95; P=.03), suggesting that efficacy expectancies decreased least in the combined expectancy condition and the control condition.

Conclusions: To our knowledge, this is the first empirical study investigating whether efficacy expectancies can be successfully induced in a specifically designed placebo smartphone-based mental health intervention. Our findings may pave the way to diminish or exploit digital placebo effects and help to improve the efficacy of digital mental health interventions.

Trial Registration: Clinicaltrials.gov NCT02365220; https://clinicaltrials.gov/ct2/show/NCT02365220.

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KEYWORDS

digital placebo effect; efficacy expectancies; ecological momentary assessment; mHealth; mobile phone; placebo effect; randomized controlled trial; smartphone-based intervention

Introduction

Background

Mental disorders are highly prevalent and cause a high global burden of disease [1,2]. A large proportion of persons with mental disorders do not receive adequate treatment, among other reasons, due to the limited availability of face-to-face psychotherapy, particularly in low- and middle-income countries [3]. To address these challenges, the World Health Organization has defined research priorities to improve the lives of people with mental disorders [4]. One of these research priorities is the development of mobile and information technologies to increase access to evidence-based care. Furthermore, several people with mental disorders do not respond to traditional face-to-face psychotherapy [5]. Therefore, new forms of treatment are required [6].

Numerous health-related smartphone apps have been applied, for instance, for the prevention and treatment of depressive or anxiety disorders [7-10]. Research on the efficacy and effectiveness of these apps is only at its beginning. Recent meta-analyses of randomized controlled trials (RCTs) reported small to moderate effect sizes, suggesting that delivering psychological treatment with smartphone-based devices may be an efficacious approach to treat, for instance, anxiety and depressive symptoms [11,12]. However, there is a lack of knowledge on the potential mechanisms of change in mental health interventions delivered by smartphone apps. Firth et al [11] found that effect sizes of smartphone interventions were smaller in studies with active control conditions, as compared with waitlist or inactive controls, suggesting that the use of a smartphone itself may provide psychological benefit. In this regard, Torous and Firth [13] considered the consequences of a potential placebo effect and introduced the concept of a digital placebo effect, defined as "placebo-like effects seen from mobile health interventions, such as smartphone apps."

The placebo effect is understood as a range of positive changes occurring after patients have been provided with an inert or inactive treatment [14]. Traditionally, placebo effects have been discussed in the field of blinded RCTs in which study participants in a control group received placebos in the form of inert pills or sham procedures. Active treatments need to outperform placebos in RCTs to be considered effective. In this context, placebo effects should be minimized to ensure a valid investigation of the drug's efficacy [15].

An important factor underlying placebo effects are outcome expectancies of patients, which means that a therapeutic intervention can produce a placebo effect because the person receiving the treatment believes it will have an effect [14,16]. Previous studies found positive associations between favorable outcome expectancies of patients and positive therapeutic effects for a wide range of medical conditions and mental disorders, such as Parkinson disease, hypertension, depression, anxiety, and pain [16-20]. Accordingly, some authors claimed that placebo effects should be maximized to improve treatment outcomes by enhancing patients' expectancies [15,20]. Gruszka et al [21] stated that despite its therapeutic potential, the validation of efficacy of placebo interventions, such as expectancy interventions, has been neglected. Mobile apps provide a novel approach to provide highly standardized expectancy interventions in a blinded manner and have several advantages for investigating expectancy interventions [21].

In summary, there is an urgent need to (1) further scrutinize smartphone-based mental health interventions in the context of the World Health Organization grand challenge on the development of mobile and information technologies to increase access to evidence-based care; (2) explore potential mechanisms of change underlying smartphone-based mental health interventions that are already widespread but are not validated; and (3) scrutinize and exploit efficacy expectancies as a potential factor underlying placebo effects, using smartphone-based interventions with respect to their methodological advantages.

Objectives

Previous studies in the context of digital placebo effects introduced the concept [13], focused on methodological recommendations for RCTs of smartphone-based interventions [21,22], or used a sham version of an active app as control condition [23]. However, to the best of our knowledge, no study has investigated efficacy expectancies as a potential mechanism of the digital placebo effect in a particularly designed inert smartphone-based mental health intervention. Therefore, the aim of our study is to investigate whether efficacy expectancies could be successfully induced in a smartphone-based placebo mental health intervention. We designed a smartphone-based placebo mental health intervention that lasted 20 consecutive days and induced different efficacy expectancies regarding the effects of the intervention on mood and stress in participants, with emotional state being associated with major depression and anxiety as the most frequent mental disorders [1,24]. We differentiated between *prospective expectancy*, which we induced at the beginning of the smartphone-based placebo mental health intervention, and *retrospective expectancy*, which we induced during several days, immediately after participants had completed the smartphone-based digital placebo mental health intervention. We hypothesized that trajectories of efficacy expectancies throughout the smartphone-based placebo mental health intervention differed between conditions. Furthermore, we hypothesized that efficacy expectancies were highest in the combined expectancy condition, followed by a comparable level in the prospective expectancy condition and the retrospective expectancy condition, and were lowest in the control condition.

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Methods

Overall Study Procedure

We report the results of a randomized, controlled, single-blinded, superiority trial with a multi-arm parallel design, registered at Clinicaltrials.gov (Identifier: NCT02365220). The aim of this larger study is to investigate the placebo effect in a smartphone-based mental health intervention. The Institutional Review Board of the Department of Psychology of the University of Basel, Switzerland, approved the study protocol (no.: 005-14-2). All participants provided written informed consent in accordance with the Declaration of Helsinki. The study was conducted between February and October 2015 at the Department of Psychology of the University of Basel, Switzerland. The study consisted of an introductory session and 20 consecutive days of ambulatory smartphone-based intervention (Multimedia Appendix 1). The data presented here were collected at the introductory session and on intervention days 1, 7, 14, and 20 when efficacy expectancies had been measured with the Credibility and Expectancy Questionnaire (CEQ; for further details see the section *Outcome Variable: Efficacy Expectancies With CEQ*).

Introductory Session

In the introductory session, we informed participants about the aim and procedure of the study and assessed inclusion criteria, sociodemographic information, and information on their general and mental health (Patient Health Questionnaire—German version [25,26] and Perceived Stress Scale—10-items version [27,28]). Irrespective of potential condition assignment, we informed all participants that in our study we would be interested in how mood and perceived stress fluctuated in daily life and whether smartphones would be suitable to assess their temporal trajectories. We instructed participants to download and install the *ohmage* app [29] from the Google Play Store on their Android-based smartphones. *Ohmage* is an open mobile system consisting of a smartphone app for self-reported data collection and a server system for web-based data storage, management, and administration. We set up and maintained our own *ohmage* server at the information technology division of the Department of Psychology.

Smartphone-Based Digital Placebo Mental Health Intervention

The second part of the study consisted of a 20-day smartphone-based ambulatory mental health intervention. Participants started with the intervention 3 days after they had attended the introductory session. The detailed procedure of each session is illustrated in Multimedia Appendix 2. The placebo mental health intervention consisted of a green picture or a mock sound, delivered in a video file on the Enterprise Feedback Suite survey, which participants accessed via their Android-based smartphones. The videos lasted for 2 minutes each and alternated daily between green color and mock sound. Regarding the mock sound, we told participants in the initial instructions that the sound would be a very soft tone acoustically not perceivable for the human ear and completely innocuous. On intervention days 1, 4, 7, 10, and 13, we asked participants to take a self-portrait with their smartphone camera within the *ohmage* app. After this second self-portrait, we provided participants with written feedback regarding the self-portrait in the *ohmage* app that we had programmed in advance. On intervention days 1, 7, 14, and 20, we asked participants to rate efficacy expectancies, measured with the CEQ (for further details see the section *Outcome Variable: Efficacy Expectancies With CEQ*).

Induction of Efficacy Expectancies

Efficacy expectancies in the 4 conditions were induced in 2 ways: (1) instructions on the purpose of the study on intervention day 1 and (2) the written feedback following the second (ie, post placebo intervention) self-portrait on intervention days 1, 7, 14, and 20. The initial instructions in our experiment served to induce prospective expectancies in participants, the feedback on the self-portraits served to induce retrospective expectancies (see Figure 1 for a fourfold table of the 4 conditions). In the control condition, on intervention day 1, participants received the same information about the purpose of the study as in the introductory session, according to which, we were interested in establishing how mood and perceived stress fluctuated in daily life and whether smartphones were suitable to assess their temporal trajectories. We did not give any explanation on the purpose of the self-portraits. After having sent the post placebo intervention self-portrait, participants received a *Thank you* message from us. In the prospective expectancy–only condition, on intervention day 1, we told participants that we were interested in whether a smartphone-based intervention lasting several weeks might have a positive effect on mood and stress perception. Moreover, we explained that previous studies had demonstrated that green light and soft tones beyond the acoustic detection threshold had positively affected the activity of certain brain regions, such as the insular lobe. We provided further details on the role of the insular lobe in the formation of unpleasant emotions and the release of stress hormones. We told participants that we assumed that daily exposure to a green picture or an inaudible sound would positively affect their mood and perceived stress in general and their ratings of emotional pictures in particular. Regarding self-portraits, the procedures were identical to the control condition. In the retrospective expectancy–only condition, initial instructions on the purpose of the study were identical to the control condition. Regarding the self-portraits, we told participants that the *ohmage* app would compare the emotional facial expression of the 2 self-portraits, which might differ according to the levels of mood and perceived stress. After having taken the post placebo intervention self-portrait, participants were informed by the *ohmage* app that their picture was currently being analyzed. Then, we provided participants with feedback that their stress level and mood had improved to a certain extent. We had programmed the reported levels of improvement for mood and perceived stress in advance. They were identical for each participant but different for each self-portraying intervention day, to make the deception more plausible. In the combined expectancy condition, initial instructions on the purpose of the study were identical to the prospective expectancy–only condition. Procedures regarding the analysis of the self-portraits were identical to the retrospective expectancy–only condition (for detailed instructions, see Multimedia Appendix 3).

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Figure 1. Fourfold table of different conditions.

	No prospective expectancy	Prospective expectancy
No retrospective expectancy	Control (n=32)	Prospective expectancy only (n=33)
Retrospective expectancy	Retrospective expectancy only (n=33)	Combined expectancy (n=34)

Outcome Variable: Efficacy Expectancies With CEQ

We measured efficacy expectancies as outcome variables with CEQ, which was developed to measure treatment expectancy and rationale credibility in clinical outcome studies [30]. Further details on the structure of the CEQ and how we built the subscales' credibility and expectancy can be found in the study by Smeets et al [31]. The CEQ exhibits good psychometric properties [30]. It was administered at the introductory session (day 0) and on intervention days 1, 7, 14, and 20, after participants had completed the smartphone-based mental health intervention and the International Affective Picture System picture ratings.

Participants

Participants were recruited from the bachelor student body of the University of Basel, Switzerland, in psychology and other lectures, where we presented our study. Advertisements of our study were posted on the website of the psychology students' Facebook group and on local bulletin boards of the Department of Psychology. We compensated psychology students with signatures for study completion, which they required as parts of their bachelor's studies. If participants dropped out before completion, compensation was granted proportionally. For students of other faculties, we offered participation in a lottery drawing for a tablet computer as compensation. For study participation, students had to use their own smartphones for 20 consecutive days. Only participants with access to an Android-based smartphone were included because the app we used in our study was available for Android only, that is, potentially interested participants with iOS-based smartphones could not be included in the study. Due to low recruitment rates during the initial data collection, students with access to an Android-based tablet computer were also accepted for participation in our study (7 participants in total). The following inclusion criteria were applied: no severe visual impairment, no dyschromatopsia, no severe defective hearing, no regular intake of medication (eg, antidepressants), and no severe mental disorders (eg, schizophrenia, other psychotic disorders, or severe affective disorders).

Randomization and Masking

Participants who met the inclusion criteria were randomly assigned to 1 of the 4 conditions as well as to whether they would start the ambulatory smartphone-based placebo exposure by either green color or mock sound, resulting in 8 groups (1:1:1:1:1:1:1:1). Randomization was stratified by sex and included a randomly permuted block procedure with fixed block sizes of 8, 16, and 24 participants. To account for the presumably higher percentage of female participants, the female strata included 6 blocks grouped into 2 pairs of 3 blocks, each containing 1 block for each of the 3 block sizes, whereas the male strata included only 3 blocks, 1 block for each block size. Randomization was performed in RStudio (version 0.99.891; R Project for Statistical Computing [32]) by an independent party.

Participants were enrolled and assigned to the different conditions by 2 masters-level students, according to predefined rules of a standard operating procedure, which included the utilization of predefined impersonal standard emails and SMS to invite and remind participants to participate in the study. In cases of unexpected events, the master's students communicated via email with participants, which was reduced to a necessary extent. Eligible participants were blinded to their allocation. At the end of intervention day 20, we debriefed participants via the *ohmage* app on the actual aims of the study and that we had exposed them to a placebo intervention.

Statistical Analyses

We estimated the sample size using a priori power analysis. As no comparable RCTs were available in the literature, our assumptions regarding effect sizes were speculative. We assumed that a sample size of 30 participants in each condition (120 participants in total) would be required to detect small to moderate effects on a two-sided 5% level of significance and a power of 80%. As we anticipated an exclusion rate of 10%, we intended to assess at least 132 students for eligibility.

For descriptive analyses of baseline characteristics, we calculated absolute frequencies for categorical variables as well as means and SDs and ranges for continuous variables, each separated by condition as well as for the total number of participants. For descriptive analyses of the CEQ as an outcome

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measure, we first inspected histograms and Q-Q-plots for normality. As visual inspection delivered ambiguous results, we conducted the Shapiro-Wilk test, which was significant for credibility ($P<.001$) and expectancy ($P<.001$), indicating not normally distributed data. Thus, we calculated medians and IQRs.

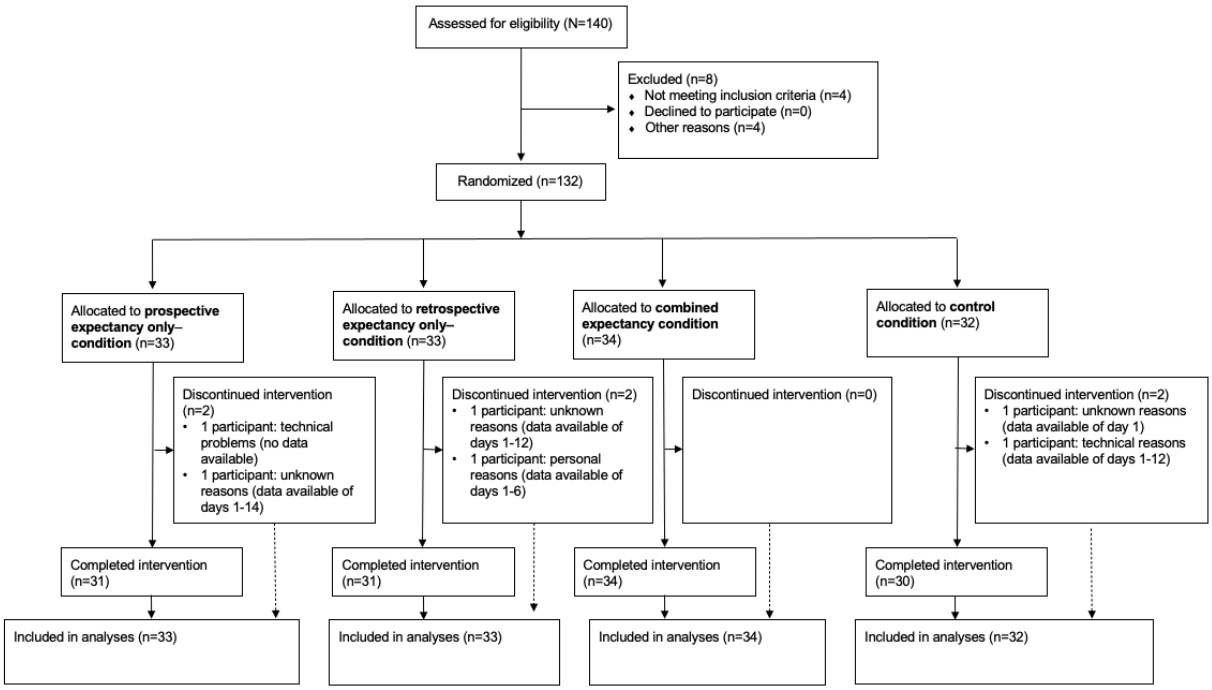
For our main analyses, we applied linear mixed models, taking into account individual variations in efficacy expectancies across days and accommodating missing data. For the calculation of the 2 subscales credibility and expectancy of the CEQ, we equalized the 6 items of the CEQ to values from 1 to 9 according to the study by Smeets et al [31] and then calculated the row sums for each subscale. We split the 4 different conditions into 2 factors consisting of 2 levels each: prospective expectancy condition (yes vs no) and retrospective expectancy condition (yes vs no), and we entered these variables separately into the models. The variable intervention day was logarithmized with base 10 and centered. The 2 subscales of the CEQ were entered as outcome variables in separate linear mixed-effects models [33] to estimate changes in credibility or expectancy across intervention days, depending on the condition. For our main analyses, we entered the following predictors into the models: (1) intervention day (dimensional, days 0, 1, 7, 14, 20, logarithmized with base 10 and centered); (2) prospective expectancy (yes vs no); and (3) retrospective expectancy (yes vs no), as well as the interactions of intervention day with prospective expectancy and retrospective expectancy. We entered random intercept and random slope parameters as this improved model fit, the latter assessed based on Akaike Information Criterion [33], allowing time trajectories of participants to vary per participant and intervention day. With respect to our hypothesis, we were especially interested in a condition×time interaction effect (three-way interaction as condition was entered as 2 separate variables). We checked residual plots for linearity and the normal distribution of residuals.

In additional analyses, we conducted separate linear mixed models, each controlling for the effects of either prospective expectancy or retrospective expectancy. When controlling for prospective expectancy, we conducted separate models for cases with prospective expectancy (yes), respectively, without (no), and the predictors (1) intervention day and (2) retrospective expectancy, as well as the interaction of intervention day with retrospective expectancy. Likewise, when controlling for retrospective expectancy, we conducted separate models for cases with retrospective expectancy (yes), respectively, without (no), and the predictors (1) intervention day and (2) prospective expectancy, as well as the interaction of intervention day with prospective expectancy.

We calculated 95% CIs using the Wald method. For our mixed model analyses, we included all subjects of the intention-to-treat population (Figure 2).

We conducted all tests 2-tailed and set the level of significance at .05. We used the statistical software package RStudio (version 0.99.891; R Project for Statistical Computing [32]) for all data analyses and statistical testing, including the package to conduct the mixed models *lme4* [34]. For data preparation and descriptive statistics, we used the packages *haven* [35], *dplyr* [36], *tidyr* [37], *car* [38], *ggplot2* [39], *lsmeans* [34], *lmerTest* [40], and *data.table* [41].

Figure 2. Flow of study participants. Note: as part of our intention-to-treat analyses, we included all study participants in our main analyses who were randomized to one of the 4 conditions.



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Results

Participant Flow

The flow of participants is presented in Figure 2, according to the Consolidated Standards of Reporting Trials [42]. Of the 140 participants who were assessed for eligibility, 8 were excluded before randomization because they did not meet inclusion criteria or for other reasons (eg, technical problems with their Android-based smartphones). In total, we included 132 participants in our intention-to-treat analyses.

Baseline Characteristics of Study Participants

Baseline characteristics of study participants are presented in Table 1.

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Table 1. Baseline characteristics of participants included in the analyses.

