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Viewpoint

A Path to Better-Quality mHealth Apps

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Abstract

The rapid growth of mobile health (mHealth) apps has resulted in confusion among health care providers and the public about which products rely on evidence-based medicine. Only a small subset of mHealth apps are regulated by the US Food and Drug Administration. The system similar to that used to accredit and certify laboratory testing under the Clinical Laboratory Improvement Amendment offers a potential model for ensuring basic standards of quality and safety for mHealth apps. With these products expanding into the realm of diagnosis and treatment, physicians and consumers are in a strong position to demand oversight that delivers safe and high-quality mHealth apps.

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KEYWORDS

mobile apps; smartphone; software validation; medical device legislation; United States Food and Drug Administration

Introduction

Since smartphones first went on the market a decade ago, the estimated number of available mobile health (mHealth) apps increased to approximately 325,000 in 2017 [1]. These tools could have a significant positive impact on health and health care. Yet, they also pose novel challenges for patients and clinicians faced with a virtually infinite choice of unproven products.

Doctors struggle with which apps to recommend for patients and patients don't know which apps may be useful. Physicians must consider the value of an mHealth app before they recommend one since most apps have been created without medical expert involvement or appropriate testing validation [2]. There is a paucity of evidence about the effectiveness of most mHealth apps. One team of US and European researchers went to the iTunes App Store and Google Play in January 2017 in search of apps that can help people cope with anxiety disorders. Of the 52 apps selected, the majority (33/52, 63.5%) offered no information about the intervention. More than two-thirds (35/52, 67.3%) did not offer information about the professional credentials of the app developers or consultants.

Only 4% (2/52) offered any information about the efficacy data supporting the apps [3].

Furthermore, apps that provide patient information to physicians must also abide by federal laws protecting personal data and should demonstrate that they are based on best medical practices. Doctors who recommend mHealth apps should be aware that they face potential liability if claims made by app developers are fraudulent [4]. The stakes are rising as new apps and wearable devices come on the market with the ability to gather patient-specific data that can provide clinicians with diagnostic and treatment recommendations. These offer tools that are potentially useful but could affect patients if they rely on false or obsolete medical information [2]. As a result, doctors are wary of recommending mHealth apps. Patients are equally unsure and therefore infrequently get advice about the use of apps from their health care provider.

Regulatory Efforts

What can patients and physicians do to ensure high-quality mHealth apps? At least four models have evolved for ensuring that organizations who provide products or services to the public

meet basic standards of safety and effectiveness. They are regulatory approval by a federal agency, accreditation by an organization with deeming authority under federal law or regulation, voluntary accreditation by a nonprofit organization, and the European Union's (EU's) decentralized system driven by its member states. The US Food and Drug Administration (FDA) applies regulatory oversight only to a small subset of mHealth apps. The FDA has indicated that it will regulate only those apps it defines as a medical device and those which potentially pose a risk to patient safety. In a series of nonbinding guidance documents, the FDA has clarified that it will only apply regulatory oversight to apps that "pose a risk to a patient's safety if the mobile app were to not function as intended" [5]. The FDA also said it intends to regulate those apps that "transform a mobile platform into a regulated medical device" [5] by using display screens, sensors, or other methods. The FDA also reserves "enforcement discretion" for all mHealth apps, meaning it retains the right to regulate what it calls low-risk medical apps [5].

Researchers have defined four broad categories of mHealth apps: (1) information apps, which provide the public with general health information; (2) diagnostic apps, which are used to input patient information and help guide the physician to a diagnosis; (3) control apps, which allow remote monitoring and control of medical devices such as insulin pumps; and (4) adapter apps, which essentially transform a smartphone into a mobile medical device [6].

Applying these definitions to the FDA guidelines, the agency appears willing to regulate control and adapter apps, which essentially transform mobile platforms into medical devices. The FDA has clarified that it will not regulate informational apps that coach or prompt patients to manage their health or allow them to track their health data [5].

But diagnostic apps have constituted a grey area in the FDA's regulatory purview. In December 2017, the FDA issued a new draft guidance based on the agency's interpretation of the 21st Century Cures Act approved by Congress in 2016. The guidance is intended to inform app developers how it intends to regulate what are called clinical decision support (CDS) apps, which provide diagnostic and treatment recommendations to physicians [7]. CDS apps are distinct and differ from patient decision support (PDS) apps which provide information only to the patient.

The guidance indicates that CDS apps that allow physicians "to independently review the basis for the recommendations" [7] will not be subject to FDA regulation as a medical device. In other words, the FDA said it does not intend to regulate CDS apps that allow the user "to reach the same recommendation on his or her own without relying primarily on the software function" [7].

Examples of apps that may not be covered by FDA regulation under the new guidance include those that provide physicians with recommendations for diagnosing illnesses such as influenza or diabetes mellitus and those that recommend the use of a prescription drug. Also excluded are apps that make chemotherapeutic suggestions to doctors based on a patient's history, test results, and other factors [7].

The FDA's narrow regulatory framework leaves a large gap for physicians and patients trying to choose an appropriate mHealth app. Attempts to provide clarity have come from state legislation, voluntary certification, patient advocacy groups, professional associations, and commercial services. But the dynamic world of app development so far has defied attempts to regulate or certify these products.

Attempts at voluntary certification for mHealth apps have failed in the past. A group of companies published standards in 2013 for a voluntary app certification program that was to be funded by app developers who paid to have their apps certified [4]. The program was intended to make apps more appealing to customers and to give clinicians greater confidence in recommending them to patients. But the companies suspended the program later that year after it was exposed that two of the certified apps had security problems. The program also suffered from a lack of interest by app developers, of whom only a handful participated [4].

The European regulatory system offers another potential model. In the EU, each member state can file an approval application for a high-risk medical device [8]. The device is then evaluated by a notified body (NB) established within that state and authorized by the state's public health agency. NBs have the authority to issue the device a Conformité Européenne (CE) mark. This mark denotes conformity with relevant EU requirements for medical devices. A device bearing a CE mark can be sold in any EU member state. Europe has about 76 NBs, which are private for-profit companies that contract with manufacturers to supply the certifications for a fee [8].

Since the European model was developed to foster commercial policies that encourage trade among member states, not to provide consumer protection, this system has been criticized. For instance, NBs may be reluctant to deny approval of a medical device for fear of losing its client to a competitor [8]. In addition, although the CE mark indicates that the device is in full compliance with European legislation, medical devices approved in Europe need only show safety and performance, but not clinical efficacy [8]. These potential weaknesses have led to criticism that the European NB system values innovation and trade over consumer protection.

Potential Solution

The US should consider an effective and proven approach that would be analogous the system now used to regulate diagnostic testing. This model, established in 1988 by the Clinical Laboratory Improvement Amendment (CLIA) certifies and ensures the quality of testing in approximately 254,000 US laboratories [9]. Federal agencies rely on nonprofit accrediting agencies with deeming authority under CLIA to ensure that labs comply with federal regulatory standards. Quality standards include staff qualifications, quality control, and recordkeeping. The CLIA approach is unique among federal oversight programs in that it combines oversight with an educational and collaborative approach to ensure quality testing that has allowed tens of thousands of facilities unfamiliar with laboratory technique to comply with federal quality standards. The requirements have been phased in over a period of years to allow

greater participation and improvement in the quality and delivery of testing. Virtually all diagnostic testing laboratories comply with CLIA processes today [10].

A similar approach applied to app developers could help ensure that mHealth apps comply with at least basic standards in three areas, namely (1) accessibility, including inclusion of clear language, ease of use, affordability, and usability on all mobile platforms; (2) privacy, including assurances that apps appropriately secure patient records and prohibit data sharing with third parties, such as insurance companies and advertisers; and (3) content, indicating that apps are developed with expert involvement, contain accurate medical information, limit in-app advertising, and reveal both monetization practices, and potential conflicts of interest [2].

The proven CLIA model provides a successful approach to the oversight of mHealth apps and ensures that they are both safe and clinically effective. The science of laboratory medicine has evolved rapidly in the three decades since CLIA was enacted, and the model also has been nimble in responding to new technology and approaches [11].

As CLIA has evolved in the three decades since Congress passed the law, health care providers no longer do business with laboratories that are not CLIA certified. Passage of similar legislation regulating CDS apps may have a similar effect over time, since certification gives the app credibility. Physicians would use or recommend apps preferentially as a result of the certification. Ultimately, accrediting bodies could require it as they now require laboratory certification.

A formal certification process for mHealth apps, particularly those that involve clinical decision making, would give doctors and patients greater confidence in these products as they enter the medical mainstream. Health professionals, patients, and consumer groups must lead the drive for better information, transparency, and usefulness for mHealth apps. As new products enter the realm of diagnosis and treatment, physicians are in a strong position to demand that apps are effective and protect patients, whether used to treat disease or improve health and wellness.

Conflicts of Interest

None declared.

References

1. Research2Guidance. <https://Research2guidance.com>. 2017. 325,000 Mobile Health Apps Available in 2017 URL: <https://research2guidance.com/325000-mobile-health-apps-available-in-2017/> [accessed 2018-03-13] [WebCite Cache ID 6xtegy7i]
2. Cook VE, Ellis AK, Hildebrand KJ. Mobile health applications in clinical practice: pearls, pitfalls, and key considerations. *Ann Allergy Asthma Immunol* 2016 Aug;117(2):143-149. [doi: [10.1016/j.anai.2016.01.012](https://doi.org/10.1016/j.anai.2016.01.012)] [Medline: [27499542](https://pubmed.ncbi.nlm.nih.gov/27499542/)]
3. Sucala M, Cuijpers P, Muench F, Cardo R, Soflau R, Dobrea A, et al. Anxiety: There is an app for that. A systematic review of anxiety apps. *Depress Anxiety* 2017 Dec;34(6):518-525. [doi: [10.1002/da.22654](https://doi.org/10.1002/da.22654)] [Medline: [28504859](https://pubmed.ncbi.nlm.nih.gov/28504859/)]
4. Palmer S. Swipe Right for Health Care: How the State May Decide the Future of the mHealth App Industry in the Wake of FDA Uncertainty. *J Leg Med* 2017;37(1-2):249-263. [doi: [10.1080/01947648.2017.1303289](https://doi.org/10.1080/01947648.2017.1303289)] [Medline: [28910227](https://pubmed.ncbi.nlm.nih.gov/28910227/)]
5. FDA. 2015. Mobile Medical Applications: Guidance for Industry and FDA Staff URL: <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf> [accessed 2018-03-13] [WebCite Cache ID 6xthUIAbN]
6. Roth V. North Carolina Journal of Law and Technology. The mHealth Conundrum: Smartphones & Mobile Medical Apps - How Much FDA Medical Device Regulation Is Required URL: <http://scholarship.law.unc.edu/cgi/viewcontent.cgi?article=1245&context=ncjolt> [accessed 2018-03-13] [WebCite Cache ID 6xtiyJREI]
7. FDA. 2017. Clinical and Patient Decision Support Software: Guidance for Industry and FDA Staff URL: <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm587819.pdf> [accessed 2018-03-13] [WebCite Cache ID 6xthyIHd7]
8. Van Norman G. Drugs and Devices: Comparison of European and US Approval Processes. *JACC: Basic to Translational Science* 2016 Aug 01;1(5):399-412 [FREE Full text]
9. CMS. Center for Medicare and Medicaid Services; March 9, 2018. Clinical Laboratory Improvement Amendments (CLIA) URL: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html> [accessed 2018-03-14] [WebCite Cache ID 6xuzio8ys]
10. Yost JA. Laboratory Inspection: The View From CMS. *Laboratory Medicine* 2003 Feb 01;34(2):136-140. [doi: [10.1309/UV7DPFOU581Y2M8H](https://doi.org/10.1309/UV7DPFOU581Y2M8H)]
11. Kaul KL, Sabatini LM, Tsongalis GJ, Caliendo AM, Olsen RJ, Ashwood ER, et al. The Case for Laboratory Developed Procedures: Quality and Positive Impact on Patient Care. *Acad Pathol* 2017;4:2374289517708309 [FREE Full text] [doi: [10.1177/2374289517708309](https://doi.org/10.1177/2374289517708309)] [Medline: [28815200](https://pubmed.ncbi.nlm.nih.gov/28815200/)]

Abbreviations

CDS: clinical decision support

CE: Conformité Européenne
CLIA: Clinical Laboratory Improvement Amendment
EU: European Union
FDA: Food and Drug Administration
mHealth: mobile health
NB: notified body
PDS: patient decision support

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Review

Challenges and Potential Opportunities of Mobile Phone Call Detail Records in Health Research: Review

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Abstract

Background: Call detail records (CDRs) are collected by mobile network operators in the course of providing their service. CDRs are increasingly being used in research along with other forms of big data and represent an emerging data type with potential for public good. Many jurisdictions have infrastructures for health data research that could benefit from the integration of CDRs with health data.

Objective: The objective of this study was to review how CDRs have been used in health research and to identify challenges and potential opportunities for their wider use in conjunction with health data.

Methods: A literature review was conducted using structured search terms making use of major search engines. Initially, 4066 items were identified. Following screening, 46 full text articles were included in the qualitative synthesis. Information extracted included research topic area, population of study, datasets used, information governance and ethical considerations, study findings, and data limitations.

Results: The majority of published studies were focused on low-income and middle-income countries. Making use of the location element in CDRs, studies often modeled the transmission of infectious diseases or estimated population movement following natural disasters with a view to implementing interventions. CDRs were used in anonymized or aggregated form, and the process of gaining regulatory approvals varied with data provider and by jurisdiction. None included public views on the use of CDRs in health research.

Conclusions: Despite various challenges and limitations, anonymized mobile phone CDRs have been used successfully in health research. The use of aggregated data is a safeguard but also a further limitation. Greater opportunities could be gained if validated anonymized CDRs were integrated with routine health records at an individual level, provided that permissions and safeguards could be put in place. Further work is needed, including gaining public views, to develop an ethically founded framework for the use of CDRs in health research.

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KEYWORDS

call detail records; mobile phone data; health research

Introduction

Background

There are already over 5 billion unique mobile device subscribers globally, and the number of mobile connections

exceeds the world population at over 8 billion [1]. Mobile phone penetration is constantly rising and is predicted to exceed 5 billion users by 2019 [2]. As mobile phones are now an integral part of modern life, their potential to be used as a means of improving health care is increasingly promising. Call Detail

Records (CDRs) are collected by mobile network operators (MNOs) in the course of providing their service. Each time a mobile phone user connects to a mobile network, either by voice call or text message, a record is generated that includes the starting time of the call (or message), its duration, the caller and receiver phone numbers, and their locations [3]. Locations are estimated from the positions of activated cell towers and can be made more precise via tower triangulation and Wi-Fi connections [3]. Unlike interaction with mobile phone apps, CDRs result from passive data collection requiring no additional effort by the end user. MNOs receive billions of CDRs globally; they are necessary for billing, monitoring data usage, and for understanding and targeting customers according to their mobile phone use [3].

Due to the lack of landline infrastructures, mobile phones are the preferred method of communication in low- to middle-income countries (LMICs) [4], and they are playing a crucial part in these countries' socioeconomic developments [5]. Using mathematical modeling techniques, researchers are able to use CDRs to estimate the location of different populations and how this changes over time. Information on migratory patterns within and between countries can offer valuable information to policy makers in areas such as agriculture, transportation, poverty, conflict prevention, and disaster response and humanitarian aid [6]. In the last 5 years, CDR data have been used to improve health and health care, for example, via the generation of epidemiological models that can infer the spatial spread of infectious diseases from human mobility patterns [7].

Unlike for some of these LMIC settings, many developed countries have created data-intensive health research infrastructures, integrating multiple sources of anonymized routine health and administrative data for secondary uses. Main models vary between centralized repositories [8,9] and federated systems with distributed data nodes [10,11]. Typically, in a repository model, data are centralized for integration, whereas in a federated model data remain distributed among their original sources, with various permutations on these models and on how a user accesses data. Data provision to researchers can entail, subject to information governance regimes, external release of linked data to researchers [12], access via a data-safe haven and release of results [8], or by using privacy-preserving distributed data mining that computes distributed data without revealing sensitive information [13,14]. Address-based grid reference location data used with routine data present additional opportunities by enabling health geography studies but also present particular disclosure risks that must be mitigated so the data can be used safely [15]. CDRs represent an alternative type of spatial data that could add to, or augment, routine data collections to enable new opportunities for health research.

Objective

The objective of this study was two-fold: (1) to review the ways in which CDRs (particularly the location elements) have been used in health research to identify the challenges encountered and benefits gained, and (2) to use this information to explore the issues that would need to be addressed to enable wider use

of CDRs for health research, including their integration with routine health and administrative data.

Methods

A literature review was conducted using structured search terms making use of major search engines. Predetermined eligibility criteria were set and adhered to in order to avoid the introduction of bias and to preclude the selection of studies on the basis of whether they favored a particular conclusion. To be included in the review, studies must have been published in the English language and in either peer-reviewed journals or conference proceedings. Studies must have used CDR data to answer a research question. Therefore, methodological papers, for example, outlining different mathematical approaches for analyzing mobile phone datasets, were excluded. Studies using data derived from mobile phone apps were also excluded. Research on any study population and health-related condition was included.

A search strategy was devised based on these inclusion criteria aided by identifying keywords from seminal works in this field [3]. The search terms were as follows: (mobile phone location data) OR (mobile phone call data) OR (mobile phone data) OR (cell phone data) OR (cell phone call data) OR (cell phone location data) OR (call detail records). These keywords were chosen in order to conduct a sensitive, rather than a specific search to ensure a higher probability of including all relevant articles. The strategy was customized according to the stipulations of each database for building search strings. Searches covered studies published up until January 2017 with no restrictions on the earliest date of publication. The following databases were searched from February 7-25, 2017: the Cochrane Central Register of Controlled Trials (CENTRAL) [16], Google Scholar [17], PubMed [18], Scopus [19], Web of Science [20], and WorldPop [21]. It was not intended as an exhaustive review, but we took a pragmatic approach to identify a comprehensive range of health-related studies to identify benefits and challenges with reasonable confidence.

All search results were imported into an online reference generator [22] and duplicate references were removed. The title and abstracts of these results were screened against the inclusion criteria as outlined above to identify potentially eligible studies for which the full texts were reviewed. Two reviewers independently performed the search, and disagreements between the reviewers were resolved by consensus. The reference lists of the eligible articles were searched to identify additional studies.

The following data were extracted for each eligible study: author, year published, title of article, country of population studied, research topic area, how datasets were used, findings, information governance, and limitations of the data.

Results

Overview

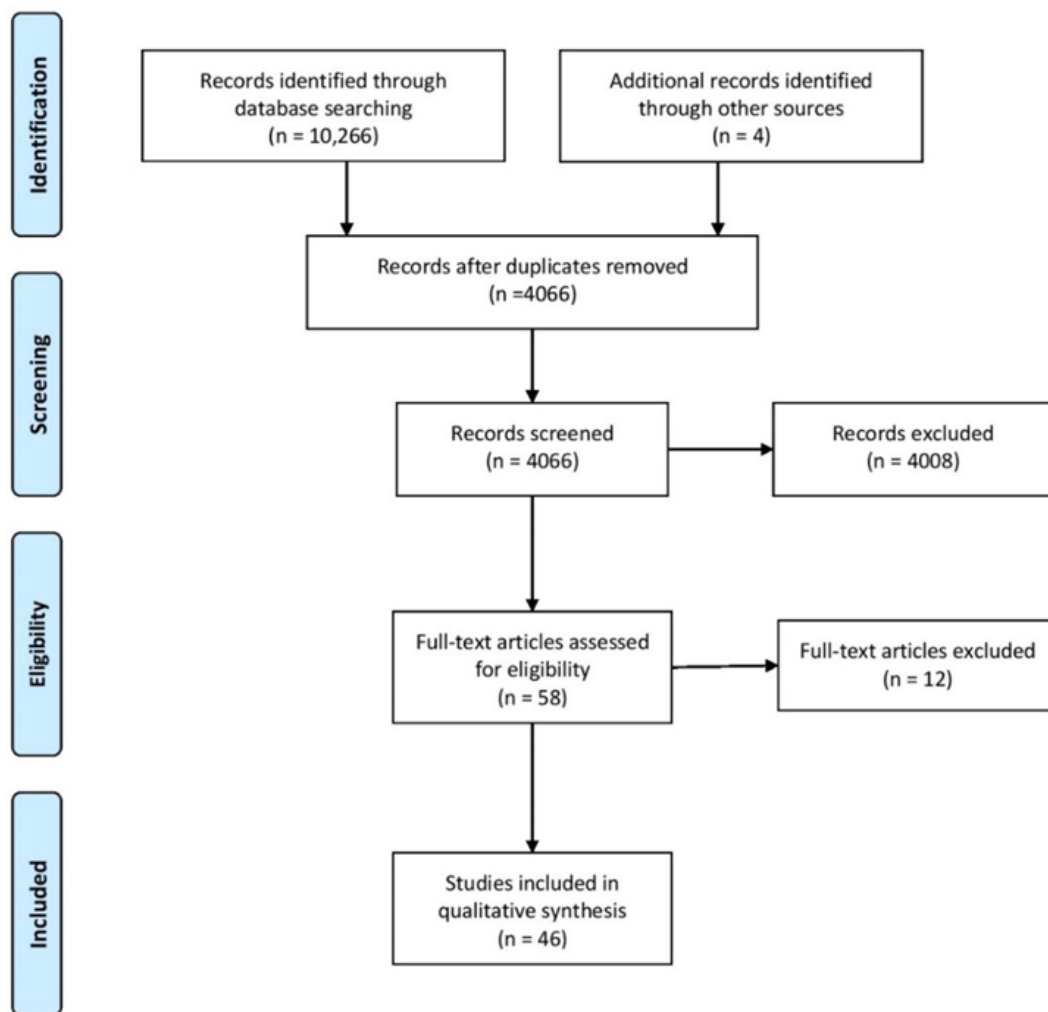
The search initially identified 4066 studies. Of these, 4008 were excluded on the basis of title and abstract alone as they did not meet the inclusion criteria. Most of the studies initially excluded

tended to not be either research studies or health-related. Fifty-eight full-text articles were assessed for eligibility, and a further 12 were subsequently rejected for not meeting the inclusion criteria. Of these, two papers were excluded as they were not research studies, but rather described anonymization processes; four were excluded as they did not use CDR data; five were excluded as they were geographical studies but not on health-related research; and one study was excluded as it was a methodology paper. Figure 1 shows the study process flowchart according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [23]. As a result of the screening process, 46 full-text articles were included in the qualitative synthesis. Multimedia Appendix 1 presents the included studies [24-69]. Studies using CDR data for health research are summarized. CDR data were used alone or in conjunction with additional datasets for a variety of health-related purposes. In each study, CDR data were used in mathematical modeling to predict or identify population movement or to construct and predict social networks. A narrative description, based on the information provided in the publications, is given here to provide further details and draw out notable issues.

Research Topic Area and Findings

As is evident from Multimedia Appendix 1, the majority of studies (n=42) focused on LMICs, with the other four using data from Belgium (n=2), Austria, and Italy. By using mathematical modeling, CDR location data were used to predict the movement of a population. Often, CDR data were used to develop models to address pressing concerns on infectious disease transfer. These included (numbers of studies shown where >1) malaria (n=11), HIV (n=3), cholera (n=3), influenza (n=3) dengue fever, Ebola virus, schistosomiasis, Rubella, meningitis, and tuberculosis. Other studies made use of CDR data to model population movement after disasters, to design and target public health interventions by identifying the location of at risk populations, to model hospital catchments, to model effects of air quality, and to explore options to arresting infectious diseases at outbreak. Where additional datasets were used, these were overlaid and compared with existing CDR data. For example, virological data were used to understand how cases of influenza were spreading. These were then used to verify mathematical models generated using CDR location data by mapping how populations move [27]. Although this is a method of integrating data, none of the included studies actually linked CDRs on an individual level to other datasets.

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



Datasets and Data Governance

Thirteen of the articles were on studies from the 2013 Orange Data for Development Challenge on Mobile Phone Data focused on Ivory Coast [70]. Orange is a large, international mobile network operator, who allowed international research laboratories access to anonymized CDRs generated by 5 million of their Ivory Coast customers dating between December 2011 and April 2012. Researchers were tasked to use the data in a way that could potentially contribute to the socioeconomic development of the country. CDRs were anonymized by Orange Ivory Coast and processed by Orange Labs in Paris. In addition, the geographical locations of the mobile phone masts were blurred to protect the commercial interests of Orange. These datasets were then released to researchers [70].

Four datasets of varying granularity were provided by Orange:

1. The number and duration of calls between a pair of antennae aggregated by each hour. These data were provided for the whole of the observation period.
2. High spatial resolution data (which published antenna identifiers) of individual movement trajectories. To reduce the possibility of identification, these data were supplied on a random sample of 50,000 individuals for a 2-week time period only.
3. Data for the entire observation period but with reduced spatial resolution to mitigate the risk of identification. Spatial resolution was reduced by using the subprefectures of the mobile phone antenna location rather than specific antenna identifiers.
4. Social network subgraphs using call data generated by 5000 randomly selected individuals. These were divided into 2-week time periods for the entire duration of observation [70].

A year later, Orange issued a second challenge, this time using data from Senegal [71]. Twelve of the studies included in this review used the data provided by this challenge. The data were pseudonymized locally in Dakar by Sonatel in the first instance. Orange Labs in Paris then undertook several layers of anonymization on the data. As with the Ivory Coast data, the true geolocations of mobile phone masts were masked. Again, to reduce the risk of identification, datasets of high granularity were restricted in time span, and coarser aggregated data covered longer periods of time [72]. An internal ethics workgroup reviewed the governance of each application to receive access to the data. An additional safeguard was also put in place for this particular challenge. An external ethical review panel was set up that consisted of 14 international members who provided the Orange team with advice on information governance, particularly to review risks in publishing findings. As well as privacy concerns, the external review panel considered political concerns and issues of civil unrest (eg, regarding the Ebola epidemic).

Of the studies not involved with either of the Orange Data for Development challenges, all studies apart from three [38,39,64] stated that the mobile phone CDRs they used in their research were anonymized. Few studies described the anonymization process as this was usually undertaken by the MNO beforehand. However, we have assumed, at the very least, that personal

identifiers were removed from the data. MNO anonymization was not carried out in in one study [32] where researchers were provided with a raw dataset and undertook the anonymization process themselves. High- and low-volume users were excluded from analysis in this study to protect privacy. A second dataset from a different provider was used by the researchers in this same study. This dataset had been anonymized by the MNO: identifiable information was replaced by a hashed ID and encryption keys were exclusively managed by the MNO.

Wilson et al [67] stated that they followed the Groupe Spéciale Mobile Association (GSMA) privacy guidelines that advise that any analyses on mobile phone records should be done using de-identified data and that individual level data should not leave MNO servers [73]. All analyses conducted by this team were performed by connecting remotely to a Linux server with only aggregated data transferred outside the operator.

Wesolowski et al [66] detailed how they complied with the laws and regulations of Pakistan and the MNO Telenor, by using only data aggregated to tehsil level (an administrative unit of Pakistan). This was processed on their behalf by Telenor employees. The following measures were implemented to preserve the privacy of Telenor Pakistan's customers: (1) the CDR/mobility data were processed on a back-up and recovery server made available by Telenor Pakistan, with only Telenor employees having access to the detailed CDR/mobility data, (2) given the server arrangements, no detailed CDR/mobility data were taken out of Pakistan or left the premises of Telenor Pakistan, and (3) the processing of the detailed CDR/mobility data resulted in aggregations of the data on a tower-level granularity that was accessed only by Telenor employees.

Eight other studies mentioned explicitly that they used aggregated data in their analyses. There was no evidence to suggest that studies had a higher tendency to use aggregation if additional datasets had been used, but all additional datasets containing individual level data were de-identified. Three studies explicitly stated that they sought ethical approval from their own institution before beginning their research [28,36,57].

Data Limitations

Several researchers commented on the limitations of the data, some of which are common to many data types and some specific to phone data. Gavric et al [41] reported that using aggregated data due to privacy concerns decreased the precision of their analyses. Differential mobile phone ownership due to financial means and socioeconomic status was noted as a potential source of bias whereby different sectors of a population may be over- or underrepresented [32,37,45,60]. For countries within Africa in particular, phone sharing is common, thus creating another potential source of bias since the network tracks the subscriber identification module (SIM), not the person. This would limit the value of studies focused on particular groups rather than general population movement [60].

Discussion

Principal Findings: Opportunities and Challenges

Emerging data types, such as mobile phone CDR data present valuable new opportunities for health research, particularly

when used in combination with additional datasets. This study reports on a structured literature review on the use of CDR data for health research, showing that the immense volumes of CDR data collected and held globally by MNOs can be used for public health benefit. Of particular interest is the location element that can be used to track phone user movement at various levels of granularity. Most of the studies included in this review used CDR data to create mathematical models based on population movement to predict the spread of disease epidemics. Where additional datasets were used, often these verified the validity of these models.

Using CDRs in health research has a number of benefits. These data are routinely and passively collected via mobile phones without any effort needed by the end user. It could be argued that creating these big datasets in this way is far easier and more effective than recruiting and consenting participants into a research study individually. Also, CDRs can be generated from basic mobile phones and do not require the use of smartphone. Therefore, their use in research does not preclude those from low socioeconomic groups in the way that GPS data would, for instance. An individual's home and work setting can be derived from CDR data, which is particularly valuable for countries where no integrated infrastructures exist for population census [74]. However, there are limitations that need to be taken into account in evaluating the use of CDRs in health research and in considering opportunities for their wider use. Data availability, formats, and levels of aggregation vary with MNO, and this will influence the type of analysis that can be done. For studies that require CDRs to be collected by multiple operators, researchers face the issue of having to join anonymized datasets: a difficult, although not insurmountable task [75]. There is an unknown level of discrepancy between phone owner and main user when phones are shared or bought for another person. This can call into question the validity of study findings focusing on particular demographics, since the extent of group representation is not known. Differential ownership of mobile phones among different sectors, particularly in LMICs where much of CDR research takes place, also calls into question the representativeness of the data and thus the findings that ensue [76]. However, it has also been observed that despite biases, there are few, if any, data sources that can provide such rich spatial and temporal movement data, particularly for much-needed research in LMICs [63,66].

A number of common patterns in data governance emerged from the review. Datasets were provided to researchers at different levels of spatial granularity and over variously restricted time periods to mitigate disclosure risks. These varied by study, or by programs of study. In some cases, data were subjected to several layers of anonymization and the true geolocations of mobile phone masts were masked. The use of anonymized (or strongly pseudonymized) data was the norm, with few studies outside this model and with many additionally using aggregation and the suppression of rare or extreme records. Reports of formal ethical review varied, but proposals were routinely submitted to an internal ethics workgroup, and in some cases to an independent external group for wider considerations such as political implications, societal benefits, and risk versus utility.

Concerns have been published on the ethics of using mobile phone data in research and the potential threats to privacy. Although MNOs have legal and organizational policies and researchers have jurisdictional health research governance to abide by, there is an absence of a clear, holistic, ethical, and regulatory framework to guide research using CDRs [3]. Most published research reports use anonymized data and many go further to protect against re-identification via aggregation. Nevertheless, examples of how anonymization and aggregation do not guarantee privacy in location data are abundant in the literature [77-79]. Furthermore, breaches in group privacy do not rely on the re-identification of individuals. It is considered that individuals who belong to certain groups on the basis of their gender, sexual orientation, ethnicity, or political preferences could become visible in CDR data [80]. There is clearly a need for an ethically founded framework for the use of CDRs in research for public good.

Considering that CDR data are collected about members of the general public, such a framework should take into account public viewpoints on the use of CDRs for research. Public engagement is, of course, a common feature in health research and in the use of large-scale, anonymized person-based data [81,82]. But it is acknowledged that similar work is both lacking and needful in the case of CDR data [3]. Although there have been surveys of public views on other aspects of mobile phone usage [83], there is no known literature on public perceptions of using CDRs for health research. Research using CDRs is still in its relative infancy, which means it is an ideal time to engage with the public so that their views can be taken into account in developing an ethically founded framework. This can be compared to similar work that has been done on genomic data sharing, another controversial area of health data science, where strong public views have necessitated the development of clear data sharing policies (eg, the Global Alliance for Genomics and Health [84]) [85-87].

Wider Use and Future Work

From the review conducted in this study, plus seminal studies and reports [3,88], it is clear that CDR data can be valuable in health-related research. But as the majority of studies have focused on LMICs, the question arises of whether this can be translated into wider use in more developed countries, in particular where there are data-intensive infrastructures for health research that already have (or can gain) access to more traditional geolocation data, in the form of verified address-based grid references. Basically, it is a question of whether CDR data is valuable for health research per se, or only in particular settings. In support of the former position, some of the studies reviewed focused on Belgium, Austria, and Italy. Furthermore, Orange is not the only mobile network operator whose CDR datasets are being applied to health-related issues, as Telefonica have demonstrated via their Smart Steps initiative in various countries [89]. It may be that CDR data will prove to be a valuable resource for the public health sector, where, for example, the location element of the data could shed light on the way health promotion campaigns impact hospital attendances. Used in conjunction with additional datasets (eg, air quality monitoring databases, infection/virus outbreak data, emergency department attendance records), CDR location data

may bring about new opportunities for health research. However, during the course of this study, a number of issues have been revealed that impact on opportunities for the wider use of CDRs for health research and that can be learned from in moving forward. These are considered here in relation to their integration with other relevant datasets for use in data-intensive infrastructures, but they are also relevant to smaller-scale health research endeavors.

An essential and primary issue is data availability since CDRs reside with the network operator. This alone could be a show-stopper for various reasons, including that GSMA guidance states that individual level CDR data should not leave MNO servers [73,90]. Assuming data could be accessible, there would need to be suitable mutually beneficial agreements between the MNO and research program owner, with the prerequisite of a shared vision for data use [88]. Following modeling exercises in conjunction with Vodafone, the UK Office of National Statistics is planning to use CDRs to monitor commuter travel and collect census data [91]. There will, of course, be a financial cost for the use of the data, the extent of which is not known. But to be viable, this will need to be lower than current costs and/or provide valuable new information. Cost is a second major operator-related issue that may preclude the wider use of CDRs in health research unless suitable collaborative arrangements can be made.

Limitations inherent in the data (outlined earlier) need to be quantified and addressed for greater confidence in research findings. Encouragingly, there are reports that propose how bias in phone data can be addressed [74], but other issues remain. It would be useful to see a series of studies that have assessed the validity of CDRs in health research compared to other forms of geolocation data, for example, with Bluetooth data [92], photographic data [93], and flight data [94]. Such efforts would strengthen the evidence base on whether investment in the wider use of CDR data is warranted.

As with the use of any person-based data type, suitable physical, technical, and procedural controls need to be agreed between the data provider (MNO) and data user, as part of a proportionate data governance regime. This is true, though the stipulations may differ, whatever infrastructural and data access models are in place. The fact that anonymized and even aggregated data can pose identity disclosure risks is beyond doubt. Disclosure risks in the use of CDRs have not been studied to the same extent, and further work would be beneficial [15]. Ideally, this should be done in collaboration with an amenable network operator and be based on integrating CDRs with health records. However, this could be a challenge for reasons already described, but modeling a variety of data use scenarios using metadata (if available) could be a useful compromise and still yield meaningful information. This, along with the identified need for the input of public views on the use of CDR data for health research, would also inform the much needed consistent, holistic, ethically founded framework.

Public engagement forms an important part of an ethical framework for data use, beyond strict legal compliance requirements. Consultation with the public to gain their views

on the use of CDRs for health research would gauge knowledge and expectations and, as with other emerging data types, would inform the socially acceptable use of the data. This is not too much to ask, since after all, CDRs originate with individuals and are based on their activities. It would be interesting to know more about the public's actual awareness of data collected by mobile operators and the ways data are used in-house and by external agencies.

A last consideration is of the ultimate feasibility of integrating CDRs with health record data in terms of whether there is an appetite for it among the participating stakeholders. This is not a question that can be answered easily without seeing how the many challenges could be addressed so that the risk versus utility of such a development could be evaluated. A definite appetite and strong drivers to move initiatives forward will be needed for success.

Strengths and Limitations

This study adds to the discussion on the suitability of CDRs for health research and raises issues to be addressed if the wider use of CDRs is to become a reality. It is the only known study to carry out a review of publications using CDRs in health research in order to learn from their practices and identify challenges. It also considers the use of CDRs in relation to data-intensive infrastructures and sets out problems to be solved to enable informed decisions on whether investment in seeking CDR integration is warranted. In accordance with other authors, this study recommends the development of an ethically founded framework for the use of CDRs in health research, but furthermore, it recommends that public views on the use of CDR data should be integral.

However, there are some limitations to consider. This study focused on articles using CDRs for health-related topics published in peer-reviewed journals and conference proceedings; it does not claim to be an exhaustive review. The use of health monitoring apps is outside the scope of the study, like Ginger.io [95] and the work of Sandy Pentland who, for example, used behavioral information from voice recordings and texting to detect signs of posttraumatic stress disorder in returning soldiers [96]. It also drew on reports published by MNOs and other organizations. However, operators will also have proprietary information not shared publicly, which may contain planned developments to address pertinent issues and take forward the use of CDRs for public benefit.

Conclusion

All things considered, there are possibilities for the wider use of CDR data in health research but there are also major challenges to be addressed. Some important points have been discussed here, but this is not an exhaustive list of issues. Questions remain around the suitability of CDRs for wider use in health research and particularly as part of data-intensive infrastructures for population-scale studies. A concerted effort will be needed to create solutions to determine if mobile phone CDRs are a worthwhile data type to pursue and invest in to augment currently used geolocation data.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Summary of included studies.

[[PDF File \(Adobe PDF File\), 80KB - mhealth_v6i7e161_app1.pdf](#)]

References

1. GSMA Intelligence. 2018. URL: <https://www.gsmaintelligence.com/> [accessed 2018-07-11] [WebCite Cache ID 70pfRxy8b]
2. Statista. 2018. URL: <https://www.statista.com/statistics/470018/mobile-phone-user-penetration-worldwide/> [WebCite Cache ID 70pnBIHWe]
3. Vinck P, Letouzé E, Kammourieh L. DataPop Alliance. 2015. The law, politics and ethics of cell phone data analytics URL: http://datapopalliance.org/wpcontent/uploads/2015/04/WPS_LawPoliticsEthicsCellPhoneDataAnalytics.pdf [accessed 2018-07-11] [WebCite Cache ID 70pnJbx6T]
4. How mobile phones are changing the developing world.: Consumer Technology Association; 2017. URL: <https://www.cta.tech/News/Blog/Articles/2015/July/How-Mobile-Phones-Are-Changing-the-Developing-World.aspx> [WebCite Cache ID 70pnXKpg5]
5. Arie S. Can mobile phones transform healthcare in low and middle income countries? *BMJ* 2015 Apr 22;350(apr22):h1975-h1975 [FREE Full text] [doi: [10.1136/bmj.h1975](https://doi.org/10.1136/bmj.h1975)]
6. Mobile policy handbook: an insider's guide to the issues.: GSMA; 2017. URL: https://www.gsma.com/publicpolicy/wpcontent/uploads/2016/08/Mobile_Policy_Handbook_2017_EN.pdf [accessed 2018-07-11] [WebCite Cache ID 70pnhtw80]
7. Mobile phone network data for development.: Global Pulse; 2013. URL: http://www.unglobalpulse.org/sites/default/files/Mobile%20Data%20for%20Development%20Primer_Oct2013.pdf [accessed 2018-07-11] [WebCite Cache ID 70pnkjhGI]
8. SAIL Databank. URL: <https://saildatabank.com/> [WebCite Cache ID 70pnseCAi]
9. Population Data BC. 2018. URL: <https://www.popdata.bc.ca/> [WebCite Cache ID 70poL1fC1]
10. CNODES. URL: <https://www.cnodes.ca/> [accessed 2018-07-11] [WebCite Cache ID 70pwBoYVs]
11. SHRINE. URL: <https://catalyst.harvard.edu/services/shrine/> [WebCite Cache ID 70pwIE2Ht]
12. Data Linkage Western Australia. URL: <https://www.datalinkage-wa.org.au/> [accessed 2018-07-11] [WebCite Cache ID 70pwQvUK2]
13. Aggarwal CC, Yu PS. A General Survey of Privacy-Preserving Data Mining Models and Algorithms. In: Aggarwal CC, Yu PS, editors. *Privacy-Preserving Data Mining. Advances in Database Systems*. New York, NY: Springer; 2008:11.
14. Hailemichael MA, Yigzaw KY, Bellika JG. Emnet: A tool for privacy-preserving statistical computing on distributed health data. In: *13th Scandinavian Conference on Health Informatics*. 2015 Presented at: Scandinavian Conference on Health Informatics; June 15-17, 2015; Tromsø, Norway.
15. Carter A, Liddle J, Hall W, Chenery H. Mobile Phones in Research and Treatment: Ethical Guidelines and Future Directions. *JMIR Mhealth Uhealth* 2015 Oct 16;3(4):e95 [FREE Full text] [doi: [10.2196/mhealth.4538](https://doi.org/10.2196/mhealth.4538)] [Medline: [26474545](https://pubmed.ncbi.nlm.nih.gov/26474545/)]
16. The Cochrane Central Register of Controlled Trials (CENTRAL). URL: <http://www.cochranelibrary.com/about/central-landing-page.html> [accessed 2018-07-11] [WebCite Cache ID 70pwW4tm0]
17. Google Scholar. URL: <https://scholar.google.co.uk/> [accessed 2018-07-11] [WebCite Cache ID 70pwYm3hZ]
18. PubMed. URL: <https://www.ncbi.nlm.nih.gov/pubmed/> [accessed 2018-07-11] [WebCite Cache ID 70pockTas]
19. Scopus. URL: <https://www.elsevier.com/solutions/scopus> [accessed 2018-07-11] [WebCite Cache ID 70pwbEWGL]
20. Web of Science. URL: <http://apps.webofknowledge.com/> [WebCite Cache ID 70pwmVyx]
21. Worldpop. URL: http://worldpop.org.uk/about_our_work/publications%20/ [accessed 2018-07-11] [WebCite Cache ID 70pwtYFdk]
22. Cite this for me. URL: <http://www.citethisforme.com/walkthrough> [accessed 2018-07-11] [WebCite Cache ID 70pwwQUZy]
23. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JPA, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. *BMJ* 2009 Jul 21;339(jul21 1):b2700-b2700 [FREE Full text] [doi: [10.1136/bmj.b2700](https://doi.org/10.1136/bmj.b2700)]
24. Agarwal R, Gauthier V, Becker M. Information dissemination using human mobility in realistic environment (E-Inspire). In: *D4D Challenge 2013 special session*. 2013 Presented at: NetMob 2013; May 1-3, 2013; Boston, MA URL: <https://perso.uclouvain.be/vincent.blondel/netmob/2013/D4D-book.pdf>

25. Arai A, Honorant A, Witayangkurn R, Shibasaki R. Neighbourhood structures in socio-demographic and HIV infection conditions: indication of the potential of mHealth for tackling HIV/AIDS in Ivory Coast. 2013 Presented at: NetMob 2013; May 1-3, 2013; Boston, MA URL: <https://perso.uclouvain.be/vincent.blondel/netmob/2013/D4D-book.pdf>
26. Azman A, Urquhart E, Zaitchik B, Lesser J. Using mobile phone data to supercharge epidemic models of cholera transmission in Africa: a case study of Cote d'Ivoire. 2013 Presented at: Boston, MA; May 1-3, 2013; NetMob 2013 URL: <https://perso.uclouvain.be/vincent.blondel/netmob/2013/D4D-book.pdf>
27. Baldo N, Closas P. Disease outbreak detection by mobile network monitoring: a case study with the D4D datasets. 2013 Presented at: NetMob 2013; May 1-3, 2013; Boston, MA URL: <https://perso.uclouvain.be/vincent.blondel/netmob/2013/D4D-book.pdf>
28. Bengtsson L, Lu X, Thorson A, Garfield R, von Schreeb J. Improved response to disasters and outbreaks by tracking population movements with mobile phone network data: a post-earthquake geospatial study in Haiti. *PLoS Med* 2011 Aug;8(8):e1001083 [FREE Full text] [doi: [10.1371/journal.pmed.1001083](https://doi.org/10.1371/journal.pmed.1001083)] [Medline: [21918643](https://pubmed.ncbi.nlm.nih.gov/21918643/)]
29. Bengtsson L, Gaudart J, Lu X, Moore S, Wetter E, Sallah K, et al. Using mobile phone data to predict the spatial spread of cholera. *Sci Rep* 2015 Mar 09;5:8923 [FREE Full text] [doi: [10.1038/srep08923](https://doi.org/10.1038/srep08923)] [Medline: [25747871](https://pubmed.ncbi.nlm.nih.gov/25747871/)]
30. Chunara R, Nsoesie EO. Large-scale measurements of network topology and disease spread: a pilot evaluation using mobile phone data in Cote d'Ivoire. 2013 Presented at: NetMob 2013; May 1-3, 2013; Boston, MA URL: <https://perso.uclouvain.be/vincent.blondel/netmob/2013/D4D-book.pdf>
31. Deka D, Vishnawath S. On models characterizing cellular social networks. 2013 Presented at: NetMob 2013; May 1-3, 2013; Boston, MA URL: <https://perso.uclouvain.be/vincent.blondel/netmob/2013/D4D-book.pdf>
32. De Monasterio J, Salles A, Lang C, Weinberg D, Minnoni M, Travizano M, et al. Analyzing the spread of chagas disease with mobile phone data. 2016 Presented at: IEEE/ACM International Conference on Advances in Social Networks Analysis and Mining (ASONAM); Aug. 18-21, 2016; San Francisco, CA URL: <http://ieeexplore.ieee.org/document/7752298/> [doi: [10.1109/ASONAM.2016.7752298](https://doi.org/10.1109/ASONAM.2016.7752298)]
33. Dewulf B, Neutens T, Van Dyck D, de Bourdeaudhuij I, Int Panis L, Beckx C, et al. Dynamic assessment of inhaled air pollution using GPS and accelerometer data. *Journal of Transport & Health* 2016 Mar;3(1):114-123. [doi: [10.1016/j.jth.2015.10.004](https://doi.org/10.1016/j.jth.2015.10.004)]
34. Djotio NT, Nganmeni Z, Nouho N. Design and implementation of a tool for the Correlation between the rate of prevalence of a pathology and the flow of communication between diverse localities. 2013 Presented at: NetMob 2013; May 1-3, 2013; Boston, MA URL: <https://perso.uclouvain.be/vincent.blondel/netmob/2013/D4D-book.pdf>
35. Enns EA, Amuasi JH. Human mobility and communication patterns in Cote d'Ivoire: a network perspective for malaria control. 2013 Presented at: NetMob 2013; May 1-3, 2013; Boston, MA URL: <https://perso.uclouvain.be/vincent.blondel/netmob/2013/D4D-book.pdf>
36. Farrahi K, Emonet R, Cebrian M. Epidemic contact tracing via communication traces. *PLoS One* 2014;9(5):e95133 [FREE Full text] [doi: [10.1371/journal.pone.0095133](https://doi.org/10.1371/journal.pone.0095133)] [Medline: [24787614](https://pubmed.ncbi.nlm.nih.gov/24787614/)]
37. Finger F, Genolet T, Mari L, de Magny GC, Manga NM, Rinaldo A, et al. Mobile phone data highlights the role of mass gatherings in the spreading of cholera outbreaks. *Proc Natl Acad Sci U S A* 2016 Jun 07;113(23):6421-6426 [FREE Full text] [doi: [10.1073/pnas.1522305113](https://doi.org/10.1073/pnas.1522305113)] [Medline: [27217564](https://pubmed.ncbi.nlm.nih.gov/27217564/)]
38. Frias-Martinez V, Rubio A, Frias-Martinez E. Measuring the impact of epidemic alerts on human mobility. 2013. URL: <http://www.vanessafriasmartinez.org/uploads/epidemics.pdf> [accessed 2018-07-11] [WebCite Cache ID 70px93ht9]
39. Frias-Martinez E, Williamson G, Frias-Martinez V. Simulation of Epidemic Spread using Cell-Phone Call Data: H1N1 Case Study. 2014. URL: <http://www.vanessafriasmartinez.org/uploads/h1n1netmob13.pdf> [accessed 2018-07-11] [WebCite Cache ID 70pxF99nF]
40. Gariazzo C, Pelliccioni A, Bolignano A. A dynamic urban air pollution population exposure assessment study using model and population density data derived by mobile phone traffic. *Atmospheric Environment* 2016 Apr;131:289-300 [FREE Full text] [doi: [10.1016/j.atmosenv.2016.02.011](https://doi.org/10.1016/j.atmosenv.2016.02.011)]
41. Gavric K, Brdar S, Culibrk D, Crnojevic V. Linking the human mobility and connectivity patterns with spatial HIV distribution. 2013 Presented at: NetMob 2013; May 1-3, 2013; Boston, MA URL: <https://perso.uclouvain.be/vincent.blondel/netmob/2013/D4D-book.pdf>
42. Guzetta G, Staiano G, Ajell M, Kirschner D, Lepri B, Merler S. Impact and scale of human mobility on the spatial transmission dynamics of tuberculosis in Senegal. 2014. URL: http://www.d4d.orange.com/fr/content/download/43453/406503/version/1/file/D4DChallengeSenegal_Book_of_Abstracts_Scientific_Papers.pdf
43. Hamaoka Y. Detecting Anomalies and Supporting Community To Ensure Healthy Society. 2014. URL: http://www.d4d.orange.com/fr/content/download/43453/406503/version/1/file/D4DChallengeSenegal_Book_of_Abstracts_Scientific_Papers.pdf
44. Kafsi M, Kazemi E, Maystre L, Yartseva L, Grossglauser M, Thiran P. Mitigating epidemics through mobile micro-measures. 2013 Presented at: NetMob 2013; May 1-3, 2013; Boston, MA URL: <https://perso.uclouvain.be/vincent.blondel/netmob/2013/D4D-book.pdf>
45. Le Menach A, Tatem AJ, Cohen JM, Hay SI, Randell H, Patil AP, et al. Travel risk, malaria importation and malaria transmission in Zanzibar. *Sci Rep* 2011 Sep;1:93 [FREE Full text] [doi: [10.1038/srep00093](https://doi.org/10.1038/srep00093)] [Medline: [22355611](https://pubmed.ncbi.nlm.nih.gov/22355611/)]

46. Leidig JP, Kitsumi Y, O'Hearn KA, Sauer CM, Scripps J, Wolffe G. Applying mobile datasets in computational public health research. 2013 Presented at: NetMob 2013; May 1-3, 2013; Boston, MA URL: <https://perso.uclouvain.be/vincent.blondel/netmob/2013/D4D-book.pdf>
47. Leidig JP, Theisen C, Vogel N, Graham DH, Scripps J, Wolffe G. Modeling Ebola Virus Diffusion in Senegal using Mobile Phone Datasets and Agent-based Simulation. 2014. URL: http://www.d4d.orange.com/fr/content/download/43453/406503/version/1/file/D4DChallengeSenegal_Book_of_Abstracts_Scientific_Papers.pdf
48. Lima A, De Domenico M, Pejovic V, Musolesi M. Exploiting cellular data for disease containment and information campaigns strategies in country-wide epidemics. 2013 Presented at: NetMob 2013; May 1-3, 2013; Boston, MA URL: <https://perso.uclouvain.be/vincent.blondel/netmob/2013/D4D-book.pdf>
49. Lima A, Pejovic V, Rossi L, Musolesi M, Gonzalez M. Progmosis: Evaluating Risky Individual Behaviour During Epidemics Using Mobile Network Data. 2014. URL: http://www.d4d.orange.com/fr/content/download/43453/406503/version/1/file/D4DChallengeSenegal_Book_of_Abstracts_Scientific_Papers.pdf
50. Mari L, Casagrandi R, Ciddio M, Sokolow SH, De Leo G, Gatto M. Uncovering the impact of human mobility on schistosomiasis via mobile phone data. 2014. URL: http://www.d4d.orange.com/fr/content/download/43453/406503/version/1/file/D4DChallengeSenegal_Book_of_Abstracts_Scientific_Papers.pdf
51. Matamalas JT, Domenico MD, Arenas A. Weakening the Incidence of Transmittable Diseases by Taking Advantage of Mobile Phone Activity. 2014. URL: http://www.d4d.orange.com/fr/content/download/43453/406503/version/1/file/D4DChallengeSenegal_Book_of_Abstracts_Scientific_Papers.pdf
52. Milushelva S. Quantifying the Effect of Movement Associated with Holidays on Malaria Prevalence Using Cell Phone Data. 2014. URL: http://www.d4d.orange.com/fr/content/download/43453/406503/version/1/file/D4DChallengeSenegal_Book_of_Abstracts_Scientific_Papers.pdf
53. Mutafungwa E. Mobile Data as Public Health Decision Enabler: A Case Study of Cardiac and Neurological Emergencies. 2014. URL: http://www.d4d.orange.com/fr/content/download/43453/406503/version/1/file/D4DChallengeSenegal_Book_of_Abstracts_Scientific_Papers.pdf
54. Perez-Saez J, Finger F, Mari L, Rinaldo A, Bertuzzo E. Human mobility and the spreading of waterborne diseases. 2014. URL: http://www.d4d.orange.com/fr/content/download/43453/406503/version/1/file/D4DChallengeSenegal_Book_of_Abstracts_Scientific_Papers.pdf
55. Resch B, Arif A, Krings G, Vankeerberghen G, Buekenhout M. Deriving hospital catchment areas from mobile phone data. 2016. URL: http://www.berndresch.com/download/work/publications/resch-et-al_catchment-areas-mobile-phones_giscience_2016.pdf [WebCite Cache ID 70ps5AJD2]
56. Saravanan M, Karthikeyan P, Aarthi A, Kiruthika M, Suganya S. Exploring community structure to understand disease spread and control using mobile call detail records. 2013 Presented at: NetMob 2013; May 1-3, 2013; Boston, MA URL: <https://perso.uclouvain.be/vincent.blondel/netmob/2013/D4D-book.pdf>
57. Tatem A, Huang Z, Narib C, Kumar U, Kandula D, Pindolia D, et al. Integrating rapid risk mapping and mobile phone call record data for strategic malaria elimination planning. *Malar J* 2014 Feb 10;13:52 [FREE Full text] [doi: [10.1186/1475-2875-13-52](https://doi.org/10.1186/1475-2875-13-52)] [Medline: [24512144](https://pubmed.ncbi.nlm.nih.gov/24512144/)]
58. Tatem AJ, Qiu Y, Smith DL, Sabot O, Ali AS, Moonen B. The use of mobile phone data for the estimation of the travel patterns and imported Plasmodium falciparum rates among Zanzibar residents. *Malar J* 2009 Dec 10;8:287 [FREE Full text] [doi: [10.1186/1475-2875-8-287](https://doi.org/10.1186/1475-2875-8-287)] [Medline: [20003266](https://pubmed.ncbi.nlm.nih.gov/20003266/)]
59. Tompkins AM, McCreech N. Developing an agent based migration model for Senegal for malaria transmission. 2014. URL: http://www.d4d.orange.com/fr/content/download/43453/406503/version/1/file/D4DChallengeSenegal_Book_of_Abstracts_Scientific_Papers.pdf
60. Tompkins AM, McCreech N. Migration statistics relevant for malaria transmission in Senegal derived from mobile phone data and used in an agent-based migration model. *Geospat Health* 2016 Mar 31;11(1 Suppl):408 [FREE Full text] [doi: [10.4081/gh.2016.408](https://doi.org/10.4081/gh.2016.408)] [Medline: [27063741](https://pubmed.ncbi.nlm.nih.gov/27063741/)]
61. Vogel N. Mining Enormous Mobile Datasets to Improve Mitigation Strategies for Limiting the Spread of Infectious Disease. 2014 Presented at: Big Data Conference 2014; 2014; Michigan URL: http://scholarworks.gvsu.edu/bigdata_conference2014/12/
62. Wesolowski A, Buckee C. Are gravity models appropriate for estimating the spatial spread of malaria? 2013 Presented at: NetMob 2013; May 1-3, 2013; Boston, MA URL: <https://perso.uclouvain.be/vincent.blondel/netmob/2013/D4D-book.pdf>
63. Wesolowski A, Metcalf C, Eagle N, Kombich J, Grenfell BT, Bjørnstad ON, et al. Quantifying seasonal population fluxes driving rubella transmission dynamics using mobile phone data. *Proc Natl Acad Sci U S A* 2015 Sep 01;112(35):11114-11119 [FREE Full text] [doi: [10.1073/pnas.1423542112](https://doi.org/10.1073/pnas.1423542112)] [Medline: [26283349](https://pubmed.ncbi.nlm.nih.gov/26283349/)]
64. Wesolowski A, Eagle N, Tatem AJ, Smith DL, Noor AM, Snow RW, et al. Quantifying the impact of human mobility on malaria. *Science* 2012 Oct 12;338(6104):267-270 [FREE Full text] [doi: [10.1126/science.1223467](https://doi.org/10.1126/science.1223467)] [Medline: [23066082](https://pubmed.ncbi.nlm.nih.gov/23066082/)]
65. Wesolowski A, Stresman G, Eagle N, Stevenson J, Owaga C, Marube E, et al. Quantifying travel behavior for infectious disease research: a comparison of data from surveys and mobile phones. *Sci Rep* 2014 Jul 14;4:5678 [FREE Full text] [doi: [10.1038/srep05678](https://doi.org/10.1038/srep05678)] [Medline: [25022440](https://pubmed.ncbi.nlm.nih.gov/25022440/)]

66. Wesolowski A, Qureshi T, Boni MF, Sundsøy PR, Johansson MA, Rasheed SB, et al. Impact of human mobility on the emergence of dengue epidemics in Pakistan. *Proc Natl Acad Sci U S A* 2015 Sep 22;112(38):11887-11892 [[FREE Full text](#)] [doi: [10.1073/pnas.1504964112](https://doi.org/10.1073/pnas.1504964112)] [Medline: [26351662](https://pubmed.ncbi.nlm.nih.gov/26351662/)]
67. Wilson R, Zu E, Albert M, Power D, Tudge S, Gonzalez M, et al. Rapid and Near Real-Time Assessments of Population Displacement Using Mobile Phone Data Following Disasters: The 2015 Nepal Earthquake. *PLoS Curr* 2016 Feb 24;8 [[FREE Full text](#)] [doi: [10.1371/currents.dis.d073fbcce328e4c39087bc086d694b5c](https://doi.org/10.1371/currents.dis.d073fbcce328e4c39087bc086d694b5c)] [Medline: [26981327](https://pubmed.ncbi.nlm.nih.gov/26981327/)]
68. Wu H, Gosh S, Ramakrishnan N. Forecasting Influenza in Senegal with Call Detail Records. 2014. URL: https://people.cs.vt.edu/~prithwi/resources/papers/haonetmob14_d4dSenegal.pdf [accessed 2018-07-11] [[WebCite Cache ID 70q02R1cr](#)]
69. Yu Y. Individual-based modelling of contact networks of epidemic diffusion using real-life data. 2014. URL: http://www.d4d.orange.com/fr/content/download/43453/406503/version/1/file/D4DChallengeSenegal_Book_of_Abstracts_Scientific_Papers.pdf
70. Blondel V, Esch M, Chan C, Clerot F, Deville P, Huens E, et al. The D4D challenge on mobile phone data. 2013. URL: <https://arxiv.org/pdf/1210.0137.pdf> [accessed 2018-07-11] [[WebCite Cache ID 70ptEb6vq](#)]
71. Orange. Challenge 4 development. 2014. URL: <http://www.d4d.orange.com/en/Accueil> [[WebCite Cache ID 70q253A17](#)]
72. De Montjoye Y, Smoreda Z, Trinquart R, Ziemlicki C, Blondel V. D4D-Senegal: The Second mobile phone data for development challenge. 2014. URL: <https://arxiv.org/pdf/1407.4885.pdf> [accessed 2018-07-11] [[WebCite Cache ID 70q001oig](#)]
73. Mobile privacy principles - public policy.: GSMA; 2012. URL: <http://www.gsma.com/publicpolicy/mobile-and-privacy/mobile-privacy-principles> [accessed 2018-07-11] [[WebCite Cache ID 70ptHLfef](#)]
74. Pestre G, Letouze E, Zagheni E. Assessing biases in call detail records for development estimates, , No. AFD Research Paper Series 2016;32.
75. Wang K, Fung B, Dong G. Integrating private databases for data analysis. In: Kantor P, Roberts F, Wang FY, Muresan G, Zeng D, Chen H, et al, editors. *Intelligence and Security Informatics*. Berlin: Springer; 2005:171-182.
76. Wesolowski A, Buckee C, Engø-Monsen KC, Metcalf C. Connecting Mobility to Infectious Diseases: The Promise and Limits of Mobile Phone Data. *J Infect Dis* 2016 Nov 14;214(suppl 4):S414-S420. [doi: [10.1093/infdis/jiw273](https://doi.org/10.1093/infdis/jiw273)]
77. Zang H, Bolot J. Anonymization of location data does not work. In: *MobiCom '11*. 2011 Presented at: 17th Annual International Conference on Mobile Computing and Networking; Sept. 19-23, 2011; Las Vegas, NV URL: <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.651.44&rep=rep1&type=pdf>
78. Song Y, Dahlmeier D, Bressan S. Not So Unique in the Crowd: a Simple and Effective Algorithm for Anonymizing Location Data. 2014. URL: <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.663.4441&rep=rep1&type=pdf>
79. Narayanan A, Felten E. No silver bullet: De-identification still doesn't work. 2014. URL: <http://randomwalker.info/publications/no-silver-bullet-de-identification.pdf> [accessed 2018-07-11] [[WebCite Cache ID 70q0Yjq6M](#)]
80. Taylor L, Floridi L, Sloot B. *Group Privacy. New Challenges of Data Technologies*. Berlin: Springer; 2016.
81. Cameron D, Pope S, Clemence M. Dialogue on data: Exploring the public's views on using administrative data for research purposes. 2014. URL: <https://esrc.ukri.org/files/public-engagement/public-dialogues/dialogue-on-data-exploring-the-public-s-views-on-using-linked-administrative-data-for-research-purposes/> [accessed 2018-07-11] [[WebCite Cache ID 70q0mxHmf](#)]
82. Wellcome Trust. The One-Way Mirror: Public attitudes to commercial access to health data. 2016. URL: <https://wellcome.ac.uk/sites/default/files/public-attitudes-to-commercial-access-to-health-data-wellcome-mar16.pdf> [accessed 2018-07-11] [[WebCite Cache ID 70q0qGJt](#)]
83. GSMA. Mobile Privacy: Consumer research insights and considerations for policymakers. 2014. URL: https://www.gsma.com/publicpolicy/wp-content/uploads/2014/02/MOBILE_PRIVACY_Consumer_research_insights_and_considerations_for_policymakers-Final.pdf [accessed 2018-07-11] [[WebCite Cache ID 70q0tYII0](#)]
84. GA4GH. Global Alliance for Genomics and Health. 2014. URL: <https://www.ga4gh.org/> [accessed 2018-07-11] [[WebCite Cache ID 70q0vxc9q](#)]
85. Shabani M, Bezuidenhout L, Borry P. Attitudes of research participants and the general public towards genomic data sharing: a systematic literature review. *Expert Rev Mol Diagn* 2014 Nov;14(8):1053-1065. [doi: [10.1586/14737159.2014.961917](https://doi.org/10.1586/14737159.2014.961917)] [Medline: [25260013](https://pubmed.ncbi.nlm.nih.gov/25260013/)]
86. Majumder M, Cook-Deegan R, McGuire AL. Beyond Our Borders? Public Resistance to Global Genomic Data Sharing. *PLoS Biol* 2016 Nov;14(11):e2000206 [[FREE Full text](#)] [doi: [10.1371/journal.pbio.2000206](https://doi.org/10.1371/journal.pbio.2000206)] [Medline: [27806054](https://pubmed.ncbi.nlm.nih.gov/27806054/)]
87. Haeusermann T, Greshake B, Blasimme A, Irdam D, Richards M, Vayena E. Open sharing of genomic data: Who does it and why? *PLoS One* 2017;12(5):e0177158 [[FREE Full text](#)] [doi: [10.1371/journal.pone.0177158](https://doi.org/10.1371/journal.pone.0177158)] [Medline: [28486511](https://pubmed.ncbi.nlm.nih.gov/28486511/)]
88. GSMA. The state of mobile data for social good report. 2017. URL: http://unglobalpulse.org/sites/default/files/MobileDataforSocialGoodReport_29June.pdf [accessed 2018-07-11] [[WebCite Cache ID 70q0zWy1B](#)]
89. Telefonica. Telefonica Digital's Smart Steps. 2018. URL: <http://datacollaboratives.org/cases/telefonica-digitals-smart-steps.html> [accessed 2018-07-11] [[WebCite Cache ID 70q17L2L0](#)]
90. Office for National Statistics. ONS methodology working paper series No. 8. 2017. Statistical uses for mobile phone data: literature review URL: <https://www.ons.gov.uk/methodology/methodologicalpublications/generalmethodology/>

- [onworkingpaperseries/onmethodologyworkingpaperseriesno8statisticalusesformobilephonedataliteraturereview](#) [accessed 2018-07-11] [WebCite Cache ID 70q1KGNpy]
91. Office for National Statistics. Research Outputs: Using mobile phone data to estimate commuting flows. 2017. URL: <https://www.ons.gov.uk/census/censustransformationprogramme/administrativedatacensusproject/administrativedatacensusresearchoutputs/populationcharacteristics/researchoutputsusingmobilephonedatatoestimatecommutingflows> [accessed 2018-07-11] [WebCite Cache ID 70q1PiK06]
 92. Farrahi K, Emonet K, Cebrian M. Predicting a Community's Flu Dynamics with Mobile Phone Data. 2015. URL: <https://hal.archives-ouvertes.fr/hal-01146198/document> [accessed 2018-07-11] [WebCite Cache ID 70q1Eikbe]
 93. Barchiesi D, Preis T, Bishop S, Moat HS. Modelling human mobility patterns using photographic data shared online. R Soc Open Sci 2015 Aug;2(8):150046 [FREE Full text] [doi: [10.1098/rsos.150046](https://doi.org/10.1098/rsos.150046)] [Medline: [26361545](https://pubmed.ncbi.nlm.nih.gov/26361545/)]
 94. Lemey P, Rambaut A, Bedford T, Faria N, Bielejec F, Baele G, et al. Unifying viral genetics and human transportation data to predict the global transmission dynamics of human influenza H3N2. PLoS Pathog 2014 Feb;10(2):e1003932 [FREE Full text] [doi: [10.1371/journal.ppat.1003932](https://doi.org/10.1371/journal.ppat.1003932)] [Medline: [24586153](https://pubmed.ncbi.nlm.nih.gov/24586153/)]
 95. Ginger.io. 2018. URL: <http://www.ginger.io/> [WebCite Cache ID 70q1iDLgj]
 96. Matheson R. Watch your tone. 2016. URL: <http://news.mit.edu/2016/startup-cogito-voice-analytics-call-centers-ptsd-0120> [WebCite Cache ID 70q1n4TOf]

Abbreviations

CDR: call detail record

GSMA: Groupe Spéciale Mobile Association

LMIC: low- to middle-income country

MNO: mobile network operator

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Original Paper

Digital Food Records in Community-Based Interventions: Mixed-Methods Pilot Study

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Abstract

Background: A pressing need exists to understand and optimize the use of dietary assessment tools that can be used in community-based participatory research (CBPR) interventions. A digital food record, which uses a mobile device to capture the dietary intake through text and photography inputs, is a particularly promising mobile assessment method. However, little is understood about the acceptability and feasibility of digital food records in CBPR and how to best tailor dietary assessment tools to the needs of a community.

Objective: The objective of our study was to evaluate the acceptability and feasibility of digital food records among church-based populations in resource-limited wards of Washington, DC, USA, using a mixed-methods approach.

Methods: This community-based pilot study was conducted as part of the Washington, DC Cardiovascular Health and Needs Assessment. Participants (n=17) received a mobile device (iPod Touch) to photodocument their dietary intake for a 3-day digital food record using a mobile app, FitNinja (Vibrent Health). The acceptability of the digital food record was explored through the thematic analysis of verbatim transcripts from a moderated focus group (n=8). In addition, the feasibility was evaluated by the percentage of participants complying with instructions (ie, capturing both before and after meal photos for at least 2 meals/day for 3 days).

Results: Qualitative themes identified were related to (1) the feasibility and acceptability of the mobile device and app, including issues in recording the dietary information and difficulty with photodocumentation; (2) suggestions for additional support and training experiences; and (3) comparisons with other mobile apps. Overall, the participants accepted the digital food record by demonstrating satisfaction with the tool and intent to continue the use (eg, participants recorded an average of 5.2, SD 7, consecutive

days). Furthermore, of the 17 participants, 15 photodocumented at least 1 meal during the study period and 3 fully complied with the digital food record instructions.

Conclusions: This study demonstrated digital food records as an acceptable tool in CBPR and identified contributors and barriers to the feasibility of digital food records for future research. Engaging community members in the implementation of novel assessment methods allows for the tailoring of technology to the needs of the community and optimizing community-based interventions.

Trial Registration: ClinicalTrials.gov NCT01927783; <https://www.clinicaltrials.gov/ct2/show/NCT01927783> (Archived by WebCite at <http://www.webcitation.org/70WzaFWb6>)

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KEYWORDS

mHealth; diet; community-based participatory research; qualitative research; focus group, obesity

Introduction

Cardiovascular disease (CVD) is the leading cause of death in the United States, and modifiable behaviors can drastically reduce the risk for CVD [1]. Poor diet, in particular, is associated with increased risk for CVD [2] and is especially suboptimal among resource-limited populations [3,4], placing these individuals at amplified risk for CVD. Interventions aimed at improving the dietary intake to reduce risk for CVD in this population could be most effective when designed and implemented in partnership with community stakeholders [5-7]. Although reliable and valid assessment tools are fundamental in measuring an intervention's efficacy, little is known about how best to tailor dietary assessment tools to the needs of a community. Therefore, a pressing need exists to understand and optimize the use of dietary assessment tools that could be used in community-based participatory research (CBPR) interventions.

Traditional dietary measures, such as food frequency questionnaires, 24-hour dietary recalls, recovery biomarkers of nutrient intake, and observational studies, can be costly to implement, burdensome to participants, limited by recall bias, have reduced ecological validity [8-10], and suboptimal in assessing how dietary intake changes over time—an integral measure in intervention research [11]. Ecological momentary assessments (EMAs) allow for data collection to occur in “real time” in participants' environment, eliminate error associated with participant recall, and increase the ecological validity; however, participants might still perceive a high time burden associated with this method and unintentionally document inaccurate information [8,9,12].

mHealth technology shows considerable potential as a data collection platform. A digital food record (DFR), which involves the use of a mobile device to capture dietary intake through descriptive text and before and after meal photography, is a particularly promising mHealth assessment method that can address some of the limitations of traditional dietary measures and other EMA methods [11-16]. In addition, DFRs have the potential to maximize the validity of the dietary intake data collected by providing researchers with pictures documenting portion sizes consumed, additional undocumented food items, and the rate of food consumption. Moreover, they may also reduce the burden on participants to record the precise intake

information [14-17], which could be particularly useful for populations with lower literacy [18,19]. Previous research has demonstrated the feasibility [14,20-23] and validity of DFRs [12,18-20,24-26]. Furthermore, the use of DFRs was shown to have high acceptability and validity in pediatric and adolescent populations [18,19,23,27], a college population [26], overweight and diabetic populations [22,27,28], and a free-living adult population [29].

While numerous studies support the use of DFRs for dietary intake assessment within research contexts [19-21], little is understood about how acceptable and feasible DFRs are for use in CBPR. In fact, the majority of research examining the feasibility of DFRs has been conducted in a laboratory or a controlled setting (eg, provided with meals and snacks to consume at home) [12], suggesting a need to examine the use of DFRs within a community setting. Furthermore, it remains unknown whether DFRs are well suited for resource-limited communities, most of which are at risk for CVD. CBPR provides feedback from community members, captures input on the feasibility of novel tools for use in future studies and interventions, and allows for the “tailoring” of assessment methods to the needs of the community through this involvement [7]. Therefore, using CBPR to examine the usability of DFRs might be most advantageous.

Recent work from our research team assessed the feasibility of a Web-based and wearable technology to measure physical activity among faith-based communities in Washington, DC, USA, where the CVD risk is the highest and resources for physical activity and healthy nutrition are most limited, compared with other wards in DC (NCT01927783 [30]). To complement this work, the feasibility of mHealth technology measurements of the dietary intake were examined within these same communities. Increasing knowledge regarding the usability of digital technology to measure the dietary intake in CBPR could provide opportunities to tailor methods to the needs of the community, improve interventions that promote healthy eating, reduce cardiovascular (CV) health disparities, and improve health outcomes among resource-limited, at-risk populations.

This analysis had two specific aims: (1) to determine the feasibility and acceptability of using a mobile DFR app with a camera to take photographs of dietary intake in an economically disadvantaged population and (2) to examine benefits and

barriers to use of DFRs in community-based interventions using a mixed-methods approach. We hypothesized that the use of DFRs is a feasible and acceptable method for capturing the dietary intake in the faith-based community of interest.

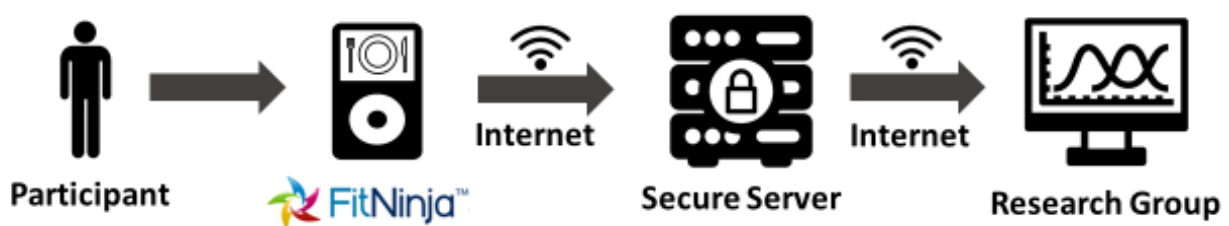
Methods

Study Design

We conducted a CBPR mixed-methods study that incorporated a focus group and pilot testing of a DFR app, FitNinja (Vibrent Health, Fairfax, VA, USA). The data collection process (Figure 1) involved a secure internet server to allow for the secure transfer and uploading of data from the DFR app. To consult on the planning and implementation of this and other community-based initiatives, we established the DC CV Health and Obesity Collaborative (DC CHOC), a community advisory board comprising a diverse group of community representatives and a multidisciplinary research team. Representatives included epidemiologists, behavioral scientists, and community leaders from faith-based organizations, academia, health care, and governmental organizations, as described previously [30]. The first research project designed by the DC CHOC, the Washington, DC CV Health and Needs Assessment, included a subset of studies designed to examine the proposed mobile technology in a sample from the target population before testing on a larger population in the CV Health and Needs Assessment. This series of focus groups and pilot tests were called the CV Health and Needs Assessment Qualitative Study and was the focus of this study. The National Heart, Lung, and Blood Institute Division of Intramural Research Institutional Review Board (Protocol 13-H-0183) approved the CV Health and Needs Assessment and the CV Health and Needs Assessment Qualitative Study. All participants provided written informed consent.

All participants (n=17) received a mobile device (iPod, Apple, Cupertino, CA, USA) and were instructed to take pictures of their meals for a 3-day DFR using the FitNinja mobile app. Participants were instructed to take pictures before and after each meal for at least 3 days (2 weekdays and 1 weekend day) using the mobile app. Participants classified their own meals, with the options of breakfast, lunch, dinner, or a snack. In addition, participants were instructed to take date- and time-stamped photos. Each participant was given a fiducial marker (a 4 × 4-cm card) to place by their meal when taking pictures as a reference image in determining the portion size.

Figure 1. Secure data collection process.



While photos were not translated into nutritional or caloric composition data, these were used for descriptive purposes for meals or snacks eaten. Providing descriptive information regarding the meal quality is of unique value for diet counseling focused on the portion size, meal timing, and adherence to “MyPlate” recommendations and can therefore inform other uses of this type of tool.

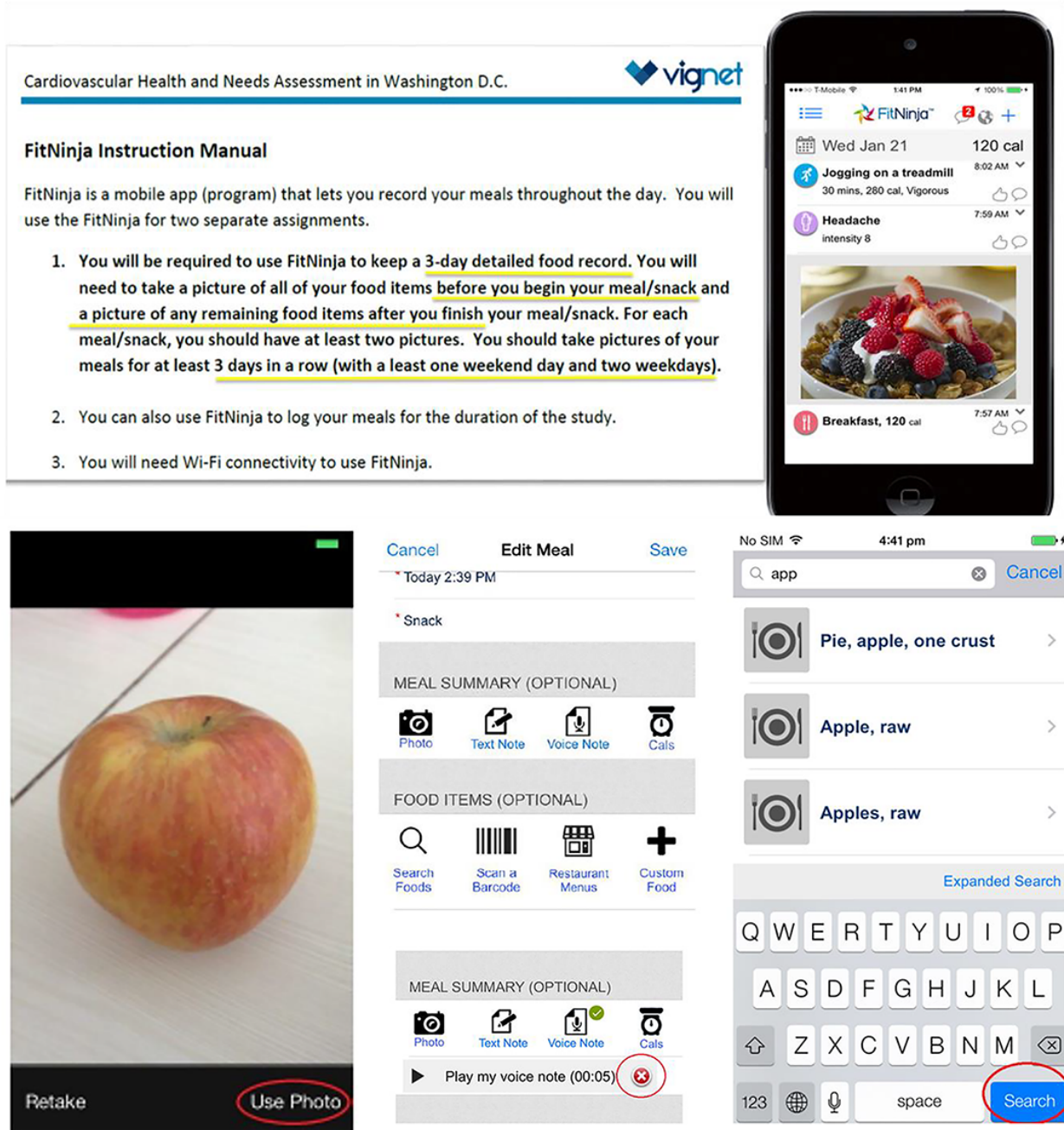
We conducted a focus group for a subset of qualitative study participants (n=8) after 2 weeks of using the mobile device and FitNinja app. The outcomes of interest in this study were as follows: (1) the feasibility of DFR as measured by the text and photography input in the FitNinja app and (2) the acceptability of the system determined by the results of a moderated focus group discussion. The focus group discussion was designed to elicit participants’ opinions about their experiences with the technology and FitNinja app and to prompt their suggestions for incorporating similar technologies in future behavioral interventions within their communities.

Digital Food Record

Participants were introduced to the FitNinja mobile app and trained on how to use it with a PowerPoint presentation developed by the app developers, with the approval of the research team that paralleled the FitNinja instruction manual. In addition, the training session involved hands-on practice using the app with the support of a research team member. We provided each participant with his or her own instruction manual for reference; the instruction manual provided detailed steps on how to use the app, including how to connect to Wi-Fi, log in to the FitNinja app, take photos of foods consumed, create text and voice notes describing foods consumed, and search the food database. Moreover, the manual described how to scan barcodes of food items, browse restaurant menus, create food items or recipes, add calories, and edit or delete previously recorded meals. Useful tips and clarifications regarding the use of the app were also included as part of the instruction manual, referred to in the manual as “helpful hints.” Figure 2 displays text excerpts from the manual that guided participants through an example of meal recording with photography using the FitNinja app.

The iPod Touch devices were collected from participants after completing up to 30 days of participation. In addition, the data from the devices were uploaded directly to a secured website, where the research team could access and download the data for analysis.

Figure 2. Excerpts from the instruction manual for FitNinja.



Focus Group

At the end of the study period, we conducted a focus group for a random subset of participants to provide feedback on their experiences with DFR. Participants in this study were compensated with a US \$25 gift card, compatible with the time required for the focus group. The detailed description of the focus group data collection process, including the moderator’s guide that included preselected questions and probes, is available elsewhere [30].

Study Population

We recruited participants for the CV Health and Needs Assessment Study and its accompanying CV Health and Needs

Assessment Qualitative Study from 3 churches in economically disadvantaged wards of Washington, DC, USA,—wards in which the median income was lower than the median income in other wards of DC—where resources for healthy nutritional options were mostly limited and the obesity prevalence was the highest between December 2013 and January 2015 [31,32]. Participants were eligible for this study if they were between the ages of 19 and 85 years and possessed sufficient English language proficiency to execute study tasks. We recruited 8 participants for the CV Health and Needs Assessment Qualitative Study focus group, which was within the recommended range for the qualitative research group discussion of 6-10 participants and comparable with other mHealth initial

pilot testing groups [33-36]. Furthermore, additional 9 participants were randomly selected from the larger CV Health and Needs Assessment Study to complete DFR for 17 participants.

Quantitative Data Analysis

The number of photos captured before and after eating for the 3-day food record was determined for participants to evaluate the feasibility of this tool for the population. For additional quantitative data in the study, we measured food record quality and adherence to food record instructions, including complete adherence to instructions to log “before” and “after” pictures of all recorded meals for 3 consecutive days.

Qualitative Data Analysis

The focus group was audiorecorded, and the recording was transcribed verbatim by an independent clinical research organization (Social Solutions International, Inc, Silver Spring, MD, USA). The discussion of reliability checks of the transcribing process, development of a codebook of themes, the coding process, and evaluation of the trustworthiness of qualitative analyses are available in previously published work [30,37].

Results

Demographic Characteristics

In this study, 53% (9/17) of participants were females, with ages ranging from 28 to 80 years and with an average age of 56.3 (SD 11.8) years. All participants were African American, and the majority was married (n=11), had received at least some postsecondary education (n=14), and reported annual household incomes of more than US \$60,000 (n=11), as shown in [Table 1](#).

Quantitative Study Results

The participation rate for this study was approximately 88%, with 15 of the 17 participants capturing a photo of at least one meal over the study period. We recorded an average of 6 (SD 7.3) days per participant, with an average of 18.2 (SD 23.8) meals (ie, breakfast, lunch, dinner, or snack) recorded over the study period per participant. In addition, consecutive daily recording, defined as the number of days in a row where at least one meal was photodocumented, ranged from 0 (n=2) to 25 days (n=1), with an average of 5.2 (SD 6.6) consecutively recorded days.

Table 1. Participants' characteristics (n=17); CV Health and Needs Assessment Qualitative Study.

Variable	Value
Sex, n (%)	
Female	9 (53)
Male	8 (47)
Age, mean (SD), range	56.3 (12), 28-80
Race (Black or African American), n (%)	17 (100)
Marital status, n (%)	
Married	11 (65)
Single	3 (18)
Divorced	2 (12)
Widowed	1 (6)
Education, n (%)	
High school diploma or GED ^a	3 (18)
Some college or technical degree	5 (29)
College degree	3 (18)
Graduate or professional degree	6 (35)
Annual household income (>US \$60,000), n (%) ^b	11 (69)
Participation rate (logged at least one meal), n (%)	15 (88)
Days recorded, mean (SD)	6.0 (7)
Meals recorded, mean (SD)	18.2 (24)
Consecutive days recorded, mean (SD), range	5.2 (7), 0-25

^aGED: General Equivalency Diploma.

^bOne participant refused to answer.

Table 2. Participation descriptive statistics (n=17); CV Health and Needs Assessment Qualitative Study.

Description	Mean (SD)	Min	Max
Photos per day recorded	2.9 (2.0)	0	10
Photos per meal recorded	1.4 (1.0)	0	9
Meals per day	2.6 (1.2)	0	4
Breakfasts per day	0.8 (0.3)	0	1
Lunches per day	0.6 (0.4)	0	1
Dinners per day	0.7 (0.4)	0	2
Snacks per day	0.5 (0.5)	0	3

Table 3. Measures of adherence to the digital food record instructions; CV Health and Needs Assessment Qualitative Study.

Measure of Adherence	Value
General Adherence, %	
Meals with “before” and “after” picture	26.7
Meals recorded without pictures	10.6
Meals with only “before” picture	57.6
Meals with only “after” picture	5.1
Percent of days with 3 meals (breakfast, lunch, dinner) per day	39.2
Participant Adherence (n=17), n (%)	
Participants who logged at least 1 day with ≥ 3 meals	11 (65)
Participants who logged at least 1 meal with a “before” and “after” picture	14 (82)
Participants who logged 3 consecutive days with “before” and “after” picture	3 (18)

The majority of participants recorded their dietary intakes on Sunday, Monday, and Tuesday, with Monday being the modal day in terms of participation rates. The participants logged an average of 2.6 (SD 1.2) meals per day. Breakfast was logged more frequently than other meals, and snacks were logged the least. On average, 2.9 (SD 2.0) photos of meals were taken per day, with an average of 1.4 (SD 1.0) photos taken per meal. [Table 2](#) provides additional descriptive statistics related to DFR.

Most meals (89%) were recorded with one or more photos. However, it was unlikely for participants to log meals with both “before” and “after” photos, with 26.7% of meals having both “before” and “after” pictures recorded. Finally, 18% (3/17) of participants completely adhered to the study directives, which were to record “before” and “after” photos for all meals for 3 consecutive days ([Table 3](#)).

Participants included a description with photos about 47% of the time, and the food search feature was used to accompany approximately 16% of the photo records. A common issue with the photos involved was not being able to distinguish all food items in a photo. On average, 67% of the photos had completely distinguishable contents, as determined by a member of the research team (LRY). In determining whether the contents of the photo were distinguishable, the research team member focused on whether all the food items in an image could be

recognized (ie, Was the image clear or blurry? Was the photo close enough? Was the whole plate seen? Were all described foods included if a caption was provided? Were the components of a beverage or mixed food item, such as a sandwich, clear?), with the objective of quantifying the feasibility of food photography and not on the validity of food contents. Some of the most common errors in taking photos of meals included being unable to determine what kind of beverage was in a cup or how much of the beverage was consumed; being unable to distinguish the general contents of photos without referring to a text description (if provided); condiments, sauces, or other ingredients were not logged or distinguishable; and portion sizes were indeterminable from photos. For example, condiments and beverages were properly documented 34% and 50% of the time, respectively.