Variable and category	Condition				Total (N=131[a])
	Combined[b] (n=34)	Prospective[c] (n=32)	Retrospective[d] (n=33)	Control[e] (n=32)	
Categorical variables, n (%[f])					
Sex					
Male	4 (12)	5 (16)	5 (15)	5 (16)	19 (14.5)
Female	30 (88)	27 (84)	28 (85)	27 (84)	112 (85.5)
Age group (years)					
18-24	32 (94)	28 (88)	26 (79)	27 (84)	113 (86.3)
25-29	0 (0)	2 (6)	2 (6)	3 (9)	7 (5.3)
30-39	1 (3)	2 (6)	3 (9)	2 (6)	8 (6.1)
40 or older	1 (3)	0 (0)	2 (6)	0 (0)	3 (2.3)
Nationality					
Swiss only	23 (68)	22 (69)	22 (67)	27 (84)	94 (71.8)
European country	7 (21)	3 (9)	6 (18)	2 (6)	18 (13.7)
Other foreign country	0 (0)	0 (0)	1 (3)	0 (0)	1 (0.8)
Double nationality (either of them is Swiss)	4 (12)	7 (22)	4 (12)	3 (9)	18 (13.7)
Education category[g]					
Vocational education	0 (0)	0 (0)	1 (3)	0 (0)	1 (0.8)
High school diploma[h]	31 (91)	30 (94)	28 (85)	30 (94)	119 (90.8)
University or college degree	3 (9)	2 (6)	3 (9)	2 (6)	10 (7.6)
Other	0 (0)	0 (0)	1 (3)	0 (0)	1 (0.8)
Working part-time					
Yes	19 (56)	15 (47)	15 (46)	19 (59)	68 (51.9)
No	15 (44)	17 (53)	18 (55)	13 (41)	63 (48.1)
Relationship status					
Single	15 (44)	16 (50)	14 (42)	14 (44)	59 (45.0)
In a romantic relationship	18 (53)	15 (47)	15 (46)	18 (56)	66 (50.4)
Married	1 (3)	0 (0)	3 (9)	0 (0)	4 (3.1)
Divorced	0 (0)	1 (3)	1 (3)	0 (0)	2 (1.5)
Occurrence of depressive symptoms for the last 2 weeks[i]	9 (27)	8 (25)	4 (12)	9 (28)	30 (22.9)
Occurrence of anxiousness, nervousness, strain, or excessive worriedness for the last 4 weeks[j]	0 (0)	1 (3)	0 (0)	1 (3)	2 (1.5)
Continuous variables, mean (SD), range (min[k]-max[l])					
Full time education (years)	13.7 (2.3), (5-19)	13.7 (2.5), (5-22)	14.0 (2.4), (9-20)	13.7 (2.8), (3-20)	13.8 (2.5), (3-22)
Duration to complete the 20 days intervention	23.5 (3.5), (19-41)	25.1 (8.8), (19-62)	26.1 (7.2), (19-50)	23.9 (5.9), (19-62)	24.6 (6.6), (19-62)
PSS-10[m]	16.1 (4.8), (6-26)	15.4 (4.8), (5-25)	15.2 (6.6), (4-30)	17.0 (6.9), (4-32)	15.9 (5.8), (4-32)

[a]Although we included all 132 study participants of the intention-to-treat sample in our main analyses, here, we report the data of only 131 study participants because for 1 study participant, the data presented here were missing.

[b]Combined: combined expectancy condition.

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[c]Prospective: prospective expectancy–only condition.

[d]Retrospective: retrospective expectancy–only condition.

[e]Control: control condition.

[f]Percentages may not total 100% due to rounding.

[g]The categories no formal education, compulsory education, and higher vocational education (including school for technicians and professional school) have been dropped due to the lack of cases.

[h]In the German version of the questionnaire, participants were asked for *Matura*, which is the secondary school leaving certificate in Switzerland, equivalent to International Standard Classification for Education 34.

[i]Items of the Patient Health Questionnaire-German version, with the following scale: 1=not at all, 2=on single days, 3=on more than half of the days, and 4=almost every day, categorization according to meeting at least the criteria for other depressive syndrome according to the manual of the Patient Health Questionnaire-German version.

[j]Items of Patient Health Questionnaire-German version, with the following scale: 1=no and 2=yes, categorization according to meeting at least the criteria for panic syndrome or other anxiety syndromes.

[k]min: minimum.

[l]max: maximum.

[m]PSS-10: Perceived Stress Scale, 10 items version.

Results From the Mixed Model Analyses

Credibility

Descriptive statistics are shown in Table 2 and in the interaction plots of Figure 3. The results of the main mixed models are presented in Table 3. We found a significant main effect of *intervention day* (β=−1.63; 95% CI −2.37 to −0.89; *P*<.001), suggesting that credibility decreased over the intervention days, irrespective of condition. We found a significant three-way interaction: intervention day×prospective expectancy×retrospective expectancy (β=2.05; 95% CI 0.60-3.50; *P*=.006). Results from additional analyses (Multimedia Appendix 4) suggest that the significant three-way interaction was driven by 2 opposite two-way interactions: intervention day×retrospective expectancy, one positive in cases with prospective expectancy (β=1.18; 95% CI 0.31-2.05; *P*=.009) and one negative in cases with no prospective expectancy (β=−0.87; 95% CI −2.06 to 0.33; *P*=.15), with 95% CIs of estimates minimally overlapping. When controlling for retrospective expectancy, the two-way interaction pattern intervention day×prospective expectancy was comparable. In line with Figure 3, these findings suggest that credibility decreased least in the combined expectancy condition and in the control condition.

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Table 2. Outcome measures: median scores of the Credibility and Expectancy Questionnaire per intervention day.

Outcome and intervention day	Condition								Total (N=131)[a]	
	Combined[b] (n=34)		Prospective[c] (n=33)		Retrospective[d] (n=33)		Control[e] (n=32)			
	Median (IQR)	Number of patients	Median (IQR)	Number of patients	Median (IQR)	Number of patients	Median (IQR)	Number of patients	Median (IQR)	Number of patients
Credibility										
0	16 (4.75)	34	16 (5.25)	32	16 (4)	33	15 (4.25)	32	16 (4)	131
1	12.5 (7)	34	14 (5.5)	32	12 (5)	33	12.5 (7.25)	32	13 (7)	131
7	11.5 (7)	34	11 (8)	32	8 (7)	32	10 (8)	31	10 (8)	129
14	12.5 (8)	34	9.5 (6.75)	32	8 (6)	31	10 (6.75)	30	9 (8.5)	127
20	11.5 (6.5)	32	8 (7)	31	7 (7.5)	31	9.5 (8.75)	30	9 (9)	124
Expectancy										
0	11.5 (5.75)	34	12 (4.5)	32	11 (5)	33	10 (7.75)	32	11 (5.25)	131
1	10.5 (4.75)	34	10 (5.25)	32	9 (4)	33	11 (7.25)	32	10 (6)	131
7	10 (5)	34	8 (5.25)	32	6 (3.25)	32	8 (5.5)	31	8 (5)	129
14	8.5 (5)	34	7 (5.5)	32	6 (5.5)	31	7.5 (10)	30	7 (7)	127
20	7.5 (5.25)	32	7 (3.5)	31	6 (4.5)	31	8.5 (9.75)	30	7 (7)	124

[a]Although we included all 132 study participants of the intention-to-treat sample in our main analyses, here, we report the data of only 131 study participants because for 1 study participant, the data presented here were missing. Means and SDs were calculated based on the existing values. N values per intervention day and condition are given in the table.

[b]Combined: combined expectancy condition.

[c]Prospective: prospective expectancy–only condition.

[d]Retrospective: retrospective expectancy–only condition.

[e]Control: control condition.

Figure 3. Time trajectories of credibility throughout intervention days (means). Note: means were calculated based on existing values.

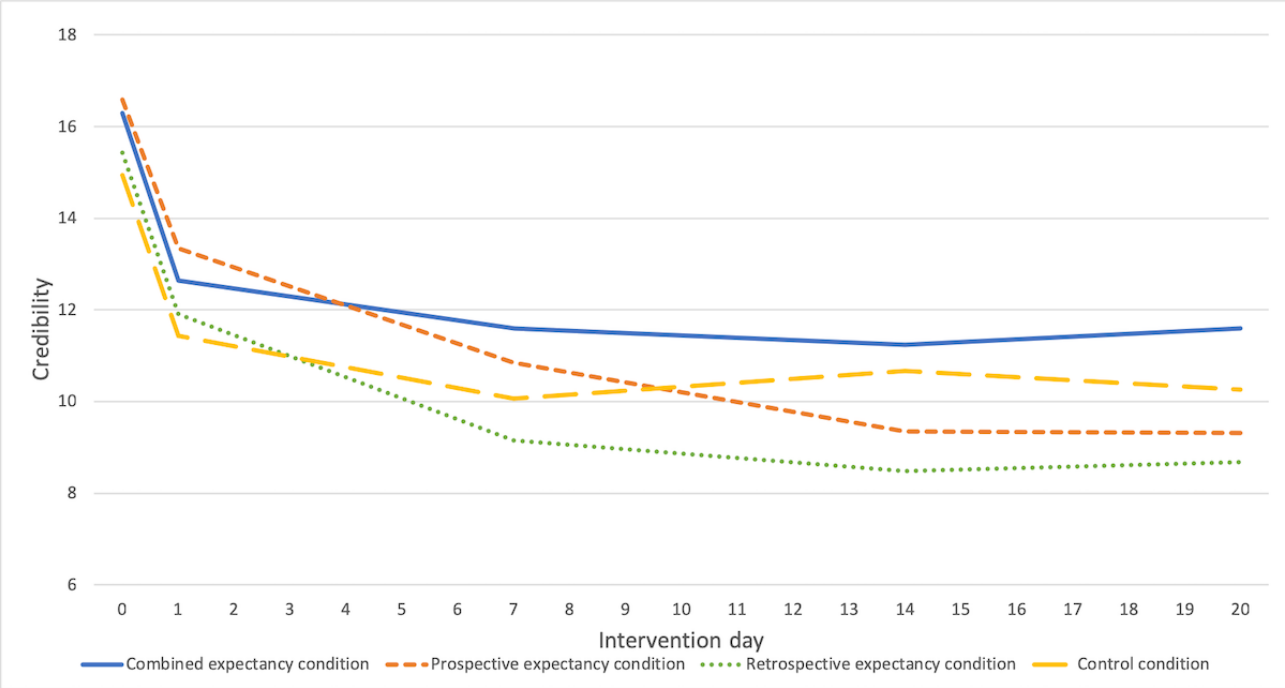

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Table 3. Results of linear mixed models (N=131)[a].

Predictors[b]	*b*	95% CI	*P* values
Credibility			
Intercept	11.35	10.04 to 12.66	<.001
Intervention day (time[c]; logarithmized)	−1.630	−2.37 to −0.89	<.001
PE[d]	0.497	−1.35 to 2.34	.60
RE[e]	−0.590	−2.43 to 1.25	.53
Time×PE	−1.130	−2.16 to −0.09	.03
Time×RE	−0.869	−1.91 to 0.17	.10
PE×RE	1.467	−1.11 to 4.05	.26
Time×PE×RE	2.046	0.60 to 3.50	.006
Goodness of fit			
AIC[f]	3559.2	—[g]	—
Expectancy			
Intercept	9.715	8.45 to 10.98	<.001
Intervention day (time; logarithmized)	−0.770	−1.49 to −0.05	.04
PE	−0.425	−2.21 to 1.36	.64
RE	−1.373	−3.15 to 0.40	.13
Time×PE	−0.871	−1.88 to 0.13	.09
Time×RE	−0.744	−1.75 to 0.26	.15
PE×RE	2.099	−0.39 to 4.59	.10
Time×PE×RE	1.548	0.14 to 2.95	.03
Goodness of fit			
AIC	3378.7	—	—

[a]We included 132 study participants of the intention-to-treat sample in our data set. As from 1 participant there were no data available for at least one intervention day, statistical analyses were conducted with the data of only 131 participants.

[b]For interpretation purposes, we entered the 4 conditions as 2 separate variables: prospective expectancy (PE; yes vs no) and retrospective expectancy (RE; yes vs no) in the mixed models. This means combined expectancy condition corresponds to PE=yes and RE=yes, prospective expectancy–only condition corresponds to PE=yes and RE=no, retrospective expectancy–only condition corresponds to PE=no and RE=yes, and control condition corresponds to PE=no and RE=no.

[c]time: intervention day.

[d]PE: prospective expectancy (yes vs no).

[e]RE: retrospective expectancy (yes vs no).

[f]AIC: Akaike information criterion.

[g]—: not available.

Expectancy

Descriptive statistics can be found in Table 2 and in the interaction plots of Figure 4. The results of the main mixed models are presented in Table 3. We found a significant main effect of *intervention day* (β=−0.77; 95% CI −1.49 to −0.05; *P*=.04), suggesting that expectancy decreased over the intervention days. We found a significant three-way interaction: intervention day×prospective expectancy×retrospective expectancy (β=1.55; 95% CI 0.14-2.95; *P*=.03). Results from additional analyses (Multimedia Appendix 5) suggest that the significant three-way interaction was driven by 2 opposite two-way interactions: intervention day×retrospective expectancy, one positive in cases with prospective expectancy (β=.81; 95% CI −0.01 to 1.62; *P*=.05) and one negative in cases with no prospective expectancy (β=−.74; 95% CI −1.92 to 0.44; *P*=.21), with 95% CIs of estimates minimally overlapping. When controlling for *retrospective expectancy*, the two-way interaction pattern intervention day×prospective expectancy was comparable. In line with Figure 4, these findings suggest that expectancy decreased least in the combined expectancy condition and in the control condition.

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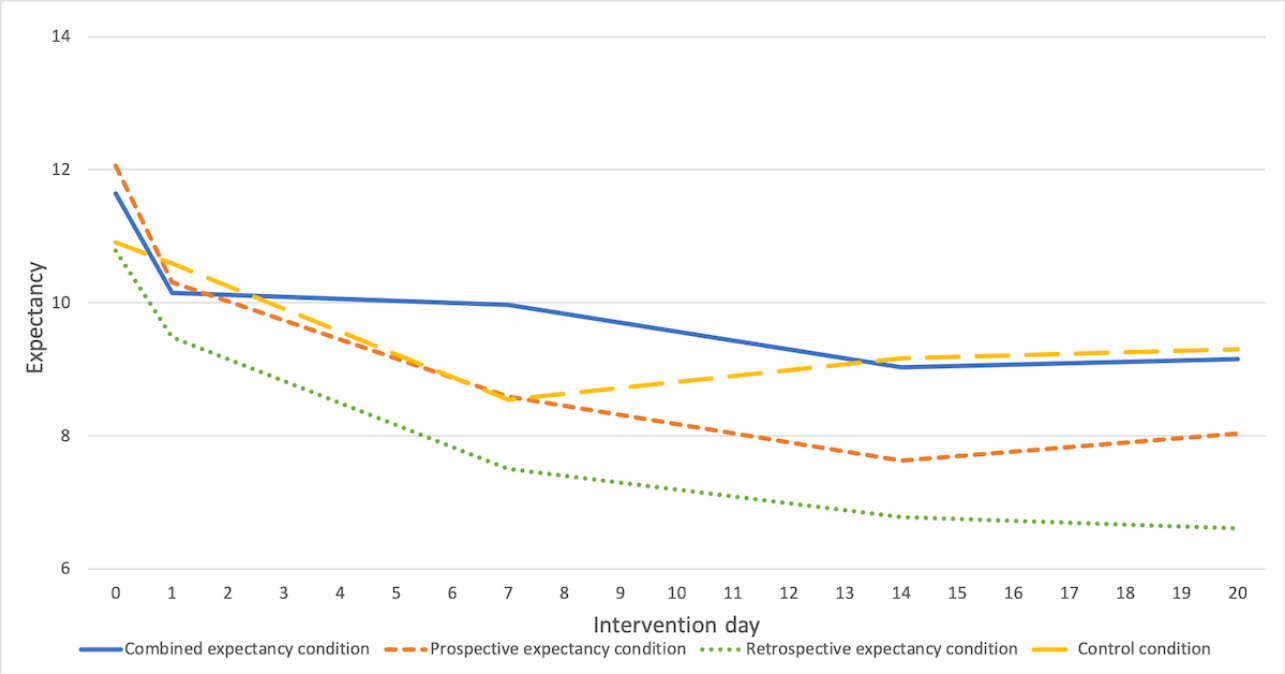
Figure 4. Time trajectories of expectancy throughout intervention days (means). Note: means were calculated based on existing values.



Discussion

Principal Findings

To the best of our knowledge, this is the first empirical study investigating whether efficacy expectancies can be successfully induced in a smartphone-based placebo mental health intervention. We found that efficacy expectancies decreased throughout the intervention days, irrespective of the condition. Efficacy expectancies decreased least in the combined expectancy and the control condition and most in the prospective expectancy–only condition and the retrospective expectancy–only condition.

The finding that efficacy expectancies decreased throughout intervention days may partly be explained by the length and monotony of the intervention. Some participants mentioned in their feedback at the end of the intervention that the duration of the smartphone-based intervention and the daily exposure to green color or mock sound were too long.

Efficacy expectancies decreased least in the combined expectancy and in the control condition, followed by the prospective expectancy–only and the retrospective expectancy–only condition. As displayed in Figures 3 and 4, the verbal instructions given in the prospective expectancy–only condition alone did not seem to have an effect on efficacy expectancies, as they continued to decrease after intervention day 1, on which the instructions had been given. A potential explanation may be that our verbal instructions were not potent enough to raise efficacy expectancies. Accordingly, Rief et al [43] encouraged study participants of the PSY-HEART study to develop very clear expectations of how their daily life would change after successful heart surgery. Due to these more personal associations, study participants may have been more convinced and may have formed stronger expectancies. Future studies may further explore potential study protocols to maximize expectancies, regarding types (eg, conditioning procedure instead of verbal instructions [14,16]), timepoint, number of repetitions, and intervals of expectancy induction.

Strengths and Limitations

Our study has several strengths. First, we set up the study in the frame of an RCT, which is the gold standard in psychotherapy research. Second, the smartphone-based placebo intervention as well as efficacy expectancies were delivered in a standardized way by providing them in the preprogrammed surveys in the Android-based smartphone app as well as on the web-based platform, through which heterogeneity due to different experimenters or protocols could be reduced. Although randomization and allocation concealment were not done automatically in the Android-based smartphone app but by experimenters, in most cases, they did not have any personal contact with study participants after randomization, thereby reducing experimenter bias. Third, our results have high ecological validity, because participants used their own smartphones in daily life at a specific time of the day and from intervention day 15 in situations when they felt stressed. Fourth, by adapting the open-source *ohmage* app to the purpose of our study, we provide a minimal cost intervention that enables fully identical replications as well as their utilization in low- and middle-income countries in which there is a lack of financial resources. Fifth, with the use of mixed model analyses, we took into account individual variations in efficacy expectations across intervention days and accounted for missing data.

Our results may be interpreted in light of several limitations. First, we designed the smartphone-based intervention in line with the aim of our study to create an inert intervention. We did not focus on making the intervention particularly attractive to study participants, for instance, by integrating elements of gamification [44], which may have affected the decrease in efficacy expectancies throughout the intervention. It may be hypothesized that the time trajectories in efficacy expectancies may differ in a study using a smartphone-based app designed

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to have a specific effect. Still, in contrast to the law of attrition, which describes the observation of high rates of discontinuation in eHealth trials [45], we have a high completion rate, with data available for 97.3% (642/660) of cases, which makes our findings relatively robust. Second, the study sample was quite homogenous, with most of the participants being female psychology students. As our sample did not consist of a clinical sample, it may rather reflect subjects using smartphones for preventive purposes. Hence, the findings may be generalizable rather to populations seeking prevention. Notably, in a clinical population, participants' desire to get an effect out of the intervention is expected to be higher than in a healthy sample, which has been found to modulate placebo analgesia in irritable bowel syndrome patients [46]. Therefore, it may even be easier to induce a digital placebo effect in a clinical sample, as compared with ours, which, however, requires further investigation. Another limitation regarding our sample is that data collection took place in 2015, and it would have been preferable to use more recent data, particularly in a fast-emerging field such as mobile health. However, the latency between data collection and dissemination of findings in our study is comparable with other relevant studies in this field [23,47]. Furthermore, although timely dissemination of findings from clinical trials would be important to base clinical decisions on best scientific evidence, a previous study [48] found that only 29% of completed RCTs of US academic medical centers are published within 2 years after study completion, indicating that, to reduce publication bias, older data need to be disseminated as well. Nonetheless, our findings require imminent replication. For replication, it would also be preferable to increase the sample size, which, however, encompassed 132 participants in our main statistical analyses; thus, it was above the median of comparable RCTs included in 2 recent meta-analyses [11,12]. Third, some participants reported technical or usability problems with the *ohmage* app, which may have led to a certain level of frustration throughout the course of the intervention and may have diminished efficacy expectancies. However, as the reported frequency of technical problems with the app was low (0.6% of all cases), we do not assume that this aspect has reduced the validity of our findings. Fourth, as participants entered the study at different points of time, we cannot exclude that participants who had already finished the study might have informed others about the actual study purpose before study completion, which may have reduced the effect of the induction of efficacy expectations, particularly in the experimental conditions. However, we speculate that this may have affected efficacy expectancies of only a few participants because (1) participants might not have remembered and passed all the details of the study design to others; (2) it might have been in the interest of most of the psychology students to promote the study; and (3) students from fields other than psychology might have not systematically participated, and thus, they might not have shared details of the purpose of the study. Fifth, we included only participants with access to an Android-based smartphone, which limits the generalizability to iPhone and other operating systems users. However, a recent study found that personality traits (eg, well-being, self-esteem, optimism, pessimism, and the Big Five) that might affect efficacy expectancies differed only slightly between iOS and Android users [49].