Qualitative Study Results

Themes

The thematic analysis guided the interpretation of the qualitative data. Themes identified within the data collected from the focus group included (1) the iPod or Dietary app, containing 6 related subthemes; (2) support and training; (3) the Hawthorne effect; and (4) device comparisons. [Table 4](#) provides illustrative quotes extracted from the focus group transcript for each subtheme.

Table 4. Focus group themes, subthemes, and illustrative quotes; CV Health and Needs Assessment Qualitative Study.

Focus Group Themes	Illustrative Quotes
1. iPod or Dietary App	
Feasibility or Acceptability	<ul style="list-style-type: none"> • <i>For me, I couldn't do it during the work week...It would be a challenge.</i> [Male, 55 years] • <i>I had absolutely no problem in taking pictures. I'm retired and whenever I got up and got together I'd take a picture.</i> [Male, 69 years] • <i>The difference will come in if I take this pictures and sit down with [the researcher], and she's able to say to me, "On Monday you had bacon, eggs, grits, juice, fruit, and then I see over here you had a sticky bun. Okay, why don't we cut the sticky bun in half. Eat everything else."</i> [Female, 59 years]
Suggestions for improvement	<ul style="list-style-type: none"> • <i>I thought it would be cool to have data [on] how I prepared that food...Did I use canola oil, did I use peanut oil? ...Did I boil it or did I steam it? Did I put it in the microwave? Did I bake it or did I fry it?</i> [Male, 55 years]
Social media	<ul style="list-style-type: none"> • <i>I would have liked to post this to social media, you know the pictures and calories and everything.</i> [Male, 49 years]
Ambiguity over project goals	<ul style="list-style-type: none"> • <i>Can I ask what the purpose was of wanting to see an empty plate or to see what I decided to leave on the plate?</i> [Female, 59 years] • <i>I'm glad that I misunderstood [the project goals] so that it energized us [to make our diet healthier] and now we're off and running.</i> [Female, 59 years]
Issues in recording dietary information	<ul style="list-style-type: none"> • <i>I would take the camera out when eating and put it beside my food so it's right there to take the picture. But somehow after you finish [eating] you just move on.</i> [Male, 55 years] • <i>Calorie counting was off...I figured out even though I was scanning the barcodes...I'd look at the calories on my bottles and I looked at the calories on what was scanned and it didn't match.</i> [Male, 49 years]
Feedback	<ul style="list-style-type: none"> • <i>If there was somebody out there checking in on me...and I could get an email saying great job or here's something I'd like for you to do...Something like that out there would be a motivator.</i> [Female, 59 years] • <i>[It would be helpful if someone provided feedback] every 2 weeks, just to check in because you'd hate to go for three weeks or a month and be like we are way off track. You know, so you can make those adjustments as quick as you can.</i> [Female, 59 years]
2. Support and Training	
Level of technology literacy	<ul style="list-style-type: none"> • <i>The helpful hints were very, very helpful.</i> [Female, 62 years] • <i>I think maybe when you're dealing with computers and people who may be 65, 70, and above you may want to give more instructions on the use of computers.</i> [Male, 69 years]
3. Hawthorne Effect	
	<ul style="list-style-type: none"> • <i>I adjusted our diet, bought things that were healthy...fixed things different, presented them differently so that the representation of us would be one that I would be okay with everyone knowing.</i> [Female, 59 years] • <i>I gave you something [pictures] I thought you might want.</i> [Female, 59 years]
4. Device Comparisons	
	<ul style="list-style-type: none"> • <i>My Fitness Pal has also added other devices that it syncs with, other apps it syncs with.</i> [Female, 43 years] • <i>The one feature that I really like about the Nike trainer is that you get your data...You can see everything instantly on the screen so if I want to share it or track it I have it there instantly when I finish.</i> [Female, 43 years]

Acceptability

The acceptability in feasibility studies can be defined as the extent to which a new measure is judged as suitable, satisfying, or attractive to program recipients [38], and can be evaluated by examining participants' satisfaction, perceived appropriateness, and intent to continue use, among other outcomes of interest. Several participants conveyed an interest in receiving feedback regarding the quality of their dietary intake, including tips for modifications and behavioral changes, indicating a potential interest in continuing the use of DFR. In

addition, some communicated their interest in sharing their dietary record information across social media platforms, suggesting the app would be improved with the addition of a connection to email or other sharing platforms. Overall, the focus group participants showed a strong interest in using the app, recording accurate data, sharing content, receiving feedback, and self-monitoring their behavior and indicated satisfaction with the tool.

iPod or Dietary App

Participants acknowledged the extra time burden of completing the food record. One participant stated that “it would be a challenge” to complete the log during the work week. Another acknowledged that retirement had provided them with surplus leisure time, so he had “no problem” photodocumenting his dietary intake.

Feedback on the composition of their diets was a popular suggestion from participants; however, suggestions for the delivery of this feedback varied. One participant stated she would like real-time, immediate feedback from experts by email with suggestions for diet alterations, whereas another suggested an in-person check-in every couple of weeks, “because you’d hate to go for 3 weeks or a month and be like we are way off track...” [Female, 59 years]. Other suggestions for improvement included ideas to increase the depth of data from the records, such as requesting information on food preparation.

Issues associated with recording intake were categorized into two main categories: issues with the iPod or app and issues with consistent photodocumentation. Diligent recorders noticed instances when the number of calories on the nutritional label of a product was incongruent with the number of calories recorded in FitNinja when using the barcode scanner. One participant highlighted that he often had to adjust the serving size from the default serving size after scanning a food item, and this helped to eliminate this discrepancy. In addition, also it was noted that recording was not feasible if Wi-Fi was not available for participants. Furthermore, frustrations were expressed toward the iPod and malfunctions related to the device.

Participants shared their issues with the photodocumentation part of the record, particularly emphasizing the difficulty in remembering to take the “after” picture. One participant said he would place the camera right next to his meal as a reminder to take the “after” picture, but also said that, “somehow after you finish, you just move on.” Another had a rationale for her behavior, stating, “I didn’t always take the after picture. I tried to. Figured since I’m eating everything anyways...” [Female, 59 years]. One of the 2 participants who failed to record any dietary data stated that she failed to record anything because she disliked having to carry two devices (eg, her phone and the iPod for the study); the other participant stated that he did not have adequate time to document his diet.

Several participants shared thoughts about the app that reflected uncertainty in the goals of the study and the purpose of the photodocumentation. One participant stated explicitly that she misunderstood the study goals but was glad she did because it was motivation to improve her and her partner’s diet. Likewise, several other participants echoed this sentiment, agreeing that they interpreted the study as being a behavioral intervention.

Support and Training

Two participants in this study shared their frustrations with the technological literacy level necessary to effectively utilize the FitNinja program and the iPod device. Citing their ages, they suggested increased training on more basic functions of device operation, as well as additional training with the app. Favorable

comments were made regarding the “helpful hints” provided to participants.

Hawthorne Effect

The Hawthorne effect refers to the impact of the evaluation and monitoring without intervention on research participants’ behavior [39,40]. Many participants were acutely aware of the effect of photodocumentation of their diets on their actual behaviors. Participants shared their nutritional improvements with pride and were highly satisfied with this positive effect of DFR on the quality of their diet. Notably, however, 1 participant stated that she would document more of her preparticipation diet, “if I know that there is somebody there to help me adjust.”

Device Comparisons

Several focus group participants described the experience using different apps, devices, and programs for self-monitoring their dietary intakes and provided unsolicited comparisons across these devices. They primarily drew attention to features of other technologies that the FitNinja lacked, such as sharing or syncing abilities with other programs and devices (eg, sharing to social media or connecting with a physical activity tracker).

Discussion

Principal Findings

Using a mixed-methods approach, this study examined the usability of DFRs among resource-limited communities in Washington, DC, USA. The participation rates were fair; 15 of the 17 total participants recorded at least one meal over the study period, but only 18% (3/17) were totally compliant with instructions to record “before” and “after” photos for all meals for 3 consecutive days. We identified themes through thematic analysis of the focus group transcript related to the feasibility and acceptability, issues in recording, and support and training experiences. The higher likelihood of capturing only the “before” picture of a meal was acknowledged among participants in the focus group. Overall, participants were accepting our photodocumentation tool, as demonstrated by their expressed satisfaction, interest in continued use of the tool, and perceived appropriateness of the measure [38], as well as enthusiastically contributed suggestions for improvements in the DFR app.

Benefits of Digital Food Record

The benefits of digital recording of dietary intake with inclusion of photography of meals have been well demonstrated across clinical and lab settings [19-21], and its value as a valid assessment tool has been shown previously [24-26]. This pilot study demonstrates that those benefits extend to the use of DFRs in resource-limited community settings. Photodocumentation creates a unique opportunity for researchers to capture patterns of eating, support or enrich textual food records, examine portion sizes, decrease participant burden [19], and potentially improve the validity of dietary assessments [18,19]. The overall acceptability and enthusiasm toward DFR expressed by participants in the focus group demonstrates its potential for use among this population and is similar to previous findings where participants tended to express satisfaction with DFRs

[19,26,29]. Photodocumentation is less intensive and burdensome than completing 24-hour dietary recalls or completing daily diet diaries [26] and can be particularly accessible for those with lower levels of literacy [17-19].

Our DFR tool collected data in real-time, providing an opportunity to provide real-time feedback to community members. Participants in the focus group were open and eager to receive feedback regarding their diets. Previous work has examined the effect of daily feedback messages on changes in diet among obese adults, finding favorable effects [41]. While many participants expressed interest in receiving feedback, the preferred delivery method (eg, in-person vs electronically) and preferred time frame (eg, real-time vs twice a month) varied across participants. Interventions with DFRs might consider designing feedback options that can be tailored according to participants' preferences or determining which method and dosage are optimal for the behavioral change. Overall, this study suggests that this tool would be a well-accepted delivery method for dietary interventions among community populations.

Barriers to the Use of Digital Food Records in Community Settings

As far as can be determined, this feasibility pilot study is the first to use qualitative data to identify barriers to the use of DFRs within a community setting. One prominent theme within the qualitative data was technology literacy and prior device knowledge. While participants were trained to use the app, they likely began the study with varying levels of experience with technology. Of note, 2 participants cited their age stating that they had difficulty in using the technology, and 1 mentioned he had his daughter demonstrate how to operate some features of the device and app. It may be useful for future studies using DFRs to measure eHealth literacy [42] and include advanced training sessions for those participants who might have lower technology literacy or request additional training.

Participants expressed difficulty in remembering to take "before" and "after" meal pictures, particularly with taking "after" meal pictures. The willingness of participants to devise strategies to improve their documentation and the photodocumentation rates of "after" meal photos suggests that participants might benefit from a tailored system of before or after meal reminders. Previous studies have addressed this barrier by sending either standard or customized EMA prompts to participants' mobile phones reminding them to photodocument [24] or by eliminating the burden of photodocumentation with wearable, automated cameras [15,43]. However, more research is warranted to completely understand issues involved with wearable cameras for capturing the food intake, especially in community settings. Another potential strategy to improve photodocumentation rates would involve greater articulation of study goals by the research team during participant training. Some participants expressed uncertainty about the purpose of the photodocumentation part of the food record. It is possible that the utility of photos was underemphasized, thereby resulting in less documentation. It is also possible that the participants might not have taken the after picture because they did not understand the point of taking a picture of an empty plate. In this case, the inclusion of a checkbox that can be used to indicate that the entire meal was

consumed could be beneficial for both participants and researchers.

This pilot study revealed that the quality of images captured by participants could be improved. It might be necessary to introduce photo quality control methods to the app, such as those proposed by the Remote Food Photography Method [24], whereby computer software surveys image data to detect missing or poor quality imagery and sends tailored prompts to participants to improve the overall data quality. In addition, the software could require participants to retake the poor quality photograph to enable all contents to be distinguishable, and food recognition software could identify and estimate the energy and nutrient content of any other detected food items in the image [44].

In addition, participants might have changed their eating behavior merely because of participating in this study and monitoring and recording their food intake, as described by the Hawthorne effect. Diet self-monitoring is a common theoretically based behavioral change strategy [45], and a review of self-monitoring in weight loss research found consistent positive effects of adherence to diet self-monitoring [46], particularly when using mobile technology [40]. Hawthorne effects might not have been all positive in this study. For example, the purposeful omission of certain meals, snacks, or drinks that are associated with socially undesirable outcomes is possible. This is, however, a weakness of all self-reported dietary measures. Although Hawthorne effects could have contributed to errors in reporting or changes in the eating behavior of participants, they do not affect the conclusions of this study. A rigorous study design will prevent Hawthorne effects from weakening tests of intervention efficacy and effectiveness with future use of DFRs. In fact, the self-monitoring aspect of recording data in real-time inherent in DFRs enhances their value in intervention research by allowing them to serve as both an assessment tool and a behavioral change strategy [47].

Limitations

Participation in DFR was extremely variable. Indeed, the data collected show that 2 participants failed to take *any* photographs over the study period. While this could be from participants' nonresponse, it could also be a result of technological issues (eg, participants had issues with the device). However, gathering qualitative data allowed us to examine rich accounts of participants' experiences with DFR and to hypothesize strategies to decrease participants' nonresponse. In addition, this study allowed us to examine participation rates outside of a laboratory setting in the participants' natural environments, where life pressures can detract from consistent recording. Furthermore, this study is limited by its inclusion of one focus group, and future studies should include multiple focus groups.

This study did not examine the validity of the food records. Future studies should involve larger sample sizes and test the psychometric properties of DFRs to examine the reliability and validity of these dietary assessment methods within CBPR, as well as compare DFRs to a standard measure of dietary intake, such as a 24-hour diet recall [48] or objectively measured energy expenditure (doubly labeled water) [12,14,20]. Furthermore,

conclusions regarding the longer-term use of DFR cannot be drawn. Future work should use a longer study period to examine engagement, adherence, attrition, and retention.

Finally, the FitNinja app was available for participants to use and log their food intake over Wi-Fi. Notably, data collection is not feasible in Wi-Fi-limited regions. Reliance on Wi-Fi for documentation may, therefore, not be ideal in some populations.

Conclusions and Recommendations

To the best of our knowledge, this study is one of the first to demonstrate the feasibility and acceptability of DFRs in a faith-based community setting. The participation rates were fair, leaving room for improvement. This study identified many barriers to the use of digital food tracking tools (eg, inconsistent use and indistinguishable pictures), providing opportunities for future research to address these barriers. For instance, it might be useful for future studies to develop, implement, and test the efficacy of techniques to increase the adherence to DFR instructions, such as implementing a tailored system of reminders to increase before or after meal photodocumentation. In addition, future work could aim to decrease ambiguity and increase motivation or participation by improving the communication of project goals and the utility of digital records.

To address technological and app literacy issues, follow-up studies using DFR might wish to provide several community participants with additional, extensive training and designate these “super-users” as expert resources within the community who can provide assistance to other users if issues or questions arise. Furthermore, future interventions could use our DFR to deliver timely feedback to individuals about their diet. Finally, higher consideration should be given to identifying potential barriers to the use of digital food tracking apps across diverse populations, particularly if these tools are to be suggested for use in interventions or clinical settings to promote improvement in diet.

Community-based and engaged research allows for the tailoring of technology to the needs of the community. Therefore, it is essential to gain community feedback when testing novel assessment methods and to address barriers to their use. Until health equity is achieved, researchers must examine the use of novel technologies among at-risk and vulnerable populations, where interventions are most vital. Increasing the knowledge regarding the usability of digital technology to measure dietary intake in CBPR could improve interventions that promote healthy eating and reduce CV health disparities.

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Conflicts of Interest

None declared.

References

1. Writing GM, Mozaffarian D, Benjamin EJ, Go AS, Arnett DK, Blaha MJ, et al. Heart Disease and Stroke Statistics-2016 Update: A Report From the American Heart Association. *Circulation* 2016 Jan 26;133(4):e38-360. [doi: [10.1161/CIR.0000000000000350](https://doi.org/10.1161/CIR.0000000000000350)] [Medline: [26673558](https://pubmed.ncbi.nlm.nih.gov/26673558/)]
2. World Health Organization and Food and Agriculture Organization. Diet, nutrition and the prevention of chronic diseases. *World Health Organ Tech Rep Ser* 2003;916:i-viii, 1. [Medline: [12768890](https://pubmed.ncbi.nlm.nih.gov/12768890/)]
3. Chou S, Grossman M, Saffer H. An economic analysis of adult obesity: results from the Behavioral Risk Factor Surveillance System. *J Health Econ* 2004 May;23(3):565-587. [doi: [10.1016/j.jhealeco.2003.10.003](https://doi.org/10.1016/j.jhealeco.2003.10.003)] [Medline: [15120471](https://pubmed.ncbi.nlm.nih.gov/15120471/)]
4. Grafova IB, Freedman VA, Kumar R, Rogowski J. Neighborhoods and obesity in later life. *Am J Public Health* 2008 Nov;98(11):2065-2071. [doi: [10.2105/AJPH.2007.127712](https://doi.org/10.2105/AJPH.2007.127712)] [Medline: [18799770](https://pubmed.ncbi.nlm.nih.gov/18799770/)]
5. Ammerman A, Corbie-Smith G, St GDM, Washington C, Weathers B, Jackson-Christian B. Research expectations among African American church leaders in the PRAISE! project: a randomized trial guided by community-based participatory research. *Am J Public Health* 2003 Oct;93(10):1720-1727. [Medline: [14534228](https://pubmed.ncbi.nlm.nih.gov/14534228/)]
6. Sloane DC, Diamant AL, Lewis LB, Yancey AK, Flynn G, Nascimento LM, et al. Improving the nutritional resource environment for healthy living through community-based participatory research. *J Gen Intern Med* 2003 Jul;18(7):568-575 [FREE Full text] [Medline: [12848840](https://pubmed.ncbi.nlm.nih.gov/12848840/)]
7. Newman SD, Andrews JO, Magwood GS, Jenkins C, Cox MJ, Williamson DC. Community advisory boards in community-based participatory research: a synthesis of best processes. *Prev Chronic Dis* 2011 May;8(3):A70 [FREE Full text] [Medline: [21477510](https://pubmed.ncbi.nlm.nih.gov/21477510/)]

8. Bingham SA. Limitations of the various methods for collecting dietary intake data. *Ann Nutr Metab* 1991;35(3):117-127. [Medline: [1952811](#)]
9. Shim J, Oh K, Kim HC. Dietary assessment methods in epidemiologic studies. *Epidemiol Health* 2014;36:e2014009 [FREE Full text] [doi: [10.4178/epih/e2014009](#)] [Medline: [25078382](#)]
10. Hu F. Dietary assessment methods. In: *Obesity Epidemiology*. New York, NY: Oxford University Press, Inc; 2008:84-118.
11. DiFilippo KN, Huang W, Andrade JE, Chapman-Novakofski KM. The use of mobile apps to improve nutrition outcomes: A systematic literature review. *J Telemed Telecare* 2015 Feb 12. [doi: [10.1177/1357633X15572203](#)] [Medline: [25680388](#)]
12. Boushey CJ, Spoden M, Delp EJ, Zhu F, Bosch M, Ahmad Z, et al. Reported Energy Intake Accuracy Compared to Doubly Labeled Water and Usability of the Mobile Food Record among Community Dwelling Adults. *Nutrients* 2017 Mar 22;9(3) [FREE Full text] [doi: [10.3390/nu9030312](#)] [Medline: [28327502](#)]
13. Boushey CJ, Spoden M, Zhu FM, Delp EJ, Kerr DA. New mobile methods for dietary assessment: review of image-assisted and image-based dietary assessment methods. *Proc Nutr Soc* 2016 Dec 12:1-12. [doi: [10.1017/S0029665116002913](#)] [Medline: [27938425](#)]
14. Pettitt C, Liu J, Kwasnicki RM, Yang G, Preston T, Frost G. A pilot study to determine whether using a lightweight, wearable micro-camera improves dietary assessment accuracy and offers information on macronutrients and eating rate. *Br J Nutr* 2016 Jan 14;115(1):160-167. [doi: [10.1017/S0007114515004262](#)] [Medline: [26537614](#)]
15. Gemming L, Doherty A, Kelly P, Utter J, Ni MC. Feasibility of a SenseCam-assisted 24-h recall to reduce under-reporting of energy intake. *Eur J Clin Nutr* 2013 Oct;67(10):1095-1099. [doi: [10.1038/ejcn.2013.156](#)] [Medline: [24002044](#)]
16. Gemming L, Utter J, Ni MC. Image-assisted dietary assessment: a systematic review of the evidence. *J Acad Nutr Diet* 2015 Jan;115(1):64-77. [doi: [10.1016/j.jand.2014.09.015](#)] [Medline: [25441955](#)]
17. Sharp DB, Allman-Farinelli M. Feasibility and validity of mobile phones to assess dietary intake. *Nutrition* 2014;30(11-12):1257-1266. [doi: [10.1016/j.nut.2014.02.020](#)] [Medline: [24976425](#)]
18. Ptomey LT, Willis EA, Goetz JR, Lee J, Sullivan DK, Donnelly JE. Digital photography improves estimates of dietary intake in adolescents with intellectual and developmental disabilities. *Disabil Health J* 2015 Jan;8(1):146-150. [doi: [10.1016/j.dhjo.2014.08.011](#)] [Medline: [25281035](#)]
19. Higgins JA, LaSalle AL, Zhaoxing P, Kasten MY, Bing KN, Ridzon SE, et al. Validation of photographic food records in children: are pictures really worth a thousand words? *Eur J Clin Nutr* 2009 Aug;63(8):1025-1033. [doi: [10.1038/ejcn.2009.12](#)] [Medline: [19259111](#)]
20. Ptomey LT, Willis EA, Honas JJ, Mayo MS, Washburn RA, Herrmann SD, et al. Validity of energy intake estimated by digital photography plus recall in overweight and obese young adults. *J Acad Nutr Diet* 2015 Sep;115(9):1392-1399 [FREE Full text] [doi: [10.1016/j.jand.2015.05.006](#)] [Medline: [26122282](#)]
21. Martin CK, Han H, Coulon SM, Allen HR, Champagne CM, Anton SD. A novel method to remotely measure food intake of free-living individuals in real time: the remote food photography method. *Br J Nutr* 2009 Feb;101(3):446-456 [FREE Full text] [doi: [10.1017/S0007114508027438](#)] [Medline: [18616837](#)]
22. Rollo ME, Ash S, Lyons-Wall P, Russell AW. Evaluation of a Mobile Phone Image-Based Dietary Assessment Method in Adults with Type 2 Diabetes. *Nutrients* 2015;7(6):4897-4910 [FREE Full text] [doi: [10.3390/nu7064897](#)] [Medline: [26091234](#)]
23. Casperson SL, Sieling J, Moon J, Johnson L, Roemmich JN, Whigham L. A mobile phone food record app to digitally capture dietary intake for adolescents in a free-living environment: usability study. *JMIR Mhealth Uhealth* 2015;3(1):e30 [FREE Full text] [doi: [10.2196/mhealth.3324](#)] [Medline: [25775506](#)]
24. Martin CK, Correa JB, Han H, Allen HR, Rood JC, Champagne CM, et al. Validity of the Remote Food Photography Method (RFPM) for estimating energy and nutrient intake in near real-time. *Obesity (Silver Spring)* 2012 Apr;20(4):891-899 [FREE Full text] [doi: [10.1038/oby.2011.344](#)] [Medline: [22134199](#)]
25. Wang D, Kogashiwa M, Ohta S, Kira S. Validity and reliability of a dietary assessment method: the application of a digital camera with a mobile phone card attachment. *J Nutr Sci Vitaminol (Tokyo)* 2002 Dec;48(6):498-504. [Medline: [12775117](#)]
26. Wang D, Kogashiwa M, Kira S. Development of a new instrument for evaluating individuals' dietary intakes. *J Am Diet Assoc* 2006 Oct;106(10):1588-1593. [doi: [10.1016/j.jada.2006.07.004](#)] [Medline: [17000191](#)]
27. Frøisland DH, Årsand E. Integrating visual dietary documentation in mobile-phone-based self-management application for adolescents with type 1 diabetes. *J Diabetes Sci Technol* 2015 May;9(3):541-548 [FREE Full text] [doi: [10.1177/1932296815576956](#)] [Medline: [25901020](#)]
28. Ehrmann BJ, Anderson RM, Piatt GA, Funnell MM, Rashid H, Shedden K, et al. Digital photography as an educational food logging tool in obese patients with type 2 diabetes: lessons learned from a randomized, crossover pilot trial. *Diabetes Educ* 2014;40(1):89-99 [FREE Full text] [doi: [10.1177/0145721713508826](#)] [Medline: [24168836](#)]
29. Dahl LA, Poulsen S, Ernst L, Kaae AK, Biloft-Jensen A, Tetens I. Evaluation of a digital method to assess evening meal intake in a free-living adult population. *Food Nutr Res* 2010;54 [FREE Full text] [doi: [10.3402/fnr.v54i0.5311](#)] [Medline: [21085516](#)]
30. Yingling LR, Brooks AT, Wallen GR, Peters-Lawrence M, McClurkin M, Cooper-McCann R, et al. Community Engagement to Optimize the Use of Web-Based and Wearable Technology in a Cardiovascular Health and Needs Assessment Study:

- A Mixed Methods Approach. *JMIR Mhealth Uhealth* 2016 Apr 25;4(2):e38 [FREE Full text] [doi: [10.2196/mhealth.4489](https://doi.org/10.2196/mhealth.4489)] [Medline: [27113680](https://pubmed.ncbi.nlm.nih.gov/27113680/)]
31. DC DOH. The District of Columbia Department of Health. 2014. Obesity in the District of Columbia, 2014 URL: <https://doh.dc.gov/sites/default/files/dc/sites/doh/publication/attachments/Obesity%20Report%202014.pdf> [accessed 2018-06-27] [WebCite Cache ID 70XNMR8k7]
 32. DC DOH. The District of Columbia Department of Health. 2014. District of Columbia Community Health Needs Assessment URL: https://dchealth.dc.gov/sites/default/files/dc/sites/doh/page_content/attachments/DC%20DOH%20CHNA%20%28v5%2000%29%2005%2007%202014%20-%20FINAL%20%282%29.pdf [accessed 2018-06-30] [WebCite Cache ID 70Zkh5Dxp]
 33. Fukuoka Y, Vittinghoff E, Jong SS, Haskell W. Innovation to motivation--pilot study of a mobile phone intervention to increase physical activity among sedentary women. *Prev Med* 2010;51(3-4):287-289 [FREE Full text] [doi: [10.1016/j.ypmed.2010.06.006](https://doi.org/10.1016/j.ypmed.2010.06.006)] [Medline: [20600263](https://pubmed.ncbi.nlm.nih.gov/20600263/)]
 34. US Centers for Disease Control and Prevention (CDC). 2011. Behavioral risk factor surveillance system survey questionnaire URL: <http://www.cdc.gov/brfss/questionnaires/pdf-ques/2011brfss.pdf> [WebCite Cache ID 6FBHnUH6D]
 35. Bellenger D, Bernhardt K, Goldstucker J. *Qualitative research in marketing*. Chicago: American Marketing Association; 1976:A.
 36. Smith J. *Interviewing in marketsocial research*. London: Routledge & K. Paul; 1972.
 37. Wallen GR, Saygbe JN, Brooks AT, McClurkin M, Thomas S, Powell-Wiley TM. Engaging Community Leaders in the Development of a Cardiovascular Health Behavior Survey Using Focus Group-Based Cognitive Interviewing. *Health Serv Insights* 2017;10:1178632917701123 [FREE Full text] [doi: [10.1177/1178632917701123](https://doi.org/10.1177/1178632917701123)] [Medline: [28469458](https://pubmed.ncbi.nlm.nih.gov/28469458/)]
 38. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, et al. How we design feasibility studies. *Am J Prev Med* 2009 May;36(5):452-457 [FREE Full text] [doi: [10.1016/j.amepre.2009.02.002](https://doi.org/10.1016/j.amepre.2009.02.002)] [Medline: [19362699](https://pubmed.ncbi.nlm.nih.gov/19362699/)]
 39. McCambridge J, Witton J, Elbourne DR. Systematic review of the Hawthorne effect: new concepts are needed to study research participation effects. *J Clin Epidemiol* 2014 Mar;67(3):267-277 [FREE Full text] [doi: [10.1016/j.jclinepi.2013.08.015](https://doi.org/10.1016/j.jclinepi.2013.08.015)] [Medline: [24275499](https://pubmed.ncbi.nlm.nih.gov/24275499/)]
 40. Acharya SD, Elci OU, Sereika SM, Styn MA, Burke LE. Using a personal digital assistant for self-monitoring influences diet quality in comparison to a standard paper record among overweight/obese adults. *J Am Diet Assoc* 2011 Apr;111(4):583-588 [FREE Full text] [doi: [10.1016/j.jada.2011.01.009](https://doi.org/10.1016/j.jada.2011.01.009)] [Medline: [21443993](https://pubmed.ncbi.nlm.nih.gov/21443993/)]
 41. Ambeba EJ, Ye L, Sereika SM, Styn MA, Acharya SD, Sevick MA, et al. The use of mHealth to deliver tailored messages reduces reported energy and fat intake. *J Cardiovasc Nurs* 2015;30(1):35-43. [doi: [10.1097/JCN.0000000000000120](https://doi.org/10.1097/JCN.0000000000000120)] [Medline: [24434827](https://pubmed.ncbi.nlm.nih.gov/24434827/)]
 42. Norman C. eHealth literacy 2.0: problems and opportunities with an evolving concept. *J Med Internet Res* 2011 Dec;13(4):e125 [FREE Full text] [doi: [10.2196/jmir.2035](https://doi.org/10.2196/jmir.2035)] [Medline: [22193243](https://pubmed.ncbi.nlm.nih.gov/22193243/)]
 43. Gemming L, Rush E, Maddison R, Doherty A, Gant N, Utter J, et al. Wearable cameras can reduce dietary under-reporting: doubly labelled water validation of a camera-assisted 24 h recall. *Br J Nutr* 2015 Jan 28;113(2):284-291. [doi: [10.1017/S0007114514003602](https://doi.org/10.1017/S0007114514003602)] [Medline: [25430667](https://pubmed.ncbi.nlm.nih.gov/25430667/)]
 44. Zhang W, Yu Q, Siddiquie B, Divakaran A, Sawhney H. "Snap-n-Eat": Food Recognition and Nutrition Estimation on a Smartphone. *J Diabetes Sci Technol* 2015 May;9(3):525-533 [FREE Full text] [doi: [10.1177/1932296815582222](https://doi.org/10.1177/1932296815582222)] [Medline: [25901024](https://pubmed.ncbi.nlm.nih.gov/25901024/)]
 45. Burke LE, Conroy MB, Sereika SM, Elci OU, Styn MA, Acharya SD, et al. The effect of electronic self-monitoring on weight loss and dietary intake: a randomized behavioral weight loss trial. *Obesity (Silver Spring)* 2011 Feb;19(2):338-344 [FREE Full text] [doi: [10.1038/oby.2010.208](https://doi.org/10.1038/oby.2010.208)] [Medline: [20847736](https://pubmed.ncbi.nlm.nih.gov/20847736/)]
 46. Burke LE, Wang J, Sevick MA. Self-monitoring in weight loss: a systematic review of the literature. *J Am Diet Assoc* 2011 Jan;111(1):92-102 [FREE Full text] [doi: [10.1016/j.jada.2010.10.008](https://doi.org/10.1016/j.jada.2010.10.008)] [Medline: [21185970](https://pubmed.ncbi.nlm.nih.gov/21185970/)]
 47. Brand T, Pischke CR, Steenbock B, Schoenbach J, Poettgen S, Samkange-Zeeb F, et al. What works in community-based interventions promoting physical activity and healthy eating? A review of reviews. *Int J Environ Res Public Health* 2014 Jun;11(6):5866-5888 [FREE Full text] [doi: [10.3390/ijerph110605866](https://doi.org/10.3390/ijerph110605866)] [Medline: [24886756](https://pubmed.ncbi.nlm.nih.gov/24886756/)]
 48. Rangan AM, O'Connor S, Giannelli V, Yap ML, Tang LM, Roy R, et al. Electronic Dietary Intake Assessment (e-DIA): Comparison of a Mobile Phone Digital Entry App for Dietary Data Collection With 24-Hour Dietary Recalls. *JMIR Mhealth Uhealth* 2015 Oct 27;3(4):e98 [FREE Full text] [doi: [10.2196/mhealth.4613](https://doi.org/10.2196/mhealth.4613)] [Medline: [26508282](https://pubmed.ncbi.nlm.nih.gov/26508282/)]

Abbreviations

- CBPR:** community-based participatory research
CVD: cardiovascular disease
DFR: digital food record
EMA: ecological momentary assessments

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Original Paper

You Will Know That Despite Being HIV Positive You Are Not Alone: Qualitative Study to Inform Content of a Text Messaging Intervention to Improve Prevention of Mother-to-Child HIV Transmission

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Abstract

Background: Prevention of mother-to-child HIV transmission (PMTCT) relies on long-term adherence to antiretroviral therapy (ART). Mobile health approaches, such as text messaging (short message service, SMS), may improve adherence in some clinical contexts, but it is unclear what SMS content is desired to improve PMTCT-ART adherence.

Objective: We aimed to explore the SMS content preferences related to engagement in PMTCT care among women, male partners, and health care workers. The message content was used to inform an ongoing randomized trial to enhance the PMTCT-ART adherence.

Methods: We conducted 10 focus group discussions with 87 HIV-infected pregnant or postpartum women and semistructured individual interviews with 15 male partners of HIV-infected women and 30 health care workers from HIV and maternal child health clinics in Kenya. All interviews were recorded, translated, and transcribed. We analyzed transcripts using deductive and inductive approaches to characterize women's, partners', and health care workers' perceptions of text message content.

Results: All women and male partners, and most health care workers viewed text messages as a useful strategy to improve engagement in PMTCT care. Women desired messages spanning 3 distinct content domains: (1) educational messages on PMTCT and maternal child health, (2) reminder messages regarding clinic visits and adherence, and (3) encouraging messages that provide emotional support. While all groups valued reminder and educational messages, women highlighted emotional support more than the other groups (partners or health care workers). In addition, women felt that encouraging messages would assist with acceptance of their HIV status, support disclosure, improve patient-provider relationship, and provide support for HIV-related challenges. All 3 groups valued not only messages to support PMTCT or HIV care but also messages that addressed general maternal child health topics, stressing that both HIV- and maternal child health-related messages should be part of an SMS system for PMTCT.

Conclusions: Women, male partners, and health care workers endorsed SMS text messaging as a strategy to improve PMTCT and maternal child health outcomes. Our results highlight the specific ways in which text messaging can encourage and support HIV-infected women in PMTCT to remain in care, adhere to treatment, and care for themselves and their children.

Trial Registration: ClinicalTrials.gov NCT02400671; <https://clinicaltrials.gov/ct2/show/NCT02400671> (Archived by WebCite at <http://www.webcitation.org/70W7SVIVJ>)

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KEYWORDS

HIV; ART; PMTCT; SMS text messaging; adherence; retention

Introduction

Globally, over 90% of pediatric HIV infections are attributed to mother-to-child HIV transmission (MTCT), with 160,000 children newly infected with HIV in 2016 [1]. Lifelong antiretroviral therapy (ART; known as Option B+) is recommended for prevention of MTCT (PMTCT), but it depends on consistent retention in care and adherence to ART during pregnancy, postpartum, and beyond. Waning ART adherence and poor retention in care, particularly postpartum after the risk of MTCT diminishes, hinder the effectiveness of Option B+ [2-4]. Barriers to ART adherence in Option B+ stem from an interplay of sociocultural and structural factors [5-7]. Thus, identifying and addressing these barriers is important to improve PMTCT.

There is evidence from some randomized controlled trials (RCTs) and meta-analyses that short message service (SMS) text messages sent to individuals on ART may improve retention, adherence, and viral suppression in nonpregnant adults [8-10]. These findings, combined with the growing ubiquity and low cost of mobile phone technology in regions most affected by HIV, have led the World Health Organization to include SMS text message reminders as a recommendation for promoting adherence to ART as part of a package of adherence interventions [11].

There is limited understanding of the message content desired by text message recipients, or the mechanism by which messages may impact ART adherence, especially in the context of pregnancy and the postpartum period. While the design of text messaging interventions for ART adherence for PMTCT may draw on lessons learned from studies in other HIV-infected populations, the unique context of pregnancy and postpartum may influence ART adherence, and text messaging may need to be adapted accordingly. Few previous studies have explored the desired text message content to support women's uptake of PMTCT services [12-15]. These studies reported a desire for polite, encouraging SMS text messages that provide information and reminders to take ART, attend postnatal visits, and engage partners. While health care workers (HCWs) and male partners have been shown to play important roles in influencing peripartum women's health behaviors and health care utilization [16-19], only two studies, to date, have included these stakeholder groups in evaluating the acceptability and desired content of text messages [12,15].

In this study, we examined the preferred SMS text message content and perceived text message function to support Option

B+ PMTCT. We incorporated the perspectives of HIV-infected pregnant and postpartum women, male partners and HCWs.

Methods

Study Design and Population

We conducted a qualitative study to inform the text message content for the Mobile WACH-X study (NCT02400671), a triple-arm, placebo-controlled, unblinded RCT designed to assess the impact of unidirectional and bidirectional SMS text messaging on maternal adherence, retention, and clinical outcomes in PMTCT-ART programs in Kenya [20]. Using purposive sampling, we recruited women, male partners, and HCWs from three sites; two in rural Western Kenya and one in periurban Nairobi. Focus group discussions (FGDs) were conducted with HIV-infected pregnant women seeking antenatal care (ANC) services or HIV-infected postpartum women who had an uninfected child aged ≤ 2 years. Women were purposively recruited during routine visits to ANC clinics, comprehensive HIV care clinics, and maternal child health (MCH) clinics. To provide a range of experiences and perspectives, we selected pregnant and postpartum women based on the following experiences with ART: using ART in the peripartum period only; using ART within and outside of the peripartum period; and no ART experience. Women were eligible to participate if they were aged ≥ 14 years, were HIV-infected and pregnant or postpartum, had daily access to a mobile phone, and were willing to receive SMS text messages.

We conducted semistructured individual interviews with male partners and HCWs. Both HIV-infected and -uninfected male partners were recruited for participation. We recruited HIV-infected men in concordant relationships during their routine HIV clinic visits. In addition, HIV-uninfected men were referred to the study by HIV-infected female partners attending MCH clinics; female partners were given a referral form inviting male partners to the clinic to learn more about the study. Eligible men were aged ≥ 18 years and had an HIV-infected female partner who was pregnant or had a child aged ≤ 2 years and was accessing ANC or MCH services. We purposively recruited providers aged ≥ 18 years from ANC and MCH clinics where they worked. Men were eligible to participate if they were directly involved in caring for HIV-infected pregnant women or HIV-exposed infants. Overall, 87 women participated in 10 FGDs (6-10 women per FGD); 15 men and 30 HCWs participated in semistructured individual interviews.

Data Collection

We conducted two rounds of data collection between January and June 2015. In the first round, 6 FGDs were conducted with HIV-infected women, 15 individual interviews were conducted with male partners, and 30 individual interviews were conducted with HCWs. The objectives of the first round of data collection were to explore general opinions about health-related SMS text messages, determine comprehension and acceptability of predeveloped text messages, and elicit ideas for additional messaging themes in order to refine the message content. A second round of 4 FGDs elicited women's feedback on the refined message content.

Both FGDs and interviews were conducted using a semistructured discussion guide including open-ended questions exploring three main topic areas: (1) challenges and resources for attending a clinic and adhering to ART, (2) perspectives on using SMS text messaging to support adherence, and (3) perceptions of specific message content to guide message refinement. We asked participants to provide feedback on messages in four content areas: general support, breastfeeding, family planning, and ART adherence. All messages shared a common format: they opened with a greeting to the recipient from a nurse ("[Name], this is [nurse name] at [clinic name]"), followed by a message addressing one of the content areas (Supplementary Material 1) [20]. Interviews and FGDs were conducted by a trained Kenyan social scientist who was not involved in providing clinical care for participants. Pilot messages were read aloud by the discussion facilitator, and participants were probed for additional message content they would like to receive, beyond what was included in initial pilot messages. Sociodemographic information for all participants was collected via a tablet-based questionnaire using Open Data Kit. Interviews and FGDs were conducted in English, Kiswahili, and Dholuo, depending on participants' preference. FGDs ranged from 90 to 130 minutes in length, and interviews ranged from 19 to 49 minutes. All interviews and FGDs were audiorecorded, transcribed, and translated into English, if necessary, by the interviewer, who was fluent in all three languages.

Ethical Considerations

This study was reviewed and approved by the University of Washington Institutional Review Board and Kenyatta National Hospital and University of Nairobi Ethics and Research Committee. All study participants provided written informed consent.

Statistical Analysis

We performed a descriptive content analysis to identify key concepts emerging between and across groups of women, male partners, and HCWs. Dedoose software (version 7.6.6, Sociocultural Research Consultants LLC, Los Angeles, CA) was used for data management and analysis. An initial codebook was deductively and inductively generated by JF, KBS, and KR after reviewing the literature and reading a subset of FGD and interview transcripts. Next, the codebook was refined iteratively by reviewing additional transcripts and revising initial codes.

We used the final codebook to perform consensus coding and facilitate discussion until reaching an agreement on the code application. All transcripts were coded independently by one team member (JF, KBS, or KR) and reviewed by another team member. All disagreements in code application were resolved through group discussion with all three coders. The analytic framework focused on challenges living with HIV, current resources or strategies used to engage in HIV care, preferences and perceived utility of the specific SMS text message content, and benefits or challenges to using SMS text messaging to engage in care. Furthermore, we identified themes related to the analytic framework categories and combined them into a conceptual diagram.

Results

Participant Characteristics

Demographic characteristics of women, male partners, and HCWs are summarized in Table 1. Female participants (N=87) were young (median age, 26 years), most (64/87, 74%) had completed at least primary education, and about one-third (30/87, 34.5%) were pregnant. The majority (60/87, 69%) had experience with ART during and outside of the peripartum period, and a little over half (48/87, 55%) were Dholuo speakers. Male participants (N=15) were older than female participants (median age, 37 years) and had similar levels of education (12/15, 80%, had completed at least primary education); most (12/15, 80%) were HIV-infected and had experience with ART. The median age of HCWs was 36 years, and they had a median experience of 6 years in their current profession. Providers included clinical officers (n=7), nurses (n=13), counselors (n=6), a peer counselor (n=1), and others (n=3).

SMS Text Messaging is Acceptable but Design Requirements and Challenges Exist

Overall, participants in all stakeholder groups (women, male partners, and HCWs) were supportive of using SMS text messages to overcome HIV-related challenges. Women generally found SMS text messaging acceptable and discussed its many potential benefits, including enabling remote connection to HCWs and providing anonymity that facilitates open communication about sensitive or potentially embarrassing topics.

It is eas[er] to share information about shameful diseases by SMS than telling the doctor face-to-face. For instance, when I have a wound in my private parts...I can send him a message and he gives me a response immediately to use a particular medicine. [Postpartum woman]

[The SMS messages] keep records of treatment and conversations for future reference for the patients, and also helps you to identify your patients individually and that creates a bond between you and your patients; they feel that you have them at heart, and then they feel that you are concerned about their health. [Clinical officer, 4 years in profession]

Table 1. Focus group and interview participant characteristics.

Participant characteristics	Value
Female FGD^a participants (N=87)	
Age (years), median (IQR ^b)	26 (23-32)
Pregnant (vs postpartum), n (%)	30 (35)
ART^c experience, n (%)	
Peripartum only	19 (22)
Peripartum and nonperipartum	60 (69)
None	8 (9)
Education, n (%)	
Less than primary	23 (26)
Primary completed	43 (49)
Secondary completed	18 (21)
Above secondary	3 (3)
Language, n (%)	
Dholuo	48 (55)
Kiswahili	39 (45)
Male interview participants (N=15)	
Age (years), median (IQR)	37 (32-44)
Education, n (%)	
Less than primary	3 (20)
Primary completed	8 (53)
Secondary completed	2 (13)
Above secondary	2 (13)
HIV-infected, n (%)	12 (80)
ART experienced, n (%)	12 (80)
Provider interview participants (N=30)	
Age (years), median (IQR)	35.5 (31.0-44.0)
Years in profession, median (IQR)	6 (4.0-15.5)
Profession, n (%)	
Clinical officer	7 (23)
MCH ^d nurse	6 (20)
Other nurse	5 (17)
Family planning nurse	2 (7)
Counselor	6 (20)
Peer counselor	1 (3)
Other	3 (10)

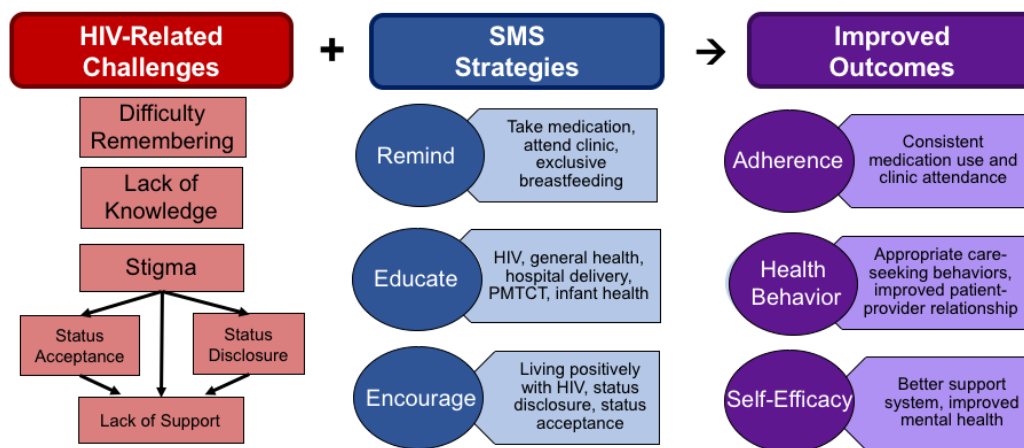
^aFGD: focus group discussion.

^bIQR: interquartile range.

^cART: antiretroviral therapy.

^dMCH: maternal child health.

Figure 1. Summary of themes discussed in focus group discussions and interviews. PMTCT: prevention of mother-to-child HIV transmission. SMS: short message service.



However, a few providers expressed concerns about the ability to reach patients using SMS text messaging, specifically noting inability to confirm message receipt and challenges related to requirements for patients to have a phone, be literate, and have access to electricity.

I don't know whether the SMS can work, but maybe a phone call [is better] so that you are very sure that the message has reached the client...comparing the two, I prefer the phone call. However, automated messages has worked in several occasions, in other fields, but what I am saying that it depends on the people or rather the region you are dealing with. If they have phone and [are] staying in a powered house, it is well and good, but in villages that may be a setback. [Nurse, 8 years in profession]

While many participants were supportive of delivering health education on HIV care, several women and HCWs expressed concerns about SMS text message privacy and risks of HIV status disclosure if messages were read by people other than the intended recipient. All 3 stakeholder groups commented that the risk of inadvertent disclosure by other individuals reading SMS text messages should be minimized and the phrasing of HIV-related health education should be tailored based on the recipients' disclosure status and desires. These concerns are discussed in detail in another publication [21].

Figure 1 summarizes topic areas included in the interview guides and related themes that emerged during FGDs and interviews. The figure shows the challenges that participants identified for women receiving PMTCT care, potential roles for text messages to address these challenges, and possible pathways through which text messaging may impact clinical outcomes. Discussions on the desired text message content highlighted three types of messages with different perceived functions: (1) reminders for medication and clinic attendance; (2) health education messages; and (3) encouragement to remain in care, seek support, and live positively.

SMS Text Messages May Serve as Adherence Reminders During the Stressful Peripartum Period

and Avoid Stigmatizing HCW Interactions Due to Missed Visits

Women identified forgetting to take medication or attend clinic as a major challenge in ART adherence and believed that SMS text message reminders could help overcome this obstacle. They attributed forgetfulness to various stressors, including some stressors unique to or heightened during pregnancy or postpartum, such as caring for newborns.

There are...those who take...medicine, but considering how busy they are, she is the breadwinner, so sometimes she is occupied until time passes. She forgets, so when you send her a message she will remember "tomorrow I am to go to the hospital." Like here...some of us go to work on the rice farms, others to the farm, others casual labor, maybe that is what she depends on because she is the mother and the father. So when she receives a message, it will alert her. [Postpartum woman]

Women also described negative interactions with HCWs, including feeling stigmatized and being treated harshly, if they missed appointments or delayed seeking HIV care. Women and providers suggested that text message reminders to attend scheduled appointments could help prevent conflict with providers.

I think that SMS is better than the card that we are given because sometimes you leave out the card somewhere and you forget and by the time you remember it has passed by one day, and if you are reminded you will be quarreled [with] at the hospital, yet it is just forgetfulness that makes you to default. [Postpartum woman]

Providers concurred with the sentiments expressed by women, noting that text messages could reduce missed visits due to forgetfulness and ensure timely follow-up for women.

I think for SMS...it's good for them because some they tend to forget, others...they say I didn't know when to attend the clinic, [it's] when I have seen my bottle is empty, or I have seen my child...is 10 months

already (you know at 9 months that is the time when you have to bring the child for [HIV] antibody [testing])...So when the SMS is there, the services will be at the right time and evaluation will be done early. [Nurse, 4 years in profession]

Both women and their partners noted that male partners had an important role in reminding women to take medication and attend clinic if women disclosed their status to them. Indeed, male partners thought that text messages could complement the role they played in reminding their partners, especially when they could not be physically present.

Just like sometimes someone may forget, so you send a message to alert her that on a particular day she should be going to the clinic. So that would help her, it would also help me because I may not be at home to remind her that she should go for medicine or to the clinic. [HIV-infected male partner]

SMS Text Messaging May Provide Health Education About PMTCT-ART, Information on Clinical Status, Answers to Questions, and May Catalyze Discussions With Others

Women expressed a desire for educational messages to fill gaps in their knowledge and understanding about HIV care, including obtaining information about common ART side effects, modes of MTCT, and effective PMTCT strategies. Women believed that educational SMS text messages could inform them about PMTCT and the ability to have healthy, HIV-uninfected babies even if they are HIV-infected and that improved knowledge would increase motivation to engage in care throughout pregnancy and breastfeeding.

What I would like to know, I thought that if you are sick then you cannot give birth to a healthy baby, but I hear that if you are on HIV care and treatment, then you can give birth to a healthy baby who is HIV negative. [Postpartum woman]

Women frequently stated that they wanted to receive SMS text message advice on how to discuss HIV and ART with partners. Some women believed that SMS text messages containing credible information could be shared with their partners and served as a catalyst to engage in conversation.

I can say that [SMS] can help. My husband has refused to accept [being tested], but he helps me financially when I have hospital appointments. So I think that the SMS can help: if I give him to read he can be encouraged and he may decide to come out and know his status. [Postpartum woman]

Additionally, several participants viewed SMS text messages as a platform to receive updates on their viral load, CD4 count, and treatment status. Delivery of test results through SMS text messages was seen as a way to remove physical barriers to the clinic and prevent delay in information that women could use to make personal health choices in real time.

Sometimes I go to do CD4 test, and I will get the result later...so I can ask by SMS before my clinic date and get the results, so when the time for clinic

reaches if the doctors asks me if I know my CD4 results I will say that it [is] like this and this. [Postpartum woman]

Both male partners and HCWs found it acceptable and beneficial to deliver educational content to women via SMS and highlighted the importance of delivering this information quickly and efficiently since traveling to a clinic for basic health information was often burdensome. Some participants suggested that using SMS text messages to address minor health questions could enable triaging and avert unnecessary clinic visits.

[SMS] is good, it is one-on-one. If you have any problems [the provider] can help you, you can ask questions, and you just handle it then when you are at home without going to the hospital. It might be small issues like rashes you handle and need not go to the hospital. [HIV-uninfected male partner]

Similarly, HCWs commented that delivering educational information via SMS text messages would be beneficial not only to women but also to themselves, as it would ease their workload.

To me, I think...use of SMS, it will be good. It will be good [be]cause sometimes...mothers come to flock here, [be]cause of even minor illnesses that you could have just given advice...So in order to decongest MCH, such minor cases maybe if we can use SMS, it will be of a great [help] to us... [Nurse, 20 years in profession]

SMS Text Messages May Provide General Encouragement to Improve Self-Acceptance and Combat Stigma, Which, in Turn, Could Motivate ART Adherence

Many women thought that text messages could provide encouragement and motivation to help engage in HIV care, adhere to ART, and accept their status. Although women reported that encouraging text messaging would help them engage in HIV care, they did not feel this required language directly addressing HIV-related topics. Rather, many women expressed desire for text messages providing encouragement to live a healthy and positive life while pregnant or postpartum, to stay strong and have a positive outlook on life for themselves and their children, and to not lose hope. Women frequently mentioned that they would feel happy and encouraged if they received an SMS text message from their provider, even if it was simply to ask about potential challenges they may be facing (related or unrelated to their HIV care). In addition, many women commented on the potential of text messages to provide a sense of connection and acceptance from the sender during times of hopelessness or isolation, highlighting that this connection would lift their morale and improve their ability to engage in HIV care.

If you receive the message...you will not feel lonely, you will know that there is someone who is concerned about you and that despite being HIV positive you are not alone. [Postpartum woman]

Indeed, some participants indicated that their sense of feeling cared for grew out of the knowledge that the sender had invested

time to send a text message, rather than the use of encouraging language *per se* in the message.

[SMS] will help to encourage me that someone was concerned about me by taking their time to send the messages. It costs you, and I get help. So, I think that it helps to encourage knowing that someone somewhere is concerned and has accepted me. [Pregnant woman]

Similarly, some male partners indicated that text messages could encourage and support women struggling with status acceptance and help them identify other sources of support.

The messages...should be sent to let [people] know that they are not alone. So many people are undergoing what they are going through so they are not left alone, and there are people who are always there to assist them...[S]o they should accept the situation and try as much as they can to maybe look for people who...can be there for them. [HIV-infected male partner]

HCWs placed a stronger emphasis on using text messages to provide reminders and health education than on their use for emotional support. However, some providers noted that text messages had the potential to serve as an encouragement system, working beyond “tracing defaulters.”

I think [SMS] will be really good for the newly diagnosed mothers to give them that psychosocial support that they lack. Because we usually see them after 2 weeks—you know [in] 2 weeks there is so much that can happen—so that by the time she is coming back after 2 weeks, she is really happy. [Nurse, 25 years in profession]

General MCH SMS Text Message Content Was Felt to Be Useful in Addition to PMTCT Content

Although discussions with all participants were framed as addressing experiences of HIV-infected women with PMTCT, women, men, and HCW repeatedly expressed a desire for text messages to support general MCH care in addition to supporting HIV care. The topics requested included breastfeeding instructions, challenges to exclusive breastfeeding, and maternal nutrition. Functionally, the MCH-related messages that participants suggested were mostly educational rather than reminders or supportive messages.

[Please include messages] about nutrition during pregnancy: what a woman can eat so that at the time of birth she has enough strength to deliver and enough milk to breastfeed the baby. [Pregnant woman]

How can we help a baby who is not feeding? Because you cannot tell it to breastfeed, yet when you give it breastmilk it does not suckle, yet this first milk is what it must take, so the doctor should help us with that because we don't know. [HIV-infected male partner]

Discussion

Principal Results

In this study, HIV-infected women, male partners, and HCWs in Kenya endorsed SMS text messaging as a way to optimize retention and adherence to PMTCT-ART. Participants proposed the following three text message content areas that could serve complementary functions: reminders, education, and encouragement. In addition, all participants endorsed text messages as a useful mechanism for reminding women to take medication and return for clinic visits. Text message reminders were reported to be particularly useful in the peripartum period, when the stresses of delivery and newborn care increase forgetfulness. Additionally, women and HCWs indicated that difficult interactions following missed visits could be avoided with reminder text messages. Health education was also valued, including reinforcement of the importance of ART to prevent infant HIV and the likelihood of success in having a healthy baby. Women desired timely access to their clinical data and to interactive messaging to ask questions without the need for an in-person clinic visit or embarrassing face-to-face conversation. Additionally, text messaging was viewed as a promising intervention to engage and inform partners, if disclosed, to leverage their influence on maternal ART adherence [18,19,22]. Text messaging was also viewed as an important enabler of emotional support and encouragement. Women perceived text messages as providing a connection with HCWs and validating that they were worthy of care, which improved their mental health, helped them overcome internalized stigma, and increased their motivation to adhere to treatment. Importantly, in addition to HIV-related topics, women, partners, and HCWs were interested in SMS text messages that supported women's general MCH care, for example, breastfeeding, maternal nutrition, and facility delivery.

Comparison With Prior Work

Previous qualitative studies have explored the acceptability and content preferences of SMS text messaging interventions to improve ART adherence in the general HIV-infected population, reporting desired content prior to text messaging interventions [23,24], or postintervention perspectives [25]. Four studies focused on text message content preferences to support PMTCT [12-15]. Of these, two were conducted in Kenya prior to roll-out of Option B+ PMTCT, when PMTCT involved short-term antiretroviral regimens during the period of highest risk of MTCT [12,13]. One study interviewed postpartum women, male partners, and HCWs and reported that all were supportive of SMS text messages as appointment reminders and as education providers regarding ANC, facility delivery, and partner engagement [12]. The other study only involved peripartum women and reported that they desired encouraging, educational messages about postpartum visit attendance and infant HIV testing [13]. Our findings were similar to those of these studies in that participants desired text messages regarding general MCH topics as well as HIV-related information. Additionally, we found that women desired text messages for emotional support in the face of isolation and internalized stigma. Two studies were conducted after Option B+ roll-out: one interviewed pregnant women in South Africa [14] and the

other interviewed women, partners, and HCWs in Kenya [15]. These studies reported a desire for text messages as reminders, information, and encouragement, but did not identify a need for messaging about general MCH topics beyond HIV care. Our findings are consistent with those of these studies as well and provide additional insights regarding the need for encouragement and messaging related to MCH.

One potential implication of the differences between our findings and those of previous studies may be that the need and perceived utility of text messages for emotional support are greater in the context of long-term ART adherence than in short-course PMTCT. Indeed, the ability of SMS text messages to serve a supportive, caring function regardless of the message content has been suggested by previous studies on SMS text messaging for long-term adherence support in the general HIV-infected population. A qualitative evaluation of the experiences of recipients of real-time adherence monitoring and SMS text message reminders showed that recipients interpreted simple reminder messages as a sign of caring from the health system [25]. Similarly, results from the WelTel trial, one of the first studies to report that an SMS text messaging intervention improved ART adherence, suggested that participants viewed a sense of support and caring as an important function of text messages [26-28]. These findings are consistent with the association of depression and low social support with poor ART adherence reported in some studies [29-31].

PMTCT is HIV care in the context of pregnancy, childbirth, and postpartum. Many women receiving PMTCT perceive these life events as at least as important, if not more important, than their HIV infection. Thus, addressing HIV without acknowledging concerns about pregnancy, delivery, and infant health in text messages does not address women's needs for holistic care. In this study, women desired text messages on MCH topics such as breastfeeding, infant health, and maternal nutrition. It is perhaps unsurprising that women's experiences and needs as peripartum women were not fully defined by their HIV status, but this observation highlights the demand and untapped potential for SMS-based interventions to provide comprehensive care to peripartum women. An important question for future investigation is whether in addressing both MCH and ART adherence, SMS text messages lose focus and effectiveness to improve ART adherence.

Strengths and Limitations

This study has several strengths and limitations. The qualitative design allowed for in-depth understanding of SMS text message perceptions and content preferences among HIV-infected pregnant and postpartum women. We purposively sampled both pregnant and postpartum women with a range of ART experiences to capture a wide array of perspectives. Additionally, the inclusion of HCW and male partner perspectives provided complementary insights into how text messages may improve the delivery of Option B+ and fit into the broader context of influences on women receiving care. Study limitations include the possibility that participants felt uncomfortable discussing personal experiences if they perceived these as criticisms of the health care facility. This was mitigated by having interviewers who were unrelated to the facility and conducting interviews in a private room. Furthermore, the study population was drawn from women engaged in care and may not be generalizable to women out of care. Similarly, the recruitment of men by referral from their female partners likely excluded men who were unaware or unsupportive of their partners' care; these men may have different views about their partners receiving SMS text messages. Finally, the desired text messages are not necessarily effective, and it will be important to further examine not only whether text messaging improves outcomes but also which text messages are specifically helpful. Nevertheless, inputs from women, partners, and HCWs are essential to design messages that address a felt need and have relevance.

Conclusions

In summary, our findings support the use of SMS text messaging to enhance PMTCT and general MCH care. SMS text messages may meet women's desires for medication and appointment reminders, health education, and emotional support and may complement partners' supportive roles and enable efficiencies in HCWs' care provision. Moreover, our findings shed light on the unique needs of HIV-infected peripartum women and indicate that these women desire support for not only HIV and PMTCT care but also their general health and their children's health. In addressing these desires, text messaging approaches can provide comprehensive PMTCT and MCH support, but may face challenges in balancing and focusing effective messaging strategies to improve ART adherence.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Focus group and interview guides.

[[PDF File \(Adobe PDF File\), 52KB - mhealth_v6i7e10671_app1.pdf](#)]

References

1. UNAIDS. UNAIDS Data 2017. 2017. URL: http://www.unaids.org/sites/default/files/media_asset/20170720_Data_book_2017_en.pdf [accessed 2018-06-14] [WebCite Cache ID 70AUEOTGF]
2. Haas AD, Tenthani L, Msukwa MT, Tal K, Jahn A, Gadabu OJ, et al. Retention in care during the first 3 years of antiretroviral therapy for women in Malawi's option B+ programme: an observational cohort study. *Lancet HIV* 2016 Apr;3(4):e175-e182 [FREE Full text] [doi: [10.1016/S2352-3018\(16\)00008-4](https://doi.org/10.1016/S2352-3018(16)00008-4)] [Medline: [27036993](https://pubmed.ncbi.nlm.nih.gov/27036993/)]
3. Tenthani L, Haas AD, Tweya H, Jahn A, van OJJ, Chimbandira F, et al. Retention in care under universal antiretroviral therapy for HIV-infected pregnant and breastfeeding women ('Option B+') in Malawi. *AIDS* 2014 Feb 20;28(4):589-598 [FREE Full text] [doi: [10.1097/QAD.000000000000143](https://doi.org/10.1097/QAD.000000000000143)] [Medline: [24468999](https://pubmed.ncbi.nlm.nih.gov/24468999/)]
4. Erlwanger AS, Joseph J, Gatora T, Muzunze B, Orne-Gliemann J, Mukungunugwa S, et al. Patterns of HIV care clinic attendance and adherence to antiretroviral therapy among pregnant and breastfeeding women living with HIV in the context of Option B+ in Zimbabwe. *J Acquir Immune Defic Syndr* 2017 Dec 01;75 Suppl 2:S198-S206. [doi: [10.1097/QAI.0000000000001347](https://doi.org/10.1097/QAI.0000000000001347)] [Medline: [28498190](https://pubmed.ncbi.nlm.nih.gov/28498190/)]
5. Clouse K, Schwartz S, Van RA, Bassett J, Yende N, Pettifor A. "What they wanted was to give birth; nothing else": barriers to retention in option B+ HIV care among postpartum women in South Africa. *J Acquir Immune Defic Syndr* 2014 Sep 01;67(1):e12-e18. [doi: [10.1097/QAI.0000000000000263](https://doi.org/10.1097/QAI.0000000000000263)] [Medline: [24977376](https://pubmed.ncbi.nlm.nih.gov/24977376/)]
6. Ngarina M, Popenoe R, Kilewo C, Biberfeld G, Ekstrom AM. Reasons for poor adherence to antiretroviral therapy postnatally in HIV-1 infected women treated for their own health: experiences from the Mitra Plus study in Tanzania. *BMC Public Health* 2013 May 07;13:450 [FREE Full text] [doi: [10.1186/1471-2458-13-450](https://doi.org/10.1186/1471-2458-13-450)] [Medline: [23647555](https://pubmed.ncbi.nlm.nih.gov/23647555/)]
7. Nachega JB, Uthman OA, Anderson J, Peltzer K, Wampold S, Cotton MF, et al. Adherence to antiretroviral therapy during and after pregnancy in low-income, middle-income, and high-income countries: a systematic review and meta-analysis. *AIDS* 2012 Oct 23;26(16):2039-2052 [FREE Full text] [doi: [10.1097/QAD.0b013e328359590f](https://doi.org/10.1097/QAD.0b013e328359590f)] [Medline: [22951634](https://pubmed.ncbi.nlm.nih.gov/22951634/)]
8. Thakkar J, Kurup R, Laba T, Santo K, Thiagalingam A, Rodgers A, et al. Mobile telephone text messaging for medication adherence in chronic disease: A meta-analysis. *JAMA Intern Med* 2016 Mar;176(3):340-349. [doi: [10.1001/jamainternmed.2015.7667](https://doi.org/10.1001/jamainternmed.2015.7667)] [Medline: [26831740](https://pubmed.ncbi.nlm.nih.gov/26831740/)]
9. Mayer JE, Fontelo P. Meta-analysis on the effect of text message reminders for HIV-related compliance. *AIDS Care* 2017 Apr;29(4):409-417 [FREE Full text] [doi: [10.1080/09540121.2016.1214674](https://doi.org/10.1080/09540121.2016.1214674)] [Medline: [27477580](https://pubmed.ncbi.nlm.nih.gov/27477580/)]
10. Kanters S, Park JJH, Chan K, Socias ME, Ford N, Forrest JI, et al. Interventions to improve adherence to antiretroviral therapy: a systematic review and network meta-analysis. *Lancet HIV* 2017 Jan;4(1):e31-e40. [doi: [10.1016/S2352-3018\(16\)30206-5](https://doi.org/10.1016/S2352-3018(16)30206-5)] [Medline: [27863996](https://pubmed.ncbi.nlm.nih.gov/27863996/)]
11. World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. 2nd edition. Recommendations for a Public Health Approach. Geneva; 2016 Jun. URL: <http://www.who.int/hiv/pub/arv/arv-2016/en/> [accessed 2018-06-14] [WebCite Cache ID 70AVd46Vn]
12. Jennings L, Ong'ech J, Simiyu R, Sirengo M, Kassaye S. Exploring the use of mobile phone technology for the enhancement of the prevention of mother-to-child transmission of HIV program in Nyanza, Kenya: a qualitative study. *BMC Public Health* 2013;13:1131 [FREE Full text] [doi: [10.1186/1471-2458-13-1131](https://doi.org/10.1186/1471-2458-13-1131)] [Medline: [24308409](https://pubmed.ncbi.nlm.nih.gov/24308409/)]
13. Odeny TA, Newman M, Bukusi EA, McClelland RS, Cohen CR, Camlin CS. Developing content for a mHealth intervention to promote postpartum retention in prevention of mother-to-child HIV transmission programs and early infant diagnosis of HIV: a qualitative study. *PLoS One* 2014;9(9):e106383 [FREE Full text] [doi: [10.1371/journal.pone.0106383](https://doi.org/10.1371/journal.pone.0106383)] [Medline: [25181408](https://pubmed.ncbi.nlm.nih.gov/25181408/)]
14. Nachega JB, Skinner D, Jennings L, Magidson JF, Altice FL, Burke JG, et al. Acceptability and feasibility of mHealth and community-based directly observed antiretroviral therapy to prevent mother-to-child HIV transmission in South African pregnant women under Option B+: an exploratory study. *Patient Prefer Adherence* 2016;10:683-690 [FREE Full text] [doi: [10.2147/PPA.S100002](https://doi.org/10.2147/PPA.S100002)] [Medline: [27175068](https://pubmed.ncbi.nlm.nih.gov/27175068/)]
15. Musoke P, Gakumo CA, Abuogi LL, Akama E, Bukusi E, Helova A, et al. A text messaging intervention to support Option B+ in Kenya: A qualitative study. *J Assoc Nurses AIDS Care* 2018;29(2):287-299. [doi: [10.1016/j.jana.2017.09.009](https://doi.org/10.1016/j.jana.2017.09.009)] [Medline: [29029867](https://pubmed.ncbi.nlm.nih.gov/29029867/)]
16. Cataldo F, Chiwaula L, Nkhata M, van Lettow M, Kasende F, Rosenberg NE, PURE Malawi Consortium. Exploring the Experiences of Women and Health Care Workers in the Context of PMTCT Option B Plus in Malawi. *J Acquir Immune Defic Syndr* 2017 Dec 15;74(5):517-522 [FREE Full text] [doi: [10.1097/QAI.0000000000001273](https://doi.org/10.1097/QAI.0000000000001273)] [Medline: [28045712](https://pubmed.ncbi.nlm.nih.gov/28045712/)]
17. Woldesenbet SA, Jackson DJ, Lombard CJ, Dinh T, Ramokolo V, Doherty T, et al. Structural level differences in the mother-to-child HIV transmission rate in South Africa: A multilevel assessment of individual-, health facility-, and provincial-level predictors of infant HIV transmission. *J Acquir Immune Defic Syndr* 2017 Dec 15;74(5):523-530 [FREE Full text] [doi: [10.1097/QAI.0000000000001289](https://doi.org/10.1097/QAI.0000000000001289)] [Medline: [28107227](https://pubmed.ncbi.nlm.nih.gov/28107227/)]
18. Takah NF, Kennedy ITR, Johnman C. The impact of approaches in improving male partner involvement in the prevention of mother-to-child transmission of HIV on the uptake of maternal antiretroviral therapy among HIV-seropositive pregnant women in sub-Saharan Africa: a systematic review and meta-analysis. *BMJ Open* 2017 Nov 25;7(11):e018207 [FREE Full text] [doi: [10.1136/bmjopen-2017-018207](https://doi.org/10.1136/bmjopen-2017-018207)] [Medline: [29175889](https://pubmed.ncbi.nlm.nih.gov/29175889/)]

19. Aluisio AR, Bosire R, Bourke B, Gatuguta A, Kiarie JN, Nduati R, et al. Male partner participation in antenatal clinic services is associated with improved HIV-free survival among infants in Nairobi, Kenya: A prospective cohort study. *J Acquir Immune Defic Syndr* 2016 Dec 01;73(2):169-176 [FREE Full text] [doi: [10.1097/QAI.0000000000001038](https://doi.org/10.1097/QAI.0000000000001038)] [Medline: [27124363](https://pubmed.ncbi.nlm.nih.gov/27124363/)]
20. Drake AL, Unger JA, Ronen K, Matemo D, Perrier T, DeRenzi B, et al. Evaluation of mHealth strategies to optimize adherence and efficacy of Option B+ prevention of mother-to-child HIV transmission: Rationale, design and methods of a 3-armed randomized controlled trial. *Contemp Clin Trials* 2017 Dec;57:44-50. [doi: [10.1016/j.cct.2017.03.007](https://doi.org/10.1016/j.cct.2017.03.007)] [Medline: [28315480](https://pubmed.ncbi.nlm.nih.gov/28315480/)]
21. Ronen K, Unger JA, Drake AL, Perrier T, Akinyi P, Osborn L, et al. SMS messaging to improve ART adherence: perspectives of pregnant HIV-infected women in Kenya on HIV-related message content. *AIDS Care* 2018 Apr;30(4):500-505. [doi: [10.1080/09540121.2017.1417971](https://doi.org/10.1080/09540121.2017.1417971)] [Medline: [29254362](https://pubmed.ncbi.nlm.nih.gov/29254362/)]
22. Kiarie JN, Kreiss JK, Richardson BA, John-Stewart GC. Compliance with antiretroviral regimens to prevent perinatal HIV-1 transmission in Kenya. *AIDS* 2003 Jan 03;17(1):65-71 [FREE Full text] [doi: [10.1097/01.aids.0000042938.55529.e1](https://doi.org/10.1097/01.aids.0000042938.55529.e1)] [Medline: [12478070](https://pubmed.ncbi.nlm.nih.gov/12478070/)]
23. Mbuagbaw L, Bonono-Momnougui RC, Thabane L. Considerations in using text messages to improve adherence to highly active antiretroviral therapy: a qualitative study among clients in Yaoundé, Cameroon. *HIV AIDS (Auckl)* 2012 Apr;4:45-50 [FREE Full text] [doi: [10.2147/HIV.S29954](https://doi.org/10.2147/HIV.S29954)] [Medline: [22570574](https://pubmed.ncbi.nlm.nih.gov/22570574/)]
24. Rana Y, Haberer J, Huang H, Kambugu A, Mukasa B, Thirumurthy H, et al. Short message service (SMS)-based intervention to improve treatment adherence among HIV-positive youth in Uganda: focus group findings. *PLoS One* 2015;10(4):e0125187 [FREE Full text] [doi: [10.1371/journal.pone.0125187](https://doi.org/10.1371/journal.pone.0125187)] [Medline: [25881059](https://pubmed.ncbi.nlm.nih.gov/25881059/)]
25. Ware NC, Pisarski EE, Tam M, Wyatt MA, Atukunda E, Musimenta A, et al. The meanings in the messages: How SMS reminders and real-time adherence monitoring improve antiretroviral therapy adherence in rural Uganda. *AIDS* 2016 May 15;30(8):1287-1294. [doi: [10.1097/QAD.0000000000001035](https://doi.org/10.1097/QAD.0000000000001035)] [Medline: [26807967](https://pubmed.ncbi.nlm.nih.gov/26807967/)]
26. Lester RT, Ritvo P, Mills EJ, Kariri A, Karanja S, Chung MH, et al. Effects of a mobile phone short message service on antiretroviral treatment adherence in Kenya (WelTel Kenya1): a randomised trial. *Lancet* 2010 Nov 27;376(9755):1838-1845. [doi: [10.1016/S0140-6736\(10\)61997-6](https://doi.org/10.1016/S0140-6736(10)61997-6)] [Medline: [21071074](https://pubmed.ncbi.nlm.nih.gov/21071074/)]
27. van der Kop ML, Karanja S, Thabane L, Marra C, Chung MH, Gelmon L, et al. In-depth analysis of patient-clinician cell phone communication during the WelTel Kenya1 antiretroviral adherence trial. *PLoS One* 2012;7(9):e46033 [FREE Full text] [doi: [10.1371/journal.pone.0046033](https://doi.org/10.1371/journal.pone.0046033)] [Medline: [23049928](https://pubmed.ncbi.nlm.nih.gov/23049928/)]
28. Lester RT. Ask, don't tell-mobile phones to improve HIV care. *N Engl J Med* 2013 Nov 07;369(19):1867-1868. [doi: [10.1056/NEJMc1311318](https://doi.org/10.1056/NEJMc1311318)] [Medline: [24195568](https://pubmed.ncbi.nlm.nih.gov/24195568/)]
29. Haberer JE, Sabin L, Amico KR, Orrell C, Galárraga O, Tsai AC, et al. Improving antiretroviral therapy adherence in resource-limited settings at scale: a discussion of interventions and recommendations. *J Int AIDS Soc* 2017;20(1):21371 [FREE Full text] [doi: [10.7448/IAS.20.1.21371](https://doi.org/10.7448/IAS.20.1.21371)] [Medline: [28630651](https://pubmed.ncbi.nlm.nih.gov/28630651/)]
30. Uthman OA, Magidson JF, Safren SA, Nachega JB. Depression and adherence to antiretroviral therapy in low-, middle- and high-income countries: a systematic review and meta-analysis. *Curr HIV/AIDS Rep* 2014 Sep;11(3):291-307 [FREE Full text] [doi: [10.1007/s11904-014-0220-1](https://doi.org/10.1007/s11904-014-0220-1)] [Medline: [25038748](https://pubmed.ncbi.nlm.nih.gov/25038748/)]
31. Kaufman MR, Cornish F, Zimmerman RS, Johnson BT. Health behavior change models for HIV prevention and AIDS care: practical recommendations for a multi-level approach. *J Acquir Immune Defic Syndr* 2014 Aug 15;66 Suppl 3:S250-s258 [FREE Full text] [doi: [10.1097/QAI.0000000000000236](https://doi.org/10.1097/QAI.0000000000000236)] [Medline: [25007194](https://pubmed.ncbi.nlm.nih.gov/25007194/)]

Abbreviations

- ANC:** antenatal care
- ART:** antiretroviral therapy
- FGD:** focus group discussions
- HCW:** health care workers
- MCH:** maternal child health
- MTCT:** mother-to-child HIV transmission
- PMTCT:** prevention of mother-to-child HIV transmission
- RCT:** randomized controlled trials
- SMS:** short message service

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Original Paper

A Novel 12-Lead Electrocardiographic System for Home Use: Development and Usability Testing

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Abstract

Background: Cardiovascular diseases (CVD) are the leading cause of morbidity and mortality worldwide. Early diagnosis is of pivotal importance for patients with cardiac arrhythmias and ischemia to minimize the consequences like strokes and myocardial infarctions. The chance of capturing signals of arrhythmias or ischemia is substantially high when a 12-lead electrocardiogram (ECG) can be recorded at the moment when a patient experiences the symptoms. However, until now, available diagnostic systems (Holter monitors and other wearable ECG sensors) have not enabled patients to record a reliable 12-lead ECG at home.

Objective: The objective of this project was to develop a user-friendly system that enables persons with cardiac complaints to record a reliable 12-lead ECG at home to improve the diagnostic process and, consequently, reduce the time between the onset of symptoms and adequate treatment.

Methods: Using an iterative design approach, *ECGraph* was developed. The system consists of an ECG measurement system and a mobile app, which were developed with the help of several concept tests. To evaluate the design, a prototype of the final design was built and a final technical performance test and usability test were executed.

Results: The ECG measurement system consists of a belt and 4 limb straps. Ten wet Ag/AgCl electrodes are placed in the belt to optimize skin-electrode contact. The product is controlled via an app on the mobile phone of the user. Once a person experiences symptoms, he or she can put on the belt and record ECGs within a few minutes. Short instructions, supported by visualizations, offer guidance during use. ECGs are sent wirelessly to the caregiver, and the designated expert can quickly interpret the results. Usability tests with the final prototype (n=6) showed that the participants were able to put on the product within 8 minutes during first-time use. However, we expect that the placement of the product can be executed faster when the user becomes more familiar with the product. Areas of improvement focus mainly on confidence during product use. In the technical performance test, a 12-lead ECG was made and reproduced 6 times.

Conclusions: We developed a new 12-lead ECG system for home use. The product is expected to be more user-friendly than current hospital ECG systems and is designed to record more reliable data than current ECG systems for home use, which makes it suitable for expert interpretation. The system has great potential to be incorporated into an outpatient practice, so that arrhythmias and ischemia can be diagnosed and treated as early as possible.

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KEYWORDS

12-lead ECG system; electrocardiography; home use; handheld; user-centered design

Introduction**Background**

According to the World Health Organization, cardiovascular diseases (CVD) were the leading cause of morbidity and mortality worldwide in 2015 [1]. An estimated 17.7 million people died from CVDs in 2015, representing 32% of all global deaths. Around 7 million people in this group died of ischemic heart disease. Cardiac ischemia refers to decreased blood flow to the heart muscle, resulting in a shortage of oxygen. This can cause damage to or death of a part of the heart muscle known as a myocardial infarction.

Acute ischemic heart disease and myocardial infarction are diagnosed, among others, with the help of a pivotal test: the registration of an electrocardiogram (ECG). The test is performed when a patient presents with acute chest pain, after which the treatment and prognosis can be determined immediately.

A standard ECG measures the depolarization of cardiac muscle tissue [2] and consists of 12 leads, recorded from 10 electrodes that are placed on the skin (Figure 1). The leads gather information from different sides of the heart. To obtain a complete and reliable overview of heart activity, all 10 electrodes need to be placed at the prescribed locations shown in Figure 1 [3].

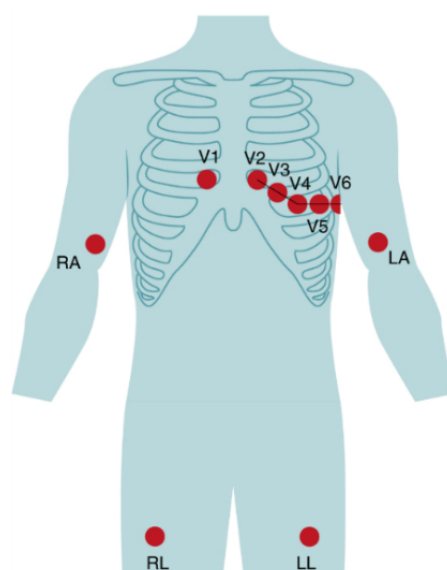
It is estimated that 1.5 million to 3 million ECGs are performed worldwide every day, making it one of the most commonly used cardiovascular diagnostic procedures and a fundamental tool in clinical practice [4,5]. For patients with ischemia, early diagnosis is of great importance because cardiac hypoxemia can lead to irreversible damage to the heart muscle known as myocardial infarction. In 2015, there were an estimated 7.29 million acute myocardial infarctions worldwide [6]. Myocardial ischemia is

often indicated by chest pain. However, most of the affected individuals are unfamiliar or unaware of the typical symptoms. Consequently, they ignore the symptoms, resulting in a delayed diagnosis and treatment. Another reason for a delay in diagnosing myocardial ischemia is the availability of 12-lead ECG systems, which are limited to hospital settings or specialized health care facilities. Taken together, these circumstances often lead to a substantial delay between the onset of symptoms and the moment a medical doctor can make a correct diagnosis, thereby delaying appropriate treatment, which leads to a worse prognosis.

Apart from assisting in the diagnosis of myocardial ischemia, a 12-lead ECG can help accurately establish cardiac arrhythmias. Atrial fibrillation is the most common arrhythmia. Globally, there were an estimated 33.3 million prevalent cases of atrial fibrillation in 2015 [6]. Untreated atrial fibrillation causes up to 26% of all strokes [7], which can be prevented in 64% of patients with oral antithrombotic prophylactic therapy [8]. This shows that early diagnosis is of great importance.

Individuals with arrhythmias often have symptoms for a short period of time. These symptoms often subside when the affected individual visits the outpatient clinic, thus, severely reducing the sensitivity of a 12-lead ECG for establishing a diagnosis of transient ischemic heart disease. Therefore, the patients are often advised to wear a Holter monitor, which continuously records ECGs, for 24 or 48 hours. However, symptoms often do not occur during this relatively short monitoring period, which can result in a delayed diagnosis and treatment and can elicit feelings of insecurity within the affected individual. The abovementioned problems underscore the need to perform an ECG as soon as symptoms arise. This accelerates the diagnostic process, so that the patient can be treated faster, which will eventually limit the consequences of the disease.

Figure 1. Placement of the electrodes of the standard 12-lead electrocardiographic system; LA: left arm; LL: left leg; RA: right arm; RL: right leg; V1 to V6: the 6 precordial electrodes.



Existing Solutions and Their Limitations

With the rising number of CVD patients, the demand for home monitoring products that improve cardiac care is increasing. At present, two groups of ECG products are available for home monitoring.

The first group comprises products that are applied by health care professionals. This group includes Holter monitors that record very reliable information and are a key tool for diagnosing arrhythmias [9]. These systems are too complex to be used by laymen, and they are uncomfortable to wear. The sensor wires restrict the daily movements and interfere with the sleep of the wearer, and the electrode patches may damage the skin when removed. Therefore, from a user point of view, these systems are not ideal.

The second group comprises handheld ECG systems that are applied and used by patients themselves. These systems are, in contrast to the Holter systems, very easy to use and understand. Although these systems can, in some cases, support the diagnostic process of arrhythmias, they are not suitable for the detection and diagnosis of ischemia since the information is not as complete and reliable as the recordings of the standard 12-lead systems.

A short overview of the existing handheld ECG systems for consumer use follows. Note that well-being and fitness wearables, which measure heart rate, like the Fitbit, were not included in this overview since these are not classified as medical devices and are not suitable for diagnosing heart diseases [10,11].

Handheld ECG systems for consumer use generally consist of a measuring device that is controlled via an app on a mobile phone. The measuring equipment can be integrated into a patch [12] or a belt [13] for measurement on the chest. Alivecor developed Kardia, which, instead of using electrodes that are placed on the chest, requires the user to place his or her fingers onto two sensor pads, so that ECG data can be collected [14].

The aforementioned systems, having just a few leads, record too little information for diagnosing ischemia. The Smartheart Pro from SHL Telemedicine [15,16] is a system with multiple electrodes from which 12 leads are calculated. Electrodes are placed on a strap, which can be tied around the chest. However, synthesized ECGs from a reduced number of leads can approximate, but not duplicate, the tracings obtained using the standard leads [4]. This makes this system less reliable for ischemia detection compared with the standard 12-lead ECG systems.

In the past few years, research has been performed to integrate ECG sensors into textiles. Several 12-lead ECG shirts were developed for continuous health monitoring [17-19]. In these products, dry electrodes are integrated into the shirts. Unfortunately, dry electrodes are less robust and the signal-to-noise ratio is too low for diagnosing myocardial ischemia.

Design Gap

To conclude, current ECG solutions for home monitoring are either easy to use but not reliable enough for diagnosing

arrhythmias and ischemia or they are very reliable but too complex to be used by laymen. This shows that there is a need to design a novel 12-lead ECG device for home use that can be incorporated into daily medical protocols to speed up the diagnostic process. This new product-service system should enable patients themselves to make *reliable* 12-lead ECGs as soon as symptoms arise at home. By creating an *easy-to-use* product-service system, patients will be empowered to record essential data for diagnosing arrhythmias and ischemia.

This paper describes the development of a novel 12-lead ECG system for home use. The new system consists of a physical product, which includes the measurement system, and a service, which gives feedback during use. In this paper, we have focused on the embodiment of the physical product. The service is briefly explained. In addition, we have discussed the results of a recent technical performance study and a usability study that were conducted with a prototype of the new product to evaluate the design.

Methods

Development Process

During the design phase, the design methodology written by Roozenburg and Eekels [20] provided guidance to deal with all potential design problems in a systematic way. As can be seen in Figure 2, the process was split into 3 phases. We started the project with an analysis phase, resulting in a design vision and list of criteria. This phase was followed by a design phase where three concepts were developed and one of them was chosen. The chosen concept was developed further and designed in detail. In the third phase, a final prototype was created and several tests were performed to evaluate the product.

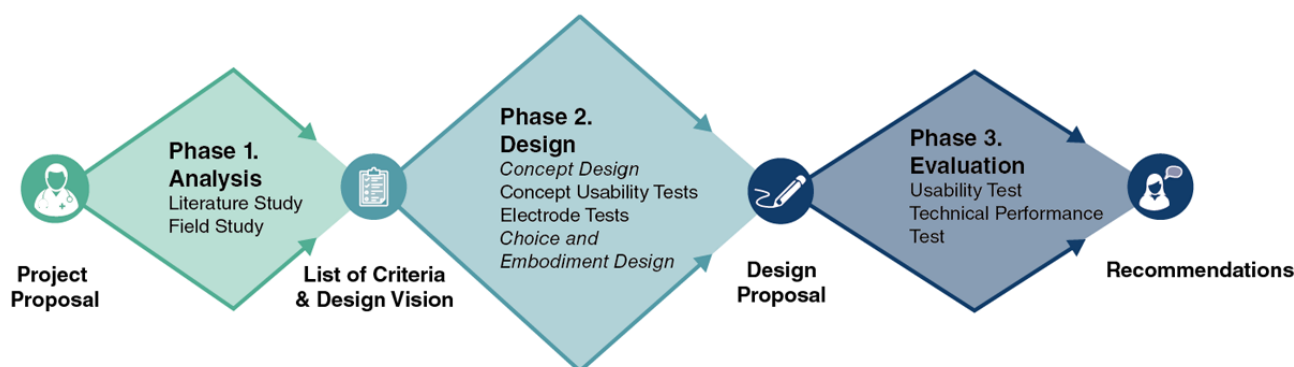
Phase 1. Analysis: Design Vision and List of Criteria

We conducted a literature study and field research during the analysis phase of the project. We interviewed participants with arrhythmias or ischemia, cardiologists, and specialized nurses and observed standard ECG procedures. Then, we mapped out the insights from the literature study and the field research and defined a list of design criteria and a design vision.

Phase 2. Design: Process and Prototypes

The two core values that were highlighted in the design vision are *reliability* and *ease of use*. These values served as a guide through the design process. For each core value, the most important tests and subsequent decisions are mentioned in the next paragraphs. Note that, in reality, the mentioned activities formed an iterative process together with the design steps. The design vision served as a start of the design process. More than 60 ideas were generated, and the most promising ideas were developed into three concepts [20]. Prototypes of these concepts were made, which were evaluated with users on usability and comfort. Parallel to this, we performed technical performance tests with different electrode-skin contact designs. We further developed the best scoring concept into a final design proposal.

Figure 2. Visualization of the process.



Designing an Easy-To-Use Electrocardiographic System

During the whole process, we used a user-centered design approach [21]. Potential users of the ECG system were involved throughout the process to ensure that the product fits the needs and expectations of the user group. In order to evaluate the comfort and usability of the different concepts, we made simple mock-ups of the three concepts. We asked 5 participants to use the mock-ups and assess them on device comfort and usability in a structured interview. All participants gave informed consent before participating.

As shown by the empirical studies discussed by Kanis [22], this user trialing can be seen as an obvious way to enable designers to accommodate prospective user activities in everyday product design.

The participants were on average 65.6 (SD 16.2) years old. Of them, 3 were women and 4 participants had experienced an ECG test before. None of the participants had a heart disease.

First, the project goal and the procedure were explained to the participants. Second, each participant was asked to try to put on each mock-up with the help of simple visualizations that show how the device is worn. We measured the time of the actions and observed the actions. After the use of the mock-ups, the participants were interviewed.

Designing a Reliable Electrocardiographic System

To design a feasible solution for laymen to record reliable ECGs at home, we took several main steps. First, correct placement of the electrodes needed to be facilitated for people with different shapes and sizes. To identify the difference in the distance between the electrodes, we retrieved the three-dimensional (3D) body scan data of approximately 1250 people from the Delft University of Technology database WEAR [23] and calculated P5 (5th percentile) and P95 (95th percentile) of the circumference under the bust (for the Dutch population, only measured for females). The electrodes were positioned at a P5 and P95 3D scan following the anatomic guidelines of electrode placement of a standard 12-lead system. After this, the difference was calculated.

Second, optimal skin-electrode contact is needed to ensure that the signal can be captured without recording too much noise. The aim of the electrode-skin contact tests was to find out which concepts ensured the best skin-electrode contact on the chest.

We gathered several electrode samples that enhanced electrode-skin contact. 3M Red Dot Electrodes [24], two types of reusable electrodes of PLUX Wireless Biosignals [25], and electrodes with foam from Somnomedics [26] were used. To compare the different electrodes, we made an ECG with a three-electrode bipolar lead system [27]. To check how well the electrodes were connected to the skin, we measured the electrode impedance and interpreted the ECG recordings. By comparing the ECG results, we identified the best performing electrode.

Phase 3. Evaluation: Usability Study and Technical Performance Study

Based on the different test results, we selected one concept for further development in detail, which resulted in a final design proposal. To evaluate the proposal, we created a prototype for the final usability study and technical performance study.

Usability Study

We performed the final user tests to evaluate the user-friendliness of the newly designed device and to identify the bottlenecks in its use. Six participants from the potential target group were invited to use and assess the prototype. All participants were older than 60 years with a mean age of 73.7 (SD 7.8) years. The user group included 4 females and 2 males. Five participants had experienced an ECG test in the past, but no one had seen the new design before. All participants gave informed consent.

First, the project goal and the procedure were explained to the participants. Second, a preliminary version of the manual was presented to each participant on a laptop. We asked each participant to try to put on the prototype with the help of the manual while the researchers timed and observed the users' actions. After the use of the device, the participants completed structured interviews. We asked questions about the perceived usefulness and ease of use since these factors greatly influence the users' decision about how and when to use the new product [28].

Technical Performance Study

Following the usability test, a first technical performance test was performed. In this test, we checked whether all the electrodes in the final prototype made good contact with the skin of one female participant. We also checked whether the

belt fitted well and investigated which parameters needed to be adjusted.

At the outpatient clinic in the hospital in Zaandam (Zaans Medisch Centrum), the wires of a standard 12-lead resting ECG monitor were connected to the electrodes on the prototype of the belt. A series of ECGs using the standard equipment of the 12-lead resting ECG system were made first as a reference. Subsequently, a 12-lead ECG was made with one prototype 6 times. After each recording, the belt and straps were taken off and the electrodes were replaced. The test was performed multiple times to check whether the results were reproducible.

Results

Phase 1. Analysis: Design Vision and List of Criteria

Based on the literature study and field research, design criteria were formulated. The most important design criteria are described below:

1. The product-service system should enable a patient without experience in electrocardiography to make an ECG of medical quality himself or herself.
2. The product should contain 10 electrodes, from which 12 leads can be derived.
3. The product-service system should contain a communication channel for quick interpretation of the ECGs by a health care professional.
4. The location of the precordial electrodes should never differ more than 3 cm from the anatomically defined locations in the body [29].
5. The product should be put on and used by the person whose ECG needs to be recorded.
6. ECGs should be recorded with the patient in a supine position.
7. Users should be able to make an ECG within 10 minutes. Somerville et al reported that the average time to perform a conventional 12-lead ECG is 10.6 minutes [30].
8. The patient should be able to communicate his or her complaints together with the recordings to the health care specialist in a simple way.
9. The results of the test should be clearly communicated to the patient.

The design vision was stated as follows: “We want to design a product-service system that enables subjects to make a reliable 12-lead ECG at the moment they have complaints at home. With the help of an easy-to-use product-service system, patients are empowered to record essential data for diagnosing arrhythmias and ischemia.” Two core values can be highlighted in this vision: reliability and ease of use. The product should enable the user to make 12-lead ECGs of good quality, suitable for interpretation by a cardiologist; at the same time, the product-service system should be very easy to use and understand.

Phase 2. Design: Process and Prototypes

In this section, the preliminary design concepts are presented first, followed by an explanation of the final design. Figure 3 shows the sketches of the three design concepts and the three

mock-ups that were used in the concept user tests. Concept 1, from now on called *ECGraph* was chosen for further development. This system consists of a belt and 4 limb straps. When placed around the chest, the belt will stretch and the electrodes will move with respect to each other. In this way, the electrodes will automatically be placed at the right location on the body and would not need to be placed at the right location one by one, like in the conventional systems. Positioning the middle part of the product in the middle of the body and above the nipples is sufficient. This makes the product very user-friendly. Note that the limb electrodes are placed on the actual limbs like in the current hospital procedures, which increases the acceptance of the product by cardiologists.

We chose the design of the electrodes with the help of electrode-skin contact tests. The samples that were tested are shown in Figure 4. The test results showed that the Ag/AgCl-gelled disposable electrodes (samples 1, 2) made the best contact with the skin. If users have to add the gel manually, like for sample 3, good contact cannot be guaranteed.

Final Design

Figures 5 and 6 illustrate the final design. *ECGraph* is a stretching belt (see #1 in Figure 5) that is placed under the bust. The belt is connected to 4 straps (see #2 in Figure 5) that need to be placed around the limbs and contain the limb electrodes. The 6 electrodes of the precordial leads are integrated into the belt, and with a simple closure system, the belt can be placed around the chest.

The limb electrodes are integrated into the 4 straps. The straps are preformed so that they can be wrapped around the limb with one hand. They are connected to the belt through rolling mechanisms to ensure that the wires do not get entangled. The limb straps need to be connected to the belt through wires because all the electrodes and the associated readout circuit need to have a common ground. In case a wireless connection without a ground cable is used, the ECG measurement will be significantly deteriorated due to noise and interference (Dr J Xu, personal communication, December 8, 2016).

Standard disposable Ag/AgCl electrodes (sample 1) are integrated into the final design because they ensure good electrode-skin contact. The adhesive part of these electrodes is removed because the belt will keep the electrodes in place during the recording, enhancing comfort. Figure 7 shows how the electrodes are placed on the belt using a commonly used press stud system. For ease of use, the precordial electrodes are already positioned on one sticker sheet that can be easily pulled off.

Figure 8 shows how the electrode system is integrated into the belt. The belt will be available in two sizes to minimize pressure on the body for larger individuals, once again enhancing comfort. Figure 9 presents an overview of the product-service system. The user can record the ECGs by putting on the belt and the straps. The user's phone can connect to the belt via Bluetooth. Once the Bluetooth connection is made and the user turns on the device, the system automatically checks whether the electrodes have made good contact with the skin. Afterwards, the user can record the ECGs.

Figure 3. Concept design and mock-ups.



Figure 4. Samples used in electrode-skin contact tests.

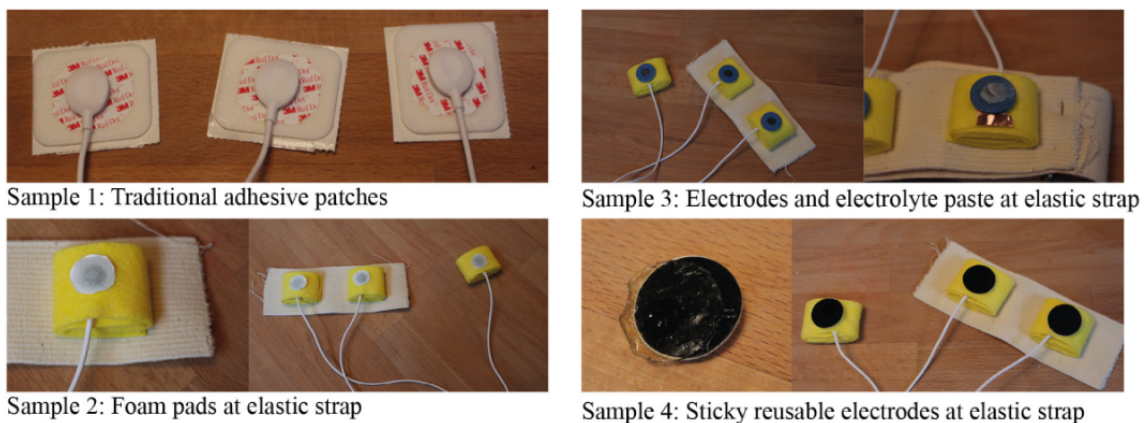
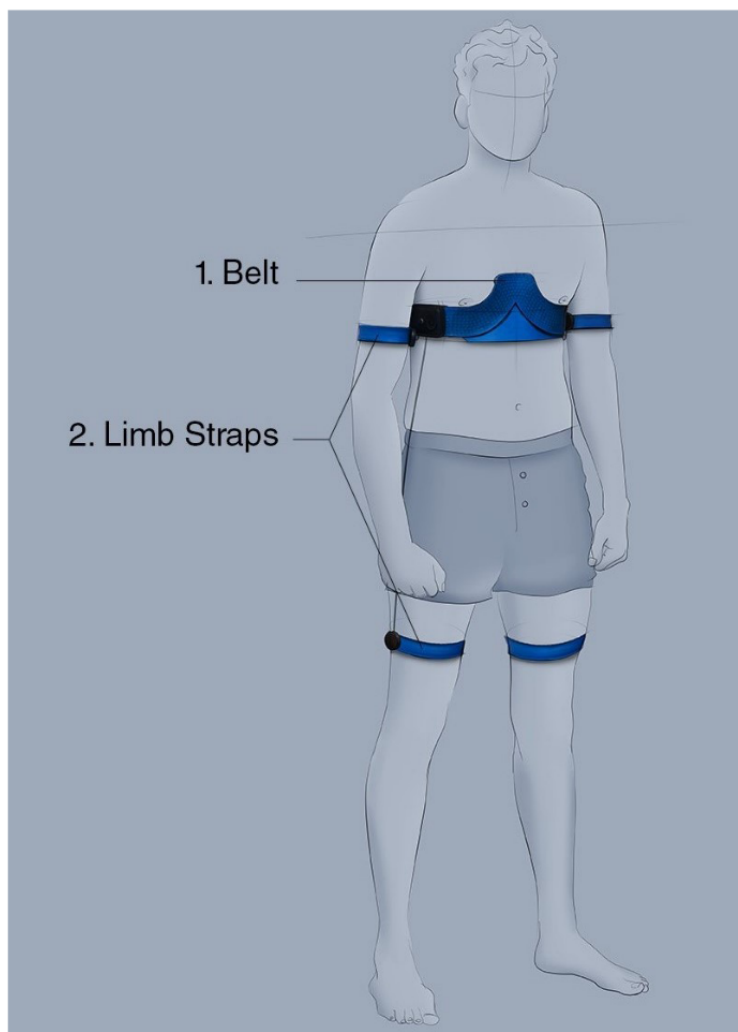
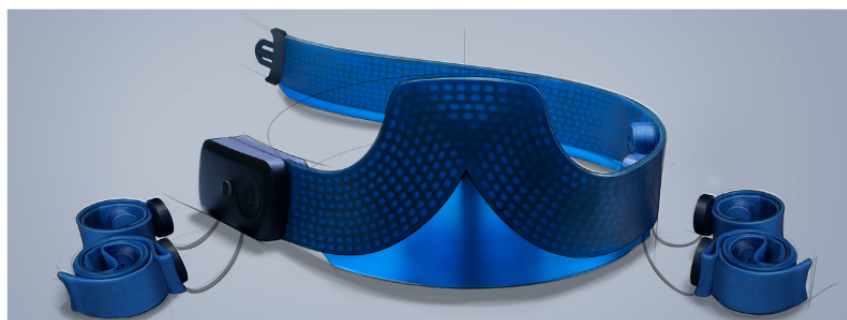


Figure 5. Positioning of the final design.**Figure 6.** Final design: main belt connected with the limb straps through rolling mechanisms.

The user can store the ECGs and send them, together with a description of his or her complaints, to the hospital database via Wi-Fi or a 4G network. The nurses or medical assistants examine the ECGs. When excessive noise is detected by the nurses and when the ECGs are uninterpretable, the patient is asked to repeat the process. When the ECGs are of good quality, they are electronically forwarded to the cardiologist. The cardiologist interprets the ECGs and formulates an advice based on the results. The advice is sent to the patient in a text message via the app. It lets the patient know whether direct action is required. To envision the service, a more detailed service blueprint was made and some screens of the app were created

(see [Multimedia Appendix 1](#)) [3]. To make the user feel confident about recording the ECGs and to ensure that he or she can record ECGs of good quality, the user is asked to record a “test ECG” at the moment he or she receives the product. After opening the app, the user first makes a connection with his cardiologist. After the cardiologist confirms the connection, the user is asked to record a test ECG with the help of the app. The ECGs are checked by the cardiologist, and the user gets feedback on the results. Last, during product use, the user is guided by a visual manual that is shown in the app. Some important steps from this manual are shown in [Figure 10](#). In this manual, all the important requirements of use are highlighted.

Figure 7. The electrodes are preplaced on a sticker sheet and connected to the belt using press studs. When the electrodes are connected, the sheet can be pulled off.

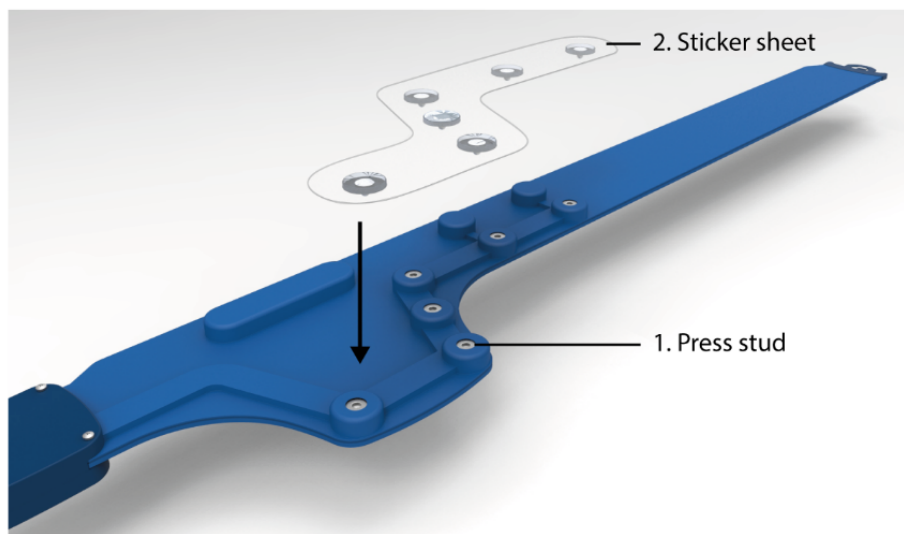


Figure 8. The electrode system is sandwiched between two layers of cast rubber, one of which is perforated to create a larger strain.

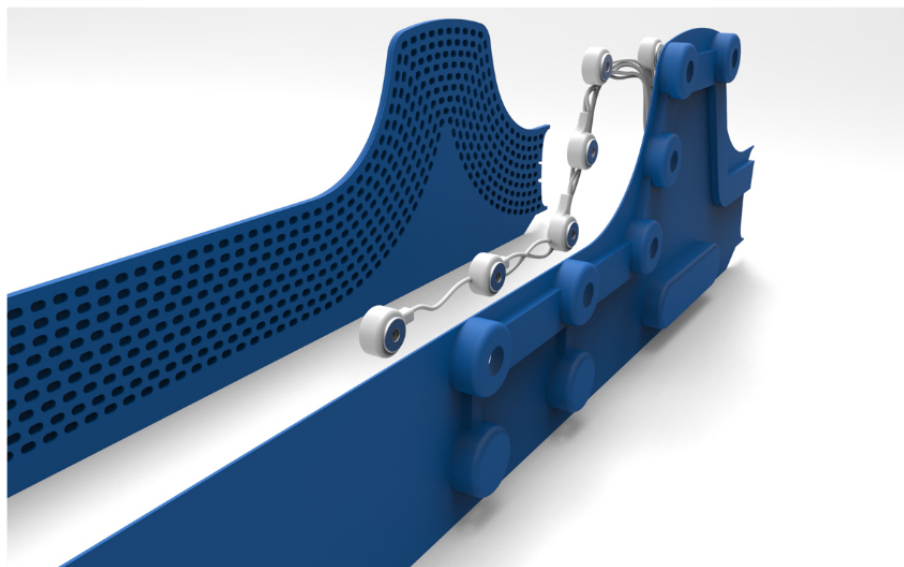


Figure 9. Overview of the product-service system.

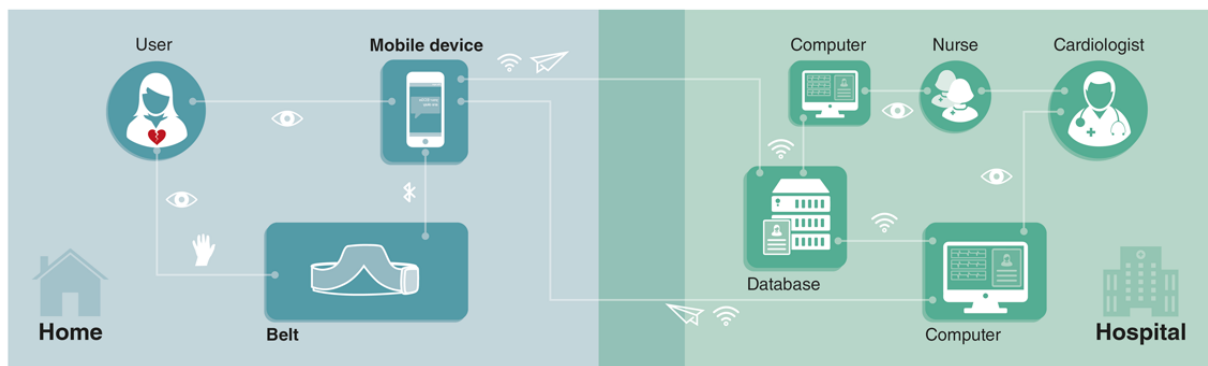
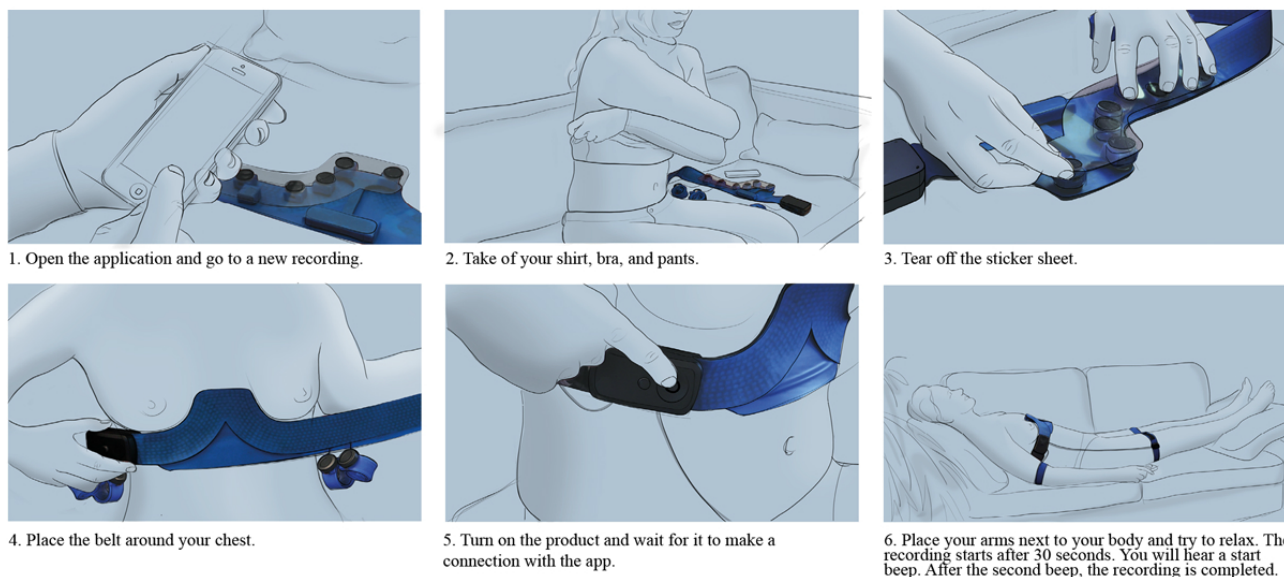


Figure 10. A selection of steps from the manual.



Phase 3. Evaluation: Usability Study and Technical Performance Study

In this section, the results of the final usability study and technical performance study are presented. We used these results to evaluate the final design.

Usability Study

The user tests proceeded smoothly. All users were able to put on the prototype within 8 minutes. Table 1 shows the main issues that were identified during the usability study (n=6).

All participants placed the limb straps at the correct locations during the test. Concerning the placement of the belt, one participant had the tendency to place the belt on the chest at a level lower than that in the picture (Issue 1). All participants had the tendency to ask questions about whether they were using the prototype in the right way. They did not feel confident during handling the device, although they were actually doing it very well. Besides, they explained in the interviews that they would feel even less confident using the device when they were experiencing symptoms of a heart disease. On the other hand, all participants assented that they would feel more confident if they had used the product before.

Table 1. Major issues identified during the usability study.

Issue #	Participants	Task	Issue
1	P4	Placement of the belt	The belt was placed too low around the chest.
2	P1, P2, P5, P6	Placement of the limb straps	Although every participant placed the straps around the right limb, the majority of them were not sure about which strap should be placed around which limb.
3	P3, P6	Placement of the limb straps	Some participants were not sure about the location of the electrode on each limb. They were not informed that this was not important for measurement reliability as long as the electrode was placed on the correct limb.
4	P2, P4, P6	Check before recording	Several participants were not sure whether they will feel confident enough to use the system when they have real complaints.

Technical Performance Study

Figures 11 and 12 show the set-up during the technical performance test. A series of ECGs using the standard equipment of the 12-lead resting ECG system, were made first as a reference. Subsequently, a 12-lead ECG was made using the prototype 6 times. Figure 13 depicts a standard recording, and Figure 14 shows an ECG recording made using the prototype. The ECG results were compared by a cardiologist, who confirmed a good reproducibility of the ECGs made with the prototype.

Second, the standard ECG was compared with the ECGs made with the prototype. It was noticed from the graphs that the placements of V4 till V6 were slightly different when the prototype was used. As indicated by the arrows in Figure 14, the T-waves of V4 till V6 were larger than those in Figure 13.

This can be explained by the fact that in the test with the standard ECG system, the patches were placed a little lower because the participant was wearing a bra. Although the signal-to-noise ratio appeared to be lower when the prototype was used, this did not influence the diagnostic characteristics of the ECG.

Figure 11. The standard 12-lead monitoring equipment connected to the prototype.



Figure 12. Detailed picture of the prototype (blue) connected to the standard electrocardiogram monitoring equipment. Note that in the final design, the electrode wires will be integrated into the belt.

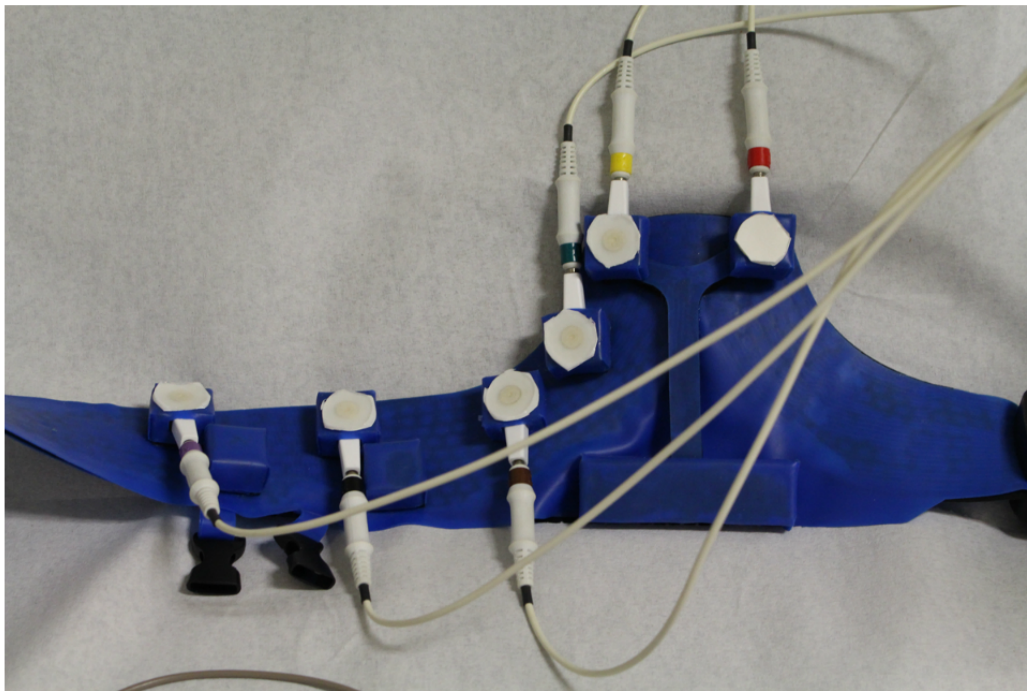


Figure 13. Standard electrocardiogram recording made using adhesive patches. Limb electrodes were placed on the limbs.

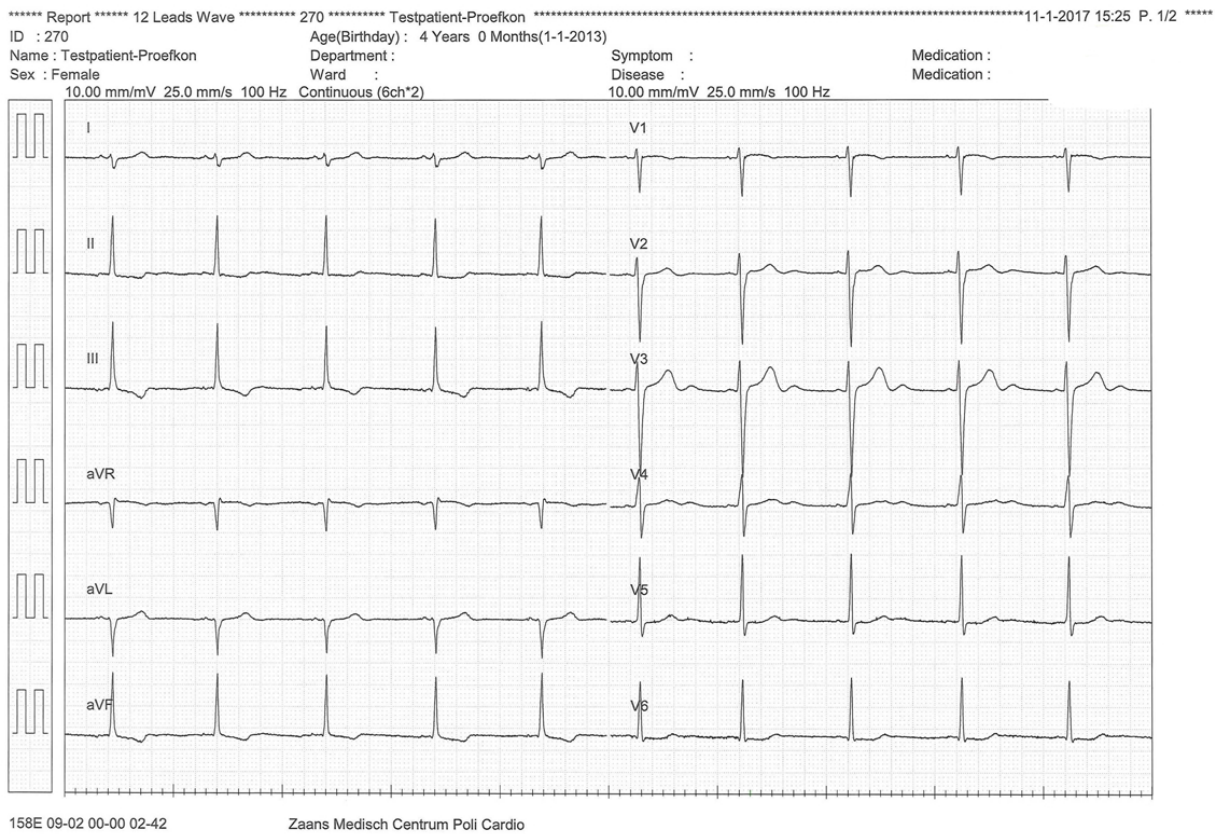
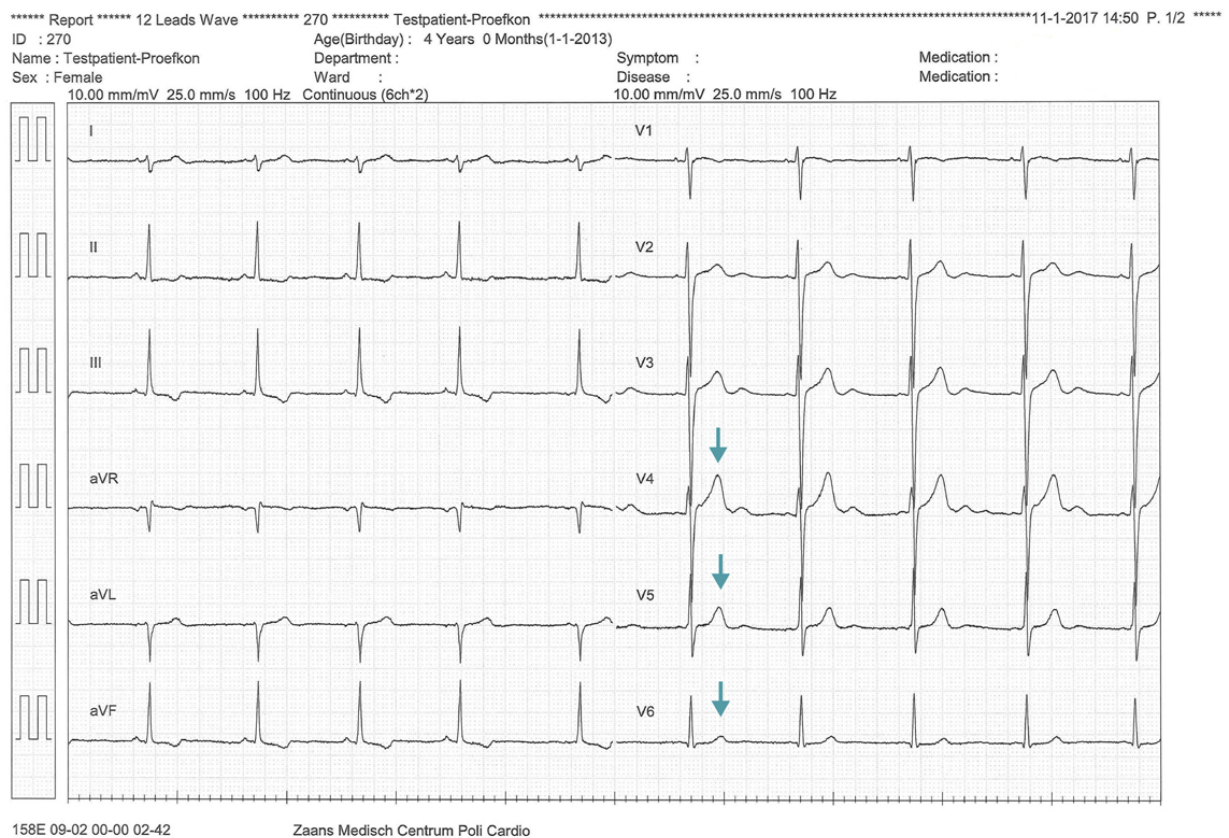


Figure 14. Electrocardiogram recording made using the prototype.



Discussion

Principal Findings

In this paper, we described the design and development of *ECGraph*, which is the first product-service system that enables individuals to record reliable standard 12-lead ECGs at home at the moment they have complaints. The design vision contained two core values. First, the novel 12-lead ECG system must record ECGs of clinical quality. The measurements must be reliable and suitable for clinical interpretation. Second, individuals using the system need to be able to record the ECGs themselves. Therefore, an easy-to-use product-service system had to be made. We have discussed whether the designed product-service system (*ECGraph*) adheres to these core values. Recommendations to improve these key aspects are presented as well.

Technical Performance

Several design aspects contribute to the reliability of the system. First, the new ECG system makes use of 10 electrodes, just like the standard 12-lead ECG systems. In contrast to many competitors who use measurement systems with fewer leads, we designed a full 12-lead system, which has been shown to be more reliable [4]. Disposable wet electrodes, which ensure good skin contact, are placed in the belt and straps. These features offer an advantage over the existing products for home use, namely that the product can be used in clinical practice for diagnosing infarctions and arrhythmias.

A first technical performance test with the final prototype was performed to find out whether the new design allowed the electrodes to make a good contact with the skin. From this test, we concluded that ECGs of clinical quality could be made. Five repetitive ECG measurements confirmed the system's good reproducibility.

Usability

In the design phase, ease of use was prioritized. Several user tests were performed to evaluate the ease of use and to improve the design. This led to a lot of design elements that contributed to the ease of use of the device. The precordial electrodes were integrated into a belt; the replacement of the patches was facilitated by a sticker sheet, which contains the precordial electrodes; preformed arm straps were made; and rolling mechanisms for the wires were used. Besides, the product has very simple interface buttons, and an app supports the user during product use.

In the final usability test, all the users were able to put on the product correctly within 8 minutes. We expect that the product can be used much faster once the users familiarize themselves with it. One participant placed the belt slightly lower on the chest than pictured in the manual. This would influence the ECG results, but it can be solved by adding an extra remark to the digital manual in the app stating that the top electrodes need to be placed between the breasts, above the nipples.

From the final usability test, we discovered that lack of confidence among the users during the procedure was a major issue. To make the users feel more confident, the manual should

be improved, and it should contain some extra remarks and check points. We found that the participants wanted more information about whether they were handling the product correctly. This emphasizes the importance of making a "test ECG" that will be checked by the cardiologist when a user receives the product for the first time. An instruction video or demonstration in the hospital can also increase confidence during use.

Last, some design elements led to ease of use for the health care professional. The use of a traditional, 12-lead system facilitates implementation in the current health care system. On top of that, the effort required from the cardiologist is minimal since he or she only has to send a message with the outcome of the test to the user.

Limitations

Because of the short time span of this project, there are several limitations that warrant discussion. First, during the usability test, the participants were wearing clothes. Thus, the available wet electrodes were not placed in the prototype during the test. In the next phase, a new user test needs to be performed where the participants will have to take off their clothes and the wet electrodes will be placed in the prototype to simulate the real user scenario.

Second, the prototype was made from laser-cut segments of polychloroprene and latex because there was insufficient time to create a mold and fabricate a belt by casting. These segments were glued together, which made the belt less robust than the intended product. The fragility of the prototype may have influenced the perception of the product and, therefore, the results of the user tests.

Third, during the technical performance test, ECGs of a person with a small thoracic circumference (700 mm) were made. We currently have no data on the quality of ECGs in persons with a relatively large thoracic circumference; this should also be tested in the future.

Last, in this paper, we described the first step, namely the design phase, of creating a 12-lead ECG system for home use that can be incorporated into clinical practice. The system has not yet been put into test on patients who are suffering from a cardiac disease. A clinical study to test whether the new device can speed up the diagnostic process of patients with a cardiac pathology has been planned as the next step.

Conclusions

In this project, a new 12-lead ECG system for home use was developed. The product (*ECGraph*) is designed to be more user-friendly than current hospital ECG systems, and the product architecture enables integration of ECG components that have a superior sensitivity for diagnosing cardiac pathology compared with outpatient surrogate ECG devices. By performing a thorough context and user research, we have tried to create an accessible product for both patients and health care professionals. We believe that *ECGraph* has great potential to be incorporated into current clinical practice models and is a step forward toward faster diagnosis and treatment of patients with cardiac pathology.

Conflicts of Interest

None declared.

Multimedia Appendix 1

App screenshots.

[[JPG File, 1MB - mhealth_v6i7e10126_app1.jpg](#)]

References

1. World Health Organization. WHO fact sheet. 2017. Cardiovascular diseases (CVDs) URL: <http://www.who.int/mediacentre/factsheets/fs317/en/> [accessed 2017-12-01] [WebCite Cache ID 6vgLSKV9U]
2. American Heart Association. 2015. Electrocardiogram (ECG or EKG) URL: http://www.heart.org/HEARTORG/Conditions/HeartAttack/DiagnosingaHeartAttack/Electrocardiogram-ECG-or-EKG_UCM_309050_Article.jsp [accessed 2016-09-09] [WebCite Cache ID 6vgLfjsAK]
3. Steijlen A. ECGraph, designing a 12-lead electrocardiographic system for home use. Delft: TU Delft Repository 2017 [FREE Full text]
4. Kligfield P, Gettes LS, Bailey JJ, Childers R, Deal BJ, Hancock EW, American Heart Association Electrocardiography Arrhythmias Committee, Council on Clinical Cardiology, American College of Cardiology Foundation, Heart Rhythm Society. Recommendations for the standardization and interpretation of the electrocardiogram: part I: the electrocardiogram and its technology a scientific statement from the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society endorsed by the International Society for Computerized Electrocardiology. *J Am Coll Cardiol* 2007 Mar 13;49(10):1109-1127 [FREE Full text] [doi: [10.1016/j.jacc.2007.01.024](https://doi.org/10.1016/j.jacc.2007.01.024)] [Medline: [17349896](https://pubmed.ncbi.nlm.nih.gov/17349896/)]
5. Shenasa M. Learning and teaching electrocardiography in the 21st century: A neglected art. *J Electrocardiol* 2018 Feb 20. [doi: [10.1016/j.jelectrocard.2018.02.007](https://doi.org/10.1016/j.jelectrocard.2018.02.007)] [Medline: [29499830](https://pubmed.ncbi.nlm.nih.gov/29499830/)]
6. Roth GA, Johnson C, Abajobir A, Abd-Allah F, Abera SF, Abyu G, et al. Global, Regional, and National Burden of Cardiovascular Diseases for 10 Causes, 1990 to 2015. *J Am Coll Cardiol* 2017 Jul 04;70(1):1-25 [FREE Full text] [doi: [10.1016/j.jacc.2017.04.052](https://doi.org/10.1016/j.jacc.2017.04.052)] [Medline: [28527533](https://pubmed.ncbi.nlm.nih.gov/28527533/)]
7. Gnononfoun D, Adjien C, Gnimavo R, Goudjinou G, Hotcho C, Nyangui MJ, et al. Ischemic stroke due to embolic heart diseases and associated factors in Benin hospital setting. *J Neurol Sci* 2018 Apr 15;387:124-128. [doi: [10.1016/j.jns.2018.01.024](https://doi.org/10.1016/j.jns.2018.01.024)] [Medline: [29571848](https://pubmed.ncbi.nlm.nih.gov/29571848/)]
8. Hart RG, Pearce LA, Aguilar MI. Meta-analysis: Antithrombotic Therapy to Prevent Stroke in Patients Who Have Nonvalvular Atrial Fibrillation. *Ann Intern Med* 2007 Jun 19;146(12):857-867. [doi: [10.7326/0003-4819-146-12-200706190-00007](https://doi.org/10.7326/0003-4819-146-12-200706190-00007)]
9. Greenstein E, Rosenthal J. ECG telemetry and long term electrocardiography. In: *Practical signal and image processing in clinical cardiology*. Chicago Illinois: Springer; 2010:303-317.
10. Lang M. Heart Rate Monitoring Apps: Information for Engineers and Researchers About the New European Medical Devices Regulation 2017/745. *JMIR Biomed Eng* 2017 Aug 18;2(1):e2 [FREE Full text] [doi: [10.2196/biomedeng.8179](https://doi.org/10.2196/biomedeng.8179)]
11. Lang M. Beyond Fitbit: a critical appraisal of optical heart rate monitoring wearables and apps, their current limitations and legal implications. *Albany Law J of Sci and Techn* 2017;28(1):39-72 [FREE Full text]
12. Clearbridge Vital signs. 2010. Cardioleaf URL: <http://www.clearbridgevitalsigns.com/fit.html> [accessed 2017-05-05] [WebCite Cache ID 6vgM9E4PR]
13. Qardio. 2016. Qardiocore URL: <https://www.getqardio.com/nl/qardiocore-wearable-ecg-ekg-monitor-iphone/> [accessed 2017-12-13] [WebCite Cache ID 6vgMKkNX2]
14. Albert D, Satchwell BR, Barnett KN. Heart rate monitoring system usable with a smartphone or computer. Patent nr. WO011156374 A2 2011.
15. SHL Telemedicine. 2014. Smartheart Pro: Quick Guide URL: <http://www.smartheartpro.com/quick-guide/> [accessed 2017-12-13] [WebCite Cache ID 6vgMkYwCv]
16. Alroy Y, Reinhold H. Portable ECG signaling device. Patent nr. WO01070101 A2 2001.
17. Morrison T, Silver J, Otis B. A single-chip encrypted wireless 12-lead ECG smart shirt for continuous health monitoring. 2014 Presented at: Symposium on VLSI Circuits Digest of Technical Papers; 2014; Seattle: University of Washington. [doi: [10.1109/VLSIC.2014.6858433](https://doi.org/10.1109/VLSIC.2014.6858433)]
18. Health Watch Technologies. 2015. Master Caution solutions, setting a new standard in remote cardiac monitoring & alerting URL: <https://tinyurl.com/y9odnfcj> [accessed 2017-01-08] [WebCite Cache ID 6wJwVwfy9]
19. Boehm A, Yu X, Neu W, Leonhardt S, Teichmann D. A Novel 12-Lead ECG T-Shirt with Active Electrodes. *Electronics* 2016 Nov 08;5(4):1-15. [doi: [10.3390/electronics5040075](https://doi.org/10.3390/electronics5040075)]
20. Roozenburg NFM, Eekels J. Product design, fundamentals and methods. Chichester: Wiley; 1995:13-16,227-230.

21. Muller MJ, Kuhn S. Participatory design. *Commun. ACM* 1993;36(6):24-28. [doi: [10.1145/153571.255960](https://doi.org/10.1145/153571.255960)]
22. Kanis H. Usage centred research for everyday product design. *Applied Ergonomics* 1998;29(1):75-82. [doi: [10.1016/s0003-6870\(97\)00028-8](https://doi.org/10.1016/s0003-6870(97)00028-8)]
23. Molenbroek J. Blackboard TU Delft. The Netherlands; 2002. WEAR - 3D body scans URL: [https://blackboard.tudelft.nl/webapps/blackboard/content/listContent.jsp?course_id= 55277_1&content_id= 2636006_1](https://blackboard.tudelft.nl/webapps/blackboard/content/listContent.jsp?course_id=55277_1&content_id=2636006_1) [accessed 2016-10-21] [WebCite Cache ID 6vgN8GANq]
24. 3M. 3M Red Dot Multi-Purpose Monitoring Electrodes with Sticky Gel 2560 Electrode. 2017. URL: <http://multimedia.3m.com/mws/media/6312850/2560-multi-purpose-mon-electrodes-with-sticky-gel-datasheet.pdf> [accessed 2018-07-16] [WebCite Cache ID 70xAlWPt0]
25. Plux Wireless Biosignals SA. Electrodes. URL: <https://store.plux.info/28-electrodes> [accessed 2018-07-16] [WebCite Cache ID 6vgGPF3Qm]
26. Somnomedics. Consumable supplies URL: <http://somnomedics-diagnostics.com/products/accessories/miscellaneous-accessories/consumable-supplies/> [accessed 2017-12-13] [WebCite Cache ID 6vgNMhxzc]
27. BITalino. (r)evolution Board Kit BT URL: <http://bitalino.com/en/board-kit-bt> [accessed 2017-12-13] [WebCite Cache ID 6vgNVqS9f]
28. Venkatesh V, Davis FD. A Theoretical Extension of the Technology Acceptance Model: Four Longitudinal Field Studies. *Management Science* 2000 Feb 01;46(2):186-204. [doi: [10.1287/mnsc.46.2.186.11926](https://doi.org/10.1287/mnsc.46.2.186.11926)]
29. Wenger W, Kligfield P. Variability of precordial electrode placement during routine electrocardiography. *Journal of Electrocardiology* 1996 Jul;29(3):179-184. [doi: [10.1016/S0022-0736\(96\)80080-X](https://doi.org/10.1016/S0022-0736(96)80080-X)] [Medline: [8854328](https://pubmed.ncbi.nlm.nih.gov/8854328/)]
30. Somerville S, Somerville J, Croft P, Lewis M. Atrial fibrillation: a comparison of methods to identify cases in general practice. *Br J Gen Pract* 2000 Sep;50(458):727-729 [FREE Full text] [Medline: [11050790](https://pubmed.ncbi.nlm.nih.gov/11050790/)]

Abbreviations

CVD: cardiovascular diseases

ECG: electrocardiogram/electrocardiography

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Original Paper

Using Mobile Health to Enhance Outcomes of Noncommunicable Diseases Care in Rural Settings and Refugee Camps: Randomized Controlled Trial

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Abstract

Background: Rural areas and refugee camps are characterized by poor access of patients to needed noncommunicable disease (NCD)-related health services, including diabetes and hypertension. Employing low-cost innovative eHealth interventions, such as mobile health (mHealth), may help improve NCDs prevention and control among disadvantaged populations.

Objective: The aim of this study was to assess the effect of employing low-cost mHealth tools on the accessibility to health services and improvement of health indicators of individuals with NCDs in rural areas and refugee camps in Lebanon.

Methods: This is a randomized controlled trial study in which centers were allocated randomly into control and intervention sites. The effect of an employed mHealth intervention is assessed through selected quality indicators examined in both control and intervention groups. Sixteen primary health care centers (eight controls, eight interventions) located in rural areas and Palestinian refugee camps across Lebanon were included in this study. Data on diabetic and hypertensive patients—1433 in the intervention group and 926 in the control group—was extracted from patient files in the pre and postintervention periods. The intervention entailed weekly short message service messages, including medical information, importance of compliance, and reminders of appointments or regular physician follow-up. Internationally established care indicators were utilized in this study. Descriptive analysis of baseline characteristics of participants, bivariate analysis, logistic and linear regression were conducted using SPSS (IBM Corp).

Results: Bivariate analysis of quality indicators indicated that the intervention group had a significant increase in blood pressure control ($P=.03$), as well as a significant decrease in the mean systolic blood pressure ($P=.02$), mean glycated hemoglobin (HbA_{1c} ; $P<.01$), and in the proportion of HbA_{1c} poor control ($P=.02$). Separate regression models controlling for age, gender, and setting showed a 28% increase in the odds of blood pressure control ($P=.05$) and a 38% decrease in the odds of HbA_{1c} poor control ($P=.04$) among the intervention group in the posttest period. Females were at lower odds of HbA_{1c} poor control ($P=.01$), and age was statistically associated with annual HbA_{1c} testing ($P<.01$). Regression models for mean systolic blood pressure, mean diastolic blood pressure, and mean HbA_{1c} showed that a mean decrease in HbA_{1c} of 0.87% ($P<.01$) pretest to posttest period was observed

among the intervention group. Patients in rural areas belonging to the intervention group had a lower HbA_{1c} score as compared with those in refugee camps ($P < .01$).

Conclusions: This study underlines the importance of employing integrative approaches of diseases prevention and control in which existing NCD programs in underserved communities (ie, rural and refugee camps settings) are coupled with innovative, low-cost approaches such as mHealth to provide an effective and amplified effect of traditional NCD-targeted care that can be reflected by improved NCD-related health indicators among the population.

Trial Registration: ClinicalTrials.gov NCT03580330; <https://clinicaltrials.gov/ct2/show/NCT03580330> (Archived by WebCite at <http://www.webcitation.org/70mhVEUwQ>)

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KEYWORDS

noncommunicable diseases; hypertension; diabetes mellitus; telemedicine; mobile health; rural health; refugees

Introduction

Prevalence of Noncommunicable Diseases

Noncommunicable diseases (NCDs) and its associated risk factors, including diabetes mellitus and hypertension (HTN), have become the leading cause of death and disability globally [1]. In 2015, NCDs accounted for 70% of the estimated 56.4 million deaths in the world [2]. Around 80% of deaths associated with NCDs occur in low- and middle-income countries (LMIC), with disproportional effects on underprivileged populations [3-5].

In the Eastern Mediterranean Region (EMR), the burden of NCDs is growing at an alarming rate, with approximately 57% of deaths in the region attributed to NCDs, an equivalent of 2.2 million death per year [6]. Around 51% of these deaths are premature (ie, below the age of 70 years) [6-8]. Unhealthy diets, physical inactivity, hyperglycemia, hyperlipidemia, elevated blood pressure (BP), and obesity are among the most prevalent underlying risk factors; linked to 65% of NCDs-related deaths [7,9,10].

Limited Access to Health Care in Rural Settings and Refugee Camps

Despite the rising burden of NCDs, health care systems of the majority of LMIC remain focused on treatment with minimal unsustainable investment in primary health care (PHC) [11]. Different economic, sociocultural, and geographic factors were also found to limit access of patients to NCDs preventive health care services in these settings [12,13]. Lack of essential knowledge and awareness on NCDs prevention, especially among underserved populations, often results in poor management of their disease, manifested in substandard health-related indicators manifested in poor glycemic or BP control and other preventable morbidities [14-22]. For refugees in specific, the situation is further aggravated by their restricted access to health care services because of a range of factors, including financial barriers, geographic attainability, safety, as well as cultural and language impediments [14]. NCD-specific care requires a systematic approach ranging from case finding and early detection, to identification of unhealthy behaviors, and compliance to regular long-term follow-up [23]. Such an approach is constrained by the limited health facility-based resources in rural and refugee settings, which hinders the ability

to implement proper NCD preventive measures in those settings. Further compounding the situation is the ongoing displacement of Palestinian and Syrian refugees and the protracted crises in the EMR, adding burden to already fragmented health systems of refugee-hosting countries regionally [7,18].

Use of Mobile Health as an Effective Add-On to Traditional Care

Despite the fact that remarkable efforts have been invested to decrease the burden of NCDs in EMR [21,22], a comprehensive change in the approach to NCDs in these settings remains necessary to meet the health needs of the displaced populations and host communities [14,16,20]. A systematic review of primary care models for NCDs interventions in LMIC recommends a programmatic structure focused on monitoring and evaluation of indicators, standardized care, and compliance to follow-up [24].

With the spread of mobile technology, mobile Health (mHealth) is regarded as a promising approach that is being increasingly explored to improve community health outcomes. As a subset of electronic health (eHealth), mHealth is defined as the use of mobile devices in health care delivery, mainly through short message service (SMS) messaging, voice calls, mobile phone apps, tablets, or wearable devices' apps [25]. SMS is an mHealth tool that holds great promise in addressing NCDs through health education and self-management, improving prevention and treatment strategies, and providing appointment reminders to improve compliance and the attendance of appointments in PHC centers (PHCCs). SMSs are also attractive because of their potential in overcoming financial and geographic barriers facing hard-to-reach populations [26-33]. A number of academic studies showed that mHealth helps improve prevention and control of diseases, including HTN and diabetes, by providing targeted interventions to disadvantaged populations living in remote areas where health services are often limited [26,34-43].

Lebanese Context and Relevance of the Study

According to recent reports, Lebanon faces an elevated NCDs-related mortality reaching as high as 85% [44]. Furthermore, the country hosts a large proportion of the world's Palestinian refugees, accounting around 10% of the country's population [45]. The burden of NCDs, namely diabetes and HTN, is expanding among underprivileged populations residing in rural areas and refugee camps primarily because of poor

screening and low early detection rates [46]. Suffering from limited availability of resources and fragmented infrastructure, PHCCs are to a large extent the sole convenient health facilities serving people in Lebanese rural areas where most refugees are residing [47]. The 2011 assessments of the United Nations Relief and Works Agency (UNRWA) revealed that one-third of Palestinian refugees in Lebanon residing in camps face hardships related to NCDs [48]. The refugees' struggle is aggravated by the unsatisfactory health services in such contexts [49]. Exploring innovative and effective strategies that can complement existing traditional care remains necessary in such settings to appropriately tackle the growing trend of NCDs in the country.

Mobile phone use is very common in Lebanon, reaching as high as 92.16% in 2015 [50]. A situational assessment study on Syrian refugees and digital health in Lebanon reported refugees as frequent users of mobile communications, including SMS, with each household having at least one mobile phone, suggesting the likely reach that an mHealth intervention could have in this context [51].

Despite the proven abundance of mobile phones in underserved settings, the potential role that mHealth could have in enhancing access of disadvantaged populations to adequate NCD care has never been investigated in Lebanon.

This study aims to assess the effect of employing a low-cost mHealth intervention on access to health services and improvement of health indicators of individuals suffering from NCDs in rural areas and refugee camps in Lebanon. The mHealth intervention is of dual components addressing both patients and health providers through informative health SMSs targeting the former and online training modules and support forums targeting the latter. This study, implemented in collaboration with the Lebanese Ministry of Public Health (MOPH) and UNRWA, is the first to employ a mHealth intervention in Lebanon in rural and refugee settings. The results will provide evidence that could help in restructuring existing NCDs action plan at the systems level to optimally respond to the needs of displaced refugees and host communities and enhance compliance to adequate care while containing cost through adopting an innovative preventive approach.

Methods

Study Design

This study reports on a community trial in which PHC centers, along their respective catchment areas, were randomly allocated into control and intervention sites with the aim of assessing the change in selected NCD care quality indicators (QIs) among community individuals and patients. Patients in the intervention sites received a 1-year mHealth intervention, and their pre- and postintervention outcomes were assessed through measurement of QIs. The study was conducted over a period of 2 years, covering 1 year of preintervention collection of QIs and 1 year of delivery of the mHealth intervention, followed by a postintervention period of 1 month of postintervention QIs collection (Figure 1).

Participants Selection and Data Collection

The study population comprised sixteen PHCCs in Lebanon: ten located in rural areas and belonging to the Lebanese MOPH PHC National Network [52] and six are UNRWA centers chosen from Palestinian refugee camps in Lebanon. These centers were randomly assigned into intervention and control groups. Five MOPH and three UNRWA centers were allocated to each of the intervention and control groups for a total of eight sites in each of the groups.

One QI collector was hired at each of the sixteen PHCCs included in the study (both intervention and control) to collect relevant QIs from patients' records at two points in time: (1) at baseline period, also noted as the preintervention period, where QIs were collected from records of all patients visiting included PHCCs for the 1-year preintervention period from March 2014 to March 2015 and (2) after delivery of intervention, also noted as the postintervention period, where QIs were collected from records of patients visiting the PHCCs for the 1-year intervention period from June 2015 to June 2016.

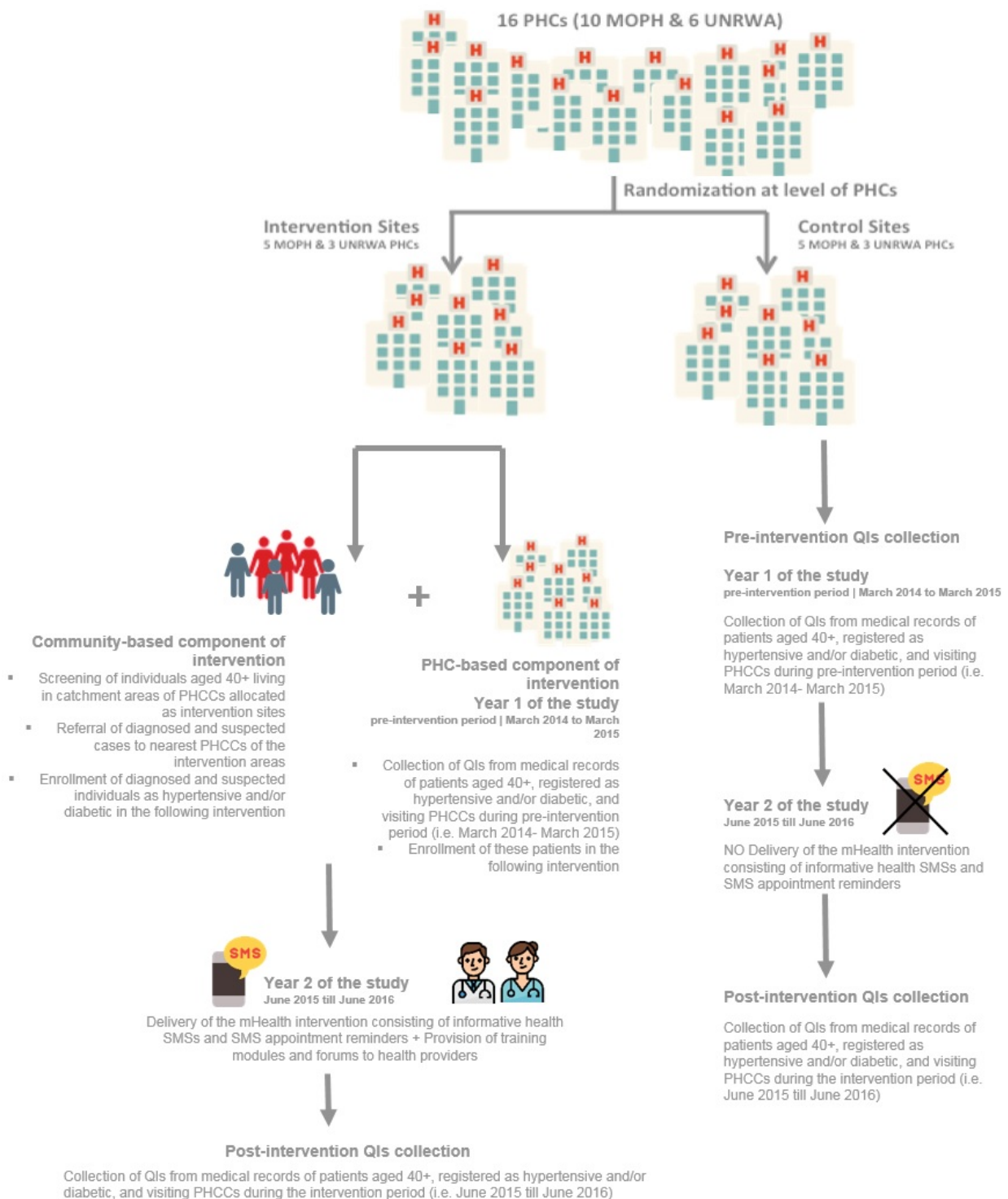
The inclusion criteria of the records of patients during the QIs collection periods was based on the health status and age of the patients. To be included in this study, patients had to be registered at the PHCCs as diabetics or hypertensive and aged 40 years or more. Only Lebanese patients registered at the included MOPH PHCCs in rural areas and Palestinian refugee patients registered at the included UNRWA health centers were eligible for inclusion if the aforementioned criteria were met. Records of patients whose nationality was not Lebanese nor Palestinian and whose age was less than 40 years were not eligible for inclusion. No exclusion based on gender, educational and literacy level, disability, or presence of other medical conditions took place. Data were extracted from patients' medical records for all patients meeting the inclusion criteria. Demographics including gender, age, and telephone number, in addition to medical information related to the QIs such as last result of BP, last result of glycated hemoglobin (HbA_{1c}), smoking status, and dates of last visit for HbA_{1c} testing, for eye check-up, or foot exam, were collected. Numerical values and dates were reported whenever available within the corresponding data collection period; otherwise, not reported was entered for missing values.

Intervention

The eSahha project is a two-pronged mHealth interventional project targeting catchment areas of PHCCs located in Lebanese rural areas and Palestinian refugee camps, where access to health knowledge and health services is known to be limited.

The overall eSahha intervention consisted of two related components: one that is community-based and another that is PHC center-based. The community-based component included community screening for HTN and diabetes by trained community health workers among individuals falling within the age group at higher risk of developing NCDs—40 years or older—in the catchment areas of the eight intervention centers.

Figure 1. Summary of the methodology of the study. MOPH: Ministry of Public Health; PHC: primary health care; PHCC: primary health care center; QI: quality indicator; SMS: short message service; UNRWA: United Nations Relief and Works Agency.



Individuals already diagnosed with or suspected of being diabetic, hypertensive, or both were referred to the nearest intervention PHCC for NCD-specific clinical care and were targeted by SMS messages originating from a preexisting mobile communication platform used for mass messaging hosted by a Lebanese telecommunication company and scheduled for delivery by a research assistant of the research team. The SMSs were developed by a family physician based on the MOPH guidelines for prevention and management of HTN and diabetes.

A weekly educational health SMS was sent every Monday afternoon for the intervention period of 1 year. SMS content covered different health themes providing health information on lifestyle, dietary habits, body weight, smoking, medications, importance of compliance, as well as symptoms and self-management of HTN and diabetes. Community individuals who were diagnosed and were receiving necessary care previous to our intervention were sent weekly informative health SMS, as well as customized SMSs reminders to follow up on their

scheduled medical appointments (eg, to check their HbA_{1c} levels and have their annual foot or eye exams). The messages were sent to mobile phones of the targeted individuals suffering from HTN or diabetes included in the intervention or, in cases where the targeted individuals did not own a mobile phone, messages were sent with their consent to the cell phones of their respective closest relatives (eg, son, daughter, or husband). Individuals in the control group (ie, living in catchment areas of control PHCCs) did not receive SMS messages and were thus receiving the usual care. The messages were initially formulated in English and then translated to Arabic and sent using simplified Arabic terms to match the different levels of health literacy of the target lay population. The length of each message was restricted to a maximum of 70 characters. On the other hand, the PHC center-based component of the intervention consisted of sending the same weekly informative health SMS, as well as appointment reminders customized to the respective time for check-ups to patients registered as diabetic or hypertensive at baseline at the PHCCs belonging to the intervention group. Patients receiving the SMSs were not required to reply to the SMSs at any point in time.

The PHC center-based component of the intervention also included training of health care providers, namely physicians and nurses, working in the intervention PHCCs, using eHealth tools consisting of (1) Online modules focusing on clinical guidelines for treating diabetes and HTN and others on provider-patient communication strategies (ie, increasing compliance) and (2) Online forums and frequently asked questions mainly dedicated to peer-to-peer knowledge sharing of treatment and communication techniques.

Measurements of Quality Indicators

A set of internationally recognized QIs for diabetes and HTN were employed to monitor the effectiveness of the intervention (Table 1). The choice of indicators was based on their wide acceptance and use in evaluating care effectiveness on one hand and on the ability of the health information system available in the included MOPH and UNRWA PHCCs to extract the needed data on the other hand.

Statistical Analysis

Data on BP (systolic blood pressure, SBP or diastolic blood pressure, DBP), HbA_{1c}, smoking status, as well as dates of eye and foot check-ups were obtained and analyzed using statistical software package SPSS (version 24.0). Sample baseline characteristics were summarized for the intervention and control groups using mean and SD for numerical variables and frequency and percentage for categorical variables. Annual check-ups, including eye and foot exams, as well as HbA_{1c} testing were considered acceptable if done according to recommended guideline periods, while a 30-days grace period was allowed. Pearson chi-square test (χ^2) and independent *t* test were used to assess the difference in quality indicators before and after the intervention. Logistic regression was used to evaluate the impact of the intervention on HbA_{1c} poor control, BP control, and annual HbA_{1c} testing, while controlling for age, gender, and setting. Similarly, linear regression was used to assess the impact on mean SBP, DBP, and HbA_{1c}, while controlling for age, gender, and setting. All analyses were carried at a .05 significance level.

Table 1. Selected quality indicators to monitor the effectiveness of the intervention.

Domain and Measure	Measure description
Hypertension	
Mean blood pressure	Means SBP ^a and DBP ^b were assessed after collecting the most recent result of each patient's blood pressure in terms of SBP or DBP
Blood pressure control	Percentage of patients with most recent blood pressure <140/90 mmHg
Annual eye check-up	Percentage of patients receiving at least one eye check-up annually as per recommended guideline (date within the data collection period, while a 30-day grace period was allowed)
Diabetes	
Annual HbA _{1c} ^c testing	Percentage of patients with one or more HbA _{1c} tests annually as per recommended guideline (date within the data collection period, while a 30-day grace period was allowed)
Mean HbA _{1c}	Mean HbA _{1c} was assessed after collecting each patient's most recent result of HbA _{1c}
HbA _{1c} poor control	Percentage of patients with most recent HbA _{1c} level >9.0% (poor control); Mean HbA _{1c} is also assessed
Annual smoking status check	Percentage of patients whose smoking status was ascertained and documented annually
Annual foot exam	Percentage of patients receiving at least one foot exam annually as per recommended guideline (date within the data collection period, while a 30-day grace period was allowed)
Annual eye check-up	Percentage of patients receiving at least one eye check-up annually as per recommended guideline (date within the data collection period, while a 30-day grace period was allowed)

^aSBP: systolic blood pressure.

^bDBP: diastolic blood pressure.

^cHbA_{1c}: glycated hemoglobin.

Ethical Considerations

Ethical approval was obtained from the American University of Beirut Institutional Review Board before conducting the study. As per the approved protocol, approval of participation and informed consent were obtained from PHC centers' directors. Directors and QI collectors recruited from the centers in the two groups were informed about the purpose of the study and its expected outcomes. Confidential handling of all data collected was ensured throughout the study period. In addition, SMS messages were sent to patients in the intervention group after obtaining their consent. In case the targeted patients did not own a mobile phone, their consent was received to send the messages to the phone of their selected closest relatives (eg, son, daughter, or husband). Those relatives in turn had to also consent to receiving those messages and passing them to the patients.

Results

Participants' Demographic Characteristics

Table 2 presents the baseline demographic and clinical characteristics of patients in the intervention and control groups. The data of 1433 patients in the intervention groups and 926 patients in the control groups were included in the analysis. At baseline, more than half of patients were females, 56.3% (454/807) in the intervention group and 56.2% (292/520) in the control group. As for age distribution, a higher proportion was in the age range of 56 to 70 years, representing 44.1% (353/800)

of those in the intervention group and 40.1% (200/499) of those in the control. Majority of patients in both groups were living in Lebanese rural areas (61.97%, 888/1433 and 60.8%, 563/926 respectively). In the intervention group, 64.27% (921/1433) of patients were hypertensive, and 35.73% (512/1433) were diabetic. On the other hand, 67.6% (626/926) of patients in the control group were hypertensive, and 32.4% (300/926) were diabetic. There was no statistical difference between the two groups except for age ($P=.003$; Table 2).

Hypertension Quality Indicators

Bivariate analyses of quality indicators are shown in Table 3. All dates are considered acceptable if done within the recommended guideline periods, while a 30-day grace period was allowed (refer to Table 1). A significant increase in BP control was observed in the intervention group between the pre- and the posttest periods (58.2%, 530/911 to 63.6%, 426/670, $P=.03$), which was not replicated in the control group ($P=.37$). Similarly, a significant drop in the mean SBP was observed among the intervention group (133.7 mmHg, SD 16.1 pretest and 131.8 mmHg, SD 15.8 posttest, $P=.02$) but not in the control group ($P=.65$). In both study groups, a lower proportion of annual eye check-up was observed in the post test as compared with the pretest (48.4%, 446/921 to 38.9%, 268/689 in intervention group and 27.8%, 174/626 to 21.1%, 133/630 in the control group, $P<.01$ for both). No statistical significance was found in the pre- or posttest difference in the mean DBP in either groups ($P=.14$ and $P=.81$, respectively).

Table 2. Baseline demographic and clinical characteristics of participants by study group. No significant differences between gender, setting, and disease category across the two groups were identified using chi-square test; the difference in age groups between intervention and control at baseline is statistically significant ($P=.003$). Bonferroni post-hoc test reveals that the difference is in the age group ≥ 71 years.

Variable	Intervention, n (%)	Control, n (%)
Total number of participants ^a	1433 (100.0)	926 (100.0)
Gender		
Male	353 (43.7)	228 (43.8)
Female	454 (56.3)	292 (56.2)
Age group (years)		
40-55	252 (31.5)	134 (26.9)
56-70	353 (44.1)	200 (40.1)
≥ 71	195 (24.4)	165 (33.1)
Setting		
Rural areas	888 (62.0)	563 (60.8)
Palestinian refugee camps	545 (38.0)	363 (39.2)
Disease category		
Diabetes	512 (35.7)	300 (32.4)
Hypertension	921 (64.3)	626 (67.6)

^aSome numbers under some categories may not add up to the total because of missing values.

Table 3. Bivariate analysis of hypertension (HTN) and diabetes mellitus quality indicators by study group.

Type of quality indicators	Intervention			Control		
	Pretest	Posttest	<i>P</i> value	Pretest	Posttest	<i>P</i> value
HTN quality indicators						
BP ^a controlled, n (%)	530 (58.2)	426 (63.6)	.03 ^b	316 (60.9)	362 (58.4)	.37
SBP ^c , mean mmHg (SD)	133.69 (16.10)	131.80 (15.79)	.02 ^b	133.24 (17.08)	133.68 (16.91)	.65
DBP ^d , mean mmHg (SD)	79.16 (9.13)	78.47 (9.09)	.14	78.24 (9.41)	78.09 (8.97)	.81
Annual eye check-up, n (%)	446 (48.4)	268 (38.9)	<.01 ^b	174 (27.8)	133 (21.1)	<.01 ^b
Diabetes mellitus quality indicators						
Annual HbA _{1c} ^e testing, n (%)	264 (51.6)	397 (74.1)	<.01 ^b	100 (33.3)	208 (71.2)	<.01 ^b
HbA _{1c} poor control, n (%)	75 (28.2)	82 (20.3)	.02 ^b	22 (21.8)	46 (22.2)	.93
HbA _{1c} , mean % (SD)	8.00 (1.89)	7.20 (2.06)	<.01 ^b	7.73 (1.72)	7.69 (1.84)	.88
Proportion of smokers, n (%)	159 (35.0)	169 (31.8)	.29	60 (36.1)	64 (31.4)	.33
Annual foot exam, n (%)	224 (43.8)	227 (42.4)	.65	118 (39.3)	105 (36.0)	.40
Annual eye check-up, n (%)	266 (52.0)	183 (34.1)	<.01 ^b	111 (37.0)	68 (23.3)	<.01 ^b

^aBP: blood pressure.

^bIndicates to statistical significance at .05 CI.

^cSBP: systolic blood pressure.

^dDBP: diastolic blood pressure.

^eHbA_{1c}: glycated hemoglobin.

Diabetes Quality Indicators

In the intervention group, glycemic control results improved in the intervention group but not in the control group. The proportion of HbA_{1c} poor control decreased significantly in the intervention group from 28.2% to 20.3% ($P=.02$), whereas it remained unchanged in the control group (21.8% vs 22.2%, $P=.93$). Likewise, a significant reduction in the mean HbA_{1c} was noted in the intervention group (8.00%, SD 1.9 to 7.2%, SD 2.1, $P<.01$) but not in the control group ($P=.88$). Furthermore, the proportion of annual HbA_{1c} testing done within recommended guideline period increased for both groups (51.6%-74.1% in the intervention and 33.3%-71.2% in the control, $P<.01$ for both). However, the proportion of annual eye check-up done within recommended guideline period decreased significantly in both groups (52.0% down to 34.1% in intervention and 37.0% down to 23.3% in control, $P<.01$ for both). Differences in proportions of smoking and annual foot exam within recommended guideline period were not statistically significant in either group.

Regression Models

Separate regression models were run to gauge the intervention impact on the study groups while controlling for baseline characteristics: age, gender, and setting. Table 4 shows the results of the logistic regressions, where BP control, HbA_{1c} poor control, and annual HbA_{1c} testing act as the dependent variables (consecutively). Annual HbA_{1c} testing is within recommended guideline: dates are considered acceptable if done within the

recommended guideline period, while a 30-day grace period was allowed (refer to Table 1). When considering BP control, Table 4 indicates that for the intervention group, there was a 28% increase in the odds of BP control in the posttest period as compared with the pretest period (odds ratio, OR 1.28, 95% CI 1.00-1.64, $P=.05$), independent of age, gender, and setting. The OR for study period was not statistically significant in the control group ($P=.11$). Rural areas reported lower odds of BP control as compared with refugee camps in both study groups (OR 0.31, 95% CI 0.24-0.40 intervention group; OR 0.22, 95% CI 0.15-0.30 control group; $P<.01$ for both). A 38% decrease in the odds of HbA_{1c} poor control among the intervention group from the pretest to the posttest study periods was observed (OR 0.62, 95% CI 0.39-0.97; $P=.04$), independent of age, gender, and setting. The study period OR was not statistically significant among the control group ($P=.26$). Females were at lower odds of HbA_{1c} poor control among the intervention group (OR 0.59, 95% CI 0.39-0.89; $P=.01$), whereas age ORs were statistically significant for both study groups (OR 0.97 for both, $P<.01$ and $P=.03$, respectively). With regard to annual HbA_{1c} testing, the results reveal that both groups had an increase in the odds of doing the test with recommended guideline period (OR 2.52, 95% CI 1.81-3.49 for intervention and OR 4.26, 95% CI 2.79-6.49 for control; $P<.01$ for both). Age was statistically associated with annual HbA_{1c} testing (OR 0.98, $P<.01$) for the intervention group, and rural settings were at higher odds of conforming with HbA_{1c} testing guidelines in both study groups as compared with refugee camps participants (OR 4.43 for intervention and OR 2.22 for control; $P<.01$ for both).

Table 4. Logistic regression model of blood pressure (BP) control, glycated hemoglobin (HbA_{1c}) poor control, and annual HbA_{1c} testing by study group.

Indicator	Intervention		Control	
	OR ^a (95% CI)	<i>P</i> value	OR (95% CI)	<i>P</i> value
BP control				
Study period				
Posttest	1.28 (1.00-1.64)	.05 ^b	1.28 (0.95-1.72)	.11
Pretest	— ^c	—	—	—
Gender				
Female	1.12 (0.88-1.44)	.36	0.97 (0.74-1.29)	.85
Male	—	—	—	—
Age (continuous)	0.99 (0.98-1.00)	.06	0.99 (0.98-1.00)	.03 ^b
Setting				
Rural areas	0.31 (0.24-0.40)	<.01 ^b	0.22 (0.15-0.30)	<.01 ^b
Palestinian refugee camps	—	—	—	—
HbA_{1c} poor control				
Study period				
Posttest	0.62 (0.39-0.97)	.04 ^b	0.68 (0.35-1.33)	.26
Pretest	—	—	—	—
Gender				
Female	0.59 (0.39-0.89)	.01 ^b	0.84 (0.47-1.49)	.56
Male	—	—	—	—
Age (continuous)	0.97 (0.96-0.99)	<.01 ^b	0.97 (0.95-1.00)	.03 ^b
Setting				
Rural areas	0.71 (0.45-1.11)	.13	0.81 (0.43-1.51)	.51
Palestinian refugee camps	—	—	—	—
Annual HbA_{1c} testing				
Study period				
Posttest	2.52 (1.82-3.49)	<.01 ^b	4.26 (2.79-6.49)	<.01 ^b
Pretest	—	—	—	—
Gender				
Female	1.17 (0.85-1.61)	.34	1.04 (0.69-1.56)	.87
Male	—	—	—	—
Age (continuous)	0.98 (0.97-0.99)	<.01 ^b	1.01 (0.99-1.03)	.37
Setting				
Rural areas	4.43 (3.20-6.13)	<.01 ^b	2.22 (1.46-3.39)	<.01 ^b
Palestinian refugee camps	—	—	—	—

^aOR: odds ratio.^bIndicates to statistical significance of .05 CI.^cReference category.

Table 5. Linear regression model of the means systolic blood pressure (SBP), diastolic blood pressure (DBP), and glycated hemoglobin (HbA_{1c}) by study group.

Indicator	Intervention			Control		
	Beta	SE	<i>P</i> value	Beta	SE	<i>P</i> value
Mean SBP						
Study period						
Posttest	-1.12	0.90	.21	-1.83	1.18	.12
Pretest	— ^a	—	—	—	—	—
Gender						
Female	-.59	0.90	.51	.30	1.11	.79
Male	—	—	—	—	—	—
Age (continuous)	.08	0.04	.03 ^b	.12	0.04	.01 ^b
Setting						
Rural areas	7.98	0.92	<.01 ^b	9.07	1.21	<.01 ^b
Palestinian refugee camps	—	—	—	—	—	—
Mean DBP						
Study period						
Posttest	-.49	0.53	.36	-.90	0.65	.16
Pretest	—	—	—	—	—	—
Gender						
Female	-1.89	0.53	<.01 ^b	-.73	0.61	.23
Male	—	—	—	—	—	—
Age (continuous)	-.02	0.02	.26	-.07	0.02	<.01 ^b
Setting						
Rural areas	1.66	0.54	<.01 ^b	2.17	0.67	<.01 ^b
Palestinian refugee camps	—	—	—	—	—	—
Mean HbA_{1c}						
Study period						
Posttest	-.87	0.19	<.01 ^b	-.22	0.27	.41
Pretest	—	—	—	—	—	—
Gender						
Female	-.42	0.17	.01 ^b	-.21	0.22	.35
Male	—	—	—	—	—	—
Age (continuous)	-.01	0.01	.12	-.03	0.01	<.01 ^b
Setting						
Rural areas	-.65	0.19	<.01 ^b	.07	0.25	.76
Palestinian refugee camps	—	—	—	—	—	—

^aRefers to reference category.

^bRefers to statistical significance at .05 CI.

Table 5 summarizes the regression models for mean SBP, mean DBP, and mean HbA_{1c}. After controlling for age, gender, and setting, the mean changes in SBP and DBP across the study period were not statistically significant (beta=-1.12 mmHg, SD

0.90, *P*=.21 for mean SBP intervention group; beta=-1.83 mmHg, SD 1.18, *P*=.12 for mean SBP control group; beta=-.49 mmHg, SD 0.53, *P*=.36 for mean for DBP intervention group; and beta=-.90 mmHg, SD 0.65, *P*=.16 for mean DBP control

group). Only mean HbA_{1c} retained statistical significance in the multivariate analysis. A mean decrease in HbA_{1c} of 0.87 pretest to posttest period was observed among the intervention group (beta=-.87, SD 0.19, $P<.01$) but not in the control group ($P=.41$). This change was independent of age, gender, and setting. On average, females in the intervention group had a lower HbA_{1c} score compared with their male counterparts (beta=-.42, SD 0.17, $P=.01$). Age was associated with a decrease in HbA_{1c}, which was seen in the control group only (beta=-.03, SD 0.01, $P<.01$), and patients in rural areas belonging to the intervention group had a lower HbA_{1c} score as compared with refugee camps (beta=-.65, SD 0.19, $P<.01$).

Discussion

Principal Findings

First of its kind in the country, the study revealed promising findings in regard to the use of mobile phone SMS technology to improve the management of NCDs among individuals living in rural areas and Palestinian refugee camps in Lebanon. Postintervention measurements of quality health indicators in the intervention group showed remarkable improvement in comparison with preintervention assessments through enhanced BP control, reduced mean SBP, as well as decrease in HbA_{1c} levels and HbA_{1c} poor control. Comparison across the two settings (ie, rural areas vs refugee camps) showed differential improvements in diabetes and HTN quality indicators where patients living in refugee camps exhibited improved BP control and lower means of SBP and DBP compared with patients from rural areas. Patients in rural areas had comparatively lower HbA_{1c} scores and were at higher odds of conforming to HbA_{1c} testing. No clear direct effect of the implemented mHealth intervention on change in smoking habits, patients' utilization of PHC services, and compliance with visits for HbA_{1c} testing, eye check-ups, and foot exams were noted.

Our findings of a considerable increase in BP control only in patients receiving the mHealth intervention are in agreement with those of similar studies conducted in Spain, South Korea, and Russia [40,53,54]. In contrast, Wald et al and Orsama et al had findings showing no statistically significant patterns for amelioration neither in BP control nor in means SBP and DBP in the SMS intervention group [55,56]. After controlling for age, gender, and setting, only BP control retained statistical significance in the regression model, with a 28% increase in the odds of BP control in the posttest period as compared with the pretest period. No significant difference for BP control was found across age and gender. There is a paucity of data in the literature with regard to differences in intervention outcomes among hypertensive patients based on age, gender, or setting [40,53,54].

The group that received SMS messages had a clinically important and statistically significant change in glycemic control. More specifically, the intervention group showed a significant decrease both in HbA_{1c} levels (from 8.00%, SD 1.89 to 7.2%, SD 2.06) and in HbA_{1c} poor control (from 28.2%-20.3%) after a 1-year SMS intervention. The control

group, on the other hand, showed a slight increase in HbA_{1c} poor control within the same period. The 38% decrease in the odds of HbA_{1c} poor control among the intervention group from the pretest to the posttest study periods was independent of age, gender, and setting in the multivariate analysis. The same applied for the reported change in HbA_{1c} (drop by 0.8%) in the intervention group. This finding concurs with those of a study from Bangladesh, where HbA_{1c} levels dropped by a mean of 0.85% after the SMS intervention [38]. Furthermore, this reported change is higher than those from previous studies, such as a 0.7% reduction in HbA_{1c} posttest in Iraq [57], 0.4% in Saudi Arabia [58], 0.53% in a meta-analysis by Arambepola et al [26], and 0.39% in a meta-analysis by Liu and Ogwu [59]. Other studies have shown a higher reductions in HbA_{1c} posttest ranging from 0.89% to 2.76% [60-63]. In this study, it was shown that HbA_{1c} levels and HbA_{1c} poor control differed significantly across gender, with females in the intervention group having a lower HbA_{1c} score and a lower odds of HbA_{1c} poor control compared with their male counterparts. One explanation relates to females being more attentive to SMS messages [38]. However, such explanation requires confirmation in future studies. On the other hand, in an Iraqi study [57] and a systematic review of 17 articles [64], changes in HbA_{1c} levels following SMS intervention were not related to any of the demographic factors including age, gender, and nationality. Similarly, age was not associated with a decrease in HbA_{1c} in our study's intervention group, yet the odds of having HbA_{1c} poor control decreased with age for both study groups.

Difference in Quality Indicators Across Setting

The logistic regression model revealed that participants living in rural areas reported lower odds of BP control compared with patients living in refugee camps in both study groups. This was also apparent in the linear regression model, where the means SBP and DBP were higher among participants in rural areas as compared with their refugee camps counterparts. In contrast, patients living in rural areas had a lower HbA_{1c} score in intervention group and were also at higher odds of conforming to HbA_{1c} testing guidelines in both study groups as compared with Palestinian refugee camps participants. The fact that the improvement in diabetes and HTN quality indicators do not align across the two settings flags an improvement opportunity in the mHealth program design and in the NCD care configurations across the two settings. It also highlights an opportunity for learning across the two settings. The fact that BP control was better among patients living in refugee camps in both study groups might reflect the role of the UNRWA's NCD program integrated in the intervention and control centers and entailing primary, secondary, and tertiary NCDs' prevention [10]. The presence of such a program at UNRWA may have enhanced the effectiveness of the mHealth interventions and facilitated improved access to services. However, as our study reveals, further efforts are needed to improve diabetes prevention and care for Palestinian refugees in regards to improving their glycemic control and treatment compliance [65]. Furthermore, the finding that patients' conforming to HbA_{1c} testing guidelines was better among patients from rural areas in both study groups

echoes that the MOPH NCD program was more effective in diabetes management and control as compared with HTN [66]. The presence of an advanced diabetes control program may have enhanced the effectiveness of the mHealth interventions employed in this study. Our study reveals that the success and effectiveness of mHealth interventions is contingent on the service configurations and care programs employed at PHCCs. Despite the best efforts of the research team to ensure comparable service configuration at both rural PHCCs and those at UNRWA refugee camps, it appears that the maturity of the existing programs and the service configurations at each setting played an important role in the care outcomes at the end of the study. This underlines the importance of employing integrative approaches of diseases prevention and control in which existing NCD programs in underserved communities (ie, rural and refugee camps settings) are coupled with innovative approaches such as mHealth to provide an amplified effect of traditional NCD-targeted care.

Changes in Smoking Habits

Our study revealed an unremarkable and insignificant reduction in the proportion of smokers in intervention and control groups after a 1-year SMS intervention. This is in agreement with a study that showed that lifestyle behaviors such as smoking were not modified throughout the self-care education intervention whether via SMS, pamphlets or face-to-face meetings [36]. However, our finding is in contrast with other studies carried out in Iran, United Kingdom, and New Zealand [63,67,68], the three of which revealed a significant positive modification in smoking cessation in the intervention group based on SMSs. mHealth has the potential to support smoking cessation, especially when considered as an add-on to other smoking cessation services [67,69]. This again reveals that a successful mHealth program is contingent on the presence of other programs to support the creation of successful and sustainable change in behavior. Yet, it is worth mentioning that achieving actual changes in smoking habits and attaining smoking cessation necessitate employing integrated theoretical models of health behavioral change to design effective health behavior interventions. Such models recognize that behavioral change is dependent on a number of factors that are necessary for it to take place [70]. These factors include the individual's strong intention to perform this behavior; having necessary information, skills, and capabilities required to actually perform it; and is not faced by any environmental constraints that may hinder the behavioral performance [70]. Although our mHealth intervention may have supported one of these factors toward the achievement of changes in smoking habits, it may have not interfered with other factors that are necessary to address to witness a significant and sustainable change.

Changes in Patients' Utilization of Primary Care Services

In this study, targeted SMSs for reminders did not generate a clear intervention effect on patients' utilization of primary care services, as well as their compliance with visits for HbA_{1c} testing, eye check-ups, and foot exams. Both bivariate and multivariate analyses revealed that access for annual HbA_{1c} testing increased significantly in both the intervention and

control groups. This can be explained by the initiatives of the MOPH and UNRWA's NCD programs aiming at the early detection of NCDs, proper management of these diseases, and the promotion of health awareness in all MOPH and UNRWA centers. However, the results of this study's QIs reveal that these efforts were translated into measurement but not into outcomes, except for the intervention group where patients were receiving SMS messages. Furthermore, intervention bias could have taken place because QI collectors at PHCCs were aware of data collection post intervention. As a matter of fact, the increased percentage of recorded dates of visits to PHCCs for HbA_{1c} testing in both the control and intervention groups may be the result of improved documentation rather than an actual enhanced access to PHC services. Nonetheless, clinical measurements of QIs, such as HbA_{1c} levels, as well as SBP and DBP levels, reflect the general centers' performance as they represent actual results rather than recorded dates. In addition, age was found to be statistically associated with annual HbA_{1c} testing for the intervention group, reflecting a better compliance. Similarly, in New Jersey, older age seemed to have contributed to enhanced access to health services as older individuals may have conditions which necessitate a closer follow-up in PHCCs [71].