Implications

In this study, we focused on the investigation of whether we succeeded in inducing efficacy expectancies in a smartphone-based placebo mental health intervention. A required next step would be to investigate whether the induction of efficacy expectancies affected behavioral outcomes, such as mood and stress (Stalujanis et al, unpublished data, January 2021). In the field of placebo research, there are situations in which placebo effects should be diminished and others in which placebo effects should be enhanced [15,21]. Further investigation of time trajectories of efficacy expectancies as a potential mechanism of digital placebo effects may help to improve research on the efficacy of smartphone-based mental health interventions by disentangling digital placebo effects from specific effects. A potential study design may provide participants with a smartphone-based inert intervention until placebo effects are supposed to be flattened and then deploy the actual intervention, which may then be less distorted by placebo effects. In addition, it is well known that, after initial involvement, users of digital mental health interventions tend to put those away [50]. If smartphone-based mental health interventions work only every second or third time, users may lose their motivation and might not see any gain from the intervention. Personalized prediction of the effects of efficacy expectancies may foster long-term utilization of smartphone-based interventions. In a previous study, we found that, by using a machine learning approach, predictions of smartphone-based psychotherapeutic microintervention success could be improved, as compared with the initial success rate within and between participants [51]. Future studies should investigate predictors of efficacy expectancies at an intra- and interindividual level to design tailor-made individualized interventions to contribute to further advancement in the growing field of precision medicine [52].

Conclusions

To the best of our knowledge, this is the first empirical study investigating whether efficacy expectancies could be successfully induced in a smartphone-based placebo mental health intervention. We found that efficacy expectancies decreased throughout the intervention days. Efficacy expectancies decreased least in the combined expectancy condition and in the control condition and most in the retrospective expectancy–only condition and the prospective expectancy–only condition. Our findings may pave the way for both diminishing and exploiting effects of outcome expectancies as a potential mechanism of the digital placebo effect and help to improve the treatment efficacy of digital mental health interventions.

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Authors' Contributions

ES conceptualized and designed the study, acquired data, carried out the statistical analyses, analyzed and interpreted data, drafted the initial manuscript, critically reviewed the manuscript, and approved the final version of the manuscript. JN conceptualized and designed the study, acquired data, analyzed and interpreted data, critically reviewed the manuscript, and approved the final version of the manuscript. MS conceptualized and designed the study, acquired data, analyzed and interpreted data, critically reviewed the manuscript, and approved the final version of the manuscript. AB analyzed and interpreted data, critically reviewed the manuscript, and approved the final version of the manuscript. MT conceptualized and designed the study, analyzed and interpreted data, critically reviewed the manuscript, approved the final version of the manuscript, and obtained funding. GM supervised the study as the principal investigator, conceptualized and designed the study, acquired data, analyzed and interpreted data, critically reviewed the manuscript, approved the final version of the manuscript, and obtained funding. All authors had full access to all the data (including statistical reports and tables) in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Outline of the larger study.
[PDF File (Adobe PDF File), 191 KB - mhealth_v9i2e20329_app1.pdf]

Multimedia Appendix 2
Study design of the larger study.
[PDF File (Adobe PDF File), 102 KB - mhealth_v9i2e20329_app2.pdf]

Multimedia Appendix 3
Instructions of the four conditions of the study. Note. Those instructions were translated from German to English by the first author for illustration purposes. The original German original versions are available on request by the authors.
[PDF File (Adobe PDF File), 123 KB - mhealth_v9i2e20329_app3.pdf]

Multimedia Appendix 4
Results of additional analyses of linear mixed models with credibility as outcome (N=131).
[DOCX File , 19 KB - mhealth_v9i2e20329_app4.docx]

Multimedia Appendix 5
Results of additional analyses of linear mixed models with expectancy as outcome (N=131).
[DOCX File , 19 KB - mhealth_v9i2e20329_app5.docx]

Multimedia Appendix 6
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 400 KB - mhealth_v9i2e20329_app6.pdf]

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Abbreviations

CEQ: Credibility and Expectancy Questionnaire
RCT: randomized controlled trial

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Original Paper

Heart Rate Variability and Firstbeat Method for Detecting Sleep Stages in Healthy Young Adults: Feasibility Study

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Abstract

Background: Polysomnography (PSG) is considered the only reliable way to distinguish between different sleep stages. Wearable devices provide objective markers of sleep; however, these devices often rely only on accelerometer data, which do not enable reliable sleep stage detection. The alteration between sleep stages correlates with changes in physiological measures such as heart rate variability (HRV). Utilizing HRV measures may thus increase accuracy in wearable algorithms.

Objective: We examined the validity of the Firstbeat sleep analysis method, which is based on HRV and accelerometer measurements. The Firstbeat method was compared against PSG in a sample of healthy adults. Our aim was to evaluate how well Firstbeat distinguishes sleep stages, and which stages are most accurately detected with this method.

Methods: Twenty healthy adults (mean age 24.5 years, SD 3.5, range 20-37 years; 50% women) wore a Firstbeat Bodyguard 2 measurement device and a Geneactiv actigraph, along with taking ambulatory SomnoMedics PSG measurements for two consecutive nights, resulting in 40 nights of sleep comparisons. We compared the measures of sleep onset, wake, combined stage 1 and stage 2 (light sleep), stage 3 (slow wave sleep), and rapid eye movement (REM) sleep between Firstbeat and PSG. We calculated the sensitivity, specificity, and accuracy from the 30-second epoch-by-epoch data.

Results: In detecting wake, Firstbeat yielded good specificity (0.77), and excellent sensitivity (0.95) and accuracy (0.93) against PSG. Light sleep was detected with 0.69 specificity, 0.67 sensitivity, and 0.69 accuracy. Slow wave sleep was detected with 0.91 specificity, 0.72 sensitivity, and 0.87 accuracy. REM sleep was detected with 0.92 specificity, 0.60 sensitivity, and 0.84 accuracy. There were two measures that differed significantly between Firstbeat and PSG: Firstbeat underestimated REM sleep (mean 18 minutes, P=.03) and overestimated wake time (mean 14 minutes, P<.001).

Conclusions: This study supports utilizing HRV alongside an accelerometer as a means for distinguishing sleep from wake and for identifying sleep stages. The Firstbeat method was able to detect light sleep and slow wave sleep with no statistically significant difference to PSG. Firstbeat underestimated REM sleep and overestimated wake time. This study suggests that Firstbeat is a feasible method with sufficient validity to measure nocturnal sleep stage variation.

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KEYWORDS

electroencephalogram; actigraphy; polysomnography; sleep; heart rate; rapid eye movements

Introduction

Sleep stages alternate throughout the typical nighttime sleep period. After the initial sleep onset, nonrapid eye movement (NREM) sleep stages 1 (N1), 2 (N2), and 3 (N3) emerge alongside rapid eye movement (REM) sleep [1]. Together, both NREM and REM sleep stages form sleep cycles, which, in healthy adults, rotate approximately four or five times over the course of a single night [2]. This alteration between stages correlates with changes in physiological measures such as muscle tonus [3,4], blood pressure [5-7], temperature regulation [8,9], as well as heart rate and heart rate variability (HRV) [10,11].

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More specifically, NREM sleep stages are related to stability in the cardiovascular system and stronger parasympathetic cardiac modulation. This, in turn, is reflected in REM sleep so that the heart rate increases and becomes less stable [5,7]. Within NREM sleep stages, the differences between deep sleep (N3, or slow wave sleep [SWS]) and lighter sleep stages (N1 and N2) also have some physiological differences, but these are less pronounced than those between REM and NREM [12]. Specifically, the deeper the sleep, the stronger the parasympathetic cardiac modulation (ie, SWS is associated with a lower heart rate compared to N2 and N1) [13,14].

Polysomnography (PSG) is considered the gold-standard means for measuring sleep stages, as the combination of electromyography (EMG) and electroencephalograph (EEG) is, by definition, the only way to distinguish between the different sleep stages [1]. Although PSG provides reliable data on sleep, other less laborious methods are needed as the increasing prevalence of sleep disorder diagnoses [15] has highlighted an urgent gap to be filled in the development of reliable, cost-efficient sleep study tools for both clinical and consumer use [16].

Some recent studies suggest that HRV might provide a noninvasive marker for detecting sleep behavior such as differentiating between sleep stages [10,11]. HRV has also been widely utilized for assessing phenomena such as stress and recovery [17], physical activity [18], and oxygen consumption [19]. Recently, a sleep analysis method was developed based on HRV and acceleration data (Firstbeat Technologies Oy, Jyväskylä, Finland) for providing personalized feedback and guidance regarding the quantity and quality of sleep. HRV as measured by a single-lead ECG device (Firstbeat Bodyguard 2, Firstbeat Technologies Oy) can estimate atrial fibrillation accurately [20], making it a reliable measurement device regarding HRV-related phenomena.

Based on the need to evaluate the validity of commonly available and easy-to-administer sleep measurement solutions, we investigated how PSG and the Firstbeat sleep analysis algorithm correlate in detecting sleep stages. From analog measurements, we estimated the sensitivity, specificity, and accuracy of the Firstbeat method in relation to PSG measurement over two nights.

Methods

Participants

The study protocol has been described in detail in a previous publication [21]. We recruited 20 voluntary participants (mean age 24.5 years, SD 3.5, range 20-37 years; 10 [50%] women) by word of mouth in Helsinki, Finland. Participants were recruited from the research team's circle of acquaintances: if the acquaintance showed initial interest in participating, they received a detailed description of the procedure via email. After reading the description, if the potential participant was still interested in taking part in the sleep study, they were screened for suitability. Their sleep was then measured for two consecutive nights using PSG, chest-worn Firstbeat Bodyguard 2, and a wrist-worn Geneactiv actigraph (Activinsights Ltd, Kimbolton, United Kingdom). The inclusion criteria were as follows: aged between 20 and 45 years, and a relatively stable sleep schedule (eg, no shift work or jet lag). Exclusion criteria were any diagnosed sleep disorder, the use of any medication that could affect sleep, acute sickness (eg, the flu), and gold allergy (as the electrodes used for the PSG recording were gold-plated). Each participant received a compensation of 100 euros (US $115) and structured feedback on their sleep stages. Written informed consent was obtained from all participants. The study was approved by the Ethical Committee of the Helsinki University Central Hospital. All procedures followed were in accordance with the Helsinki Declaration and its later amendments.

In our previous study, we investigated two different intervention groups within this setting, and demonstrated that these groups did not differ significantly from each other [21]. The Pittsburgh Sleep Quality Index (PSQI) scores of the participants, ranging from 2 to 12 points, indicate some variation in sleep quality. For the purpose of this study, all nights from all participants were pooled together for comparisons of PSG and Firstbeat sleep metrics.

Procedure

A research assistant visited participants at their homes on two consecutive nights. Participants had been asked not to consume alcohol or caffeine after 4 PM on the measurement nights. The evening visit started between 6 and 10 PM, depending on the participant's current sleeping schedule. The research assistant attached the measurement electrodes to the participant during the house call and began the recording. Before the research assistant left, participants were given instructions for the night; the participants were instructed to spend the evening as usual but to refrain from vigorous activities. They were also asked to keep their phones and any other electrical devices with transmitters at least 2 meters away from the bed so they would not interfere with the PSG recording. Participants were instructed to sleep normally, and the visit for the following morning was scheduled according to the participant's expected wake-up time. The research assistant arrived the following morning approximately 0 to 30 minutes after the wake-up time.

Physical Measurements

We measured HRV with Firstbeat Bodyguard 2, including two chest electrodes and 3-axis acceleration data obtained from the wrist with a Geneactiv actigraph. The Firstbeat sleep analysis method evaluates the physiological state of the person as being awake or asleep based on HRV and acceleration data, and scores sleep as N1+N2 (light), N3, or REM. The method uses a neural network–based algorithm with HRV, HRV-derived respiration rate, movement, and time of day data for sleep and wake detection and for sleep classification. To align the measurement modes, we combined PSG-measured sleep stages N1 and N2 to correspond to "light" sleep of the Firstbeat method.

We used overnight PSG to measure sleep at home (SOMNOscreen plus, SOMNOmedics GmbH, Germany) with the following recorded parameters: EEG (left and right for F, C, O), left and right electrooculogram (EOG), left and right EMG, and ECG. The setup for the PSG and the removal in the

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morning were carried out by a trained research assistant. EEG measurements were recorded with gold cup electrodes at 6 EEG locations (F3, F4, C3, C4, O1, and O2) and 2 channels for the mastoids (A1, A2) according to the standardized 10/20 system. The ECG, EOG, and EMG were measured using disposable adhesive electrodes (Ambu Cardiology Blue Sensor M; Ambu Neuroline 715, Ambu A/S, Denmark) with two locations for ECG and EOG, and three locations for EMG. In addition, an online reference Cz and a ground electrode in the middle of the forehead were used. The sampling rate was 256 Hz. All signals were filtered with a pass band of 0.5-40 Hz (Hamming windowed sinc zero-phase FIR filter, cutoff [−6 dB] 0.25 Hz and 44.3 Hz, respectively) and rereferenced to the average signal of A1 and A2 electrodes. Sleep stages from PSG data were scored manually with the DOMINO program version 2.7 (SOMNOmedics GmbH, Germany) by two experienced researchers in 30-second epochs. The scoring was completed with both researchers visually inspecting the data together and agreeing over each epoch. The scoring was paused if any disagreement emerged and continued after agreement was found based on careful inspection of all channels, in accordance with the rules published by the American Academy of Sleep Medicine (AASM) [1].

Statistical Analyses

Following standard sleep score practices in the AASM manual [1], we used 30-second epochs for sleep stage comparisons. The entire data were compared side by side after lights off; following AASM scoring rules, sleep onset was defined as the first epoch of any sleep stage as detected by the PSG measurement. We compared how Firstbeat was able to detect the actual sleep onset by calculating the difference between the two time points, which were statistically evaluated using a paired *t* test. All comparisons of sleep staging between PSG and Firstbeat were performed from the PSG-measured actual sleep onset onward.

First, we used paired-sample *t* tests to compare sleep metrics for evaluating differences between PSG and Firstbeat in sleep onset, and minutes spent in wake, light sleep, SWS, and REM sleep. Second, we conducted epoch-by-epoch comparisons between Firstbeat and PSG to calculate the sensitivity (ability of Firstbeat to detect true sleep), specificity (ability of Firstbeat to detect true wake), and accuracy (ability of Firstbeat to detect both sleep and wake). This comparison was performed across all sleep stages, as well as for overall sleep-wake comparisons between PSG and Firstbeat.

Third, we used a confusion matrix to compare epoch-by-epoch measures of true positives, true negatives, false positives, and false negatives between Firstbeat and PSG across all measured nights for sleep versus wake as well as for light sleep, SWS, and REM sleep stages. True positives arise when both the PSG and Firstbeat score the 30-second epoch as sleep. True negatives arise when both the PSG and Firstbeat score the epoch as awake. False positives arise when the PSG scores the epoch as sleep but Firstbeat scores it as wake. False negatives arise when the PSG scores the epoch as wake but Firstbeat scores it as sleep.

Fourth, we evaluated the differences between the amount of sleep scored as wake, light sleep, SWS, or REM sleep when comparing Firstbeat and PSG using minute-based Bland-Altman plots, and visually demonstrate how many observations remained within a 30-minute window of the PSG measure.

Finally, we used *t* tests to compare whether specificity, sensitivity, and accuracy differed based on sex, measurement night, or the intervention we reported previously [21].

Results

The 40 nights from 20 participants measured with both PSG and Firstbeat were included in all analyses with no exclusions. Table 1 shows the participants' characteristics as well as their mean sleep measures.

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Table 1. Characteristics of the sample (N=20).

Characteristic	Value
Age (years), mean (SD)	24.50 (3.50)
Sex (female), n (%)	10 (50)
BMI (kg/m^2), mean (SD)	23.64 (3.10)
PSQI[a] score, mean (SD)	5.40 (2.35)
Poor sleep quality (PSQI score>5), n (%)	5 (25)
Polysomnography-measured sleep, mean (SD)	
Sleep onset (hour:minute)	23:44 (1:05)
TST[b] (hour:minute)	7:28 (0:49)
Sleep efficiency (%)	91.55 (5.82)
N1[c] of TST (%)	4.68 (2.71)
N2[d] of TST (%)	47.46 (6.14)
N3[e] of TST (%)	22.18 (7.11)
REM[f] of TST (%)	25.68 (5.48)

[a]PSQI: Pittsburgh Sleep Quality Index.
[b]TST: total sleep time.
[c]N1: sleep stage 1 (light sleep).
[d]N2: sleep stage 2 (light sleep).
[e]N3: sleep stage 3 (slow wave sleep).
[f]REM: rapid eye movement.

Table 2 shows paired *t* test comparisons and the mean differences between Firstbeat and PSG sleep stage scores. Sleep onset did not differ significantly between Firstbeat and PSG (mean difference 0, SD 9 minutes, SE 1 minute; t_{39}=0.578, *P*=.57). Three nights' sleep onset was detected accurately, whereas for 12 nights, the Firstbeat method assumed earlier sleep onset than PSG. To detect the true difference in detecting sleep onset, we calculated the absolute difference between Firstbeat onset to PSG onset, and found a mean difference of 7.06 minutes (SD 6.64 minutes).

Table 2. Paired comparisons and mean differences of sleep parameters recorded by Firstbeat and polysomnography.

Parameter (minutes)	Mean difference[a] (SD)	SE	95% CI	*t* (*df*=39)	*P* value
Wake	14.03 (16.65)	2.63	8.70 to 19.35	5.327	<.001
Light sleep	–0.80 (42.25)	6.68	–14.31 to 12.72	–0.120	.91
Slow wave sleep	4.68 (46.79)	7.40	–10.29 to 19.64	0.632	.53
REM[b] sleep	–17.90 (50.44)	7.98	–34.03 to –1.77	–2.244	.03

[a]Mean differences calculated as Firstbeat – polysomnography.
[b]REM: rapid eye movement.

When comparing Firstbeat and PSG, there were some differences in how well the Firstbeat method was able to detect different sleep stages. The mean specificity, sensitivity, and accuracy in detecting wake was 0.77 (SD 0.16), 0.95 (SD 0.03), and 0.93 (SD 0.03), respectively. The specificity, sensitivity, and accuracy in detecting light sleep was 0.69 (SD 0.15), 0.66 (SD 0.10), and 0.69 (SD 0.06), respectively. The specificity, sensitivity, and accuracy in detecting SWS was 0.91 (SD 0.06), 0.72 (SD 0.17), and 0.87 (SD 0.04), respectively. REM sleep was detected with 0.92 (SD 0.7) specificity, 0.60 (SD 0.24) sensitivity, and 0.84 (SD 0.06) accuracy.

Table 3 shows the confusion matrix [22] regarding the two measurement devices and their differences.