Studies have shown that SMS reminders considerably ameliorate the prospect of attending clinical appointments in general [33,72,73]. However, there is a notable gap in the literature with regard to whether SMS reminders sent to patients' mobiles are successful and effective in decreasing nonattendance and increasing compliance to eye check-ups and foot exams among diabetic and hypertensive patients. In this study, there was a decrease in the access for annual eye check-up and foot exam among patients in both groups, in the posttest as compared with the pretest. This decrease was significant only for annual eye check-up among both hypertensive and diabetic patients. Intervention and control PHCCs assured that the same ophthalmologists are still providing eye care in these centers, and none of them quitted. Yet, the decrease in the access for annual eye check-up and foot exam can be explained by the considerable strain that the Syrian refugee influx in Lebanon is putting on host communities and on the resources in PHCCs. Consequently, the demand for chronic diseases' care has increased dramatically leading to long waiting times in PHCCs and causing providers to practice in more than one center. Hence, Lebanese patients are adversely affected by an increased competition for accessing services. Although this was less evident in the general care for chronic diseases because of the presence of a good number of providers, competition for services was more pronounced in referral to specialist care as in the case of ophthalmologists as their numbers in rural and refugee camps is quite limited.

Additional efforts should be made from the providers' side to underscore the importance of improved patients' compliance with visits for HbA_{1c} testing, eye check-ups, and foot exams. Providers are encouraged to utilize the integrated online modules, one of this study's provider-side eHealth tools, especially the provider-patient communication strategies to focus on the importance of increasing compliance. Conveying face-to-face healthy information has a beneficial effect on

adherence. Therefore, using SMSs as a reminder can come after face-to-face education to support it [36,42].

Limitations

A number of limitations in this study are worth mentioning. Data on age and gender of certain participants in both the intervention and control groups were missing. In addition, the study is characterized by its large sample size, which may have led to statistical significance without necessarily a parallel clinical or practical significance. Our results cannot be solely attributed to our intervention; the presence of advanced NCD programs at both the MOPH and UNRWA PHCC networks may have biased the findings, especially in the cases where a control site showed a significant change. Given that in some cases the owners of the phone numbers to which the SMSs were sent were not the patients themselves but rather family members, the interventional SMS messages may have not been transmitted to their final recipients (ie, patients) who are the target population of our study.

Other limitations may be embedded in the design of the intervention itself. For example, patients of low literacy level may have not benefitted optimally from the intervention because of a decreased capacity of understanding its content. Thus, it is worth bringing to attention for future research the need for pilot testing the SMS text messages interventions with individuals of low literacy level, using further simplified content of messages, and more importantly coupling SMS text messages with voice messages to enhance equitable access of illiterate patients to the information shared [74].

Policy and Practice Recommendations

Findings from this study should be considered by decision makers at the MOPH and the UNRWA, as the employed eHealth strategies, especially SMS messages, could be easily implemented within the PHC context and adapted to suit all diabetic and hypertensive patients across all centers. Given that the proposed eHealth interventions stem from the needs of the communities served, decision makers are advised to scale-up and use mHealth as a strategy for improving access to PHC, especially with the ongoing influx of Syrian refugees. However,

decision makers are reminded to ensure the presence of adequate NCD curative and preventive services to enhance the effectiveness of mHealth programs. The study can also serve as a guidance in the formulation of the national eHealth policy in Lebanon. The findings should also be of interest to primary care providers, who should be adequately trained on accessing the proposed eHealth tools, while emphasizing to patients the importance of SMSs as a method to increase awareness about diseases and compliance to treatment. As mHealth is promising in delivering messages to hard-to-reach populations, the findings of this study may be applicable to similar contexts in the region.

Conclusions

Given the potential benefits of mHealth, more specifically SMS-based health interventions for the management and control of chronic conditions, its implementation in the EMR, and specifically Lebanon, is crucial. In this study, the statistically significant improvements in clinical measurements of NCD-related QIs among diabetic and hypertensive patients in Lebanese rural areas and Palestinian refugee camps reveal that the employment of SMSs may make a difference in NCDs care. The most pronounced effect was observed in improved BP control, mean SBP, HbA_{1c} poor control, and mean HbA_{1c} among patients who received weekly SMSs for 1 year. Further studies are needed to provide concrete evidence with regard to the effectiveness and usefulness of reminder SMSs for improving compliance and access to services in PHC centers. Future research is also advisable on patients' perceptions and views on the acceptability and utility of the SMS service, as well as providers' attitudes and barriers toward the full implementation of clinical guidelines. A separate analysis of different activities using this project's eHealth interventions is currently underway with promising results. mHealth is a simple and a socially acceptable technique that can be integrated into routine care at a low cost. As mobile phones are widely accessible across the globe, including hard to reach and underserved populations, the need is underscored for additional studies to provide evidence on the utility of SMS-based health interventions and their impact on the care of underserved individuals and communities.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.1).

[[PDF File \(Adobe PDF File\), 788KB - mhealth_v6i7e137_app1.pdf](#)]

References

1. World Health Organization. 2012. The top 10 causes of death URL: <http://www.who.int/en/news-room/fact-sheets/detail/the-top-10-causes-of-death> [WebCite Cache ID 6z7EhUNNC]
2. World Health Organization. 2015. NCD mortality and morbidity, Global Health Observatory (GHO) data URL: http://www.who.int/gho/ncd/mortality_morbidity/en/ [WebCite Cache ID 6z7EmRx5V]
3. Boutayeb A. The double burden of communicable and non-communicable diseases in developing countries. *Trans R Soc Trop Med Hyg* 2006 Mar;100(3):191-199. [doi: [10.1016/j.trstmh.2005.07.021](https://doi.org/10.1016/j.trstmh.2005.07.021)] [Medline: [16274715](https://pubmed.ncbi.nlm.nih.gov/16274715/)]
4. The PLoS Medicine Editors. Addressing global disparities in the burden of noncommunicable diseases: call for papers. *PLoS Med* 2012 Dec 27;9(12):e1001360. [doi: [10.1371/journal.pmed.1001360](https://doi.org/10.1371/journal.pmed.1001360)]
5. Reddy KS. Cardiovascular diseases in the developing countries: dimensions, determinants, dynamics, and directions for public health action. *Public Health Nutr* 2002 Feb;5(1A):231-237. [Medline: [12027289](https://pubmed.ncbi.nlm.nih.gov/12027289/)]
6. World Health Organization. 2016. Regional Office of the Eastern Mediterranean: Non-Communicable diseases URL: <http://www.emro.who.int/entity/ncds/index.html> [WebCite Cache ID 6z7FPAqFG]
7. Rahim HF, Sibai A, Khader Y, Hwalla N, Fadhil I, Alsiyabi H, et al. Non-communicable diseases in the Arab world. *Lancet* 2014 Jan 25;383(9914):356-367. [doi: [10.1016/S0140-6736\(13\)62383-1](https://doi.org/10.1016/S0140-6736(13)62383-1)] [Medline: [24452044](https://pubmed.ncbi.nlm.nih.gov/24452044/)]
8. The world health report 2002 - reducing risks, promoting healthy life. Geneva: World Health Organization (WHO); Oct 2002.
9. Islam SM, Purnat TD, Phuong NT, Mwingira U, Schacht K, Fröschl G. Non-communicable diseases (NCDs) in developing countries: a symposium report. *Global Health* 2014 Dec 11;10:81 [FREE Full text] [doi: [10.1186/s12992-014-0081-9](https://doi.org/10.1186/s12992-014-0081-9)] [Medline: [25498459](https://pubmed.ncbi.nlm.nih.gov/25498459/)]
10. Shahin Y. World Health Organization. 2016. UNRWA's NCD Programme URL: <http://www.who.int/global-coordination-mechanism/working-groups/STKH-1PHC-UNRWA-shahin.pdf?ua=1> [WebCite Cache ID 6z7FMwf5t]
11. Arokiasamy P, Uttamacharya, Kowal P, Capistrant BD, Gildner TE, Thiele E, et al. Chronic noncommunicable diseases in 6 low-and middle-income countries: findings from wave 1 of the World Health Organization's study on global ageing and adult health (SAGE). *Am J Epidemiol* 2017 Dec 15;185(6):414-428. [doi: [10.1093/aje/kww125](https://doi.org/10.1093/aje/kww125)] [Medline: [28399566](https://pubmed.ncbi.nlm.nih.gov/28399566/)]
12. Craig J, Patterson V. Introduction to the practice of telemedicine. *J Telemed Telecare* 2005;11(1):3-9. [doi: [10.1177/1357633X0501100102](https://doi.org/10.1177/1357633X0501100102)] [Medline: [15829036](https://pubmed.ncbi.nlm.nih.gov/15829036/)]
13. Mechael P, Batavia H, Kaonga N, Searle S, Kwan A, Goldberger A, et al. Barriers and gaps affecting mHealth in low and middle income countries: Policy white paper. New York, NY: Center for Global Health and Economic Development Earth Institute, Columbia University; 2010. URL: http://www.globalproblems-globalsolutions-files.org/pdfs/mHealth_Barriers_White_Paper.pdf [WebCite Cache ID 6zJ4t0qng]
14. Amara AM, Aljunid SM. Noncommunicable diseases among urban refugees and asylum-seekers in developing countries: a neglected health care need. *Global Health* 2014 Apr 03;10:24 [FREE Full text] [doi: [10.1186/1744-8603-10-24](https://doi.org/10.1186/1744-8603-10-24)] [Medline: [24708876](https://pubmed.ncbi.nlm.nih.gov/24708876/)]
15. El-Jardali F, Lavis JN, Ataya N, Jamal D, Ammar W, Raouf S. Use of health systems evidence by policymakers in eastern Mediterranean countries: views, practices, and contextual influences. *BMC Health Serv Res* 2012 Jul 16;12:200 [FREE Full text] [doi: [10.1186/1472-6963-12-200](https://doi.org/10.1186/1472-6963-12-200)] [Medline: [22799440](https://pubmed.ncbi.nlm.nih.gov/22799440/)]
16. Maher D, Ford N, Unwin N. Priorities for developing countries in the global response to non-communicable diseases. *Global Health* 2012 Jun 11;8:14 [FREE Full text] [doi: [10.1186/1744-8603-8-14](https://doi.org/10.1186/1744-8603-8-14)] [Medline: [22686126](https://pubmed.ncbi.nlm.nih.gov/22686126/)]
17. Maher D, Harries AD, Zachariah R, Enarson D. A global framework for action to improve the primary care response to chronic non-communicable diseases: a solution to a neglected problem. *BMC Public Health* 2009 Sep 22;9:355 [FREE Full text] [doi: [10.1186/1471-2458-9-355](https://doi.org/10.1186/1471-2458-9-355)] [Medline: [19772598](https://pubmed.ncbi.nlm.nih.gov/19772598/)]
18. Norris SL, Chowdhury FM, Van Le K, Horsley T, Brownstein JN, Zhang X, et al. Effectiveness of community health workers in the care of persons with diabetes. *Diabet Med* 2006 May;23(5):544-556. [doi: [10.1111/j.1464-5491.2006.01845.x](https://doi.org/10.1111/j.1464-5491.2006.01845.x)] [Medline: [16681564](https://pubmed.ncbi.nlm.nih.gov/16681564/)]
19. Ouma S, Herselman ME. E-health in rural areas: case of developing countries. *Int J Humanit Soc Sci* 2008;2(4):194-200.
20. Samb B, Desai N, Nishtar S, Mendis S, Bekedam H, Wright A, et al. Prevention and management of chronic disease: a litmus test for health-systems strengthening in low-income and middle-income countries. *Lancet* 2010 Nov 20;376(9754):1785-1797. [doi: [10.1016/S0140-6736\(10\)61353-0](https://doi.org/10.1016/S0140-6736(10)61353-0)] [Medline: [21074253](https://pubmed.ncbi.nlm.nih.gov/21074253/)]
21. Wakerman J, Humphreys JS. Sustainable primary health care services in rural and remote areas: innovation and evidence. *Aust J Rural Health* 2011 Jun;19(3):118-124. [doi: [10.1111/j.1440-1584.2010.01180.x](https://doi.org/10.1111/j.1440-1584.2010.01180.x)] [Medline: [21605224](https://pubmed.ncbi.nlm.nih.gov/21605224/)]
22. Wilson NW, Couper ID, De Vries E, Reid S, Fish T, Marais BJ. A critical review of interventions to redress the inequitable distribution of healthcare professionals to rural and remote areas. *Rural Remote Health* 2009;9(2):1060 [FREE Full text] [Medline: [19530891](https://pubmed.ncbi.nlm.nih.gov/19530891/)]
23. Beaglehole R, Epping-Jordan J, Patel V, Chopra M, Ebrahim S, Kidd M, et al. Improving the prevention and management of chronic disease in low-income and middle-income countries: a priority for primary health care. *Lancet* 2008 Sep 13;372(9642):940-949. [doi: [10.1016/S0140-6736\(08\)61404-X](https://doi.org/10.1016/S0140-6736(08)61404-X)] [Medline: [18790317](https://pubmed.ncbi.nlm.nih.gov/18790317/)]

24. Kane J, Landes M, Carroll C, Nolen A, Sodhi S. A systematic review of primary care models for non-communicable disease interventions in Sub-Saharan Africa. *BMC Fam Pract* 2017 Mar 23;18(1):46 [FREE Full text] [doi: [10.1186/s12875-017-0613-5](https://doi.org/10.1186/s12875-017-0613-5)] [Medline: [28330453](https://pubmed.ncbi.nlm.nih.gov/28330453/)]
25. Hyder AA, Wosu AC, Gibson DG, Labrique AB, Ali J, Pariyo GW. Noncommunicable disease risk factors and mobile phones: a proposed research agenda. *J Med Internet Res* 2017 May 05;19(5):e133 [FREE Full text] [doi: [10.2196/jmir.7246](https://doi.org/10.2196/jmir.7246)] [Medline: [28476722](https://pubmed.ncbi.nlm.nih.gov/28476722/)]
26. Arambepola C, Ricci-Cabello I, Manikavasagam P, Roberts N, French DP, Farmer A. The impact of automated brief messages promoting lifestyle changes delivered via mobile devices to people with type 2 diabetes: a systematic literature review and meta-analysis of controlled trials. *J Med Internet Res* 2016 Apr 19;18(4):e86 [FREE Full text] [doi: [10.2196/jmir.5425](https://doi.org/10.2196/jmir.5425)] [Medline: [27095386](https://pubmed.ncbi.nlm.nih.gov/27095386/)]
27. Berrouiguet S, Baca-García E, Brandt S, Walter M, Courtet P. Fundamentals for future mobile-health (mHealth): a systematic review of mobile phone and web-based text messaging in mental health. *J Med Internet Res* 2016 Dec 10;18(6):e135 [FREE Full text] [doi: [10.2196/jmir.5066](https://doi.org/10.2196/jmir.5066)] [Medline: [27287668](https://pubmed.ncbi.nlm.nih.gov/27287668/)]
28. Bobrow K, Brennan T, Springer D, Levitt N, Rayner B, Namane M, et al. Efficacy of a text messaging (SMS) based intervention for adults with hypertension: protocol for the StAR (SMS Text-message Adherence suppoRt trial) randomised controlled trial. *BMC Public Health* 2014 Jan 11;14:28 [FREE Full text] [doi: [10.1186/1471-2458-14-28](https://doi.org/10.1186/1471-2458-14-28)] [Medline: [24410738](https://pubmed.ncbi.nlm.nih.gov/24410738/)]
29. Burner ER, Menchine MD, Kubicek K, Robles M, Arora S. Perceptions of successful cues to action and opportunities to augment behavioral triggers in diabetes self-management: qualitative analysis of a mobile intervention for low-income Latinos with diabetes. *J Med Internet Res* 2014 Jan 29;16(1):e25 [FREE Full text] [doi: [10.2196/jmir.2881](https://doi.org/10.2196/jmir.2881)] [Medline: [24476784](https://pubmed.ncbi.nlm.nih.gov/24476784/)]
30. Caburnay CA, Graff K, Harris JK, McQueen A, Smith M, Fairchild M, et al. Evaluating diabetes mobile applications for health literate designs and functionality, 2014. *Prev Chronic Dis* 2015 May 07;12:E61 [FREE Full text] [doi: [10.5888/pcd12.140433](https://doi.org/10.5888/pcd12.140433)] [Medline: [25950568](https://pubmed.ncbi.nlm.nih.gov/25950568/)]
31. Cole-Lewis H, Kershaw T. Text messaging as a tool for behavior change in disease prevention and management. *Epidemiol Rev* 2010 Mar 30;32(1):56-69. [doi: [10.1093/epirev/mxq004](https://doi.org/10.1093/epirev/mxq004)] [Medline: [20354039](https://pubmed.ncbi.nlm.nih.gov/20354039/)]
32. Müssener U, Bendtsen M, McCambridge J, Bendtsen P. User satisfaction with the structure and content of the NEXit intervention, a text messaging-based smoking cessation programme. *BMC Public Health* 2016 Dec 22;16(1):1179 [FREE Full text] [doi: [10.1186/s12889-016-3848-5](https://doi.org/10.1186/s12889-016-3848-5)] [Medline: [27876031](https://pubmed.ncbi.nlm.nih.gov/27876031/)]
33. Youssef A. Use of short message service reminders to improve attendance at an internal medicine outpatient clinic in Saudi Arabia: a randomized controlled trial/Utilisation de rappels par minimessages afin d'améliorer l'assiduité des patients dans un service de consultations externes en médecine interne en Arabie saoudite: essai contrôlé randomisé. *East Mediterr Health J* 2014 Jun 09;20(5):317-323. [Medline: [24952289](https://pubmed.ncbi.nlm.nih.gov/24952289/)]
34. Axler RE, Strong KA, Jordens C, Ankeny RA, Barlow-Stewart K, Kerridge IH. What's in a name? searching the web for information about ethically contentious and emerging healthcare technologies. *J Commun Healthc* 2013 Jul 18;2(2):173-183. [doi: [10.1179/cih.2009.2.2.173](https://doi.org/10.1179/cih.2009.2.2.173)]
35. Capozza K, Woolsey S, Georgsson M, Black J, Bello N, Lence C, et al. Going mobile with Diabetes support: a randomized study of a text message-based personalized behavioral intervention for type 2 diabetes self-care. *Diabetes Spectr* 2015 May;28(2):83-91 [FREE Full text] [doi: [10.2337/diaspect.28.2.83](https://doi.org/10.2337/diaspect.28.2.83)] [Medline: [25987806](https://pubmed.ncbi.nlm.nih.gov/25987806/)]
36. Golshahi J, Ahmadzadeh H, Sadeghi M, Mohammadifard N, Pourmoghaddas A. Effect of self-care education on lifestyle modification, medication adherence and blood pressure in hypertensive adults: randomized controlled clinical trial. *Adv Biomed Res* 2015 Sep 28;4:204 [FREE Full text] [doi: [10.4103/2277-9175.166140](https://doi.org/10.4103/2277-9175.166140)] [Medline: [26601092](https://pubmed.ncbi.nlm.nih.gov/26601092/)]
37. van Heerden A, Tomlinson M, Swartz L. Point of care in your pocket: a research agenda for the field of m-health. *Bull World Health Organ* 2012 May 01;90(5):393-394 [FREE Full text] [doi: [10.2471/BLT.11.099788](https://doi.org/10.2471/BLT.11.099788)] [Medline: [22589575](https://pubmed.ncbi.nlm.nih.gov/22589575/)]
38. Shariful Islam SM, Niessen L, Ferrari U, Ali L, Seissler J, Lechner A. Effects of mobile phone SMS to improve glycemic control among patients with type 2 diabetes in Bangladesh: a prospective, parallel-group, randomized controlled trial. *Diabetes Care* 2015 Aug;38(8):e112-e113. [doi: [10.2337/dc15-0505](https://doi.org/10.2337/dc15-0505)] [Medline: [26207059](https://pubmed.ncbi.nlm.nih.gov/26207059/)]
39. Kasparian NA, Lieu N, Winlaw DS, Cole A, Kirk E, Sholler GF. eHealth literacy and preferences for eHealth resources in parents of children with complex CHD. *Cardiol Young* 2017 May;27(4):722-730. [doi: [10.1017/S1047951116001177](https://doi.org/10.1017/S1047951116001177)] [Medline: [27641539](https://pubmed.ncbi.nlm.nih.gov/27641539/)]
40. Kiselev AR, Gridnev VI, Shvartz VA, Posnenkova OM, Dovgalevsky PY. Active ambulatory care management supported by short message services and mobile phone technology in patients with arterial hypertension. *J Am Soc Hypertens* 2012 Sep;6(5):346-355. [doi: [10.1016/j.jash.2012.08.001](https://doi.org/10.1016/j.jash.2012.08.001)] [Medline: [22995803](https://pubmed.ncbi.nlm.nih.gov/22995803/)]
41. Krishna S, Boren SA. Diabetes self-management care via cell phone: a systematic review. *J Diabetes Sci Technol* 2008 May;2(3):509-517 [FREE Full text] [doi: [10.1177/193229680800200324](https://doi.org/10.1177/193229680800200324)] [Medline: [19885219](https://pubmed.ncbi.nlm.nih.gov/19885219/)]
42. Okuboyejo S, Eyesan O. mHealth: using mobile technology to support healthcare. *Online J Public Health Inform* 2014;5(3):233 [FREE Full text] [doi: [10.5210/ojphi.v5i3.4865](https://doi.org/10.5210/ojphi.v5i3.4865)] [Medline: [24678384](https://pubmed.ncbi.nlm.nih.gov/24678384/)]

43. Riley WT, Rivera DE, Atienza AA, Nilsen W, Allison SM, Mermelstein R. Health behavior models in the age of mobile interventions: are our theories up to the task? *Transl Behav Med* 2011 Mar;1(1):53-71 [FREE Full text] [doi: [10.1007/s13142-011-0021-7](https://doi.org/10.1007/s13142-011-0021-7)] [Medline: [21796270](https://pubmed.ncbi.nlm.nih.gov/21796270/)]
44. World Health Organization. 2014. Noncommunicable diseases and mental health- Lebanon URL: http://www.who.int/nmh/countries/lbn_en.pdf [WebCite Cache ID 6z7Joh5k5]
45. UNRWA. Where we work URL: <https://www.unrwa.org/where-we-work/lebanon> [WebCite Cache ID 6zIq1e3IO]
46. Yamout R, Adib SM, Hamadeh R, Freidi A, Ammar W. Screening for cardiovascular risk in asymptomatic users of the primary health care network in Lebanon, 2012-2013. *Prev Chronic Dis* 2014 Jul 17;11:e120 [FREE Full text] [doi: [10.5888/pcd11.140089](https://doi.org/10.5888/pcd11.140089)] [Medline: [25032835](https://pubmed.ncbi.nlm.nih.gov/25032835/)]
47. Chen B, Cammett M. Informal politics and inequity of access to health care in Lebanon. *Int J Equity Health* 2012 May 09;11:23 [FREE Full text] [doi: [10.1186/1475-9276-11-23](https://doi.org/10.1186/1475-9276-11-23)] [Medline: [22571591](https://pubmed.ncbi.nlm.nih.gov/22571591/)]
48. UNRWA. 2011. Palestine refugees in Lebanon: a special case URL: <https://www.unrwa.org/userfiles/20111002306.pdf> [WebCite Cache ID 6z7JuDEAI]
49. Habib RR, Seyfert K, Hojeij S. Health and living conditions of Palestinian refugees residing in camps and gatherings in Lebanon: a cross-sectional survey. *Lancet* 2012 Oct;380:S3. [doi: [10.1016/S0140-6736\(13\)60189-0](https://doi.org/10.1016/S0140-6736(13)60189-0)]
50. Union I. Union IT. 2016. Time series by country (until 2015): mobile-cellular subscriptions URL: <https://www.itu.int/en/ITU-D/Statistics/Pages/stat/default.aspx> [WebCite Cache ID 6z7K4tiy4]
51. Talhouk R, Mesmar S, Thieme A, Balaam M, Olivier P, Akik C, et al. Syrian refugees and digital health in Lebanon: opportunities for improving antenatal health. In: CHI '16 Proceedings of the 2016. 2016 Presented at: CHI Conference on Human Factors in Computing Systems; 07-12 May, 2016; San Jose, California, USA p. 331-342. [doi: [10.1145/2858036.2858331](https://doi.org/10.1145/2858036.2858331)]
52. MOPH. 2016. Strategic plan for the medium term (2016 to 2020) URL: <https://www.moph.gov.lb/en/Pages/0/11665/strategic-plan-2016-2020-> [WebCite Cache ID 6zItnUVCB]
53. Márquez Contreras E, de la Figuera von Wichmann M, Gil Guillén V, Ylla-Catalá A, Figueras M, Balaña M, et al. [Effectiveness of an intervention to provide information to patients with hypertension as short text messages and reminders sent to their mobile phone (HTA-Alert)]. *Aten Primaria* 2004 Nov 15;34(8):399-405 [FREE Full text] [Medline: [15546536](https://pubmed.ncbi.nlm.nih.gov/15546536/)]
54. Park LG, Beatty A, Stafford Z, Whooley MA. Mobile phone interventions for the secondary prevention of cardiovascular disease. *Prog Cardiovasc Dis* 2016;58(6):639-650 [FREE Full text] [doi: [10.1016/j.pcad.2016.03.002](https://doi.org/10.1016/j.pcad.2016.03.002)] [Medline: [27001245](https://pubmed.ncbi.nlm.nih.gov/27001245/)]
55. Wald DS, Bestwick JP, Raiman L, Brendell R, Wald NJ. Randomised trial of text messaging on adherence to cardiovascular preventive treatment (INTERACT trial). *PLoS One* 2014 Dec 05;9(12):e114268 [FREE Full text] [doi: [10.1371/journal.pone.0114268](https://doi.org/10.1371/journal.pone.0114268)] [Medline: [25479285](https://pubmed.ncbi.nlm.nih.gov/25479285/)]
56. Orsama AL, Lähteenmäki J, Harno K, Kulju M, Wintergerst E, Schachner H, et al. Active assistance technology reduces glycosylated hemoglobin and weight in individuals with type 2 diabetes: results of a theory-based randomized trial. *Diabetes Technol Ther* 2013 Aug;15(8):662-669. [doi: [10.1089/dia.2013.0056](https://doi.org/10.1089/dia.2013.0056)] [Medline: [23844570](https://pubmed.ncbi.nlm.nih.gov/23844570/)]
57. Haddad NS, Istepanian R, Philip N, Khazaal FA, Hamdan TA, Pickles T, et al. A feasibility study of mobile phone text messaging to support education and management of type 2 diabetes in Iraq. *Diabetes Technol Ther* 2014 Jul;16(7):454-459. [doi: [10.1089/dia.2013.0272](https://doi.org/10.1089/dia.2013.0272)] [Medline: [24502284](https://pubmed.ncbi.nlm.nih.gov/24502284/)]
58. Bin Abbas B, Al-Fares A, Jabbari M, El Dali A, Al-Orifi F. Effect of mobile phone short text messages on glycemic control in type 2 diabetes. *Int J Endocrinol Metab* 2015 Jan 01;13(1):e18791 [FREE Full text] [doi: [10.5812/ijem.18791](https://doi.org/10.5812/ijem.18791)] [Medline: [25745493](https://pubmed.ncbi.nlm.nih.gov/25745493/)]
59. Liu L, Ogwu S. A meta-analysis of mobile health and risk reduction in patients with diabetes mellitus: challenge and opportunity. *J Mob Technol Med* 2012;1(3):17-24. [doi: [10.7309/jmtm.18](https://doi.org/10.7309/jmtm.18)]
60. Kim SI, Kim HS. Effectiveness of mobile and internet intervention in patients with obese type 2 diabetes. *Int J Med Inform* 2008 Jun;77(6):399-404. [doi: [10.1016/j.ijmedinf.2007.07.006](https://doi.org/10.1016/j.ijmedinf.2007.07.006)] [Medline: [17881285](https://pubmed.ncbi.nlm.nih.gov/17881285/)]
61. Goodarzi M, Ebrahimzadeh I, Rabi A, Saedipoor B, Jafarabadi MA. Impact of distance education via mobile phone text messaging on knowledge, attitude, practice, and self efficacy of patients with type 2 diabetes mellitus in Iran. *J Diabetes Metab Disord* 2012 Aug 31;11(1):10 [FREE Full text] [doi: [10.1186/2251-6581-11-10](https://doi.org/10.1186/2251-6581-11-10)] [Medline: [23497632](https://pubmed.ncbi.nlm.nih.gov/23497632/)]
62. Arora S, Peters AL, Burner E, Lam CN, Menchine M. Trial to examine text message-based mHealth in emergency department patients with diabetes (TEXT-MED): a randomized controlled trial. *Ann Emerg Med* 2014 Jun;63(6):745-54.e6. [doi: [10.1016/j.annemergmed.2013.10.012](https://doi.org/10.1016/j.annemergmed.2013.10.012)] [Medline: [24225332](https://pubmed.ncbi.nlm.nih.gov/24225332/)]
63. Hussein WI, Hasan K, Jaradat AA. Effectiveness of mobile phone short message service on diabetes mellitus management; the SMS-DM study. *Diabetes Res Clin Pract* 2011 Oct;94(1):e24-e26. [doi: [10.1016/j.diabres.2011.07.025](https://doi.org/10.1016/j.diabres.2011.07.025)] [Medline: [21840079](https://pubmed.ncbi.nlm.nih.gov/21840079/)]
64. Cole-Lewis H, Kershaw T. Text messaging as a tool for behavior change in disease prevention and management. *Epidemiol Rev* 2010;32:56-69 [FREE Full text] [doi: [10.1093/epirev/mxq004](https://doi.org/10.1093/epirev/mxq004)] [Medline: [20354039](https://pubmed.ncbi.nlm.nih.gov/20354039/)]
65. UNRWA. 2017. International conference explores how to improve diabetes prevention and care for refugees URL: <https://www.unrwa.org/newsroom/press-releases/international-conference-explores-how-improve-diabetes-prevention-and-care> [WebCite Cache ID 6zIzJksne]

66. MOPH. 2015. Integration of non-communicable disease services within primary health care URL: <http://www.moph.gov.lb/en/Pages/6/776/non-communicable-disease-program-primary-health-care> [WebCite Cache ID 6zIzSODgb]
67. Free C, Knight R, Robertson S, Whittaker R, Edwards P, Zhou W, et al. Smoking cessation support delivered via mobile phone text messaging (txt2stop): a single-blind, randomised trial. *Lancet* 2011 Jul 02;378(9785):49-55. [doi: [10.1016/S0140-6736\(11\)60701-0](https://doi.org/10.1016/S0140-6736(11)60701-0)] [Medline: [21722952](https://pubmed.ncbi.nlm.nih.gov/21722952/)]
68. Rodgers A, Corbett T, Bramley D, Riddell T, Wills M, Lin RB, et al. Do u smoke after txt? results of a randomised trial of smoking cessation using mobile phone text messaging. *Tob Control* 2005 Aug;14(4):255-261 [FREE Full text] [doi: [10.1136/tc.2005.011577](https://doi.org/10.1136/tc.2005.011577)] [Medline: [16046689](https://pubmed.ncbi.nlm.nih.gov/16046689/)]
69. McIvor A, Kayser J, Assaad JM, Brosky G, Demarest P, Desmarais P, et al. Best practices for smoking cessation interventions in primary care. *Can Respir J* 2009 Jul;16(4):129-134 [FREE Full text] [Medline: [19707607](https://pubmed.ncbi.nlm.nih.gov/19707607/)]
70. Fishbein M, Yzer MC. Using theory to design effective health behavior interventions. *Commun Theory* 2003 May 01;13(2):164-183. [doi: [10.1111/j.1468-2885.2003.tb00287.x](https://doi.org/10.1111/j.1468-2885.2003.tb00287.x)]
71. Parikh A, Gupta K, Wilson AC, Fields K, Cosgrove NM, Kostis JB. The effectiveness of outpatient appointment reminder systems in reducing no-show rates. *Am J Med* 2010 Jun;123(6):542-548. [doi: [10.1016/j.amjmed.2009.11.022](https://doi.org/10.1016/j.amjmed.2009.11.022)] [Medline: [20569761](https://pubmed.ncbi.nlm.nih.gov/20569761/)]
72. Downer SR, Meara JG, Da Costa AC. Use of SMS text messaging to improve outpatient attendance. *Med J Aust* 2005 Oct 03;183(7):366-368. [Medline: [16201955](https://pubmed.ncbi.nlm.nih.gov/16201955/)]
73. Guy R, Hocking J, Wand H, Stott S, Ali H, Kaldor J. How effective are short message service reminders at increasing clinic attendance? A meta-analysis and systematic review. *Health Serv Res* 2012 Apr;47(2):614-632 [FREE Full text] [doi: [10.1111/j.1475-6773.2011.01342.x](https://doi.org/10.1111/j.1475-6773.2011.01342.x)] [Medline: [22091980](https://pubmed.ncbi.nlm.nih.gov/22091980/)]
74. Zaman SB, Hossain N, Ahammed S, Ahmed Z. Contexts and opportunities of e-health technology in medical care. *J Med Res Innov* 2017 May 01;1(2):AV1-AV4. [doi: [10.15419/jmri.62](https://doi.org/10.15419/jmri.62)]

Abbreviations

- BP:** blood pressure
- DBP:** diastolic blood pressure
- eHealth:** electronic health
- EMR:** Eastern Mediterranean Region
- HbA_{1c}:** glycated hemoglobin
- HTN:** hypertension
- mHealth:** mobile health
- MOPH:** Ministry of Public Health
- LMIC:** low- and middle-income countries
- NCD:** noncommunicable disease
- OR:** odds ratio
- PHC:** primary health care
- PHCC:** primary health care center
- QI:** quality indicator
- SBP:** systolic blood pressure
- SMS:** short message service
- UNRWA:** United Nations Relief and Works Agency

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Original Paper

Improving Linkage to HIV Care Through Mobile Phone Apps: Randomized Controlled Trial

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Abstract

Background: In HIV treatment program, gaps in the “cascade of care” where patients are lost between diagnosis, laboratory evaluation, treatment initiation, and retention in HIV care, is a well-described challenge. Growing access to internet-enabled mobile phones has led to an interest in using the technology to improve patient engagement with health care.

Objective: The objectives of this trial were: (1) to assess whether a mobile phone-enabled app could provide HIV patients with laboratory test results, (2) to better understand the implementation of such an intervention, and (3) to determine app effectiveness in improving linkage to HIV care after diagnosis.

Methods: We developed and tested an app through a randomized controlled trial carried out in several primary health care facilities in Johannesburg. Newly diagnosed HIV-positive patients were screened, recruited, and randomized into the trial as they were giving a blood sample for initial CD4 staging. Trial eligibility included ownership of a phone compatible with the app and access to the internet. Trial participants were followed for a minimum of eight months to determine linkage to HIV care indicated by an HIV-related laboratory test result.

Results: The trial outcome results are being prepared for publication, but here we describe the significant operational and technological lessons provided by the implementation. Android was identified as the most suitable operating system for the app, due to Android functionality and communication characteristics. Android also had the most significant market share of all smartphone operating systems in South Africa. The app was successfully developed with laboratory results sent to personal smartphones. However, given the trial requirements and the app itself, only 10% of screened HIV patients successfully enrolled. We report on issues such as patient eligibility, app testing in a dynamic phone market, software installation and compatibility, safe identification of patients, linkage of laboratory results to patients lacking unique identifiers, and present lessons and potential solutions.

Conclusions: The implementation challenges and lessons of this trial may assist future similar mHealth interventions to avoid some of the pitfalls. Ensuring sufficient expertise and understanding of the programmatic needs by the software developer, as well as in the implementation team, with adequate and rapid piloting within the target groups, could have led to better trial

recruitment. However, the majority of screened patients were interested in the study, and the app was installed successfully in patients with suitable smartphones, suggesting that this may be a way to engage patients with their health care data in future.

Trial Registration: ClinicalTrials.gov NCT02756949; <https://clinicaltrials.gov/ct2/show/NCT02756949> (Archived by WebCite at <http://www.webcitation.org/6z1GTJCNW>)

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KEYWORDS

cell phones; app; Africa; linkage to care; HIV; patient information

Introduction

Joint United Nations Programme on HIV/AIDS (UNAIDS) and World Health Organization have driven the “90-90-90” initiative since 2015, to maximize the impact of expanded antiretroviral therapy (ART) coverage for both individual health and for decreasing new infections among the population. The initiative calls for 90% of HIV positive people to know their status, 90% of those who are eligible for ART to be initiated on ART, and 90% of those on ART to maintain viral suppression [1].

The *HIV care cascade* shows significant patient attrition between HIV diagnosis and entry into HIV care [2]. This means delayed access to ART, with avoidable illness and mortality, as well as unnecessary transmission of the virus. Interventions have been tested to decrease this attrition, most involving expediting HIV or CD4 (cluster of differentiation) T-cell staging results by health workers [3]. In a 2015 cohort study in South African primary health care facilities, only 64% of persons newly diagnosed with HIV who had been assessed for CD4 staging returned to the clinic for the CD4 result [4]. Improved access to the point of care CD4 counts, widely anticipated to increase linkage to HIV care, has yielded limited success, suggesting that other types of interventions are required, [5] including interventions for patient empowerment and better patient involvement in their own care.

Interest in using cell phones to facilitate health care has increased in recent years in Africa, due to high levels of cell phone ownership [6]. Recent evidence using short message service (SMS) text messaging showed modest adherence benefits [7,8,9]. Mobile apps on “smart” mobile phones, have become a major part of people’s lives, from providing simple access to information (eg, Google), Global Positioning System (GPS) tracking and engagement with services (eg, Uber), to banking (eg, all South African banks), social media (eg, Facebook), and instant messaging (eg, WhatsApp). We are unaware of any study that has used a mobile phone app to link HIV positive patients to care.

We conducted a randomized controlled trial in multiple Johannesburg HIV testing sites, recruiting between October 2015 and June 2016 and following up till February 2017, to test whether providing newly diagnosed HIV patients their laboratory results and supporting information securely on their mobile phones, via an app, would improve linkage to HIV care [10]. This article reflects on the significant operational challenges in the project, including data linkage, software design, trial eligibility, interoperability of systems and devices, and general management and delivery of the intervention. The

results on whether the intervention was effective in improving linkage to care will be published as soon as they become available.

Methods

Setting

South Africa has the world’s largest number of people living with HIV, with antiretroviral care provided freely through the state sector to over 3.5 million people [11]. The country has formal HIV testing, staging (CD4) and care guidelines, followed by all public health facilities, with a National Health Laboratory System (NHLS) providing laboratory testing for the majority of South Africans, including for the HIV program [12,13]. HIV testing is largely facility-based and conducted by lay counselors, with blood drawn for a CD4 count test after a positive HIV diagnosis is made and the patient told to return to a health facility. Around 350,000 people annually are started on ART in South Africa [11].

The trial was conducted by Wits Reproductive Health and HIV Institute, an academic research and program implementation organization, in partnership with the NHLS and the World Bank, in public sector clinics and hospitals in inner-city Johannesburg, a densely populated urban area with a well-established HIV testing and ART program. This inner-city location is an area with significant levels of immigration, unemployment, alcohol abuse, sex work, poverty, and gender violence. We were specifically interested in sampling young people between the age of 18 and 30 years and men, representing two key groups under-represented in South African treatment program, and with poorer linkage to care [1,11].

Mobile Phone Variety, App Design, and Data Linkage

A preliminary assessment conducted from March-April 2015 at the largest recruitment site found 160/373 (42.9%) of patients had mobile phones, which matches the reported national data statistics of 35%-50% [13]. Apps have to be designed for different operating systems or “platforms” (eg, Android, iOS). It’s an evolving area as phone manufacturers upgrade and move between platforms. The locally popular Blackberry and Nokia phones have recently switched to an Android platform and carry different skills regarding development. The most common mobile phone operating system from our formative research phase of the trial was Android 67/158 (42.4%) followed by Blackberry OS, Windows Phone, WebOS, Firefox OS and Symbian, each with less than 20%. The iPhone ownership was extremely low at 4/158 (2.5%). Similar results were shown in a survey done by the project team in early 2016 in the Eastern

Cape, a far more rural province, where an even greater proportion of patients had Android devices, probably as Blackberry and Nokia by then had stopped making less expensive mobile phones for the local market.

The decision to use the Android platform for the app development was based on several issues beyond Android-based phones were the most common. Android functionality allowed for third-party “push” notifications, had secure app-based data transmission essential for laboratory results, both of which were a key aspect of the intervention. Additionally, resource constraints did not allow for development of additional platforms, most of which had been declining in popularity for years.

Developing the app, which was called SmartLink, consisted of selecting the necessary features for the study, creating the app layout and the health content, combining the features and the health content in the app layout, and conducting field testing. The app developer was selected by an existing relationship and was identified to be suitable for the task based on experience with a similar project involving interfacing an Android app with NHLs laboratory data. The developer was provided with a user interface outline developed by the research team.

App content was created by HIV clinicians and an experienced HIV psychosocial support team, who also included graphics to better convey information. The app was developed to be as compact as possible, while also being interactive, dynamic and informative for patients. Laboratory results were color-coded, based on red-yellow-green traffic lights, to help patients quickly understand their results. Images were used to split up larger pieces of informational text, while also providing a visual example of relevant topics (Figures 1 and 2). Development of the app took approximately two and a half months including field testing. Individuals within the study team were used to test installation of the app on Android cell phones. Members of a community advisory group including some living with HIV who use public health facilities tested the app for usability.

Although field testing was done, the final app was not placed on Google Play Store, an access point for downloadable apps for Android devices, due to possible disclosure issues. The app would only be downloaded by confirmed HIV positive people; this meant any software updates needed to be done manually on individual phones, rather than through the Google Play app store. SmartLink had a final installation size of 12.5 MB and intended to work on any version of Android version 4.2 or higher and on any phone with at least 350 MB of random access memory (RAM).

Figure 1. Screenshots of the SmartLink app, showing the login procedure and illustrative home screen.

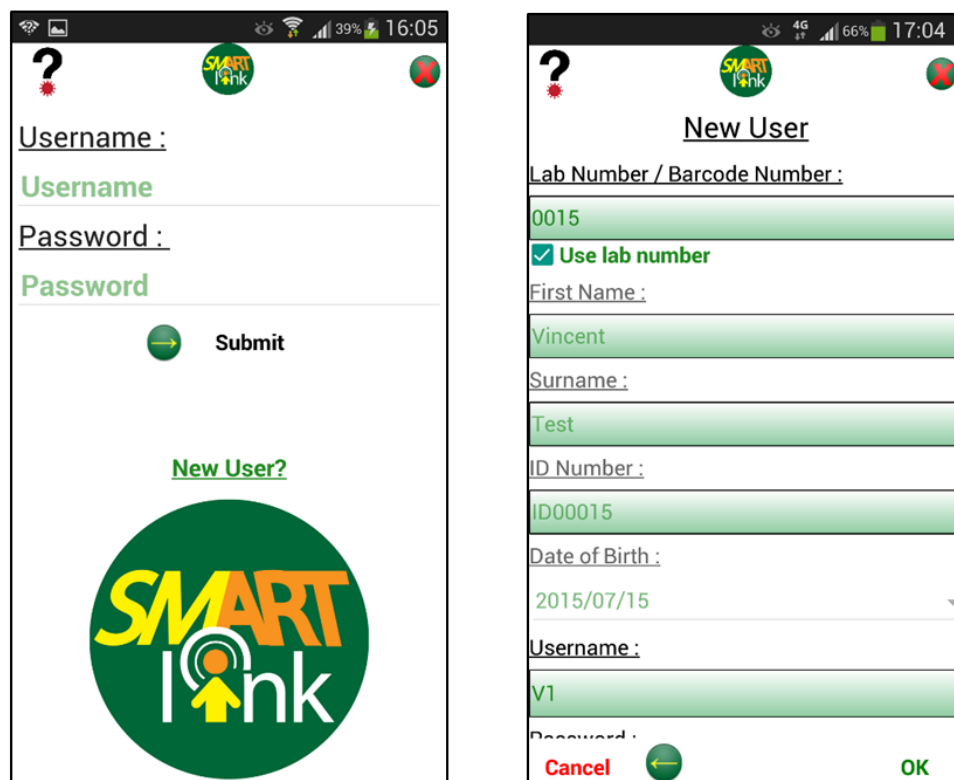
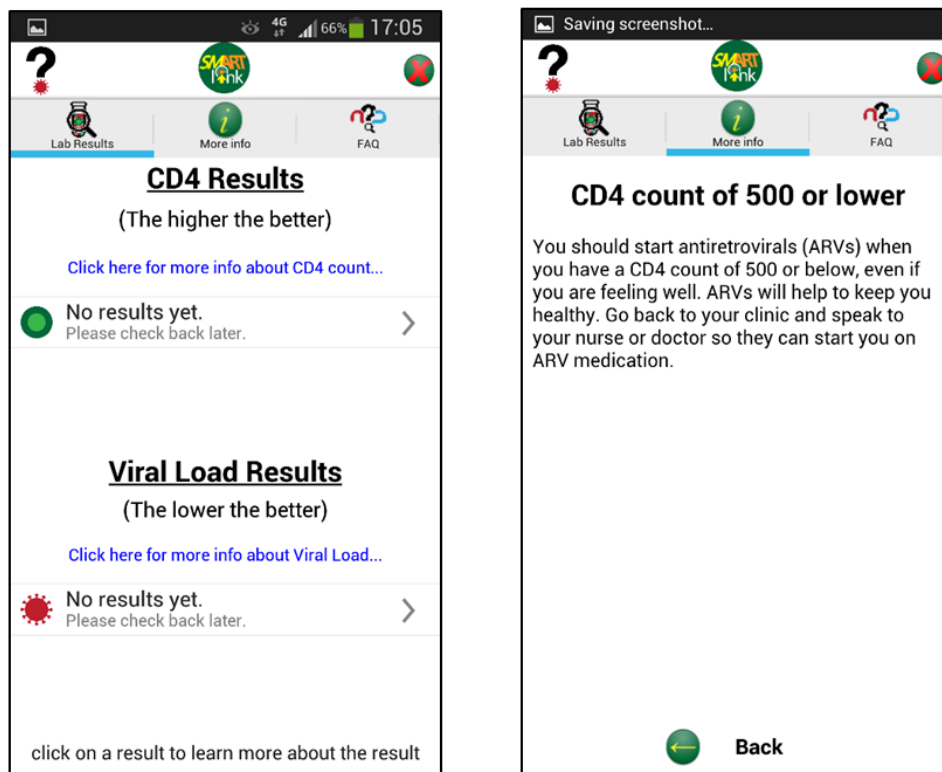


Figure 2. Screenshots of the SmartLink app, illustrating the results format and an example of advice given.



Free internet is available in selected public urban areas within South Africa, but this varies widely regarding geography and reliability and is often limited in speed and time. The vast majority of internet users use their mobile phone with a prepaid system for data usage through their mobile network provider and are acutely aware of the costs of usage. Within the app, all reference material, images, and contact information are built in the initial download. For the study, SmartLink was installed by study staff from an Android install file and Wi-Fi dongle which allowed access to the installation file at no cost to the participant. This meant that app users only needed to download laboratory results, resulting in minimal data usage, which was key for app acceptability. Once installed, it was calculated that throughout the year of the study, data transfer would cost the participant less than 1 Rand (<US \$0.10). Participants received a 50 Rand (\approx US \$4) phone credit at recruitment to ensure all app-related costs were covered.

Intervention

Newly diagnosed HIV-positive patients were recruited to the study by trained study staff at five local HIV testing sites, in and around inner-city Johannesburg. The testing sites consisted of three public health clinics, a provincial community health center, and later in the study a tertiary hospital. Inclusion criteria were: being newly diagnosed with HIV, being a local resident, aged 18 years and older, not pregnant on the date of recruitment, able to read English or isiZulu (ie, the most commonly used local language), carrying a photo identification (ID) during prescreening, and having a data-enabled mobile phone with Android 4.2 or higher and sufficient RAM to allow app installation, done during screening). Staff responsible for recruitment were provided with training on the study protocols and the use of Research Electronic Data Capture, a data

collection and participant randomization system, on a tablet device.

Eligible and consenting participants were randomized to either the app intervention arm or the standard-of-care control arm of the trial, where participants were simply referred to their local ART initiation site where they could collect their CD4 result and initiate treatment if needed. Simple socio-economic and phone ownership data were collected from all newly diagnosed HIV patients during eligibility screening. Our statistical sample size calculation suggested 1000 participants in each arm would give us sufficient power to evaluate the rates of linkage to HIV care the two subgroups (ie, men and younger participants).

Project staff assisted participants randomized to the app arm with the installation of SmartLink and shown how to view their laboratory results and access HIV related support information. At the time of enrolment, app use was relatively low in this population, and may not be necessary today. The app was accessible using a password and personal information number (PIN) system, as used by the local banks, preventing access to confidential information by third parties with access to the phone; initial access to the app required the user to insert both the password and the PIN while subsequent access just required the PIN. The app was set up to communicate two laboratory results, CD4 count and viral load, in simple language which included the date and time, a visual colored-coded scale and "normal" values, and a short explanation of what the result means and what action, if any, should be taken. The app also provided participants with access to information about HIV, ART adherence, and laboratory tests in English and isiZulu.

At the time of the study (2015-2016), the South African CD4 ART initiation threshold was 500 cells/ μ l; after a positive HIV

test, patients had a blood draw for CD4 staging and were told to return for the result, and ART started based on the CD4 count (<500 cells/ μ l), clinical status, and treatment readiness. As part of informed consent and regardless of study arm, all participants were instructed to attend their clinics within the next few weeks for a follow-up, as per the instructions given to them by the clinic staff, and not simply wait for results on their phone for the intervention arm.

The trial protocol obtained approval from the University of Witwatersrand's Medical Human Research Ethics Committee, the City of Johannesburg and Gauteng's Department of Health at the provincial level and was registered in ClinicalTrials.gov (NCT02756949). All participants provided written informed consent before enrolment.

Results

The study screened over 4500 patients at five HIV testing sites, but only randomized 353/4537 (7.78%) participants. There were some diverse challenges in implementing the study, which significantly impacted on the speed with which the study was implemented, as well as the number of participants recruited.

Recruitment and Eligibility

In 2015, before the trial commenced, between 40 and 90 new HIV cases were being identified daily [14]. Based on this, the

study team estimated that three months of study recruitment would be sufficient to meet the study sample requirement. For example, 17 individuals recruited per day for three months for a total of 1000 participants across all study sites.

However, when we began the study in October 2015, the number of new HIV cases had dropped to 10-15 per day, and recruitment was therefore compromised. This is likely due to the introduction of decentralized testing to numerous surrounding facilities at the time of the trial. To increase recruitment, the protocol was changed to add a nearby busy HIV testing site at the tertiary hospital, but the local site negotiation and reapplication to regulators meant this site came on very late, contributing only 24.9% (88/353) of the participants, and thus could not compensate for the low absolute recruitment number.

During study recruitment, from October 12, 2015, to June 17, 2016, 4537 individuals were identified as being HIV positive (Table 1). Of those, 3540/4537 (78.02%) were willing to participate in the trial, were aged over 18 years, could read English or isiZulu, had a photo ID to confirm their identity, and had access to a mobile phone, with 754/3540 (21.30%) having an Android mobile phone with data access. Approximately 1.92% (87/4537) of people could not participate as they did not read English or IsiZulu.

Table 1. Recruitment cascade with reasons for ineligibility.

Characteristics	Participants, n (%) ^a
Prescreened (HIV-positive)	4537 (100.0)
Declined participation	90 (2.0)
Under 18 years old	12 (0.3)
Pregnant	269 (5.9)
Cannot read English or isiZulu	87 (1.9)
No photo identification (before requirement removed on 17 December 2015)	539 (11.9)
Passed prescreening	3540 (78.0)
Screened	3540 (100.0)
No working phone	498 (14.1)
No active SIM ^b card	8 (0.3)
No android phone	2100 (59.3)
Do not use data	226 (6.4)
Insufficient RAM ^c	133 (3.8)
Android version lower than 4.2	222 (6.3)
Passed screening	353(10.0)
Randomized	353 (100.0)
Intervention (mobile app)	181 (51.3)
Standard of care (control)	172 (48.7)

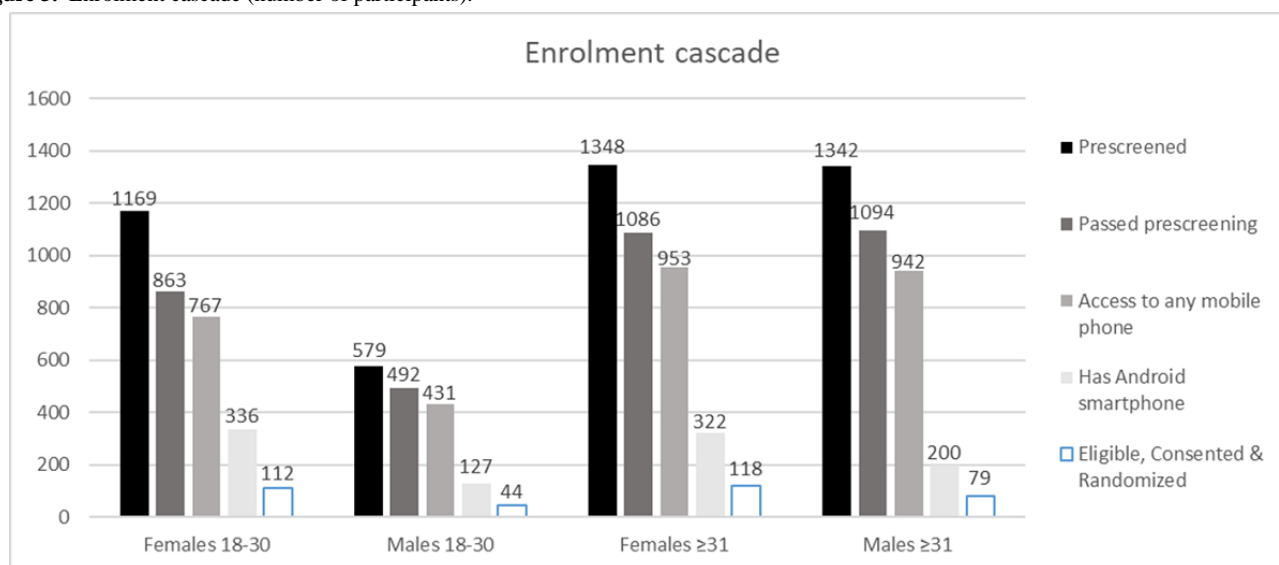
^aTotals might not add to 100% due to decimal rounding.

^bSIM: subscriber identification module.

^cRAM: random access memory.

Table 2. Reasons for initial refusal to enrol in study (N=90).

Reason	n (%)
Not interested	30 (33.7)
Not ready to discuss/disclose status	18 (20.2)
In a hurry	16 (18.0)
Sick and not able to talk	6 (6.7)
Do not feel comfortable	5 (5.6)
In denial	3 (3.4)
Other	9 (9.0)
Blank/missing reason	3 (3.4)

Figure 3. Enrolment cascade (number of participants).

A proportion of trial candidates did not have a working phone or active subscriber identification module (SIM) card (506/3540, 14.29%). Not having an Android mobile phone was the single most important factor of ineligibility for the trial (2100/3540, 59.32%), and this was compounded by related factors such as not having the correct Android version, adequate RAM or mobile data (581/3540, 16.41%). A small number were not willing to participate in the study, for the reasons listed in Table 2. The enrolment cascade by age group and gender is shown in Figure 3. Only 44/3540 (1.24%) young men were recruited, a key target group for the study.

Photo Identification

Enrolment in the study initially required verification of identity using photo ID due to the concern that without photo ID it would be difficult to verify the true identity of a person and therefore there would be a risk of disclosing confidential laboratory information to the wrong person. However, almost two thirds (529/824, 64.2%) of the patients screened did not have a photo ID at trial screening. The requirement for photo ID was therefore removed from the study eligibility criteria, with the consent of the Human Research Ethics Committee on 17 December 2015. To address the aforementioned disclosure concern the study team manually checked the NHLS database for each participant at the time of enrolment to ensure that the participant was new

to the NHLS system and therefore would not have access to confidential laboratory results of a potentially different person. Access to the NHLS database was limited to preauthorised study personnel.

App Design and Mobile Phone Platforms

The projected percentage of Android phone ownership was as anticipated through the life of the trial. However, the features required by the final version of the app, including security settings, limiting access, and live notifications sent to users, required a relatively new version of Android that was not supported by more than a third (222/575, 38.6%) of the Android phones our participants used, hampering eligibility for trial recruitment. The research project team met or spoke with the developer on an almost weekly basis during the design, implementation and analysis phase of the project. Many of the concerns regarding the app only became apparent as the study was being implemented, and capacity to rectify these were limited by the project timelines. Some mobile phones, despite being modern and supporting the up-to-date Android platform, did not have adequate RAM to allow app installation (Table 2) and we, therefore, had to exclude an additional 133/3540 (3.76%) patients as a result. RAM is an expensive part of the phone, and cheaper smartphones had smaller levels of RAM, a problem we did not anticipate. The next unexpected challenge was that

the app, despite field testing from the developer on one type of tablet, did not work on Android tablet devices that some patients had, again limiting recruitment, although this only affected a small number of trial candidates (n=15).

These problems were identified after the study had started. At that time recruitment was already severely behind schedule and the study team therefore elected to proceed with the study. As previously mentioned, the app was not made available through portals such as Google Play Store, as the study was HIV-specific and hence a download would have violated confidentiality around diagnosis. The Play Store has compatibility checking algorithms that are used before products are allowed to be released through the platform; this would likely have made explicit the app's minimum requirements earlier and reduced the number of issues we encountered. Without this check, the study team had to make the developer aware each time a problem was identified after the study was initiated.

Data Systems and Interoperability

A unique cross-facility patient identifier not available in the clinic or NHLS's patient information systems. This meant that the investigators had to create a method to keep track of trial participants and their laboratory results across multiple databases that did not communicate directly with each other. As a result, any single error in patient information collection and transcription during recruitment, clinic blood specimen collection or blood analysis led to difficulties in identifying that patient in the other databases. Throughout the trial, data quality processes were challenging because of the manual process of searching for participant information in NHLS's TrakCare user interface. The investigators found that 20.4% (72/353) of participants who had initially been identified as lost to follow up (ie, no follow up CD4 or viral load) using the laboratory request data which includes names and birth dates were actually linked to care at 8 months post-recruitment when a manual search of the NHLS database was conducted that included variations of names and dates of births. The different NHLS and research trial REDCap data systems all relied on positive ID of individual patients but lacked a unique patient ID between the systems.

Full interoperability for data exchange between the relevant systems and devices could not be achieved during the trial. A substantial number of participants in the trial arm did not receive their laboratory data through SmartLink, despite the successful installation of the app, and despite the data being available within the NHLS database. We are still working with the software designer to try to understand the causes of this problem. While participants were verbally instructed during trial enrolment to attend their clinics according to the standard South African HIV care and treatment protocol that all newly diagnosed patients receive and not simply wait for results on their app, the fact that some results were not received via the app does compromise the trial assessment of the effectiveness of the app.

Discussion

Principal Findings

A mobile phone-based intervention in urban South Africa still excludes at least 40% of newly diagnosed persons living with HIV simply based on the fact that they do not own or have access to a mobile phone. This combined with other trial entry requirements, such as needing to have Android 4.2 version or higher, app installation space and data, and the lower number of new HIV cases due to decreasing yield and decentralization of HIV testing made meeting the sample size requirement a challenge. In the end, less than 10% of people newly diagnosed with HIV at the study sites who were screened for the trial were enrolled in the study, although interest in participating in the study was high, with only 90/4537 (1.98%) people approached not wanting to join. Over 4500 new HIV cases were screened for trial participation, but only 353/4537 (7.78%) could be randomized. Of concern, the app only worked on more expensive or newer mobile phones, disadvantaging poorer patients.

Creating apps is complex and requires attention to an evolving technological environment. The software developer selected had a prior engagement with the NHLS and came recommended. Despite the fact that a number of the project team members were experienced in working in mobile health (mHealth), only one person, working within the NHLS, had experience in app creation—a tuberculosis (TB) app used by nurses and specifically designed for tablets, allowing for dynamic notifications, scheduling future notifications and matching patient data from two databases without a unique identifier. Additionally, the software development company that was hired to create our app had much experience with databases but very limited experience creating Android apps.

The team's inexperience with working with studies centralized around Android app-based interventions, as well as the difficulty in the relationship with the developer, meant that there was little ability to manoeuvre within the tight project timelines. This lack of experience from the project and Android software development teams likely contributed to the multiple app-creation challenges encountered. Having independent mechanisms to assess software development and technical support to the process by more expert teams would have been helpful.

The implications of these challenges are that any future similar app design or upgrade has to take the different platforms and phone operating systems into account, based on shifting preference for different phones. At the moment, Android apps have the maximum market share, and this was the platform we elected to use. Additional advantages of Android systems are that they allow for third-party push communication, their security systems ensure secure transmission and viewing of personal health data, and programming is easier compared to other operating systems. SmartLink itself has the potential to meet all these requirements if done by an experienced Android app developer.

Table 3. Study challenges and solutions.

Challenges	Potential solutions
Phone compatibility, data availability especially for poorer participants and feasibility of implementation across databases	<ul style="list-style-type: none"> • Adequate compatibility testing • Enable innovative access to data (either access to free WIFI hotspots, or vouchers) • Pilot implementation adequately with the target group
Lack of app availability across platforms	<ul style="list-style-type: none"> • Resources available for development across common platforms, if platforms differ at the time of implementation
Poor app development and testing	<ul style="list-style-type: none"> • Ensure sufficient expertise in app development and testing within the study team • Implement “agile” software development approaches, including field testing on “entry-level” commonly used mobile phone • Use of access points (eg, Google Play Store) to quality check app
Manual installation of the app, with training	<ul style="list-style-type: none"> • Use of access points for easier downloads • Improve usability to minimize instruction
Recruitment speed	<ul style="list-style-type: none"> • Ensure majority of the target population are eligible, through ensuring entry restrictions are minimized (data access, phone type, etc) • Piloting should be done mainly on a target group, not proxies such as staff, advisory groups or participants within existing clinics
Lack of photo identification of potential study participants	<ul style="list-style-type: none"> • Have alternative ways of registering patients against the database • Utilise future single patient identifiers that allow for cross-database identification

Given its functionality, SmartLink’s graphics and code could be compressed to get the install size down to under 5 MB. This is a reasonable size of an app with the functions of SmartLink, and the code could be optimized to lower the minimum RAM requirements. Developers need to ensure that software used in lower resourced settings can be used on older and less powerful phones.

There was a lack of availability of photo ID. In future, if a similar intervention is being rolled out, it is probable that some verifiable ID will be required for people to have routine access to their laboratory results. Educating health care clients that they need to bring this form of ID with them will be required at scale. Ideally, a unique clinic ID that links to both the NHLS database and the app would be available.

In line with the Department of Health’s mHealth Strategy and National Adherence Guidelines, which advocates for the use of cell phone technology to improve patient experiences with health systems and adherence to medication and visit schedules, we had planned to expand the use of the app beyond HIV testing and linkage to care; initial expansion of the app was planned to ART clinics, where patients are stable on ART, to communicate routine monitoring results; in future, it was to be used to communicate follow up actions and medication availability [15,16]. There were also plans to extend the service to TB and diabetic patients and increase the app’s functionality to allow doctors and nurses at a clinic level to send messages to individual patients if laboratory results are unexpected. Finally, we planned to use the app to support research participants, allowing communication between the site and the participant, possibly allowing us to assess self-testing devices used by patients to monitor their own chronic condition. While all these aspirations still stand, the current app will require substantial upgrading and operational testing before being deployed in such a variety of situations.

A large number of operational issues encountered suggest that far more care at a project management level and sufficient software expertise are required before an expansion of this approach to improving linkage to care (Table 3). The research team is looking at new approaches that would be accessible to a greater proportion of the population.

Conclusion

This study was trying to demonstrate something fundamental—that empowering patients with information would lead to more engagement in care, not that a specific technology works. The fact that the technology and operational issues were significant obstacles means we were not able to test our starting hypothesis.

Formal conventional scientific studies that evaluate mHealth interventions aiming to improve health outcomes suffer from the fact that the design and execution of these studies often take years, in an environment where changes in technology and social media are often measured in months. This project was far more complex than we anticipated, with multiple unanticipated challenges. Only a small minority of patients were able to access our intervention; those without mobile phones were excluded, and alternative methods may be required for these patients.

The importance of understanding health clients’ needs and preferences to design systems from a client perspective cannot be overemphasized. Conducting market research among clients with less access to health services and lower adherence should be prioritized. Learning from commercial sector systems especially mobile banking, which satisfy compliance standards and are widely used across socio-economic strata, may also be beneficial, as well as understanding the user experiences with such systems. Gradually building a module based mHealth system might work best, commencing with a component like client access to laboratory results, as in this trial, and expanding

to the challenging and interlinked areas of laboratory results-dependent rescripting and drug refill schemes with participating pharmacies and clinics. If functional, these could relieve pressure from clinics and make long-term treatment more convenient to patients.

Mobile health approaches are exciting, with the potential to engage patients in their own care in a way that's unprecedented. However, there is substantial work to be done on how to do this most effectively, and expertise in multiple areas of implementation is required.

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Authors' Contributions

All authors contributed to study conceptualization, design, analysis, and manuscript preparation. JC, MP, and VLC were involved in study execution with oversight from all authors.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.1).

[[PDF File \(Adobe PDF File\), 93KB - mhealth_v6i7e155_app1.pdf](#)]

References

1. UNAIDS. Global AIDS Update. Geneva: UNAIDS; 2017. URL: http://www.unaids.org/en/resources/documents/2017/2017_data_book [WebCite Cache ID 6rmpUsmLQ]
2. Rosen S, Fox MP. Retention in HIV care between testing and treatment in sub-Saharan Africa: a systematic review. *PLoS Med* 2011 Jul;8(7):e1001056 [FREE Full text] [doi: [10.1371/journal.pmed.1001056](https://doi.org/10.1371/journal.pmed.1001056)] [Medline: [21811403](https://pubmed.ncbi.nlm.nih.gov/21811403/)]
3. Fox MP, Rosen S, Geldsetzer P, Bärnighausen T, Negussie E, Beanland R. Interventions to improve the rate or timing of initiation of antiretroviral therapy for HIV in sub-Saharan Africa: meta-analyses of effectiveness. *J Int AIDS Soc* 2016;19(1):20888 [FREE Full text] [Medline: [27507249](https://pubmed.ncbi.nlm.nih.gov/27507249/)]
4. Fomundam H. What have we learned about the second 90? Evidence from the districts, in satellite: Making 90-90-90 a Reality: Business Unusual in South Africa. 2016 Presented at: 21st International AIDS Conference; 18 - 22 July 2016; Durban, South Africa URL: <http://programme.aids2016.org/PAGMaterial/PDF/Satellites/Thursday.pdf%20accessed%2007%20July%202017>
5. Larson BA, Schnippel K, Brennan A, Long L, Xulu T, Maotoe T, et al. Same-Day CD4 Testing to Improve Uptake of HIV Care and Treatment in South Africa: Point-of-Care Is Not Enough. *AIDS Res Treat* 2013;2013:941493 [FREE Full text] [doi: [10.1155/2013/941493](https://doi.org/10.1155/2013/941493)] [Medline: [23956850](https://pubmed.ncbi.nlm.nih.gov/23956850/)]
6. Kreutzer T. Online and Digital Media Usage on Cell Phones among low-Income Urban Youth in Cape Town, Jan 2009, URL: https://open.uct.ac.za/bitstream/item/9149/thesis_hum_2009_kreutzer_t.pdf?sequence=1 [accessed 2018-03-21] [WebCite Cache ID 6y5JyVybm]
7. Mbuagbaw L, Mursleen S, Lytvyn L, Smieja M, Dolovich L, Thabane L. Mobile phone text messaging interventions for HIV and other chronic diseases: an overview of systematic reviews and framework for evidence transfer. *BMC Health Serv Res* 2015 Jan 22;15:33 [FREE Full text] [doi: [10.1186/s12913-014-0654-6](https://doi.org/10.1186/s12913-014-0654-6)] [Medline: [25609559](https://pubmed.ncbi.nlm.nih.gov/25609559/)]
8. Barron P, Pillay Y, Fernandes A, Sebidi J, Allen R. The MomConnect mHealth initiative in South Africa: Early impact on the supply side of MCH services. *J Public Health Policy* 2016 Nov;37(Suppl 2):201-212. [doi: [10.1057/s41271-016-0015-2](https://doi.org/10.1057/s41271-016-0015-2)] [Medline: [27899795](https://pubmed.ncbi.nlm.nih.gov/27899795/)]
9. Boudes P. The treatment of Wegener's granulomatosis with sulfamethoxazole and trimethoprim. *Arch Intern Med* 1989 Jun;149(6):1467, 1471. [Medline: [2786399](https://pubmed.ncbi.nlm.nih.gov/2786399/)]
10. ClinicalTrials.gov. Smart Linkage-to-HIV Care Via a Smartphone App (SmartLtC). 2016. ClinicalTrials.gov Identifier: NCT02756949 URL: <https://clinicaltrials.gov/ct2/show/NCT02756949?term=Venter+app&rank=2> [WebCite Cache ID 6rmq5USRE]
11. The South African National Aids Council. 2017 Feb 15. Turn Around – The Story of South Africa's HIV Response: Foreword URL: <http://sanac.org.za/2017/02/15/turn-around-the-story-of-sas-hiv-response-foreword/> [accessed 2017-07-07] [WebCite Cache ID 6rmqAa4rj]
12. Southern African HIV Clinicians Society. URL: <http://www.sahivsoc.org/SubHeader?slug=ndoh-and-who-guidelines> [accessed 2017-07-07] [WebCite Cache ID 6rmqZpdfT]

13. Stevens WS, Marshall TM. Challenges in implementing HIV load testing in South Africa. *J Infect Dis* 2010 Apr 15;201 Suppl 1:S78-S84. [doi: [10.1086/650383](https://doi.org/10.1086/650383)] [Medline: [20225952](https://pubmed.ncbi.nlm.nih.gov/20225952/)]
14. Poushter J, Pew Research Center. Smartphone Ownership and Internet Usage Continues to Climb in Emerging Economies. *Global Attitudes & Trends* URL: <http://www.pewglobal.org/2016/02/22/smartphone-ownership-and-internet-usage-continues-to-climb-in-emerging-economies/> [WebCite Cache ID 6rmql6212]
15. South African National Department of Health. URL: <https://ndoh.dhmis.org/owncloud/index.php/s/R5cmdp0gY4Fa43Z?path=/M%20Health%20Strategy> [WebCite Cache ID 6rmrCezcP]
16. Department of Health, Pretoria. National Adherence Guidelines for HIV: tuberculosis and non-communicable diseases. 2016. URL: <https://www.nacosa.org.za/wp-content/uploads/2016/11/Integrated-Adherence-Guidelines-NDOH.pdf> [WebCite Cache ID 6rmrZXOMi]

Abbreviations

ART: antiretroviral therapy
CD: cluster of differentiation
GPS: Global Positioning System
ID: identification
mHealth: mobile health
NHLS: National Health Laboratory System
PIN: personal information number
RAM: random access memory
SIM: subscriber identity module
SMS: short messaging services
TB: tuberculosis
UNAIDS: Joint United Nations Programme on HIV/AIDS

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Original Paper

Mobile-Based Nutrition Counseling and Unconditional Cash Transfers for Improving Maternal and Child Nutrition in Bangladesh: Pilot Study

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Abstract

Background: Inappropriate feeding practices, inadequate nutrition knowledge, and insufficient access to food are major risk factors for maternal and child undernutrition. There is evidence to suggest that the combination of cash transfer and nutrition education improves child growth. However, a cost-effective delivery platform is needed to achieve complete, population-wide coverage of these interventions.

Objective: This study aimed to assess the feasibility, acceptability, and perceived appropriateness of an intervention package consisting of voice messaging, direct counseling, and unconditional cash transfers all on a mobile platform for changing perceptions on nutrition during pregnancy and the first year of a child's life in a poor rural community in Bangladesh.

Methods: We conducted a mixed-methods pilot study. We recruited 340 pregnant or recently delivered, lactating women from rural Bangladesh. The intervention consisted of an unconditional cash transfer combined with nutrition counseling, both delivered on a mobile platform. The participants received a mobile phone and BDT 787 per month (US \$10). We used a voice messaging service to deliver nutrition-related messages. We provided additional nutrition counseling through a nutrition counselor from a call center. We carried out cross-sectional surveys at baseline and at the end of the study, focus group discussions, and in-depth interviews with participants and their family members.

Results: Approximately 89% (245/275) of participants reported that they were able to operate the mobile phones without much trouble. Charging of the mobile handsets posed some challenges since only approximately 45% (124/275) households in our study had electricity at home. Approximately 26% (72/275) women reported they had charged their mobile phones at their neighbor's house, while 34% (94/275) reported that they charged it at a marketplace. Less than 10% (22/275) of women reported difficulties understanding the voice messages or direct counseling through mobile phones, while only 3% (8/275) of women reported they had some problems withdrawing cash from the mobile bank agent. Approximately 87% (236/275) women reported spending the cash to purchase food for themselves and their children.

Conclusions: The nature of our study precludes any conclusion about the effectiveness of the intervention package. However, the high coverage of our intervention and the positive feedback from the mothers were encouraging and support the feasibility, acceptability, and appropriateness of this program. Further research is needed to determine the efficacy and cost-effectiveness of mobile-based nutrition counseling and unconditional cash transfers in improving maternal and child nutrition in Bangladesh.

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KEYWORDS

unconditional cash transfer; mHealth; voice message; undernutrition

Introduction

Maternal and child undernutrition remains one of the most serious health problems in low- and middle-income countries [1,2]. Maternal and child undernutrition together cause 35% of child deaths annually [2,3] and account for approximately 11% of disability-adjusted life years lost each year globally [3]. A global review of childhood undernutrition in 2012 revealed that Bangladesh was one of the top 20 countries, with a very high prevalence of stunted growth among children [4].

In recent years, Bangladesh has achieved a significant reduction in maternal and child undernutrition [5]. However, persistent socioeconomic inequality means that the overall prevalence of undernutrition has increased [6]. A recent paper reported that the prevalence of stunted growth is considerably higher in children from lower socioeconomic households than children from higher socioeconomic households [6]. Over the last two decades, the government has made substantial investments in the nutrition sector and implemented several large nutrition programs [7]. However, access and utilization of health services are still determined by income, education, and other social determinants of health, and frequently, the poor do not receive desired benefits from such programs [8,9].

Behavioral risk factors at the household level including, inappropriate maternal and infant feeding practices, insufficient access to food, and poor water and sanitation facilities lead to maternal and child undernutrition [3]. The current strategy of counseling for improved maternal diets and appropriate infant and young child feeding may not be enough to ensure reductions in maternal and child undernutrition without providing additional resources to the family, especially in poor and food-insecure households [10]. In Bangladesh and other low- and middle-income countries, nutrition education and counseling have been delivered in person by health workers and local volunteers through community-based platforms [1]. However, an insufficient number of health workers and low utilization of antenatal care by women from lower socioeconomic households challenges high-coverage delivery of nutrition education and counseling, especially among poor households [5,7].

Mobile phones are useful tools for sharing information. There is wide coverage of mobile phones in Bangladesh. In 2017, the number of active mobile phone subscribers in the country was 129.6 million [11]. With such high community penetration of mobile phones, messages through interactive voice response (IVR) systems or direct counseling via call centers could be a viable solution for the dissemination of nutritional behavior change messages in Bangladesh and other resource-poor settings. Direct counseling over mobile phones can also reach a larger population more cost-effectively than face-to-face counseling [12,13].

Cash transfers are increasingly being used, in both developmental and emergency contexts, to reduce poverty, to improve access to food and health and education outcomes. The provision of conditional cash transfers to poor households

positively impacts overall health [14] and nutrition outcomes [15-17]. These programs can improve food consumption, food security, and dietary diversity, all of which are part of the causal pathway for child undernutrition. Compared to conditional cash transfers, there has been less research on unconditional cash transfers. However, a meta-analysis examining cash transfers on nutrition outcomes found small but nonsignificant impacts on height-for-age and also found that conditional programs had similar effects on unconditional cash transfers [18]. The arguments in favor of unconditional cash transfer programs are that the poor are rational actors and will invest some of their cash transfer on nutrition and health. Some also say that conditionality interferes with an individual's right to choose [19]. Cash transfer programs are often associated with high administrative costs and require strong monitoring mechanisms to avert fraud. These pose significant barriers for implementing such interventions in low-resource settings.

We envisaged that combining unconditional cash transfers with mobile-based nutrition education and counseling would be a cost-effective intervention for reducing maternal and child undernutrition in poor households, with the potential for scale-up in Bangladesh and other resource-poor settings. This study sought to assess the feasibility, acceptability, and perceived appropriateness of an intervention package consisting of voice messaging, direct counseling, and unconditional cash transfers, all on a mobile platform, for changing perceptions on nutrition during pregnancy and the first year of a child's life in a poor rural community in Bangladesh.

Methods**Study Design**

We conducted a mixed-methods pilot study. The study received approval from the research review committee and the ethical review committee of the International Center for Diarrheal Disease Research, Bangladesh (icddr,b). We obtained written consent from all study participants before enrollment, household surveys, and qualitative interviews. We conducted the study in selected villages of two unions (local administrative unit) in Kendua Upazilla (subdistrict) under the Netrokona district. We purposively selected the villages and unions because of their overall low socioeconomic conditions. During the study period, more than 50% of the population was classified as poor and approximately 35% were classified as extremely poor [16]. According to the Bangladesh Bureau of Statistics definition, extremely poor households are those households whose total expenditures are less than or equal to the lower poverty line, which is commensurate with 1805 calories per person per day. The poor are those households whose total expenditures are less than or equal to the upper poverty line, which is commensurate with 2125 calories per person per day [20]. The study health workers made door-to-door visits across the study area covering 5429 households and identified pregnant women or recently delivered, lactating women. We recruited all women in our study area who were pregnant or had had a birth in the last 6

months and were currently lactating and expressed their willingness to participate in the assessment procedures. We followed up all participants for at least 6 months.

Brief Description of the Intervention

Free Mobile Phone

Once registered, each woman received a mobile phone (Micromax X248 handset) with a standard connection from Banglalink, one of the largest mobile connection providers in the country. We also provided them with limited mobile credit of BDT 70 per month (US \$0.89) for approximately 10 calls to the call center.

Prerecorded Mobile Voice Messages

We used life cycle stage-appropriate, prescheduled, voice messages from an IVR system called “Aponjon” for nutrition behavior change communication. Aponjon is a mobile-based mHealth service for expecting and new mothers in Bangladesh under the sponsorship of Mobile Alliance for Maternal Action. The Ministry of Health and Family Welfare has approved the content of Aponjon messages for wider distribution. A previous study, which assessed the efficacy of Aponjon messages, found no significant association between Aponjon messages and maternal healthcare behaviors. However, the study had inadequate power to detect any meaningful associations [21]. Aponjon covers topics like diet and care during pregnancy, breastfeeding, complementary feeding, care during child illnesses, and basic hygiene. We recorded all messages in Bangla, using a female voice. The duration of the messages was between 40 and 55 seconds. The Aponjon IVR system sent 2 voice messages per week to every participant for 24 weeks.

Direct Nutrition Counseling Through Mobile Phones

Trained nutrition counselors also provided nutrition support and information through a call center set up at the icddr,b. The counselors made biweekly calls to every participant for 24 weeks. The counselors listened to the women’s experience with their diet and feeding their children and offered suggestions and support. The call center provided nutrition-specific educational messages to all participants, depending on the women’s gestational age or age of the child. The counselors also regularly checked if the woman had been listening to and understood the voice messages sent to them through Aponjon, enquiring about the last message sent to the mother during their biweekly calls. Direct counseling focused on appropriate nutrition (amount of food, frequency of food) for pregnant and lactating women, exclusive breast feeding, complementary feeding, dietary diversity, appropriate care, health care seeking in pregnancy, hand washing, personal hygiene, sanitation, and other relevant topics.

Unconditional Cash Transfer Through Mobile Banking

We planned cash transfers of BDT 787 per month (US \$10) and delivered them to the participants’ mobile phone. This amount represents approximately 17% of the average monthly income of the poorest 40% of rural households (approximately US \$60 per month) [17]. Although we intended to make monthly transfers, we disbursed the total cash amount in 3 installments

over 6 months due to logistical issues. Cash was transferred directly to the women’s bKash, mobile bank accounts, which greatly reduced the chance of illegal practices and also empowered the participating women. The study staff trained the participants about basic phone maintenance, receiving and listening to voice messages, and bKash mobile banking.

Quantitative Data Collection

We used a single-arm experimental pre-post design. We conducted the baseline survey before we delivered the intervention. Then, after 8 months of implementing the intervention, a further end-line survey was conducted. We enrolled and interviewed 340 women in the pilot study during the baseline survey. However, we were able to interview only 275 (81%) women at the end of the project, mainly due to out-migration. We collected detailed information on household socioeconomic conditions, the use and usability of voice messaging and direct counseling, perceptions of the importance and usefulness of nutrition education, willingness to pay for such information services in future, understanding the content and knowledge retention, expenditure patterns of the project cash, compliance, barriers to mobile banking and nutrition education, and other related topics.

Qualitative Data Collection

The qualitative study was conducted 8 months after the start of the intervention, between February and March 2016. Qualitative assessment included in-depth interviews, key informant interviews, and focus group discussions (FGD). For the qualitative interviews, we applied a purposive sampling strategy. Table 1 describes the methods and number of participants in the qualitative assessment. We developed separate semistructured guidelines for each type of respondent to guide the in-depth interviews and FGD. The guidelines were later translated into Bangla, in consultation with the local researchers, and were pretested with pregnant women, men, and a key informant. Based on the results of the pretest, the guidelines were adjusted.

Data Analysis

Data captured during the household surveys were analyzed using Stata (StataCorp, 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP). We mostly used frequency analyses for all quantitative data. To measure the average time or willingness to pay, we calculated both the median and mean with SD. We used principal components analysis to construct a wealth index from available information on assets. We used information on ownership of household assets (such as TVs, radios, bicycles, motorcycles/scooters, tables, chairs, and wardrobes), housing materials (floor, wall, and roof materials), access to utilities (electricity, safe water, and clean energy), and house and land ownership to construct the household wealth index [22]. We later grouped the wealth index score into quintiles, with quintile 1 representing the poorest segment of the population and quintile 5, the wealthiest. To measure household food security, we used the Household Food Insecurity Access Scale, developed by the Food and Nutrition Technical Assistance Project [23].

Table 1. Methods, numbers, and types of respondents for the qualitative information.

Method and type of respondent	Number (N=21)
In-depth interview	
Enrolled pregnant women	7
Enrolled recently delivered mothers	7
Husbands of enrolled women	5
Focus group discussion	
Mothers-in-law of enrolled women	2

For qualitative data, all interviews were recorded using digital audio recorders. Audio recordings of all interviews and group discussions were transcribed verbatim in Bangla, the local language, by the research team. A qualitative expert (AA), who speaks Bangla, randomly checked the transcriptions against the audio recordings to ensure the quality of the interviews and transcription. We conducted thematic coding based on the data collection guidelines, but since our study was explorative, we were open to including any important themes that emerged in the transcript. We then discussed and summarized the text supporting each thematic code and have presented the findings using quotes and text tables.

Results

Quantitative Findings

Demographic Characteristics of the Women

We recruited 340 pregnant or recently delivered, lactating women between March 2015 and April 2015. Table 2 presents the baseline characteristics of all 340 participants who were recruited in the study, as well as of the 275 participants for whom we had complete information. Approximately half of the women were 15-24 years old. About one-third of the women had minimal education (ie, no education or incomplete primary level) but approximately two-thirds had completed the primary level of education. More than half of the women belonged to food-insecure households, with one-fifth belonging to severely food-insecure households. About 20% (65/340) of women were lost to follow-up in the end-line survey due to out-migration. However, we found no differences regarding sociodemographic characteristics between women who migrated out and women who remained in the study area.

Barriers to Using the Mobile Platform for Nutrition Counseling and Cash Transfer

Approximately 11% (30/275) of the women reported that they had faced some difficulty operating their mobile phones. Almost half the participants either had to go to their neighbor's house or to a marketplace to charge their mobile phones. The median time duration when a mobile phone was switched off due to a dead battery was 2 days (Table 3).

Feasibility and Perceived Appropriateness of Nutrition Education Through Mobile Voice Messaging

About 2 out of 3 women reported missing at least one voice message from the Aponjon service over the 6-month study period. The mean and median number of missed voice messages

was 3.1 (SD 2.4) and 2.0, respectively. Most women cited household responsibilities and dead batteries as the main reasons for failing to receive some of the voice message calls. Also, about a third of the participants reported having difficulty hearing the voice messages due to poor mobile network connections. Approximately 96% (263/275) of women reported that they did not know how to replay earlier messages they had received. Most women had no difficulties understanding the content of the messages. Nearly all of the mothers reported that they found the messages relevant to the stage of their pregnancy or the age of their child, and a similar percentage said the amount of information provided in each message was appropriate. They also found the frequency of messages (2 per week) adequate for their needs (Table 4).

Feasibility and Perceived Appropriateness of Direct Nutrition Counseling Through Mobile Phone

During the 6 month study period, the call center made a total of 4290 attempts (daily average of 32) and was successful in reaching the mothers in 81% (3475/4290) of cases. Each woman was scheduled to receive at least 12 calls from the call center, but approximately two-thirds of the women reported missing at least 1 call. The mean and median number of missed calls was 2.7 (SD 1.7) and 2 respectively. Being busy with household chores was cited as the most common reason for missing calls from the call center. About half of our participants reported making at least one call to the counselor, and the mean number of calls from the participants was 2.5 (SD 1.5). Approximately 95% (221/232) of our participants reported that they were satisfied with the counseling and the answers provided to their queries. However, unlike the voice message service, approximately 22% (60/275) of women said that biweekly calls were not sufficient. The women were asked to tell their preferred medium for nutrition communication. Approximately 62% (171/275) said they liked both communication channels, while one-third of women said they preferred direct counseling (Table 5).

Feasibility and Acceptability of Cash Transfers Through the Mobile Banking System

We also assessed the feasibility of transferring unconditional cash through the bKash mobile banking system. More than half of the participants opened their bKash mobile bank account in their name, while 35.6% (98/275) of the women had their account in their husband's name (Table 6). The mean and median number of days to open a bKash account was 7.5 (SD 8.9) and 6 days, respectively.

Table 2. Characteristics of study participants at baseline and the end of the study.

Characteristic	Baseline (n=340), n (%)	End of study (n=275), n (%)
Age (years)		
15-24	179 (52.9)	140 (50.9)
25-34	144 (42.4)	120 (43.6)
35-44	16 (4.7)	14 (5.1)
Women's education		
No education	42 (12.4)	35 (12.7)
Primary incomplete	84 (24.7)	69 (25.1)
Primary complete	59 (17.4)	49 (17.8)
Secondary incomplete	118 (34.7)	95 (34.5)
Secondary or higher	36 (10.6)	26 (9.5)
Husband's education		
No education	107 (31.5)	90 (32.7)
Primary incomplete	76 (22.4)	63 (22.9)
Primary complete	43 (12.7)	35 (12.7)
Secondary incomplete	72 (21.2)	54 (19.6)
Secondary or higher	42 (12.4)	32 (11.6)
Husband's occupation		
Unskilled laborer	102 (30.0)	89 (32.4)
Skilled worker	59 (17.4)	47 (17.1)
Business/Trade	57 (16.8)	46 (16.7)
Service holder	41 (12.1)	28 (10.2)
Others	79 (23.2)	64 (23.3)
Household wealth index		
Poorest	69 (20.5)	58 (21.1)
Second	66 (19.6)	56 (20.4)
Middle	68 (20.2)	56 (20.4)
Fourth	67 (19.90)	51 (18.5)
Richest	67 (19.9)	53 (19.3)
Household had at least one mobile	303 (89.1)	243 (88.4)
Household had electricity	158 (46.5)	124 (45.1)
Household food security		
Secure	164 (48.7)	138 (50.2)
Mildly food-insecure	9 (2.7)	5 (1.8)
Moderately food-insecure	93 (27.6)	81 (29.5)
Severely food-insecure	71 (21.1)	50 (18.2)

Table 3. Barriers in using mobile platform for nutrition counseling and cash transfer (n=275).