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Table 3. Confusion matrix of the Firstbeat method and polysomnography sleep stage epoch comparisons.

Firstbeat (N)	Polysomnography (N)				
	Light	SWS[a]	REM[b]	Wake	Total
Light	12,737[c]	2189	3445	492	18,863
SWS	2683	5867[c]	40	96	8686
REM	2072	131	5576[c]	205	7984
Wake	1435	125	355	2598[c]	4513
Total	18,927	8312	9416	3391	40,046[c]
Correct stage classification (%)	67.3	70.6	59.2	76.6	N/A[d]

[a]SWS: slow wave sleep.

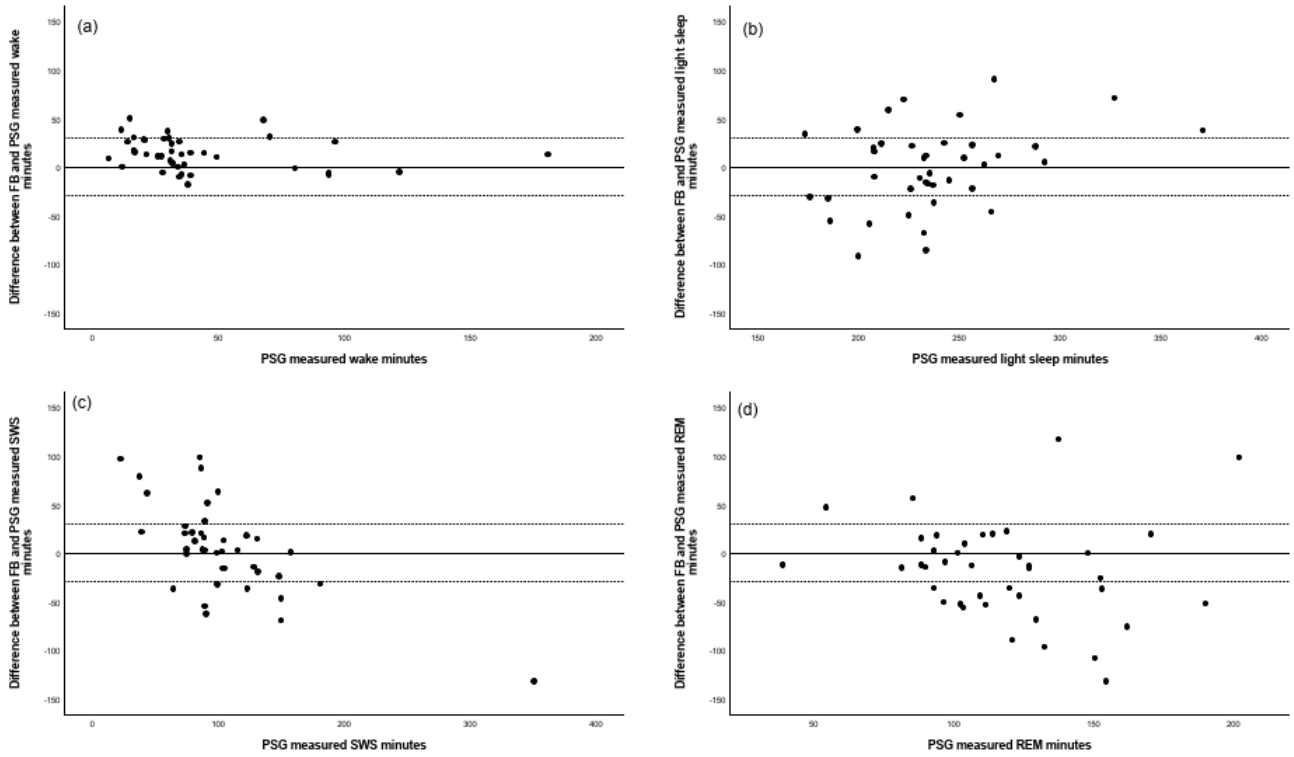
[b]REM: rapid eye movement.

[c]Diagonals indicate the number of correctly categorized epochs in the respective sleep stage.

[d]N/A: not applicable.

Figure 1 shows the Bland-Altman mean difference plots, which illustrate the share of observations that were within 30 minutes from each other in wake state, or in different sleep stages as measured with different devices.

Figure 1. Bland-Altman plots comparing differences in Firstbeat (FB) and polysomnography (PSG) in wake state (a), light sleep stages N1+N2 (b), slow wave sleep (SWS) (c), and rapid eye movement (REM) sleep (d).



As a further sensitivity check, we compared the means of specificity, sensitivity, and accuracy to detect possible differences based on sex, measurement night, or the intervention reported previously [21]. Compared to females, there was a better specificity in REM sleep in male participants (0.95 vs 0.89, P=.004), but there were no other differences between sexes (P>.06). There was no first- or second-night effect in the specificity, sensitivity, and accuracy (all P>.38), nor regarding the presence of the previously reported music or slow-breathing intervention (all P>.13).

Discussion

Principal Findings

Wearable devices have gained a significant share of the health and well-being consumer market, and new wearable devices and algorithms emerge frequently. Although a great majority of this research aims to detect sleep quality and duration based on data derived from accelerometer sensors [23], other measures such as respiratory signals have also been utilized [24]. Several reviews have evaluated the accuracy of accelerometer-based sleep wearables [23,25,26], and a recent review summarized an

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overall evaluation of wearables utilizing other sensors [27]. They concluded that detecting sleep from wake is relatively successful in many devices, but when wearables aim to classify sleep stages as opposed to simply distinguish between sleep and wake, there is a challenge in distinguishing four choices (wake, light, deep, and REM sleep) [27], which makes the result more inaccurate.

Commercial accelerometers typically yield accuracy between 0.81 and 0.91, sensitivity values between 0.87 and 0.99, and specificity values between 0.10 and 0.52 in distinguishing sleep from wake [26]. However, when attempting to detect sleep stages, the results are less consistent. A recent review focusing on commercial accelerometers identifying sleep stages found great variation in accuracy depending on the study [26]. For instance, accuracy in detecting light sleep varied between 69% and 81%, accuracy in detecting SWS was between 36% and 89%, and that for REM sleep ranged between 62% and 89%. Such variation suggests that acceleration itself may not be sufficient in reliably identifying sleep stages.

Previous studies have implied that HRV may be a useful marker for detecting sleep stages [10,11]. One study reported an accuracy of up to 89% in detecting SWS, but their method included respiratory signals alongside HRV [28]. When detecting sleep stages by utilizing both HRV and accelerometer data, one study managed to identify 75% of SWS correctly [29]. In that study, REM sleep was identified correctly in over 70% of epochs, whereas light sleep detection was the weakest with correct identification varying between 42% and 52%. Our findings are of similar accuracy, which further supports the notion of combining accelerometer and HRV-based measures for reproducible sleep staging.

This study was performed to evaluate the ability of HRV- and acceleration-based Firstbeat sleep analysis methods to detect sleep and different sleep stages. In pairwise comparisons, the Firstbeat method detected light sleep and SWS with no statistically significant difference to the gold-standard PSG method. There were two measures that differed significantly between the Firstbeat method and PSG: Firstbeat underestimated REM sleep (mean 18 minutes) and overestimated wake (mean 14 minutes). Considering the number of minutes in the context of a typical night's sleep, the differences are not alarmingly high in practice, especially when measuring sleep over repeated nights. Sleep onset detection was very accurate, which is in accordance with a review published earlier this year [30].

Sleep stages can only be detected using PSG, as the stages are, by definition, separated by different patterns in ECG, EOG, and ECM. REM sleep is particularly difficult to detect without measuring activity from EOG and EMG channels. Thus, relying on other physiological measures as a means for separating sleep stages is always based on secondhand information. Although HRV has both previously [10,11] and in this study reflected sleep stages relatively well, it cannot detect the immediate changes in EEG, EOG, and EMG. However, this study suggests that HRV-assisted sleep stage detection can serve as a good estimate of sleep architecture despite being less accurate in detecting specific sleep stages.

When observing the comparisons in more analytical detail, we found that comparing the Firstbeat method against PSG yielded good specificity, and excellent sensitivity and accuracy in detecting wake. Regarding light sleep, the measures of specificity, sensitivity, and accuracy were less convincing. SWS detection had excellent specificity, adequate sensitivity, and good accuracy, while REM sleep was detected with similarly excellent specificity, adequate sensitivity, and good accuracy. These results suggest that the Firstbeat method is best at detecting sleep stages that have strong parasympathetic cardiac markers; however, light sleep is typically not significantly differentiated based its physiological fingerprint [12,14].

Strengths and Limitations

Our study was fully balanced in sex distribution and we were able to evaluate the Firstbeat method across two different nights in two different settings in the participants' own homes. Thus, the ecological validity in this study can be considered excellent.

As a limitation, even though our sample had some variation in PSQI-measured sleep quality, this study did not include any participants with diagnosed sleep disorders. Our study included only healthy participants, and the results are likely to be different if any health issues, particularly cardiovascular, or any sleep disorders are present. This is a question to solve before utilizing the Firstbeat method in clinical contexts.

Conclusion

Combining HRV with accelerometer measurements can be considered a feasible method with sufficient validity to measure nocturnal sleep stage variation. We found that the specificity, sensitivity, and accuracy were the weakest in detecting light sleep. Nevertheless, considering its availability, affordability, and ease of administration, Firstbeat may be a useful tool in various contexts, particularly in consumer-based sleep-measuring environments to produce an overview of sleep structures.

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Conflicts of Interest

None declared.

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Abbreviations

AASM: American Academy of Sleep Medicine
EEG: electroencephalography
EMG: electromyography
EOG: electrooculogram
HRV: heart rate variation
N1: stage 1 (nonrapid eye movement) sleep
N2: stage 2 (nonrapid eye movement) sleep
N3: stage 3 (nonrapid eye movement) sleep (slow wave sleep)
NREM: nonrapid eye movement
PSG: polysomnography
PSQI: Pittsburgh Sleep Quality Index
REM: rapid eye movement
SWS: slow wave sleep

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Original Paper

An Innovative Wearable Device For Monitoring Continuous Body Surface Temperature (HEARThermo): Instrument Validation Study

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Abstract

Background: Variations in body temperature are highly informative during an illness. To date, there are not many adequate studies that have investigated the feasibility of a wearable wrist device for the continuous monitoring of body surface temperatures in humans.

Objective: The objective of this study was to validate the performance of HEARThermo, an innovative wearable device, which was developed to continuously monitor the body surface temperature in humans.

Methods: We implemented a multi-method research design in this study, which included 2 validation studies—one in the laboratory and one with human subjects. In validation study I, we evaluated the test-retest reliability of HEARThermo in the laboratory to measure the temperature and to correct the values recorded by each HEARThermo by using linear regression models. We conducted validation study II on human subjects who wore HEARThermo for the measurement of their body surface temperatures. Additionally, we compared the HEARThermo temperature recordings with those recorded by the infrared skin thermometer simultaneously. We used intraclass correlation coefficients (ICCs) and Bland-Altman plots to analyze the criterion validity and agreement between the 2 measurement tools.

Results: A total of 66 participants (age range, 10-77 years) were recruited, and 152,881 completed data were analyzed in this study. The 2 validation studies in the laboratory and on human skin indicated that HEARThermo showed a good test-retest reliability (ICC 0.96-0.98) and adequate criterion validity with the infrared skin thermometer at room temperatures of 20°C-27.9°C (ICC 0.72, $P<.001$). The corrected measurement bias averaged –0.02°C, which was calibrated using a water bath ranging in temperature from 16°C to 40°C. The values of each HEARThermo improved by the regression models were not significantly different from the temperature of the water bath ($P=.19$). Bland-Altman plots showed no visualized systematic bias. HEARThermo had a bias of 1.51°C with a 95% limit of agreement between –1.34°C and 4.35°C.

Conclusions: The findings of our study show the validation of HEARThermo for the continuous monitoring of body surface temperatures in humans.

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KEYWORDS

body surface temperature; wearable device; validation; continuous monitoring

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Introduction

Background

Abnormalities in body temperature are the key indicators for the prognosis of various illnesses [1-4] and the most common symptoms of defensive immune responses [4]. Abnormal body temperature patterns are informative and specific to poor progress during an illness, regardless of whether people meet the criteria for fever or not [5-10]. Large body temperature variations before the development of a fever indicate the evolution of sepsis syndrome [9]. A retrospective study found that afebrile critically ill patients with abnormal temperature patterns in any 24-hour period had a 4.43-fold risk for subsequent diagnosis of sepsis as compared to patients without such patterns, and the sensitivity and specificity of the abnormal temperature curves to predict sepsis were 0.69 and 0.76, respectively [8]. At the individual level, an unexplained variation in 1 SD increase in body temperature among outpatients is a significant predictor linked to 8.4% higher rate of 1-year mortality [11]. Therefore, body temperature is one of the most important vital signs for evaluating human health, and continuous monitoring should be done for the early identification of patients who are at a risk for poor prognosis [12,13].

Thermometers such as glass mercury thermometers, electronic thermometers, infrared ear thermometers, and infrared forehead thermometers are used to measure the human body temperature. They are usually used at predetermined intervals or when a patient's condition changes [7,14]. Considering the equivalents of intravascular or direct brain thermometry, the measurement tools for continuous body temperature monitoring in clinical practice are invasive and include urinary catheters or esophageal temperature probes [15]. However, such invasive continuous body temperature measurement tools might not be applicable to the general population.

To date, wearable devices with the advantage of minimizing discomfort and interference with normal human activities have garnered increased attention in the field of continuous monitoring of body temperatures [13,16,17]. Different wearable devices, including skin-like arrays of precision temperature sensors or wearable adhesive devices such as watches, vest, patches, and earphones, have been developed to continuously examine the body temperature [18-21]. Among the human body parts, the wrist is the most responsive body part for wearable devices that measure thermal sensation [19,22]. However, the applications of wearable devices in the continuous monitoring of body temperature are still limited in terms of pilot studies [18,20,23]. In addition, the validity of wrist skin temperature monitoring using novel wearable devices in both laboratory settings and on human subjects has not been sufficiently investigated.

Prior Work and Objective of This Study

An early study conducted in 2006 was the first study to use iButton, which has a mean accuracy of 0.05°C through a validation study by using a water bath with different temperatures and a reference thermometer. This study further underscored the generalizability of laboratory findings to clinical settings [24]. Most studies were conducted to assess the feasibility of the wrist skin temperature measured by iButtons in terms of the human circadian system [25-27]. Two studies conducted on approximately 100 university students in Spain proved that the wrist temperature rhythm is a valuable index for assessing the circadian rhythm [25,26]. Another study conducted on 121 shift workers in Korea provided evidence that lower wrist temperature amplitudes appeared more in the nightshift workers than in the dayshift workers [27]. In addition, several studies were conducted to assess the effects of continuously monitoring body temperature by using wearable devices for the detection of worsening conditions in patients [6,10,23,28,29]. A prospective observational study consisting of 56 patients was carried out to explore the effects of a Holter device with both central and peripheral infrared temperatures being recorded and stored every minute for 24 hours. It was found that 0.7 peaks of fever per patient could be detected by continuous monitoring but this was unobserved during conventional care, and 16% of the patients considered afebrile by conventional care had at least one fever peak detected during continuous monitoring [29]. Another pilot study of pediatric patients indicated that 2 fever events could not be detected by routine temperature monitoring but they could be detected 12 hours earlier by a continuous temperature monitoring patch [23]. However, the limitations of these devices included a long response time due to their relatively large sizes, and the maximum sampling rate was 1 per minute [24]. Moreover, these studies did not show the reliability and validity of the wearable devices in terms of monitoring body surface temperature [25-27]. Therefore, the objective of this study was to validate the performance of HEARThermo, an innovative wearable device, which was developed to continuously monitor the body temperature in humans.

Methods

Study Design

We used a multi-method research design in this study, which included 2 validation studies—one in the laboratory and one with human subjects. We conducted these studies to determine the reliability of HEARThermo in the laboratory setting and the agreement and validity of HEARThermo for application on human skin. The Institutional Review Board at the National Cheng Kung University Hospital (no. B-BR-106-044) approved this study's protocol.

Study Participants

Snowball sampling was conducted to recruit people who were able to communicate in Taiwanese or Mandarin, who lived in the Tainan community, and who were willing to participate in this study. The exclusion criteria included people (1) with fever or if they experienced physical discomfort 3 days before participation in this study; (2) with severe brain injury, neurological disease, severe cardiovascular disease, ear structure problem, peripheral artery disease, or musculoskeletal disease in the limbs; (3) with mental disorders or cognitive disability; and (4) under medication with effects on the vital markers such as corticosteroids, nonsteroidal anti-inflammatory drugs, or anti-fever medications 4 hours before the commencement of this study.

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We recruited 66 participants in this study and all of them completed the experimental study. The power analysis was calculated using "ICC.Sample.Size" packages by R Version 3.4.1 (R Statistics Software). The post hoc power analysis indicated a sample size of 66 participants to detect a high-power level (power=0.99).

Data Collection

Validation Study I

The methods of validating HEARThermo in the laboratory setting used in this study were conducted in accordance with Section 4.5.1 "Operating Environment Tests" cited in the "National Standards of the Republic of China (CNS) 15043 Standard specification for electronic thermometer for intermittent determination of patient temperatures" [30]. According to the instructions for wearable devices, they were stabilized for 1 hour before the validation tests. We tested HEARThermo in a water bath at 16°C and 40°C thrice and recorded the measurement error range. We verified the temperature of the water bath with the reference mercury thermometer.

Validation Study II

We conducted a validation study II to determine the correlation between the body surface temperature obtained by HEARThermo and that obtained by the infrared skin thermometer. We used HEARThermo to continuously monitor the participants' body surface temperatures until the end of the study. The time to participate in the study was between 9 AM and 11 AM, and the rooms for the study were fixed to avoid any potential bias from the environment. Since the emissivity of infrared thermometers might be affected by environmental temperature [31], the different room temperatures, humidity, and activity levels were taken into consideration as confounders in the validation study. Figure 1 shows the details of the validation study II protocol.

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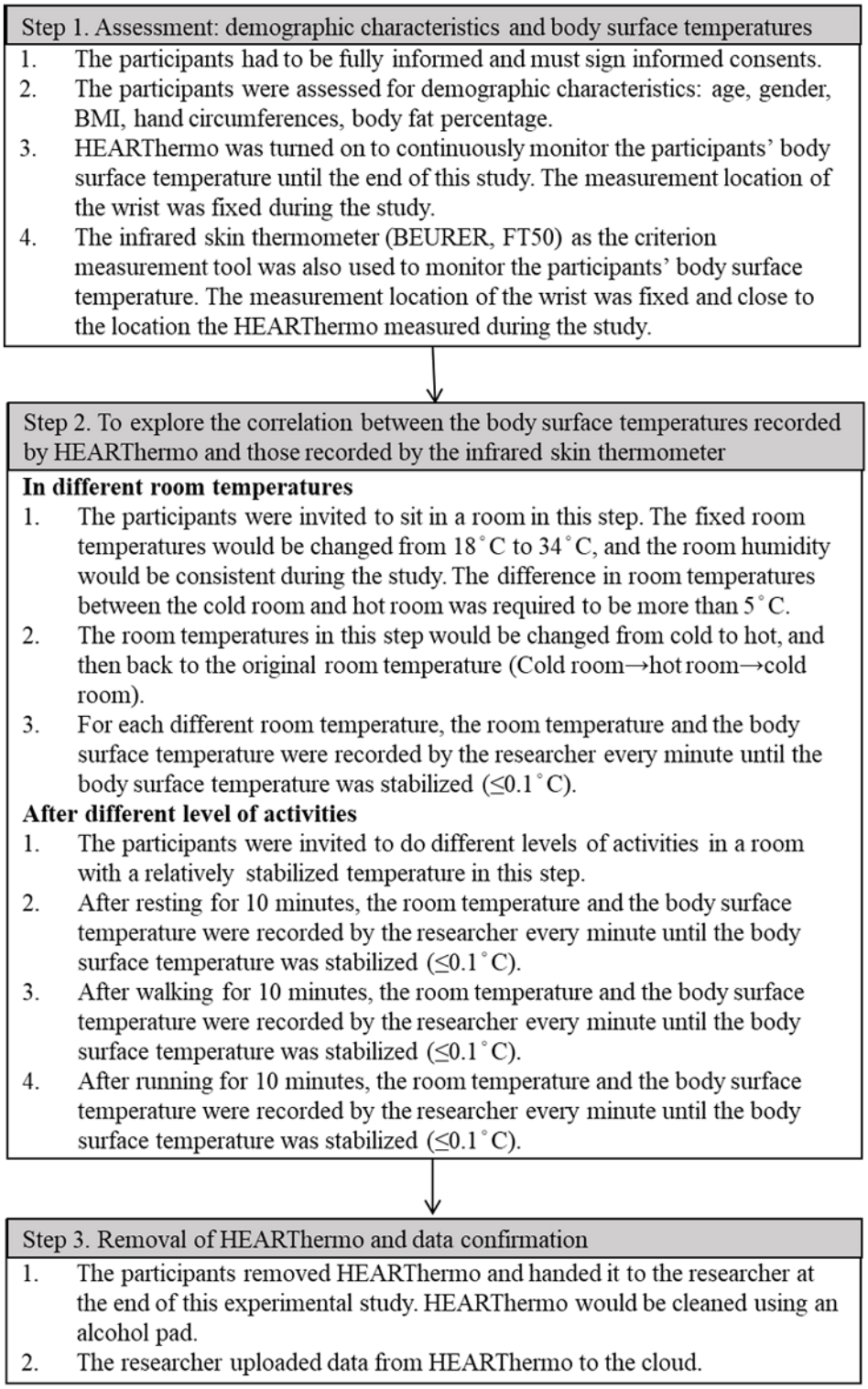
Figure 1. The protocol for validation study II.