Barrier	n (%)
Quality of the mobile set	
Very good	87 (31.6)
Good	140 (50.9)
Average	37 (13.4)
Not good	11 (4.0)
Had difficulties receiving calls	16 (5.8)
Had difficulties making calls	30 (10.9)
Place of mobile charging	
Home	142 (51.64)
Neighbor's house	72 (26.18)
Marketplace	94 (34.18)

Table 4. Feasibility and perceived appropriateness of nutrition education through mobile voice messaging (n=275).

Voice message outcomes	n (%)
Received all voice messages ^a	101 (36.8)
Missed at least one voice message	173 (63.1)
Reasons for failing to receive voice messages ^b	
Was busy with household chores	119 (66.5)
Mobile was out of charge	60 (33.5)
Family members received messages (at least once)	87 (32.8)
Had difficulties in hearing the messages (at least once)	
Due to poor network	86 (90.5)
Due to too much ambient noise	9 (9.5)
Knew how to listen to an old message	
Yes	11 (4.0)
No	263 (96.0)
Had difficulties understanding the messages (at least once)	22 (8.0)
Received text message mistakenly (at least once)	30 (10.9)
Messages were appropriate as per pregnancy and child age	265 (96.0)
The frequency of messages was appropriate	230 (78.8)
Amount of information in each message was appropriate	263 (96.0)

^aThe total number of voice messages was 48.

^bAmong women who reported missing at least 1 message.

Table 5. Feasibility and perceived appropriateness of direct nutrition counseling through mobile phone (n=275).

Call center outcomes	n (%)
Received all calls from the call center ^a	92 (33.4)
Ever missed any call from the call center	183 (66.5)
Reasons for failing to receive a voice message	
Was busy with household chores	108 (59.0)
Mobile was out of charge	61 (33.3)
Other family members spoke to the counselor (at least once)	80 (29.1)
Called the call center on her own (at least once)	151 (50.9)
Reasons for not calling the call center	
Didn't feel the need	114 (84.5)
Satisfied with the counseling and response to queries	221 (95.2)
Counseling was appropriate as per pregnancy and child age	270 (98.2)
Frequency of counseling was appropriate	215 (78.2)
Direct counseling should be more frequent	60 (21.9)
Amount of information in each counseling was appropriate	270 (98.2)
Preference for nutrition communication medium	
Voice messaging	14 (5.1)
Direct counseling from the call center	90 (32.7)
Both	171 (62.2)

^aThe total number of counseling calls was 12.

In almost two-thirds of cases the women's husbands were responsible for collecting the money. The mean and median times to go to the nearest bKash agent were approximately 24 (SD 14.7) and 20 minutes, respectively. Approximately 97% (264/272) of the participants reported having faced no problem withdrawing the money (Table 6). The mean and median times between the debit and withdrawal of cash were approximately 4 days (SD 6.8) and 2 days, respectively.

Willingness to Participate and Pay for Similar Services in the Future

We asked the participants whether or not they would be interested in receiving similar services in their next pregnancy and if they would be willing to pay for such services. Approximately 93% (255/275) and 92% (252/275) of the women expressed their willingness to receive voice message services and direct counseling in the future, respectively, and a similar percentage of women showed their willingness to pay and even join using their own mobile phones. On average they were willing to pay BDT 3 (US \$0.04) for each voice message (median) and BDT 5 (US \$0.06) for each counseling (median) call from the call center (Table 7).

Qualitative Findings

Several significant themes emerged from our analyses, revealing the feasibility and acceptability of our intervention. We have illustrated the emergent themes with exemplary quotations. Many of the qualitative findings supported the quantitative findings presented above. Most participants referred to the voice

messaging as a call from "Daktar Apa" (Doctor Sister) and the direct counseling from the call center as a call from "Pushti Apa" (Nutrition Sister).

Barriers to Operating Mobile Phones

Most participating women stated that they had no difficulties operating their mobile phones, even though some of them had no previous experience using mobile phones. Most women reported that on only a few occasions, they failed to receive the call, which supports our findings from the quantitative analysis. Most participants identified household responsibilities as a major factor related to missing calls. However, the majority successfully overcome this barrier by implementing their own, specific strategies, including organizing time and getting support from their families.

I used to keep myself free and wait on Monday and Wednesday around 8 in the morning for Daktar Apa's call (voice message). [A pregnant woman]

I told my mother about this program, and she would always make sure that I never miss a call. [A pregnant woman]

Perceived Appropriateness of Voice Messaging and Direct Counseling

Women and family members felt the information provided was very important and beneficial for both mother and child. The majority perceived that they learned many new things. Some women believed they also experienced positive outcomes due to this intervention.

Table 6. Feasibility and acceptability of cash transfer through mobile banking from the end of study survey (n=275).

Cash transfer and mobile banking outcomes	n (%)
A mobile bank account in the participant's name	150 (54.6)
A mobile bank account in the name of participant's husband	98 (35.6)
A mobile bank account in the name of another family member	27 (9.8)
Difficulties understanding the cash transfer notification	73 (24.91)
Reason for failing to understand the notification	
Failed to read or understand the short message service (SMS)	37 (50.68)
Could not check the balance	34 (46.58)
Person responsible for withdrawing the cash in the family	
Husband	169 (61.5)
Self	70 (25.5)
Other family members	36 (13.0)
Main reasons for not going to withdraw cash by herself	
Restriction from the family	97 (48.0)
Mobile agent office was too far	64 (31.7)
Did not know where to withdraw cash	34 (16.8)
No bank account on her name	19 (9.4)
Difficulties withdrawing cash	8 (2.9)
Person responsible for deciding how to spend the cash	
Herself	165 (60.6)
Husband	56 (20.6)
Both	40 (14.7)
Expenditure pattern	
Purchase food for mother and child	236 (86.8)
Purchased food for the family	42 (15.4)
Used for another family purpose	14 (5.2)
Used to buy livestock	11 (4.0)
Savings	44 (16.2)

Table 7. Willing to participate and pay for similar services in future from the end of study survey (n=275).

Willingness to participate and pay	n (%)
Willing to receive nutrition education via voice message service in future	255 (93.1)
Willing to pay for voice messaging	234 (91.8)
Amount to pay for voice message, mean (SD); median	5.3 (6.5); 3.0
Willing to receive counseling via call center in future	252 (91.6)
Willing to pay for counseling	241 (95.6)
Amount to pay for each counseling, mean (SD); median	6.2 (6.1); 5.0
Willing to join similar services even if no phone is given	251 (91.2)
Will use my old phone	108 (43.0)
Would buy a new phone	64 (25.5)
Husband's phone	71 (28.3)
Others	8 (3.2)

My babu (child) used to throw-up everything after feeding. Pushti Apa told me to tap on the back after each feeding. Now he does not throw up anymore. [A lactating woman]

Now, I don't have to go to Netrokona (district town) to seek consultations with doctors. Pushti Apa is fulfilling all her needs over the telephone. [Husband of a pregnant woman]

I used to be skinny; now I have gained weight. I have eaten everything that they have advised me to eat. [A pregnant woman]

The women understood the information provided through both voice messaging and direct counseling. Almost all the women reported that they did not have any problem understanding the language, the accent of the recorded voice, or the voice of the live counselor. The majority of women felt that both voice messaging and direct counseling were delivered in an easy to understand language.

I loved to listen to the messages, they spoke in such a nice language. [A pregnant woman]

In response to the prompted question about the content of the last voice message or counseling from a nutrition counselor, the majority of women were able to recall the message's content.

Daktar Apa told me (in the last call) that during diarrhoea we should not stop feeding our children and also continue the breastfeeding. They also told us to give oral saline and another medicine. [A lactating woman]

Daktar Apa told me not to use any oil or water on newborn umbilicus. If the umbilicus (child's) remain wet after 15 days, we should go and see a doctor. [A pregnant woman]

Regarding appropriateness of message frequency, the majority felt 2 voice messages per week were sufficient, but the frequency of calls from the call center was inadequate.

A call after 15 or 20 days is sometime too late. There was an occasion when my child was vomiting, but I could not inform Apa (referring to the Counselor) before another two weeks. [A lactating woman]

Preference Between Voice Messaging and Direct Counseling

Most women and family members liked the combination of voice messages and counseling by direct phone calls, and the opportunity to call the nutrition counselor when needed. They said each had a unique advantage. However, when asked to choose the best communications channel the majority chose direct counseling.

I liked the direct one (call), I could talk to Pushti Apa and ask for her advice if I have any problem with my child. [A lactating woman]

I liked the direct call better; sometimes my wife doesn't understand the voice message. [Husband of a lactating woman]

But, there were a few participants who preferred the voice messages as they contained a wider range of topics and more detailed information.

The one that comes twice a week (voice message) is more useful. It provides information on different subjects. [A lactating woman]

Barriers to Using Mobile Banking

Most women reported that the process of opening a bKash account was not complicated. However, the mandatory requirement of showing a national ID as a proof of identity did provide a barrier for some women.

My mother-in-law opened the bKash account for me, and she used my sister-in-law's NID card as I had no NID card at that time. [A pregnant woman]

In most cases, the participant's husband went to the bKash agent to withdraw the mobile money. The majority said during pregnancy or immediately after childbirth, it is not customary for a woman to go outside, especially to the marketplace, which is far from the house. Also due to the women's physical conditions, it might have been difficult to walk for long distances.

Use of Cash

Our findings revealed that for most families the cash received from the project was used for purchasing food, and on some occasions for treatments or medicines. The majority of women said they bought fruit, milk, eggs, vegetables, iron or calcium supplements, and suji (semolina) for themselves or their children, as advised by the nutrition counselor.

My husband bought me five egg-laying chickens. I can now eat eggs every day. [A pregnant woman]

She used most of the money for herself like she bought banana, milk, and eggs for her. [Husband of a pregnant woman]

A few families also used some of the money for other urgent needs, such as health care for their ill child and ill-mother. Some women invested some of the money in income-generating activities, such as buying poultry or saving money.

I have enough food in my house, so I spent the money for buying medicines and other household items. [A participating woman]

I have saved around 1000 taka (US \$12) and bought some poultries. [A participating woman]

I consider the cash as a saving; if I can't manage to get something for her from my own income, I will use the cash from the project. [Husband of a pregnant woman]

Involvement of the Family

There was provision for providing a second number to the Aponjon voice message system, and many women provided their husband's mobile number as the secondary number. However, very few of them reported receiving any voice messages on the secondary number. Some of the pregnant and

lactating women tried to engage other family members in listening to the messages on their own.

My father-in-law, mother-in-law, sister-in-law – all appreciated this project. They are from old days and didn't know a lot of things. They also have learnt many things from Daktar and Pushti Apa. [A lactating woman]

I have learnt that my "abu" (grandchild) requires more nutritious food. It is important that we give him green leafy vegetables, chicken liver, khichuri (rice and lentil mixture). We didn't know much about the importance of these foods. [Mother-in-law of a lactating woman]

Our findings revealed widespread cooperation from the participating women's husbands, who contributed to the decision-making regarding the spending of the money. No women reported any problems in using the money as they intended.

Since the family belongs to both husband and wife, it is wise to take decision together and spend accordingly. [A lactating woman]

Discussion

We found that our intervention of using mobile phones for nutrition counseling and cash transfer was a feasible and acceptable option for changing perceptions on nutrition during pregnancy and the first year of a child's life among low-income families in rural Bangladesh. The women in the rural community found that this intervention was appropriate given their needs. Their willingness to participate and pay for the services further supports the acceptability of our intervention. The women were interested both in listening to the voice messages and in interacting with the nutrition counselor, which indicates that the combination of structured voice messaging and direct phone counseling could be the most effective communication strategy.

The current study also highlights the potential reach of mobile-based nutrition interventions in resource-constrained environments. Despite recruiting our study participants from a poor community and with one-third of our participants having no education or minimal education, we found that only a few of the study participants faced barriers to the use of mobile phones. Poor network or lack of mobile signal posed some difficulties in transmitting voice messages. However, the mobile networks in Bangladesh have grown significantly over recent years. Bangladesh currently has over 130 million mobile subscribers. Currently, mobile networks cover more than 99% of the country. Charging of the mobile phone also posed a barrier since almost half of the families did not have electricity at home. But most families were able to find a solution either by charging the phone at a neighbor's house or taking the phone to the marketplace where there were commercial outlets for mobile charging.

We also found that cash transfer through the mobile banking system was a feasible means of distributing cash. In the majority of cases, women opened the account in their names. However, due to cultural and physical barriers (eg, distance) husbands

were primarily responsible for withdrawing the money. The majority of the participants reported having faced no problem withdrawing the money. Regarding the use of cash, our study reported that one of the highest priorities for low-income families was purchasing food, although some families used the money for other urgent needs, such as healthcare for their ill child. Women from poor, but slightly better off, families tended to save some money to meet future needs or invest in income-generating activities, such as buying chickens.

Our results should be interpreted in the light of some of the limitations of our study. First, we used an existing voice messaging service, which was primarily developed for maternal health. However, we mitigated this by focusing on nutrition during the direct counseling. Second, we could not disburse the cash monthly as originally planned. There were some delays in the disbursement. Icdrr is a research organization and not structured as a service-providing organization. There was no system in place to ensure regular monthly payments to a large number of participants outside the organization. This is unlikely to happen in program settings with organizations that have appropriate financial systems and experience to make regular cash transfer payments. The reduced frequency might have reduced the barriers; for example, it would have been a much higher opportunity cost for the families if they had to withdraw the money every month. Also, we do not know if the use of the cash would have been different if they received monthly payments, as originally planned. Third, the follow-up rate was not very high. We failed to follow up with 20% of the study participants at the end of the study. However, we did not find any differences between women who migrated from our study area and women who continued to reside there. Finally, in this study we did not aim to compare mobile counseling versus face-to-face counseling or to assess the impact of the different communication strategies, and hence, there was no comparison group.

In Bangladesh, the government and different development organizations are showing strong interest in using nutrition counseling and cash transfer as tools to fight maternal and child undernutrition. Since we originally developed the concept of cash and counseling on a mobile platform, there is new evidence from Bangladesh supporting the combination of counseling and cash transfer as an intervention to reduce child undernutrition. A recently completed cluster-randomized controlled trial in rural Bangladesh, which followed the participants for 24 months, reported that the combination of cash transfers and nutrition behavior change communication decreased the rate of stunted growth by 7.3 percentage points, which is almost three times the average national decline [24]. The Government of Bangladesh, with assistance from World Bank, has recently launched a large program (Income Support Program for the Poorest, ISPP), which aims to reach 600,000 of the poorest households across Bangladesh with an objective to reduce poverty and improve child nutrition. The program will provide cash to the mothers, on the condition that they attend school and monthly nutrition sessions for mothers, including growth monitoring of the children [25]. However, a key limitation of these interventions is the intensity and level of human resources needed for face-to-face nutrition counseling, which makes it

unlikely to be translated into large-scale programs. Also, most of the programs in Bangladesh, and elsewhere, especially in Latin America, use conditions for the cash transfer. The common conditions used in the programs include medical check-ups and school attendance [26-31]. However, health conditions only work best where the health system is ready to cater to the needs of an additional population who otherwise would not have come to the health center. With high community penetration of mobile phones, nutrition communication on mobile platforms is one of the most viable solutions for attaining high coverage for many low- and middle-income countries. Mobile-based communications can reach a larger population and help maintain the standard of counseling with simpler monitoring mechanisms [32]. Our pilot intervention of providing nutrition counseling through mobile platform thus provides an alternative approach that has the potential for upscale to reach across the country.

In Bangladesh, most cash transfer programs hand out cash directly to participants. In the ISPP program, the participating mothers will receive cash transfers into their post office accounts. We used mobile banking to disburse cash in our project. Mobile banking has been found to play a key role in financial inclusiveness for low-value transactions. Use of mobile cash transfers significantly reduces the costs to participants for obtaining the cash transfers and also reduces the implementing

agency's variable implementation costs [33]. In Bangladesh, mobile financial services are increasingly used across the country, and the daily transaction amount across all mobile banks was over BDT 47 million (US \$603,000) in 2015 [34].

Although there is a great deal of interest and excitement surrounding nutrition counseling and cash transfer in Bangladesh, there is insufficient evidence documenting their effectiveness. Using the lessons learned in the pilot study for establishing a mobile-based system to send voice messages, provide direct counseling, and deliver cash transfer, we now plan to investigate the impact of this intervention on stunted growth in children in a larger randomized trial. We have already developed one such large study using a cluster-randomized controlled trial design where we aim to assess the effectiveness of mobile phones and nutrition behavior change communication, combined with unconditional cash transfers, for reducing the prevalence of stunted growth in children at 24 months. We will commence this 4-year study in 2018. The proposed trial will provide high-level evidence of the efficacy and cost-effectiveness of mobile phones and nutrition behavior change communication, combined with unconditional cash transfers, in reducing child undernutrition in a low-income and food-insecure population.

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Conflicts of Interest

None declared.

References

1. Bhutta ZA, Das JK, Rizvi A, Gaffey MF, Walker N, Horton S, Lancet Nutrition Interventions Review Group, the MaternalChild Nutrition Study Group. Evidence-based interventions for improvement of maternal and child nutrition: what can be done and at what cost? *Lancet* 2013 Aug 03;382(9890):452-477. [doi: [10.1016/S0140-6736\(13\)60996-4](https://doi.org/10.1016/S0140-6736(13)60996-4)] [Medline: [23746776](https://pubmed.ncbi.nlm.nih.gov/23746776/)]
2. Black RE, Allen LH, Bhutta ZA, Caulfield LE, de OM, Ezzati M, MaternalChild Undernutrition Study Group. Maternal and child undernutrition: global and regional exposures and health consequences. *Lancet* 2008 Jan 19;371(9608):243-260. [doi: [10.1016/S0140-6736\(07\)61690-0](https://doi.org/10.1016/S0140-6736(07)61690-0)] [Medline: [18207566](https://pubmed.ncbi.nlm.nih.gov/18207566/)]
3. Maternal and Child Nutrition Study Group, Black RE, Alderman H, Bhutta ZA, Gillespie S, Haddad L, et al. Maternal and child nutrition: building momentum for impact. *Lancet* 2013 Aug 03;382(9890):372-375. [doi: [10.1016/S0140-6736\(13\)60988-5](https://doi.org/10.1016/S0140-6736(13)60988-5)] [Medline: [23746778](https://pubmed.ncbi.nlm.nih.gov/23746778/)]
4. Stevens G, Finucane MM, Paciorek CJ, Flaxman SR, White RA, Donner AJ, Nutrition Impact Model Study Group (Child Growth). Trends in mild, moderate, and severe stunting and underweight, and progress towards MDG 1 in 141 developing countries: a systematic analysis of population representative data. *Lancet* 2012 Sep 01;380(9844):824-834 [FREE Full text] [doi: [10.1016/S0140-6736\(12\)60647-3](https://doi.org/10.1016/S0140-6736(12)60647-3)] [Medline: [22770478](https://pubmed.ncbi.nlm.nih.gov/22770478/)]
5. The DHS Program. 2014. BANGLADESH DEMOGRAPHIC AND HEALTH SURVEY 2014 URL: <https://dhsprogram.com/pubs/pdf/FR311/FR311.pdf> [accessed 2018-06-14] [WebCite Cache ID 70APgrB5n]
6. Huda T, Hayes A, El AS, Dibley MJ. Social determinants of inequalities in child undernutrition in Bangladesh: A decomposition analysis. *Matern Child Nutr* 2018 Jan;14(1). [doi: [10.1111/mcn.12440](https://doi.org/10.1111/mcn.12440)] [Medline: [28271627](https://pubmed.ncbi.nlm.nih.gov/28271627/)]
7. World Bank Study. 2015. Bangladesh National Nutrition Services Assessment Of Implementation Status URL: <https://openknowledge.worldbank.org/bitstream/handle/10986/22377/9781464806407.pdf?sequence=1> [accessed 2018-06-14] [WebCite Cache ID 70AQBg4cb]
8. Celik Y, Hotchkiss DR. The socio-economic determinants of maternal health care utilization in Turkey. *Soc Sci Med* 2000 Jun;50(12):1797-1806. [Medline: [10798333](https://pubmed.ncbi.nlm.nih.gov/10798333/)]

9. Gwatkin DR, Bhuiya A, Victora CG. Making health systems more equitable. *Lancet* 2004;364(9441):1273-1280. [doi: [10.1016/S0140-6736\(04\)17145-6](https://doi.org/10.1016/S0140-6736(04)17145-6)] [Medline: [15464189](https://pubmed.ncbi.nlm.nih.gov/15464189/)]
10. Ruel M, Alderman H, Maternal and Child Nutrition Study Group. Nutrition-sensitive interventions and programmes: how can they help to accelerate progress in improving maternal and child nutrition? *Lancet* 2013 Aug 10;382(9891):536-551. [doi: [10.1016/S0140-6736\(13\)60843-0](https://doi.org/10.1016/S0140-6736(13)60843-0)] [Medline: [23746780](https://pubmed.ncbi.nlm.nih.gov/23746780/)]
11. Mustafa K, Mujeri, Azam SE. Interoperability of Digital Finance in Bangladesh: Challenges and Taking-Off Options. In: <http://inm.org.bd/wp-content/uploads/2018/06/Working-Paper-54.pdf>. Dhaka, Bangladesh: Institute for Inclusive Finance and Development (InM); Apr 2018.
12. Liao Y, Wu Q, Tang J, Zhang F, Wang X, Qi C, et al. The efficacy of mobile phone-based text message interventions ('Happy Quit') for smoking cessation in China. *BMC Public Health* 2016 Dec 19;16(1):833 [FREE Full text] [doi: [10.1186/s12889-016-3528-5](https://doi.org/10.1186/s12889-016-3528-5)] [Medline: [27543164](https://pubmed.ncbi.nlm.nih.gov/27543164/)]
13. Zhao J, Freeman B, Li M. Can Mobile Phone Apps Influence People's Health Behavior Change? An Evidence Review. *J Med Internet Res* 2016 Oct 31;18(11):e287 [FREE Full text] [doi: [10.2196/jmir.5692](https://doi.org/10.2196/jmir.5692)] [Medline: [27806926](https://pubmed.ncbi.nlm.nih.gov/27806926/)]
14. Rasella D, Aquino R, Santos CAT, Paes-Sousa R, Barreto ML. Effect of a conditional cash transfer programme on childhood mortality: a nationwide analysis of Brazilian municipalities. *Lancet* 2013 Jul 06;382(9886):57-64. [doi: [10.1016/S0140-6736\(13\)60715-1](https://doi.org/10.1016/S0140-6736(13)60715-1)] [Medline: [23683599](https://pubmed.ncbi.nlm.nih.gov/23683599/)]
15. Fernald L, Gertler PJ, Neufeld LM. 10-year effect of Oportunidades, Mexico's conditional cash transfer programme, on child growth, cognition, language, and behaviour: a longitudinal follow-up study. *Lancet* 2009 Dec 12;374(9706):1997-2005. [doi: [10.1016/S0140-6736\(09\)61676-7](https://doi.org/10.1016/S0140-6736(09)61676-7)] [Medline: [19892392](https://pubmed.ncbi.nlm.nih.gov/19892392/)]
16. Leroy JL, García-Guerra A, García R, Dominguez C, Rivera J, Neufeld LM. The Oportunidades program increases the linear growth of children enrolled at young ages in urban Mexico. *J Nutr* 2008 Apr;138(4):793-798. [doi: [10.1093/jn/138.4.793](https://doi.org/10.1093/jn/138.4.793)] [Medline: [18356337](https://pubmed.ncbi.nlm.nih.gov/18356337/)]
17. Fernald L, Gertler PJ, Neufeld LM. Role of cash in conditional cash transfer programmes for child health, growth, and development: an analysis of Mexico's Oportunidades. *Lancet* 2008 Mar 08;371(9615):828-837 [FREE Full text] [doi: [10.1016/S0140-6736\(08\)60382-7](https://doi.org/10.1016/S0140-6736(08)60382-7)] [Medline: [18328930](https://pubmed.ncbi.nlm.nih.gov/18328930/)]
18. Manley J. , S. Gitter, and V. Slavchevska, How Effective are Cash Transfers at Improving Nutritional Status? *World Development* 2013;48:133-155.
19. Robertson L, Mushati P, Eaton JW, Dumba L, Mavise G, Makoni J, et al. Effects of unconditional and conditional cash transfers on child health and development in Zimbabwe: a cluster-randomised trial. *Lancet* 2013 Apr 13;381(9874):1283-1292 [FREE Full text] [doi: [10.1016/S0140-6736\(12\)62168-0](https://doi.org/10.1016/S0140-6736(12)62168-0)] [Medline: [23453283](https://pubmed.ncbi.nlm.nih.gov/23453283/)]
20. Bangladesh Bureau of Statistics, Dhaka, Bangladesh. Bangladesh - Household Income and Expenditure Survey 2010 URL: <http://catalog.ihns.org/index.php/catalog/2257> [accessed 2018-06-14] [WebCite Cache ID 70ASjE4jQ]
21. Alam M, D'Este C, Banwell C, Lokuge K. The impact of mobile phone based messages on maternal and child healthcare behaviour: a retrospective cross-sectional survey in Bangladesh. *BMC Health Serv Res* 2017 Dec 24;17(1):434 [FREE Full text] [doi: [10.1186/s12913-017-2361-6](https://doi.org/10.1186/s12913-017-2361-6)] [Medline: [28645278](https://pubmed.ncbi.nlm.nih.gov/28645278/)]
22. Vyas S, Kumaranayake L. Constructing socio-economic status indices: how to use principal components analysis. *Health Policy Plan* 2006 Nov;21(6):459-468. [doi: [10.1093/heapol/czl029](https://doi.org/10.1093/heapol/czl029)] [Medline: [17030551](https://pubmed.ncbi.nlm.nih.gov/17030551/)]
23. Food and Agriculture Organization of the United Nations. Household Food Insecurity Access Scale (HFIAS) for Measurement of Household Food Access: Indicator Guide URL: http://www.fao.org/fileadmin/user_upload/eufao-fsi4dm/doc-training/hfiass.pdf [accessed 2018-06-14] [WebCite Cache ID 70AT33E0T]
24. Ahmed, AU, Hoddinott JF, Roy S, Sraboni E, Quabili WR, Margolies A. Which Kinds of Social Safety Net Transfers Work Best for the Ultra Poor in Bangladesh?: Operation and Impacts of the Transfer Modality Research Initiative. In: <https://catalog.princeton.edu/catalog/10397293>. Dhaka, Bangladesh: International Food Policy Research Institute and UN World Food Program; 2016.
25. Ferre C, Sharif I. Can Conditional Cash Transfers Improve Education and Nutrition Outcomes for Poor Children in Bangladesh? Evidence from a Pilot Project. In: Policy Research Working Paper;No. 7077. Washington, DC: World Bank Group; 2014.
26. Fernald L, Gertler PJ, Neufeld LM. Role of cash in conditional cash transfer programmes for child health, growth, and development: an analysis of Mexico's Oportunidades. *Lancet* 2008 Mar 08;371(9615):828-837 [FREE Full text] [doi: [10.1016/S0140-6736\(08\)60382-7](https://doi.org/10.1016/S0140-6736(08)60382-7)] [Medline: [18328930](https://pubmed.ncbi.nlm.nih.gov/18328930/)]
27. Leroy JL, García-Guerra A, García R, Dominguez C, Rivera J, Neufeld LM. The Oportunidades program increases the linear growth of children enrolled at young ages in urban Mexico. *J Nutr* 2008 Apr;138(4):793-798. [doi: [10.1093/jn/138.4.793](https://doi.org/10.1093/jn/138.4.793)] [Medline: [18356337](https://pubmed.ncbi.nlm.nih.gov/18356337/)]
28. Fernald LCH, Gertler PJ, Neufeld LM. 10-year effect of Oportunidades, Mexico's conditional cash transfer programme, on child growth, cognition, language, and behaviour: a longitudinal follow-up study. *Lancet* 2009 Dec 12;374(9706):1997-2005. [doi: [10.1016/S0140-6736\(09\)61676-7](https://doi.org/10.1016/S0140-6736(09)61676-7)] [Medline: [19892392](https://pubmed.ncbi.nlm.nih.gov/19892392/)]
29. Paxson C, Schady N. Does money matter? The effects of cash transfers on child development in rural Ecuador. *Econ Dev Cult Change* 2010;59(1):187-229. [Medline: [20821896](https://pubmed.ncbi.nlm.nih.gov/20821896/)]

30. Segura-Pérez S, Grajeda R, Pérez-Escamilla R. Conditional cash transfer programs and the health and nutrition of Latin American children. *Rev Panam Salud Publica* 2016 Aug;40(2):124-137 [[FREE Full text](#)] [Medline: [27982370](#)]
31. Baird S., C. McIntosh, and B. Özler, Cash or condition? Evidence from a cash transfer experiment. *The Quarterly Journal of Economics* 2011;126(4):1709-1753.
32. Lester R, Mills EJ, Kariri A, Ritvo P, Chung M, Jack W, et al. The HAART cell phone adherence trial (WeTel Kenya1): a randomized controlled trial protocol. *Trials* 2009 Sep 22;10:87 [[FREE Full text](#)] [doi: [10.1186/1745-6215-10-87](#)] [Medline: [19772596](#)]
33. Aker J, Boumniel R, McClelland A, Tierney N. Payment Mechanisms and Antipoverty Programs: Evidence from a Mobile Money Cash Transfer Experiment in Niger. *Economic Development and Cultural Change* 2016 Oct;65(1):1-37. [doi: [10.1086/687578](#)]
34. Parvez J, Islam A, Woodard J. Mobile Financial Services in Bangladesh A Survey of Current Services, Regulations, and Usage in Select USAID Projects. Dhaka, Bangladesh: USAID; Apr 2015.

Abbreviations

FGD: focus group discussions

IVR: interactive voice response

ISPP: Income Support Program for the Poorest

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Original Paper

A Novel mHealth Approach for a Patient-Centered Medication and Health Management System in Taiwan: Pilot Study

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Abstract

Background: Mobile health (mHealth) apps have recently demonstrated the potential to engage and empower people to improve their own health. Although the availability of health-related apps is increasing, their adoption rate in Taiwan is exceptionally low mainly due to the preponderance of Western culture-based app designs that are challenging for non-English-speaking individuals. To our knowledge, no mHealth app is available in Taiwan that is culturally tailored for Chinese-speaking users and that applies a patient-centered approach to self-manage medication and health.

Objective: The purpose of this study was to design and deploy a culturally tailored mHealth system that could be easily integrated into current clinical practice and to evaluate how this mHealth system could support the continuity of patient care in Taiwan.

Methods: An mHealth information system and a mobile app were designed. To promote the best patient experience, a Quick Response (QR) code system was developed to enable efficient registration of personal medication information through the mobile app. The app also supported notifications for drug utilization, refills, and symptom checks. Patients were encouraged to record medication use, symptoms, and self-assessments in the app during their treatment period. Evaluation of the novel mHealth system was conducted from August 1, 2016 to December 31, 2016 at MacKay Memorial Hospital, Taipei, Taiwan. Population data and app usage statistics were analyzed.

Results: During the 5-month implementation period, a total of 25,909 users downloaded the app with an overall 7-day retention rate of 15.4% (SD 3.9). Young male adults (range 25-44 years) were the predominant user population. Patients' feedback on app usability and design, QR code system as drug input method, medication reminders, and linking family or friends into care networks was generally positive. Physicians showed great interest in utilizing patient-generated data in their care process, and the positive medication adherence rate was the most highly valued component of this system.

Conclusions: This pilot study demonstrated the value of a novel mHealth approach for individualized medication and health management in Taiwan. The mHealth system shows the potential to optimize personalized care into existing clinical services and may help hospitals and health authorities perform continuous quality improvement and policy development.

KEYWORDS

mHealth; mobile app; QR code; medication management; medication adherence

Introduction

In 2003, the World Health Organization (WHO) reported that medication nonadherence was a global concern, especially for long-term therapies and resulted in increased morbidity [1], mortality [2], and unnecessary medical expenditure [3]. In Taiwan, unnecessary medical expenditure caused by medication nonadherence is a serious problem. A 2016 statistical report of the Taiwan National Health Insurance Administration stated that the average number of prescribed drugs per prescription of each patient in Taiwan was 3.16, which was higher than that in Western countries [4]. Approximately 25% of prescribed drugs are not taken by patients (costing at least NT \$30 billion), and 2.6 tons of unused and expired drugs are discarded annually [5]. These phenomena indicate that solving the problem of medication nonadherence in Taiwan is a critical issue.

Medication nonadherence may be caused by patients' intentional or unintentional behaviors. Intentional nonadherence refers to deciding not to take a medication based on the patient's own perceptions [6-8]. For instance, incomplete medication knowledge may result in the fear of adverse side effects and is often the intentional reason for medication nonadherence. In contrast, unintentional nonadherence means that the patient intends to take a medication as prescribed but fails to do so because of forgetfulness or carelessness. Patients' demographic and clinical characteristics, complicated regimens associated with polypharmacy, and patient-physician interaction may cause unintentional medication nonadherence [6-10]. For years, many interventions such as reminders, counseling, reinforcement, or education have been used to improve medication adherence by changing patients' behaviors [11,12]. Awareness and appropriate selection the elements of intentional and nonintentional determinants for the target population are necessary for the design and development of tailored solutions for medication adherence.

Recently, the popularization of internet technology and mobile health (mHealth) tools for public health or medical care purposes have transformed human life significantly [13,14]. Short message service text messages, sent by mobile phones using reminder systems, have produced positive effects on medication adherence in patients with chronic diseases and those requiring health care services [15-17]. Studies indicate that mHealth apps have been widely applied in the medical management of patients with cancer [18], diabetes [19,20], cardiovascular disease [21,22], and other chronic diseases [23]. Although many health-related apps are available in the market, the use of these apps in Taiwan is low because most apps are designed based on Western cultures. For instance, many medication apps, including MediSafe (Medisafe Project Ltd), DoseCast (Montuno Software, LLC) and MyMeds (MyMeds, Inc), aim to help patients improve their medication adherence [24]. However, the English user interface of these apps poses a challenge for non-English speaking users. The language barrier makes it

difficult for Chinese people to identify English drug names, thus reducing their willingness to better understand personal medications [25]. Also from a culture perspective, Chinese patients less frequently use somatic symptom descriptions, compared with Western patients, and instead use Yin-Yang energy balance to discuss illness [26]. Compared with Western patients, Chinese patients normally include family members as important influencers in medical decision-making processes [26]. To our knowledge, no app is available in Taiwan that is culturally tailored for Chinese-speaking users and which provides a patient-centered approach for personal health self-management. The current mHealth Apps in Taiwan are mainly used for operational purposes, such as appointment scheduling, medication refill notification, patient queue monitoring, and mobile payment [27].

The purpose of this study was to deploy a novel mHealth system that could help Chinese-speaking patients to self-manage their medication and health and to understand how this mHealth system could support the continuity of patient care in Taiwan. The new system leverages cloud technologies to integrate with existing hospital information systems and applies a patient-centered design principle for culturally tailoring to Chinese people, with easy-to-use medication registration, symptom tracking, drug information review, and quick health self-assessment. This system also aims to facilitate the coordination of care by seamless information sharing among patients and families.

Methods

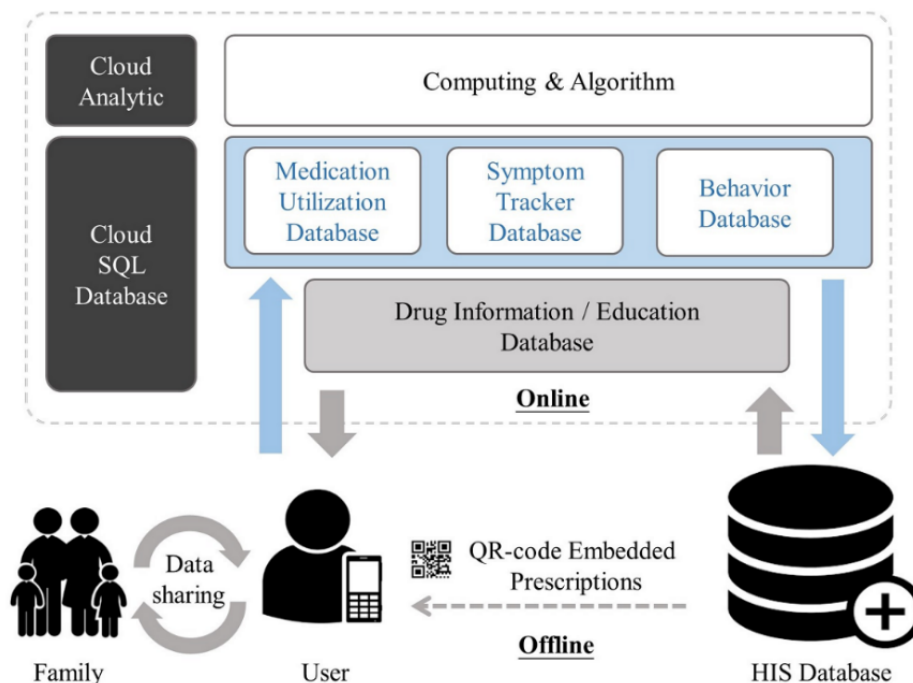
System Design and Informational Framework of the mHealth Solution

The mobile app was developed cooperatively by MacKay Memorial Hospital (MMH), Taiwan, and HTC Corporation, Taiwan, for use on iOS and Android platforms. The information structure and design of the mHealth system is illustrated in [Figure 1](#). A simple Quick Response (QR) code system was designed specifically to interoperate our mHealth cloud system with the current hospital information system (HIS) in Taiwan. Our medical prescription notes and drug packages for patients routinely carry the information and posology of the prescribed drugs. We integrated all this information into a QR code and incorporated it into the present prescription notes and drug packaging system so that personal medications could be easily registered in the mobile app by simply scanning QR codes in an offline environment. More information about prescription drugs, including photos, side effects, and interaction cautions can be synchronized with the hospital drug database, as long as the user's mobile phone is online. This 2-step operational design allowed rapid placement of new mHealth systems, to comply with national safety and security regulations, without the need to adjust existing HIS architecture. All usage data, including medication utilization, symptoms, and drug-related behaviors,

are stored in the cloud structured query language (SQL) database. After registering the medications, users were notified when to take each medication. In addition to self-managing

medications, users can also share their actual medication utilization status with family members and physicians.

Figure 1. Systemic architecture for the mHealth system. HIS: hospital information system, QR: Quick Response, SQL: structured query language.



Introduction to the Mobile App for Personal Medication Management

The app features 3 main functions tailored for Chinese culture that cover several determinants of medication adherence: (a) medication self-management, (b) care circle, and (c) symptom records and global self-assessment. The app operation procedure is illustrated in detail in Figure 2a. At MMH, prescription notes for chronic diseases and all drug packaging are printed with QR codes that contain personal drug information, including the drug name, prescribing physician's name, and dosage frequency and duration of every drug. After scanning the QR code with the app, all the above-mentioned information plus detailed medication information in the Chinese language will be immediately transmitted to the users' mobile phones, and users can share their data with their family or friends for mutual support and better engagement, which may help to reduce the intentional determinants of medication nonadherence (Figure 2b). To further eliminate the unintentional determinants of medication adherence, the app also provided a personal notification function, according to the original prescription, as a medication reminder to each user. For a patient's medication self-management, the system will establish daily, weekly, and monthly statistical reports of each patient's completion rates by analyzing their medication utilization records (Figure 2c). In addition, users were encouraged to record their symptoms or discomforts, as well as global self-assessment, through a user-friendly interface design (Figure 2d). Global self-assessment enables users to quickly determine their degree of current treatment outcomes using a 5-grade Likert scale as a quantitative rating.

Implementation of the Pilot Study

The deployment process of the system consisted of different channels and activities in the hospital from August 1, 2016 to December 31, 2016. First, for general users, the app was initially launched through iOS and Google Play stores. However, we realized that patients were the major target audience in this pilot study, and several promotional materials, including posters, flyers, and videos, were widely distributed within MMH. Help desks were also set up at several specific locations in the hospital, such as the pharmacy and reception counter, where in-house staff and project-recruited volunteers were able to interact with patients and help them download and use the app. Second, we promoted the system in some consultation rooms and partnered with medical care providers to help deploy the app at outpatient clinics. In this pilot study period, we selected cardiology, cardiovascular surgery, and rheumatology clinics as our target groups. The patients were encouraged to use the app by their primary care physicians so that the physicians could understand the patients' medication usage reports on their return visits. Third, for hospitalized patients from internal medicine wards, instruction manuals and consultations were provided before discharge so that they could then self-manage their medications and to better bridge their care from in-hospital to outpatient status.

Data Analysis

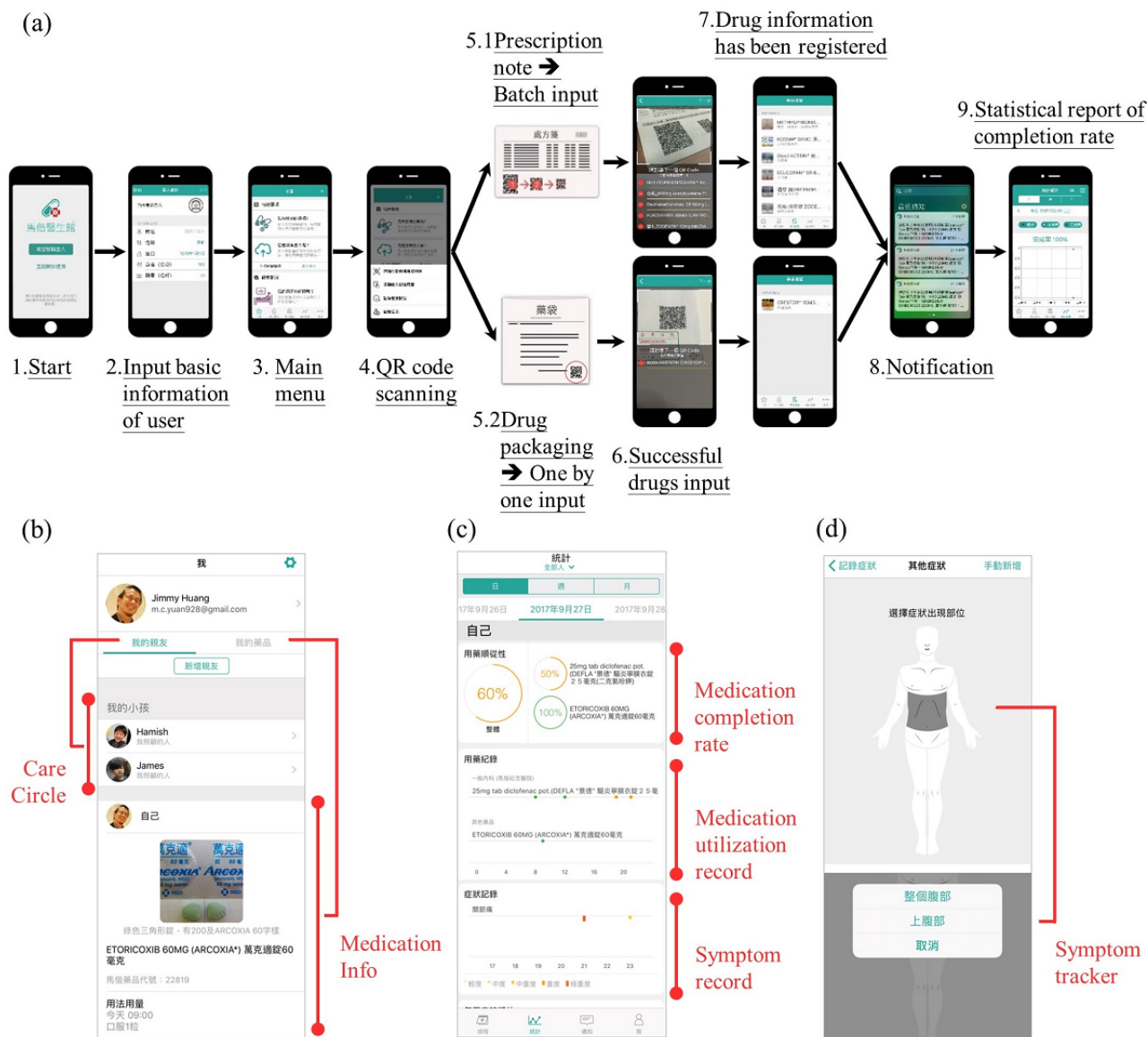
Collected Measures

Data of all participants from the pilot study were recorded by computational backend. In our cloud, the SQL database used a python framework (3.0) to automatically retrieve predefined information from the cloud database. We collected the behavior,

number, age, and gender of users, as well as the numbers of drugs by scanning prescription note (batch) or drug packaging (single) and count by browsing the information for each drug. The 7-day active users were defined as those users who used

the app any time during the previous 7 days. Data were automatically collected every week. The 7-day retention rate was defined as the percentage of unique users who were still using the app for 7 consecutive days after the first installation.

Figure 2. Screenshots of the (a) operation procedures for medication entry by the Quick Response (QR) code system, (b) care circle feature, (c) user medication completion reports, and (d) symptom checker of the app.



Analyses

IBM SPSS Statistics version 19 (IBM Corp, Armonk, NY, USA) was used to analyze the data. The proportion of each scanned drug was defined as the scanning counts of each drug divided by the total scanning counts of all drugs. The completion rate was defined as the doses of each medication that were taken by the user divided by those of each medication prescribed by the physician. The number of 7-day active users, number of daily clicks per user, and 7-day retention rate are presented as mean (SD). The data for age, gender, and drugs were only accessible from the Android platform. Feedback from the users of the system, including Google star rating and comments, were also assessed. Feedback taken by convenience sampling at outpatient

clinics from the physicians was also collected for suggestions and future collaboration.

Ethics Approval

This study was approved by the Institutional Review Board of Taipei Mackay Memorial Hospital, Taiwan (No.18MMHIS016e).

Results

Evaluation of User Behaviors

The pilot test for evaluating the new mHealth system was initially conducted at MMH from August 1, 2016 to December 31, 2016. A total of 25,909 users downloaded the app, and the mean of 7-day active users over a 7-day interval during the

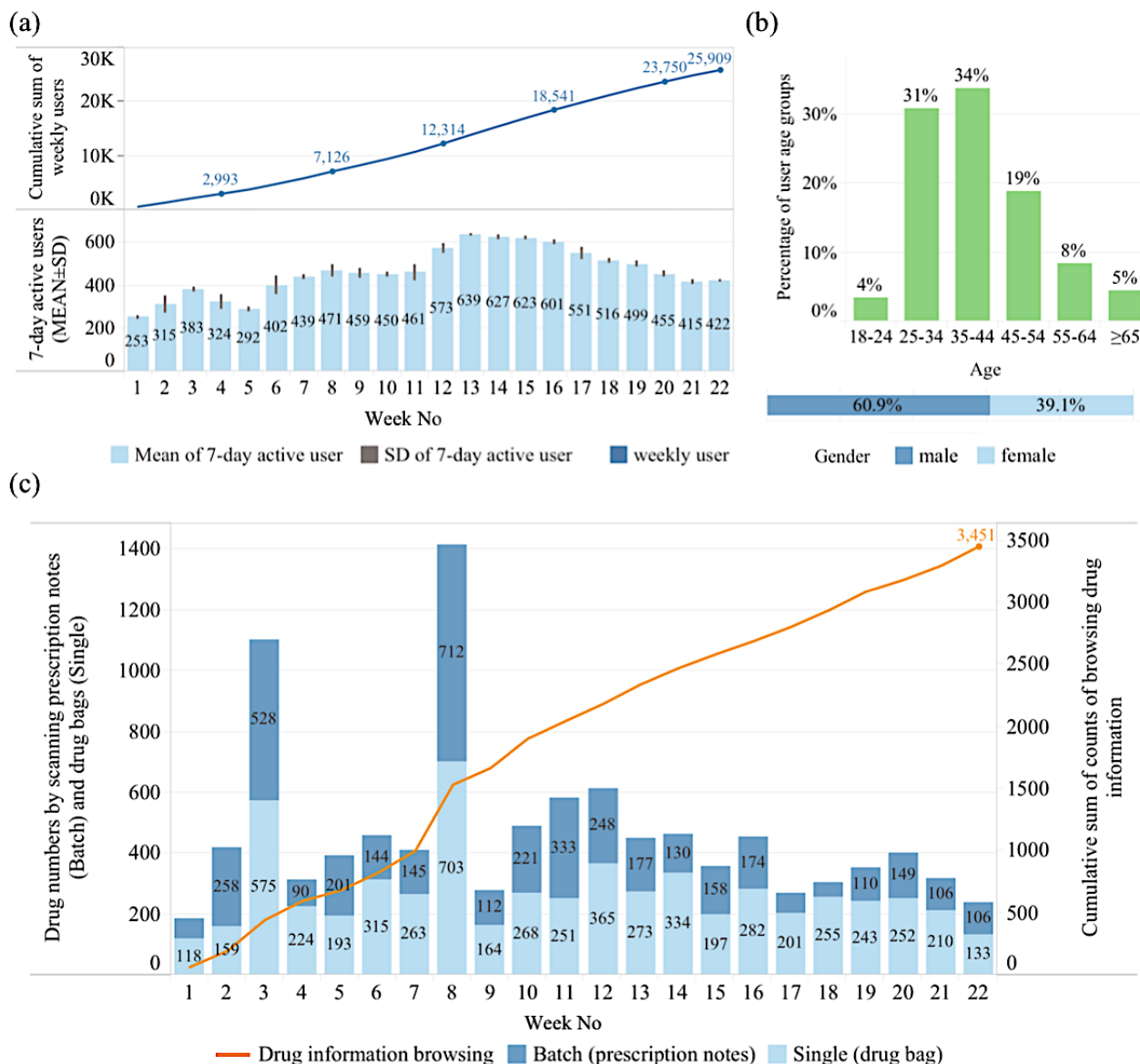
implementation period ranged from a minimum of 253 (8; week 1, Aug 1-7) to a maximum of 638 (7; week 13, Oct 24-30) people, with increasing numbers of users every week since implementation (Figure 3a). In addition to one underage person (age < 18 years) who was not allowed to register the app, the age distribution of the total user population was divided into 6 groups, including 18-24, 25-34, 35-44, 45-54, 55-64, and >65 years old. The percentages of age and gender distribution were shown in Figure 3b. The demographic results demonstrated that younger adults (range 25-44 years), especially males, were the highest user population that engaged in the study in the 5-month implementation period at MMH.

The ways of registering medications were also investigated. In the app system design, users could register their drugs by scanning the QR code on the prescription note or drug packaging. As shown in Figure 3c, based on statistical analysis of the cumulative drug numbers scanned from the drug packaging, the numbers ranged from a minimum of 118 (week 1, Aug 1-7) to a maximum of 703 (week 8, Sep 19-25). Based on the scanning of prescription notes, the cumulative drug numbers ranged from a minimum of 48 (week 18, Nov 28 to

Dec 4) to a maximum of 712 (week 8, Sep 19-25). Thus, during the implementation period, the number of drugs scanned from drug packaging (single input, green bar) was higher than that from the prescription notes (batch input, blue bar). These results indicated that the users preferred to scan the drug packaging as a means of registering their medications in the app, rather than using the prescription notes.

Statistical analysis of browsing the drug screen, which included drug pictures and detailed information, was used to initially assess whether the system could help users to enhance their knowledge of medications. Medication information surfing behavior via the app gradually increased over time, reaching 3445 times at the fifth month of the study (Figure 3c), which suggested that more patients were familiar with the system as a channel through which they could acquire their medication knowledge. Of the 25,909 users, a 7-day retention rate of 15.4% (SD 3.9) was observed during the implementation period. Among daily active users, the counts of browsing the drug screen per person, 0.13 (SD 0.15) times (data not shown), were much less than daily total clicks in the app per person, 30.6 (SD 5.8) times.

Figure 3. (a) The cumulative user number and average of 7-day active users, (b) age and gender demographics, and (c) the cumulative count of browsing drug information and the number of medication registration by scanning prescription notes or drug packaging during the 5-month pilot period illustrated by 7-day interval (week).



Evaluation of Feedback

The Google star rating of the app was 4.493 points out of 5, over a total of 64 reviews, and some of the comments from the users are as follows:

It was very convenient that I could manage all the drugs by scanning the QR codes on the prescription note or drug packaging and was notified for each scheduled drug without forgetting to take each medication.

The App was a useful tool for me because I could inquire about the function of my drugs and record my symptoms when I was uncomfortable.

Feedback taken by convenience sampling from physicians at hospital outpatient clinics was mostly positive. Physicians generally showed great interest in seeing the patients' medication usage reports for the first time, including medication

completion rate, symptoms, and global self-assessment of the patient at every return visit (formats of reports are shown in step 9 of Figure 2a-c).

It does make me feel comfortable when my patient tells me that he uses this software to remind him to take medicine. And I know that the patient is engaged and motivated by the intervention.

Seeing the patient in my clinic showing me the software with the number of his personal medication completion and symptom status really make me understand my patients better.

Evaluation of Drug Registration

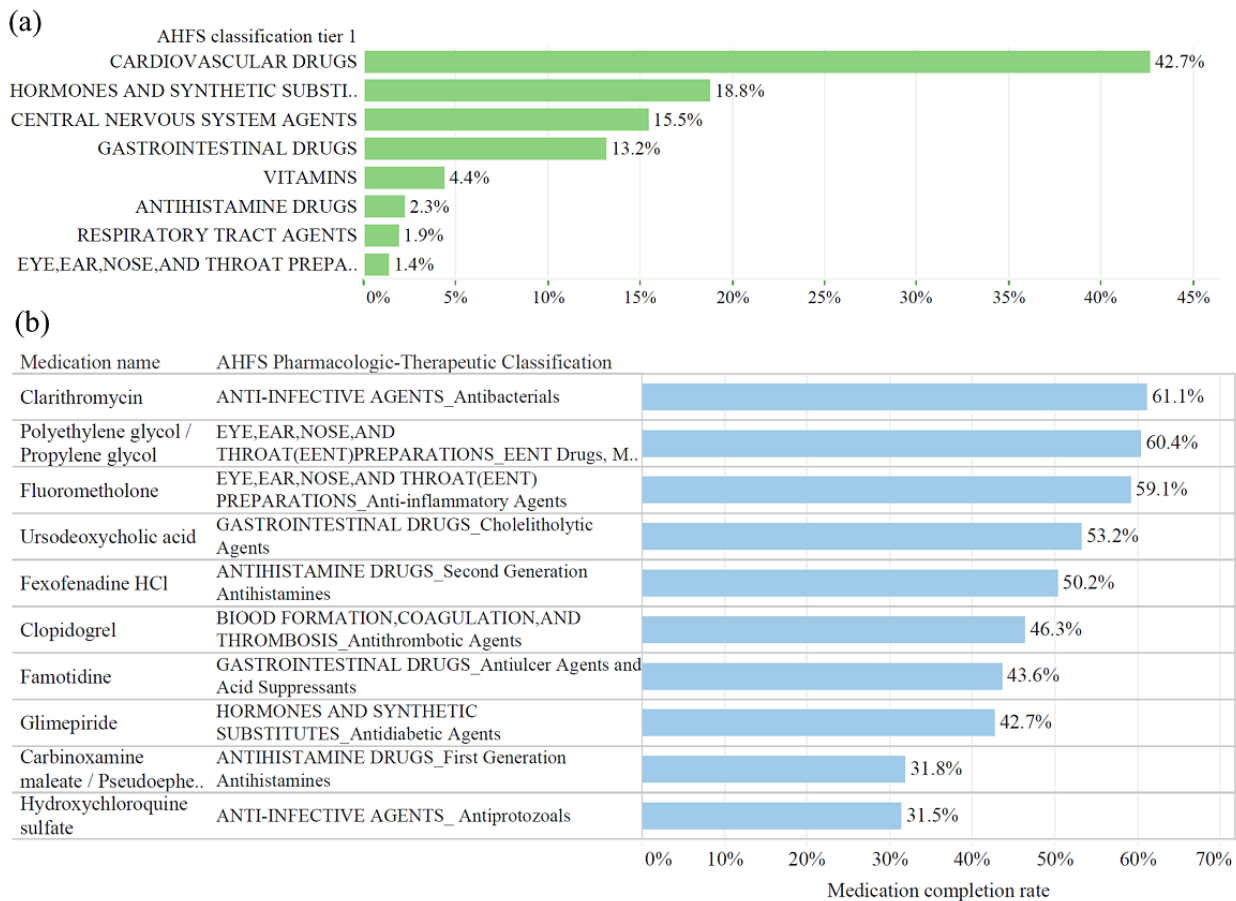
The counts of total medication accessed by scanning the prescription notes or drug packaging were extracted from computational backend. A total of 25,267 scanning counts were analyzed using first-tier and second-tier drug categories based on the American Hospital Formulary Service classification,

2017 edition, and the top 30 registered drugs are listed in [Multimedia Appendix 1](#). Drugs for chronic diseases, including cardiovascular drugs (42.7%), hormones and synthetic substitutes (18.8%), and central nervous system drugs (15.5%), represented the three major drug categories among the top registered drugs of the system ([Figure 4a](#)).

The medication usage status could be also tracked and analyzed by computational backend, and the top 10 drugs ranked by

completion rate are shown in [Figure 4b](#) and [Multimedia Appendix 2](#). Drugs for anti-infective agents, ophthalmic preparations, gastrointestinal drugs, and antiallergic agents showed the highest level of medication adherence, with completion rates greater than 50%. It is interesting that, although the chronic disease medication was most highly registered, the completion rate was low.

Figure 4. (a) Categories of top 30 registered medications and (b) the top 10 drugs ranked by completion rate from the mHealth system in 5-month pilot period.



Discussion

Principal Findings

As the population ages and cost pressures increases, the health care industry continues to face challenges and must find ways to enhance the role of patients in the management of their diseases. One of the ways by which patients can better manage their disease is to adhere to their medication regimens. This pilot study aimed to examine how to make patients familiar with using a new mHealth app for their medical treatments and to investigate the efficacy of integrating an mHealth system into clinical practice at a Taiwan hospital. Our experience suggests that the novel mHealth approach for personal medication and health management in Taiwan is feasible and that the mobile solution incorporating a QR code system and an innovative 2-step system design can provide an integrative

solution for other medical institutions in Taiwan as a digital tool for engaging patients to encourage self-management.

Although many users were recruited during the implementation period, we found that the 7-day retention rate of the new mHealth app was low, 15.4% (SD 3.9), compared with previous randomized controlled trials for medication adherence [28,29]. This may be because our app was initially launched to the public as a free download to participate in the pilot study, rather than to perform a rigorous clinical trial for a specific population. The finding is also consistent with previous studies showing that frequent use of the app declined substantially within the first 2 months [30,31]. The high attrition rate for this intervention may reflect users' interest in the novelty of the app, which declined rapidly as the novelty disappeared. The low 7-day retention rate implies that human factors play an important role in developing a better patient-centered mHealth app for better retention. Also, awareness of the digital health experience was still low among

users in Taiwan, and more efforts are needed to establish greater awareness and use of mHealth services.

In addition, the differences between daily counts of browsing the drug screen per person, 0.13 (SD 0.15) times, and daily clicks in the app per person, 30.6 (SD 5.8) times, demonstrated that the users preferred to use notifications, symptom records, global self-assessments, and statistical reports of completion rates rather than the medication information. This suggests that it is imperative we strengthen patients' knowledge of medication in Taiwan.

In this study, younger adult males (range 25–44 years) were the predominant population who volunteered to engage with the app. This finding is consistent with previous studies [30,32–34] and demonstrates that younger adults are more likely to accept mobile devices. Simultaneously, this finding also suggests that a “digital divide” continues to exist between the genders, and males are more engaged in using mobile technology than females. Our findings also indicate that the demographic characteristics of mobile technology in the United States and Germany, as well as in Taiwan, follow similar trends [34,35]. Although elderly patients (>65 years) with chronic diseases are typically considered to be a population who often needs additional tools to address low medication adherence because of their complicated comorbidities and polypharmacy, we observed that in this pilot study, few elderly patients used the mHealth app in Taiwan. Interestingly, previous studies demonstrated differences between older adults and younger adults in their perceptions, preferences, and adoption of mobile technology [30,36,37]. The “Ambient Assisted Living Project” reported that the older group of patients had very high acceptance of 7-inch tablet computers used as a medication management app [30,38]. Applying appropriate assistive devices may be as important as developing well-designed mobile apps for establishing an mHealth strategy for elderly patients.

Historically, several methods for measuring medication adherence, such as pill counts, refill rates, patient self-reports, biological and electronic monitoring, have been proposed [39–41]. In this study, the Taiwanese population-based medication usage behavior could be timely tracked for the first time, and the results highlighted that the adherence to medications for chronic diseases was relatively low. This objective data has the potential to provide reference values for quality improvement measures and policy development by hospital and government administrations. Another advantage of the new mHealth system is that it allowed our patients to be able to report the objective measures of their medication adherence to health care providers. However, results of this pilot study also showed fragmented completion rates of drug usage, suggesting that even though users were notified by the system, patients continued to forget to take medications and some never even used the app. In addition to medication administration reminders for patients, an alarm system may be needed to integrate with current care circle design to ensure patients' medication intake by instantly alerting the members of the care circle when the system detects that the patient was not taking medication. Our results also suggest that the next stage for improving the new mHealth system is to understand

how to engage Taiwanese patients to continue reporting their medication utilization status and outcome measures.

Limitations and Solutions

During the 5-month implementation period, the pilot project showed certain limitations worth discussing and resolving. First, demographic results, including age and gender as well as the drug categories ranked by completion rate, were only extracted from the Android platform because our computational backend had no access to extract the data from the iOS platform. We tried to analyze the statistical numbers collected from the two platforms separately and found that there was no significant difference between the platforms, suggesting that the two populations showed similar usage behaviors. However, additional technical support is still needed to solve this problem in continuing updates of the new mHealth app.

Second, the patients tended to use the system in a repetitive way (ie, drug packaging, single input) to register each drug instead of registering all drugs just once (ie, prescription notes, batch input). However, the QR codes were unclear because of blurry prints, and creases caused medication registration in the app to fail at a relatively high rate during the implementation period. Therefore, QR codes must be printed on the prescription notes not only for chronic diseases but also for other diseases, and more promotion activities must be implemented to assist patients. By encouraging patients to register their medications through the prescription notes, we hope to avoid wasting time and reduce registration failures.

Third, in the predefined data retrieval, we only defined clicks either from browsing the drug screen or from other information check, including drug notification, symptom records, global self-assessment, and statistical reports of completion. Under this circumstance, we are unable to provide specific data for each function usage. We also could evaluate different periods of retention rate, other than 7 days, in our current system. For example, it would be interesting to know whether the 30-day retention rate is even lower to determine if patients would not use the app over a long term for medication compliance. Furthermore, since we did not retrieve users' information from the cloud database, we were unable to know the sources of users. As a result, we cannot analyze if the behaviors are different among users from the public, clinics, or hospitalization.

Finally, although the physicians could search patients' medication usage reports and symptoms from the smartphone at every return visit, this additional action still increases physician consultation time. Therefore, the collaborative patient-physician interaction needs to be optimized by building an encrypted Web-based information system so that physicians can directly access the patients' medication reports and symptoms by using HIS, thereby reducing physician consultation time.

Future Developments

We believe that the promising achievements of this project will lead to further improvements for the innovative mHealth system. First, we will investigate the unmet needs of patients and physicians in their collaborative interaction and continually expand functions of the app to further optimize the newly

developed patient-centered mHealth system. Second, we plan to execute a clinical trial to validate whether the mHealth app can significantly improve patients' medication adherence after we receive informed consent from patients, following approval of the institutional review board at MMH.

Understanding the benefits of the system, physicians from different specialties, such as cardiovascular surgeons and pediatric rheumatologists, were especially interested in this system as their patients were among those with the most chronic conditions, involving multiple and complicated medications, with typically difficult self-management. The statistical numbers from the active users within the 5-month period indicated that the mHealth app would be a potential health care tool for Taiwanese patients. Moreover, we plan to provide tailored mHealth solutions for other physicians with different specialties and to help patients with different diseases have better therapeutic outcomes. Finally, we believe that the quality and design of our digital health solution for personal medication and health management can be easily integrated into other hospitals and will be the foundation that allows health care

institutions to provide a more versatile and personalized approach toward advanced health care.

Conclusion

This pilot study investigated the role of a culturally tailored mHealth system for personal medication and health management in Taiwan. Study results show that the app's medication registration and notification system helped users self-manage their complicated polypharmacy regimens. The most important feature of the new patient-centered mHealth system was that it reflected patients' actual medication utilization status, symptoms, and self-assessment. The information is readily available to their physicians through optimization of the patient-physician digital experience so that health care providers and patients can function in a collaborative manner and facilitate patients' medication adherence. The innovative mHealth solution has the potential to understand Chinese-speaking patients' medication adherence and therapeutic outcomes as well as to engage patients and family as partners in long-term medical care.

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Authors' Contributions

W-TH, Y-CS, H-LH, and M-YH conceived and designed the study; W-TH and H-LH implemented the study; W-TH analyzed the data; W-TH, Y-CS, H-LH, and M-YH contributed to the interpretation of the results; W-TH and M-YH wrote the original draft; Y-CS and M-YH reviewed and edited the draft; M-YH administrated the project.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The top 30 registered drugs by the mHealth system.

[[PDF File \(Adobe PDF File\), 36KB - mhealth_v6i7e154_app1.pdf](#)]

Multimedia Appendix 2

Top 10 drugs ranked by completion rate.

[[PDF File \(Adobe PDF File\), 29KB - mhealth_v6i7e154_app2.pdf](#)]

References

1. Chowdhury R, Khan H, Heydon E, Shroufi A, Fahimi S, Moore C, et al. Adherence to cardiovascular therapy: a meta-analysis of prevalence and clinical consequences. *Eur Heart J* 2013 Oct;34(38):2940-2948 [[FREE Full text](#)] [doi: [10.1093/eurheartj/ehz295](https://doi.org/10.1093/eurheartj/ehz295)] [Medline: [23907142](https://pubmed.ncbi.nlm.nih.gov/23907142/)]
2. Rasmussen JN, Chong A, Alter DA. Relationship between adherence to evidence-based pharmacotherapy and long-term mortality after acute myocardial infarction. *JAMA* 2007 Jan 10;297(2):177-186. [doi: [10.1001/jama.297.2.177](https://doi.org/10.1001/jama.297.2.177)] [Medline: [17213401](https://pubmed.ncbi.nlm.nih.gov/17213401/)]
3. Roebuck MC, Liberman JN, Gemmill-Toyama M, Brennan TA. Medication adherence leads to lower health care use and costs despite increased drug spending. *Health Aff (Millwood)* 2011 Jan;30(1):91-99 [[FREE Full text](#)] [doi: [10.1377/hlthaff.2009.1087](https://doi.org/10.1377/hlthaff.2009.1087)] [Medline: [21209444](https://pubmed.ncbi.nlm.nih.gov/21209444/)]
4. Medical Service Indicator. 2017 Apr 10. Medical Service Indicator URL: https://www.nhi.gov.tw/Resource/webdata/20520_2_201703_National%20Health%20Insurance%204.pdf [accessed 2017-04-11] [[WebCite Cache ID 6pdOskD2a](#)]

5. Chien H, Ko J, Chen Y, Weng S, Yang W, Chang Y, et al. Study of Medication Waste in Taiwan. *Journal of Experimental & Clinical Medicine* 2013 Apr;5(2):69-72. [doi: [10.1016/j.jecm.2013.02.003](https://doi.org/10.1016/j.jecm.2013.02.003)]
6. Dalebout GMN, Broadbent E, McQueen F, Kaptein AA. Intentional and unintentional treatment nonadherence in patients with systemic lupus erythematosus. *Arthritis Care Res (Hoboken)* 2011 Mar;63(3):342-350 [FREE Full text] [doi: [10.1002/acr.20411](https://doi.org/10.1002/acr.20411)] [Medline: [21120967](https://pubmed.ncbi.nlm.nih.gov/21120967/)]
7. Lehane E, McCarthy G. Intentional and unintentional medication non-adherence: a comprehensive framework for clinical research and practice? A discussion paper. *Int J Nurs Stud* 2007 Nov;44(8):1468-1477. [doi: [10.1016/j.ijnurstu.2006.07.010](https://doi.org/10.1016/j.ijnurstu.2006.07.010)] [Medline: [16973166](https://pubmed.ncbi.nlm.nih.gov/16973166/)]
8. Wroe AL. Intentional and unintentional nonadherence: a study of decision making. *J Behav Med* 2002 Aug;25(4):355-372. [Medline: [12136497](https://pubmed.ncbi.nlm.nih.gov/12136497/)]
9. Meichenbaum D, Turk DC. *Facilitating treatment adherence: A practitioner's guidebook*. New York: Plenum; 1987.
10. Osterberg L, Blaschke T. Adherence to medication. *N Engl J Med* 2005 Aug 4;353(5):487-497. [doi: [10.1056/NEJMra050100](https://doi.org/10.1056/NEJMra050100)] [Medline: [16079372](https://pubmed.ncbi.nlm.nih.gov/16079372/)]
11. Graves MM, Roberts MC, Rapoff M, Boyer A. The efficacy of adherence interventions for chronically ill children: a meta-analytic review. *J Pediatr Psychol* 2010 May;35(4):368-382 [FREE Full text] [doi: [10.1093/jpepsy/jsp072](https://doi.org/10.1093/jpepsy/jsp072)] [Medline: [19710248](https://pubmed.ncbi.nlm.nih.gov/19710248/)]
12. Haynes RB, McKibbon KA, Kanani R. Systematic review of randomised trials of interventions to assist patients to follow prescriptions for medications. *Lancet* 1996 Aug 10;348(9024):383-386. [Medline: [8709739](https://pubmed.ncbi.nlm.nih.gov/8709739/)]
13. Silva BMC, Rodrigues JJPC, de LTDI, López-Coronado M, Saleem K. Mobile-health: A review of current state in 2015. *J Biomed Inform* 2015 Aug;56:265-272. [doi: [10.1016/j.jbi.2015.06.003](https://doi.org/10.1016/j.jbi.2015.06.003)] [Medline: [26071682](https://pubmed.ncbi.nlm.nih.gov/26071682/)]
14. Van DBTH, Engelen LJLPG, Berben SAA, Schoonhoven L. Definition of Health 2.0 and Medicine 2.0: a systematic review. *J Med Internet Res* 2010;12(2):e18 [FREE Full text] [doi: [10.2196/jmir.1350](https://doi.org/10.2196/jmir.1350)] [Medline: [20542857](https://pubmed.ncbi.nlm.nih.gov/20542857/)]
15. Kannisto KA, Koivunen MH, Välimäki MA. Use of mobile phone text message reminders in health care services: a narrative literature review. *J Med Internet Res* 2014;16(10):e222 [FREE Full text] [doi: [10.2196/jmir.3442](https://doi.org/10.2196/jmir.3442)] [Medline: [25326646](https://pubmed.ncbi.nlm.nih.gov/25326646/)]
16. Thakkar J, Kurup R, Laba T, Santo K, Thiagalingam A, Rodgers A, et al. Mobile Telephone Text Messaging for Medication Adherence in Chronic Disease: A Meta-analysis. *JAMA Intern Med* 2016 Mar;176(3):340-349. [doi: [10.1001/jamainternmed.2015.7667](https://doi.org/10.1001/jamainternmed.2015.7667)] [Medline: [26831740](https://pubmed.ncbi.nlm.nih.gov/26831740/)]
17. Vervloet M, Linn AJ, van WJCM, de BDH, Bouvy ML, van DL. The effectiveness of interventions using electronic reminders to improve adherence to chronic medication: a systematic review of the literature. *J Am Med Inform Assoc* 2012;19(5):696-704 [FREE Full text] [doi: [10.1136/amiainjnl-2011-000748](https://doi.org/10.1136/amiainjnl-2011-000748)] [Medline: [22534082](https://pubmed.ncbi.nlm.nih.gov/22534082/)]
18. Bender JL, Yue RYK, To MJ, Deacken L, Jadad AR. A lot of action, but not in the right direction: systematic review and content analysis of smartphone applications for the prevention, detection, and management of cancer. *J Med Internet Res* 2013;15(12):e287 [FREE Full text] [doi: [10.2196/jmir.2661](https://doi.org/10.2196/jmir.2661)] [Medline: [24366061](https://pubmed.ncbi.nlm.nih.gov/24366061/)]
19. Arnhold M, Quade M, Kirch W. Mobile applications for diabetics: a systematic review and expert-based usability evaluation considering the special requirements of diabetes patients age 50 years or older. *J Med Internet Res* 2014;16(4):e104 [FREE Full text] [doi: [10.2196/jmir.2968](https://doi.org/10.2196/jmir.2968)] [Medline: [24718852](https://pubmed.ncbi.nlm.nih.gov/24718852/)]
20. Hood M, Wilson R, Corsica J, Bradley L, Chirinos D, Vivo A. What do we know about mobile applications for diabetes self-management? A review of reviews. *J Behav Med* 2016 Dec;39(6):981-994. [doi: [10.1007/s10865-016-9765-3](https://doi.org/10.1007/s10865-016-9765-3)] [Medline: [27412774](https://pubmed.ncbi.nlm.nih.gov/27412774/)]
21. Chow CK, Ariyaratna N, Islam SMS, Thiagalingam A, Redfern J. mHealth in Cardiovascular Health Care. *Heart Lung Circ* 2016 Aug;25(8):802-807. [doi: [10.1016/j.hlc.2016.04.009](https://doi.org/10.1016/j.hlc.2016.04.009)] [Medline: [27262389](https://pubmed.ncbi.nlm.nih.gov/27262389/)]
22. Neubeck L, Lowres N, Benjamin EJ, Freedman SB, Coorey G, Redfern J. The mobile revolution--using smartphone apps to prevent cardiovascular disease. *Nat Rev Cardiol* 2015 Jun;12(6):350-360. [doi: [10.1038/nrcardio.2015.34](https://doi.org/10.1038/nrcardio.2015.34)] [Medline: [25801714](https://pubmed.ncbi.nlm.nih.gov/25801714/)]
23. Wang J, Wang Y, Wei C, Yao NA, Yuan A, Shan Y, et al. Smartphone interventions for long-term health management of chronic diseases: an integrative review. *Telemed J E Health* 2014 Jun;20(6):570-583. [doi: [10.1089/tmj.2013.0243](https://doi.org/10.1089/tmj.2013.0243)] [Medline: [24787747](https://pubmed.ncbi.nlm.nih.gov/24787747/)]
24. Santo K, Richtering SS, Chalmers J, Thiagalingam A, Chow CK, Redfern J. Mobile Phone Apps to Improve Medication Adherence: A Systematic Stepwise Process to Identify High-Quality Apps. *JMIR Mhealth Uhealth* 2016 Dec 02;4(4):e132 [FREE Full text] [doi: [10.2196/mhealth.6742](https://doi.org/10.2196/mhealth.6742)] [Medline: [27913373](https://pubmed.ncbi.nlm.nih.gov/27913373/)]
25. Hsu Y, Mao C, Wey M. Antihypertensive medication adherence among elderly Chinese Americans. *J Transcult Nurs* 2010 Oct;21(4):297-305. [doi: [10.1177/1043659609360707](https://doi.org/10.1177/1043659609360707)] [Medline: [20675538](https://pubmed.ncbi.nlm.nih.gov/20675538/)]
26. Jin L, Acharya L. Cultural Beliefs Underlying Medication Adherence in People of Chinese Descent in the United States. *Health Commun* 2016;31(5):513-521. [doi: [10.1080/10410236.2014.974121](https://doi.org/10.1080/10410236.2014.974121)] [Medline: [26422467](https://pubmed.ncbi.nlm.nih.gov/26422467/)]
27. Liu H, Lee W, Sun Y, Fen J, Chen T, Chou L, et al. Hospital-Owned Apps in Taiwan: Nationwide Survey. *JMIR Mhealth Uhealth* 2018 Jan 16;6(1):e22 [FREE Full text] [doi: [10.2196/mhealth.8636](https://doi.org/10.2196/mhealth.8636)] [Medline: [29339347](https://pubmed.ncbi.nlm.nih.gov/29339347/)]
28. Morawski K, Ghazinouri R, Krumme A, McDonough J, Durfee E, Oley L, et al. Rationale and design of the Medication adherence Improvement Support App For Engagement-Blood Pressure (MedISAFE-BP) trial. *Am Heart J* 2017 Apr;186:40-47. [doi: [10.1016/j.ahj.2016.11.007](https://doi.org/10.1016/j.ahj.2016.11.007)] [Medline: [28454831](https://pubmed.ncbi.nlm.nih.gov/28454831/)]

29. Mira JJ, Navarro I, Botella F, Borrás F, Nuño-Solinís R, Orozco D, et al. A Spanish pillbox app for elderly patients taking multiple medications: randomized controlled trial. *J Med Internet Res* 2014;16(4):e99 [FREE Full text] [doi: [10.2196/jmir.3269](https://doi.org/10.2196/jmir.3269)] [Medline: [24705022](https://pubmed.ncbi.nlm.nih.gov/24705022/)]
30. Becker S, Kribben A, Meister S, Diamantidis CJ, Unger N, Mitchell A. User profiles of a smartphone application to support drug adherence--experiences from the iNepbro project. *PLoS One* 2013;8(10):e78547 [FREE Full text] [doi: [10.1371/journal.pone.0078547](https://doi.org/10.1371/journal.pone.0078547)] [Medline: [24194946](https://pubmed.ncbi.nlm.nih.gov/24194946/)]
31. Boulos MNK, Wheeler S, Tavares C, Jones R. How smartphones are changing the face of mobile and participatory healthcare: an overview, with example from eCAALYX. *Biomed Eng Online* 2011;10:24 [FREE Full text] [doi: [10.1186/1475-925X-10-24](https://doi.org/10.1186/1475-925X-10-24)] [Medline: [21466669](https://pubmed.ncbi.nlm.nih.gov/21466669/)]
32. Becker S, Brandl C, Meister S, Nagel E, Miron-Shatz T, Mitchell A, et al. Demographic and health related data of users of a mobile application to support drug adherence is associated with usage duration and intensity. *PLoS One* 2015 Jan;10(1):e0116980 [FREE Full text] [doi: [10.1371/journal.pone.0116980](https://doi.org/10.1371/journal.pone.0116980)] [Medline: [25629939](https://pubmed.ncbi.nlm.nih.gov/25629939/)]
33. Smith A. Pew Research Center. 2012 Mar 1. Nearly half of American adults are smartphone owners URL: <http://www.pewinternet.org/2012/03/01/nearly-half-of-american-adults-are-smartphone-owners/> [accessed 2018-06-21] [WebCite Cache ID 70L8jYOLn]
34. Destatis Statistisches Bundesamt. 2016 Dec 05. 81 % der Internetnutzer gehen per Handy oder Smartphone ins Internet URL: https://www.destatis.de/DE/PresseService/Presse/Pressemitteilungen/2016/12/PD16_430_63931.html [accessed 2018-06-21] [WebCite Cache ID 70SMZgEPs]
35. Jane SK. 2010 Apr 9. How smartphones are changing health care for consumers and providers URL: <https://www.chcf.org/publication/how-smartphones-are-changing-health-care-for-consumers-and-providers/> [accessed 2018-01-30] [WebCite Cache ID 6wqitYsg]
36. Fallah M, Yasini M. A Medication Reminder Mobile App: Does It Work for Different Age Ranges. *Stud Health Technol Inform* 2017;235:68-72. [Medline: [28423757](https://pubmed.ncbi.nlm.nih.gov/28423757/)]
37. Vicente P, Lopes I. Attitudes of older mobile phone users towards mobile phones. *Communications* 2016;41(1):71-86. [doi: [10.1515/commun-2015-0026](https://doi.org/10.1515/commun-2015-0026)]
38. Wojciechowski M, Ristok H, Brandes W, Lange B, Baumgarten G. Architecture of the 'Daily Care Journal' for the Support of Health Care Networks. In: *Ambient Assisted Living*. Berlin, Germany: Springer; Jan 25, 2011:3-16.
39. Garfield S, Clifford S, Eliasson L, Barber N, Willson A. Suitability of measures of self-reported medication adherence for routine clinical use: a systematic review. *BMC Med Res Methodol* 2011 Nov 03;11:149 [FREE Full text] [doi: [10.1186/1471-2288-11-149](https://doi.org/10.1186/1471-2288-11-149)] [Medline: [22050830](https://pubmed.ncbi.nlm.nih.gov/22050830/)]
40. Claxton AJ, Cramer J, Pierce C. A systematic review of the associations between dose regimens and medication compliance. *Clin Ther* 2001 Aug;23(8):1296-1310. [Medline: [11558866](https://pubmed.ncbi.nlm.nih.gov/11558866/)]
41. Cramer JA, Mattson RH, Prevey ML, Scheyer RD, Ouellette VL. How often is medication taken as prescribed? A novel assessment technique. *JAMA* 1989 Jun 9;261(22):3273-3277. [Medline: [2716163](https://pubmed.ncbi.nlm.nih.gov/2716163/)]

Abbreviations

HIS: hospital information system
mHealth: mobile health
MMH: MacKay Memorial Hospital
QR: Quick Response
SQL: structured query language
WHO: World Health Organization

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Original Paper

Diabetes Educators' Insights Regarding Connecting Mobile Phone– and Wearable Tracker–Collected Self-Monitoring Information to a Nationally-Used Electronic Health Record System for Diabetes Education: Descriptive Qualitative Study

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Abstract

Background: Diabetes educators are integral to a clinical team in providing diabetes self-management education and support; however, current mobile and Web-based self-management tools are not integrated into clinical diabetes care to support diabetes educators' education efforts.

Objective: The objective of our study was to seek diabetes educators' insights regarding the development of an interface within the Chronicle Diabetes system, a nationally used electronic health record (EHR) system for diabetes education documentation with behavioral goal-setting functions, to transfer mobile phone- and wearable tracker-collected self-monitoring information from patients to diabetes educators to facilitate behavioral goal monitoring.

Methods: A descriptive qualitative study was conducted to seek educators' perspectives on usability and interface development preferences in developing a connected system. Educators can use the Chronicle Diabetes system to set behavioral goals with their patients. Individual and group interviews were used to seek educators' preferences for viewing mobile phone- and wearable tracker-collected information on diet, physical activity, and sleep in the Chronicle Diabetes system using open-ended questions. Interview data were transcribed verbatim and analyzed for common themes.

Results: Five common themes emerged from the discussion. First, educators expressed enthusiasm for and concerns about viewing diet and physical activity data in Chronicle Diabetes system. Second, educators valued viewing detailed dietary macronutrients and activity data; however, they preferred different kinds of details depending on patients' needs, conditions, and behavioral goals and educators' training background. Third, all educators liked the integration of mobile phone-collected data into Chronicle Diabetes system and preferably with current EHR systems. Fourth, a need for a health care team and a central EHR system to be formed was realized for educators to share summaries of self-monitoring data with other providers. Fifth, educators desired advanced features for the mobile app and the connected interface that can show self-monitoring data.

Conclusions: Flexibility is needed for educators to track the details of mobile phone- and wearable tracker-collected diet and activity information, and the integration of such data into Chronicle Diabetes and EHR systems is valuable for educators to track patients' behavioral goals, provide diabetes self-management education and support, and share data with other health care team members to facilitate team-based care in clinical practice.

KEYWORDS

wearable; connected health; mHealth; diabetes; self-management; lifestyle intervention; electronic health record; self-monitoring; behavior modification; usability

Introduction

Research has demonstrated the effectiveness of behavioral lifestyle interventions that focus on goal setting and diet and physical activity self-monitoring to improve glycemic control for patients with type 2 diabetes [1]. Recent studies have used mobile and Web-based technologies to enhance goal-setting and self-monitoring interventions in diabetes care [2,3]. A recent systematic review of the literature on technologies used for diabetes self-management education and support revealed that there were four essential elements in effective technologies that worked on improving glycemic control: two-way communication, analyzed patient-generated health data (PGHD), tailored education, and individualized feedback [4]. However, the highlighted technologies that enabled two-way communication and PGHD did not include the use of electronic health record (EHR) systems that health care provider teams use on a daily basis for care management or for connecting PGHD to EHRs. Furthermore, previous studies have only demonstrated the effective use of mobile [5,6] and Web-based systems [7,8] that were not connected with EHRs in supporting diabetes self-management behaviors. Connected systems that engage both patients and clinical health care providers, including diabetes educators, are essential to ensure expert care for patients with diabetes. It is equally important to also take advantage of mHealth technologies, including mobile phone apps and wearable trackers, to engage patients in self-care behaviors. Thus far, none of the published literature on diabetes education has explored the integration of PGHD collected via mobile technology to EHRs to facilitate the translation of effective technology-based interventions into diabetes education practice.

Diabetes educators are the frontline health care professionals providing diabetes self-management education and support to patients with diabetes across the United States. Diabetes educators can be registered nurses (RNs), registered dietitians (RDs), pharmacists, medical doctors, exercise physiologists, etc [7]. The Chronicle Diabetes system is a nationally used Web-based system for diabetes education documentation with behavioral goal-setting functions, and it is available free of charge to all American Diabetes Association (ADA)-recognized diabetes education programs [9]. Although it is a comprehensive system for diabetes educators to set, document, and track behavioral goals, monitoring of and following up on patient behavioral goals can be challenging for both patients and diabetes educators [9]. To facilitate evidence-based goal-setting and self-monitoring interventions into the diabetes education process, we propose using the Chronicle Diabetes system currently available to diabetes educators to set patient diet and physical activity goals and connecting patient self-monitoring information collected from mobile devices to the Chronicle Diabetes system to facilitate educators' monitoring of patients' adherence to their goals. To seek educators' insights regarding

the development of a connected interface within the Chronicle Diabetes system, we conducted individual and group interviews to gain educators' perspectives on usability and interface preferences in developing such a connected system.

Methods

Design

This was a descriptive qualitative study designed to answer the research question "What are diabetes educators' perspectives on integrating patient-monitored diet and physical activity into the practice of diabetes self-management education and support?" We conducted semistructured and in-depth interviews to elicit diabetes educators' views on using an interface built in the Chronicle Diabetes system to connect self-monitoring data collected from mobile devices. To ensure data consistency, one moderator conducted all interviews using a protocol with open-ended questions to obtain diabetes educators' perceptions on mobile-collected information and their preferences for viewing this information in the Chronicle Diabetes system [10]. The moderators comprised a trained qualitative researcher who understood both the Chronicle Diabetes and Jawbone UP24 systems and another researcher who had developed the Chronicle Diabetes system and was involved in developing the interface in this system to integrate Jawbone-collected information. The study was approved by the Institutional Review Boards of the University of Texas Health Science Center at Houston and the University of Pittsburgh.

Sample and Setting

We recruited the diabetes educators from western Pennsylvania, where the Chronicle Diabetes system was first implemented, and Houston, TX, where the educators had little knowledge about the system, to get a balanced sample of the educators' views on the proposed connected interface within the Chronicle Diabetes system. Educators were informed about the study through an email. Diabetes educators who responded to our invitation emails were selected to participate in this study if they were certified diabetes educators practicing in a recognized diabetes education program. When the moderators heard recurring but no new information from the study participants, we stopped the study and did not further recruit study participants. Study participants received a gift card as compensation for devoting their time to our study.