Variable Measurements

Demographic Characteristics

The individual demographic data collected for this study included age, gender, height, weight, BMI, body fat percentage, and hand circumference.

Body Surface Temperature

We used an infrared skin thermometer (BEURER, FT50) to measure the body surface temperature in the experimental study. The researcher first cleaned specific places on the monitored hands, and after the skin was dry, an infrared skin thermometer was placed on the skin surface of the hands. The measured temperature appeared on the display along with a face symbol after the SCAN button was released. According to the instructions for the infrared skin thermometer used in this study,

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the measurement error range is ±0.3°C at temperatures from 10°C to 50°C and ±0.1°C at temperatures from 37°C to 39°C [32]. The sampling frequency of the infrared skin thermometer is 512 scanning sequences per second [32]. The accuracy test of the infrared skin thermometer used in this study was conducted in accordance with Section 5.1.5 "Operating Environment Tests" cited in the "CNS 15042 Standard specification for infrared thermometer for intermittent determination of patient temperatures" [31]. First, the infrared skin thermometer was stabilized for 30 minutes before the accuracy tests. The infrared skin thermometer was then tested 6 times in a water bath at 23°C, 30°C, and 38°C, and the measurement error range was recorded. The results revealed that the infrared skin thermometer meets the acceptance criteria of the CNS standards, for which the maximum measurement error is required to be ±0.3°C.

HEARThermo, which was developed in cooperation with the technology manufacturer (AMobile Intelligent Corp Ltd), was used to continuously measure the body surface temperature in the validation study II (Figure 2). In contrast to the previously developed devices with thermistors and integrated circuits sensors [23,24,29,33,34], this wearable device comprises the TEMPUS Digital Far Infrared Thermopile Sensor to measure the far infrared energy emitted from the body surface and presents the temperatures immediately. The signal measurement rate of HEARThermo is >500 Hz. Besides, the sensors of HEARThermo also include g-sensor, gyroscope, heart rate, and 3D accelerometer. In this study, the researcher first cleaned specific places on the monitored hands, and after the skin was dry, HEARThermo was lightly placed on the skin surface of the wrist. When HEARThermo was turned on, the measured parameters, including temperature and heart rate, appeared on the display every second. These physiological biomarkers were uploaded through the Bluetooth Low Energy gateway to the National Cheng Kung University cloud.

Figure 2. HEARThermo device.

Room Temperature and Humidity

We used a room temperature data logger (Elitech, RC-4) to measure the room temperature in this study. According to the manufacturer's instructions, the temperature accuracy was ±0.5°C at temperatures from –20°C to 40°C [35]. A room humidity data logger (N Dr.AV, GM-108) was used to measure the room humidity. According to the manufacturer's instructions, the humidity accuracy is ±10% for humidity ranging from 20%-90% [36].

Data Analysis

We examined the differences between the groups by using analysis of variance and chi-square test for the categorical variables. Then, we calculated the measurement bias of each HEARThermo as the mean (SD) of the differences between the temperatures of HEARThermo and that of the water bath. Moreover, we calculated the linear regressions between the temperatures of the water bath and each HEARThermo to determine the relationship between the values of the wearable devices and those of the water bath. We applied the linear regression model for each HEARThermo to an independent data set to correct the values of each wearable device and tested the improvements in the values with a two-tailed paired *t* test by using the biases of the absolute values. To determine the test-retest reliability of the individual wearable device, we analyzed the intraclass correlation coefficient (ICC) of each HEARThermo. We analyzed the agreement between HEARThermo and the infrared skin thermometer by using Bland-Altman plots. Additionally, we calculated the means, namely bias, and SD, namely precision, of the differences, and 95% limits of agreement. Furthermore, we analyzed the criterion

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validity of the HEARThermo by using ICC two-way random effect model with 95% CIs. We conducted all the statistical analyses by using R Version 3.4.1.

Results

Study Population

We included 66 participants in Tainan City, Taiwan for this experimental study (Multimedia Appendix 1). A total of 325,022 data were observed, and 152,881 completed data were analyzed. The age of the participants ranged from 10 years to 77 years, with a mean (SD) age of 39.47 (19.02) years, and 39 out of the 66 participants (59%) were female. The mean (SD) height of these participants was 161.4 (10.85) cm, the mean (SD) weight was 60.82 (14.83) kg, the mean (SD) BMI was 23 (3.41), the mean (SD) body fat percentage was 26.61 (6.98)%, and the mean (SD) hand circumference was 15.38 (1.61) cm. The mean (SD) stabilized time after walking was 357.06 (192.24) seconds, and the mean (SD) stabilized time after running was 790.67 (259.69) seconds.

Validation Study I: Reliability of HEARThermo in the Laboratory Setting

We tested 39 wearable devices thrice in a water bath at 16°C and 40°C. The mean (SD) measurement bias at 16°C amounted to −1.16 (1.84)°C (range –4.91°C to 2.18°C). The mean (SD) measurement bias at 40°C amounted to 1.21 (2.01)°C (range –2.39°C to 5.63°C). The ICC for the water bath at 16°C was 0.96, whereas the ICC for the water bath at 40°C was 0.98 (Table 1).

Table 1. Distributions of the temperatures of the 39 HEARThermo devices in the water bath.

Temperature of the water bath	Tests (n)	Minimum (°C)	Median (Q1-Q3)	Maximum (°C)	Mean (SD)	CV[a]	ICC[b]
16°C	117	11.09	14.94 (13.3-16.49)	18.18	14.84 (1.84)	12.38	0.96
40°C	117	37.61	41.04 (39.72-42.8)	45.63	41.21 (2.01)	4.876	0.98

[a]CV: coefficient of variance.

[b]ICC: intraclass correlation coefficient.

We conducted linear regressions to calibrate each wearable device. The intercept calibration coefficients ranged from –3.20 to 7.07°C and the slope calibration coefficients ranged from 0.77 to 1.11°C. The corrected measurement bias averaged –0.02 (SD 0.28)°C (range –1.79°C to 0.81°C). The values of each HEARThermo improved by the regression models were not significantly different from the temperatures of the water bath (P=.19).

Validation Study II: Agreement and Validity of HEARThermo for Application on Humans

Figure 3 shows the level of agreement of body surface temperatures between HEARThermo and the infrared skin thermometer. The mean (SD) temperature of HEARThermo was 31.94 (2.04)°C as compared with 30.43 (2.02)°C for the infrared skin thermometer. Bland-Altman analyses indicated that the bias of HEARThermo was 1.51°C (95% CI 1.50-1.51) with a precision of 1.45. The limit of agreement was –1.34°C (95% CI –1.35 to –1.32) to 4.35°C (95% CI 4.34-4.36). Table 2 shows the ICC values between the wearable devices and the infrared skin thermometer at different room temperatures, which included ≤19.9°C, 20°C-27.9°C, and ≥28°C. The ICC was high with an estimate of 0.72 for the room temperatures of 20°C-27.9°C. At room temperatures of 20°C-27.9°C, the mean (SD) temperature of HEARThermo was 32.44 (1.67)°C (range 25.45°C-37.53°C) compared with 30.86 (1.85)°C (range 25.7°C-36.6°C) for the infrared skin thermometer. The ICC values declined rapidly with variations in room temperature with low ICC values of 0.45 and 0.49. At room temperature ≤19.9°C, the mean (SD) temperature of HEARThermo was 28.41 (0.92)°C (range 24.07°C-29.81°C) compared with 26.72 (2.05)°C (range 23.0°C-29.4°C) for the infrared skin thermometer. At room temperatures ≥28°C, the temperature variation of HEARThermo was 34.17 (1.22)°C (range 26.93°C-36.49°C) compared with 33.42 (1.78)°C (range 30.2°C-36.6°C) for the infrared skin thermometer.

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Figure 3. Bland-Altman plots of level of agreement between HEARThermo and the infrared skin thermometers.

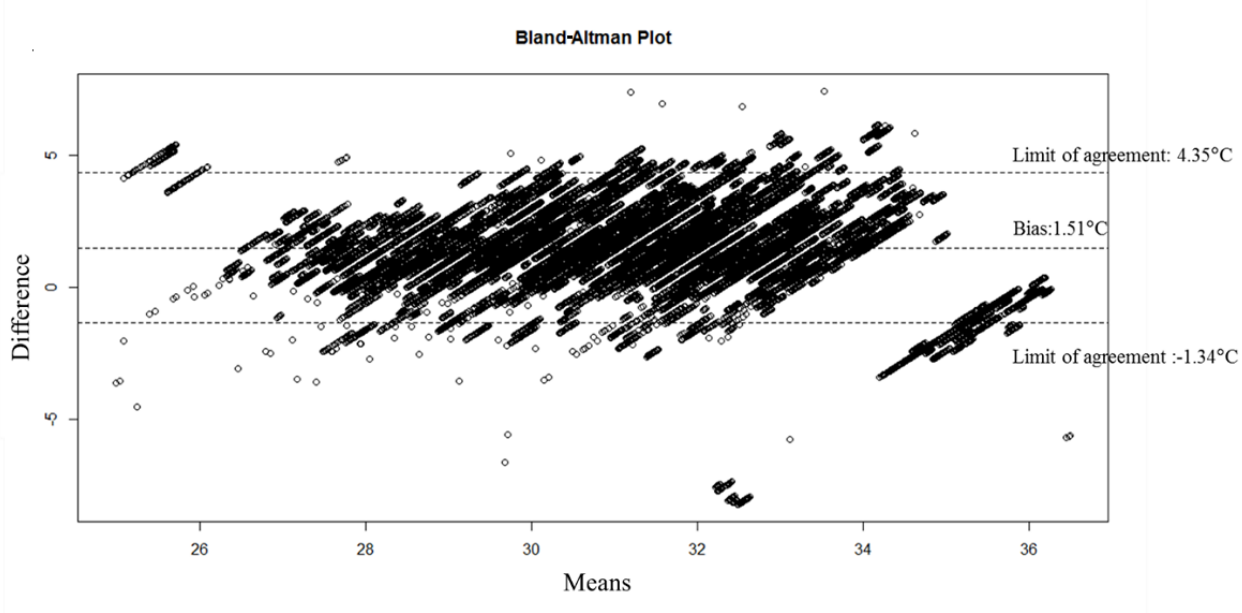

Table 2. Intraclass correlation coefficients between HEARThermo and infrared skin thermometer.

Room temperature (°C)	Intraclass correlation coefficient	95% CI	*F* value *(df)*	*P* value
≤19.9	0.45	0.40-0.49	2.62 (1354)	<.001
20-27.9	0.72	0.71-0.72	6.04 (140292)	<.001
≥28	0.49	0.48-0.51	2.94 (11233)	<.001

Discussion

Overview of the Findings

This is the first study to investigate the reliability and validity of novel wearable wrist devices with thermopiles for continuous monitoring of body surface temperature in a laboratory setting and on human subjects. Our study findings indicated that HEARThermo shows good reliability and adequate validity with infrared skin thermometers. The validated HEARThermo could be expected to provide more useful information by continuously monitoring variations in the body surface temperatures to support medical decisions more effectively. HEARThermo is a reliable device with a high ICC of 0.96-0.98 for the repeated measurement of body surface temperatures, which is consistent with that reported in a previous comparative study conducted on humans [37]. A recent systematic review of the measurement of body surface temperatures using contact thermometry showed that 94% of the studies lack detailed information about sensor calibration, thereby resulting in reduced validity of the data [38]. In this study, HEARThermo devices were calibrated using a water bath, and the corrected measurement bias averaged –0.02°C, which was smaller than that of the previously developed devices with ranges from 0.05°C to 0.2°C [23,24,29,33]. Measurement bias less than 0.5°C is considered minor [38]. However, the correction models should be adjusted occasionally because of the complex process of validating results due to the high demands on the specifications of the calibration methods and the reference thermometer [24]. Therefore, we suggest that the validation and calibration process for an innovative device should be based on the purposes of application in monitoring body surface temperatures under different scenarios.

HEARThermo was sufficiently validated with the infrared skin thermometer at room temperatures ranging from 20°C to 27.9°C, which concurred with the comparative study between iButton and reference mercury thermometer in a temperature-controlled water bath [39]. Studies have shown that the most used sensors in wearable wrist devices for monitoring body surface temperatures are thermistors [21,34,38], but only limited studies have tried to validate these wearable devices by using a temperature-controlled water bath from 19°C to 41°C [19,24,40]. Our study is the first to provide supporting evidence for the validity of infrared wearable devices in real time for measuring body temperatures in humans. Furthermore, HEARThermo showed no visualized systematic bias in terms of the criterion for infrared skin thermometers. However, the limits of agreement between the 2 measurement tools were wider than was the case in previous studies, which suggested that the range for the adequate agreement should be within 1°C in in vivo studies [38] and 0.5°C in clinical practice [41]. The effects of external factors on changing emissivity of the body surface may be more significant for infrared skin thermometers than for wearable devices due to the intermittent measurements by infrared skin thermometers [19,42], which may account for the wider range of limits of agreement found in this study. Our results reinforce that measuring body surface temperature using wearable devices should consider the tight contact with the skin surface. To date, wearable devices in the form of patches to

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monitor body temperature with features of tight contact have been developed and approved by the US Food and Drug Administration [23]. However, the ability to compare the agreement among different measurement tools for body surface temperatures might be limited due to the lack of a universal gold standard method for measuring body surface temperatures [38]. Further studies are needed to calibrate and validate the agreement between HEARThermo and different forms of medical thermometers in clinical settings.

Limitations

This study has the following limitations. First, the sensors of HEARThermo could not be calibrated using a high-precision blackbody while controlling the source of thermal radiation in this study. Second, a gold standard for measuring body surface temperatures is lacking, which might cause validation results to vary from one criterion measurement tool to another. Therefore, our study only highlights the relationship between HEARThermo and the infrared skin thermometer used in this study. Third, the generalizability of the study findings was limited to people aged ≥10 years since there was no appropriate size of bracelet for children aged 0-9 years. In addition, relatively healthy people with greater willingness might be recruited because of the snowball sampling method. However, as compared to the previous studies with small sample sizes and only males, this study tried to recruit both females and males and involved a larger sample size and wider age range to improve the generalizability of the findings. Fourth, the results of this study would be more applicable in Asian countries as only Asian people were recruited in this study. We recommend that further studies be conducted in different countries and races to validate wearable devices with infrared sensors in consideration of the emissivity of different human skin tones.

Conclusion

HEARThermo showed good test-retest reliability in the laboratory setting, with the highest correlation with the infrared skin thermometer at room temperatures of 20°C-27.9°C. Moreover, HEARThermo showed no visualized systematic bias and had a bias of 1.51°C with the criterion for infrared skin thermometers. This study validated an innovative wearable device for continuous monitoring of body surface temperatures. Further studies are needed to calibrate and validate the agreement between HEARThermo and different forms of medical thermometers in clinical practice.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Characteristics of the 66 study participants.
[DOCX File , 16 KB - mhealth_v9i2e19210_app1.docx]

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Abbreviations

CNS: National Standards of the Republic of China
ICC: intraclass correlation coefficient

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Corrigenda and Addenda

Correction: Smart Data Collection for the Assessment of Treatment Effects in Irritable Bowel Syndrome: Observational Study

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Related Article:

Correction of: https://mhealth.jmir.org/2020/11/e19696

(JMIR Mhealth Uhealth 2021;9(2):e27998) doi:10.2196/27998

In "Smart Data Collection for the Assessment of Treatment Effects in Irritable Bowel Syndrome: Observational Study" (JMIR Mhealth Uhealth 2020;8(11):e19696) the authors noted one error.

The phone number originally published in the Corresponding Author address has been removed from the paper for privacy reasons.

The correction will appear in the online version of the paper on the JMIR Publications website on February 18, 2021, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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Corrigenda and Addenda

Correction: Addressing Implementation Challenges to Digital Care Delivery for Adults With Multiple Chronic Conditions: Stakeholder Feedback in a Randomized Controlled Trial

Kelly Williams[1*], MPH, PhD; Sarah Markwardt[1*], MID; Shannon M Kearney[1*], CPH, MPH, DrPH; Jordan F Karp[2*], MD; Kevin L Kraemer[3*], MD; Margaret J Park[4*], MDiv; Paul Freund[5*], MEd; Andrew Watson[6*], FACS, M Litt, MD; James Schuster[1*], MBA, MD; Ellen Beckjord[1*], MPH, PhD

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Related Article:

Correction of: https://mhealth.jmir.org/2021/2/e23498

(JMIR Mhealth Uhealth 2021;9(2):e27996) doi:10.2196/27996

In "Addressing Implementation Challenges to Digital Care Delivery for Adults With Multiple Chronic Conditions: Stakeholder Feedback in a Randomized Controlled Trial" (JMIR Mhealth Uhealth 2021;9(2):e23498) the authors noted one error.

In the originally published article, the affiliation for author Kevin L Kraemer:

> *Center for Research on Health Care, Division of General Internal Medicine, University of Pittsburgh School of Medicine, Pittsburgh, PA, United States*

was inadvertently removed and replaced by the affiliation:

> *Department of Psychiatry, College of Medicine-Tucson, University of Arizona, Tuscon, AZ, United States*

In the originally published article, the full list of authors and affiliations was listed as follows:

> *Kelly Williams[1], MPH, PhD; Sarah Markwardt[1], MID; Shannon M Kearney[1], CPH, MPH, DrPH; Jordan F Karp[2], MD; Kevin L Kraemer[2], MD; Margaret J Park[3], MDiv; Paul Freund[4], MEd; Andrew Watson[5], FACS, M. Litt, MD; James Schuster[1], MBA, MD; Ellen Beckjord[1], PhD, MPH*
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This has been corrected to:

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The correction will appear in the online version of the paper on the JMIR Publications website on February 26, 2021, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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Letter to the Editor

The Kurbo App: The Freemium Model and Developmental Behavior Concerns. Comment on "Impact of a Mobile App–Based Health Coaching and Behavior Change Program on Participant Engagement and Weight Status of Overweight and Obese Children: Retrospective Cohort Study"

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Comment on: https://mhealth.jmir.org/2019/11/e14458

(JMIR Mhealth Uhealth 2021;9(2):e17492) doi:10.2196/17492

KEYWORDS

childhood obesity; intervention; app

Recently, WW (the rebranded Weight Watchers) has launched the WW *Kurbo* app, which was designed to help overweight/obese children aged 8-17 years to lose weight with or without parental assistance if they are older than 13 years. A recent publication in this journal, authored by Cueto et al [1], is the first scientific study evaluating the impact of the *Kurbo* app on engagement and weight status among overweight children and adolescents. All the study data from children were provided by the *Kurbo* app and were obtained retrospectively. The analysis and conclusions, which should be considered with limitations, were done with users enrolled in coaching sessions, and the weight was self-reported. The impact on weight reduction was observed for those with more coaching sessions, which confirms that childhood obesity requires professional support. This app is available only upon payment. There is no information, so far, about its impact on obese children when they and their families downloaded the app for free and started to monitor the children's food intake according to the traffic light diet.