Data Collection Procedures

We conducted individual and group interviews in this study. Individual interviews were conducted when study participants could not make it to a focus group session or not enough participants could agree upon a common time for a focus group session. We used a script, including an introductory statement and primary and probe questions, in all of the individual or group interviews. The introductory statement included general

statements of focus group to encourage open discussion and diverse opinions; a description of study purpose; and a description of the mobile app, fitness tracker, and Chronicle Diabetes system. We administered a demographic questionnaire to collect diabetes educators' information. For each primary question, we first asked a general question to prompt the participants' perceptions and then used "probe" questions to explore any further new information and encourage participants to elaborate on their experience. Our primary interview questions, in particular, were based on the features of the Chronicle Diabetes system interface and the wearable device with its companion mobile phone app. We started our primary questions on how educators use their current EHR system to document diabetes education and support, and then, we asked them to imagine if we had the ability connect mobile device data to their system, how they would want it to look like. We also provided visual aids (ie, PowerPoint slides) of the designs of the Chronicle Diabetes system interface and the mobile phone app to participants and asked them about the features of the "connected" systems that facilitated their education sessions. The interviews were recorded using a digital audio recorder.

The Electronic Health Record System for Diabetes Education: The Chronicle Diabetes System

The Chronicle Diabetes system provides tools for diabetes educators to document, track, and report on their patients' education process according to the National Standards for Diabetes Self-Management Education and ADA education recognition program (ERP) requirements. We chose the Chronicle Diabetes system over other EHRs and other Web-based systems in our study mainly due to the following reasons: (1) its detailed features to support goal setting and self-monitoring in diabetes self-management education and support, (2) its potential to be disseminated nationally, (3) its capabilities to connect with various EHRs in the future, and (4) its national impact on supporting diabetes education practice documentation, which will facilitate efforts for securing reimbursement for incorporating digital health solutions in diabetes education practice in the future. Educators use the Chronicle Diabetes system to record patients' required behavior goals at baseline and continue, modify, or discontinue them at follow-up visits. Behavior goals are categorized as follows: nutrition, activity, medications, monitoring, prevention and treatment of acute complications, prevention and treatment of chronic complications, and psychosocial adjustment or healthy coping. Patient goal achievement at baseline and follow-up can be scored at 0%, 25%, 50%, 75%, and 100%. In addition to goal setting, patient education plans and program processes are recorded. After the one-to-one or group class education session is completed and documented, all aspects of the education process are automatically summarized in a format that meets ADA ERP documentation requirements.

Patient-Monitored Diet and Activity Data Using UP24 Jawbone Wristband and Companion Mobile Phone App

UP24 by Jawbone is a wristband that objectively tracks individuals' physical activity and sleep; its companion mobile phone app shows this tracked information and includes features

to search or track food intake. We compared a few commercially available fitness trackers prior to the study and chose the Jawbone UP24 in this study due to its feature of distinguishing between calories burned from planned exercise minutes and resting calorie burn. This feature supports the evidence-based self-monitoring intervention used in the Diabetes Prevention Program that focused on tipping the calorie balance through noting the calories burned through planned exercise. It should be noted that this device is no longer in production or actively supported. However, the knowledge gained from using UP24 by Jawbone can be transferred to other fitness tracker products that are now providing the same features as this device.

Data Management and Analysis

All audiotapes were transcribed verbatim in English by a professional transcription service company. Any information that could refer to patient data in the transcripts was either removed or de-identified. Two trained researchers analyzed the transcribed data and the notes taken during the interviews using conventional content analysis [11,12] for thematic patterns based on the categories derived from coded text segments. Concepts or emerging thematic patterns were frequently cross-checked within and across transcripts to ensure data quality. The interpretation of the data was reviewed and refined by the investigators; two coders had open discussions to achieve agreement when there were discrepancies in data interpretation. Common themes related to the educators' experience in using the Chronicle Diabetes system interface and wearable devices and example quotations are presented below in the Results section.

Results

Sample Characteristics

We recruited 8 diabetes educators (3 RNs and 5 RDs) from Pittsburgh, PA, and Houston, TX. They had an average of 22 years of general practice experience and an average of 13 years of practice experience in diabetes education. On average, the participants had approximately 1.75 years of experience using the Chronicle Diabetes system.

Thematic Analysis Findings

Five individual interviews and one focus group session were conducted. Each interview or focus group session lasted from 30 to 60 minutes, and all six sessions generated a total of about 233 pages of transcribed text. The five common themes that emerged from the interview responses are described in the following subsections, which also include excerpts from the interviews or focus group sessions.

Enthusiasm and Concerns About Viewing Self-Monitoring Data in the Chronicle Diabetes System

All diabetes educators expressed strong enthusiasm toward viewing diet and physical activity information in the Chronicle Diabetes system. Some educators were more enthusiastic about certain diet and activity data than others. Most educators were not very enthusiastic about seeing sleep data. They did not think monitoring sleep was necessary, unless patients had sleep disorders; others felt that sleep data are beyond the scope of

diabetes education practice, while one educator thought that knowing patients' total hours of sleep may be helpful for understanding their general health.

If I was visually looking at it, my number one things would be calories, carbs, protein, and fiber...But I work in the Weight Management Center, and protein and fiber are all we really focus on.

Total active time...total burn calories would be important for me...I would like to know total times that they're active throughout the day...total burned calories would be important so we know...their caloric intake is matching up or negative, if they want to lose weight.

I wouldn't exactly know what to do with all the information (sleep). Like, if some, if somebody...sleep apnea, you could talk about it, but it's not something I'm as familiar with as a diabetes educator.

Some educators expressed concerns regarding how often patients would monitor their activity. They thought that constant self-monitoring might cause patients to feel overwhelmed. Instead, they preferred that patients monitor themselves for only a few weekdays or only on weekends, whereby educators could still detect discernable patterns in patients' self-monitoring behaviors. The educators also expressed concerns about patient compliance. They questioned whether data collected on mobile devices would exactly reflect patients' activities because some patients may log their data based on how they would like their providers or educators to view their behaviors. These may impact their decisions when they view the connected self-monitoring data during a diabetes education visit.

Don't overload them.

Don't put the expectations so high.

So there's a lot of information on that page that might be a little bit overwhelming, even from my perspective, as a professional.

It would be used mainly for educational reasons, but after a while...I think that patients would get wise to it and put in the foods that look good...

After a couple of months, if they're seeing that they're not pleasing their physician or whomever is looking at this stuff, they'll start putting in the things that they know calculate to be the right thing.

Varied Preference Toward the Kinds of Details Displayed Depending on Patients' Needs, Conditions, and Behavioral Goals and Educators' Training Background

The educators valued viewing detailed dietary macronutrient and activity data from patient self-monitoring. When viewing patient self-monitoring data, some educators factored in patients' health conditions and status to select specific information that would be more relevant to individualized diabetes education.

RDs for sure want to track food logs and carb counting, fiber, and calories...

Fiber, protein, calories are important for weight loss purposes...Depending on the patient issues, the needed

values are different...personalize which factors to see individualized to each patient. For example, if the patient has high lipids, cholesterol is important to see. If the patient has kidney issues, protein and sodium are important to see.

Some educators preferred viewing information about calorie counting and carbohydrates, whereas others wanted to see percentages of calories from fat, carbohydrates, and proteins in a graphical chart on a daily basis.

Most say macronutrients are more important than percentages, while RDs may have different views. Some want to calculate carbs specifically from sugar and calculate other carbs altogether...Others want to see what percent of carbs come from sugar.

My number one things would be calories, carbs, protein, and fiber...But I work in the Weight Management Center, and protein and fiber are, like, all we really focus on

Preference for a Diabetes Education System That is Connected to and Integrated Into the Electronic Health Record

All the participants found integrating mobile phone- and wearable tracker-collected self-monitoring data into the Chronicle Diabetes system extremely helpful and particularly favored integrating the current EHR system with the Chronicle Diabetes system. Documenting detailed diabetes self-management education and support information, along with required information for education program recognition in the Chronicle Diabetes system and required documentation in the hospital or practice EHR system, should be all integrated into one connected system.

Then we wouldn't have to double document it. If we could put it in there and it would automatically go, that would be nice.

Well that'd be great because then I wouldn't have to chart so dang much. Like, it—all the information would already be in the chart.

Interprofessional Team-Based Care Using Connected Electronic Health Record

A health care team and a central EHR system need to be formed for educators to share summaries of self-monitoring diet and physical activity data to communicate with other health care providers in diabetes education. Most educators agreed that the patient-monitored diet and activity information would be helpful for primary care providers, such as family physicians. Some said that they would like to see all self-monitoring data, but other educators thought that physicians would not have time to use the Chronicle Diabetes system. Instead, they thought that physicians may be able to obtain information indirectly from other health care providers, such as an educator or a dietician. The diabetes educators wanted a space in the Chronicle Diabetes system to include comments and share opinions with other health care providers. The preferences regarding the frequency and timing of comments varied across the educators.

The information in Chronicles will be good supporting data.

They would develop teams. It would be the educator on the team. If there was a team approaching a physician practice...to collaborate and take [it] to the physicians...that would be very helpful. It would have to come from another health professional...

And you would think that they would look at using this kind of technology, but they're being pushed in so many different directions...I'm sure they don't perceive that they have the time for this.

I don't know if people have time to read. I think doctors like to have it there and if they need to refer to it, they really like that.

Primary care physicians or the nurse practitioners, physician assistants (should be able to view the data). Whoever their primary care is and whoever is following them through the diabetes (treatment).

No.

I wish we could say yes.

They don't. Unless—they would develop teams. It would be the educator on the team. If there was a team approaching a physician practice

If Rob had this data to collaborate and take to the physicians...Yes...that would be very helpful. It would have to come from another health professional...Right...to the physician to pay attention to it. The patient brought it in. They'd scan through it. Say—pretend like they were really digesting it and say, "Oh. This is great! You need to exercise more."

Advanced Features for the Mobile App, Chronicle Diabetes system, and the Display of Patient Self-Monitoring Data

For the mobile app, educators suggested adding voice search rather than barcode scanning or manual entry to help patients log their foods more easily, as well as a function that automatically records physical activity to allow more accurate real-time data.

If they had an app that could—if you could...talk into your phone...and it types what you say...People would love that as opposed to choosing it on an app where you have to go in or the one that reads the scanning bars.

Some educators suggested adding a new function to Chronicle Diabetes system that would allow them to merge their preferred self-monitoring data at once to observe the effects of multiple behavior interactions in diet and activity with blood sugar or weight.

When we're talking about blood glucose...in addition to just knowing the number or the time of day...if they're exercising, you can track their blood sugar level in relation to movement...And the same with food...

I need a place where the patient can put in their carbs, their weight, their calories, and their glucose all in one place and to be able to see how the amount of carbs that they ate corresponded to their blood sugar...

I would like the blood glucose to interact with the exercise and the blood glucose to interact with the nutrition.

Several educators wanted to view a variety of data (eg, nutrition, exercise, blood glucose) in separate tabs in Chronicle Diabetes system and suggested different formats for daily, weekly, or monthly summary reports.

The blood sugar level, and on the graph, show the exercise...but I know I would want a separate tab for exercise and a separate tab for nutrition.

I would like to have a tab that—where you can see all the blood sugar levels no matter what time of the day.

I would want to look at the carbs and the protein and...I would want to look at their total fat intake as well...

I like the summary ones the best, for the week...I'm not liking the daily one again as much...

If they're coming to me with a problem, I want to look at the past seven days more than the month because then it'll dilute the statistics...

Discussion

Principal Findings

Our study demonstrates that diabetes educators are enthusiastic about the incorporation of self-monitoring information into the Chronicle Diabetes system to monitor patients and ensure patient adherence to behavioral goals during diabetes self-management education and support. Integrating such data into a centralized system facilitates robust data collection, synthesis, and analysis and has the potential for developing precision diabetes management with context-aware, individualized guidance presented to the patient and caregivers in a coordinated fashion [13]. The diabetes educators' insights regarding information display, interface design, and data integration effectively show how the wearable fitness tracker and its companion dietary self-monitoring app can support diabetes educators' clinical work to improve diabetes self-care behaviors, care coordination, and patient outcomes. The 2017 National Standards for Diabetes Self-Management Education and Support recommend the provision of individualized diabetes education based on the patient's medical history, health beliefs and attitudes, diabetes knowledge, and self-management skills and also support the use of evidence-based technology-based solutions for delivery of diabetes self-management education and support [7]. A recent study in the United Kingdom exploring patients' unmet diabetes self-management education and support needs highlighted their needs for support in behavior change, particularly in physical activity and dietary changes, using digital technology [14]. Our findings indicate that diabetes educators prefer the reporting of self-monitoring information that is closely relevant to improving

diabetes outcomes and is within the scope of diabetes educators' practice. Accordingly, patients' diet and physical activity reports were thought to be of greater relevance than sleep activity since the latter was deemed to be beyond the scope of diabetes education practice. Future studies can explore whether summarizing sleep data with actionable insights would address educators' lack of confidence in handling sleep data. The educators in our study also suggested that all types of macronutrient (eg, protein, carbohydrates, calories, fat) and activity (eg, exercise type and duration, steps) information are needed so that educators with different training backgrounds can always find information relevant to enhance diabetes education and outcomes, even for patients with different health conditions.

While the mobile app itself does not provide personalized education or therapeutic support to patients, the integration of mobile-based self-monitoring information into the Chronicle Diabetes system would overcome this limitation by enabling educators to focus and interpret self-monitored diet and exercise information that is relevant to specific patient needs, rather than spending education time on dietary recalls with patients. Other studies have recommended employing a health coach or a certified diabetes educator who is not part of a health care team to provide diabetes self-management support based on mobile phone- or wearable tracker-collected self-monitoring data [2,8]. Our study assessing insights from diabetes educators who are part of a current health care team can provide some unique perspectives. The 2017 National Standards for Diabetes Self-Management Education and Support recommend the use of evidence-based technology-based solutions for delivery of diabetes self-management education and support [7]. The findings from our study not only expressed educators' insights regarding using mobile- and wearable tracker-collected self-monitoring data in one diabetes education EHR system but also provided foundational knowledge in facilitating other evidence-based digital health solutions to be integrated into clinical workflow through EHR integration. With the increasing use of digital health and wearable solutions, there is expanding availability of PGHD to diabetes educators. The advantages of utilizing such data are obvious; even no data or missing data could provide meaningful information regarding patients' engagement with their self-management and lead to product patient-educator conversations. However, potential shortcomings deserve further research and attention. The usability of connected digital health solutions need to be firmly addressed to provide summarized PGHD with actionable and relevant information to facilitate current clinical workflow, and it should not take clinicians away from their interaction with patients. Our educators also expressed concerns regarding patient

compliance and data accuracy, and other matters (like patient privacy and confidentiality, data ownership, information overload, liabilities, efficiency and clarity of the data, lack of reimbursement) are also potential issues that deserve further research.

In this study, diabetes educators expressed the need to connect the Chronicle Diabetes system with existing EHR systems for managing patient care and expressed a desire to play a more active role in reviewing mobile data and connecting with physicians and other prescribing providers such as nurse practitioners to provide team-based care. In a previous study in which patients were provided mobile self-management support, the physicians' prescribing behaviors did not seem to change [15]. Additional research is needed to determine whether an integrated system with mobile data connected to the EHR system would influence physicians' prescribing behavior through an interprofessional team-based approach, where a diabetes educator takes the leading role to review the summarized PGHD.

Limitations

There are several limitations to this study. First, our study sample was small; thus, it may not be representative of the general diabetes educator population. Second, there may be self-selection bias in our sample because all diabetes educators were self-selected into the study after seeing the advertisement. Third, we only chose one mobile app with patient-monitored diet and activity information to show to the diabetes educators at the interviews; viewing other brands with different interfaces may trigger different insights from the diabetes educators. Future research is needed to expand the sample size and representation and to include other PGHD pertinent to diabetes self-management education and support practice.

Conclusions

A full range of tracking details of mobile phone- and wearable tracker-collected diet and activity information is needed to support educators' preferences, and the integration of such data into Chronicle Diabetes and EHR systems is valuable for educators to track patients' behavioral goals and provide precise diabetes self-management education and support. Diabetes educators' perspectives need to be incorporated as we develop future mobile and connected systems to support team-based diabetes care and education in clinical practice. The study findings were used to inform the development of a connected interface in the Chronicle Diabetes system to integrate Jawbone-collected self-monitoring diet and physical activity information, and the connected system is currently being tested in a multisite randomized clinical trial [16].

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Conflicts of Interest

None declared.

References

1. Look AHEAD Research Group, Wing RR. Long-term effects of a lifestyle intervention on weight and cardiovascular risk factors in individuals with type 2 diabetes mellitus: four-year results of the Look AHEAD trial. *Arch Intern Med* 2010 Sep 27;170(17):1566-1575 [FREE Full text] [doi: [10.1001/archinternmed.2010.334](https://doi.org/10.1001/archinternmed.2010.334)] [Medline: [20876408](https://pubmed.ncbi.nlm.nih.gov/20876408/)]
2. Wayne N, Perez DF, Kaplan DM, Ritvo P. Health Coaching Reduces HbA1c in Type 2 Diabetic Patients From a Lower-Socioeconomic Status Community: A Randomized Controlled Trial. *J Med Internet Res* 2015 Oct 05;17(10):e224 [FREE Full text] [doi: [10.2196/jmir.4871](https://doi.org/10.2196/jmir.4871)] [Medline: [26441467](https://pubmed.ncbi.nlm.nih.gov/26441467/)]
3. Holmen H, Torbjørnsen A, Wahl AK, Jenum AK, Småstuen MC, Arsand E, et al. A Mobile Health Intervention for Self-Management and Lifestyle Change for Persons With Type 2 Diabetes, Part 2: One-Year Results From the Norwegian Randomized Controlled Trial RENEWING HEALTH. *JMIR Mhealth Uhealth* 2014 Dec 11;2(4):e57 [FREE Full text] [doi: [10.2196/mhealth.3882](https://doi.org/10.2196/mhealth.3882)] [Medline: [25499872](https://pubmed.ncbi.nlm.nih.gov/25499872/)]
4. Greenwood DA, Gee PM, Fatkin KJ, Peeples M. A Systematic Review of Reviews Evaluating Technology-Enabled Diabetes Self-Management Education and Support. *J Diabetes Sci Technol* 2017 Sep;11(5):1015-1027 [FREE Full text] [doi: [10.1177/1932296817713506](https://doi.org/10.1177/1932296817713506)] [Medline: [28560898](https://pubmed.ncbi.nlm.nih.gov/28560898/)]
5. Quinn CC, Shardell MD, Terrin ML, Barr EA, Ballew SH, Gruber-Baldini AL. Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. *Diabetes Care* 2011 Sep;34(9):1934-1942 [FREE Full text] [doi: [10.2337/dc11-0366](https://doi.org/10.2337/dc11-0366)] [Medline: [21788632](https://pubmed.ncbi.nlm.nih.gov/21788632/)]
6. Wang J, Cai C, Padhye N, Orlander P, Zare M. A Behavioral Lifestyle Intervention Enhanced With Multiple-Behavior Self-Monitoring Using Mobile and Connected Tools for Underserved Individuals With Type 2 Diabetes and Comorbid Overweight or Obesity: Pilot Comparative Effectiveness Trial. *JMIR Mhealth Uhealth* 2018 Apr 10;6(4):e92 [FREE Full text] [doi: [10.2196/mhealth.4478](https://doi.org/10.2196/mhealth.4478)] [Medline: [29636320](https://pubmed.ncbi.nlm.nih.gov/29636320/)]
7. Beck J, Greenwood DA, Blanton L, Bollinger ST, Butcher MK, Condon JE, 2017 Standards Revision Task Force. 2017 National Standards for Diabetes Self-Management Education and Support. *Diabetes Care* 2017 Dec;40(10):1409-1419. [doi: [10.2337/dci17-0025](https://doi.org/10.2337/dci17-0025)] [Medline: [28754780](https://pubmed.ncbi.nlm.nih.gov/28754780/)]
8. Downing J, Bollyky J, Schneider J. Use of a Connected Glucose Meter and Certified Diabetes Educator Coaching to Decrease the Likelihood of Abnormal Blood Glucose Excursions: The Livongo for Diabetes Program. *J Med Internet Res* 2017 Jul 11;19(7):e234 [FREE Full text] [doi: [10.2196/jmir.6659](https://doi.org/10.2196/jmir.6659)] [Medline: [28698167](https://pubmed.ncbi.nlm.nih.gov/28698167/)]
9. Wang J, Siminerio LM. Educators' insights in using chronicle diabetes: a data management system for diabetes education. *Diabetes Educ* 2013;39(2):248-254. [doi: [10.1177/0145721713475844](https://doi.org/10.1177/0145721713475844)] [Medline: [23427239](https://pubmed.ncbi.nlm.nih.gov/23427239/)]
10. Morgan DL. Focus Groups. *Annu Rev Sociol* 1996 Aug;22(1):129-152. [doi: [10.1146/annurev.soc.22.1.129](https://doi.org/10.1146/annurev.soc.22.1.129)]
11. Hsieh H, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res* 2005 Nov;15(9):1277-1288. [doi: [10.1177/1049732305276687](https://doi.org/10.1177/1049732305276687)] [Medline: [16204405](https://pubmed.ncbi.nlm.nih.gov/16204405/)]
12. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Educ Today* 2004 Feb;24(2):105-112. [doi: [10.1016/j.nedt.2003.10.001](https://doi.org/10.1016/j.nedt.2003.10.001)] [Medline: [14769454](https://pubmed.ncbi.nlm.nih.gov/14769454/)]
13. Heintzman ND. A Digital Ecosystem of Diabetes Data and Technology: Services, Systems, and Tools Enabled by Wearables, Sensors, and Apps. *J Diabetes Sci Technol* 2015 Dec 20;10(1):35-41 [FREE Full text] [doi: [10.1177/1932296815622453](https://doi.org/10.1177/1932296815622453)] [Medline: [26685994](https://pubmed.ncbi.nlm.nih.gov/26685994/)]
14. Pal K, Dack C, Ross J, Michie S, May C, Stevenson F, et al. Digital Health Interventions for Adults With Type 2 Diabetes: Qualitative Study of Patient Perspectives on Diabetes Self-Management Education and Support. *J Med Internet Res* 2018 Jan 29;20(2):e40 [FREE Full text] [doi: [10.2196/jmir.8439](https://doi.org/10.2196/jmir.8439)] [Medline: [29463488](https://pubmed.ncbi.nlm.nih.gov/29463488/)]
15. Quinn CC, Sareh PL, Shardell ML, Terrin ML, Barr EA, Gruber-Baldini AL. Mobile Diabetes Intervention for Glycemic Control: Impact on Physician Prescribing. *J Diabetes Sci Technol* 2014 Mar;8(2):362-370 [FREE Full text] [doi: [10.1177/1932296813514503](https://doi.org/10.1177/1932296813514503)] [Medline: [24876589](https://pubmed.ncbi.nlm.nih.gov/24876589/)]
16. Wang J, Coleman DC, Kanter J, Ummer B, Siminerio L. Connecting Smartphone and Wearable Fitness Tracker Data with a Nationally Used Electronic Health Record System for Diabetes Education to Facilitate Behavioral Goal Monitoring in Diabetes Care: Protocol for a Pragmatic Multi-Site Randomized Trial. *JMIR Res Protoc* 2018 Apr 02;7(4):e10009 [FREE Full text] [doi: [10.2196/10009](https://doi.org/10.2196/10009)] [Medline: [29610111](https://pubmed.ncbi.nlm.nih.gov/29610111/)]

Abbreviations

ADA: American Diabetes Association

EHR: electronic health record
ERP: education recognition program
PGHD: patient-generated health data
RD: registered dietitians
RN: registered nurses

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Original Paper

An mHealth Intervention for Persons with Diabetes Type 2 Based on Acceptance and Commitment Therapy Principles: Examining Treatment Fidelity

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Abstract

Background: Web-based interventions are becoming an alternative of treatment aimed to support behavioral changes and several advantages over traditional treatments are reported. New ways of delivering an intervention may result in new challenges regarding monitoring of treatment fidelity (TF) which is essential to ensure internal and external validity. Despite the importance of the theme, only a few studies in this field are reported.

Objective: To examine TF of a mobile phone delivered intervention based on Acceptance and Commitment Therapy (ACT) with electronic diaries and written situational feedback for persons with diabetes mellitus type 2, the recommendations from the Behavior Change Consortium (BCC) established by The National Institutes of Health (NHI) were applied. To analyze fidelity, they recommend 5 areas to be investigated (1) design of the study, (2) provider training, (3) delivery of treatment, (4) receipt of treatment, and (5) enactment of treatment. In the current study, these areas were examined based on the analysis of therapists' adherence to the treatment protocol and participants' and therapists' experience with the intervention.

Methods: To investigate the therapists' adherence to the treatment protocol, a total of 251 written feedback text messages were divided into text segments. Qualitative thematic analyses were then performed to examine how ACT and other therapeutic processes were used in the feedback by the therapists. For the therapists' and participants' experience analysis, participants answered a self-reported questionnaire and participated in 2 interviews. The therapists continuously reported their experiences to the researcher responsible for the project.

Results: The results show high adherence to the TF strategies 20/21 (95%) applicable items of the fidelity checklist recommended by NHI BCC were identified in the present study. Measured provider skill acquisition post-training was the only item absent in the fidelity checklist. The results also show high therapists' adherence to the treatment protocol. All ACT processes (values, committed action, acceptance, contact with the present moment, self as context and cognitive defusion) were found in the coded text segments of the feedback in addition to communication and motivation strategies. For 336/730 (46%) of total possible text segments coded independently by 2 researchers, the interrater reliability measured by Cohen's kappa was .85. The evaluation of participants' and therapists' experience with the intervention was generally positive.

Conclusions: Based on the analyses of therapists' adherence to the treatment protocol grounded by ACT-principles and participants' and therapists' experience with the intervention, the 5 areas of TF recommended by NHI BCC were analyzed indicating a high level of TF. These results ensure an appropriate level of internal and external validity of the study and reliable intervention results and facilitate a precise replication of this intervention concept. Web-based psychological interventions to

support people with chronic conditions are becoming increasingly more common. This study supports the results from a previous study which indicated that ACT could be reliably delivered in a written web-based format.

Trial Registration: ClinicalTrials.gov NCT01297049; <https://clinicaltrials.gov/ct2/show/NCT01297049> (Archived by WebCite at <http://www.webcitation.org/70WC4Cm4T>)

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KEYWORDS

diabetes mellitus type 2; Acceptance and Commitment Therapy; mobile phone; Web-based; treatment fidelity; mHealth

Introduction

Overview

Internet and mobile phone technology have opened new ways to deliver health-related counseling and therapy making health care more accessible to people, especially for those who suffer from chronic illness and live far from hospitals and qualified therapists. Several advantages over face-to-face treatments such as convenience, reduced cost, and the ability to adjust plans and feedback to a participant's individual needs are reported [1]. Treatments delivered by the internet can also enhance health literacy and health-related knowledge and support people to cope with their health problems [2]. Challenges also exist, such as technological problems and absence of face-to-face interaction. When transforming face-to-face interventions into online interventions, there is a need to evaluate if, and how, the principles of the intervention are applied in the new modus, but only a few studies in this field are reported [3]. To avoid Type I (ie, reject the null hypothesis) and Type II (ie, reject the false null hypothesis) errors, due to misinterpretation of intervention results, it is essential to plan, monitor and evaluate Treatment Fidelity (TF). The National Institutes of Health (NIH) established a Behavior Change Consortium (BCC) and defined TF as *"the methodological strategies used to monitor and enhance the reliability and validity of behavioral interventions."* TF is a continuous evaluation of different aspects of the intervention essential to enhance reliability and validity of the independent variables. A high level of TF assures that the treatment protocol is performed as intended. Although approaches to establish TF in Web-based interventions differ from those used in interventions delivered in person, the same fidelity evaluation requirements need to be applied [4].

The NIH BCC also developed a TF protocol with the following 5 principal areas: (1) study design that builds on strategies to ensure that the stated hypotheses can adequately be tested in relation to the underlying theory and clinical processes, (2) provider training to ensure that all treatment providers have been satisfactorily trained to deliver the intervention, (3) delivery of treatment that build on strategies, for example treatment monitoring, to ensure that the intervention is delivered as intended, (4) treatment receipt strategies that involve assessing and optimizing the degree to which the participant understands and demonstrates knowledge to use treatment skills, and (5) treatment enactment that involves assessing and optimizing of the degree to which the participant applies the skills learned in treatment in daily life. [5,6]. According to the results of a study performed by Eaton and colleagues [4], the NIH BCC Treatment

Fidelity Guidelines were relevant when establishing TF for online delivered interventions.

The purpose of this study was to investigate the therapists' adherence [7] to the treatment protocol and participants' and therapists' experience with the mobile phone delivered intervention with electronic diaries (e-diaries) and written feedback based on Acceptance and Commitment Therapy (ACT) for persons with Diabetes Mellitus Type 2 (DMT2). Based on this investigation the 5 areas of TF recommended by NIH BCC were evaluated.

In addition to the recommendations from the NIH BCC, it is important to emphasize that an evaluation of TF of technology-based behavioral interventions carries additional challenges due to their dynamic and highly individualized nature, and elements associated with such characteristics need therefore to be evaluated as well [8]. By evaluating fidelity, it is possible to investigate if theory-based processes of the intervention are the primary mechanism of change outcomes and if they allow for precise replication and comparison amongst interventions [9].

Acceptance and Commitment Therapy

ACT is referred to as the third generation of Cognitive Behavior Therapy (CBT). Based on Functional Contextualism Philosophy and Relational Frame Theory [10], the objective of ACT is to improve patients' functioning and quality of life by increasing psychological flexibility, referred to as the ability to behave in accordance with life values and long-term goals also when interfering thoughts, emotions, and bodily symptoms are present [11]. Psychological flexibility can be achieved as the result of the treatment combining the 6 processes of ACT (see Table 1). These processes are overlapping and interrelated and can be introduced in different orders [10-12]. In most ACT-based treatments, exercises and metaphors are frequently used to discuss behaviors that may appear counterintuitive [13,14].

ACT shares critical features with traditional CBT approaches, such as behavior activation. Also, differences exist, as acceptance and cognitive defusion strategies are relatively unique for ACT [11,15]. The use of therapy based on theory, such as ACT, increases the chance that interventions aiming to support self-management in chronic illness will be effective. Clinical psychologists and health care professionals in related disciplines also play a vital role in the treatment of people with long-term conditions [16]. ACT has been evaluated in several randomized controlled trials for persons with DMT2 and other chronic conditions, and results confirm the utility of this approach for improving health outcomes [14,17-20].

Table 1. Acceptance and Commitment Therapy subprocesses.

Subprocess	Definition
Values	The deeply meaningful elements in a person's life. Values concern the ideals we have and how we want to live.
Committed action	Specific and concrete action plans guided by one's values, which also takes into account and anticipate barriers on the way.
Acceptance	Openness to experience, urges, emotions, and thoughts allowing them to come and go without a struggle.
Contact with the present moment	Being fully aware of the psychological and environmental events with openness, interest, receptiveness and without judgment.
Self as context	Allows people to be aware of psychological content without linking it to their personal identity.
Cognitive defusion	A process where people learn how to gain a perspective regarding one's thoughts, and thus manage to see their own thoughts as an outside observer and therefore avoid being affected by them.

Study Background

The intervention concept, involving the use of mobile technology to deliver the treatment based on behavioral therapy in a written format, was developed and tested first in the Netherlands in persons with irritable bowel syndrome (IBS) [21]. Later the intervention concept was refined and tested in Norway in persons with chronic widespread pain (CWP) and DMT2, respectively [22,23]. The IBS and CWP studies were randomized controlled trials (RCTs), whereas the DMT2 was a pilot. The RCTs showed positive results concerning catastrophizing, acceptance, and illness impact at a 3 and 5-month follow-up, respectively [21,22]. The participants' subjective experiences of the interventions in all studies were mostly positive. A summarized description of these studies is presented elsewhere [24]. Recently, a fidelity examination of the CWP study was published, showing a high level of treatment integrity [25]. We argued in this paper that the methodology also could be applied to other similar intervention concepts. Due to the significance of TF in behavior change interventions, and the need for more studies in this area, the present study aims to investigate TF of the DMT2 pilot study.

Methods

The current study has a mixed-method design, encompassing both qualitative and quantitative data aimed to investigate the TF of a mobile phone delivered intervention with e-diaries and written situational feedback based on ACT to support persons with DMT2.

Fidelity Strategies

In this section the strategies applied in the DMT2 pilot study aimed to ensure the 5 areas of TF recommended by NIH BCC, will be presented. These areas are: (1) study design, (2) provider

training, (3) delivery of treatment, (4) treatment receipt, and (5) treatment enactment.

DMT2 Pilot Study Design

Table 2 shows an overview of the DMT2 pilot study protocol, giving a summary of the study described by Nes and colleagues [23,24]. As mentioned before ACT was the critical component chosen to support a behavioral change in the person with DMT2. To ensure the fidelity of the DMT2 study design, and more specifically, to ensure that stated hypotheses could adequately be tested in relation to underlying theory and clinical processes, the intervention was daily monitored by a research coordinator (HE, co-author of the current paper) with an extensive experience in teaching meditation and previous experience in writing and supervising ACT/CBT based written situational feedback aimed to support women with CWP [22]. The feedback was made available to the participants after being approved by the research coordinator. The written format of the feedback facilitated this process.

Provider Training

A therapist wrote the feedback text messages in the DMT2 pilot study. She had a background in health care sciences (nursing) and attended a 3-day theoretical and practical course in ACT for clinical purpose held by Professor Steven Hayes, the founder of ACT. The therapist also received training, by the research coordinator, in how to analyze the information contained in the daily e-diaries and to write the feedback text based on the e-diaries and ACT.

The training in writing of feedback text messages lasted for 1 month. The feedback texts were provided for 2 persons with DMT2 who participated in a pre-pilot during the development phase of the intervention. These feedback messages were composed in cooperation with a multidisciplinary group including, a diabetes researcher, a diabetes nurse, a communication researcher, and a nutritionist.

Table 2. Overview of the diabetes mellitus type 2 pilot study by Nes et al [23,24].

Protocol	Description
Aim	To develop and test the feasibility of a mobile phone delivered intervention based on ACT to support self-management in persons with diabetes mellitus type 2.
Design	This was a feasibility pilot study. The intervention lasted for 12 weeks and started with a personal instructional meeting followed by daily e-diaries and feedback via a mobile phone. At a scheduled diary-completion time and to access the feedback, the participant received a short message service (SMS) text message with a link to a secure website. In this website, the diary questions could be answered and submitted back to the server, and the available feedback message could be read. There were 4 audio files with mindfulness and relaxation exercises available on the mobile phones.
Diaries	The participants completed the e-diaries 3 times daily. The diaries included 16-19 questions chosen for supporting self-monitoring (level of blood glucose, diet, medicine, and achieved activities) and awareness of health behavior, thoughts, feelings and applied self-management strategies. Most of the questions were answered by choosing predefined alternatives or by scoring on a 6-point Likert scale. The diaries also included a comment field giving participants the opportunity to write a short personal message to the therapist.
Feedback	A therapist had immediate access to submitted diaries and used the situational information to formulate personalized feedback based on Acceptance and Commitment Therapy. The purpose of the diaries and the situational feedback was to stimulate self-management. Daily written situational feedback (except weekends) was given during the first month followed by weekly feedback during the next 2 months. A multi-disciplinary group supported the development of the feedback during the first period of the study. The therapist used information from the 3 latest submitted diaries. There was no limitation on the length of the feedback.
Therapist	A nurse that was trained in Acceptance and Commitment Therapy.
Setting and recruitment	The intention was to recruit persons with type 2 diabetes through general practitioners and to include 10-15 participants to test the feasibility of the intervention in this patient group. Because of the difficulty in recruiting participants through their general practitioners, the social network of the researchers was also informed about the project and persons were asked if they knew potential candidates. The potential candidates with type 2 diabetes that met the inclusion criteria received a letter describing the study. Those interested in participating met the responsible researcher and received additional information. After receiving complementary information, the patients who agreed to participate in the project signed an informed consent form. All patients were followed by and received standard care from their general practitioners.
Outcomes	The primary outcome was the level of glycosylated hemoglobin (HBA _{1c}). This blood test shows the average level of blood sugar over the previous 2 to 3 months. This indicates how well a person with diabetes is being controlled over time. The secondary outcomes were the Audit of Diabetes Dependence Quality of Life (ADDQoL-19) [26], and Problem Areas in Diabetes (PAID) [27].
Study Sample and Data Collection	Of the 11/15 (73.3%) participants included in the study completed the intervention. The data were collected at researcher's and general practitioner's office. The baseline in the first meeting with the patients (T1) and immediately after 12-week intervention period (T2). The participants were interviewed twice. The first time halfway through and the second time at the end of intervention period.
Statistical Analysis	Descriptive statistics as means and frequencies were calculated using IBM SPSS version 18 statistical software. A descriptive summary of the information extracted from the interviews was made, the content was analyzed, and themes identified.
Effect	Most of the participants reported positive life style changes. The response rate to daily registration entries was good and few technical problems were encountered. The mean HBA _{1c} level the week before inclusion was 7.4% (SD 1.1%) and 6.9% (SD 0.8%) at the end of intervention. More detailed results regarding outcomes are reported elsewhere [23].
Feasibility	At the end of the intervention, the participants received a questionnaire to assess their experience with the study. The questionnaire had 5 main areas with the number of items varying from 8 to 20: (1) participation in the project (12 items), (2) use of mobile phone (20 items), (3) daily diaries (12 items), (4) the received feedback (12 items), and (5) self-management (8). The scoring range in the answers was on 5-point Likert scales from 0 "totally disagree" to 5 "totally agree." The mean for participation in the project was 4.2 (SD 0.5), for the use of a mobile phone it was 3.3 (SD 0.2), for diaries it was 4.4 (SD 0.4), for feedback it was 4.0 (SD 0.5), and for self-management it was 3.4 (SD 0.6). The participants also answered 7 questions about the project structure. There were 2 semi-structured interviews with each participant performed.
Conclusion	The described intervention is feasible and was evaluated as supportive and meaningful. The developed mobile phone application seems a promising tool for supporting patients with type 2 diabetes to make important lifestyle changes.

Delivery of Treatment

To ensure that the treatment was delivered as intended, a framework with principles for the development of feedback based on ACT was created (see [Multimedia Appendix 1](#)). It is important to emphasize that the feedback text messages were tailored and formulated based on several sources of input. The most important input being the first meeting with the participant, the daily e-diaries, and ACT. Therefore, the DMT2 intervention framework ([Multimedia Appendix 1](#)) must be seen as a guide rather than a fixed plan, where the therapist had the freedom to tailor the strategies to meet individual needs best. It is also important to emphasize that the written feedback text messages were expected to contain components other than ACT that are commonly used in treatment such as communication and motivation strategies. Ultimately, the feedback text messages were intended to support and stimulate the participants' self-management skills. The strategies applied by the therapist included positive reinforcement, information, metaphors, ACT exercises and questions aimed at encouraging mindfulness, willingness, and engagement in meaningful activities (see [Multimedia Appendix 2](#), for examples of feedback text messages).

Treatment Receipt

In the first individual meeting with the potential participants of the DMT2 project, the intervention was presented and explained. For those who agreed to participate, a mobile phone and an instruction manual containing all the necessary information were provided. The researcher (AAGN) instructed each participant on how to use the mobile phone, how to complete the e-diaries and how to access and read the feedback messages. The participants also received education about the importance of identifying life values and corresponding goals according to the ACT framework. To reinforce this information, they also received a workbook with voluntary written exercises aimed to help them in this process. Contact details were included in the manual. The first week of the intervention was a run-in-period, intended to familiarize the participants with the mobile phone, the e-diaries, and the feedback. All these described practices were performed to increase the participants' level of confidence to understand and undertake treatment-related behavioral and cognitive strategies. The fidelity of participant receipt of treatment is essential for Web-based studies due to the missing or minimal in-person contact, where many interactions rely on written communication where providers miss nonverbal cues of comprehension [8]. In the DMT2 project, participants interacted face-to-face with the researcher once in the first meeting, and twice during the data collection period including the interviews. The participants had only 1 telephone meeting with the therapist, before the start of the intervention. The purpose of this call was to establish a therapeutic alliance and to clarify the participants' need for support. The first meeting with the researcher, mentioned before, was also aimed to receive input from the participants related to their health-related needs. By completing the e-diaries, the participants recorded daily their glucose level, physical activities, diet, and emotions. The e-diaries contained a comment field, giving the participants the opportunity to write a message directly to the therapist. This message could be a question, extra information or a compliment.

Treatment Enactment

Fidelity of treatment enactment is vital to ensure that participants are regularly engaging with cognitive and behavioral skills emphasized during the treatment. Cognitive skills such as value identification, goal setting, and behavioral skills as action planning were reinforced to help participants meet their goal related to blood sugar level, exercise, and diet. The main way to stimulate the participants' adherence to these cognitive skills was through the daily e-diaries and personalized written feedback. In the evening e-diaries, the participants evaluated if the feedback was helpful regarding recommended physical activities, diet, blood sugar level and being aware of what was important for oneself. They could also indicate if the feedback was helpful or not. If the response was that the feedback was unhelpful, the therapist stimulated the participants to use the comment field to report their needs. Based on this daily report the therapist managed to help the participants with their difficulties, thereby increasing participants' satisfaction with feedback and treatment enactment.

Fidelity Assessment

An investigation of the therapist's adherence to the treatment protocol and participants' and therapist's experience with the intervention was done to assess the TF. Further, a checklist, containing the list of criteria (25 items) developed by Borrelli and colleagues [28], was applied. The 25 items are divided into the 5 TF categories (Design, Training, Delivery, Receipt, and Enactment) given the possibility to evaluate all the 5 areas of fidelity recommended by the NIH BCC. The authors of this checklist defined "high treatment fidelity" as those studies that have $\kappa \geq .80$ or greater proportion adherence to their checklist across all strategies.

Assessment of Providers' Adherence to the Treatment Protocol

The first part of the investigation of TF was performed by assessing the therapist's adherence to the therapy model by comparing the intended content of the feedback (see [Multimedia Appendix 1](#)) with the actual feedback given. The intention was to evaluate TF regarding the study protocol, provider training and delivery of treatment. To investigate the therapist's adherence, all data material consisting of 251 de-identified written feedback messages from the DMT2 pilot study [23] that was sent to the 11 participants who completed the intervention, was analyzed. Each participant received on average 23 feedback text messages (range 13-28). For this investigation, a coding scheme for written feedback texts developed previously [25], was refined and applied. The refinement process was divided into 3 steps: (1) a qualitative thematic analysis of the written feedback messages and identification of different codes (categories), (2) calculation of interrater reliability as one aspect of the psychometric quality of the coding scheme, and (3) coding of all feedback messages to identify how ACT principles were applied in the daily feedback text messages.

Qualitative Content Analysis

The feedback messages were analyzed qualitatively using a combined deductive and inductive approach [29]. The objective of the analysis was to investigate how ACT and other possible

processes were applied in the written situational feedback that was given to patients with DMT2 (see [Multimedia Appendix 2](#) for examples of feedback text messages). As a first step, the data were analyzed using a deductive approach [30,31], initiated by a priori themes representing the six ACT processes ([Table 1](#)) [32].

As a second step, the data was re-analyzed inductively using an editing organizing style to identify other therapeutic processes (ie, those not explicitly related to ACT). This iterative process involved a systematic reading of all data material where relevant observations were continuously coded and refined for further interpretation [30].

Interrater Reliability Assessment

Interrater reliability is a statistical measure used to examine the agreement between 2 or more people on the assignment of categories of a categorical variable [33]. It is an important measure in determining how well an application of a coding or measurement system works. The kappa statistic was chosen in this study as it is frequently used to test interrater reliability [34]. The results can, according to Cicchetti [33], range from poor to excellent (poor: $\kappa < .40$, fair: $\kappa = .40$ to $.59$, good: $\kappa = .60$ to $.74$, excellent: $\kappa = .75$ to 1.00).

To ensure the reliability of the current study, interrater reliability was assessed in 2 phases. In the first phase, 4 researchers participated in the process. They received a decoded selection of data from 5 participants of the DMT2 study where all ACT categories supposedly were represented, and the results were compared. These results are reported in an earlier publication [25], and the adaptation in the current paper was performed by AAGN, EAB and HE. The primary purpose was to check if the understanding of ACT-processes had high enough inter-coder reliability and to verify the need for refining codebook. After the inter-coder reliability control, a review process of the ACT codes was conducted. The results were compared and accordingly, the coding scheme and the codebook were adjusted, refined, and completed. The data from the 6 participants, 336/579 (58%) text segments derived from 145/251 (58%) feedback text messages, were used to calculate the final interrater reliability in the present study. The 2 researchers (AAGN & EAB) independently coded these data.

Analysis of all Feedback Messages

When the interrater reliability assessment produced excellent results ($\kappa > .75$), the remaining data material (106/251, 42% feedback messages) was coded by AAGN using the refined codebook.

Assessment of Therapists' and Participants' Experience With the Intervention

The second part of the fidelity investigation involved the assessment of the participant and therapist overall experience with the intervention. The purpose was to evaluate treatment receipt and treatment enactment. The participants completed a questionnaire at the end of the intervention period and took part in 2 individual interviews (see [Multimedia Appendix 3](#), for the

interview guide). The first interview was performed halfway through and the second at the end of intervention period. The therapist's experiences were assessed and documented during several informal meetings. These informal meetings were remote (over the telephone) between the therapist and the researcher (who took notes). During the first 4 weeks, the daily telephone meetings were held (except during weekends). After the first month, weekly telephone meetings were arranged until the end of the intervention. Based on the therapist's and participants' experiences with the intervention being relevant to feasibility evaluation, the results regarding this investigation were presented in a previous study [23]. See [Multimedia Appendix 4](#), for a summary of description and results of these analyses.

Results

The first part of the results will be presented in accordance with the completed checklist of the 5 areas of TF recommended by the NIH BCC (Study design, Provider training, Treatment delivery, Receipt, and Enactment). Also, the results of the analyses that made it possible to complete the fidelity checklist as therapist's adherence to the treatment protocol (qualitative analysis, interrater reliability, and coding of all feedback messages) will be presented. The results of participants' experience with the therapist and therapy and therapist's experience with the intervention are summarized in the [Multimedia Appendix 4](#).

Fidelity Checklist

To complete the fidelity checklist, in addition to the results presented in this section, the overview of the DMT2 pilot study ([Table 2](#)) and its results ([Multimedia Appendix 4](#)), were evaluated. The purpose was to answer questions about treatment design, treatment receipt, and treatment enactment. [Table 3](#) shows that 4/25 (16%) items of the fidelity checklist were not applicable to this study due to the design DMT2 being a single arm pilot study. A total of 20/21 (95%) remaining items of the fidelity checklist were identified in the present study. These results, according to Borrelli and colleagues [28], indicate that the DMT2 study had a high level of TF.

Qualitative Content Analysis of Therapist Feedback Text Messages

The qualitative analysis resulted in a refinement of a complete coding scheme that was previously developed in a comparable study [25]. The refined coding scheme included 12 codes, reflecting six ACT-processes (values, committed action, contact with the present moment, self as context, acceptance, and cognitive defusion) and 6 motivation and communication strategies (advice, empathic statements, stimulate participation, general information and educational information), see [Figure 1](#). The ACT process, self as context, was not present in the data material of the previous pain study [25]. This previous study also identified a motivation and communication code, called creative communication, which was not present in the data of the current study.

Table 3. Assessment of treatment fidelity strategies developed by Borrelli and colleagues [28].

Treatment fidelity strategies	Present	Absent	Not Applicable
Treatment design			
Provided information about treatment dose in the intervention condition			
Length of contact session(s)	X	—	—
Number of contacts	X	—	—
Content of treatment	X	—	—
Duration of contact over time	X	—	—
Provided information about treatment dose in the comparison condition			
Length of contact session(s)	—	—	X
Number of contacts	—	—	X
Content of treatment	—	—	X
Duration of contact over time	—	—	X
Mention of provider credentials	X	—	—
Mention of a theoretical model or clinical guidelines on which the intervention is based	X	—	—
Training providers			
Description of how providers were trained	X	—	—
Standardized provider training	X	—	—
Measured provider skill acquisition post training	—	X	—
Described how provider skills maintained over time	X	—	—
Delivery of treatment			
Included method to ensure that the content of the intervention was being delivered as specified	X	—	—
Included method to ensure that the dose of the intervention was being delivered as specified	X	—	—
Included mechanism to assess if the provider adhered to the intervention plan	X	—	—
Assessed nonspecific treatment effects	X	—	—
Used treatment manual	X	—	—
Receipt of treatment			
Assessed subject comprehension of the intervention during the intervention period	X	—	—
Included a strategy to improve subject comprehension of the intervention above and beyond what is included in the intervention	X	—	—
Assessed subject's ability to perform the intervention skills during the intervention period	X	—	—
Included a strategy to improve subject performance of intervention skills during the intervention period	X	—	—
Enactment of treatment skills			
Assessed subject performance of the intervention skills assessed in settings in which the intervention might be applied	X	—	—
Assessed strategy to improve subject performance of the intervention skills in settings in which the intervention might be applied	X	—	—

Figure 1. Refined coding scheme.

Table 4. Codebook with refined codes definitions.

Processes and strategies	Code	Definition
Acceptance and Commitment Therapy		
Values	V	<ul style="list-style-type: none"> Stimulate patient's reflection on their own values and the values' impact on their life. Helping the patient to identify the difference between goals and values. Stimulate awareness of gratitude and enthusiasm regarding feelings for increasing awareness of values.
Committed action	CA	<ul style="list-style-type: none"> Encourage the patient to committed behavior related to their own values through reflecting on strategies related to well-planned actions, barriers and follow-up. Stimulate planning of activities in the form of value-oriented goals.
Contact with present moment	PM	<ul style="list-style-type: none"> Stimulate breathing exercises for relaxation and variety in activities. Stimulate attention and awareness of internal and external experiences in the present moment.
Cognitive defusion	CD	<ul style="list-style-type: none"> Stimulate awareness of thought processes instead thought content. Stimulate understanding in thought content as a result of the context in which thoughts are a product of the specific situation(s).
Acceptance	AC	<ul style="list-style-type: none"> Encourage the patient to make active choices to act in accordance with their values, despite the difficult thoughts, emotions and physical sensations that are unpleasant, but which we cannot directly eliminate or reduce.
Self as context	SC	<ul style="list-style-type: none"> Stimulate the patient be aware of psychological content without linking it to their personal identity, creating a sense of distance between one's self and one's thoughts.
Motivation and communication		
Behavioral support	BS	<ul style="list-style-type: none"> Support the patient in the change process by recognizing the patient's willingness and efforts to change behavior. Motivate the patient in the change process through the use of praise and positive words. Provide confirmation of the patient's coping strategies. Encourage the patient to be their own supporter by practicing self-talk. Use specific records from patient diary forms in order to deliver a Message. Summarize developments during the follow-up period to emphasize key elements.
Advise	AD	<ul style="list-style-type: none"> Give specific and constructive advice for appropriate behavior or to specific situation.
Empathic statements	ES	<ul style="list-style-type: none"> Recognize the patient's experiences and feelings, showing empathy, understanding and respect.
Stimulate participation	SP	<ul style="list-style-type: none"> Encourage patient to provide written information to ensure the most individualized follow-up.
General information	GI	<ul style="list-style-type: none"> Provide information of a general, not therapeutic purpose
Educational information	EI	<ul style="list-style-type: none"> Explain scientific purpose and significance related to advice, training and or intervention

The refined coding scheme was used to refine the codebook with definitions (see [Table 4](#)). The 251/251 (100%) feedback text messages, which were divided into 722/722 (100%) text segments, were coded based on the refined coding scheme and codebook. [Table 5](#) illustrates examples of text segments and codes.

Interrater Reliability

The interrater reliability was calculated based on 336 text segments, delivered to 6/11 (55%) included participants. The number of observed agreements was 291/336 (86.61%) of the observations). The number of agreements expected by chance

was 45.9/336 (13.65%) of the observations), resulting in kappa=.85 (95% CI 0.80-0.89) and SE 0.02. [Table 6](#) displays the distribution of the codes within the dataset.

Analysis of All Feedback Messages

Out of the total text segments coded, 240/722 (33.2%) were ACT-consistent and 482/722 (66.8%) were coded as motivation or communication codes. All 11 participants received text segments that represented the V and CA codes. Of this 7/11 (64%) received text segments representing the CD code, 6/11 (55%) the AC code, 5/11 (45%) the PM code and 3/11 (27%) the SC code ([Table 7](#)).

Table 5. Example of feedback text messages divided in text segments. AD: advise; BS: behavioral support; CA: committed action; EI: education information; ES: empathetic statements; GI: general information.

Feedback Text Messages Number	Code	Text segments
3	CA	Hi. Yesterday I wrote a little about life values. If one of your life values is to achieve better health, you may set up some goals to live by according to this life value. An example of this might be that you may eat and drink according to your physician's recommendation. The goals should not be extensive, but narrow and feasible. The mobile phone you borrowed from the project has several utilities. Have you tried to use the software for diabetes that is uploaded there? You can, for example, set up goals regarding food and drink for the day and for the week. At the end of the day, record what you have eaten and been drinking, and the system provides feedback (smile faces), depending on how you performed in relation to your own personal goals.
3	EI	The software uses the terms high and low carbs. It may be a little unclear what these terms mean, so I'm going to give you a little explanation now. High carbs are carbohydrates that are rapidly absorbed by the body and rapidly increases blood sugar. Examples are drink and food that contain a lot of carbohydrates are sugary drinks like soft drinks and pasta respectively. Low carbs are carbohydrates that are slowly absorbed by body and give a slower blood sugar rise like bread with a lot of whole grains and fiber and vegetables.
3	GI	In the manual you received from Ann in the beginning of the project you can also find this explanation with other examples.
3	ES	Feel free to write in the text field if you have any questions! Have a nice day. Regards Helen.
4	BS	Hi. It looks to me like you have a plan for the day concerning taking of your medications, blood sugar control and eat and drink as recommended. I see that you manage to achieve these goals. That's great!
4	CA	You wrote in the middle of the day yesterday that you were at work, and that you had the opportunity to do physical exercises. Do you want to increase your activity level? Yesterday I wrote about setting up goals according to your life values. The goals shall not be to extensive, but narrow and achievable. Even when you set goals that you believe are achievable, there may be barriers that impede you from reaching them. It may be helpful to think about any barriers in relation to the goals you set up to yourself. Barriers may include time, effort or different thoughts and feelings. Time Barriers are anything that prevent many people from moving toward their goals. Can you think of any barriers that impede you from reaching your goals? Challenging work and a hectic schedule are barriers that prevent people being as physically active as they want. If you experience the same, you may reflect on what strategies you can use to reach your goals, despite the fact that time is limited.
4	GI	A long weekend is coming up and you will not get feedback until Monday. I will take a look at the diaries you will fill out during these days, to give you feedback on Tuesday.
4	AD	During this period, I would suggest that you reflect on what I have written to you in the feedback text messages so far. This because reflection can lead to awareness of things that are important to you. I wish you a nice Pentecost weekend! Regards Helen

Table 6. Distribution of the codes used in the interrater reliability analyses. Dashes indicate the absence of codes. AC: acceptance; AD: advise; BS: behavioral support; CA: committed action; CD: cognitive defusion; EI: education information; ES: empathetic statements; GI: general information; PM: contact with present moment; SC: self as context; SP: stimulate participation; V: values.

Code	V	CA	PM	CD	AC	SC	BS	AD	ES	SP	GI	EI	SUM
V	29	—	3	—	—	—	—	—	—	—	—	—	32
CA	3	46	—	—	—	—	—	—	—	—	—	—	49
PM	—	—	1	—	—	—	—	—	—	—	—	—	1
CD	—	—	—	9	6	—	—	—	—	—	—	2	17
AC	—	—	—	—	3	—	—	—	—	—	—	—	3
SC	—	—	—	—	—	6	—	—	—	—	—	—	6
BS	—	2	2	3	—	—	75	—	7	—	—	—	89
AD	—	1	3	—	—	—	—	29	1	—	—	—	34
ES	—	1	—	—	—	—	—	—	11	—	—	—	12
SP	—	—	—	—	—	—	—	1	—	7	—	—	8
GI	—	2	—	—	—	—	1	—	3	2	45	—	53
EI	—	—	—	1	—	—	—	—	1	—	—	30	32
SUM	32	52	9	13	9	6	76	30	23	9	45	32	336

Table 7. Overview of all data material coded. Dashes indicate the absence of codes. AC: acceptance; AD: advise; BS: behavioral support; CA: committed action; CD: cognitive defusion; EI: education information; ES: empathetic statements; GI: general information; P: participant; PM: contact with present moment; SC: self as context; SP: stimulate participation; TF: total feedback messages; TTS: total of text segments; V: values.

P	TF	V	CA	PM	CD	SC	AC	BS	AD	ES	SP	CC	GI	EI	TTS
1	21	6	14	—	2	—	—	14	7	4	2	—	11	2	62
2	25	12	22	3	—	—	—	29	8	27	7	—	15	5	128
3	15	3	7	—	2	—	2	7	5	2	6	—	9	6	49
4	18	7	13	—	—	—	—	14	2	2	9	—	12	3	62
5	27	4	12	—	3	—	2	17	6	5	6	—	6	6	69
6	26	6	14	—	3	—	4	18	10	—	1	—	6	2	64
7	13	2	4	—	—	—	—	12	2	7	—	—	5	7	39
8	27	5	12	2	—	1	2	14	3	2	3	—	5	10	59
9	24	6	4	2	3	—	3	9	12	9	3	—	8	7	66
10	28	7	10	2	3	1	—	15	3	4	1	—	6	8	60
11	27	6	10	2	3	4	3	15	4	4	1	—	6	6	64
SUM	251	64	124	11	19	6	16	164	62	66	39	—	89	62	722

Discussion

Principal Findings

To increase treatment integrity and consequently the validity of behavioral interventions and implementation, assessment of TF is necessary. The methods of implementing and evaluating TF need to be adjusted for Web-based technology interventions due to the variability within and across these interventions [6]. In this DMT2 pilot study, the 5 areas of TF recommended by NIH BCC were applied. Another TF framework that could have been applied in this study is described by Dabbs and colleagues [8]. Their TF framework was developed for Web-based technology-interventions and also recommends the evaluation of participant' acceptance of the intervention using the Technology Acceptance Model scales [35]. The Acceptance Model scales were not applied in the DMT2 pilot study. Still, owing to the importance to investigate the technology acceptance for the fidelity evaluation in mHealth interventions [8], several questions about this theme were included in the self-reported questionnaire developed to evaluate the DMT2 pilot study [23]. The positive results regarding participants' acceptance of the used technology reported in the DMT2 pilot study may have contributed to the positive results of the current study regarding treatment receipt and enactment.

The evaluation of the TF, in the current study, was based on the analysis of the delivered feedback messages and by assessing participants' and therapist's experience with the intervention. The analysis of the 251/251 (100%) written feedback messages was possible by dividing them into 722/722 (100%) text segments and subsequent coding of each segment. A comparison of the refined coding scheme and codebook with the ones developed in a previous study [25], revealed 2 differences. The first was the presence of the self as context and the second was the absence of creative communication. This result confirms that ACT processes can successfully be delivered in a written format, including self as context. Although the ACT process self as context was not present within the provided feedback in

the CWP-study, it was included as a component in the e-diaries. The use of communication strategies is a necessity in all behavior change interventions. Motivation elements contribute, along with support, to stimulate the participants to complete the intervention. In the present study, 6/7 (85.7%) codes (compared with the previous study) [25] related to motivation/communication strategies were found after the qualitative content analysis. The use of creative communication (absent in the present study) can be perceived as a therapist style of communication and may not influence the results of the fidelity analysis.

Analysis of texts has become a valuable research tool in numerous areas and coding is a crucial part of these analyses. For establishing TF, a prerequisite for such analysis is to ensure firm consistency between the text and the coding. Quality control of this consistency is essential to relate the results to the treatment [36]. In the present study, we achieved an excellent level of interrater reliability. This result confirmed that the coding scheme and the codebook were reliable tools for analyzing all feedback messages making further analyses possible. In short, the results of the feedback analyses showed that all participants received the text segments coded as "values" (V) and "committed action" (CA). These two ACT-processes are essential to build up participants' understanding of the therapeutic process. Not all participants received text segments representing all ACT codes. It is important to emphasize that although the development of feedback messages was based on ACT, this does not imply that all ACT processes are required for the treatment of each participant.

The excellent representation of the different ACT codes in the feedback messages (Table 7) confirms that these were developed according to the ACT framework and principles (Multimedia Appendix 1). This means that the intervention was delivered according to the chosen theory and as intended, indicating that the TF regarding study design, provider training, and treatment delivery was effective.

The use of ACT-elements may have contributed to the positive results achieved in the DMT2 pilot study [23]. As the impact of Web-based interventions increases, theory is used more extensively [16]. According to Riley (2011), theories may need to be revised to fit the new format of Web-based and mobile interventions [37]. Our experience is that applying ACT in a written format is well suited for Web-based interventions and enables and facilitates the analysis regarding TF. A total of 806/2231 (36%) of the coded text-segments in the previous study [25] were ACT codes against 240/722 (33%) in the present study. These results can indicate that communication and motivation strategies are essential elements of the feedback messages to deliver ACTs therapeutic processes in a written format. This hypothesis needs further investigation.

Despite the positive effects achieved in ACT-based interventions, it is common for the achieved effects to diminish over time, with the return of old cognitions and activity patterns [38,39]. Other studies also show that the long-term effect of cognitive behavioral therapies is generally limited [40,41]. This may indicate a need for more continuity and a longer duration of the intervention to support self-management in people with chronic illness. The results regarding participants' (self-reported questionnaire and interviews) and therapist's experience with the project indicate that the therapist was capable and qualified and that the participants acquired knowledge regarding their diabetes, treatment skills and how to apply this knowledge in their daily life (treatment receipt and enactment). Despite the positive results, the use of a self-reported questionnaire to assess the therapist's experience with the project would have been more reliable. The fidelity evaluation was done by applying the checklist developed by Borelli and colleagues and showed a high level of TF. This fidelity assessing tool was based on the 5 areas of TF recommended by NIH BCC being suitable for this study purpose supporting the findings of a previous study [4].

TF in online delivered intervention is an emerging area of research [42]. Therefore, methods of evaluating TF adapted to the different kinds of online interventions is needed. In the present study, the reliable and precise evaluation of therapist's adherence was possible due to a coding scheme and a codebook developed in a previous study [25]. A similar method was applied in a recent study aimed to develop and evaluate a scale for assessing therapist fidelity in Web-delivered cognitive behavior therapy [42]. The concept of using a coding system to evaluate a behavior intervention delivered in a written format provides input for future studies.

Strengths and Limitation

The coding scheme applied in the present study showed to be reliable and valid to investigate several areas of TF. In this study, a coding scheme and a codebook for ACT-oriented Web-based personal feedback developed in a previous study were refined maintaining the high level of interrater reliability. Results based on the refined coding scheme showed that the feedback provided complied with core ACT principles. The reliability of the investigation of the therapists' competence could be improved by the development of self-reported questionnaires to be filled in by the therapists.

The fact that the DMT2 intervention required e-diaries 3 times daily could be perceived as potential burden for the participants. The high percentage of dropouts 4/15 (26.7%) indicates that participants believe this as well. The DMT2 pilot study percentage of dropouts is equivalent to results that are reported in a comparable study [22]. However, it is important to emphasize that the participants who left the DMT2 pilot study never started the intervention. Despite being favorable to the intervention at the first meeting, they believed that to participate in the project would be too time-consuming, especially when completing three e-diaries a day. In contrast, all participants who started completed the intervention. Their experience with completing the diaries was assessed and reported elsewhere [23]. Only 2/11 (18.2%) participants would prefer fewer e-diaries and questions. A comparable study reported a higher level of participants burden, 3/6 (50%) participants considered the number of questions in each diary to be too high [43]. The number of questions in the DMT2 was fewer compared to this similar study, and this can explain the better results. However, it is essential to bear in mind the need to reduce the burden on the respondents as much as possible, as it has an adverse effect on the respondents' motivation and thereby impacts negatively on their response quality and TF [44]. It is essential to identify the ideal number of diaries and questions delivered per day to decrease the participant burden and subsequently reduce the risk of dropouts. Furthermore, it is important to gain an in-depth understanding of participants' reasons for early withdrawal. We encourage other researchers to consider this when planning large-scale studies requiring a large sample size and TF evaluations.

Regarding providers burden, the DMT2 pilot study revealed that it was time-consuming for the therapist to give feedback. The system did not show historical information as a summary, and it was necessary to navigate through several pages to get needed information. Also, the therapist had to look at the feedback history to avoid repeating information. After the first month, when a feedback bank was created, the time used to formulate the feedback text messages was reduced to 15–20 min, a level that providers reported as suitable [23].

Current Web-based interventions, which utilize written personalized therapeutic feedback tend to be time-consuming for the health personnel involved [22,23]. The possibilities within information technology regarding automation of parts of the feedback messages should, therefore, be explored [25]. As discussed later in the practical implication section, the automation of the feedback messages using algorithms would be possible to secure the TF in these kinds of interventions regarding study design, monitoring and treatment delivery. The potential to use artificial intelligence to analyze the relation between diaries, feedback and results continuously, is a fascinating area for future research.

The results of the present study showed that provider training was done according to the NIH BCC recommendations. The small number of participants (n=11) and the therapist (n=1), enabled the training and monitoring of the therapist as described in the method section. For a large-scale intervention, a systematic TF project should include standardized therapist training program with a focus on the appropriate diagnosis and

the appropriate treatment approach. The standardization allows for the specific skills required for intervention delivery to be improved and accentuated within providers regardless of inherent differences [6]. The therapists should also attain a certification after a comprehensive training process. All the therapists should have a bachelor degree in health care like medicine, psychology, physiotherapy or nursing because of the physical and mental symptoms of the participants' disease and the nature of the intervention (formulation of feedback messages based on information from the e-diaries and ACT) [24]. The monitoring process could be done by midterm randomized audits.

As shown in [Table 2](#), the results of the DMT2 pilot study were positive. As expected, due to the small sample size the results were not statistically significant. Because the results of the present study indicate a high level of TF it is possible to assume the DMT2 pilot intervention results were reliable. This again provides a firm basis to recommend a RCT. This can provide a more qualified answer regarding whether the offered intervention will help more people with DMT2 to achieve self-management and increase their quality of life.

As mentioned in the current paper, by evaluating fidelity, it is possible to investigate if theory-based processes of the intervention are the primary mechanism of change outcomes and if they allow for precise replication and comparison amongst interventions.

The main contribution of this paper to the use of Web-based mobile technology in health literature regarding TF is the method of analyzing therapist's adherence to the treatment protocol. The method presented in the current study allows more precise results when compared to the methods that are commonly used in TF studies based on observation and interpretation from another professional. Results that are based on the evaluation of people may carry several biases (ie, personal experience, humor, knowledge) that may influence the results.

With the method used in the present study, it was possible to demonstrate that the intervention based on ACT was performed as proposed, confirming that the chosen theory was the primary mechanism of change outcomes. However, the use of the method of evaluation of therapists' adherence proposed in the current

study is limited to a treatment delivered in a written format. To the best of our knowledge, this is the second study that analyses therapists' adherence to the study protocol using this method.

Practice Implications

A reliable and valid coding system as defined in this study is essential for exploring therapeutic change processes in this type of mobile phone-delivered interventions. The coding scheme has the potential to lay a foundation for the automation of feedback messages, together with a bank or database of these messages. Automatic feedback could be generated from a database and combined with individualized feedback if the diaries indicate this to be required. The intervention could then be developed as an application for mobile phones, reducing therapist time and costs. Making such an application available as support for clinical practices and in maintenance treatments would help treat people who do not have easy access to health care services. The use of new and innovative technology to make this kind of behavior change interventions more effective, while still taking care of the patients' individual needs, suggests an exciting future area of research. The first step would be to develop and test the concept of automation in an RCT. In a further development of the intervention, it would be interesting to explore the effects of using more technologically advanced capabilities to gather rich and complex data. This could include sensors to measure activity levels and context-triggered diary questions [37,45]. Also, the automated feedback on registered data could be provided in progress charts, graphs, and summaries. Educational information could be given by interactive animations or videos [46].

Conclusion

Web-based interventions are becoming increasingly popular and appear to be an essential and cost-effective supplement to everyday health care in the near future. The evaluation of TF is essential to interpret the results of interventions and its underlying working mechanisms. A different methodology is used to deliver interventions via the internet. To achieve TF, the evaluation methods must be adjusted to each kind of online treatment. By doing this, the TF in Web-based interventions can be maintained and monitored reliably.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Framework and principles for development of feedback based on ACT.

[[PDF File \(Adobe PDF File\), 23KB - mhealth_v6i7e151_app1.pdf](#)]

Multimedia Appendix 2

Example of a sequence of feedback from the first week of the project

[[PDF File \(Adobe PDF File\), 33KB - mhealth_v6i7e151_app2.pdf](#)]

Multimedia Appendix 3

Interview guide for evaluation of the DMT2 pilot study.

[[PDF File \(Adobe PDF File\), 22KB - mhealth_v6i7e151_app3.pdf](#)]

Multimedia Appendix 4

Assessment of provider's and participants' evaluation of intervention.

[[PDF File \(Adobe PDF File\), 27KB - mhealth_v6i7e151_app4.pdf](#)]

References

1. Gainsbury S, Blaszczynski A. A systematic review of Internet-based therapy for the treatment of addictions. *Clin Psychol Rev* 2011 Apr;31(3):490-498. [doi: [10.1016/j.cpr.2010.11.007](#)] [Medline: [21146272](#)]
2. Jacobs RJ, Lou JQ, Ownby RL, Caballero J. A systematic review of eHealth interventions to improve health literacy. *Health Informatics J* 2014 Jun 10. [doi: [10.1177/1460458214534092](#)] [Medline: [24916567](#)]
3. Slaughter SE, Hill JN, Snelgrove-Clarke E. What is the extent and quality of documentation and reporting of fidelity to implementation strategies: a scoping review. *Implement Sci* 2015 Sep 07;10:129 [FREE Full text] [doi: [10.1186/s13012-015-0320-3](#)] [Medline: [26345357](#)]
4. Eaton LH, Doorenbos AZ, Schmitz KL, Carpenter KM, McGregor BA. Establishing treatment fidelity in a web-based behavioral intervention study. *Nurs Res* 2011;60(6):430-435 [FREE Full text] [doi: [10.1097/NNR.0b013e31823386aa](#)] [Medline: [22048559](#)]
5. Bellg AJ, Borrelli B, Resnick B, Hecht J, Minicucci DS, Ory M, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol* 2004 Sep;23(5):443-451. [doi: [10.1037/0278-6133.23.5.443](#)] [Medline: [15367063](#)]
6. Sineath A, Lambert L, Verga C, Wagstaff M, Wingo BC. Monitoring intervention fidelity of a lifestyle behavioral intervention delivered through telehealth. *Mhealth* 2017;3:35 [FREE Full text] [doi: [10.21037/mhealth.2017.07.04](#)] [Medline: [28894745](#)]
7. Breitenstein SM, Gross D, Garvey CA, Hill C, Fogg L, Resnick B. Implementation fidelity in community-based interventions. *Res Nurs Health* 2010 Apr;33(2):164-173 [FREE Full text] [doi: [10.1002/nur.20373](#)] [Medline: [20198637](#)]
8. Devito DA, Song M, Hawkins R, Aubrecht J, Kovach K, Terhorst L, et al. An intervention fidelity framework for technology-based behavioral interventions. *Nurs Res* 2011;60(5):340-347 [FREE Full text] [doi: [10.1097/NNR.0b013e31822cc87d](#)] [Medline: [21878796](#)]
9. Mowbray CT, Holter MC, Teague GB, Bybee D. Fidelity Criteria: Development, Measurement, and Validation. *American Journal of Evaluation* 2016 Jun 30;24(3):315-340. [doi: [10.1177/109821400302400303](#)]
10. Hayes SC. Acceptance and Commitment Therapy, Relational Frame Theory, and the Third Wave of Behavioral and Cognitive Therapies - Republished Article. *Behav Ther* 2016 Nov;47(6):869-885. [doi: [10.1016/j.beth.2016.11.006](#)] [Medline: [27993338](#)]
11. Hayes SC, Luoma JB, Bond FW, Masuda A, Lillis J. Acceptance and commitment therapy: model, processes and outcomes. *Behav Res Ther* 2006 Jan;44(1):1-25. [doi: [10.1016/j.brat.2005.06.006](#)] [Medline: [16300724](#)]
12. Hayes SC, Levin ME, Plumb-Villardaga J, Villatte JL, Pistorello J. Acceptance and commitment therapy and contextual behavioral science: examining the progress of a distinctive model of behavioral and cognitive therapy. *Behav Ther* 2013 Jun;44(2):180-198 [FREE Full text] [doi: [10.1016/j.beth.2009.08.002](#)] [Medline: [23611068](#)]
13. Dahl JC, Lundgren T. *Living beyond Your Pain: Using Acceptance Commitment Therapy to Ease Chronic Pain*. Oakland, CA: New Harbinger Pubns Inc; 2006.
14. Gregg JA, Callaghan GM, Hayes SC, Glenn-Lawson JL. Improving diabetes self-management through acceptance, mindfulness, and values: a randomized controlled trial. *J Consult Clin Psychol* 2007 Apr;75(2):336-343. [doi: [10.1037/0022-006X.75.2.336](#)] [Medline: [17469891](#)]
15. Hayes S, Strosahl K, Wilson K. *Acceptance and commitment therapy: An experiential approach to behavior change*. New York, NY: The Guilford Press; 2003.
16. Webb TL, Joseph J, Yardley L, Michie S. Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. *J Med Internet Res* 2010;12(1):e4 [FREE Full text] [doi: [10.2196/jmir.1376](#)] [Medline: [20164043](#)]
17. Vowles KE, McCracken LM, Eccleston C. Processes of change in treatment for chronic pain: the contributions of pain, acceptance, and catastrophizing. *Eur J Pain* 2007 Oct;11(7):779-787. [doi: [10.1016/j.ejpain.2006.12.007](#)] [Medline: [17303452](#)]

18. Powers MB, Zum VSMB, Emmelkamp PMG. Acceptance and commitment therapy: a meta-analytic review. *Psychother Psychosom* 2009;78(2):73-80. [doi: [10.1159/000190790](https://doi.org/10.1159/000190790)] [Medline: [19142046](https://pubmed.ncbi.nlm.nih.gov/19142046/)]
19. Wicksell RK, Melin L, Lekander M, Olsson GL. Evaluating the effectiveness of exposure and acceptance strategies to improve functioning and quality of life in longstanding pediatric pain--a randomized controlled trial. *Pain* 2009 Feb;141(3):248-257. [doi: [10.1016/j.pain.2008.11.006](https://doi.org/10.1016/j.pain.2008.11.006)] [Medline: [19108951](https://pubmed.ncbi.nlm.nih.gov/19108951/)]
20. Wicksell RK, Kemani M, Jensen K, Kosek E, Kadetoff D, Sorjonen K, et al. Acceptance and commitment therapy for fibromyalgia: a randomized controlled trial. *Eur J Pain* 2013 Apr;17(4):599-611. [doi: [10.1002/j.1532-2149.2012.00224.x](https://doi.org/10.1002/j.1532-2149.2012.00224.x)] [Medline: [23090719](https://pubmed.ncbi.nlm.nih.gov/23090719/)]
21. Oerlemans S, van CO, Herremans P, Spreeuwenberg P, van DS. Intervening on cognitions and behavior in irritable bowel syndrome: A feasibility trial using PDAs. *J Psychosom Res* 2011 Mar;70(3):267-277. [doi: [10.1016/j.jpsychores.2010.09.018](https://doi.org/10.1016/j.jpsychores.2010.09.018)] [Medline: [21334498](https://pubmed.ncbi.nlm.nih.gov/21334498/)]
22. Kristjánsdóttir Ó, Fors EA, Eide E, Finset A, Stensrud TL, van DS, et al. A smartphone-based intervention with diaries and therapist-feedback to reduce catastrophizing and increase functioning in women with chronic widespread pain: randomized controlled trial. *J Med Internet Res* 2013;15(1):e5 [FREE Full text] [doi: [10.2196/jmir.2249](https://doi.org/10.2196/jmir.2249)] [Medline: [23291270](https://pubmed.ncbi.nlm.nih.gov/23291270/)]
23. Nes AAG, van DS, Eide E, Finset A, Kristjánsdóttir Ó, Steen IS, et al. The development and feasibility of a web-based intervention with diaries and situational feedback via smartphone to support self-management in patients with diabetes type 2. *Diabetes Res Clin Pract* 2012 Sep;97(3):385-393. [doi: [10.1016/j.diabres.2012.04.019](https://doi.org/10.1016/j.diabres.2012.04.019)] [Medline: [22578890](https://pubmed.ncbi.nlm.nih.gov/22578890/)]
24. Nes AAG, Eide H, Kristjánsdóttir Ó, van DS. Web-based, self-management enhancing interventions with e-diaries and personalized feedback for persons with chronic illness: a tale of three studies. *Patient Educ Couns* 2013 Dec;93(3):451-458 [FREE Full text] [doi: [10.1016/j.pec.2013.01.022](https://doi.org/10.1016/j.pec.2013.01.022)] [Medline: [23433735](https://pubmed.ncbi.nlm.nih.gov/23433735/)]
25. Nes A, Brembo E, van DS, Kristjánsdóttir Ó, Wicksell R, Eide H. Examining fidelity of web-based acceptance and commitment interventions for women with chronic widespread pain. *International Journal of Person Centered Medicine* 2015;4(2):115-125.
26. Bradley C, Todd C, Gorton T, Symonds E, Martin A, Plowright R. The development of an individualized questionnaire measure of perceived impact of diabetes on quality of life: the ADDQoL. *Qual Life Res* 1999;8(1-2):79-91. [Medline: [10457741](https://pubmed.ncbi.nlm.nih.gov/10457741/)]
27. Snoek FJ, Pouwer F, Welch GW, Polonsky WH. Diabetes-related emotional distress in Dutch and U.S. diabetic patients: cross-cultural validity of the problem areas in diabetes scale. *Diabetes Care* 2000 Sep;23(9):1305-1309 [FREE Full text] [Medline: [10977023](https://pubmed.ncbi.nlm.nih.gov/10977023/)]
28. Borrelli B, Sepinwall D, Ernst D, Bellg AJ, Czajkowski S, Breger R, et al. A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. *J Consult Clin Psychol* 2005 Oct;73(5):852-860. [doi: [10.1037/0022-006X.73.5.852](https://doi.org/10.1037/0022-006X.73.5.852)] [Medline: [16287385](https://pubmed.ncbi.nlm.nih.gov/16287385/)]
29. Thagaard T. Systematikk og innlevelse n innføring i kvalitativ metode. Bergen, Norway: Fakkboglaget; 2003.
30. Moltu C, Stefansen J, Svisdahl M, Veseth M. Negotiating the coresearcher mandate - service users' experiences of doing collaborative research on mental health. *Disabil Rehabil* 2012;34(19):1608-1616. [doi: [10.3109/09638288.2012.656792](https://doi.org/10.3109/09638288.2012.656792)] [Medline: [22489612](https://pubmed.ncbi.nlm.nih.gov/22489612/)]
31. King N. Using templates in the thematic analysis of text. In: Cassell C, Symon G. editors. *Essential guide to qualitative methods in organizational research*. London, England: Sage; 2004.
32. Schimmel-Bristow A, Bricker JB, Comstock B. Can Acceptance & Commitment Therapy be delivered with fidelity as a brief telephone-intervention? *Addict Behav* 2012 Apr;37(4):517-520 [FREE Full text] [doi: [10.1016/j.addbeh.2011.11.015](https://doi.org/10.1016/j.addbeh.2011.11.015)] [Medline: [22192865](https://pubmed.ncbi.nlm.nih.gov/22192865/)]
33. Cicchetti DV. Guidelines, criteria, and rules of thumb for evaluating normed and standardized assessment instruments in psychology. *Psychological Assessment* 1994;6(4):284-290. [doi: [10.1037/1040-3590.6.4.284](https://doi.org/10.1037/1040-3590.6.4.284)]
34. McHugh ML. Interrater reliability: the kappa statistic. *Biochem Med (Zagreb)* 2012;22(3):276-282 [FREE Full text] [Medline: [23092060](https://pubmed.ncbi.nlm.nih.gov/23092060/)]
35. Davis FD, Bagozzi RP, Warshaw PR. User Acceptance of Computer Technology: A Comparison of Two Theoretical Models. *Management Science* 1989 Aug;35(8):982-1003. [doi: [10.1287/mnsc.35.8.982](https://doi.org/10.1287/mnsc.35.8.982)]
36. Hruschka DJ, Schwartz D, St. John DC, Picone-Decaro E, Jenkins RA, Carey JW. Reliability in Coding Open-Ended Data: Lessons Learned from HIV Behavioral Research. *Field Methods* 2016 Jul 24;16(3):307-331. [doi: [10.1177/1525822x04266540](https://doi.org/10.1177/1525822x04266540)]
37. Riley WT, Rivera DE, Atienza AA, Nilsen W, Allison SM, Mermelstein R. Health behavior models in the age of mobile interventions: are our theories up to the task? *Transl Behav Med* 2011 Mar;1(1):53-71 [FREE Full text] [doi: [10.1007/s13142-011-0021-7](https://doi.org/10.1007/s13142-011-0021-7)] [Medline: [21796270](https://pubmed.ncbi.nlm.nih.gov/21796270/)]
38. Linton SJ, Flink IK, Schrooten MGS, Wiksell R. Understanding Co-occurring Emotion and Pain: The Role of Context Sensitivity from a Transdiagnostic Perspective. *J Contemp Psychother* 2016 Mar 15;46(3):129-137. [doi: [10.1007/s10879-016-9323-x](https://doi.org/10.1007/s10879-016-9323-x)]
39. Franks P, Chapman B, Duberstein P, Jerant A. Five factor model personality factors moderated the effects of an intervention to enhance chronic disease management self-efficacy. *Br J Health Psychol* 2009 Sep;14(Pt 3):473-487 [FREE Full text] [doi: [10.1348/135910708X360700](https://doi.org/10.1348/135910708X360700)] [Medline: [18808733](https://pubmed.ncbi.nlm.nih.gov/18808733/)]

40. de JT, Gurol-Urganci I, Vodopivec-Jamsek V, Car J, Atun R. Mobile phone messaging for facilitating self-management of long-term illnesses. *Cochrane Database Syst Rev* 2012;12:CD007459. [doi: [10.1002/14651858.CD007459.pub2](https://doi.org/10.1002/14651858.CD007459.pub2)] [Medline: [23235644](https://pubmed.ncbi.nlm.nih.gov/23235644/)]
41. Fjeldsoe BS, Marshall AL, Miller YD. Behavior change interventions delivered by mobile telephone short-message service. *Am J Prev Med* 2009 Feb;36(2):165-173. [doi: [10.1016/j.amepre.2008.09.040](https://doi.org/10.1016/j.amepre.2008.09.040)] [Medline: [19135907](https://pubmed.ncbi.nlm.nih.gov/19135907/)]
42. Hadjistavropoulos HD, Schneider LH, Klassen K, Dear BF, Titov N. Development and evaluation of a scale assessing therapist fidelity to guidelines for delivering therapist-assisted Internet-delivered cognitive behaviour therapy. *Cogn Behav Ther* 2018 Apr 25;1-15. [doi: [10.1080/16506073.2018.1457079](https://doi.org/10.1080/16506073.2018.1457079)] [Medline: [29693533](https://pubmed.ncbi.nlm.nih.gov/29693533/)]
43. Kristjánsdóttir Ó, Fors EA, Eide E, Finset A, van DS, Wigers SH, et al. Written online situational feedback via mobile phone to support self-management of chronic widespread pain: a usability study of a Web-based intervention. *BMC Musculoskelet Disord* 2011 Feb 25;12:51 [FREE Full text] [doi: [10.1186/1471-2474-12-51](https://doi.org/10.1186/1471-2474-12-51)] [Medline: [21352516](https://pubmed.ncbi.nlm.nih.gov/21352516/)]
44. Morren M, van DS, Ouwerkerk J, Bensing J. Compliance with momentary pain measurement using electronic diaries: a systematic review. *Eur J Pain* 2009 Apr;13(4):354-365. [doi: [10.1016/j.ejpain.2008.05.010](https://doi.org/10.1016/j.ejpain.2008.05.010)] [Medline: [18603458](https://pubmed.ncbi.nlm.nih.gov/18603458/)]
45. Miller G. The Smartphone Psychology Manifesto. *Perspectives on Psychological Science* 2012 May 16;7(3):221-237. [doi: [10.1177/1745691612441215](https://doi.org/10.1177/1745691612441215)]
46. Ritterband LM, Thorndike F. Internet interventions or patient education web sites? *J Med Internet Res* 2006 Sep 29;8(3):e18; author reply e19 [FREE Full text] [doi: [10.2196/jmir.8.3.e18](https://doi.org/10.2196/jmir.8.3.e18)] [Medline: [17032634](https://pubmed.ncbi.nlm.nih.gov/17032634/)]

Abbreviations

AC: acceptance
AD: advise
ACT: Acceptance and Commitment Therapy
ADDQoL-19: Audit of Diabetes Dependence Quality of Life
BCC: Behavior Change Consortium
BS: behavioral support
CA: committed action
CD: cognitive defusion
CBT: Cognitive Behavior Therapy
CWP: chronic widespread pain
DMT2: diabetes mellitus type 2
e-diaries: electronic diaries
EI: education information
ES: empathetic statements
GI: general information
HBA_{1c}: glycosylated hemoglobin
IBS: irritable bowel syndrome
NIH: National Institutes of Health
PAID: Problem Areas in Diabetes
PM: contact with present moment
RCT: randomized controlled trial
SC: self as context
SMS: short message service
SP: stimulate participation
TF: treatment fidelity
V: values

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Review

Mobile Apps to Support the Self-Management of Hypertension: Systematic Review of Effectiveness, Usability, and User Satisfaction

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Abstract

Background: Hypertension is a chronic disease that is considered to be a public health problem and requires efforts by patients to manage themselves. The global growth in the use of mobile phones and tablets has been accompanied by the increased use of health apps. Many of these apps support the self-management of hypertension and, therefore, they have the potential benefits of lowering blood pressure. Despite this, there is currently a lack of evidence for their effectiveness, usability, and patient satisfaction with their use.

Objective: A systematic review was conducted to assess the effectiveness of apps in lowering blood pressure, as well as their usability and patients' satisfaction with their use.

Methods: We conducted searches in the following databases: MEDLINE (OVID), EMBASE (OVID), PsycINFO (OVID), CINAHL, the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library), IEEE Xplore ASSIAN, Google Scholar and the main Arabic databases Al Manhal, AskZad, and Mandumah. We looked for studies that used apps in the self-management of hypertension from 2008-2016. We also checked the reference lists of the review papers and all the primary studies for additional references.

Results: A total of 21 studies with a total of 3112 participants were included in the review. Of the 14 studies that assessed the effectiveness of the apps in lowering blood pressure, 10 (71.4%) studies (6 RCTs and 4 nonrandomized studies) reported that using the apps led to significant decreases in blood pressure and seemed to be effective in the self-management of hypertension. Of these 10, only 2 (20%) RCTs and 3 (30%) nonrandomized studies had a low-moderate risk of bias. The results of this review are inconclusive regarding which combinations of functionalities would be most effective in lowering blood pressure because of variation in the studies' quality, but the data suggest that apps incorporating more comprehensive functionalities are likely to be more effective. In all the studies that assessed the usability of the apps and users' acceptance of them, all the apps seemed to be accepted and easy to use.

Conclusions: Most of the studies reported that apps might be effective in lowering blood pressure and are accepted by users. However, these findings should be interpreted with caution, as most of the studies had a high risk of bias. More well-designed, large-scale studies are required to evaluate the real effect of using apps in lowering blood pressure and to identify the most effective functionality combinations for lowering blood pressure.

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KEYWORDS

mobile phone; mobile application; mobile app; self-management; hypertension; blood pressure

Introduction

Hypertension, in which the blood pressure (BP) in the arteries is raised, is one of the most common chronic diseases in adults. Patients can be diagnosed with hypertension when their systolic blood pressure (SBP) and diastolic blood pressure (DBP) are above 140/90 mm Hg, respectively [1]. Hypertension has been recognized as a major risk factor for many diseases, such as renal failure, heart disease, and stroke [1]. Despite the effect of lowering BP on reducing the risk of renal and cardiovascular disease, most people with hypertension poorly control their BP [2]. Therefore, it is important to encourage patients' involvement in controlling their BP.

Self-management is considered an important element of chronic care management [3]. Self-management demands an active role of patients in managing their symptoms, treatment, psychosocial and physical effects, and changing lifestyle [4-6]. Achieving an optimum level of self-management behavior is difficult and requires considerable effort from patients. Mobile health technology (mHealth), defined as the use of mobile devices to deliver health care [7], has the potential to facilitate and optimize patients' self-management [8-11]. This can be performed by integrating health care with everyday life by delivering and collecting health information and services in a convenient, accessible, and interactive mode [12,13]. The use of the new generation of these mobile devices, including mobile phone and tablets, has increased rapidly in recent years, and it is estimated that by 2018 mobile phones will be used by one-third of the global population [14]. Mobile phones have become an important platform to deliver health to patients through health apps. The rapid growth in the use of these devices has been accompanied by a huge expansion in health and health-related behavior apps, and more than 100,000 of these are used by millions of people [14,15]. Many health apps are targeted to support people with hypertension in their self-management by offering self-monitoring activities, reminders, tailored information, and feedback [16,17].

To the best of our knowledge, despite the potential benefits of apps for people with hypertension and the increased use of these apps, a synthesis of studies on their effectiveness in this population has not been conducted. This systematic review will synthesize the existing evidence on the effectiveness of apps in lowering BP, as well as their usability and patients' satisfaction with their use.

Methods

A systematic review was conducted and reported per the PRISMA statement for systematic reviews [18,19].

Eligibility Criteria

The inclusion criteria were dependent on PICOS [18] as described below:

Population

The population was people with hypertension (18 years of age and over) and health care professionals (HCPs) supporting people with hypertension in their self-management in any care

setting, without limitations on the participants' gender, age or socio-demographic characteristics. Studies about people with chronic illness including hypertension as one of their inclusion criteria were also included.

Intervention

The intervention was a mobile phone or a tablet app that collects data, provides feedback, connects with HCPs or informs about hypertension to support the self-management tasks of hypertension. These tasks include self-monitoring of BP and other biometrics, healthy eating and drinking, being physically active, maintaining a healthy weight, adhering to medication, and managing stress and coping [1]. The app should also enable interactions between the user and the device via a set of interfaces (eg, a visual user interface). Studies in which a health app was the only method of delivery or in which it was a component of a blended intervention were also included.

Comparator

The comparator was either usual care or any other control intervention. Articles with no comparison were also included.

Outcomes

The outcomes of studies that were considered are: levels of BP, SBP, and DBP, as well as usability, attitudes, and satisfaction with mobile apps.

Study Designs

The eligible study designs were all quantitative, qualitative, and mixed-method studies that explore the self-management of hypertension using apps. Pilot studies were included because they might enable us to understand the status of apps.

Data Sources and Search Methods

The electronic databases EMBASE (OVID), MEDLINE (OVID), PsycINFO (OVID), the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library), CINAHL, ASSIAN, and IEEE Xplore were searched, as was Google Scholar. Hand searching through the reference lists of included studies and systematic reviews was also conducted to find more related studies. These databases were searched using the concepts of hypertension, mobile apps, telemonitoring, and self-management (see [Multimedia Appendix 2](#) for the MEDLINE search strategy). The search strategy was limited to English research published from 2008, when the first app store was launched, [12] to June 25, 2017.

Exclusion Criteria

Studies were excluded based on the criteria in [Textbox 1](#). Conference abstracts, protocols, commentaries or editorials or studies not in English or Arabic were not included.

Study Selection

Reference management software (Endnote) was utilized to collect results from databases, and to de-duplicate articles. Two reviewers (TA and SA) independently scanned titles against the eligibility criteria and in a second phase the abstracts of selected titles. Cohen kappa was calculated to determine the agreement between the reviewers for each step of selecting titles and abstracts.

Textbox 1. Exclusion criteria.

1. They were not aimed at hypertension or studies focusing only on primary prevention of hypertension or hypertension during pregnancy.
2. They examined interventions accessed by a personal digital assistant, desktop computer, laptop, netbook
3. They examined interventions accessed by a mobile phone or traditional tablet that did not permit participants to download or use any app from the app store.
4. They solely used messaging including short message service (SMS) text messaging, multimedia messaging service (MMS), websites, calls, emails or Web-based apps.
5. A mobile device was used to transmit information provided by a blood pressure monitoring device to care providers or clinicians, but in which there was no interaction with the user.
6. They describe only the technological development of a mobile system.

Titles and in the second phase abstracts received 2 points if they met the criteria, zero if not and 1 point when there was doubt. If the sum of reviewer scores for a title was 2 or more, the study was included for the next phase. Otherwise, it was excluded. Two reviewers separately reviewed the full articles when the total scores for the abstract equaled 2 points or more. Any disagreements were resolved through a discussion with other researchers (LdW and MSH).

Data Extraction and Quality Assessment

Two reviewers independently (TA and SA) extracted data and assessed the quality of the included studies. Any disagreement was resolved through a discussion with other researchers (LdW and MSH) until consensus was reached.

Data were extracted using a standardized form, which was piloted by the reviewers. The Cochrane Collaboration's Risk of Bias Tool was utilized to assess randomized controlled trials (RCTs) [20]. Nonrandomized quantitative studies were evaluated using 3 tools provided by the US National Institute of Health (NIH), March 2014 version: 1 for observational studies, 1 for controlled studies, and 1 for pre-post studies without control group [21]. The Critical Appraisal Skills Programme (CASP) was utilized for the quality assessment of qualitative studies [22].

Data Synthesis and Analysis

An overview of the basic characteristics of the studies, including the intervention, population, and outcome, was summarized in a table. Data were not combined because of differences in the designs of the studies. A narrative synthesis was conducted instead [18,23]. All research findings were classified according to review objectives.

Results

Summary of Search Results

The review steps are summarized in [Figure 1](#). Searching the electronic databases yielded a total of 6302 titles. After all duplicates were removed, 5676 records remained for title screening. Cohen kappa for agreement between the 2 reviewers was 0.72. Subsequently, the 2 reviewers (TA and SA) assessed the remaining 1968 abstracts; Cohen kappa for agreement between them in that step was 0.83. Of these, 569 went forward for full-text assessment, supplemented by 3 studies identified

from reference tracking. A total of 548 papers were excluded at full-text screening, as they did not meet the criteria relating to the participants or interventions, or they were conference abstracts, editorials, or protocols. This led to a selection of 24 publications. Only 21 of these were included in this review, as 2 publications were a subset analysis of a previous publication, and 1 publication was about a part of the sample of a larger study described in another publication.

Study Characteristics

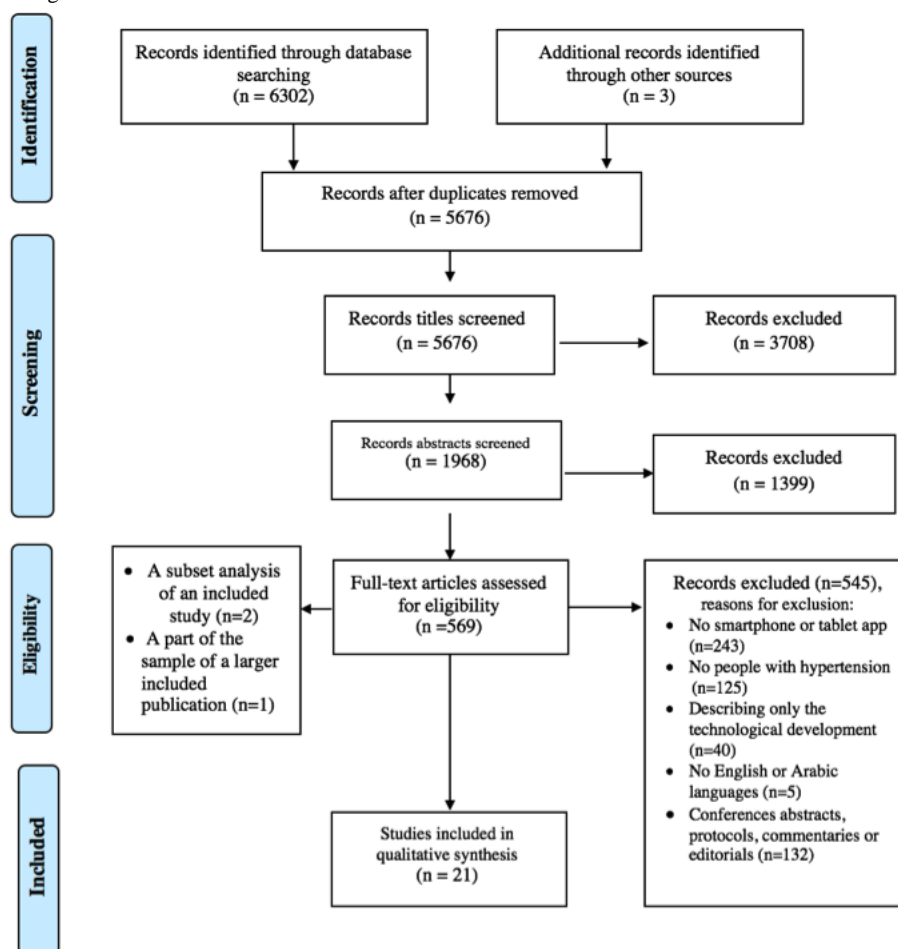
There were 21 studies included in this review. The publication year of the studies ranged from 2012 to 2017 (see [Multimedia Appendix 1](#)). Most studies (11/21, 52%) were conducted in the US [24-32] and Canada [33,34], while 7 (33.3%) were carried out in European countries, including France [35], Sweden [36-38], Spain [39,40] and Italy [41]. The remaining 3 (14.3%) studies were conducted in China [42,43] and South Korea [44].

Of the 21 studies, 9 (43%) were randomized controlled trials (RCTs) [24,25,27,28,30,33-35,42], 10 (48%) were nonrandomized studies [26,29,31,32,37,39-41,43,44], and 2 (10%) were qualitative studies [36,38].

Fourteen (14/21, 67%) studies reported on the apps' effectiveness in controlling BP. Of these studies, 4 (27%) also assessed user satisfaction and experience with the apps [27,30,31,39]. The remaining 7 (33%) studies that did not report efficacy focused on user satisfaction with and attitudes towards the apps and their usability [26,32,36,38,40,43,44]. The study duration ranged from 1-12 months. The studies included a range of 19 to 1012 participants, with a total of 3112 participants.

Participants' mean age ranged from 42.4 [27] to 69.5 [42] years of age. The population groups of the studies included individuals with hypertension [24-30,32,36-39,41-44], metabolic syndrome risk factors [34], obstructive sleep apnea with high cardiovascular risk [35], and overweight individuals [31]. Of the 21 included studies, 5 (24%) reported to having used behavioral theories, such as self-determination theory [24,26,27], motivational interviewing [30] and theory of planned behavior [43] to underpin and guide the intervention methods and the development of the technology. The other studies did not report using behavioral theories. However, an investigation of the apps' functionalities identified recognizable elements of behavioral strategies.

Figure 1. PRISMA flow diagram.



All the included studies focused on supporting self-management of hypertension. Nine (43%) of the included studies were aimed to enhance self-management without involving clinicians to monitor patients remotely [29,33,35-38,42-44]. The other 11 (52%) studies mainly involved clinicians or other HCPs remotely monitoring patient data and health status [24-28,30-32,39-41], while the remaining study involved the researcher remotely monitoring patient data and alerting physicians if needed [34,36]. In these 11 (52%) studies involving HCPs, the HCPs provided feedback, including a medication plan or adjustments [24-27,39,41], regular online coaching consultation, [31] instructions [28,30], or communication with patients [40,42] (see [Multimedia Appendix 1](#)).

Intervention Characteristics

In most studies, an app was supplemented with other interventions, such as a website [28,36-39,41], voice telephone messages [33], exercise prescription [34], a nasal mask and an auto-titrating machine [35], an electronic medication tray, email, SMS, or phone call [24-27], and education provided by a nurse [28]. The control group in the controlled studies had usual care. In some studies, this was combined with the recording of prescribed exercise [34] and the BP measurements [42] in a logbook or with the education provided by a nurse [28].

Functionalities of the Apps

The 21 reviewed studies used 16 apps. Fourteen different apps were used in 14 studies [28-35,39-44], 1 app was used in 3

studies [36-38], and another app was used in the other 4 studies [24-27].

The main functions of the apps can be categorized into the strategies involved: self-monitoring capabilities, goal setting, the reminder and alert component (the use of prompts or cues), automatic feedback, educational information, communication with HCPs and stress management. All 16 apps incorporated at least one of these functions. [Table 1](#) summarizes the characteristics of the apps and systems.

The 16 apps have some similar characteristics and functionalities. All the apps have self-monitoring capabilities for BP and other health data (medication adherence, physical activity, eating and drinking, weight, sleep, stress, symptoms, medication side effect, and self-reflection answers) [24-44]. This enables the user to track their BP and other health data over time in different formats, including graphical and/or tabular formats, and access the summary, raw data and/or analyzed results, the majority of which consisted of the BP, medication adherence, physical activity, eating and drinking, weight, and stress. The second most common functionality was a reminder and alert component that prompts self-monitoring by reminding patients about their medication time, BP measurements, hospital visits or personal goals, or the system alerts another person (eg, health professional) when a medication dose is missed or when the BP is higher than the normal level, a feature included in 13/16 (81%) apps [24-29,31-34,36-42,44].

Table 1. Intervention characteristics (identified by a check mark if they were met).

Study	Functionalities					
	Self-monitoring	Use of prompt/cues (reminder and alert)	Educational information	Communication with others	Automatic feedback	Stress management
Anglada-Martínez et al [39]	✓	✓	✓	✓	✓	—
Bengtsson et al [36]	✓	✓	—	—	✓	—
Bengtsson et al [37]	✓	✓	—	—	✓	—
Hallberg et al [38]	✓	✓	—	—	✓	—
Carrera et al [40]	✓	✓	✓	✓	✓	—
McGillicuddy et al [25]	✓	✓	—	—	✓	—
McGillicuddy et al [26]	✓	✓	—	—	✓	—
Davidson et al [24]	✓	✓	—	—	✓	—
McGillicuddy et al [27]	✓	✓	—	—	✓	—
Bloss et al [28]	✓	✓	✓	✓	✓	—
Patel et al [29]	✓	✓	✓	—	—	—
Or and Tao [42]	✓	✓	✓	—	✓	—
Logan et al [33]	✓	✓	—	—	✓	—
Petrella et al [34]	✓	✓	—	—	—	—
Albini et al [41]	✓	✓	✓	—	—	—
Mao et al [31]	✓	✓	✓	✓	—	—
Moore et al [30]	✓	—	—	✓	✓	—
Mendelson et al [35]	✓	—	✓	—	—	—
Kang et al [44]	✓	✓	✓	—	✓	—
Sun et al [43]	✓	—	—	—	—	—
Banerjee et al [32]	✓	✓	—	✓	✓	✓

Educational information [28,29,31,35,39-42,44] and automatic feedback [24-28,30,32,33,36-40,42,44] were the next most common features. Of 16 apps, 6 (38%) apps provided a tool for the users to communicate with their families and HCPs [28,30-32,39,40] and 1 app (6%) supported stress management [32]. Although setting goals is one of the most important techniques in the self-management of hypertension [45], most included studies reported that goals were set through negotiation and discussion between the patients and their HCPs without explicitly mentioning setting them in the app [24-27,29-31,34-38,42].

The most common comprehensive combination of strategies was self-monitoring, educational information, automatic feedback, reminders, and alerts. This combination was found in 5/16 (31%) apps [28,39,40,42,44], 3 of which also provided communication with HCPs [28,39,40], and patients families [28]. The second most frequently used combination was self-monitoring and prompt or cue, with the addition of either feedback [24-27,32,33,36-38] or educational information [29,31,41], with 2/7 (29%) apps providing communication with HCPs [31,32]. The remaining 4/16 (25%) apps only focused on self-monitoring [30,34,35,43] with either educational information [35], automatic feedback and communication with HCPs [30] or reminders or alerts [34] (see Table 2).

Regarding the automatic feedback feature, feedback was provided to participants using different approaches, either active feedback through self-care messages [33,40,44] and reinforcement messages [24-27], and passive feedback by representing data in different color codes to indicate whether measurement levels deviated from the normal range [28,32,40,42]. The communication with HCPs was through text messaging chats in the apps [30-32,39,40], with 1 of these 5 apps (20%) [31] adding consultations via video chats or calls in the app.

Data Input Methods

Most apps (14/16, 88%) used self-monitoring of BP and supported other self-monitoring tasks [24-28,30-38,40-44], while 2 apps (13%) focused solely on self-monitoring of medication compliance [29,39]. In 50% (7/14) of the apps, the collected BP readings were transmitted automatically from BP monitoring devices to the app using wireless transmission. In 3 of these 7 apps (42.9%), Bluetooth was employed [24-27,33,34] while for the remaining 4 apps (57%) the transmission method was not described [28,30,35,42]. Manual entry of BP data was used in 50% of apps (7/14) [31,32,36-38,40,41,43,44], one of which (14%) also automatically transmitted data [31].

Table 2. Common combinations of app functionalities (N=16).

Common Combination	n (%)
Self-monitoring + automatic feedback + prompt or cue (reminders and alerts) + educational information	5 (31)
Self-monitoring + prompt or cue (reminders and alerts) + automatic feedback	4 (25)
Self-monitoring + prompt or cue (reminders and alerts) + educational information	3 (19)
Self-monitoring + communicate with health professional + automatic feedback	1 (6)
Self-monitoring + prompt or cue (reminder and alerts)	1 (6)
Self-monitoring + educational information	1 (6)
Self-monitoring	1 (6)

Blood glucose readings were also wirelessly transmitted in 3 of the 16 apps (19%) [28,34,42] and medication data was wirelessly transmitted in 2 of the apps (13%) [24-27,30]. There was no description of the technology used. Data was inputted manually in 3 other apps (3/16, 19%) using different formats, such as choosing an option or typing [29,39,44]. Other manually inputted data include: weight in 4 apps (25%) [31,32,34,41], number of steps walked in two apps (13%) [31,34], reflective answers representing users' expectations toward their BP readings in one app [43], answers to questions about well-being, side effects, symptoms, and medication in another app [44], and other lifestyle aspects such as smoking, stress, and exercise in 2 apps [32,44].

Quality Appraisal

All 9 RCT studies presented some degree of potential bias when assessed using the Cochrane Collaboration's Risk of Bias Tool. Three of them were of low to moderate risk of bias (fair-good quality) because they met most of the criteria [33,35,42], while the remaining studies were considered to be of high risk of bias (poor quality) [24,25,27,28,30,34] (see [Multimedia Appendix 4](#)). Four of the 9 studies (44%) failed to report and apply random sequence generation [24,25,27,28]. Seven of the 9 studies (78%) presented a high risk of bias or information was not explicitly provided regarding the blinding of participants, personnel, or the outcome assessor [24,28,30,33-35,42]. Five (5/9, 56%) studies had a high risk of bias in other areas, such as small sample size [24,25,27,30,42].

One controlled study presented poor quality because of failure to apply blinding of the outcome assessor and sample size justification (see [Multimedia Appendix 5](#)). Most observational studies (4/7, 57%) were found to be of poor quality because of a high risk of bias or the lack of information concerning the sampling method and selection [32,39,43,44], and failure to clearly report the study aims, design, duration, and outcome measures [32,40], as well as high attrition rate [39,44]. The remaining 3 (43%) studies were of fair-good quality [26,31,37] (see [Multimedia Appendix 6](#)). One of the pre-post studies (1/2, 50%) presented poor quality because of selection and attrition bias [39] (see [Multimedia Appendix 7](#)). The two qualitative studies were deemed to be of low risk of bias as they met most of the CASP tool's criteria. However, both seemed to fail to adequately report the saturation of data during data collection and the relationship between researcher and participants (see [Multimedia Appendix 8](#)).

Blood Pressure

Fourteen studies (14/21, 67%) reported outcomes related to BP [24,25,27-31,33-35,37,39,41,42]. From these, 9 studies (64%) were RCTs [24,25,27,28,30,33,34,35,42], and 5 (36%) were nonrandomized studies [29,31,37,39,41]. Only 2 (14%) of them did not report the effect on DBP [25,31]. BP outcomes were presented as mean [25,27,29,39], mean change [24,28,30,33,37], or both [31,34,41,42] (see [Multimedia Appendix 3](#)).

As shown in [Table 3](#), 6/9 (67%) studies demonstrated positive effects on BP [24,25,27,30,33,42], whereas 3/9 (33%) studies reported no positive impact on BP [28,34,35]. The 6 studies that demonstrated positive effects showed a significant decrease in SBP ($P < .05$). The decrease in the intervention arm ranged from 8.7 to 34.8 mm Hg [24,25,27,30,33,42]. Significant decreases in DBP were reported in 2/6 (33%) studies, ranging from 4.9 to 12 mm Hg [24,33]. Only 1 of the 6 studies (17%) [30] reported a nonsignificant trend toward greater decrease.

Three out of 9 studies (33%) were of fair-good quality. However, the remaining 6 studies (67%) were of poor quality (see Quality Appraisal section for an in-depth discussion of this). Of the 3 studies that were fair-good quality, only 2 (67%) were positive. Five of the studies (5/14, 36%) are nonrandomized [29,31,37,39,41]. Of these, 4 (80%) reported a significant decrease in BP [29,31,37,41]. This decline ranged from 5.7 to 10.5 mm Hg and from 4.9 to 6.2 mm Hg for SBP and DBP respectively (see [Table 4](#)). Three of the 5 (60%) nonrandomized were of good-fair quality and 2 (40%) of the studies were of poor quality (see Quality Appraisal section).

Of the 6 studies with low-moderate risk of bias, 1 (17%) reported no significant effect on BP [18]. Five studies, 2 of which were RCTs (40%) [33,42] that reported positive impacts on BP. Most of these studies (4/5, 80%) used apps with functionalities including self-monitoring as well as reminders and alerts with either automatic feedback [33,37] or educational information [29,31], while 1 RCT used the most comprehensive combination of strategies including self-monitoring, reminders and/or alerts, automatic feedback and educational information [42]. Two other studies (2/14, 14%) [28,39] using apps with the same comprehensive combination of functionalities represented a high risk of bias and reported no statistically significant effects of using the app.

Table 3. Blood pressure effects and quality of randomized controlled trial (RCT).

RCT study	Follow up point, month	N	Systolic blood pressure		Diastolic blood pressure	
			Change	Effect	Change	Effect
Logan et al [33], mean (SD)						
Intervention						
Over 24 hours	12	55	-8.7 (14.7)	Positive ^a	-4.2 (9.3)	Positive
During the daytime	12	55	-9.1 (15.6)	Positive ^a	-4.6 (9.2)	Positive
Control						
Over 24 hours	12	55	-1.7 (12.1)	—	-1.1 (6.8)	—
During the daytime	12	55	-1.5 (12.2)	—	-1.3 (6.6)	—
Or and Tao [42], mean (95% CI)						
Intervention	3	33	-16.7 (-22.8 to -10.7)	Positive	-8.0 (-11.5 to -4.5)	Neutral ^b
Control	3	30	-2.1 (-8.6 to 4.4)	—	-2.1 (-8.6 to 4.4) ^c	—
Mendelson et al [35]						
Intervention	4	54	NR ^d	Neutral	NR	Neutral
Control	4	53	NR	—	NR	—
Davidson et al [24], mean						
Intervention	6	33	-34.8	Positive	-12	Positive
Control	6	30	-9.7	—	-4.5	—
McGillicuddy et al [25] (mm Hg), mean (SE)						
Intervention	12	9	132.2 (3.7)	Positive	NR	NR
Control	12	9	154.2 (5.7)	—	—	—
McGillicuddy et al [27] (mm Hg), mean						
Intervention	3	9	121.80	Positive	80.70	Neutral
Control	3	10	138.78	—	79.44	—
Moore et al [30], mean (SD)						
Intervention	3	20	-26.3 (11.9)	Positive	-13.7 (9.4)	Neutral
Control	3	22	-16.0 (12.1)	—	-8.2 (8.6)	—
Petrella et al [34]						
Intervention	13	75	NR	Neutral	NR	Neutral
Control	13	74	NR	—	NR	—
Bloss et al [28], mean						
Intervention	6	65	NR	Neutral	-3.6	Neutral
Control	6	65	NR	—	-6.1	—

^aThe app had significant positive effect on blood pressure.

^bThe app had neutral effect on blood pressure.

^c $P < .001$.

^dNR: not reported.

Table 4. Blood pressure effects and quality of nonrandomized studies.

Randomized controlled trial study	Follow up point, month	N	Systolic Blood Pressure Change	Effect	Diastolic Blood Pressure Change	Effect
Bengtsson et al [37], mean (SD)						
Intervention	2	50	-7 (18)	Positive ^a	-4.9 (10)	Positive
Control	2	50	NR ^b	—	NR	—
Patel et al [29] (mm Hg), mean						
Intervention	7	50	135	Positive	85	Positive
Control	7	30	NR	—	NR	—
Mao et al [31], mean (SE)						
Intervention	4	763	-5.96 (1.64)	Positive	NR	NR
Control	4	73	NR	—	NR	—
Albini et al [41], mean (SD)						
Intervention	6	303	-10.5 (6.3)	Positive	-6.2 (3.8)	Positive
Control	6	298	-6.1 (6.9)	—	-3.4 (4.5)	—
Anglada-Martínez et al [39] (mm Hg), mean (SD)						
Intervention	6	42	131.3 (9.8)	Neutral ^c	75.4 (6.7)	Neutral
Control	6	42	130.2 (13.9)	—	79.9 (9.6)	—

^aThe app had significantly positive effect on blood pressure.

^bNR: not reported.

^cThe app had neutral effect on blood pressure.

The evidence is therefore inconclusive about which of these functionality combinations would be more effective in lowering BP, but it suggests that apps incorporating more comprehensive functionalities are likely to be effective.

Usability, Satisfaction, and Attitudes

Two of the 21 studies (10%) explored the usability of the apps [36,40] and 9 (43%) assessed user satisfaction with and attitudes toward the apps [26,27,30-32,38,39,43,44], 1 of which (1/9, 11%) also evaluate usability among experts [44]. All of these 11 studies focused on the patient perspective, whereas 5 of them (46%) also considered the HCPs' perspective [30,36,39,40,44].

Generally, the use of the app was highly accepted by participants in all 9 studies that assessed user satisfaction [26,27,30-32,38,39,43,44]. User satisfaction was measured through the participants rating their experience with the app [30,31], administration of satisfaction questionnaires [26,27,32,39,44], or conducting interviews [38,43]. The satisfaction rate ranged from 7.2 to 9.8 [30,31,39] for studies using a 10-point satisfaction rating scale, and from 3.1 to 4.8 [27,44] for studies utilizing a 5-point satisfaction rating scale.

The participants reported that the apps were easy to use [27,32,38,39,43], convenient [38,43], helpful in effectively communicating with HCPs [26,27] and in hypertension management [27,38,43,44], including medication adherence and adjustment [26,27,43], and helped increase their active role in care, health awareness, and motivation [30,38,43]. Although some participants felt that the apps were useful only for patients with an unstable BP [38,43], elderly patients, patients with

polypharmacy or caregivers [39], most patients and HCPs stated that they would continue using the app after the study [30,39,43] and would recommend it to their friends [39]. In 3 of the 9 studies (33%) [30,38,43] the participants suggested that the app would be more useful if improvements could be made. These improvements include tailoring the graph according to the participants' preference, for example, coloring graphs, sending motivational messages according to the inputted data [38]. It also was suggested to support the self-monitoring of other conditions such as blood glucose [43], include alerts that inform patients if the BP readings are abnormal, and improving the performance of the app by loading faster [30].

One study (1/3, 33%) evaluated the app through conducting heuristic evaluation among technology and health informatics experts, and 2 studies (2/3, 67%) only conducted a usability test of the app amongst users. In the heuristic evaluation, some usability problems were identified. Of the 2 studies that assessed usability among users, 1 used direct observation of the participants [40] and the other used an observation method with specific questions asked to the participants [36]. All the participants found both apps easy to use [36,40].

Six studies assessing usability and satisfaction (6/11, 55%) were of poor quality and only 5 of the 11 (46%) presented a low-moderate risk of bias. Generally, the participants seemed satisfied with the apps, they accepted using them in managing their condition and found them easy to use.

Discussion

Principal Findings

The aim of this systematic review was to synthesize evidence about the effectiveness, acceptance, and usability of using mobile and tablet apps to reduce BP.

This review found studies about 16 apps with similar functionalities. However, they were different in the number of combined functionalities. The majority of the apps used different combinations of functionalities, whereas 1 app had only 1 function [43]. In all 9 studies that assessed users' satisfaction, the participants generally seemed to accept using apps to support the self-management of their BP. It also indicates that using the apps seems to be effective in supporting the self-management of hypertension and has the potential to lower BP as this was reported in 10 studies (6 RCTs and 4 nonrandomized studies). It should be noted that, of these, only 2 RCTs (33%) and 3 nonrandomized studies (75%) were of good quality. Due to the variety of study designs and quality the results, there is inconclusive evidence about which of these functionality combinations would be more effective in lowering BP. However, it would appear that apps incorporating more comprehensive functionalities are likely to be effective.

This study found that using apps may help reduce SBP and DBP significantly. Notably, this result was in accordance with other studies using mobile and other similar older technologies [11,46]. In 1 meta-analysis, a decrease of 5 mm Hg in DBP or 10 mm Hg in SBP was found to reduce coronary heart disease events by 22% and stroke by 41% [47], as a decrease of 1 mm Hg in SBP leads to a 5% reduction in the risk of stroke [46]. The findings of this review are in line with other systematic reviews that involved mobile phone and tablet-based intervention in managing chronic diseases, which showed that the use of apps has the potential to improve health outcomes among those living with chronic diseases [8,10,11,48,49].

The results with regard to acceptance are supported by studies assessing the acceptance and usability of mobile apps in the management of chronic diseases [49,50]. A study assessing the usability of a commercially available app for diabetes found a lack of usability for its main target users of elderly diabetics [51]. This finding, thereby, highlights the importance of assessing the usability of apps for hypertension and close cooperation and intensive usability tests with the targeted users during the development process of the apps.

In some studies, the apps were used in combination with other platforms, such as a website. The reported effects, therefore, cannot be solely attributed to the apps. The use of apps with automatic feedback without the involvement of clinicians to monitor patients remotely may be effective in controlling BP. Similarly, apps in which HCPs were involved in monitoring patients remotely and providing their feedback or instructions, with either automatic feedback or not, could also have a significant impact on BP. In short, it is possible that both approaches are effective.

The results of this review should be interpreted with caution, as some studies with a high risk of bias (6/9, 67% of RCTs;

6/10, 60% of nonrandomized studies) were included, and methodological issues have been identified in most of the included studies. These issues emerged from potential biases in some RCT studies because of the failure to implement the blinding of subjects and the assessor, lack of concealment and randomization procedures, small sample size, and short study duration. However, the blinding of subjects was impossible across the interventions due to the nature of using apps. Nonrandomized quantitative studies also had limitations, such as their small sample size, short duration, and attrition bias [39]. Many of the studies included in this paper were conducted in different health and social care settings, which means that comparisons between them are not straightforward. Consequently, the generalizability of the results of some of these studies is limited. Although evidence of the effectiveness of mHealth is increasing, there is a lack of evidence concerning the sustainability of the findings after the app intervention has ceased. This suggests that further research is warranted to determine long-term benefits and eliminate these limitations.

Strengths and Limitations of this Review

This review has some limitations that should be considered when interpreting the results. First, studies published in languages other than English were not included, which increases the likelihood of relevant research being missed. Moreover, all types of studies were included regardless of their quality as it is often helpful to have more recent findings. However, low-quality studies present more inconclusive data, which affects the results. It was not possible to conduct a meta-analysis due to the study designs heterogeneity; combining results that have been obtained from different types of randomized and nonrandomized studies will not yield useful data. In addition, the inclusion of controlled and non-controlled studies might yield a combination of possibly inconclusive results. Their inclusion may offer a wider body of evidence. Despite these limitations, this study is the first systematic review exploring the effectiveness of using mobile apps in the self-management of hypertension and their acceptance among users. Consequently, it might be a useful roadmap to guide further studies on the use of mobile apps by people with hypertension. The authors developed a comprehensive search strategy and then hand searched the reference lists of each identified full-text articles and systematic review to find potentially relevant studies for inclusion in this systemic review and considered combinations of functionalities that were used in the apps.

Recommendations for Further Study

The methodological quality of studies included in this review was generally low. This indicates that future studies should consider some essential criteria, including a sufficient number of participants and duration time, concealment and randomization procedures, blinding of the assessor, and low attrition rates. Future studies assessing the effectiveness of apps should focus on apps that incorporate more comprehensive functionalities, that are identified in this review as the most promising functionalities for self-management of hypertension, including self-monitoring, reminders and alerts with either automatic feedback or educational information or both. It is important also to assess and understand users' satisfaction with

and acceptance of these apps. A well-designed RCT with multiple arms using apps with different combinations of functionalities to enable identification of the most effective combinations would also be beneficial.

Conclusion

This systematic review indicates that the use of apps to support the self-management of hypertension are accepted by patients

and could assist in lowering and controlling their BP. It would appear that apps incorporating more comprehensive functionalities are likely to be effective. The results should be interpreted with caution, as most of the studies were of high risk of bias. More research is required to identify the effectiveness of using apps in lowering BP and to understand what functionality combinations are effective for lowering BP.

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Authors' Contributions

TA developed the review protocol and LdW and MSH significantly contributed to the development of the review protocol. TA and SA completed data screening, data extraction, and quality appraisal of relevant studies with disagreements resolved through discussion with other authors (LdW and MSH). TA also drafted the manuscript, LdW and MSH reviewed the manuscript and contributed to subsequent drafts. Authors TA, MSH, and LdW read and approved the final review.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Study characteristics.

[[PDF File \(Adobe PDF File\), 63KB - mhealth_v6i7e10723_app1.pdf](#)]

Multimedia Appendix 2

MEDLINE search strategy.

[[PDF File \(Adobe PDF File\), 2MB - mhealth_v6i7e10723_app2.pdf](#)]

Multimedia Appendix 3

Study outcomes.

[[PDF File \(Adobe PDF File\), 146KB - mhealth_v6i7e10723_app3.pdf](#)]

Multimedia Appendix 4

Cochrane checklist too for RCTs.

[[PDF File \(Adobe PDF File\), 116KB - mhealth_v6i7e10723_app4.pdf](#)]

Multimedia Appendix 5

NIH tools for non-randomized studies.

[[PDF File \(Adobe PDF File\), 80KB - mhealth_v6i7e10723_app5.pdf](#)]

Multimedia Appendix 6

NIH tools for non-randomized studies (observational cohort and cross-sectional studied).

[[PDF File \(Adobe PDF File\), 101KB - mhealth_v6i7e10723_app6.pdf](#)]

Multimedia Appendix 7

NIH tools for non-randomized studies (Pre-post studies) .

[[PDF File \(Adobe PDF File\), 60KB - mhealth_v6i7e10723_app7.pdf](#)]

Multimedia Appendix 8

CASP tool for qualitative studies.

[[PDF File \(Adobe PDF File\), 66KB - mhealth_v6i7e10723_app8.pdf](#)]

References

1. Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL, et al. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Hypertension* 2003 Dec;42(6):1206-1252 [[FREE Full text](#)] [doi: [10.1161/01.HYP.0000107251.49515.c2](https://doi.org/10.1161/01.HYP.0000107251.49515.c2)] [Medline: [14656957](#)]
2. Chow CK, Teo KK, Rangarajan S, Islam S, Gupta R, Avezum A, et al. Prevalence, awareness, treatment, and control of hypertension in rural and urban communities in high-, middle-, and low-income countries. *JAMA* 2013 Sep 04;310(9):959-968. [doi: [10.1001/jama.2013.184182](https://doi.org/10.1001/jama.2013.184182)] [Medline: [24002282](#)]
3. Ryan P, Sawin KJ. The Individual and Family Self-Management Theory: background and perspectives on context, process, and outcomes. *Nurs Outlook* 2009;57(4):217-225.e6 [[FREE Full text](#)] [doi: [10.1016/j.outlook.2008.10.004](https://doi.org/10.1016/j.outlook.2008.10.004)] [Medline: [19631064](#)]
4. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. *JAMA* 2002 Nov 20;288(19):2469-2475. [Medline: [12435261](#)]
5. Grady PA, Gough LL. Self-management: a comprehensive approach to management of chronic conditions. *Am J Public Health* 2014 Aug;104(8):e25-e31. [doi: [10.2105/AJPH.2014.302041](https://doi.org/10.2105/AJPH.2014.302041)] [Medline: [24922170](#)]
6. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. *Patient Educ Couns* 2002;48(2):177-187. [Medline: [12401421](#)]
7. Whittaker R. Issues in mHealth: findings from key informant interviews. *J Med Internet Res* 2012;14(5):e129 [[FREE Full text](#)] [doi: [10.2196/jmir.1989](https://doi.org/10.2196/jmir.1989)] [Medline: [23032424](#)]
8. Whitehead L, Seaton P. The Effectiveness of Self-Management Mobile Phone and Tablet Apps in Long-term Condition Management: A Systematic Review. *J Med Internet Res* 2016;18(5):e97 [[FREE Full text](#)] [doi: [10.2196/jmir.4883](https://doi.org/10.2196/jmir.4883)] [Medline: [27185295](#)]
9. Logan AG. Transforming hypertension management using mobile health technology for telemonitoring and self-care support. *Can J Cardiol* 2013 May;29(5):579-585. [doi: [10.1016/j.cjca.2013.02.024](https://doi.org/10.1016/j.cjca.2013.02.024)] [Medline: [23618506](#)]
10. Bonoto BC, de AVE, Godói IP, de LLLP, Godman B, Bennie M, et al. Efficacy of Mobile Apps to Support the Care of Patients With Diabetes Mellitus: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *JMIR Mhealth Uhealth* 2017 Mar 01;5(3):e4 [[FREE Full text](#)] [doi: [10.2196/mhealth.6309](https://doi.org/10.2196/mhealth.6309)] [Medline: [28249834](#)]
11. Liu S, Dunford SD, Leung YW, Brooks D, Thomas SG, Eysenbach G, et al. Reducing blood pressure with Internet-based interventions: a meta-analysis. *Can J Cardiol* 2013 May;29(5):613-621. [doi: [10.1016/j.cjca.2013.02.007](https://doi.org/10.1016/j.cjca.2013.02.007)] [Medline: [23618507](#)]
12. Eren H, Webster J. Telehealth and mobile health. In: CRC Press, editor. CRC Press. Florida USA: CRC Press; 2016:978-971.
13. Majeed-Ariss R, Baildam E, Campbell M, Chieng A, Fallon D, Hall A, et al. Apps and Adolescents: A Systematic Review of Adolescents' Use of Mobile Phone and Tablet Apps That Support Personal Management of Their Chronic or Long-Term Physical Conditions. *J Med Internet Res* 2015 Dec;17(12):e287 [[FREE Full text](#)] [doi: [10.2196/jmir.5043](https://doi.org/10.2196/jmir.5043)] [Medline: [26701961](#)]
14. Edwards EA, Lumsden J, Rivas C, Steed L, Edwards LA, Thiagarajan A, et al. Gamification for health promotion: systematic review of behaviour change techniques in smartphone apps. *BMJ Open* 2016 Oct 04;6(10):e012447 [[FREE Full text](#)] [doi: [10.1136/bmjopen-2016-012447](https://doi.org/10.1136/bmjopen-2016-012447)] [Medline: [27707829](#)]
15. Istepanian R, Woodward B. Preview this item M-Health : Fundamentals and Applications. In: IEEE Press Series on Biomedical Engineering. New Jersey USA: Wiley-IEEE Press; 2016:1119302897.
16. Kumar N, Khunger M, Gupta A, Garg N. A content analysis of smartphone-based applications for hypertension management. *J Am Soc Hypertens* 2015 Feb;9(2):130-136. [doi: [10.1016/j.jash.2014.12.001](https://doi.org/10.1016/j.jash.2014.12.001)] [Medline: [25660364](#)]
17. Parati G, Torlasco C, Omboni S, Pellegrini D. Smartphone Applications for Hypertension Management: a Potential Game-Changer That Needs More Control. *Curr Hypertens Rep* 2017 Jun;19(6):48. [doi: [10.1007/s11906-017-0743-0](https://doi.org/10.1007/s11906-017-0743-0)] [Medline: [28501982](#)]
18. CRD. Systematic reviews: crd's guidance for undertaking reviews in healthcare. York: University of York; 2009. URL: https://www.york.ac.uk/media/crd/Systematic_Reviews.pdf [accessed 2018-04-05] [[WebCite Cache ID 6ySN50dBS](#)]
19. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JPA, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. *BMJ* 2009;339:b2700 [[FREE Full text](#)] [Medline: [19622552](#)]
20. Higgins J, Green S. Cochrane handbook for systematic reviews of interventions. Version. Oxford: The Cochrane Collaboration; 2011. URL: <http://handbook-5-1.cochrane.org/> [accessed 2018-06-09] [[WebCite Cache ID 7031fhf1](#)]
21. National I. National Institutes of Health (NIH). Study quality assessment tools | national heart, lung, and blood institute (nhlbi) URL: <https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools> [accessed 2018-04-06] [[WebCite Cache ID 6yTjI3G2L](#)]

22. Critical A. Published. 2006. 10 questions to help you make sense of qualitative research URL: <https://hhs.hud.ac.uk/lqsu/Useful/critap/Qualitative%20Research%20Checklist/CASP-Qualitative-Research-Checklist-31.05.13.pdf> [WebCite Cache ID 6yR7zoK8m]
23. Booth A, Sutton A, Papaioannou D. Systematic approaches to a successful literature review. 2nd ed. London, UK: Sage; 2016.
24. Davidson TM, McGillicuddy J, Mueller M, Brunner-Jackson B, Favella A, Anderson A, et al. Evaluation of an mHealth Medication Regimen Self-Management Program for African American and Hispanic Uncontrolled Hypertensives. *J Pers Med* 2015 Nov 17;5(4):389-405 [FREE Full text] [doi: [10.3390/jpm5040389](https://doi.org/10.3390/jpm5040389)] [Medline: [26593951](https://pubmed.ncbi.nlm.nih.gov/26593951/)]
25. Pilheu JA. [The lung, macrophages and oxygen radicals]. *Medicina (B Aires)* 1989;49(1):87-90. [Medline: [2630878](https://pubmed.ncbi.nlm.nih.gov/2630878/)]
26. McGillicuddy JW, Weiland AK, Frenzel RM, Mueller M, Brunner-Jackson BM, Taber DJ, et al. Patient attitudes toward mobile phone-based health monitoring: questionnaire study among kidney transplant recipients. *J Med Internet Res* 2013;15(1):e6 [FREE Full text] [doi: [10.2196/jmir.2284](https://doi.org/10.2196/jmir.2284)] [Medline: [23305649](https://pubmed.ncbi.nlm.nih.gov/23305649/)]
27. McGillicuddy JW, Gregoski MJ, Weiland AK, Rock RA, Brunner-Jackson BM, Patel SK, et al. Mobile Health Medication Adherence and Blood Pressure Control in Renal Transplant Recipients: A Proof-of-Concept Randomized Controlled Trial. *JMIR Res Protoc* 2013;2(2):e32 [FREE Full text] [doi: [10.2196/resprot.2633](https://doi.org/10.2196/resprot.2633)] [Medline: [24004517](https://pubmed.ncbi.nlm.nih.gov/24004517/)]
28. Bloss CS, Wineinger NE, Peters M, Boeldt DL, Ariniello L, Kim JY, et al. A prospective randomized trial examining health care utilization in individuals using multiple smartphone-enabled biosensors. *PeerJ* 2016;4:e1554 [FREE Full text] [doi: [10.7717/peerj.1554](https://doi.org/10.7717/peerj.1554)] [Medline: [26788432](https://pubmed.ncbi.nlm.nih.gov/26788432/)]
29. Patel S, Jacobus-Kantor L, Marshall L, Ritchie C, Kaplinski M, Khurana PS, et al. Mobilizing your medications: an automated medication reminder application for mobile phones and hypertension medication adherence in a high-risk urban population. *J Diabetes Sci Technol* 2013 May 01;7(3):630-639 [FREE Full text] [Medline: [23759395](https://pubmed.ncbi.nlm.nih.gov/23759395/)]
30. Moore J, Marshall M, Judge D. Technology-supported apprenticeship in the management of hypertension: a randomized controlled trial. *J Clin Outcomes Manag* 2014;21(3):a.
31. Mao AY, Chen C, Magana C, Caballero BK, Olayiwola JN. A Mobile Phone-Based Health Coaching Intervention for Weight Loss and Blood Pressure Reduction in a National Payer Population: A Retrospective Study. *JMIR Mhealth Uhealth* 2017 Jun 08;5(6):e80 [FREE Full text] [doi: [10.2196/mhealth.7591](https://doi.org/10.2196/mhealth.7591)] [Medline: [28596147](https://pubmed.ncbi.nlm.nih.gov/28596147/)]
32. Banerjee A, Ramanujan R, Agnihotri S. Mobile Health Monitoring: Development and Implementation of an app in a Diabetes and Hypertension Clinic. *Mobile health monitoring; 2016 Presented at: International Conference on System Sciences; 2016; Hawaii* p. 3424-3436. [doi: [10.1109/HICSS.2016.427](https://doi.org/10.1109/HICSS.2016.427)]
33. Logan AG, Irvine MJ, McIsaac WJ, Tisler A, Rossos PG, Easty A, et al. Effect of home blood pressure telemonitoring with self-care support on uncontrolled systolic hypertension in diabetics. *Hypertension* 2012 Jul;60(1):51-57 [FREE Full text] [doi: [10.1161/HYPERTENSIONAHA.111.188409](https://doi.org/10.1161/HYPERTENSIONAHA.111.188409)] [Medline: [22615116](https://pubmed.ncbi.nlm.nih.gov/22615116/)]
34. Petrella RJ, Stuckey MI, Shapiro S, Gill DP. Mobile health, exercise and metabolic risk: a randomized controlled trial. *BMC Public Health* 2014;14:1082 [FREE Full text] [doi: [10.1186/1471-2458-14-1082](https://doi.org/10.1186/1471-2458-14-1082)] [Medline: [25326074](https://pubmed.ncbi.nlm.nih.gov/25326074/)]
35. Mendelson M, Vivodtzev I, Tamisier R. CPAP treatment supported by telemedicine does not improve blood pressure in high cardiovascular risk osa patients: a randomized, controlled trial. *Sleep* 2014;37(11):a. [Medline: [25364081](https://pubmed.ncbi.nlm.nih.gov/25364081/)]
36. Bengtsson U, Kjellgren K, Höfer S, Taft C, Ring L. Developing an interactive mobile phone self-report system for self-management of hypertension. Part 2: content validity and usability. *Blood Press* 2014 Oct;23(5):296-306 [FREE Full text] [doi: [10.3109/08037051.2014.901009](https://doi.org/10.3109/08037051.2014.901009)] [Medline: [24786778](https://pubmed.ncbi.nlm.nih.gov/24786778/)]
37. Bengtsson U, Kjellgren K, Hallberg I, Lindwall M, Taft C. Improved Blood Pressure Control Using an Interactive Mobile Phone Support System. *J Clin Hypertens (Greenwich)* 2016 Feb;18(2):101-108 [FREE Full text] [doi: [10.1111/jch.12682](https://doi.org/10.1111/jch.12682)] [Medline: [26456490](https://pubmed.ncbi.nlm.nih.gov/26456490/)]
38. Hallberg I, Ranerup A, Kjellgren K. Supporting the self-management of hypertension: Patients' experiences of using a mobile phone-based system. *J Hum Hypertens* 2016 Feb;30(2):141-146 [FREE Full text] [doi: [10.1038/jhh.2015.37](https://doi.org/10.1038/jhh.2015.37)] [Medline: [25903164](https://pubmed.ncbi.nlm.nih.gov/25903164/)]
39. Anglada-Martínez H, Martín-Conde M, Rovira-Illamola M, Sotoca-Momblona JM, Sequeira E, Aragunde V, et al. Feasibility and Preliminary Outcomes of a Web and Smartphone-Based Medication Self-Management Platform for Chronically Ill Patients. *J Med Syst* 2016 Apr;40(4):99. [doi: [10.1007/s10916-016-0456-y](https://doi.org/10.1007/s10916-016-0456-y)] [Medline: [26872781](https://pubmed.ncbi.nlm.nih.gov/26872781/)]
40. Carrera A, Pifarré M, Vilaplana J. Bpcontrol. A mobile app to monitor hypertensive patients. *Appl Clin Inform* 2016;7(4):1120-1134. [Medline: [27924346](https://pubmed.ncbi.nlm.nih.gov/27924346/)]
41. Albini F, Liu X, Torlasco C. Use of Apps to Improve Drug Adherence in Hypertensive Patients. *Drug Adherence in Hypertension and Cardiovascular Protection* 2016:517-520. [Medline: [28324932](https://pubmed.ncbi.nlm.nih.gov/28324932/)]
42. Or C, Tao D. A 3-Month Randomized Controlled Pilot Trial of a Patient-Centered, Computer-Based Self-Monitoring System for the Care of Type 2 Diabetes Mellitus and Hypertension. *J Med Syst* 2016 Apr;40(4):81. [doi: [10.1007/s10916-016-0437-1](https://doi.org/10.1007/s10916-016-0437-1)] [Medline: [26802011](https://pubmed.ncbi.nlm.nih.gov/26802011/)]
43. Sun N, Rau PP, Li Y, Owen T, Thimbleby H. Design and evaluation of a mobile phone-based health intervention for patients with hypertensive condition. *Computers in Human Behavior* 2016 Oct;63:98-105. [doi: [10.1016/j.chb.2016.05.001](https://doi.org/10.1016/j.chb.2016.05.001)] [Medline: [25904163](https://pubmed.ncbi.nlm.nih.gov/25904163/)]

44. Kang H, Park H. A Mobile App for Hypertension Management Based on Clinical Practice Guidelines: Development and Deployment. *JMIR Mhealth Uhealth* 2016 Feb 02;4(1):e12 [[FREE Full text](#)] [doi: [10.2196/mhealth.4966](https://doi.org/10.2196/mhealth.4966)] [Medline: [26839283](https://pubmed.ncbi.nlm.nih.gov/26839283/)]
45. Bosworth H, Powers B, Oddone E. Patient Self-Management Support: Novel Strategies in Hypertension and Heart Disease. *Cardiol Clin* 2010;28(4):655-663. [Medline: [20937448](https://pubmed.ncbi.nlm.nih.gov/20937448/)]
46. McLean G, Band R, Saunderson K, Hanlon P, Murray E, Little P, et al. Digital interventions to promote self-management in adults with hypertension systematic review and meta-analysis. *J Hypertens* 2016 Apr;34(4):600-612 [[FREE Full text](#)] [doi: [10.1097/HJH.0000000000000859](https://doi.org/10.1097/HJH.0000000000000859)] [Medline: [26845284](https://pubmed.ncbi.nlm.nih.gov/26845284/)]
47. Law MR, Morris JK, Wald NJ. Use of blood pressure lowering drugs in the prevention of cardiovascular disease: meta-analysis of 147 randomised trials in the context of expectations from prospective epidemiological studies. *BMJ* 2009;338:b1665 [[FREE Full text](#)] [Medline: [19454737](https://pubmed.ncbi.nlm.nih.gov/19454737/)]
48. Flores MG, Granado-Font E, Ferré-Grau C, Montaña-Carreras X. Mobile Phone Apps to Promote Weight Loss and Increase Physical Activity: A Systematic Review and Meta-Analysis. *J Med Internet Res* 2015;17(11):e253 [[FREE Full text](#)] [doi: [10.2196/jmir.4836](https://doi.org/10.2196/jmir.4836)] [Medline: [26554314](https://pubmed.ncbi.nlm.nih.gov/26554314/)]
49. Fu H, McMahan SK, Gross CR, Adam TJ, Wyman JF. Usability and clinical efficacy of diabetes mobile applications for adults with type 2 diabetes: A systematic review. *Diabetes Res Clin Pract* 2017 Sep;131:70-81. [doi: [10.1016/j.diabres.2017.06.016](https://doi.org/10.1016/j.diabres.2017.06.016)] [Medline: [28692830](https://pubmed.ncbi.nlm.nih.gov/28692830/)]
50. Cho M, Sim J, Hwang S. Development of smartphone educational application for patients with coronary artery disease. *Healthc Inform Res* 2014;20(2):117. [Medline: [24872910](https://pubmed.ncbi.nlm.nih.gov/24872910/)]
51. Arnhold M, Quade M, Kirch W. Mobile applications for diabetics: a systematic review and expert-based usability evaluation considering the special requirements of diabetes patients age 50 years or older. *J Med Internet Res* 2014;16(4):a. [Medline: [2471885](https://pubmed.ncbi.nlm.nih.gov/2471885/)]

Abbreviations

- BP:** blood pressure
CASP: Critical Appraisal Skills Programme
DBP: diastolic blood pressure
HCP: health care professional
mHealth: mobile health
SBP: systolic blood pressure
RCT: randomized controlled trial

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Original Paper

Leveraging Self-Affirmation to Improve Behavior Change: A Mobile Health App Experiment

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Abstract

Background: mHealth interventions can help to improve the physical well-being of participants. Unfortunately, mHealth interventions often have low adherence and high attrition. One possible way to increase adherence is instructing participants to complete self-affirmation exercises. Self-affirmation exercises have been effective in increasing many types of positive behaviors. However, self-affirmation exercises often involve extensive essay writing, a task that is not easy to complete on mobile platforms.

Objective: This study aimed to adapt a self-affirmation exercise to a form better suited for delivery through a mobile app targeting healthy eating behaviors, and to test the effect of differing self-affirmation doses on adherence to behavior change goals over time.

Methods: We examined how varied self-affirmation doses affected behavior change in an mHealth app targeting healthy eating that participants used for 28 days. We divided participants into the 4 total conditions using a 2×2 factorial design. The first independent variable was whether the participant received an initial self-affirmation exercise. The second independent variable was whether the participant received ongoing booster self-affirmations throughout the 28-day study. To examine possible mechanisms through which self-affirmation may cause positive behavior change, we analyzed three aspects of self-affirmation effects in our research. First, we analyzed how adherence was affected by self-affirmation exercises. Second, we analyzed whether self-affirmation exercises reduced attrition rates from the app. Third, we examined a model for self-affirmation behavior change.

Results: Analysis of 3556 observations from 127 participants indicated that higher doses of self-affirmation resulted in improved adherence to mHealth intervention goals (coefficient 1.42, SE 0.71, $P=.04$). This increased adherence did not seem to translate to a decrease in participant attrition (P value range .61-.96), although our definition of attrition was conservative. Finally, we examined the mechanisms by which self-affirmation may have affected intentions of behavior change; we built a model of intention ($R^2=.39$, $P<.001$), but self-affirmation did not directly affect final intentions (P value range .09-.93).

Conclusions: Self-affirmations can successfully increase adherence to recommended diet and health goals in the context of an mHealth app. However, this increase in adherence does not seem to reduce overall attrition. The self-affirmation exercises we developed were simple to implement and had a low cost for both users and developers. While this study focused on an mHealth app for healthy eating, we recommend that other mHealth apps integrate similar self-affirmation exercises to examine effectiveness in other behaviors and contexts.

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KEYWORDS

mHealth; self-affirmation; behavior change; attrition; adherence; health behavior; telemedicine; treatment adherence and compliance

Introduction

Background

Millions of people are turning to mHealth apps to improve their physical and mental well-being. Over 50% of mobile phone users in the United States use mHealth apps; this rate doubled from 2014 to 2016 [1]. mHealth apps may offer effective low-cost solutions to major chronic health problems, which is especially attractive now, at a time when medical expenses in the United States have more than tripled in the past 50 years [2]. mHealth apps personalize medicine on a massive scale, therefore equipping patients to confront common problems such as smoking [3]. A review of mHealth interventions concluded that there is enough evidence to indicate that these interventions are effective, but more research should focus on integrating mHealth interventions into daily practice [4]. One of the primary problems with daily practice for mHealth interventions is that they are associated with poor adherence and attrition.

Adherence and Attrition

Nearly 50% of people who started using an mHealth app at one point reported that they no longer used them [1]. Other interventions delivered remotely through the internet often have extremely high attrition rates [5]. We must tackle these adherence and attrition problems so as to have a positive impact on users of mHealth apps.

Adherence and attrition are both problematic for mHealth systems, but it is important to distinguish between them. Adherence refers to the act of following the instructions for the app or intervention. For example, if an app sets a goal for a participant to eat 5 servings of fruits and vegetables, users are considered to have adhered if they have met that goal. We define attrition similarly to Eysenbach's "nonusage attrition" [6]. Attrition refers to the population-level phenomenon of participants stopping use of an app and not returning as time goes on. This makes attrition a long-term product of poor adherence; improving one necessarily improves the other.

Attrition is not simply a fixed cost when delivering interventions electronically. Attrition can be studied, characterized, and reduced. In calling for a "science of attrition", Eysenbach [6] laid out hypothetical proposed factors influencing attrition for further study. This call was answered with studies that examined attrition in Web-based interventions. Results were disheartening. At least two of these experiments [7,8] ended by concluding that, due to attrition, "...intervention programs may reach those who need them the least" [8]. In one intervention, participants who dropped out were interviewed to closely examine their motivation for discontinuing the program [9]. One major reason for attrition was that participants found the information threatening; they were not comfortable confronting their disease in such a manner. These problems must be overcome in order to have effective mHealth interventions. One solution may be psychological interventions called self-affirmation exercises.

Self-Affirmation Exercises

An effective technique to increase adherence to recommended health behaviors is through the use of *self-affirmation exercises* [10-12]. Self-affirmation exercises are activities in which

individuals focus on and affirm personally important values. For example, a participant who highly values their family would reflect on how their lives reflect this value or specific times when this value has influenced their behavior. Self-affirmation exercises have produced positive effects in many common health goals, including reducing smoking, reducing alcohol consumption, and increasing fruit and vegetable intake [12-17]. Self-affirmations can have long-term effects on behavior, spanning years in one deployment [15]. While the mechanism of self-affirmation's effectiveness is debated, it seems to increase the likelihood that a participant will carefully consider information in a threatened realm; for example, self-affirmed smokers who read information about the deleterious effects of smoking may be less likely to outright reject the information [14]. These effects are present in other domains, including alcohol abuse [18], and in the domain of our experiment, healthy eating [19].

Unfortunately, self-affirmation exercises are often time-consuming writing prompts called values essays. These involve writing for up to 10 minutes about the importance of a single value such as friendships or family [20]. The extensive nature of the values essay makes it a poor fit for delivery through mobile phones. Writing an essay on a mobile phone is time consuming, and interventions that are time consuming may lead to participants not adhering to instructions [21]. Considering the effectiveness of self-affirmation and the increasing deliverance of interventions through mobile phones [22,23], there is a need to adapt self-affirmation exercises to the mobile medium that do not require long writing and reading tasks.

Objectives

Methods other than self-affirmation have been tested to increase adherence and reduce attrition in mHealth interventions. Adding social support to an existing physical and mental well-being intervention was found to increase adherence [24]. An adaptive intervention that modulated exercise difficulty to user ability increased adherence when compared with statically scheduled controls [25]. While these interventions may be effective, they involve major restructuring of systems. Self-affirmation exercises like the ones we implemented could be easily added to many current systems.

We developed an mHealth app called Coach to enable users to record progress toward healthy eating goals. We focused on healthy eating because self-affirmations may decrease the difficulty of motivating participants to change behavior with distant consequences. Coach delivered the self-affirmation exercises that we created. To explore self-affirmation dosing, we compared different experimental groups that completed an extensive self-affirmation exercise initially with groups that continually self-affirmed throughout the study. We addressed the following questions:

- Can self-affirmation exercises be translated to mobile delivery to produce positive changes outside of controlled laboratory settings?
- Do higher doses of self-affirmation result in greater adherence than lower doses of self-affirmation?
- Does a higher dose of self-affirmation result in less attrition due to nonuse?

- What mechanisms mediate the effects of these self-affirmation exercises on behavior?

Methods

Intervention Groups

To test our research questions, we developed and implemented the Coach app to record healthy eating behaviors and deliver our interventions. We randomly assigned participants to 4 groups, a 2 (initial self-affirmation vs control) × 2 (recurrent self-affirmation boosters vs control) factorial design (Figure 1).

In the groups receiving initial self-affirmations, participants completed a self-affirmation in the presurvey portion of the study. Groups receiving booster self-affirmations received small doses of self-affirmation exercises continually throughout the study. Thus, the initial and booster self-affirmations group received a high dose of self-affirmation through the study, while other conditions received lower doses of self-affirmation or none at all.

Recruitment

We primarily recruited participants through online means, including Craigslist (Craigslist Inc, San Francisco, CA, USA), Nextdoor (Nextdoor Inc, San Francisco, CA, USA), and Reddit (Reddit Inc, San Francisco, CA, USA). Another source was an internal email list of a US West Coast research center. Participants were primarily located in the San Francisco Bay Area. Participant eligibility was determined by 3 factors: (1) age over 18 years, (2) available laptop or desktop computer and mobile phone running the Android or iOS operating systems, and (3) fruit and vegetable consumption below recommended levels (5 combined servings per day) [26].

Participants were compensated with a gift certificate for up to a maximum of US \$50 for their participation. Compensation was prorated by amount of participation in the study. To receive full compensation, participants needed to complete the initial survey and the postsurvey, and make 20 out of 28 possible daily entries in the app.

Ethical Approval

This study protocol, HSC-2016-04, was approved on July 13, 2016 by the institutional review board at Xerox PARC, Palo

Alto, CA, USA. Participants completed informed consent forms as the very first step of the intake survey. The informed consent detailed the experiment, compensation, and the participant's ability to withdraw from the study at any time for any reason.

The Coach App System

We developed the Coach app specifically to study behavior change adherence and attrition in an mHealth setting. As such, we implemented only the most central features for reporting behavior and delivering interventions. This can be seen in the relatively unadorned interface in Figure 2. Any other features would only have obscured and confounded our primary research questions. In this experiment, the goal for participants was to consume 5 combined servings of fruit and vegetables per day.

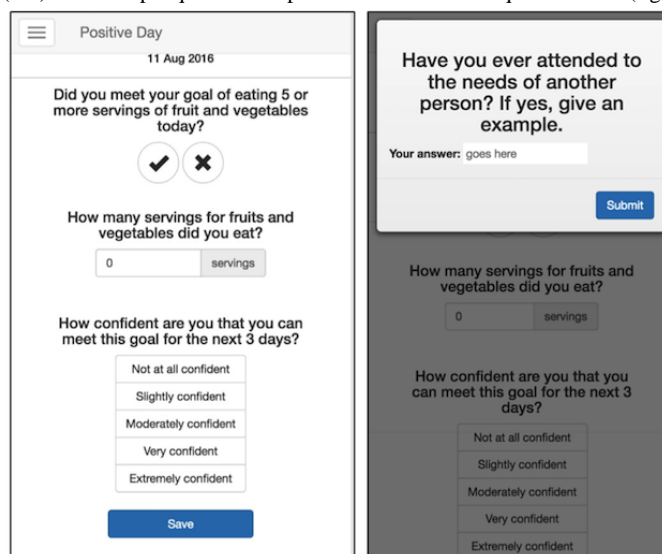
Central to the Coach app is the reporting home page (Figure 2, left). Each day, the reporting page contained 2 primary questions about their progress toward consuming 5 servings of fruits and vegetables and 1 question about their confidence in continuing to meet this goal. This page saved the reported information and was updatable throughout the entire day. At the end of the day, the 3 questions were recorded in their final form and the page was cleared to enable reporting for the upcoming day.

Ancillary to the main reporting page were the exercises that were delivered once per week (on days 5, 12, 19, and 26) to participants in the booster conditions. Users received a push notification that there were questions for them to answer in the app. On tapping the notification or manually opening the app, they were greeted with a pop-up window that asked them questions. For the groups receiving self-affirmation boosters, the self-affirming questions were shown in this pop-up window, whereas controls were shown unrelated opinion questions. After answering these questions, participants were taken to the report page.

Two other screens were accessible in the app from the main drop-down menu. The first was an About screen that described the app and linked to the terms and condition of use. The second screen consisted of instructions on how to report within the app and instructions for general use.

Figure 1. The 2x2 experimental design demonstrates the different independent variables across the groups.

<input type="checkbox"/> Initial Self-Affirmations	<input checked="" type="checkbox"/> Initial Self-Affirmations
<input type="checkbox"/> Booster Self-Affirmations	<input type="checkbox"/> Booster Self-Affirmations
<input type="checkbox"/> Initial Self-Affirmations	<input checked="" type="checkbox"/> Initial Self-Affirmations
<input checked="" type="checkbox"/> Booster Self-Affirmations	<input checked="" type="checkbox"/> Booster Self-Affirmations

Figure 2. The Coach app homepage (left) and example question adapted from the kindness questionnaire (right).

App Content

Self-Affirmation Initial Manipulation

Following Sherman et al [27], the initial affirmation was a standard values essay. First, participants rank ordered a list of 10 values, such as esthetic appreciation, relations with friends and family, and romantic values. Then participants wrote 3 reasons that their number 1–ranked value was important to them and wrote about a past experience where they demonstrated that value. Participants in the control condition were similarly asked to write about their last (10th)-ranked value and 3 reasons it could be important to someone else and how such a person might demonstrate that value.

Self-Affirmation Booster

In this work, we adapted a commonly used self-affirmation exercise [28] for use in the Coach app. The self-affirmation exercise we adapted is known as a kindness questionnaire. This kindness questionnaire is a set of 10 yes-no binary questions that participants answer and may elaborate on. The kindness questionnaire has been shown to have equal self-affirming effects to the longer values essays [29]. Previous self-affirmation interventions followed a model of extensive self-affirming, displaying threatening health information, and then evaluating participants [10]. We broke this mold to more closely examine the effects of self-affirmation timing and dose on health behavior change.

Rather than extensive self-affirming, we used multiple small self-affirmations we called *booster self-affirmations*. Booster self-affirmations were inspired by similar previous works that administered self-affirmations repeatedly over the course of longer-term experiments [15,30]. However, these experiments used the original time-consuming self-affirmation exercises that may not integrate easily into mHealth apps. A previous study suggested that there is no minimum level of engagement with self-affirmation exercises to gain their positive effects [13], which gave us room to adapt these exercises. To lessen the writing burden and make self-affirmations less time consuming

on mobile phones, we adapted the kindness questionnaire [28] to a form more suitable for mobile devices.

Rather than showing the full 10 questions to the participants during a booster affirmation, we simply showed them 2 questions for each affirmation booster. Figure 2 (right) shows an example question adapted from the kindness questionnaire. We adapted questions so participants could include both the binary answer and an example in the given text box [13]. These questions from the kindness survey were specifically constructed so that nearly everyone would answer affirmatively [28]. Participants in the control conditions for the boosters received similarly adapted questions from the control manipulation (asking non-self-affirming questions) to ensure that control participants received the same number of notifications and spent a similar amount of time in the app [28].

Manipulation Check

The manipulation check immediately followed the initial self-affirmation manipulation or control manipulation. The manipulation check consisted of a 3-item scale to assess the degree of self-affirmation that participants felt [31]. It consisted of 3 questions starting with “The task on values made me think about things,” and participants answered on scales of “Things I don’t like about myself” to “Things I like about myself;” “Things I’m bad at” to “Things I’m good at;” and “Things I don’t value about myself” to “Things I value about myself.”

Threatening Health Information

Following the manipulation check, participants were shown a document outlining the risks of not consuming enough fruit and vegetables. This is standard practice for self-affirmation interventions that attempt to improve health behaviors [10,14,19,28]. The self-affirmation seems to allow participants to better accept health information that may be threatening [18]. The threatening health information document was based on a webpage created by the UK National Health Service (NHS) [26]. These NHS recommendations mirrored United States Department of Agriculture (USDA) recommendations in [32], and the text we used was not labeled as being from the NHS. We chose the NHS text because it was more succinct than

comparable sources from the USDA. We slightly modified the text to better highlight significant health threats attributed to not consuming enough fruits and vegetables, including obesity, cancer, high blood pressure, stroke, and diabetes.

Extended Parallel Process Model Measure

We examined participants' responses to our self-affirmations and threatening stimuli in the context of the extended parallel process model (EPPM). The EPPM explains the effects of fear appeals on intentions and behavior change [33]. Recall that self-affirmation exercises often follow the outline of a fear appeal: the participant self-affirms, then they are shown threatening health information. Recent work exploring self-affirmation theory and the EPPM [12] found that self-affirmation contributed to explained variance of intentions to change consumption of fruits and vegetables but did not examine the resulting behavior. Unfortunately, Napper et al [12] ignored fear as a first-class model parameter. According to Witte [33], the entire point of the EPPM is "putting the fear back into fear appeals."

We measured the major EPPM constructs: self-efficacy, response efficacy, threat, and intention. We also measured fear responses via the Positive and Negative Affect Schedule with added measures to form a fear subscale [34]. These measures, excluding fear, were identical to the measures used in a previous study examining the EPPM and self-affirmation [12]. The measured constructs were threat, efficacy, and intentions. Threat was measured by 1 severity item ("How serious are the health consequences of not eating at least 5 portions of fruit and vegetables each day?") and 2 susceptibility items ("My chances of experiencing heart disease or some cancers in the future if I do not eat at least 5 portions of fruit and vegetables each day are..." and "How likely is it that you will experience poor health in the future if you do not eat at least 5 portions of fruit or vegetables each day?"). Efficacy was measured by 2 self-efficacy items ("I know for sure that I could adhere to eating at least 5 fruit and vegetables each day if I really wanted to" and "If I were to eat at least 5 portions of fruit and vegetables each day I would reduce my risk of heart disease and some cancers") and 1 response-efficacy item ("Eating at least 5 portions of fruit and vegetables each day will reduce my risk of heart disease and some cancers"). Previous studies indicated that these measures are internally consistent; the Cronbach alpha of the combined threat measure was .77, and the combined efficacy measure was .78 [12]. Use of self-affirmation in health-related realms follows the model of a fear appeal; thus, the EPPM should provide us with information about which variables in the model are affected by self-affirmation.

Statistical Analysis

First, we examined adherence. Our longitudinal data consisted of users tracking whether they successfully met their fruit and vegetable consumption goal each day. Given that this is a binary response variable, we modeled it using a logistic regression. However, individuals may have initial differences and there may also be temporal differences in how users respond over the course of the 28-day study. To address these differences, we used a mixed-effects logistic regression that allowed us to control for the temporal and individual differences and carefully

examine the fixed differences of the initial self-affirmation and self-affirmation boosters.

Second, we examined attrition. We used a Kaplan-Meier survival curve to visually examine the full cohort's survival curve. We then fitted a Cox proportional hazards model to examine whether the self-affirmation conditions had an effect on not just adherence, but overall attrition from the app.

Third, we examined the mechanisms behind self-affirmation using the EPPM. This analysis used a linear regression model to examine how different factors interacted with the self-affirmation to influence user intentions.

We calculated the number of participants needed for this analysis using Diggle's longitudinal power analysis [35]. We specified a significance level of .05, power of .80, $n=28$ repeated measures, and a conservative repeated measures correlation of .6. We used Fotuhi's effect size of 0.24 [36], which was the closest experimental design to ours that used self-affirmation in a health behavior context. This calculation resulted in requiring 132 participants for a fully powered experiment.

Results

Sample Characteristics

Recruitment resulted in 134 participants completing the intake survey. Among these, 127 downloaded and signed up within the Coach mobile app. Of these 127 participants, 90 identified as female, 36 identified as male, and 1 identified as nonbinary. Participants reported averaging 2.23 servings of fruits and vegetables the day before filling out the intake survey. To confirm that no group differences existed at intake, we tested baseline group differences in possible confounds. No differences existed in age ($P=.24$), sex ($P=.79$), ethnicity ($P=.89$), body mass index ($P=.50$), or prior average intake of fruits and vegetables ($P=.26$). There was no discernable difference in the manipulation check between initial conditions ($t_{119,08}=-0.34$, $P=.74$).

Self-Affirmation and Behavior Change

Our first research question concerned whether a higher dose of self-affirmation would increase goal adherence for our participants. This means that the group receiving both the initial affirmation and affirmation boosters would outperform the other conditions in meeting their daily goals of fruit and vegetable consumption. We tested this hypothesis using a mixed-effects logistic regression model. The model was specified with random effects to control for participant differences and temporal differences. Condition independent variables (initial affirmation and booster affirmation) were specified as fixed effects with an interaction. We found that participants who received both the initial affirmation and booster affirmations were significantly more likely ($P=.04$), to meet their goals of fruit and vegetable consumption throughout the study. Higher coefficients in Table 1 indicate higher log odds of a participant in each condition reporting they met their fruit and vegetable intake goal. As Figure 3 shows, this resulted in overall higher probability of adherence in the group receiving the highest dose of self-affirmation exercises.

Table 1. Coefficients for the logistic regression model of goal adherence.

Coefficients	Coefficient estimate	SE	z value	P value
(Intercept)	0.56	0.35	1.61	.11
Initial self-affirmation	-0.12	0.50	-0.25	.81
Self-affirmation boosters	-0.38	0.50	-0.76	.45
Initial * boosters	1.42	0.71	2.01	.04 ^a

^aSignificant at $P < .05$.

Figure 3. Percentage of goals met by condition.

Self-Affirmation and Attrition

Our second research question concerned the relationships of self-affirmation dose and attrition. We examined attrition using the Kaplan-Meier survival curve and Cox proportional hazards model. We defined a user to have dropped out of the study after they had missed 5 consecutive daily entries. While this may be conservative, we arrived at this number by examining the variance in total times reported compared with the longest streak of consecutive misses from the participants. We noted that variance was generally low for participants with miss streaks between 1 and 4, indicating that they generally went on to complete the remaining study. However, around a miss streak of 5, the variance grew dramatically, indicating that participants who missed 5 entries in a row became more likely to drop out and never return to the study. This method is analogous to using the well-established scree test for determining the number of factors in a factor analysis [37]. For the following attrition analyses, we defined the time of dropout as the first day in a string of 5 or more consecutive nonreports from a single participant.

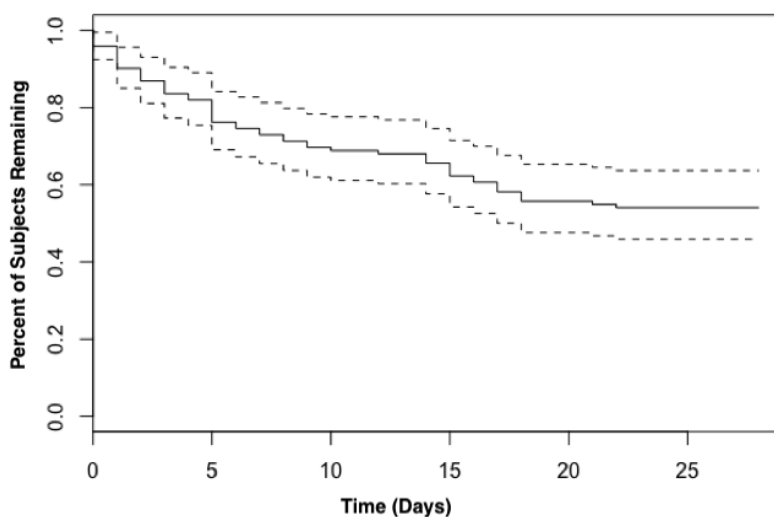
Figure 4 shows the full cohort's attrition curve with 95% confidence intervals. This was calculated using a Kaplan-Meier estimator with right-censored survival data. Right-censored data fitted our data because many participants "survived" until the end of the experiment; therefore, we don't truly know how long they would have continued reporting after the experiment finished. The survival curve generally follows what has been found previously for eHealth app adoption. The curve is fairly steep at the beginning and then gradually flattens to a core group of users over time [6].

To test for differences in survival between conditions, we calculated a Cox proportional hazards model. We specified the proportional hazards dropout using EPPM variables (intentions, threat, response efficacy, self-efficacy, and fear) and the condition. This model using EPPM variables and condition was significant at $P = .04$. Table 2 shows the coefficients of this model.

Mechanism of Self-Affirmation's Effects

Our final research question concerned what mechanisms mediate the effects of self-affirmation. To examine this, we measured and modeled the EPPM in order to see which factors of the model were modified by the initial self-affirmation exercises.

We expected that including the initial self-affirmation as a predictor in the EPPM model would increase the explained variance in intentions of the model. Consistency between subscale items in the EPPM questions was high (alpha range .80-.89) and thus we averaged the subscales to create single scores for each subitem. We specified a linear regression in the form of Napper et al [12] with the addition of the averaged fear subscale (Table 3 shows the coefficients). Given that we included fear as a primary variable, we specified fear and an interaction between self-efficacy and fear within the model in accordance with the original conception of the danger control process [33]. We found strong support for the EPPM model as a whole ($R^2 = .39$, $P < .001$), but the addition of initial affirmation and associated interactions as predictors did not improve the explanatory power of the model. Table 3 shows the final EPPM model.

Figure 4. “Survival” of Coach app participants as shown by a Kaplan-Meier survival curve with 95% confidence intervals (dashed lines).**Table 2.** Coefficients for the Cox proportional hazards model.

Coefficients	Coefficient estimate	SE	z value	P value
Initial self-affirmation	-0.02	0.43	-0.05	.96
Self-affirmation boosters	0.18	0.41	0.43	.67
Self-efficacy	0.19	0.31	0.60	.55
Response efficacy	-0.05	0.35	-0.14	.89
Intentions	0.10	0.31	0.33	.74
Fear	0.17	0.05	3.69	<.001 ^a
Initial * boosters	0.28	0.56	0.50	.61

^aSignificant at $P < .05$.

Table 3. Coefficients for the extended parallel process model linear regression model.

Coefficients	Coefficient estimate	SE	z value	P value
(Intercept)	1.52	1.17	1.31	.19
Threat	-0.45	0.36	-1.26	.21
Self-efficacy	0.05	0.39	0.12	.89
Response efficacy	0.42	0.10	4.29	<.001 ^a
Fear	0.23	0.09	2.64	<.001 ^a
Initial self-affirmation	0.59	0.53	1.13	.26
Threat * self-efficacy	0.16	0.11	1.48	.14
Fear * self-efficacy	-0.08	0.03	-3.01	<.001 ^a
Fear * initial	0.04	0.03	1.12	.27
Threat * initial	0.01	0.13	0.09	.93
Self-efficacy * initial	-0.25	0.15	-1.70	.09

^aSignificant at $P < .05$.

Discussion

Principal Results

We demonstrated that continual self-affirmation exercises resulted in increased adherence among participants using an

mHealth app targeting increasing fruit and vegetable consumption. However, our work also demonstrated the difficulty in adapting traditional laboratory-based interventions to the unstructured lives of mobile users. Traditional interventions for self-affirmation are relatively unstructured but are supported by the consistency of the laboratory environments

in which they are administered. These results indicate that carefully constructed self-affirmation exercises can be integrated into unstructured daily life through mHealth systems and may improve adherence as a result.

Self-Affirmation Promotes Adherence

We demonstrated significant positive effects on adherence for the experimental group that engaged in higher doses of self-affirmations. The group receiving an initial self-affirmation and booster self-affirmations met their daily goals 21% more than the control (72.8 [317/435] and 60.4 [306/506], respectively, where numbers in brackets show how many goals the participants met over the records the participants made of their healthy eating where they didn't meet their goals; see [Figure 2](#)); this effect is large enough to have major effects in real-world scenarios.

Perhaps even more important, we demonstrated that this effect can be achieved in the context of an mHealth app. To our knowledge, no previous work on self-affirmation has used mHealth apps. mHealth apps present problems for typical self-affirmation exercises, including constantly changing environments, competing attentional requirements, and different affordances for inputs. This work indicated that self-affirmation exercises can be adapted in ways that make them amenable to increasing adherence in mHealth contexts. In turn, this enables these increases in adherence to benefit large groups of people, since mHealth apps have the ability to be deployed to a large number of people quickly.

Self-Affirmation Exhibits Dosing Effects

We supported our primary hypothesis that repeated self-affirmation promotes goal-achieving behaviors in the context of an mHealth system designed to increase fruit and vegetable consumption. Interestingly, we seemed to have found a dose effect in the administration of self-affirmation exercises. Previous studies had increased doses of self-affirmation [15,30], but did not closely examine these effects. Our work may point toward a dose effect. The only group that significantly differed was the group that received both the initial and booster affirmations, the highest overall dose. This contrasts with previous hypotheses from Steele, the original author of the self-affirmation theory; as Steele [38] wrote: "there is no evidence yet to suggest that a minimum level of engagement with the manipulations is required before an individual is sufficiently affirmed." Our work challenges this assumption and calls for further investigation into the dose-dependent effects of self-affirmation.

Prior experiments recording participant behavior after a single self-affirmation exercise have been mixed in showing beneficial effects. Some studies demonstrated that participants made beneficial behavioral changes in the weeks and months after self-affirming [13,14,19]. Others showed that, while participants' initial attitudes and processing changed, their behavior was not affected by a single self-affirmation [18,28,39]. Similar to many of these studies, our group receiving only an initial self-affirmation did not show significant behavioral changes. Additionally, our initial self-affirmation group failed its manipulation check to differentiate it from the conditions

that did not complete the initial self-affirmation. It is possible that previous studies and this study found no differences for a single self-affirmation because these doses of self-affirmation simply were not high enough to elicit changes. Another possibility is that the instability of administering these self-affirmation exercises outside of a laboratory setting increased the threshold of the dose needed.

An alternative interpretation of our results could be that, rather than exhibiting dosing effects, different self-affirmation exercises have varying effectiveness outside of laboratory settings. The values essay that served as our initial self-affirmation was relatively unstructured; participants wrote freely in answering a prompt with a few questions. The self-affirmations that we constructed based on the kindness questionnaire were more structured; we asked participants specific targeted questions and they then answered with an example from their lives. We cannot confirm that more structured self-affirmation exercises are more effective outside of laboratory settings, but this should be explored further. However, previous results indicated that unstructured self-affirmation exercises such as a values essay may be effective in Web-based contexts [30].

Mechanism of Self-Affirmation

In agreement with previous work, the EPPM predicted intentions to change behavior ($R^2=.39$). However, unlike in previous work by Napper et al [12], in our study, the self-affirmation condition added no explanatory effect. We measured the EPPM factors only after the initial self-affirmation in groups that received it; if we had repeated this measure at the end of the study following the higher doses, it is possible that we would have seen the effects that we hypothesized.

We expected to see an interaction between self-affirmation and self-efficacy but did not find that. Self-efficacy and self-affirmation have shown strong interactions in previous studies. These studies showed that self-affirmation benefitted those who were most at risk and felt that they did not have self-resources available to make the behavior changes required. Again, we expect that the lack of interaction between self-affirmation and self-efficacy in our data was due to the small effect of the initial affirmation.

In addition, we expected that fear levels would predict intentions. The EPPM indicates that fear affects intentions only as mediated by perceived threat [33,40]. However, this experiment indicated that fear influences intentions directly, as well as in interaction with self-efficacy. In a study by Popova [40], high perceived efficacy and presence of fear influenced danger control outcomes (high intentions), although mediated by perceived threat. Our results, however, do not support this hypothesis. First, in our model perceived threat did not mediate the relationship between fear or self-efficacy and intentions. Second, we found the opposite interaction between fear or self-efficacy and intentions. We found that, at high levels of self-efficacy, higher levels of fear actually corresponded with decreased intentions. At lower levels of efficacy, fear corresponded to higher intentions.

mHealth System Recommendations

We found support for the inclusion of self-affirmation into systems promoting behavior change. We delivered self-affirmation in a way that is more amenable to mobile apps and resulted in improved adherence to health goals, thereby increasing health behaviors. Our results indicate that, in mobile environments, the dose of self-affirmation may matter greatly. This may be due to the changing environment when administering such interventions in natural settings.

As we have demonstrated, this form of self-affirmation is effective for behavior change in mHealth apps designed to improve user eating habits. Other studies have supported the effectiveness of more manual self-affirmation interventions with targets such as education [11], well-being and happiness [30], physical activity [41], smoking cessation [14], and reducing alcohol consumption [13]. Many mobile apps already exist to help support people in these realms, but none, to our knowledge, have integrated self-affirmation to increase this support. Self-affirmation could play a valuable role in increasing the effectiveness of these apps, particularly for users who may be most at risk.

Limitations

This study had a few limitations that should be acknowledged when considering the results. Our study was underpowered. Our power analysis showed that we required 132 participants to be fully powered; due to 7 dropouts between the intake survey and app download, we analyzed only 127 participants.

Additionally, 70.9% (90/127) of our sample identified as female; this could limit transferability to larger populations. It is also possible that our compensation strategy for participants influenced their adherence and attrition. While participants across conditions were all paid the same, it is possible that there was some interaction between compensation and self-affirmation that we cannot discern with this design.

Future Work

We call for other systems researchers to examine their own mobile apps with an eye toward integrating these self-affirmation exercises to enhance their systems. While we demonstrated positive effects from self-affirmation in the context of healthy eating, prior non-mHealth experiments indicated broad applicability of mHealth to different behavior change targets. Self-affirmation has the potential to be the digital analog to aspirin: an intervention that has positive effects on behavior in many apps. Our self-affirmation exercises are simple to implement and require only a short time commitment. Translating these interventions to the mobile world has created a highly scalable and customizable technique to enhance behavior change.

This work raises a question of correct self-affirmation dose and response thresholds. This work indicates that higher doses of self-affirmation exercises may be effective in increasing goal adherence. Future work could explore the effectiveness of various self-affirmation schedules in augmenting existing mHealth apps with appropriate self-affirmation dosing schedules.

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Conflicts of Interest

None declared.