The traffic light diet was first used as a part of a weight control program for overweight children aged 6-12 years with a multicomponent approach, published in 1980, including diet, exercise, and social learning principles [2]. On the other hand, there is no evidence that a traffic light system can be applied as an independent and effective tool in childhood obesity treatment. The traffic light system can be useful for the general population, labeling industry, and food education programs when the objective is to make people aware of food categories as in schools, cafeterias, and other public settings. However, food and nutrition knowledge is only the tip of the iceberg in the treatment of obesity in children. There is a large body of evidence that these children deal with emotional eating (eating in response to negative emotion or stress) [3], which makes treatment the biggest challenge of this century. The *Kurbo* app does not distinguish between the numerous factors related to childhood obesity such as etiology, overweight severity, gender, ethnicity, puberty stage, and self-esteem, and it is a dangerous oversimplification of obesity care and has a commercial interest. By providing a one-size-fits-all solution, it cannot provide the right approach to intervention, but more worrisomely it cannot control its side effects. The main criticism since it was launched is the potential risk for eating disorders since dieting is one of the most known predictors of their development [4]. Another risk of using this app is conflicts that will emerge in the child's life; simply put, a child or teenager with great expectations of solving their overweight condition will struggle to have green scores while their neurotransmitters will push them to eat palatable foods (usually high in sugar and/or fat) [5]. The frustration of facing red scores on the app screen can be an

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additional source of stress, reinforcing the need to eat tasty foods to compensate for negative feelings as a reward. Additionally, we should consider the risk of hiding, sneaking, or hoarding foods triggered by the embarrassment of eating in front of parents and others. Ignoring emotional outcomes, the *Kurbo* app design highlights the red score by displaying it in a larger size than green and yellow scores.

It is a great paradox that this app has gone public, reaching millions of children and adolescents without being evaluated by randomized trials and emotional side-effects outcomes.

Conflicts of Interest

None declared.

Editorial Notice

The corresponding author of "Impact of a Mobile App–Based Health Coaching and Behavior Change Program on Participant Engagement and Weight Status of Overweight and Obese Children: Retrospective Cohort Study" declined our invitation to reply to this commentary.

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Short Paper

A Mobile App to Facilitate Socially Distanced Hospital Communication During COVID-19: Implementation Experience

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Abstract

Background: COVID-19 has significantly altered health care delivery, requiring clinicians and hospitals to adapt to rapidly changing hospital policies and social distancing guidelines. At our large academic medical center, clinicians reported that existing information on distribution channels, including emails and hospital intranet posts, was inadequate to keep everyone abreast with these changes. To address these challenges, we adapted a mobile app developed in-house to communicate critical changes in hospital policies and enable direct telephonic communication between clinical team members and hospitalized patients, to support social distancing guidelines and remote rounding.

Objective: This study aimed to describe the unique benefits and challenges of adapting an app developed in-house to facilitate communication and remote rounding during COVID-19.

Methods: We adapted moblMD, a mobile app available on the iOS and Android platforms. In conjunction with our Hospital Incident Command System, resident advisory council, and health system innovation center, we identified critical, time-sensitive policies for app usage. A shared collaborative document was used to align app-based communication with more traditional communication channels. To minimize synchronization efforts, we particularly focused on high-yield policies, and the time of last review and the corresponding reviewer were noted for each protocol. To facilitate social distancing and remote patient rounding, the app was also populated with a searchable directory of numbers to patient bedside phones and hospital locations. We monitored anonymized user activity from February 1 to July 31, 2020.

Results: On its first release, 1104 clinicians downloaded moblMD during the observation period, of which 46% (n=508) of downloads occurred within 72 hours of initial release. COVID-19 policies in the app were reviewed most commonly during the first week (801 views). Users made sustained use of hospital phone dialing features, including weekly peaks of 2242 phone number dials, 1874 directory searches, and 277 patient room phone number searches through the last 2 weeks of the observation period. Furthermore, clinicians submitted 56 content- and phone number–related suggestions through moblMD.

Conclusions: We rapidly developed and deployed a communication-focused mobile app early during COVID-19, which has demonstrated initial and sustained value among clinicians in communicating with in-patients and each other during social distancing. Our internal innovation benefited from our team's familiarity with institutional structures, short feedback loops, limited security and privacy implications, and a path toward sustainability provided by our innovation center. Challenges in content management were overcome through synchronization efforts and timestamping review. As COVID-19 continues to alter health care delivery, user activity metrics suggest that our solution will remain important in our efforts to continue providing safe and up-to-date clinical care.

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KEYWORDS

adoption; communication; COVID-19; hospital; inpatient; mHealth; mobile app; telemedicine

Introduction

COVID-19 has fundamentally altered health care delivery. Hospitals have rapidly established and revised protocols to promote optimal patient care with minimized contact [1], particularly considering the limited supplies of personal protective equipment (PPE) [2]. Similarly, clinicians have altered the most basic aspects of patient care owing to social distancing while simultaneously adjusting to near daily changes in practice protocols. In this environment, the use of telehealth has increased substantially [3-5], bolstered by a temporary relaxation of technology requirements [6].

Owing to challenges in disseminating rapidly changing policies via email and the hospital intranet to a newly remote workforce, we adapted an existing mobile app to improve information accessibility at our institution. This app allows for direct dialing to in-patient rooms and facilitates clinician-patient communication while simultaneously minimizing contact and PPE use. This study describes the implementation and use of this app during the early stages of COVID-19 at our academic medical center as well as the benefits and challenges associated with its use.

Methods

At the onset of COVID-19, the Hospital Incident Command System (HICS) was established at the University of Chicago Medical Center and began distributing institutional policies and guidelines via email and the hospital intranet. The HICS soon determined that mobile communication might help overcome the limitations of communicating via email and the intranet, which are encountered by many frontline workers, but it was infeasible to develop a new mobile app owing to the overwhelming demands of the pandemic on the information technology (IT) team. The leadership began considering how existing communication technologies could be adapted rapidly to meet these demands.

The mobile app moblMD [7] (Multimedia Appendix 1) was initially implemented at the University of Chicago Medical Center in April 2018 as part of a feasibility study. The app provided a hospital directory, helped dial hospital phone numbers, and distributed institutional guidelines among users. Developed in-house by a cardiology fellow, it was a project of the Resident Advisory Council and has been used by 156 in-house staff since before COVID-19.

Instead of developing a new app, we rapidly adapted moblMD to (1) distribute COVID-19–related policies from the HICS team and (2) help clinicians search for and dial patient bedside phone numbers, as well as charge nurse and unit secretary phones, in order to promote social distancing and remote patient rounding.

Members of the HICS team were individuals playing different roles including nursing, strategy, and communication; they were selected to validate app content. To coordinate messaging, shared documents were used to ensure that the distribution of updates via email and the intranet were reflected in the content of moblMD. This small group of test users were provided preview access to updates before each release. After a rapid privacy and IT security review, instructions were distributed to all attending physicians, in-house staff, and advanced practitioners on March 29, 2020, and to all nurses on March 30, 2020. A new class of in-house staff was selected on June 22, 2020, and a new version of the app with a more intuitive interface for dialing patient rooms was developed from June 25, 2020. Accordingly, a reminder announcement was distributed on July 14, 2020.

Anonymized aggregate user activity data from the app server were reviewed approximately 2 months before and 4 months after the initial announcement (February 1 to July 31, 2020). Outcomes included the number of app users and user actions, the latter categorized as follows: general phone directory search, patient room phone number search, phone number dialing, and policy content review (Figure 1). Policy content reviews were examined for both frequency and page views. The institutional review board approved the use of moblMD (IRB18-0082).

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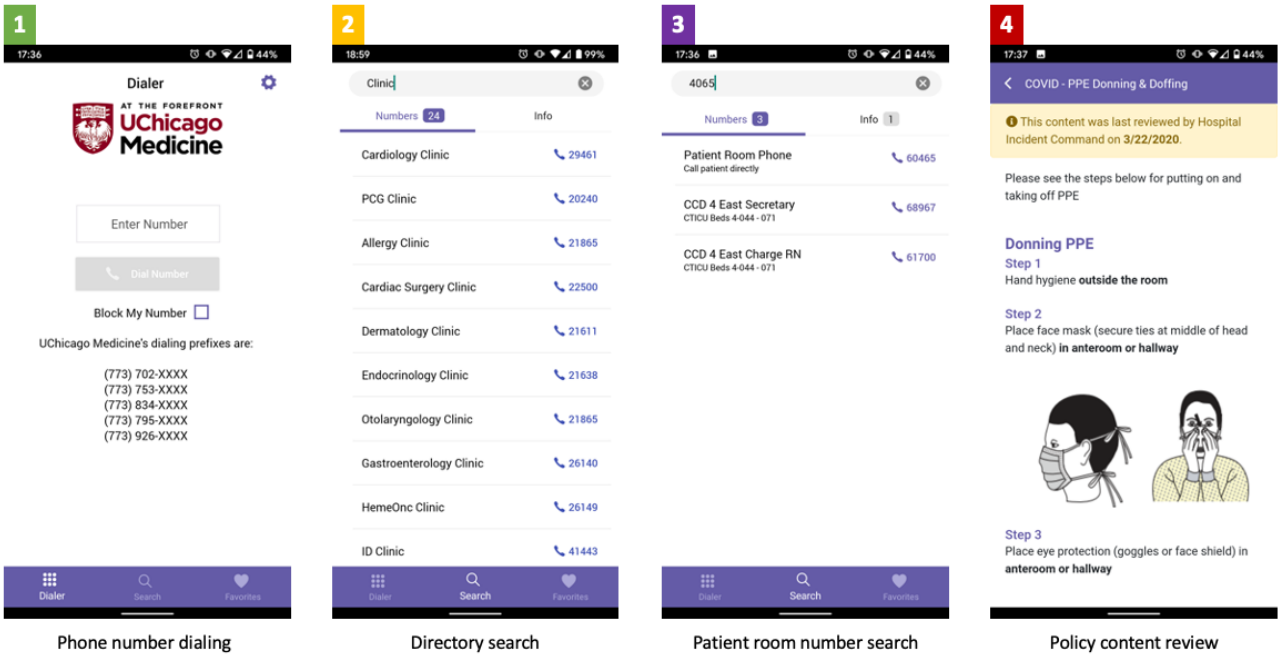
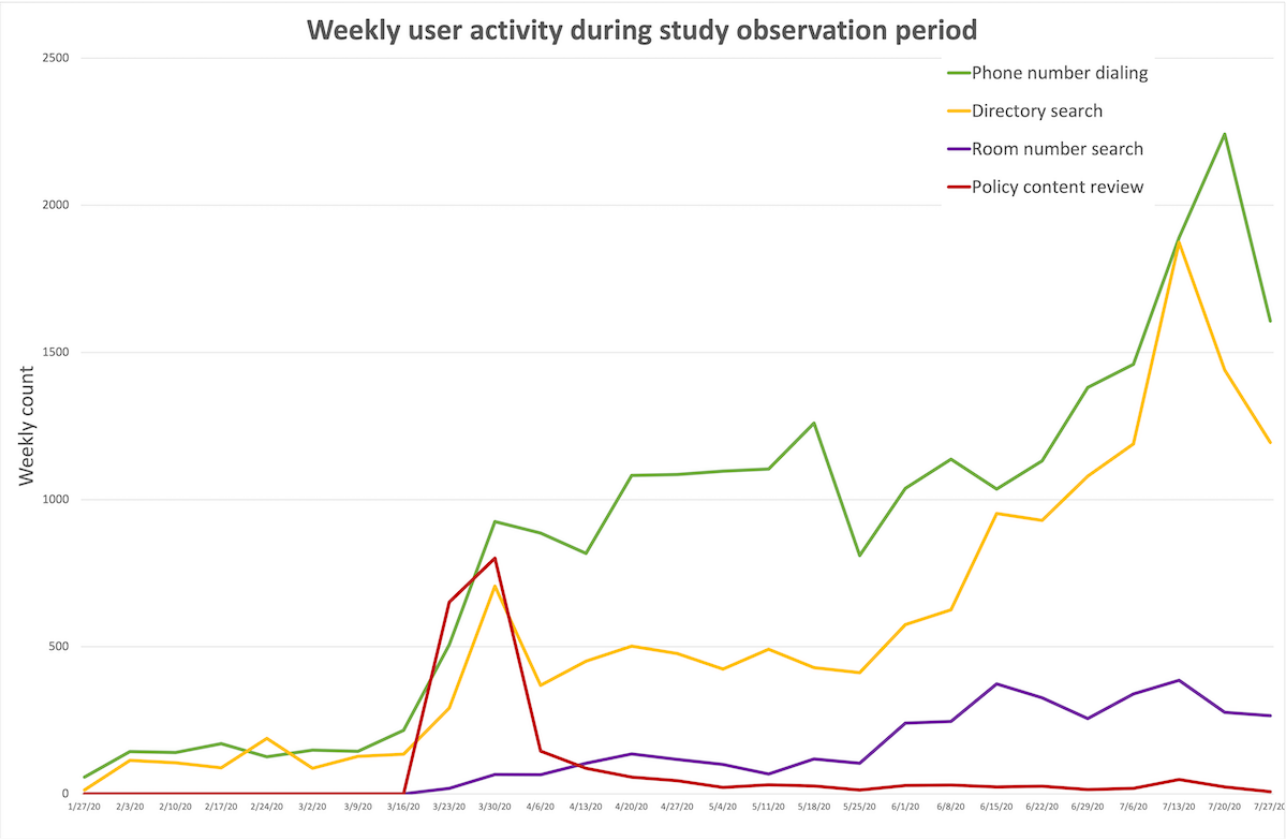
Figure 1. Representative screenshots of user activity categories within the moblMD app, ranked in descending order of usage.



Results

Within 4 months of release, 1004 unique users downloaded moblMD, with 46% (n=508) downloads within 72 hours of the first announcement, and 10% (n=110) downloads within 72 hours of the second announcement (Multimedia Appendix 2) [8,9]. Weekly total numbers of user app actions are shown in Figure 2.

Figure 2. Aggregate app user activity over the study period (February 1 to July 31, 2020). Note: The policy content review and room number search functions were not implemented until March 14, 2020. The last charted week was not a full week.



Within 72 hours of the first announcement, policy content was accessed at a similar frequency to that of directory searches and direct dialing, peaking at 801 weekly views. The most viewed policy contents during the study period were COVID-19 Important Contacts (437 views); COVID-19 Frequently Asked Questions (410 views); and COVID-19 Testing, patients under

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investigation, and Exposure (253 views) (Multimedia Appendix 3). In subsequent months, moblMD was used most frequently for hospital phone number dialing, including weekly peaks of 2242 phone number dials, 1874 directory searches, and 277 patient room phone number searches through the last 2 weeks of the observation period. Users submitted 56 content-related suggestions through the app during the observation period and many others through informal channels. The overall process for app implementation and timelines are illustrated in Multimedia Appendix 4.

Discussion

Principal Findings

During the early stages of COVID-19, we found that our in-house designed mobile app moblMD provided clinicians access to rapidly evolving institutional policies and protocols, facilitated remote patient care, and gained widespread durable use at our large academic medical center.

The most immediate impact of our intervention was to provide mobile access to new and changing hospital protocols in response to COVID-19. Prior to this, frequent communication regarding rapidly changing policies from our HICS team were only accessible via a series of emails and the intranet. These channels could be particularly ineffective and overwhelming for clinicians redeployed to new clinical roles [10]. While a mobile format improved information accessibility for frontline clinicians, it was challenging to keep disparate information sources synchronized. Aligning of moblMD content with traditional communication channels, focusing on high-impact policies on patient care (eg, PPE use, intensive care unit guidelines, etc), and labeling entries with the time of last review and the corresponding reviewer (Figure 1, box 4) helped address these challenges. Another challenge in managing app content was curating full-length content in .docx and PDF formats for brevity and mobile-friendly formatting. In a subsequent update, a toggle was enabled to link PDF documents. As expected, content views, such as instructions for PPE use and exposure protocols, peaked within 72 hours of the first announcement of the app as clinicians first consumed content, and such content was less likely to require repeated views.

The most durable impact of moblMD was the facilitation of remote patient care. Before COVID-19, our clinicians, like many others [11], routinely used their smartphones at the point of care. Although patient bedside phone numbers were previously accessible via the hospital call center or within the electronic health record, our mobile solution enhanced communication efficiency by providing a faster alternative. By facilitating mobile communication, we reduced the need for in-person communication as remote patient care became the norm to minimize PPE use and clinician exposure.

Many institutions have implemented other forms of in-patient telehealth or electronic PPE through which patients have video calls with clinicians through hospital-owned devices [12-14]. While this is a viable solution, it is costlier than in-person consultations and cannot be rapidly implemented at most institutions. Our intervention allowed for similar remote patient care in a matter of days, and clinicians had complete access to remote patient care through their smartphones.

Concurrent with previous reports, certain benefits and unique challenges are associated with internally sourced innovations [15]. Having been developed in-house, moblMD benefited from our team's understanding of the institutional culture and structure, which resulted in shorter feedback loops for content and feature updates. Feedback from the HICS team was delivered rapidly to the developer, and the app also included a feedback feature allowing clinicians to request updates. Clinicians were quick to suggest phone numbers relevant to their practice areas. Additionally, early user feedback prompted an interface update to further facilitate patient room search. Finally, although the app was largely known to the users, its distribution on the Google Play Store and the Apple App Store was based on app reviews, which took several days to obtain and needed to be factored in to discussions on feature requests.

Mobile communication and app use in health care settings has led to concerns regarding patient privacy [16] and information security [17-19]. Prior to release, an internal security audit and IT review were conducted in 5 business days despite this process typically taking much longer in general. moblMD was granted security approval expeditiously because it did not interface with the hospital infrastructure or collect user information other than an email address used for authentication. As a one-way communication channel, the risk of inappropriate transmission of patient information was limited. Following approval, the security team recommended follow-up evaluation after COVID-19 to address noncritical concerns.

Furthermore, it is important to address support and sustainability in our rollout of moblMD. Fortuitously, our Center for Healthcare Delivery Science and Innovation had recently announced an internal funding opportunity for COVID-19 innovations that provided a critical path towards sustainability. This helped advocate for our innovation within the hospital leadership, financially supported app infrastructure, and provided personnel with time to update the app content. Based on our experience, the Center for Healthcare Delivery Science and Innovation has adopted an innovation intake process to connect internal innovators with funding and resources in the IT, compliance, and legal sectors to facilitate early growth and validation [20].

Conclusion

We successfully adapted a mobile app to promptly facilitate remote patient care and disseminate COVID-19–related hospital protocols. Our mobile solution scaled without issue following announcements to thousands of users. The team's familiarity with institutional structures, short feedback loops, limited security and privacy implications, and a path toward sustainability provided by our innovation center were the key determinants to the successful implementation of our app. Challenges in content management were overcome through synchronization efforts and timestamping review. As COVID-19 continues to alter health care delivery, user activity metrics suggest that our solution will remain important in our efforts to continue providing safe and up-to-date clinical care.

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Acknowledgments

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Conflicts of Interest

ECA is the developer of the app. The app is not commercially available, and ECA receives no proceeds related to its use. The app was supported by the University of Chicago Medicine Center for Healthcare Delivery Science and Innovation. None of the other authors have any disclosures of interest.

Multimedia Appendix 1
Video demonstration of the basic functionality of the moblMD app.
[MOV File , 11017 KB - mhealth_v9i2e24452_app1.mov]

Multimedia Appendix 2
Growth of moblMD app user accounts over time. Time markers highlighting the date of the first COVID-19–related death, the start of the stay-at-home order in Illinois, and our hospital-wide app announcement.
[PNG File , 58 KB - mhealth_v9i2e24452_app2.png]

Multimedia Appendix 3
Policy content view counts during the study period (February 1 to July 31, 2020). Frequently asked questions included those regarding employee support resources, COVID-19 support clinics, blood donation/research, and donations of personal protective equipment.
[DOCX File , 13 KB - mhealth_v9i2e24452_app3.docx]

Multimedia Appendix 4
Overview of the app implementation process and timeline.
[PNG File , 111 KB - mhealth_v9i2e24452_app4.png]

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Abbreviations

HICS: Hospital Incident Command System
IT: information technology
PPE: personal protective equipment

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Original Paper

Challenges for Nontechnical Implementation of Digital Proximity Tracing During the COVID-19 Pandemic: Media Analysis of the SwissCovid App

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Abstract

Background: Several countries have released digital proximity tracing (DPT) apps to complement manual contact tracing for combatting the SARS-CoV-2 pandemic. DPT aims to notify app users about proximity exposures to persons infected with SARS-CoV-2 so that they can self-quarantine. The success of DPT apps depends on user acceptance and the embedding of DPT into the pandemic mitigation strategy.

Objective: By searching for media articles published during the first 3 months after DPT launch, the implementation of DPT in Switzerland was evaluated to inform similar undertakings in other countries. The second aim of the study was to create a link between reported DPT implementation challenges and normalization process theory for planning and optimizing complex digital health interventions, which can provide useful guidance for decision-making in DPT design and implementation.

Methods: A Swiss media database was searched for articles on the Swiss DPT app (SwissCovid) published in German or French between July 4 and October 3, 2020. In a structured process, topics were extracted and clustered manually from articles that were deemed pertinent. Extracted topics were mapped to four NPT constructs, which reflected the flow of intervention development from planning, stakeholder onboarding, and execution to critical appraisal. Coherence constructs describe sense-making by stakeholders, cognitive participation constructs reflect participants' efforts to create engagement with the intervention, collective actions refer to intervention execution and joint stakeholder efforts to make the intervention work, and reflexive monitoring refers to collective risk-benefit appraisals to create improvements.

Results: Out of 94 articles deemed pertinent and selected for closer inspection, 38 provided unique information on implementation challenges. Five challenge areas were identified: communication challenges, challenges for DPT to interface with other processes, fear of resource competition with established pandemic mitigation measures, unclear DPT effectiveness, and obstacles to greater user coverage and compliance. Specifically, several articles mentioned unclear DPT benefits to affect commitment and to raise fears among different health system actors regarding resource competition. Moreover, media reports indicated process interface challenges such as delays or unclear responsibilities in the notification cascade, as well as misunderstandings and unmet communication needs from health system actors. Finally, reports suggested misaligned incentives, not only for app usage by the public but also for process engagement by other actors in the app notification cascade. NPT provided a well-fitting framework to contextualize the different DPT implementation challenges and to highlight improvement strategies, namely a better alignment of stakeholder incentives, or stakeholder-specific communication to address their concerns about DPT.

Conclusions: Early experiences from one of the first adopters of DPT indicate that nontechnical implementation challenges may affect the effectiveness of DPT. The NPT analysis provides a novel perspective on DPT implementation and stresses the need for stakeholder inclusion in development and operationalization.

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KEYWORDS

epidemiology; normalization process theory; implementation; digital health; digital proximity tracing; digital contact tracing; COVID-19; app; surveillance; implementation; tracking; tracing; framework

Introduction

The Use of Digital Tools for Pandemic Mitigation

The current SARS-CoV-2 pandemic is one of the first global events in which digital tools have played a prominent role in epidemiological crisis management [1,2]. Earlier attempts to operationalize digital tools for infection control included crowdsourced surveillance applications for influenza (eg, [3]) or the Zika virus [4]; however, these attempts often met with limited success due to recruitment or reporting adherence challenges [5-7]. In the current SARS-CoV-2 pandemic, digital tools that rely on passive contact sensing have gained significant traction to support manual contact tracing (MCT). Often referred to as digital proximity tracing (DPT), these technologies aim to facilitate contact tracing by storing proximity contacts or visited locations through apps or wristbands [8]. Some applications rely on a GPS to track movements; however, they have the downside of not preserving privacy (in cases in which the movement data are stored centrally) and only operate within the technical limitations of GPS (eg, accuracy limitations, limited operability in buildings) [9].

A more novel approach to proximity tracing is based on peer-to-peer tracking, such as through Bluetooth low energy beacons [10]. In this approach, apps send out signals that include a user-specific identification number, which are then received by smartphones within a certain radius [11]. The signal strength correlates with proximity (the stronger the signal, the closer the sending device), which can be leveraged to determine proximity contacts that occurred within a distance that potentially enables SARS-CoV-2 transmission. If one of the proximity contacts tests positive for SARS-CoV-2, all other app users with relevant proximity within the window of infectivity are warned by the app. While the accuracy is not perfect, it appears to be fit for the purpose of DPT [11,12], as also evidenced by reports of alerted app users who tested positive (eg, [13]).

Implementation Challenges of DPT

Several countries are developing or employing DPT smartphone apps (eg, those listed in [9,14]). Early on, it was recognized that DPT needs to respect privacy [15], gain public trust [16], and adhere to ethical standards [17] to obtain a critical mass of app users required to have a significant impact on SARS-CoV-2 transmission [10]. Indeed, public surveys, some of which were conducted prior to app release, found that user acceptance of DPT strongly depends on privacy guarantees and public trust in app developers and sponsors [18-20]. Moreover, analyses of early DPT implementations, for example in Australia, suggest that technical aspects (eg, battery consumption, the need for apps to run in the foreground [21]) as well as persistent misconceptions [22,23] also play roles in user decisions and may hinder wide adoption. Therefore, privacy and trust deliberations have steered many of the academic [24] and public [25] debates as well as design decisions [26,27] related to DPT.

The following paragraphs of the introduction summarize some of these considerations before moving on to addressing the aims and contribution of this analysis. The first aim of this study was to compile and contextualize media debates regarding DPT implementation and effectiveness in Switzerland so that other countries can benefit from the experiences of one of the earliest DPT adopters. The second aim was to create a link between reported DPT implementation challenges with frameworks for analyzing complex digital health interventions, which can be useful to guide DPT design and (nontechnical) implementation decisions.

Centralized Versus Decentralized DPT

In the beginning, two initiatives presented possible DPT architecture designs, and they differed by their degree of data decentralization. Decentralization means that Bluetooth-measured proximity contacts are only stored locally on the smartphone (an approach promoted and developed by the Decentralized Privacy-Preserving Proximity Tracing [DP-3T] consortium) [27]. By contrast, the centralized DPT concept proposed by the Pan-European Privacy-Preserving Proximity Tracing (PEPP-PT) initiative [26] also foresees contact information storage (static personal identifier numbers) on a central server, thus potentially enabling the gleaning of information about a user's contact network [14]. These plans for centralized contact data storage led to privacy concerns and ensuing fears of lower population adoption rates, not only in public and academic circles [15] but also among major tech companies such as Google and Apple, who eventually decided to support the decentralized DPT architecture through the provision of smartphone application programming interfaces (APIs) [28]. As a consequence, many countries followed suit, with a majority of deployed DPT apps now being based on the decentralized DPT design [9]. In decentralized DPT, proximity contacts are evaluated locally on smartphones. The only data sent to a central server are anonymous random identifiers of persons with confirmed SARS-CoV-2 infection. These "infectious" identifiers are downloaded by all other users and compared against the locally stored identifiers of proximity encounters. If a match is found, users are notified and information on further steps is provided.

DPT Is a Complement to Manual Contact Tracing

Manual contact tracing (MCT) is a cornerstone of many countries' public health responses to SARS-CoV-2 (including Switzerland [29]). DPT is designed as a complement to MCT because it has distinct advantages. Specifically, DPT can warn exposed contacts much faster, warn multiple contacts simultaneously, and reach contacts not personally known to the index case [30]. By contrast, MCT identifies index case contacts through interviews, which is a labor-intensive process [31]. Given that exposed contacts enter quarantine upon app notification, the speed advantage of DPT should also lead to a faster interruption of transmission chains [10,32]. However, to achieve the desired goals, DPT needs adequate embedding in

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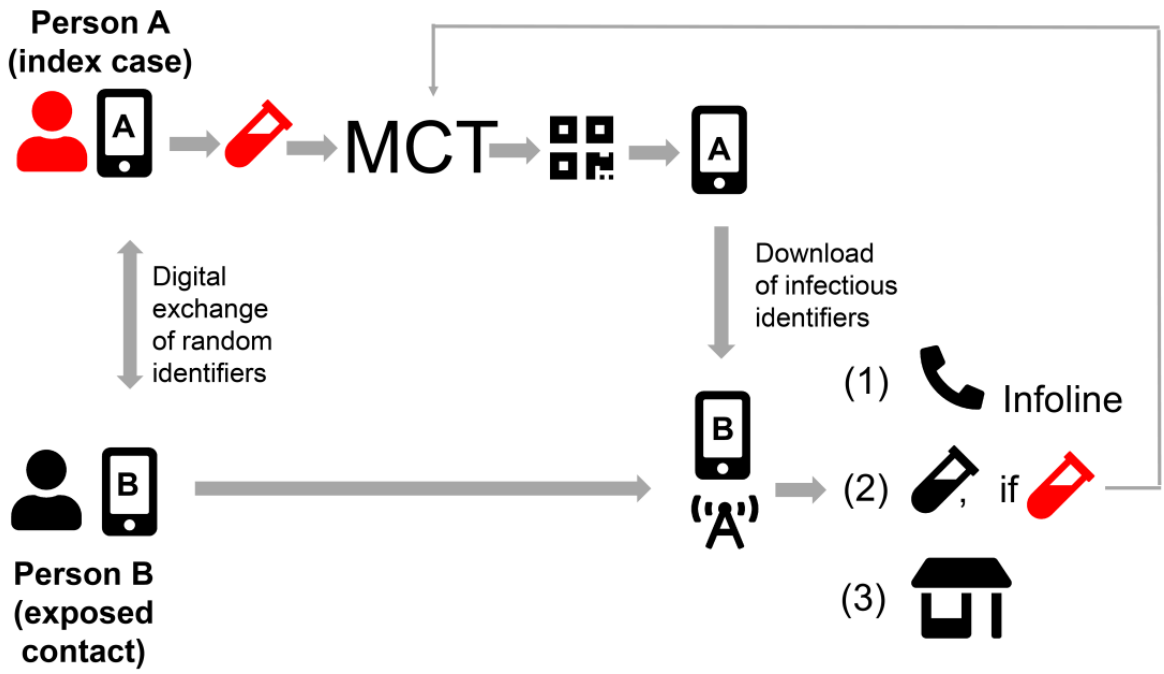
a country's overall test-trace-isolate-quarantine (TTIQ) response against the epidemic [29,33]. Furthermore, MCT remains indispensable because it enables better identification of transmission chains (eg, by including persons who do not use a DPT app) to assert prevention adherence (eg, compliance with mandatory isolation or quarantine) and obtain vital information about the time and setting of transmissions, thus providing valuable epidemiological data [31].

Implementation of DPT in Switzerland

Switzerland was one of the first countries to release its own DPT app (the SwissCovid app) on June 25, 2020, based on the decentralized, privacy-preserving proximity tracing architecture (DP-3T) [27]. The overall principle of the SwissCovid notification cascade is illustrated in Figure 1. Of note, the app notification sequence involves multiple actors, including the testing laboratory, the physician ordering the test, MCT (which also generates the "CovidCodes," that is, the authentication codes to be uploaded by the positive tested user), and an infoline that notified users are recommended to call. Although the SwissCovid infoline is centralized, MCT is organized at the level of the 26 cantons. The operational lead of MCT resides with the cantonal physician. Testing laboratories are decentrally organized private or public institutions. Guidelines and reporting forms are in place to inform the Federal Office of Public Health and the responsible cantonal health authorities about each newly detected SARS-CoV-2 case.

Figure 1. Steps in the notification cascade of digital proximity tracing. An infected person A tests positive for SARS-CoV-2 (red test tube), is referred to MCT, and receives and uploads a CovidCode to warn other app users. Person B was in close proximity and may have been infected. This person receives the app notification, upon which she has several options: calling an infoline (1), which is the recommended option, receiving a free test (2), and staying home voluntarily (3). MCT: manual contact tracing.



App-notified users have several options on how to proceed. The app notification suggests calling an official infoline. The infoline informs users that they are eligible for a free test after exposure notification and inquires more specifically about the potential risk of exposure. If indicated, the infoline recommends a voluntary quarantine (Step 1 in Figure 1). By comparison, MCT can result in order and enforcement of mandatory quarantine, but with salary compensation for working persons. Furthermore, notified app users can also directly request a free polymerase chain reaction (PCR) test (Step 2, Figure 1) or voluntarily stay at home without calling the infoline (Step 3, Figure 1), in which case they would not appear in any statistics. In the first phase after the app launch, the infoline could not directly refer callers to the responsible cantonal authorities and MCT; however, since September 2020, a respective agreement has been in place. Early on, the infoline was also confronted with erroneous calls; for example, some calls were triggered by an inaccurate translation of "weekly update notification" in Apple iOS 13.6 [34].

Some of the notification cascade steps have relatively strict timelines. Laboratories and attending physicians must report positive PCR test results to the responsible cantonal physician within two hours. The cantonal physician should generate the CovidCode and provide it to the infected app user, who has 24 hours to enter the code (after which the code expires).

Known Challenges to the Implementation of DPT

In implementation science, complex interventions are defined as "consisting of multiple behavioral, technological, and organizational components" [35]. As illustrated in Figure 1, DPT fulfills this definition of complex public health interventions because it involves several steps from laboratory testing to communication of results, notification triggering, notification receipt, and quarantine. Consequently, the success of DPT hinges on an efficient cascade of notifications from positive PCR test results to proximity contacts and involves app users, SARS-CoV-2 testing laboratories, health authorities, and

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possibly other actors. Therefore, seamless integration of DPT into broader pandemic mitigation measures (eg, testing facilities) and high app user compliance with recommended measures (eg, trigger notifications, entering quarantine) is crucial, especially in settings with voluntary DPT usage.

Emerging data provide early evidence for the effectiveness and impact of DPT on the transmission dynamics of the pandemic [36,37]. For Switzerland, the first studies about the performance of SwissCovid, both in terms of individual notification cascade steps and overall, paint a mixed picture. A recent report demonstrated proof-of-principle for the technical infrastructure of DPT [13]. Specifically, the study reports on at least 60 persons who were tested after an app notification and who were found to test positive by PCR for SARS-CoV-2. However, the same report also highlights some inefficiencies in the notification chain as described above. For example, the number of CovidCodes exceeds the number of entered codes by approximately 50%, which—in part—is a result of the voluntary nature of DPT: at each step, users can select whether or not to use the app and undertake the recommended steps, without fear of retribution. Along similar lines, a separate report examined the uptake and reasons for nonuse of the SwissCovid app [23]. For example, higher monthly household income or being a nonsmoker were associated with higher SwissCovid app uptake, whereas older age, lack of trust in health authorities, or having a non-Swiss nationality correlated with a lower uptake. Furthermore, early media coverage of SwissCovid [25], as well as a systematic review [38], unearthed some organizational challenges for DPT implementation. This is not completely surprising given the novelty and complexity of the intervention. Combined, these reports underscore the relevance of nontechnical implementation aspects for optimal DPT functioning.

Normalization Process Theory to Guide Planning and Implementation of Complex Digital Interventions

In other instances of complex intervention assessments, normalization process theory (NPT) has proven useful to systematically investigate the embedding of complex (digital) health interventions [35,39]. NPT aims to explain and promote factors that normalize an intervention, that is, to make it part of routine practice. NPT is centered around four core constructs, which also reflect the flow of an intervention development from planning, stakeholder onboarding, and intervention execution to critical appraisal [40]. Along this "life course" of an intervention, the *coherence* constructs describe how individual participants make sense of the implementation, *cognitive participation* reflects the participants' collective efforts to create commitment and engagement with the intervention, *collective action* refers to the execution of the intervention and describes the joint efforts of all actors to make it work, and *reflexive monitoring* refers to collective appraisals of risks and benefits and developing improvements by all actors [40].

Aims of the Analysis

To summarize, although some challenges and bottlenecks in DPT implementation are already known, a systematic compilation and framing of these implementation challenges is largely lacking. Furthermore, it remains unexplored whether and how generic digital health implementation frameworks help to conceptualize these DPT challenges and inform possible optimizations. Therefore, this analysis aimed to systematically scrutinize media reports on SwissCovid for statements and examples reflecting challenges to optimal intervention functioning. A major goal of this analysis was to identify and report challenges in the nontechnical implementation and embedding of DPT. These early experiences may inform other countries that are considering or actively implementing DPT about possible challenges and optimization strategies.

Furthermore, by mapping the identified challenges to the NPT constructs, the analysis also creates a link to the rich NPT literature, which provides tools and frameworks to optimize the adoption and effectiveness of digital health interventions.

Methods

Media Analysis

The present analysis was informed by Swiss media reports. The Swissdox Essentials media database was searched from July 4 to October 3, 2020 [41]. This database covers all Swiss print media and the most important web-based portals. Only entries in German or French, languages that are spoken by 85% of Swiss inhabitants [42], were considered. Using the search phrase *SwissCovid* or (*'Swiss Covid'* AND *app*), the Swissdox database was searched for unique print and web-based articles reflecting independent journalistic investigations. That is, reprinted articles or articles that referred to other articles without adding information were excluded. Live ticker transcripts were also excluded from our search.

Eligible articles were manually prescreened to determine whether they reported on problems or inefficiencies of the SwissCovid app. This screening process was facilitated by the Swissdox database, which highlighted all sentences containing the prespecified search terms. In a subsequent, more detailed screening, the selected pertinent news articles were read completely, and relevant sections were highlighted. During this process, duplicate articles were removed (along with those that simply paraphrased an earlier article), and topics were manually extracted based on the following predefined topic list (informed by subject knowledge of the author): problems referring to (a lack of) communication, technical problems or confusion regarding the app, issues related to the effectiveness of the app, delays in receiving test results, delays in receiving CovidCodes, issues related to the infoline, lack of support from participants, and competition for strained resources by SwissCovid. The key issues regarding the SwissCovid app were summarized manually and grouped by the author. All news article files are available from the author upon request.

Linking of Reported Challenges With Normalization Process Theory

Finally, the key challenges reported in the press articles were contextualized and interpreted using the NPT questions developed by Murray et al [39]. NPT was selected a priori as an assessment framework based on findings in the literature. The present study followed the guiding questions outlined by Murray et al [39]. and considered the following stakeholders

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involved in the DPT notification cascade in Switzerland (henceforth also called "participants" to remain compatible with NPT terminology): app users; SARS-CoV-2 testing laboratories; cantonal health authorities and cantonal physicians who perform MCT; the Federal Office of Public Health (FOPH), which is the product owner of the SwissCovid app; and the infoline, operated on behalf of the FOPH by a commercial telehealth company. Mapping of DPT challenges to the different NPT constructs was performed manually by the author.

Results

Findings From the Media Analysis

Figure 2 outlines the search process of the media database, which resulted in a total of 38 articles deemed relevant for the analysis. The key topics extracted from the selected articles are outlined in Table 1 (with information on the 38 articles presented in Multimedia Appendix 1).

Figure 2. Flowchart of article selection from the Swissdox media database. NPT: normalization process theory.

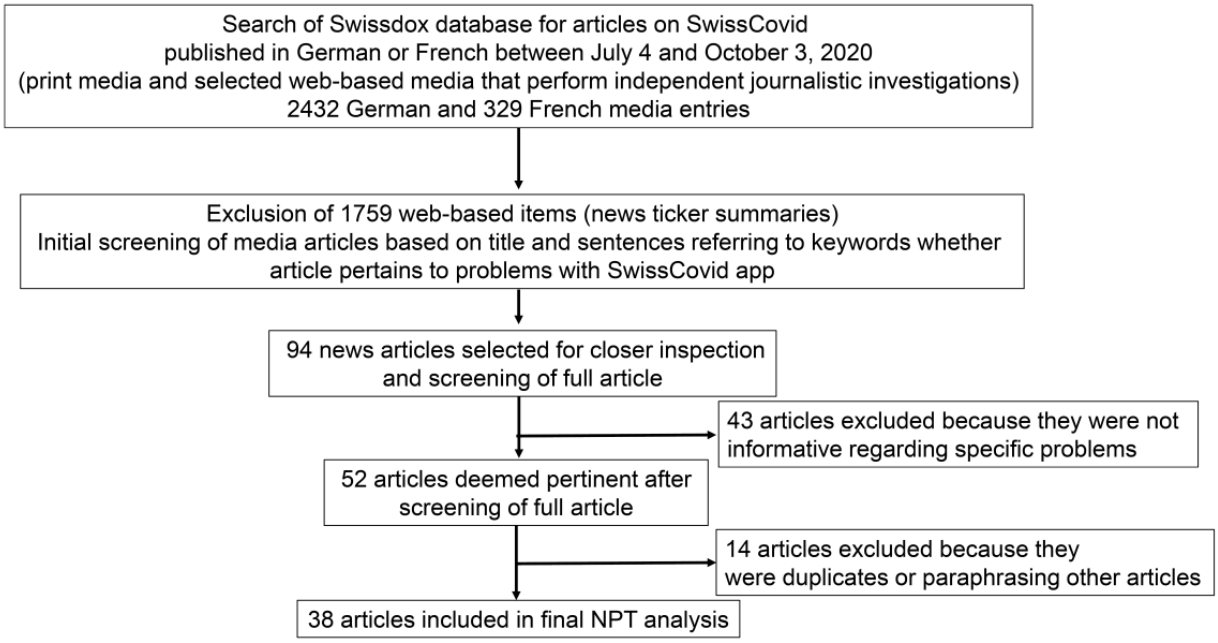

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Table 1. Major topics identified in the selected articles.

Group	Name	Item number	Topic	Media reports[a]
A	Communication	A1	Need for optimization of app error messages	#22, #28, #53
		A2	Communication concerning DPT[b] usage, privacy, and benefits could be improved	#10, #32
		A3	Unmet communication needs by some participants in the notification cascade, such as cantonal health authorities or physicians	#29, #14
B	Interfaces and processes	B1	Delays in CovidCode generation	#2, #8, #14, #17
		B2	Unclear connection between infoline and cantonal health authorities	#20
		B3	Legal hurdles for cantonal physicians to order a mandatory quarantine based on app notification	#29
		B4	Following a change of testing criteria, some confusion about procedures for obtaining free PCR[c] test upon app notification	#14
		B5	Interference with work, such as nurses with proximity contacts to patients infected with SARS-CoV-2	#61, #35
C	Competition for resources	C1	Initial fears of cantonal authorities of being overwhelmed by persons receiving app notifications	#20
		C2	Concerns that app development and operation will drain resources from other pandemic mitigation efforts	#29, #30
D	Unclear effectiveness	D1	Some disappointment when download numbers started to plateau; fears that the number of active app users will not suffice for DPT effectiveness	#5, #18
		D2	Effect on pandemic mitigation still unclear for users and other participants, such as cantonal physicians	#18, #32, #14, #29
E	Obstacles to higher user coverage and compliance	E1	The app does not work abroad	#5, #22
		E2	Lingering fears regarding privacy	#11, #12, #25
		E3	Temporary lower infection numbers reduced the urgency for app usage	#12
		E4	PCR-positive app users are not entering the CovidCodes	#2, #28
		E5	App-notified users are not calling the infoline (and do not appear in any statistics	#57, #58
		E6	Lack of personal incentives to use or regularly check the app status (could be remedied, for example, by the inclusion of news updates about pandemic); The app remains silent unless there is a notification	#42, #48

[a]#ID refers to the individual media reports listed in Multimedia Appendix 1.

[b]DPT: digital proximity tracing.

[b]PCR: polymerase chain reaction.

Topic Extraction

A more detailed analysis of the 38 pertinent articles revealed several challenges that largely fell into five topics: (1) communication challenges, (2) challenges to optimal DPT interfacing with other processes, (3) fear of competition for limited resources with established pandemic mitigation measures, (4) unclear effectiveness of DPT, and (5) obstacles to greater user coverage and compliance (Table 1).

Several articles cited communication challenges (group A, Table 1). Some reports referred to confusing app error messages, the need for intensified or improved communication to app users about the benefits and processes involved in SwissCovid, and a need for improved exchanges with other participants in the intervention, particularly the 26 cantonal health authorities. Most articles saw a solution for overcoming these challenges through intensified communication by the FOPH (being the SwissCovid product owner) with the public and other participants.

Regarding operational challenges (group B, Table 1), the most frequently echoed concern pertained to delays in sending CovidCodes to SwissCovid users with positive PCR tests for SARS-CoV-2. First media reports appeared in August 2020 after testimonies of persons who only received the codes after significant delays. Later articles also reported on procedural adjustments by cantonal health authorities to increase the speed of CovidCode generation and delivery.

In the context of delays of CovidCode generation, other processes, such as reporting of positive PCR test results by

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laboratories or access to testing, also came under scrutiny. Thereby, further potential problems surfaced that could affect the speed of the notification cascade. First, laboratories or physicians ordering PCR tests may sometimes be unable to adhere to the 2-hour timeline for communication of positive test results to cantonal authorities (eg, due to high testing volumes). Second, one physician stated that changing testing criteria and guidelines may have created some temporary confusion regarding procedures for accessing free testing by app-notified persons, which was resolved shortly after. Third, during the initial weeks after the app launch, the infoline was unable to refer app-notified callers directly to their respective cantonal health services for further evaluation. One article quoted a cantonal physician, who stated data protection reasons for this referral gap. Data protection was also stated as a reason why some health authorities found it difficult to integrate DPT into manual tracing procedures. According to one cantonal physician, the (intended) inability of DPT to provide additional data on the timing and place of potential exposure was diminishing its value for manual contact tracers.

Furthermore, some articles reported on challenges for health care workers to using the app, especially when they were engaged in the care of patients infected with SARS-CoV-2. Hospitals were concerned about frequent notifications (despite personnel wearing protective gear) and ensuing confusion. Some hospitals asked their employees to switch off SwissCovid while at work.

The third group of topics (group C, Table 1) concerned the resource situation on the part of the FOPH and the cantons. A retired FOPH official and at least two cantonal physicians were cited to have some doubts regarding DPT effectiveness and were therefore concerned that DPT would compete for scarce human resources at the FOPH and cantonal health authorities. The initial referral gap between the infoline and cantonal health authorities (cf group B) was, according to one source, driven by concerns of cantons of becoming overwhelmed by app-notified contacts.

The fourth cluster of challenges (group D, Table 1) pertained to a perceived unproven effectiveness of DPT. Because DPT was developed and released under immense time pressure and with limited real-world testing, doubts about the usefulness and contribution of DPT to pandemic mitigation persist. This uncertainty could potentially create a vicious cycle: the target population may not be inclined to use the app because of unproven effectiveness, but without widespread use, its effectiveness cannot be demonstrated. These concerns were echoed shortly after the public release of SwissCovid, when the number of active users seemed to plateau at approximately 1 million (on October 14, the SwissCovid app had 1.67 million active users and 2.5 million downloads [43]). This perceived lack of benefit was not confined to the public but also appeared to exist among some health authorities. Statements by two cantonal physicians alluded to views that DPT was considered to be an additional burden with unclear benefits by some health authority members.

The fifth cluster of topics (group E, Table 1) was related to user coverage and compliance. In July 2020, several media outlets reported on the plateauing (or even decreasing) user numbers as well as on discrepancies in the numbers of generated and uploaded CovidCodes (indicating that not all app users with positive PCR tests chose to trigger notifications). Several explanations were explored, such as lingering concerns about privacy (with a need for better communication), low overall case numbers of SARS-CoV-2 infections in July, or the inability to use the SwissCovid app abroad (eg, during vacation). A frequent conclusion by the media was a need for more communication by the FOPH to address these privacy concerns and to emphasize the potential benefits of the SwissCovid app. With increasing active SwissCovid use and the first manifestations of positive effects, these concerns moved somewhat to the background but never disappeared entirely.

Mapping of Topics to NPT Constructs

Table 2 illustrates the mapping of identified topics to different NPT constructs. Overall, the media analysis provided information for most of the NPT questions. Except for topic E1 (“The app does not work abroad”), all topics mapped well to specific NPT constructs and individual subquestions. Of the individual topics, 10 fell into the *Coherence* construct, 5 into the *Cognitive Participation* construct, 10 into the *Collective Action* construct, and 3 into the *Reflexive Monitoring* construct.

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Table 2. Mapping of topics to normalization process theory constructs.

Normalization process theory construct	Topic domains (cf Table 1)	Assessment
Coherence (making sense of the intervention, ie, meaning and sense-making by participants)		
Is the intervention easy to describe?	D1, D2, E3, E6	DPT[a] is difficult to explain; some misconceptions of what DPT should achieve (eg, generating helpful data) or requirements for success (eg, need of 60% participation rate in population to be successful).
Is it clearly distinct from other interventions?	C2	Because DPT is an adjunct to manual contact tracing, the distinction is not always obvious to all participants; DPT may even be seen as competition to manual tracing.
Does it have a clear purpose for all relevant participants?	C2, D2	There were doubts about the purpose of DPT or even the right to coexist with manual contact tracing.
Do participants have a shared sense of its purpose?	C2, D2	Not all participants are convinced, including parts of the population and cantonal health authorities.
What benefits will the intervention bring and to whom?	C1, D1, D2, E6	Benefits are abstract, not immediately visible, and partially context dependent (eg, role of second line of defense).
Are these benefits likely to be valued by potential participants?	D1, D2, E2, E4, E6	The overall potential benefits (slowing transmission) are valued by most, but doubts persist whether DPT can contribute toward that goal.
Will it fit with the overall goals and activity of [pandemic mitigation goals][b]?	N/A[c]	DPT was designed to complement manual contact tracing; In principle, DPT is well aligned with other pandemic mitigation goals.
Cognitive participation (working out participation in the intervention, ie, commitment and engagement of participants)		
Are target user groups likely to think it is a good idea?	C1, C2, D1, D2	Some doubts seem to persist among all participants. Not all actors seem convinced of the benefits.
Will they see the point of the intervention easily?	E3	DPT was released during a time when case numbers were low. Benefits remained abstract and unclear, in part also because of low infection numbers. Initially, this may have affected the willingness to engage in DPT work processes.
Will they be prepared to invest time, energy, and work in it?	C1, C2	DPT was seen as competing for time and resources with other mitigation measures by some actors. Therefore, the willingness to engage in cognitive participation may have been limited.
Collective action (executing the intervention, ie, the work participants do to make the intervention function)		
How will the intervention affect the work of [participants]?	B1, B2, B3, B4, B5	DPT introduces additional steps and processes for MCT[d]. There were also some unclarities and frictions between different processes and interfaces (eg, between testing labs and cantonal physicians or between users with positive PCR[e] tests and cantonal physicians).
Will it promote or impede their work?	B2, B5, C1, C2	DPT potentially adds to the workload of MCT; app use can be problematic for health care workers.
What effect will it have on [interactions]?	B2, B3, B4, C2	DPT notifications are an additional dimension to be covered in MCT interviews; interface between infoline and cantonal health authorities needed optimization.
Will staff require extensive training before they can use it?	A3, B4	In principle, yes, some reports indicate an additional need for instructions or communication for some (health system) actors.
How compatible is it with existing work practices?	C2, D2, E5, E6	DPT is seen as something separate that adds to the workload. Data protection apparently inhibits complete DPT integration into MCT. Notified users may take actions, but not always as recommended (eg, directly seeking tests).
What impact will it have on division of labor, resources, power, and responsibility between different professional groups?	B2, D2	Reports indicate several “interfacing” challenges, such as between infoline and cantonal health authorities. Reports of confusion regarding eligibility of free PCR testing for notified users.
Reflexive monitoring (reflecting on the intervention, ie, participants reflect on or appraise the intervention)		
How are users likely to perceive the intervention once it has been in use for a while?	D1, D2	Effectiveness still seems unclear or unproven for some actors. New case numbers of SARS-CoV-2 remained relatively low for most of the observation period, thus affecting perceived effectiveness.

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Normalization process theory construct	Topic domains (cf Table 1)	Assessment
Is it likely to be perceived as advantageous for [users and other participants]?	C2, D1, D2	This seems not to be the case for all actors.
Will it be clear what effects the intervention has had?	D1, D2	The uncertainty regarding DPT effectiveness hampers usage and implementation.
Can users/participants contribute feedback about the intervention once it is in use?	N/A, but indicated by some reports.	App users gave indirect feedback (eg, via social media). Other actors had direct interactions with the Federal Office of Public Health and the app developers.
Can the intervention be adapted or improved on the basis of experience?	N/A, but indicated by some reports.	App development is continuous; there is regular exchange about possible improvements.

[a]DPT: digital proximity tracing.

[b]Expressions in brackets reflect adaptations of the original question wordings [39] to better fit the current analysis.

[c]N/A: not applicable.

[d]MCT: manual contact tracing.

[e]PCR: polymerase chain reaction.

The greatest concerns in the *coherence* construct pertained to unclear benefits and distinctions from other processes (especially manual contact tracing). These concerns were voiced by different participants, including app users and cantonal authorities. Additionally, fears of resource competition with other mitigation measures were cited. In part, these concerns reflected the complexity of the SwissCovid app notification cascade and possibly also an incomplete understanding of the role requirements by some participants.

Multiple reports also indicated challenges in the *cognitive participation* domain that overlap with other NPT constructs. Specifically, the interplay between different actors may require optimization, as well as clarifications regarding resource situations (eg, on the part of cantonal authorities).

Furthermore, many of the reported problems in the *collective action* domain indicated a need for optimized integration of SwissCovid into existing work processes. From the viewpoint of some cantonal health authorities, SwissCovid was perceived to add to the existing workload while providing unclear benefits. Additionally, some statements reflected a need for additional communication and knowledge transfers to different participants, for which the FOPH was seen to be in the lead.

By contrast, there were fewer media reports regarding the *Reflexive Monitoring* construct. However, some reports indicate that communication between different participants (FOPH, cantonal physicians, infoline operators) is ongoing, and optimizations have been planned or even put in place (eg, better coordination between infoline and cantonal health authorities; integration of news into the SwissCovid app to provide additional user incentives).

Discussion

DPT is a complex public health intervention to mitigate the SARS-CoV-2 pandemic. Its effectiveness depends on appropriate embedding into a country's overall TTIQ strategy and requires multiple, timely actions by different actors. This article describes early experiences with DPT implementation in Switzerland, which has one of the longest track records of decentralized DPT operation.

Based on Swiss media articles published during the first three months after DPT release, this study presents different challenges in nontechnical DPT implementation. These challenges included unclear DPT benefits, which affected commitment and raised fears among different health system actors for resource competition with established pandemic mitigation measures. Moreover, media reports indicated process interface challenges in the notification cascade (eg, in the hand-over of app notified users from the infoline to responsible cantonal authorities), as well as misunderstandings and unmet communication needs on the side of some health system actors. Finally, some reports suggested misaligned incentives, both for app usage by the public as well as for process engagement by other actors in the app notification cascade [44].

Challenges Viewed Through the Lens of NPT

In the SARS-CoV-2 pandemic, timely diagnosis, isolation, and quarantine are essential processes, which DPT apps are intended to support. However, procedural frictions can lead to delays, which also affect the effectiveness of DPT. Examples are late deliveries of CovidCodes (codes to trigger notifications) or uncertainties regarding access to PCR tests upon app notification. Furthermore, most challenges identified in the media search bear close relationships to the constructs of NPT. Specifically, many identified challenges mapped well to the *coherence* (“making sense of the intervention”) and *collective action* (“executing the intervention”) domains. For example, unmet communication and training needs regarding DPT usefulness and integration into existing workflows seemed to exist, which hindered stakeholder onboarding and optimal process flows in the notification cascade. Perceived lack of usefulness is also affecting the uptake of the DPT app in the population. However, “sense-making” by different participants may also be context- and time-dependent. The SwissCovid app was released at a time of relatively low SARS-CoV-2 incidence, which meant that DPT effects could not become apparent immediately [45]. However, in late August 2020, the FOPH presented data indicating rising numbers of app users who

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sought PCR testing after a SwissCovid notification and then tested positive, which may have alleviated some of the concerns regarding effectiveness.

It is worth noting that public agenda setting also played a role in media reports, as illustrated by articles including statements of DPT developers or reports covering FOPH press conferences. For example, in one article (#6, Multimedia Appendix 1), a member of the DPT development voiced concerns about insufficient engagement of some cantonal authorities in the DPT notification cascade. In another example (#37, Multimedia Appendix 1), the FOPH presented preliminary data from an effectiveness analysis to increase public confidence and ultimately app uptake in the population, which was followed by an increase in the number of active users around the end of August 2020 [43].

Contribution to the Literature

The present analysis may contribute to the international debate on DPT on two levels. First, it provides insights into challenges of DPT implementation from a country with one of the longest track records of DPT implementation and a complex, federalistic health system. Second, by applying the NPT framework to classify different reports, the analysis also contributes on a methodological level by illustrating the usefulness of the NPT approach. NPT can provide guidance on how to bring complex digital health interventions to fruition by considering motivations, potential benefits, or operational burdens of a digital health intervention for different stakeholders who should engage in implementation. NPT postulates that individual and collective actions need to be in synchronization for a complex intervention to be successful. To quote one of the foundational papers of NPT: “The starting point of the theory is that to understand the embedding of a practice we must look at what people actually do and how they work [46].”

The present analysis indicates that NPT can indeed provide a useful framework to classify DPT challenges and may help to identify suitable optimization. For example, as suggested by the *reflexive monitoring* construct, some media reports indicate continuous DPT process adaptations, as well as constant communication with actors and assessments of potential improvements. Ideally, NPT or similar implementation frameworks should already be considered during the development and release of novel technologies, which was hindered in Switzerland by immense time pressures created by the pandemic situation.

Study Limitations

Some limitations of the study and its interpretation are worth noting. The reliance on published media reports (and not, for example, on stakeholder interviews) may have limited the diversity and level of detail of the current debates about DPT. It may also have missed aspects that were never raised by the media but were discussed bilaterally between different actors. The reliance on published media reports was an advantage, as it enhanced the reproducibility of our study. Furthermore, it should be noted that the challenges outlined in this report do not reflect the status quo, and it is not intended to pass judgment on the success of DPT or the roles of the different participants in Switzerland. Finally, extraction and classification of the media reports was performed by a single person, which should also be considered as a limitation.

To summarize, the analysis of media reports on implementation challenges for DPT in Switzerland demonstrates that the nontechnical implementation of DPT must not be forgotten. The experiences in Switzerland indicate that the technical aspects work well, but in some instances, the nontechnical processes led to bottlenecks in the notification chain. This is understandable given the multiple interactions required between different participants. The lessons from Switzerland, one of the earliest adopters of DPT, and the demonstration of the usefulness of NPT for planning and analyzing NPT implementation will hopefully serve as an inspiration for other countries that are developing their own DPT implementations.

Conflicts of Interest

The author has received funding from the Federal Office of Public Health for other studies.

Multimedia Appendix 1
Articles that were included in the topic analysis.
[DOCX File , 18 KB - mhealth_v9i2e25345_app1.docx]

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Abbreviations

API: application programming interface
DP-3T: Decentralized Privacy-Preserving Proximity Tracing
DPT: digital proximity tracing
FOPH: Federal Office of Public Health

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MCT: manual contact tracing
NPT: normalization process theory
PCR: polymerase chain reaction
PEPP-PT: Pan-European Privacy-Preserving Proximity Tracing
TTIQ: test-trace-isolate-quarantine

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