References

1. Krebs P, Duncan DT. Health app use among US mobile phone owners: a national survey. *JMIR Mhealth Uhealth* 2015;3(4):e101 [FREE Full text] [doi: [10.2196/mhealth.4924](https://doi.org/10.2196/mhealth.4924)] [Medline: [26537656](https://pubmed.ncbi.nlm.nih.gov/26537656/)]
2. Catlin AC, Cowan CA. History of health spending in the United States, 1960-2013. Baltimore, MD: Centers for Medicare & Medicaid Services; 2015 Nov 19. URL: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/HistoricalNHEPaper.pdf> [accessed 2018-06-20] [WebCite Cache ID 70Jz12g7A]
3. Steinhubl SR, Muse ED, Topol EJ. The emerging field of mobile health. *Sci Transl Med* 2015 Apr 15;7(283):283rv3. [doi: [10.1126/scitranslmed.aaa3487](https://doi.org/10.1126/scitranslmed.aaa3487)] [Medline: [25877894](https://pubmed.ncbi.nlm.nih.gov/25877894/)]
4. Elbert NJ, van Os-Medendorp H, van Renselaar W, Ekeland AG, Hakkaart-van Roijen L, Raat H, et al. Effectiveness and cost-effectiveness of ehealth interventions in somatic diseases: a systematic review of systematic reviews and meta-analyses. *J Med Internet Res* 2014;16(4):e110 [FREE Full text] [doi: [10.2196/jmir.2790](https://doi.org/10.2196/jmir.2790)] [Medline: [24739471](https://pubmed.ncbi.nlm.nih.gov/24739471/)]
5. Carter MC, Burley VJ, Nykjaer C, Cade JE. Adherence to a smartphone application for weight loss compared to website and paper diary: pilot randomized controlled trial. *J Med Internet Res* 2013;15(4):e32 [FREE Full text] [doi: [10.2196/jmir.2283](https://doi.org/10.2196/jmir.2283)] [Medline: [23587561](https://pubmed.ncbi.nlm.nih.gov/23587561/)]
6. Eysenbach G. The law of attrition. *J Med Internet Res* 2005;7(1):e11 [FREE Full text] [doi: [10.2196/jmir.7.1.e11](https://doi.org/10.2196/jmir.7.1.e11)] [Medline: [15829473](https://pubmed.ncbi.nlm.nih.gov/15829473/)]

7. Glasgow RE, Nelson CC, Kearney KA, Reid R, Ritzwoller DP, Strecher VJ, et al. Reach, engagement, and retention in an Internet-based weight loss program in a multi-site randomized controlled trial. *J Med Internet Res* 2007;9(2):e11 [FREE Full text] [doi: [10.2196/jmir.9.2.e11](https://doi.org/10.2196/jmir.9.2.e11)] [Medline: [17513282](https://pubmed.ncbi.nlm.nih.gov/17513282/)]
8. Verheijden MW, Jans MP, Hildebrandt VH, Hopman-Rock M. Rates and determinants of repeated participation in a web-based behavior change program for healthy body weight and healthy lifestyle. *J Med Internet Res* 2007;9(1):e1 [FREE Full text] [doi: [10.2196/jmir.9.1.e1](https://doi.org/10.2196/jmir.9.1.e1)] [Medline: [17478410](https://pubmed.ncbi.nlm.nih.gov/17478410/)]
9. Nicholas J, Proudfoot J, Parker G, Gillis I, Burckhardt R, Manicavasagar V, et al. The ins and outs of an online bipolar education program: a study of program attrition. *J Med Internet Res* 2010;12(5):e57 [FREE Full text] [doi: [10.2196/jmir.1450](https://doi.org/10.2196/jmir.1450)] [Medline: [21169169](https://pubmed.ncbi.nlm.nih.gov/21169169/)]
10. Epton T, Harris PR, Kane R, van Koningsbruggen GM, Sheeran P. The impact of self-affirmation on health-behavior change: a meta-analysis. *Health Psychol* 2015 Mar;34(3):187-196. [doi: [10.1037/hea0000116](https://doi.org/10.1037/hea0000116)] [Medline: [25133846](https://pubmed.ncbi.nlm.nih.gov/25133846/)]
11. van Koningsbruggen GM, Harris PR, Smits AJ, Schüz B, Scholz U, Cooke R. Self-affirmation before exposure to health communications promotes intentions and health behavior change by increasing anticipated regret. *Commun Res* 2014 Oct 28;43(8):1027-1044. [doi: [10.1177/0093650214555180](https://doi.org/10.1177/0093650214555180)]
12. Napper LE, Harris PR, Klein WMP. Combining self-affirmation with the extended parallel process model: the consequences for motivation to eat more fruit and vegetables. *Health Commun* 2013 Oct 18;29(6):610-618. [doi: [10.1080/10410236.2013.791962](https://doi.org/10.1080/10410236.2013.791962)]
13. Armitage CJ, Harris PR, Arden MA. Evidence that self-affirmation reduces alcohol consumption: randomized exploratory trial with a new, brief means of self-affirming. *Health Psychol* 2011 Sep;30(5):633-641. [doi: [10.1037/a0023738](https://doi.org/10.1037/a0023738)] [Medline: [21553966](https://pubmed.ncbi.nlm.nih.gov/21553966/)]
14. Armitage CJ, Harris PR, Hepton G, Napper L. Self-affirmation increases acceptance of health-risk information among UK adult smokers with low socioeconomic status. *Psychol Addict Behav* 2008 Mar;22(1):88-95. [doi: [10.1037/0893-164X.22.1.88](https://doi.org/10.1037/0893-164X.22.1.88)] [Medline: [18298234](https://pubmed.ncbi.nlm.nih.gov/18298234/)]
15. Cohen GL, Garcia J, Purdie-Vaughns V, Apfel N, Brzustoski P. Recursive processes in self-affirmation: intervening to close the minority achievement gap. *Science* 2009 Apr 17;324(5925):400-403 [FREE Full text] [doi: [10.1126/science.1170769](https://doi.org/10.1126/science.1170769)] [Medline: [19372432](https://pubmed.ncbi.nlm.nih.gov/19372432/)]
16. Fielden AL, Sillence E, Little L, Harris PR. Online self-affirmation increases fruit and vegetable consumption in groups at high risk of low intake. *Appl Psychol Health Well-Being* 2016 Jan 26;8(1):3-18. [doi: [10.1111/aphw.12059](https://doi.org/10.1111/aphw.12059)]
17. Harris PR, Brearley I, Sheeran P, Barker M, Klein WMP, Creswell JD, et al. Combining self-affirmation with implementation intentions to promote fruit and vegetable consumption. *Health Psychol* 2014 Jul;33(7):729-736. [doi: [10.1037/hea0000065](https://doi.org/10.1037/hea0000065)] [Medline: [24490648](https://pubmed.ncbi.nlm.nih.gov/24490648/)]
18. Harris PR, Napper L. Self-affirmation and the biased processing of threatening health-risk information. *Pers Soc Psychol Bull* 2005 Sep;31(9):1250-1263. [doi: [10.1177/0146167205274694](https://doi.org/10.1177/0146167205274694)] [Medline: [16055644](https://pubmed.ncbi.nlm.nih.gov/16055644/)]
19. Epton T, Harris PR. Self-affirmation promotes health behavior change. *Health Psychol* 2008 Nov;27(6):746-752. [doi: [10.1037/0278-6133.27.6.746](https://doi.org/10.1037/0278-6133.27.6.746)] [Medline: [19025270](https://pubmed.ncbi.nlm.nih.gov/19025270/)]
20. MCQueen A, Klein WMP. Experimental manipulations of self-affirmation: a systematic review. *Self Identity* 2006 Oct;5(4):289-354. [doi: [10.1080/15298860600805325](https://doi.org/10.1080/15298860600805325)]
21. van Dulmen S, Sluijs E, van Dijk L, de Ridder D, Heerdink R, Bensing J. Patient adherence to medical treatment: a review of reviews. *BMC Health Serv Res* 2007 Apr 17;7:55 [FREE Full text] [doi: [10.1186/1472-6963-7-55](https://doi.org/10.1186/1472-6963-7-55)] [Medline: [17439645](https://pubmed.ncbi.nlm.nih.gov/17439645/)]
22. Burke LE, Styn MA, Sereika SM, Conroy MB, Ye L, Glanz K, et al. Using mHealth technology to enhance self-monitoring for weight loss: a randomized trial. *Am J Prev Med* 2012 Jul;43(1):20-26 [FREE Full text] [doi: [10.1016/j.amepre.2012.03.016](https://doi.org/10.1016/j.amepre.2012.03.016)] [Medline: [22704741](https://pubmed.ncbi.nlm.nih.gov/22704741/)]
23. O'Malley G, Dowdall G, Burls A, Perry IJ, Curran N. Exploring the usability of a mobile app for adolescent obesity management. *JMIR Mhealth Uhealth* 2014;2(2):e29 [FREE Full text] [doi: [10.2196/mhealth.3262](https://doi.org/10.2196/mhealth.3262)] [Medline: [25098237](https://pubmed.ncbi.nlm.nih.gov/25098237/)]
24. Du H, Venkatakrisnan A, Youngblood GM, Ram A, Pirolli P. A group-based mobile application to increase adherence in exercise and nutrition programs: a factorial design feasibility study. *JMIR Mhealth Uhealth* 2016;4(1):e4 [FREE Full text] [doi: [10.2196/mhealth.4900](https://doi.org/10.2196/mhealth.4900)] [Medline: [26772910](https://pubmed.ncbi.nlm.nih.gov/26772910/)]
25. Konrad A, Bellotti V, Crenshaw N, Tucker S, Nelson L, Du H, et al. Finding the Adaptive Sweet Spot: Balancing Compliance and Achievement in Automated Stress Reduction. New York, NY: ACM Press; 2015.
26. National Health Service. Eat well: why 5 A Day? NHS Choices. London, UK: gov.uk; 2015 Dec 12. URL: <https://www.nhs.uk/live-well/eat-well/why-5-a-day/> [accessed 2018-06-18] [WebCite Cache ID 70Gja5B1i]
27. Sherman DK, Cohen GL, Nelson LD, Nussbaum AD, Bunyan DP, Garcia J. Affirmed yet unaware: exploring the role of awareness in the process of self-affirmation. *J Pers Soc Psychol* 2009 Nov;97(5):745-764. [doi: [10.1037/a0015451](https://doi.org/10.1037/a0015451)] [Medline: [19856999](https://pubmed.ncbi.nlm.nih.gov/19856999/)]
28. Reed MB, Aspinwall LG. Self-affirmation reduces biased processing of health-risk information. *Motiv Emot* 1998 Jun;22(2):99-132. [doi: [10.1023/A:1021463221281](https://doi.org/10.1023/A:1021463221281)]
29. Armitage CJ, Rowe R. Testing multiple means of self-affirmation. *Br J Psychol* 2011 Aug;102(3):535-545. [doi: [10.1111/j.2044-8295.2010.02014.x](https://doi.org/10.1111/j.2044-8295.2010.02014.x)] [Medline: [21752004](https://pubmed.ncbi.nlm.nih.gov/21752004/)]

30. Nelson SK, Fuller JAK, Choi I, Lyubomirsky S. Beyond self-protection: self-affirmation benefits hedonic and eudaimonic well-being. *Pers Soc Psychol Bull* 2014 Aug;40(8):998-1011. [doi: [10.1177/0146167214533389](https://doi.org/10.1177/0146167214533389)] [Medline: [24781897](https://pubmed.ncbi.nlm.nih.gov/24781897/)]
31. Napper L, Harris PR, Epton T. Developing and testing a self-affirmation manipulation. *Self Identity* 2009 Jan;8(1):45-62. [doi: [10.1080/15298860802079786](https://doi.org/10.1080/15298860802079786)]
32. 5 A Day. Alexandria, VA: United States Department of Agriculture. Food and Nutrition Service; 2017 May 11. URL: <https://www.fns.usda.gov/tn/5-day> [accessed 2018-06-20] [WebCite Cache ID 70K24tBZ]
33. Witte K. Putting the fear back into fear appeals: the extended parallel process model. *Commun Monogr* 1992 Dec;59(4):329-349. [doi: [10.1080/03637759209376276](https://doi.org/10.1080/03637759209376276)]
34. Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. *J Pers Soc Psychol* 1988 Jun;54(6):1063-1070. [Medline: [3397865](https://pubmed.ncbi.nlm.nih.gov/3397865/)]
35. Diggle P, Liang K, Zeger S. *The Analysis of Longitudinal Data*. Oxford, UK: Clarendon Press; 1994.
36. Fotuhi O. *Implicit Processes in Smoking Interventions* [dissertation]. Waterloo, ON: University of Waterloo; 2013.
37. Ford JK, MacCallum RC, Tait M. The application of exploratory factor analysis in applied psychology: a critical review and analysis. *Pers Psychol* 1986 Jun;39(2):291-314. [doi: [10.1111/j.1744-6570.1986.tb00583.x](https://doi.org/10.1111/j.1744-6570.1986.tb00583.x)]
38. Steele CM. The psychology of self-affirmation: sustaining the integrity of the self. *Adv Exp Soc Psychol* 1988;21:261-302. [doi: [10.1016/S0065-2601\(08\)60229-4](https://doi.org/10.1016/S0065-2601(08)60229-4)]
39. Kamboj SK, Place H, Barton JA, Linke S, Curran HV, Harris PR. Processing of alcohol-related health threat in at-risk drinkers: an online study of gender-related self-affirmation effects. *Alcohol Alcohol* 2016 Nov;51(6):756-762. [doi: [10.1093/alcac/agw013](https://doi.org/10.1093/alcac/agw013)] [Medline: [26993737](https://pubmed.ncbi.nlm.nih.gov/26993737/)]
40. Popova L. The extended parallel process model: illuminating the gaps in research. *Health Educ Behav* 2012 Aug;39(4):455-473. [doi: [10.1177/1090198111418108](https://doi.org/10.1177/1090198111418108)] [Medline: [22002250](https://pubmed.ncbi.nlm.nih.gov/22002250/)]
41. Cooke R, Trebaczyk H, Harris P, Wright AJ. Self-affirmation promotes physical activity. *J Sport Exerc Psychol* 2014 Apr;36(2):217-223. [doi: [10.1123/jsep.2013-0041](https://doi.org/10.1123/jsep.2013-0041)] [Medline: [24686957](https://pubmed.ncbi.nlm.nih.gov/24686957/)]

Abbreviations

EPPM: extended parallel process model

NHS: National Health Service

USDA: United States Department of Agriculture

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Original Paper

Mobile Phone-Based Ecological Momentary Intervention to Reduce Young Adults' Alcohol Use in the Event: A Three-Armed Randomized Controlled Trial

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Abstract

Background: Real-time ecological momentary interventions have shown promising effects in domains other than alcohol use; however, only few studies regarding ecological momentary interventions for alcohol use have been conducted thus far. The increasing popularity of smartphones offers new avenues for intervention and innovation in data collection.

Objective: We aimed to test the efficacy of an ecological momentary intervention, comprising mobile Web-based ecological momentary assessments (EMAs) and text messaging (short message service, SMS) brief interventions, delivered during drinking events using participants' mobile phones.

Methods: We conducted a three-armed randomized controlled trial to assess the effect of a mobile Web-based ecological momentary assessment with texting feedback on self-reported alcohol consumption and alcohol-related harms in young adults. Participants were enrolled from an existing observational cohort study of young adults screened for risky drinking behavior. The intervention group (ecological momentary intervention group) completed repeated ecological momentary assessments during 6 drinking events and received immediate texting-based feedback in response to each ecological momentary assessment. The second group (ecological momentary assessment group) completed ecological momentary assessments without the brief intervention, and the third did not receive any contact during the trial period. Recent peak risky single-occasion drinking was assessed at the baseline and follow-up using telephone interviews. We used a random effects mixed modeling approach using maximum likelihood estimation to provide estimates of differences in mean drinking levels between groups between baseline and 12-week follow-up.

Results: A total of 269 participants were randomized into the 3 groups. The ecological momentary intervention group exhibited a small and nonsignificant increase between baseline and follow-up in (geometric) the mean number of standard drinks consumed at the most recent heavy drinking occasion (mean 12.5 vs 12.7). Both ecological momentary assessment and control groups exhibited a nonsignificant decrease (ecological momentary assessment: mean 13.8 vs 11.8; control: mean 12.3 vs 11.6); these changes did not differ significantly between groups (Wald χ^2_2 1.6; $P=.437$) and the magnitude of the effects of the intervention were markedly small. No other significant differences between groups on measures of alcohol consumption or related harms were observed. The intervention acceptability was high despite the technical problems in delivery.

Conclusions: With a small number of participants, this study showed few effects of an SMS-based brief intervention on peak risky single-occasion drinking. Nevertheless, the study highlights areas for further investigation into the effects of EMI on young adults with heavy alcohol consumption.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12616001323415; <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=369534> (Archived by WebCite at <http://www.webcitation.org/7074mqwcs>)

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KEYWORDS

alcohol; brief intervention; ecological momentary assessment; randomized controlled trial; mHealth; mobile phone; young adults

Introduction

Risky single-occasion drinking (RSOD, defined as ≥ 5 Australian standard drinks, ie, 50 g of alcohol in one session) is a significant cause of preventable morbidity and mortality in Australia and contributes to further social, economic, and legal harms. RSOD is particularly common in young adults; almost half of 18- to 24-year-olds engage in RSOD at least monthly with approximately one-quarter of this age group doing so at least weekly [1]. Similar patterns are observed among 25- to 29-year-olds, with almost 40% engaging in RSOD at least monthly and approximately 20% at least weekly [1].

Brief interventions (BIs) are one of few individual-level strategies that have demonstrated efficacy for reducing alcohol consumption in young people [2,3]; these interventions commonly involve screening and assessing drinking behavior and providing personalized feedback. Research has revealed that BIs can be feasibly and acceptably delivered through Web-based technologies; these innovations reduce cost, enhance convenience, and expand intervention reach. A recent systematic review assessed the effects of 93 computer-delivered interventions and reported small but significant effects on 5 alcohol outcomes [4]. In young people, specifically, Kypri et al [5] and Voogt et al [6] have demonstrated the efficacy of Web-based BIs for reducing RSOD.

Researchers have harnessed mobile phone technology to study alcohol consumption and intervention in participants' natural environments. Some studies have focused solely on the use of mobile phones as remote data collection tools to conduct ecological momentary assessments (EMA), which are repeated, real-time behavioral surveys. EMAs are an alternative to the usual methods of measuring alcohol consumption, which often involve long-recall periods or averaging of usual drinking [7].

Suffoletto et al used short message service (SMS) text messaging for both data collection and intervention in their studies investigating the use of texting for reducing alcohol consumption [8,9,10]. In a feasibility trial, young adults screened for hazardous alcohol consumption in emergency departments were asked to report the total and maximum single-occasion drinking each week on either Saturday or Sunday via SMS text messaging, with the intervention group sent immediate texting feedback and advice [8]. They found that the intervention group consumed fewer drinks per drinking day in the last month at follow-up compared to controls. In a subsequent study, they expanded their method by asking young people to report their

intentions to drink on the coming weekend, commitment to reduce drinking, and later, their actual weekly drinking [9]. Tailored advice was sent to participants based on their responses. The authors found small reductions in their intervention group's self-reported drinks per day and number of drinking days, compared to the control group [9]. While both previous studies recruited participants from emergency departments, more recent research from Suffoletto et al demonstrated that texting BIs show promise as a booster to a face-to-face-delivered program for reducing alcohol consumption in college students who had violated a campus alcohol policy [10].

Further work has capitalized on the ability for texting to reach participants not only in their environments but also in real-time, as behavior occurs. EMA is a generic term that encapsulates the repeated sampling of behavior in natural environments [11] and has been used to describe both weekly and daily data collection. Kuntsche and Robert demonstrated the feasibility of collecting alcohol EMA data using SMS text message-delivered survey links [12]. In their study, on weekend nights, the participants were sent an SMS text message probing their intention to drink and motivation to drink. The following day, they were asked to report the number of drinks consumed the previous night and whether their drinking had any consequences. Previous research has demonstrated no reactivity to EMAs (ie, completing EMAs does not affect drinking behavior) [7,12].

However, EMA can also be used for event-based sampling, providing rich snapshots into participants' lives and behaviors as they unfold. EMA with event-based sampling have reduced recall bias, as participants are reporting their behaviors, experiences, and state of mind as they occur, without needing to rely on memory to reconstruct their event [11], thereby facilitating more valid inferences about the nature of time-varying, episodic behaviors, such as drinking, as well as other contextual factors associated with drinking (eg, mood, location, and smoking) [7,11]. When these data are collected together, in real time, we can gain rich and accurate insights into the dynamic patterns of behavior and experience, with an enhanced capacity to detect the antecedents and modifiers of behavior, as well as outcomes [11]. Hence, event-based EMA methods represent an important advancement in our ability to understand alcohol consumption and can be extraordinarily rich sources of data for informing our attempts to modify drinking behavior.

Ecological momentary intervention (EMI) is an extension of EMA that provides intervention based on responses provided in EMA. Logically, the design of EMI depends on the intensity and nature of EMA to which it responds. Just as EMA can be delivered during risk events, such as drinking episodes, EMI can be delivered at a point of time when a behavior of interest is occurring. Cohn et al described the potential for EMI to be delivered when individuals are at greatest risk and when they may be vulnerable to violating a behavior change goal [13]. The effectiveness of real-time interventions appears to be enhanced when EMA are used to tailor content delivered within EMI [14]. In domains other than alcohol use, real-time mobile phone interventions have shown success in improving health behaviors, including sexual health and risk behavior [15,16], smoking cessation [17,18], weight management [19,20], and physical activity [21]. However, few studies have investigated the effects of EMI on alcohol consumption.

Riordan et al focused on tertiary students during the orientation week (the week before classes start for first-year students, usually involving many social events) in their trial of SMS text message-delivered EMI [22]. They sent intervention and control groups 4 EMAs by SMS during orientation week and once per week during semester to assess alcohol consumption in the day prior to assessment. Participants in the intervention condition additionally received an SMS text message with health consequence warnings on each night of the orientation week. The authors reported a reduction in alcohol consumption in females but not in males in the intervention group during orientation week [22]. In a subsequent study of students from 2 residential colleges, Riordan et al sent intervention and control groups 2 EMAs by SMS text messages during orientation week to assess daily alcohol consumption and 7 fortnightly EMAs during the first semester to assess weekend drinking. In addition, an EMI condition comprised 2 intervention SMS text messages per night on 4 drinking-focused social events during orientation week, with content covering social consequences of alcohol use. In one college, a significant difference was found in alcohol consumption with fewer drinks consumed by the EMI condition across orientation week and over the academic year; however, no significant differences were observed between conditions in the second college [23]. A key strength of Riordan et al's later study is that they began to explore real-time intervention, that is, intervening at the time that the targeted behavior (drinking) was actually occurring. Further opportunities exist to integrate event-based sampling with "real-time EMI;" this involves tracking behavior and responding as it occurs and has proven effective in other health domains [15-21].

This study addresses a gap in this emerging area of research, contributing to the literature on mobile phone-delivered, real-time alcohol EMI. We aimed to test the efficacy of an EMI, comprising mobile Web-based EMAs and texting BIs, delivered during drinking events using participants' mobile phones. We hypothesized that the EMI group would report a reduction in the alcohol consumption compared with the control group receiving no contact.

Methods

We conducted a three-armed randomized controlled trial (RCT; ACTRN12616001323415) to assess the effect of a mobile Web-based EMA with texting feedback on self-reported alcohol consumption and alcohol-related harms in young adults. The study was registered with Australian New Zealand Clinical Trials Registration. We adhered to the recommendations of the CONSORT-EHEALTH checklist [24].

Participants

Participants were recruited from the Young Adults Alcohol Study (YAAS) [25], which is an observational cohort study of young adults living in Melbourne, Australia. This study has included annual telephone interviews, and participants have never previously been offered any intervention. The YAAS cohort study commenced in 2012 with a representative sample of 802 Melburnians aged 18-25 years, screened for engagement in very high-risk drinking (≥ 7 standard drinks in a single occasion for females and ≥ 10 for males) [25]. In 2015, the original 802 participants were contacted for a third wave of data collection and invited to participate in the current study. An additional 51 participants were recruited to YAAS in 2015, using the same random digit dialing procedure and screening criteria and were also invited to participate in the current study. Participants were eligible if they owned a smartphone and reported recent risky drinking behavior (≥ 5 drinks in a single session in the past 3 months). The 2015 YAAS data served as the baseline for this trial, at which time all participants were aged 18-29 years.

Recruitment and Procedures

Participants who agreed to be contacted about the trial were randomly allocated to one of the 3 arms as follows: an intervention group that received a BI delivered over mobile phone (EMI group) or two control groups in which the participants either completed EMAs without BI (EMA group) or did not receive any contact throughout the trial period (no-contact group). Participants were sent detailed information about their group's specific procedures and were asked to register to use the relevant intervention. The nature of the intervention meant that it was impossible to blind participants; however, they remained unaware of the detailed procedures of the other arms. Those who did not register for their intervention were followed up by telephone. A non-respondent questionnaire was administered for those contacted to document reasons for refusal. Once registered, participants in the EMI and EMA groups were immediately able to sign up for their "event nights," which were self-selected nights that they planned to drink on; reminders to sign up for nights were sent weekly for 12 weeks. Follow-up telephone interviews commenced 12 weeks after the first person registered and ran over 4 weeks. Participants were not called until they had reached 12 weeks postregistration but were contacted regardless of their adherence to the intervention (ie, an intention-to-treat approach).

Design of Ecological Momentary Assessment and Ecological Momentary Intervention

The intervention, including both EMA and intervention message components, was co-designed by young people in a development study that utilized focus group workshops, individual testing, and in-depth follow-up interviews. A total of 40 participants contributed to the development of the overall design of the intervention, including EMA questionnaires, timing, frequency, technology platforms, and message content. After testing the intervention, participants deemed the intervention content, mode of delivery, and burden as acceptable and feasible [26,27]. The content, language, and framing of the content for EMI messages was also informed by the participatory co-design process used in the development study [26], with messages refined according to principles of motivational interviewing theory [28]. We refined our message content based on feedback received in our development study follow-up interviews, which included both a survey, rating scales for individual messages received, and an in-depth interview. This refinement process included removing unpopular messages and message themes, creating alternative messages with similar text for high-rating messages (to ensure variety when tested on multiple nights), and creating new messages as suggested by participants in their follow-up interviews. We then contracted a programmer to build an online module that could capture survey data and send automated tailored SMS text message in response. We spent 4 months testing and refining the system to resolve technical errors before commencing the study.

Ecological Momentary Assessment Data Collection

Participants from the EMI and EMA groups were asked to choose 6 weekend nights on which they were planning to drink during the 12-week study period to complete EMA surveys. No minimum consumption was specified. Participants were prompted each Thursday afternoon with an SMS text message reminder to register the nights over the weekend on which they planned to drink.

The 6 pm presurvey comprised questions about the participants' intentions for the night, including how much they planned to drink, spend, and eat; a ranked list of particular adverse events they wished to avoid; their planned mode of transport home; next day plans; any alcohol consumption so far; mood; and the option of writing a message to themselves, which would be sent back to them during the night. At hourly intervals between 7 pm and 2 am, participants were sent a shorter EMA questionnaire asking about the current venue type, alcohol consumption since the last survey, spending, mood, and self-reported drunkenness. Participants were able to opt out of the intervention at the end of each questionnaire if their evening's drinking was about to end. At 11 am the next day, all participants were sent another questionnaire about alcohol consumption and spending that occurred after the final EMA (ie, after 3 am or when they completed their last EMA of the night), estimated total standard drink consumption and money spent for the night, an estimated volume of water consumed during the night, adverse events, whether a hangover was experienced, and a "fun" rating of the night.

Ecological Momentary Intervention Messages

In addition to completing EMAs, the EMI group received the texting BI component. Following submission of each EMA questionnaire throughout intervention nights, they received a tailored feedback SMS text message. All feedback SMS text messages during the night contained information reminding the EMI participants of their original intentions or motivations, tips to avoid adverse consequences, or feedback relating to cumulative consumption or spending. These messages were based on a different key variable each hour. The messages comprised a range of columns in which each message was classified by "gender," "time," "location," "drunkenness," "motivation," as well as some variables that were pertinent to a particular message type prescribed for a time point (ie, whether the participant had eaten, which was only relevant to tailoring in the first message at 6 pm). Different messages were written to ensure that there was a suitable option for different contexts that they might find themselves in. For example, participants in a nightclub might receive a message reminding them to get water next time they were at the bar, whereas a different message would be suitable for participants at a house party. A range of messages were written for each hour and context based around what participants reported their motivations to be so as to reduce the repetition of messages. The system was set up so that any participant could not receive the same message twice over the course of the whole intervention period. The length of messages varied, with shorter messages sent later in the night, and shorter, simpler messages sent to people reporting higher levels of intoxication. The development of message content for this intervention has been described in two previous publications [27,29], and further detail regarding the tailoring of messages, including examples of messages, are provided in the protocol publication [30]. The messages were underpinned by motivational interviewing and BI theory [26,27]; we used the FRAMES framework to inform our approach [28,31,32].

Control Groups

The first control group (EMA) followed the EMA data collection procedure described earlier (including registration for 6 intervention nights and all questionnaires on each night) but did not receive any feedback via an SMS text message. This EMA group was included in the trial to investigate reactivity and whether completing assessments alone (without SMS text message feedback) can affect drinking behavior. The second control group (no contact) received no contact until follow-up, which occurred 12 weeks after the baseline assessment. In this study, the no-contact group was the primary control group compared to the EMI group in analysis.

Reimbursement

Participants from the EMI and EMA groups received reimbursements based on the level of participation in this study. For each event completed (maximum 6), participants received \$10. If all 6 were completed, a bonus of \$20 was given. Participation in the follow-up survey was valued at \$20. Thus, participants who completed all 6 events and the follow-up interview received \$100 in cash or voucher. The no-contact group members received \$20 for completing the follow-up telephone survey.

Ethics

We obtained ethics approval for this RCT from the Monash University Human Research Ethics Committee (CF15/3600 - 2015001556). The Alfred Health Research Ethics Committee approved the YAAS cohort study (35/12).

Primary Outcome Measure

The primary outcome measure was the peak number of drinks consumed in a single night (peak RSOD) at baseline and follow-up, and the primary comparison was between those receiving the intervention (EMI) and the primary control participants (no contact). Our focus on heavy drinking from an occasional or binge perspective is because this pattern is the main risky drinking pattern in our target age group [25,33]. This outcome was measured by asking participants about the number of drinks consumed in their heaviest drinking occasion in the past 3 months at both baseline and follow-up telephone interviews.

Secondary Outcome Measures

Secondary outcomes of interest were measured at both baseline and follow-up interviews and included alternative measures for risky alcohol consumption and experiences of alcohol-related harms. Secondary alcohol consumption measures were derived from the graduated frequency measures [34]. The graduated frequency questionnaire included the following questions: "In the past 12 months, how often have you had 20 or more standard drinks in a day?" with response options including "Every day," "5 to 6 days a week," "3 to 4 days a week," "1 to 2 days a week," "1 day a week," "2 to 3 days a month," "About 1 day a month," and "Less often than 1 day a month." The question was then repeated inquiring about frequency of consumption: 11-19 standard drinks, 7-10 standard drinks, 5-6 standard drinks, 3-4 standard drinks, and 1-2 standard drinks. We used data from these questions to derive annual consumption of >730 standard drinks per year, as it equates to >2 standard drinks per day, which reflects the Australian National Health and Medical Research Council guidelines for alcohol consumption. If >365 drinking days were reported, the 365 heaviest drinking days were included. In addition, we reported on the monthly consumption of ≥ 11 drinks in a single session. The Australian National Drug Strategy Household Survey commonly uses the threshold of ≥ 5 drinks in a single session to define risky episodic drinking; however, our participants had already been screened for recent drinking above this threshold and it was therefore appropriate to investigate a higher threshold [25].

Reporting of alcohol-related harms included yes/no/don't know responses to items derived from the GenACIS [35] and VYADS questionnaires [36], which included the following statements that referred to occurrences of harm on their heaviest drinking occasion in the past 3 months: "Did you get into any verbal arguments or verbal fights on that occasion?," "Did you fail to do what you intended to do the day after the session?" and "Did you have any trouble getting home on that occasion?" For the transport-related question, respondents answering "yes" were asked to define the nature of the trouble; response options included the following: "Had to wait"; "Didn't have enough money"; "Missed last train/tram/bus"; "Couldn't find a

taxi/Uber"; "Taxi/Uber wouldn't take me"; "My lift/designated driver left before me"; "I had an accident (bicycle/other)"; "Got lost"; "Felt unsafe"; "Had to call someone to pick me up"; or "Other (specify)."

Illicit drug use was measured using an item derived from GenACIS [35], which included a Yes/No response to the following statement: "Did you consume any drugs on that occasion that includes illicit drugs, or pharmaceutical drugs that were not prescribed to you?" This outcome was included as reported previously that illicit drug use is associated with heavy drinking events in young people in Melbourne [37].

We assessed both feasibility and acceptability in the follow-up survey using Likert scales to rate several aspects of the respondents' experiences of the intervention. Both EMA and EMI group participants were asked to what extent they agreed with the following statements: "Filling in the surveys was quick;" "Filling in the surveys was easy;" "I enjoyed filling in the surveys;" "My friends knew that I was doing the surveys during the nights;" "Doing the surveys helped me to think about keeping track of my drinking and spending;" "Doing the surveys helped me to think about having a safer night;" "Doing the surveys didn't interrupt my night too much;" "I didn't want friends to know that I was doing the surveys;" "The surveys were too long;" and "Doing the surveys made me want to drink more."

Furthermore, we asked EMI group participants to evaluate BI message acceptability by asking to what extent they agreed with the following statements: "The messages that I received were useful;" "The messages that I received were relevant;" "I shared the message with my friends during the night;" and "Receiving the messages helped me to keep track of my drinking and spending."

Sample Size

Power calculations were based on the primary aim of reducing mean peak RSOD by 2.5 drinks in the EMI group compared to the no-contact group. Assuming an SD of the peak RSOD of 5.2, 67% endpoint participation, 90% power, and 5% significance, we estimated that a sample of 127 participants per group was required. The sample size estimate was calculated to test for a group-by-time interaction from a mixed repeated measures design, and a moderate correlation between subject measurements ($r=.45$, estimated from earlier waves of YAAS data). Further details are reported in the published protocol [30].

Statistical Analyses

For the primary outcome, we used a random effects mixed modeling approach using maximum likelihood estimation to provide estimates of differences in mean drinking levels between the EMI and no contact group between baseline and 12-week follow-up. In this model, we modeled study participants as random factors (ie, random intercept) and group allocation as a fixed factor. Our primary focus of analysis was the interaction between intervention and study time (baseline vs follow-up). As the sample distribution of participants' peak RSOD exhibited some evidence of positive skew, we estimated the natural log of the peak RSOD in mixed modeling analyses and reported geometric means. In addition, we used postestimation analyses

to derive model marginal means and performed Wald tests for differences between partial interaction terms and their joint significance. Using nested mixed modeling for each group-by-time contrast, Cohen f^2 standardized effect sizes [38], which show the proportion of variance explained for a group, were derived from the decomposition of model residual error terms. To investigate differences between groups in the secondary outcome measures, we used generalized linear mixed modeling specifying a logit link function and binomial distribution. We analyzed data from all participants who consented to participate in the trial and were randomized, regardless of their adherence to the planned intervention and participation in follow-up (ie, an intention-to-treat approach). Maximum likelihood estimation in mixed modeling provided unbiased estimates in the light of study attrition assuming missingness takes a missing at random process [39]. All statistical analyses were performed using the Stata statistical software package (version 13.1, Statacorp LLC, USA) [40].

Results

Participants

Figure 1 presents the participants' flow. Of the original 802 YAAS participants, 373 completed wave 3 in 2015, which was fewer than anticipated. A total of 59 participants were ineligible for the trial either due to not drinking at risky levels ($n=51$) or not owning a smartphone ($n=8$). Of the 314 eligible participants, 269 participants agreed to be contacted about the trial and were

randomized into 3 groups as follows: EMI ($n=90$); EMA ($n=89$); and no-contact control ($n=90$). Following receipt of the study information, 101 participants completed the online registration form (EMI=26, EMA=31, and no contact=44), falling short of our target of 300 participants [30]. Of the 81 participants who directly declined to participate over the phone or by SMS text message, the primary reason for refusal was due to work/study commitments ($n=23$); however, many also stated that they felt that their time in the YAAS cohort meant they had contributed enough to research ($n=15$). Some participants stated that they did not drink enough for the study to be relevant despite meeting the drinking-related eligibility criteria ($n=10$). A minority felt that the study design and requirement of 6 intervention nights was too intensive ($n=8$) or did not provide a reason ($n=7$). Following the 12-week study period, 87 participants could be contacted for the follow-up telephone survey. Furthermore, 2 participants were excluded from the primary outcome analysis as outliers ($SD>3.29$ from sample means; ie, $P<.001$) with respect to the peak RSOD measure.

Although rates of registration for the intervention varied between the 3 groups, at intervention commencement there were no statistically significant differences between groups in demographic characteristics (Table 1). The sample that registered to receive the intervention had more females (60%) than males, whereas the 2015 YAAS wave comprised 46% females. There were otherwise no differences in the demographic characteristics of the trial sample compared to participants from the 2015 wave.

Figure 1. CONSORT flowchart.

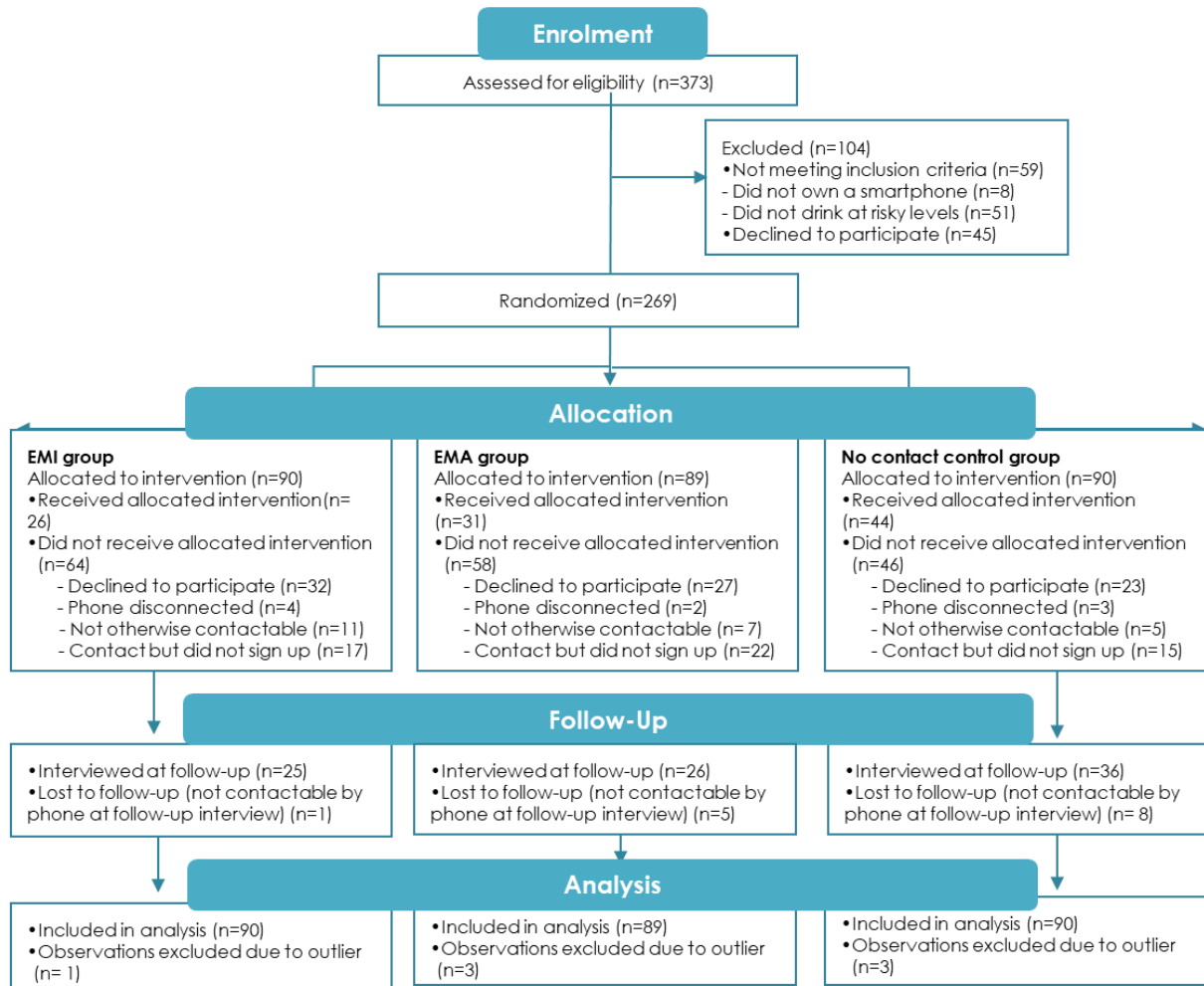


Table 1. Baseline sample characteristics by study group counts (n), percent (%), and probability values (*P* values) from chi-square inferential tests.

Sociodemographic characteristics	EMI ^a (n=90), n (%)	EMA ^b (n=89), n (%)	No contact (n=90), n (%)	Total (n=269), n (%)	<i>P</i> value
Gender					.38
Female	46 (51)	37 (42)	45 (50)	128 (48)	
Male	44 (49)	52 (58)	45 (50)	141(52)	
Age (n=263)					.69
18-24 years	59 (67)	62 (70)	56 (64)	177 (67)	
25-29 years	33 (29)	26 (30)	31 (36)	86 (33)	
Country of birth					.47
Australia	79 (88)	82 (92)	78 (87)	239 (89)	
Other country	11 (12)	7 (8)	12 (13)	40 (11)	
Recreational spending money (Aus \$)					.13
0-80	9 (10)	16 (18)	6 (7)	31 (12)	
80-160	24 (27)	21 (24)	16 (18)	61 (23)	
160-240	17 (19)	16 (18)	27 (30)	60 (22)	
240+	40 (44)	35 (39)	40 (44)	115 (43)	
Do not know	0 (0)	1 (1)	1 (1)	2 (1)	
Currently studying					.56
Full-time	24 (27)	27 (30)	30 (33)	81 (30)	
Part-time	8 (9)	6 (7)	11 (12)	25 (9)	
Not studying	58 (64)	56 (63)	49 (54)	163 (61)	
Highest level of education					.93
<Year 12	2 (2)	3 (3)	3 (3)	8 (3)	
Year 12	19 (21)	22 (25)	23 (25)	64 (24)	
Tertiary	46 (51)	46 (52)	41 (46)	133 (49)	
Diploma	13 (14)	7 (8)	12 (13)	32 (12)	
Trade	10 (11)	11 (12)	11 (12)	32 (12)	
Sexual orientation					.89
Heterosexual	80 (89)	79 (89)	81 (90)	240 (89)	
Bisexual	7 (8)	8 (9)	8 (9)	23 (9)	
Homosexual	3 (3)	2 (2)	1 (1)	6 (2)	
Living circumstances					.14
With both parents	46 (51)	49 (55)	37 (41)	132 (49)	
One parent	15 (17)	14 (16)	11 (12)	40 (15)	
Not with parents	29 (32)	26 (29)	42 (47)	97 (36)	

^aEMI: ecological momentary interventions.

^bEMA: ecological momentary assessments.

Table 2. Log peak risky single-occasion drinking (RSOD) at baseline and follow-up by study group: marginal geometric means for number of drinks consumed in most recent heavy drinking occasion, *P* value for group by time interaction, and partial group by time contrasts (standardized effect size [Cohen f^2] and *P* value) from random effects linear mixed modeling^a (n=265).

EMI ^b , marginal means ^c (CI)		EMA ^d , marginal means ^c (CI)		No contact, marginal means ^c (CI)		Group-by-time interaction, <i>P</i> value ^e	Partial group-by-time contrasts, f^2 (<i>P</i> value)		
Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up		EMI vs no contact	EMI vs EMA	EMA vs no contact
12.45 (11.0-13.9)	12.7 (10.2- 15.1)	13.8 (12.1-15.5)	11.8 (9.6-14.1)	12.3 (10.8-13.8)	11.6 (9.7-13.5)	.437	0.001 (.537)	0.02 (.442)	0.01 (.442)

^aSeven participant observations (EMI, n=1; EMA, n=3; control, n=3) were excluded because of outlying responses ($P<.001$) on the peak RSOD measure.

^bEMI: ecological momentary interventions.

^cGeometric means.

^dEMA: ecological momentary assessments.

^eJoint Wald test.

^fCohen f^2 represents the proportion of variance explained by each group in respective contrasts.

Participation

For both EMI and EMA groups, 63% (36/57) of participants signed up for 6 or more events and the majority completed surveys for all 6 events (58% [15/26] of the EMI group and 57% [18/31] of the EMA group). EMI participants signed up for a mean of 4.8 events and completed a mean of 4.5 events. EMA participants signed up for a mean of 4.5 events and completed a mean of 4.2. A small number of participants neither signed up for any event (7%; 5/57) nor completed any EMA.

Outcomes

Alcohol Use

Table 2 summarizes results from linear mixed models for the primary outcome analysis. The EMI group showed a small and nonsignificant increase between baseline and follow-up in the mean (geometric) number of standard drinks consumed at the most recent heavy drinking occasion ($M=12.5$ vs $M=12.7$). The EMA and control groups showed a nonsignificant decrease (EMA: $M=13.8$ vs $M=11.8$; control: $M=12.3$ vs $M=11.6$); these changes did not differ significantly between the groups (Wald $\chi^2_2=1.6$; $P=.437$) and the magnitude of the effects of the intervention were markedly small [38]. Table 3 shows that no significant differences existed between the groups regarding any other measures of risky alcohol consumption or experiences of harm. For illustrative purposes, the odds ratios presented in Table 3 should be interpreted as follows: the EMI group had 1.4 times higher odds of reporting long-term, high-risk alcohol consumption than the no-contact group ($P=.76$). We performed Ad hoc analyses to include the completion of the 6 “events” with EMI or EMA as a covariate in the model for the primary outcome; however, this did not make any difference in the results (data not shown).

Acceptability

Participation rates provide insight into intervention acceptability. Although the primary reasons for nonparticipation were associated with external factors, mostly work and study commitments, the EMI and EMA groups attained lower participation (EMI=26/90, 29%; EMA=31/89, 35%; randomized) than the no-contact group ($n=44/90$, 49%).

Table 4 outlines EMA and message acceptability as evaluated at the follow-up. Most participants in both EMI and EMA groups agreed that the EMA questionnaires were quick and easy to answer. The proportion of participants in the EMI group who reported that they enjoyed completing the questionnaires was higher than that in the EMA group. Participants in the EMI group were significantly more likely to report that their friends knew that they were completing the questionnaires ($P=.02$). In addition, most EMI participants reported that the messages were useful (69%; 17/25) and relevant (88%; 22/25), with just over half agreeing that “receiving the messages helped me to keep track of my drinking and spending.”

Although we tested all features of the intervention comprehensively leading up to implementation, we still encountered problems, including some questionnaire links not being sent on a requested event night, questionnaire links being sent after participants had opted out during an event, and some feedback messages not being sent for EMI participants. Table 5 describes the nature and frequency of technical difficulties encountered during the study period.

Resourcing Required for Intervention

Both message content and questionnaires were designed during the formative study [26], which took 3 months of a researcher’s time and review from 2 senior researchers. We contracted the Social Research Centre (Melbourne, Australia) to recruit and interview participants. In addition, we purchased a standard license from SurveyGizmo to develop and host our EMA surveys. We contracted SurveySignal to develop and program the online module that sent all EMA SMS text messages, captured data, and sent feedback SMS text message. Researchers spent 4 months testing and refining the program. Each SMS text message cost US \$0.10 to send. For each event night, the EMI and EMA groups were sent up to 23 and 13 SMS text messages, respectively. An additional SMS text message per participant was sent to participants in both groups as a reminder each week. Thus, to participate in the intervention as planned with six full events, the total cost of texting was US \$15 per EMI participant and US \$9 per EMA participant; this does not include participant reimbursement or additional communication regarding technical errors and queries about the research project.

Table 3. Secondary measures of risky alcohol consumption and alcohol-related harms: adjusted odds ratio (adjOR), *P* values from group-by-time interactions, and partial group-by-time contrasts from generalized linear mixed modeling (n=269).

Outcome	EMI ^a , adjOR ^c (CI)	EMA ^b -only, adjOR ^c (CI)	No contact, adjOR ^c (CI)	Group-by-time interaction, <i>P</i> value ^d	Partial group-by-time contrasts, <i>P</i> value		
					EMI vs no contact	EMI vs EMA	EMA vs no contact
Measures of risky alcohol consumption							
High-risk long-term consumption (annual volume ≤730 ASD ^e /year)	1.40 (0.16- 12.39)	2.28 (0.27- 19.08)	(ref)	.74	0.76	0.75	.45
Monthly consumption of 11+ drinks in single occasion	4.73 (0.40- 40.39)	4.62 (0.55- 38.95)	(ref)	.63	0.24	0.31	.16
Experience of harm on recent heavy drinking event							
Any harm	1.43 (0.20- 10.07)	0.63 (0.10- 4.12)	(ref)	.59	0.72	0.73	.63
Risk of verbal harm	1.15 (0.03- 41.83)	0.74 (0.06- 8.97)	(ref)	.57	0.94	0.96	.81
Risk of transport harm	0.90 (0.03- 29.19)	5.86 (0.16- 217.58)	(ref)	.32	0.95	0.44	.34
Failure to complete plans	2.13 (0.23- 19.56)	0.94 (0.13- 7.01)	(ref)	.96	0.50	0.75	.95
Use of other drugs on recent heavy drinking event							
Use of any illicit drug	1.02 (0.07- 15.19)	0.34 (0.02- 5.08)	(ref)	.92	0.99	0.69	.43

^aEMI: ecological momentary interventions.

^bEMA: ecological momentary assessments.

^cadjOR shows model interaction term between study group and time and represents the difference in the change in odds (by time) of the outcome between respective intervention groups and the no-contact group.

^dJoint Wald test.

^eASD: Australian Standard Drinks.

Table 4. Participant agreement with acceptability-related statements by study group: counts (%) and P values from chi-square inferential tests. Agreement was taken as either “agreeing” or “strongly agreeing” with a respective statement.

Statement	EMI ^a (n=25), n (%)	EMA ^b (n=26), n (%)	P value
EMA-related statements			
Filling in the surveys was quick	22 (85)	20 (65)	.09
Filling in the surveys was easy	22 (85)	23 (74)	.34
I enjoyed filling in the surveys	17 (65)	15 (48)	.20
My friends knew that I was doing the surveys during the nights	22 (85)	17 (54)	.02
Doing the surveys helped me to think about keeping track of my drinking and spending	14 (54)	17 (55)	.94
Doing the surveys helped me to think about having a safer night	14 (54)	12 (39)	.26
Doing the surveys didn't interrupt my night too much	19 (73)	15 (48)	.06
I didn't want friends to know that I was doing the surveys	0 (0)	0 (0)	—
The surveys were too long	6 (23)	4 (13)	.31
Doing the surveys made me want to drink more	1 (4)	1 (3)	.90
Brief intervention message-related statements			
The messages that I received were useful	18 (69)	N/A ^c	N/A
The messages that I received were relevant	23 (88)	N/A	N/A
I shared the message with my friends during the night	19 (73)	N/A	N/A
Receiving the messages helped me to keep track of my drinking and spending	15 (58)	N/A	N/A

^aEMI: ecological momentary intervention.

^bEMA: ecological momentary assessment.

^cN/A: not applicable.

Table 5. Participants' experience of technical difficulty by the study group trial arm: counts (%) and P values from chi-square inferential tests.

Technical difficulty type	EMI ^a (n=25), n (%)	EMA ^b (n=26), n (%)	P value
I tried to sign up for a night but nothing happened at all	13 (52)	14 (54)	.90
I signed up for a night and got a message back to say I registered, but didn't receive any surveys	11 (44)	11 (42)	.61
I signed up for a night but didn't receive all surveys	13 (52)	9 (35)	.30
I opted out of the surveys during the night but kept getting surveys through the night	1 (4)	18 (69)	<.001
I had a technical issue actually filling in a survey	9 (36)	1 (4)	.01
I received multiple reminders in one day to sign up for the surveys	15 (60)	15 (58)	.26
The surveys wouldn't display properly on my phone	4 (16)	0 (0)	.07
I was supposed to get feedback messages but they didn't come through	5 (20)	N/A	N/A

^aEMI: ecological momentary intervention.

^bEMA: ecological momentary assessment.

^cN/A: not applicable.

Discussion

Principal Findings

We tested a novel method to collect data and intervene repeatedly during drinking events. No statistically significant differences in peak RSOD or related harms were detected between the groups. Based on previous EMI and mobile phone-delivered BI studies [10,22,23,41,42], we expected to demonstrate a small but significant effect of our EMI on RSOD compared with our control group. Our development study

suggested that our method was acceptable and feasible to participants and demonstrated high levels of engagement and low dropout rate when tested on a single occasion. This study's finding may be a result of low statistical power, meaning a larger sample is needed in future research to test the effects of our intervention.

Alternative explanations for our null findings may relate to our preselection of heavy drinkers and the potential for regression to the mean [43,44]. The greatest reductions in peak RSOD and alcohol-related harms compared with the no-contact group were

observed in the assessment-only group (EMA). Based on previous EMA alcohol studies [7,12] we hypothesized that no reactivity would be observed in this group; however, it is plausible that questions about goal setting and planning in the first questionnaire per night had some intervention effect. These additional questions (recommended by participants in the co-design study for the purpose of message tailoring) require reflection and planning, such as in motivational interviewing therapies [28]. It is possible that responding to these questions could modify RSOD; if this is the case, then it is unknown why the EMA might be more effective without BI messages. The cause could be the specific content of our messages or that BIs were unhelpful in changing alcohol consumption behavior when delivered during drinking events. The latter explanation might be particularly relevant to heavy drinkers; previous research has shown that this population shows increased attentional biases that are thought to promote motivations for alcohol consumption and are resistant to manipulation [45-48]. Thus, research that extends the parameters of our study is needed to assess the effects of EMA and EMI on RSOD, which is important to clarify because if this type of EMA is shown to be effective for changing behavior without BI, then it represents a less intensive and more scalable intervention option, given the complexities involved with effective and acceptable message tailoring. In addition, more participants consented to participate in the EMA than the EMI group, suggesting that the feedback aspect of the EMI was appealing. The EMA group, however, evaluated the questionnaires less favorably than the EMI group and was more likely to drop out of the study between baseline and follow-up, suggesting that the BI messages kept participants more engaged in the intervention.

Overall, our study had lower uptake than we expected, with only 101 participants consenting to participate once they had received the full study information. Our EMI design did require more engagement than previous studies in this area, similar to that by Riordan et al [22,23]; however, we found that only a small proportion of those declining to participate cited study design factors, such as intensiveness and burden, as their reason for refusal (8/81). A far higher proportion reported that they were busy with work or study, not drinking much, or were experiencing research fatigue. From an implementation perspective, there are several other factors, which we believe were important in the small sample size obtained. There was a delay between the YAAS interviews and the RCT information being sent to participants due to the longer time taken to test

our texting system, and this may have dulled participants' enthusiasm. We also found it difficult to clearly and concisely present all information relating to the study in a format that also fulfilled the requirements of the ethics committee. Despite our use of diagrams, the description of procedures seemed overly complex, and we found that when we had the chance to explain the study verbally (in telephone calls to remind/follow-up participants), participants were more inclined to consent. Thus, visual and verbal descriptions of study procedures might be more suitable for complex interventions such as this, where participants are not engaged in-person at any point.

Although this study's findings were inconclusive, it informed new avenues of investigation for further study into the effects of EMA and BI for reducing alcohol consumption.

Limitations

This study has several limitations. First, we were unable to recruit the planned sample size; refusal data showed that a major reason was research fatigue due to participants' prior engagement with the YAAS cohort study. During the recruitment process, few potential participants reported refusal reasons related to intervention intensity or lack of interest; however, the differential recruitment rate between groups suggests that either the intervention lacked appeal or that the study information provided during the consent process was not clear or simple enough. Nonetheless, these findings will inform our future approaches to testing event-level data collection and interventions. Second, challenges related to technical difficulties interfered with the implementation of the EMA questionnaires and feedback messages. Thus, further refinement and testing will be undertaken. Finally, the study relied on self-reported data, which has the potential for reporting bias.

Conclusions

In conclusion, our study showed no significant differences in peak RSOD, other alcohol consumption measures, or alcohol-related harms between groups of young adults receiving repeated EMAs and EMIs, EMAs alone, or no contact. However, small sample sizes meant that only substantial differences could have reached significance. Our study highlights important considerations for implementing interventions of this type in larger studies. It also identifies directions for further investigation into the effects of EMAs and EMIs on young adults who report heavy alcohol consumption, including the possibility of reactivity to EMAs.

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Conflicts of Interest

PMD has received funding from Gilead Sciences Inc and Reckitt Benckiser for work unrelated to this study. The authors declare that they have no other competing interests.

Multimedia Appendix 1

CONSORT E-HEALTH checklist (V 1.6.1).

[[PDF File \(Adobe PDF File\), 832KB - mhealth_v6i7e149_app1.pdf](#)]

References

1. Australian Institute of Health and Welfare. Canberra: Australian Government: AIHW. 2014. National Drug Strategy Household Survey detailed report 2013 URL: <https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey-detailed-report-2013/contents/table-of-contents> [accessed 2017-11-10] [WebCite Cache ID 6zwAJv80D]
2. Saunders JB, Kypri K, Walters ST, Laforge RG, Larimer ME. Approaches to brief intervention for hazardous drinking in young people. *Alcohol Clin Exp Res* 2004 Feb;28(2):322-329. [Medline: [15112940](#)]
3. Kuntsche E, Kuntsche S, Thrul J, Gmel G. Binge drinking: Health impact, prevalence, correlates and interventions. *Psychol Health* 2017 Aug;32(8):976-1017. [doi: [10.1080/08870446.2017.1325889](#)] [Medline: [28513195](#)]
4. Black N, Mullan B, Sharpe L. Computer-delivered interventions for reducing alcohol consumption: meta-analysis and meta-regression using behaviour change techniques and theory. *Health Psychol Rev* 2016 Sep;10(3):341-357. [doi: [10.1080/17437199.2016.1168268](#)] [Medline: [26999311](#)]
5. Kypri K, Hallett J, Howat P, McManus A, Maycock B, Bowe S, et al. Randomized controlled trial of proactive web-based alcohol screening and brief intervention for university students. *Arch Intern Med* 2009 Sep 14;169(16):1508-1514. [doi: [10.1001/archinternmed.2009.249](#)] [Medline: [19752409](#)]
6. Voogt C, Poelen E, Kleinjan M, Lemmers L, Engels R. The effectiveness of the 'what do you drink' web-based brief alcohol intervention in reducing heavy drinking among students: a two-arm parallel group randomized controlled trial. *Alcohol Alcohol* 2013;48(3):312-321. [doi: [10.1093/alcalc/ags133](#)] [Medline: [23303466](#)]
7. Shiffman S, Stone AA, Hufford MR. Ecological momentary assessment. *Annu Rev Clin Psychol* 2008;4:1-32. [Medline: [18509902](#)]
8. Suffoletto B, Callaway C, Kristan J, Kraemer K, Clark DB. Text-message-based drinking assessments and brief interventions for young adults discharged from the emergency department. *Alcohol Clin Exp Res* 2012 Mar;36(3):552-560. [doi: [10.1111/j.1530-0277.2011.01646.x](#)] [Medline: [22168137](#)]
9. Suffoletto B, Kristan J, Callaway C, Kim K, Chung T, Monti P, et al. A text message alcohol intervention for young adult emergency department patients: a randomized clinical trial. *Ann Emerg Med* 2014 Dec;64(6):664-72.e4 [FREE Full text] [doi: [10.1016/j.annemergmed.2014.06.010](#)] [Medline: [25017822](#)]
10. Suffoletto B, Merrill JE, Chung T, Kristan J, Vanek M, Clark DB. A text message program as a booster to in-person brief interventions for mandated college students to prevent weekend binge drinking. *J Am Coll Health* 2016;64(6):481-489 [FREE Full text] [doi: [10.1080/07448481.2016.1185107](#)] [Medline: [27149662](#)]
11. Beckjord E, Shiffman S. Background for Real-Time Monitoring and Intervention Related to Alcohol Use. *Alcohol Res* 2014;36(1):9-18 [FREE Full text] [Medline: [26258996](#)]
12. Kuntsche E, Robert B. Short message service (SMS) technology in alcohol research--a feasibility study. *Alcohol Alcohol* 2009;44(4):423-428. [doi: [10.1093/alcalc/agg033](#)] [Medline: [19482879](#)]
13. Cohn AM, Hunter-Reel D, Hagman BT, Mitchell J. Promoting behavior change from alcohol use through mobile technology: the future of ecological momentary assessment. *Alcohol Clin Exp Res* 2011 Dec;35(12):2209-2215 [FREE Full text] [doi: [10.1111/j.1530-0277.2011.01571.x](#)] [Medline: [21689119](#)]
14. Heron KE, Smyth JM. Ecological momentary interventions: incorporating mobile technology into psychosocial and health behaviour treatments. *Br J Health Psychol* 2010 Feb;15(Pt 1):1-39 [FREE Full text] [doi: [10.1348/135910709X466063](#)] [Medline: [19646331](#)]
15. Levine D. Using technology, new media, and mobile for sexual and reproductive health. *Sex Res Social Policy* 2011;8(1):18-26. [doi: [10.1007/s13178-011-0040-7](#)]
16. Ybarra ML, Bull SS. Current trends in Internet- and cell phone-based HIV prevention and intervention programs. *Curr HIV/AIDS Rep* 2007 Dec;4(4):201-207. [Medline: [18366952](#)]
17. Rodgers A, Corbett T, Bramley D, Riddell T, Wills M, Lin R, et al. Do u smoke after txt? Results of a randomised trial of smoking cessation using mobile phone text messaging. *Tob Control* 2005 Aug;14(4):255-261 [FREE Full text] [doi: [10.1136/tc.2005.011577](#)] [Medline: [16046689](#)]
18. Brendryen H, Kraft P. Happy ending: a randomized controlled trial of a digital multi-media smoking cessation intervention. *Addiction* 2008 Mar;103(3):478-84; discussion 485. [doi: [10.1111/j.1360-0443.2007.02119.x](#)] [Medline: [18269367](#)]

19. Patrick K, Raab F, Adams MA, Dillon L, Zabinski M, Rock CL, et al. A text message-based intervention for weight loss: randomized controlled trial. *J Med Internet Res* 2009 Jan 13;11(1):e1 [FREE Full text] [doi: [10.2196/jmir.1100](https://doi.org/10.2196/jmir.1100)] [Medline: [19141433](https://pubmed.ncbi.nlm.nih.gov/19141433/)]
20. Sherwood NE, Jeffery RW, Pronk NP, Boucher JL, Hanson A, Boyle R, et al. Mail and phone interventions for weight loss in a managed-care setting: weigh-to-be 2-year outcomes. *Int J Obes (Lond)* 2006 Oct;30(10):1565-1573. [doi: [10.1038/sj.ijo.0803295](https://doi.org/10.1038/sj.ijo.0803295)] [Medline: [16552408](https://pubmed.ncbi.nlm.nih.gov/16552408/)]
21. King AC, Ahn DK, Oliveira BM, Atienza AA, Castro CM, Gardner CD. Promoting physical activity through hand-held computer technology. *Am J Prev Med* 2008 Feb;34(2):138-142 [FREE Full text] [doi: [10.1016/j.amepre.2007.09.025](https://doi.org/10.1016/j.amepre.2007.09.025)] [Medline: [18201644](https://pubmed.ncbi.nlm.nih.gov/18201644/)]
22. Riordan BC, Conner TS, Flett JAM, Scarf D. A Brief Orientation Week Ecological Momentary Intervention to Reduce University Student Alcohol Consumption. *J Stud Alcohol Drugs* 2015 Jul;76(4):525-529. [Medline: [26098027](https://pubmed.ncbi.nlm.nih.gov/26098027/)]
23. Riordan B, Conner T, Flett J, Scarf D. A text message intervention to reduce first year university students' alcohol use: A pilot experimental study. *DIGITAL HEALTH* 2017 Apr 26;3:1-10. [doi: [10.1177/2055207617707627](https://doi.org/10.1177/2055207617707627)]
24. Eysenbach G, CONSORT-EHEALTH Group. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. *J Med Internet Res* 2011 Dec 31;13(4):e126 [FREE Full text] [doi: [10.2196/jmir.1923](https://doi.org/10.2196/jmir.1923)] [Medline: [22209829](https://pubmed.ncbi.nlm.nih.gov/22209829/)]
25. Dietze PM, Livingston M, Callinan S, Room R. The big night out: what happens on the most recent heavy drinking occasion among young Victorian risky drinkers? *Drug Alcohol Rev* 2014 Jul;33(4):346-353. [doi: [10.1111/dar.12117](https://doi.org/10.1111/dar.12117)] [Medline: [24628682](https://pubmed.ncbi.nlm.nih.gov/24628682/)]
26. Wright CJC, Dietze PM, Crockett B, Lim MSC. Participatory development of MIDY (Mobile Intervention for Drinking in Young people). *BMC Public Health* 2016 Feb 24;16:184 [FREE Full text] [doi: [10.1186/s12889-016-2876-5](https://doi.org/10.1186/s12889-016-2876-5)] [Medline: [26911299](https://pubmed.ncbi.nlm.nih.gov/26911299/)]
27. Wright CJC, Dietze PM, Lim MSC. Beyond Basic Feedback in Mobile Brief Interventions: Designing SMS Message Content for Delivery to Young Adults During Risky Drinking Events. *JMIR Mhealth Uhealth* 2017 Jun 20;5(6):e79 [FREE Full text] [doi: [10.2196/mhealth.6497](https://doi.org/10.2196/mhealth.6497)] [Medline: [28634153](https://pubmed.ncbi.nlm.nih.gov/28634153/)]
28. Miller W, Rollnick S. Motivational interviewing: helping people change. 3rd ed. New York: Guilford Press; 2013.
29. Wright CJC, Dietze PM, Crockett B, Lim MSC. Participatory development of MIDY (Mobile Intervention for Drinking in Young people). *BMC public health* 2016;16(1):1.
30. Wright CJ, Dietze PM, Agius PA, Kuntsche E, Room R, Livingston M, et al. An Ecological Momentary Intervention to Reduce Alcohol Consumption in Young Adults Delivered During Drinking Events: Protocol for a Pilot Randomized Controlled Trial. *JMIR Res Protoc* 2017 May 25;6(5):e95 [FREE Full text] [doi: [10.2196/resprot.6760](https://doi.org/10.2196/resprot.6760)] [Medline: [28546136](https://pubmed.ncbi.nlm.nih.gov/28546136/)]
31. Humeniuk R, Henry-Edwards S, Ali R, Poznyak V, Monteiro M. The ASSIST-linked brief intervention for hazardous/harmful substance use: a manual for use in primary care. In: Geneva: WHO. Geneva: World Health Organization; 2010:a.
32. Babor T, Higgins-Biddle J. Geneva: Department of Mental Health Substance Dependence, WHO. 2001. Brief intervention for hazardous/harmful drinking: a manual for use in primary care URL: <http://apps.who.int/iris/handle/10665/67210> [accessed 2018-06-05] [WebCite Cache ID 6zwK9gAw4]
33. Kuntsche E, Gmel G. Alcohol consumption in late adolescence and early adulthood--where is the problem? *Swiss Med Wkly* 2013 Jul 25;143:w13826 [FREE Full text] [doi: [10.4414/smw.2013.13826](https://doi.org/10.4414/smw.2013.13826)] [Medline: [23888405](https://pubmed.ncbi.nlm.nih.gov/23888405/)]
34. Greenfield T. Ways of measuring drinking patterns and the difference they make: experience with graduated frequencies. *J Subst Abuse* 2000;12(1-2):33-49. [Medline: [11288473](https://pubmed.ncbi.nlm.nih.gov/11288473/)]
35. Bloomfield K, Allamani A, Beck F, Helmersson BK, Csemy L, Eisenbach-Stangl I. Institute for Medical Informatics, Biometrics & Epidemiology, Charité Universitätsmedizin Berlin. 2005. Gender, culture and alcohol problems: a multi-national study URL: https://www.researchgate.net/profile/Martha_Patricia_Mendoza/publication/309312782_Gender_Culture_and_Alcohol_Problems_a_multinational_study/links/580916cc08ae993dc0509f0f/Gender-Culture-and-Alcohol-Problems-a-multinational-study.pdf [accessed 2018-06-05] [WebCite Cache ID 6zwKO1X7a]
36. Victorian GDOHS. Victorian Youth Alcohol and Drugs Survey. Melbourne, Australia: Premier's Drug Prevention Council: Victorian Government; 2004.
37. Jenkinson R, Jolley D, Dietze P. 'Weekend on the town': discrete sessions of drug use for a sample of young psychostimulant users. *Drug Alcohol Rev* 2014 Jul;33(4):428-435. [doi: [10.1111/dar.12168](https://doi.org/10.1111/dar.12168)] [Medline: [24976190](https://pubmed.ncbi.nlm.nih.gov/24976190/)]
38. Cohen J. Statistical power analysis for the behavioural sciences. 2nd ed. New York: Psychology Press; 1988.
39. Allison P. Estimation of linear models with incomplete data. *Sociological Methodology* 1987;17:17-103.
40. StataCorp. Stata: Release 13. Statistical Software. College Station, TX: StataCorp LP; 2013.
41. Suffoletto B, Kristan J, Callaway C, Kim K, Chung T, Monti P. A text message alcohol intervention for young adult emergency department patients: a randomized clinical trial. *Ann Emerg Med* 2014;64(6):e4. [Medline: [25017822](https://pubmed.ncbi.nlm.nih.gov/25017822/)]
42. Suffoletto B, Kristan J, Chung T, Jeong K, Fabio A, Monti P. An Interactive Text Message Intervention to Reduce Binge Drinking in Young Adults: A Randomized Controlled Trial with 9-Month Outcomes. *PLoS One* 2015;10(11):A. [Medline: [26580802](https://pubmed.ncbi.nlm.nih.gov/26580802/)]
43. Cunningham JA. Regression to the mean: what does it mean? *Alcohol Alcohol* 2006;41(5):580. [doi: [10.1093/alcalc/agl039](https://doi.org/10.1093/alcalc/agl039)] [Medline: [16751218](https://pubmed.ncbi.nlm.nih.gov/16751218/)]

44. Morton V, Torgerson DJ. Effect of regression to the mean on decision making in health care. *BMJ* 2003 May 17;326(7398):1083-1084 [FREE Full text] [doi: [10.1136/bmj.326.7398.1083](https://doi.org/10.1136/bmj.326.7398.1083)] [Medline: [12750214](https://pubmed.ncbi.nlm.nih.gov/12750214/)]
45. Miller MA, Fillmore MT. Persistence of attentional bias toward alcohol-related stimuli in intoxicated social drinkers. *Drug Alcohol Depend* 2011 Sep 01;117(2-3):184-189. [doi: [10.1016/j.drugalcdep.2011.01.016](https://doi.org/10.1016/j.drugalcdep.2011.01.016)] [Medline: [21349660](https://pubmed.ncbi.nlm.nih.gov/21349660/)]
46. Weafer J, Fillmore MT. Acute alcohol effects on attentional bias in heavy and moderate drinkers. *Psychol Addict Behav* 2013 Mar;27(1):32-41 [FREE Full text] [doi: [10.1037/a0028991](https://doi.org/10.1037/a0028991)] [Medline: [22732051](https://pubmed.ncbi.nlm.nih.gov/22732051/)]
47. Field M, Cox W. Attentional bias in addictive behaviors: a review of its development, causes, and consequences. *Drug and alcohol dependence* 2008;97(1):a. [Medline: [18479844](https://pubmed.ncbi.nlm.nih.gov/18479844/)]
48. Field M, Duka T, Eastwood B, Child R, Santarcangelo M, Gayton M. Experimental manipulation of attentional biases in heavy drinkers: do the effects generalise? *Psychopharmacology (Berl)* 2007 Jul;192(4):593-608. [doi: [10.1007/s00213-007-0760-9](https://doi.org/10.1007/s00213-007-0760-9)] [Medline: [17361393](https://pubmed.ncbi.nlm.nih.gov/17361393/)]

Abbreviations

BI: brief intervention
EMA: Ecological Momentary Assessment
EMI: Ecological Momentary Intervention
RCT: randomized controlled trial
RSOD: risky single-occasion drinking
SMS: short message service
YAAS: Young Adults Alcohol Study

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Original Paper

Forecasting the Value for Money of Mobile Maternal Health Information Messages on Improving Utilization of Maternal and Child Health Services in Gauteng, South Africa: Cost-Effectiveness Analysis

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Abstract

Background: Limited evidence exists on the value for money of mHealth information programs in low resource settings.

Objective: This study sought to model the incremental cost-effectiveness of gradually scaling up text messaging services to pregnant women throughout Gauteng province, South Africa from 2012 to 2017.

Methods: Data collection occurred as part of a retrospective study in 6 health centers in Gauteng province. Stage-based short message service (SMS) text messages on maternal health were sent to pregnant women twice per week during pregnancy and continued until the infant's first birthday. Program costs, incremental costs to users, and the health system costs for these women were measured along with changes in the utilization of antenatal care visits and childhood immunizations and compared with those from a control group of pregnant women who received no SMS text messages. Incremental changes in utilization were entered into the Lives Saved Tool and used to forecast lives saved and disability adjusted life years (DALYs) averted by scaling up program activities over 5 years to reach 60% of pregnant women across Gauteng province. Uncertainty was characterized using one-way and probabilistic uncertainty analyses.

Results: Five-year program costs were estimated to be US \$1.2 million, 17% of which were incurred by costs on program development and 31% on SMS text message delivery costs. Costs to users were US \$1.66 to attend clinic-based services, nearly 90% of which was attributed to wages lost. Costs to the health system included provider time costs to register users (US \$0.08) and to provide antenatal care (US \$4.36) and postnatal care (US \$3.08) services. Incremental costs per DALY averted from a societal perspective ranged from US \$1985 in the first year of implementation to US \$200 in the 5th year. At a willingness-to-pay threshold of US \$2000, the project had a 40% probability of being cost-effective in year 1 versus 100% in all years thereafter.

Conclusions: Study findings suggest that delivering SMS text messages on maternal health information to pregnant and postpartum women may be a cost-effective strategy for bolstering antenatal care and childhood immunizations, even at very small

margins of coverage increases. Primary data obtained prospectively as part of more rigorous study designs are needed to validate modeled results.

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KEYWORDS

mHealth; cost effectiveness; cost utility analysis; digital health

Introduction

The use of mobile and wireless technology for health (mHealth) [1] has the potential to address critical gaps in timely and appropriate care-seeking across the continuum of care from pregnancy to postpartum [2]. mHealth solutions that target pregnant women have been shown to increase the utilization of antenatal care (ANC), skilled birth attendance (SBA), and childhood immunization rates [3]. While the program strategies and types of mHealth solutions have varied, delivery of health information content to pregnant women using short message service (SMS) text messaging has been effective in bolstering service utilization in several settings.

In Zanzibar and Malawi, maternal SMS text messaging initiatives have demonstrated a significant effect on the utilization of health services and health outcomes. In Zanzibar, the Wired Mothers Program provided unidirectional SMS text messaging and direct two-way communication using a free call voucher system to provide reminders for ANC visits; gestational age-specific reproductive, maternal, newborn, and child health (RMNCH) information; and an emergency medical response system. Program activities were associated with an increase in ≥ 4 ANC visits (OR 2.39, 95% CI 1.03-5.55) [4], in SBA among urban women (OR 5.73, 95% CI, 1.51-21.81) [5], and reduced perinatal mortality (OR 0.50, 95% CI 0.27-0.90) [6]. In Malawi, the Chipatala Cha Pa Foni program used a toll-free hotline to provide health information and advice, as well as tips and reminders through SMS text messaging tailored to the client's week of pregnancy or child's age. Program activities were associated with improved RMNCH knowledge and behavior including increased utilization of ANC within the first trimester, increased bed-net use for pregnant women and children, and breastfeeding within 1 hour of birth [7].

Beyond these programs, the Mobile Alliance for Maternal Action (MAMA) program has provided stage-based maternal health information using SMS text messaging in Bangladesh, India, Nigeria, and South Africa and has supported content to projects in 54 countries globally. With the exception of formative findings from activities in Bangladesh [8], evidence on the effectiveness of MAMA is limited. Findings from a retrospective case-control study in South Africa suggest a significant increase in the uptake of ≥ 4 ANC visits (Adjusted OR 3.21, 95% CI 1.73-5.98) and comprehensive care, defined as ≥ 4 ANC visits and receiving all vaccinations at 1 year of age (Adjusted OR 3.2, 95% CI 1.63-6.31) [9,10].

The emergence of data suggesting that stage-based SMS text messages on maternal health information may yield improvements in utilization across the continuum of care, from pregnancy, delivery to postpartum, is promising [4-6]. Yet, little

is known about the value for money of maternal SMS text messaging initiatives. Cost-effectiveness analyses (CEAs) aim to generate evidence on the costs and consequences of 2 or more alternatives [11]. CEAs may be used in conjunction with affordability analyses for informed decision-making on the appropriate and optimal allocation of finite resources [11]. In the context of digital health programs, the costs required to establish and support the technological components of the program, including architecture, SMS text messaging delivery, device, and other costs, when coupled with the rapid pace of technology turnover, raise questions about the long-term viability and value of these initiatives compared with alternative resource uses.

To complement efforts to determine the effectiveness of MAMA in South Africa, we modeled the incremental cost-effectiveness of gradually scaling up SMS text messaging services to pregnant women throughout Gauteng province, South Africa from 2012 to 2017. This model-based analysis is anticipated to provide an early estimate of the cost-effectiveness of MAMA and inform future efforts to prospectively monitor costs and consequences of maternal SMS text messaging programs in low- and middle-income countries.

Methods

Setting

In South Africa, 1 in 24 children die before their 5th birthday; 25% due to undernutrition, 25% in the first 28 days of life, and >50% outside of the formal health sector [12]. South Africa has the greatest number of HIV cases globally, and an estimated 32% of maternal deaths are attributed to HIV [13]. With a population of 13.5 million, Gauteng is South Africa's most populous province and comprises 24% of the country's total population [14]. An estimated 29% of the pregnant women in the study area and 12% of the total population in Gauteng were HIV+ [15]. In 2015, HIV and tuberculosis (TB) accounted for 24% of deaths among women and 27% among men 25-64 years of age [16]. In addition to the high burden of HIV and TB, noncommunicable diseases (NCDs) remain a leading cause of mortality and were the cause of over 80% of all deaths in 2015 [16]. While the utilization of care during pregnancy is universal, institutional births are high (97% in 2008-2009) [17], 86% of women receive postnatal care (PNC) in the clinic within 6 days of birth [16], and nearly all children under 1 year of age receive full immunizations [16], significant gaps persist in the timeliness, continuity, and quality of care. During pregnancy, only 49% of women attend their first ANC clinic prior to 20 weeks [16]. HIV testing coverage is the lowest in the country, and at 23%, falls well below the national average of 32%. Finally, timely diagnosis and appropriate management for

hypertension (prevalence of 36% in 2012) and other risk factors for NCDs remain poor.

Program Description

The MAMA program was initiated in 2012 in South Africa to bolster the utilization of RMNCH services among pregnant and postpartum women by sending registered users stage-based SMS text messages twice per week during pregnancy and up to the infant's first birthday [9]. Women attending ANC (n=5111) and PNC (n=4953) services in 6 health facilities from June 15, 2012 to August 19, 2014 were registered to receive bi-weekly MAMA SMS text messages during pregnancy and up to the child's first birthday. Content included information on maternal and postpartum danger signs, nutrition, and care-seeking during pregnancy, delivery, and postpartum. To approximate enrollment trends among pregnant women at scale across Gauteng, we projected the number of registered users based on the monthly trends observed during the MAMA implementation. By year 5, program activities were projected to expand to include the enrollment of an estimated 60% of all pregnant women in Gauteng.

Study Design and Sampling

Data on costs and effects were collected during exit interviews with women attending ANC services in 6 clinics in Johannesburg as part of a retrospective case-control study performed from October 2014 to June 2015. Among 608 eligible women, 356 appeared for requested face-to-face interviews. Of these women, 181 had been allocated to the intervention group and 175 to the comparison group (Multimedia appendix 1). Despite completing exit interviews, significant gaps in the recording of health information on health cards existed, and reliance, where possible, was based on patients' recall of services received. Final analyses were performed on 87 women enrolled during pregnancy to receive MAMA messages and 90 women enrolled into the comparison arm. Women with incomplete data records, those who did not show up for follow-up interviews, or who were enrolled into MAMA during the postpartum period were excluded from the final analyses.

Health Effects

Primary outcome measures assessed as part of the retrospective case-control study included attendance rates for ANC visits 1 through 4 and immunization rates at birth, 6, 10, 14 weeks, and 9 months after birth. We have also presented estimates of the proportion of children fully immunized and those who received comprehensive care (defined as at least 4 ANC visits [ANC4+] and full immunizations). Despite data limitations, findings from the retrospective case-control study suggested that women exposed to SMS text messages were more likely to attend at least the recommended 4 ANC visits (OR 3.21, 95% CI 1.73-5.98) and complete comprehensive care, (OR 3.2, 95% CI 1.63-6.31) than women not exposed [10]. Rates for individual immunizations were also observed to increase by 1%-6%. However, the high baseline rates of utilization coupled with the small number of study participants with complete data indicated that the study was not powered to detect whether these trends were significant. Nevertheless, the trends observed were entered into the Lives Saved Tool (LiST) [18] to generate an estimate

of lives saved through project activities for each year of implementation and adjusted for increases in the number of registered users over the 5-year analytic time horizon. Lives saved were translated into DALYs averted based on a 3% discount rate, no age weighting, and using a life expectancy of 66 years for a South African woman [19].

Costs

For this model-based analysis, economic costs were estimated from a societal perspective inclusive of program, health systems, and user costs for a 5-year analytic time horizon (2012-2017). Program costs were defined as the costs required to develop, start-up, and support ongoing implementation. These were captured using an ingredients approach based on program activities, drawing from financial records and informant interviews with project implementing partners (Wits RHI, Cell-Life, and Praekelt Foundation), and through observations of health care workers providing routine ANC and PNC services within facilities. Costs were further categorized into capital (costs with a life expectancy of >1 year) and recurrent costs, with the former annualized over the lifetime of the project or life span of the item as appropriate and discounted at 3%. Development and start-up phase costs were viewed as one-time activities and similarly annualized over the lifetime of the project.

Incremental costs to the health system sought to capture costs associated with registration and increases in utilization. These included provider time costs to register patients into MAMA, as well as to provide routine clinical services during pregnancy and postpartum, including immunizations. These costs were estimated based on informant interviews, with provider salaries drawn from PayScale.com, an online salary, benefits, and compensation information company, and verified by the human resources department of Wits RHI.

Costs to users included all out-of-pocket payments incurred for care or treatment-seeking, including direct costs associated with medical care (consultation fees, medicine/commodity costs) as well as costs for transport/treatment-seeking and indirect costs due to wages lost resulting from time spent seeking care or away from income-generating activities. These were measured through patient interviews in intervention and comparison arms and generalized to the sample population as rollout occurred.

Data Analysis

Costs were adjusted to 2015 USD dollars using consumer price indices [20] and a foreign exchange rate of 15.40 [21]. Capital costs were annualized using a 3% discount rate and estimates of local life expectancies. Health effects were analyzed using bivariate and multivariable logistic regression. Parameter costs and effects were adjusted to the projected sample population for each of the 5 years of implementation. Incremental costs were divided by incremental health effects to generate a deterministic estimate of the incremental cost-effectiveness ratio (ICER), expressed as a cost per life saved and cost per DALY averted. To test for uncertainty, one-way and probabilistic sensitivity analyses were conducted. The latter was performed in Microsoft Excel using a Monte Carlo simulation with 1000 iterations per analysis. The resulting mean point estimate was

obtained by dividing mean costs by mean effects. The 95% CI for the ICER is presented based on percentiles. A cost-effectiveness plane and cost-effectiveness acceptability curve were used to calculate the probability that the intervention would be cost-effective for each of the several standard thresholds of cost-effectiveness. Cost-effectiveness was ultimately determined according to thresholds set forth by the Commission for Macroeconomics and Health and World Health Organization, which stipulate that an intervention is “highly cost-effective” and “cost-effective” at 1 and 3 times, respectively, the value of per capita gross domestic product per DALY averted. To facilitate comparison with alternative resource uses, we additionally compared findings against those available in the literature, including the Disease Control Priorities Project 3rd edition, which highlights low-cost high-priority interventions for key regions globally.

Results

Figure 1 presents data on the observed and forecasted enrollment trends over the 5-year analytic time horizon of the project. In years 1 and 2, a total of 2879 and 8161 women were enrolled to receive MAMA messages, representing 1% and 3% of total pregnancies in Gauteng, respectively. Extending this monthly pattern of enrollment, we estimated a 10% monthly growth in the number of users registered to the program. This corresponds to a total of 18,419 (6% of pregnant women), 57,214 (19% of pregnant women), and 179,562 (60% of pregnant women) enrolled in years 3, 4, and 5 of the program, respectively.

Table 1 presents program costs for implementation and technology support for each year of the program. Years 1 and 2 reflect costs incurred by the program, whereas years 3-5

represent forecasted costs anticipated with the scale up of implementation across Gauteng. Among key sub-categories of costs, technology support costs comprised 63% of total program costs, half of which was spent on SMS text message delivery costs. The annual estimates of implementation support costs were primarily attributed to the annualized estimates of development costs incurred at the project’s inception to support content development and localization and the development of training materials. Overall, personnel costs comprised 18% of annual costs, including 9% for program support staff and 9% for technology support and management personnel.

Figure 2 presents data on trends in the total program cost per registered user and per case of comprehensive care (≥ 4 ANC and full immunization). **Multimedia Appendix 2** summarizes year 5 parameter inputs for the probabilistic sensitivity analyses (similar tables are presented in **Multimedia Appendices 3-6** for each of the first 4 years of the program). By year 5, out of 179,562 registered users across Gauteng, 95% of those exposed to MAMA were estimated to have received all childhood immunizations compared with 90% of non-MAMA users. Similarly, 72% of those exposed to MAMA received ≥ 4 ANC visits compared with only 46% in the comparison arm. A total of 67% of MAMA users were estimated to receive comprehensive care compared with 39% of non-MAMA users. By inputting individual coverage data into LiST, we estimated that a total of 182 (range, 109-199) lives would be saved in the year 5 of the program. **Multimedia Appendix 7** presents data on the number of individuals expected to attend ≥ 4 ANC visits and have fully immunized children and the total number of comprehensive care users by year 5 of the program along with corresponding estimates of the lives saved and DALYs averted.

Figure 1. Observed and forecasted enrollment trends over 5 years: July 2012-June 2017. Total users denote women registered to receive MAMA messaging while comprehensive care refers to the subpopulation that attended all recommended antenatal care 1 to 4 visits and had children that received the fully package of immunizations.

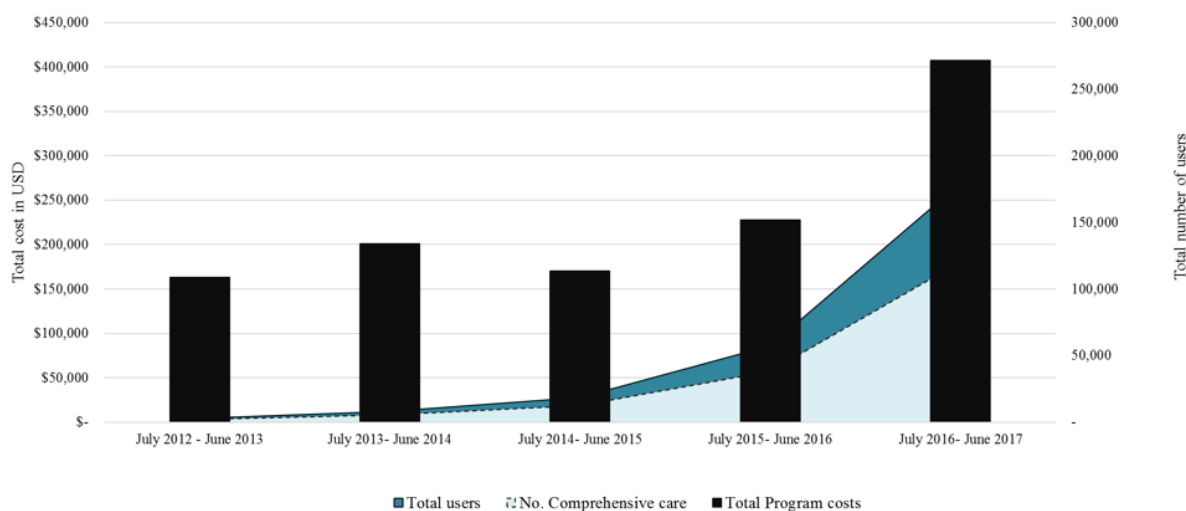
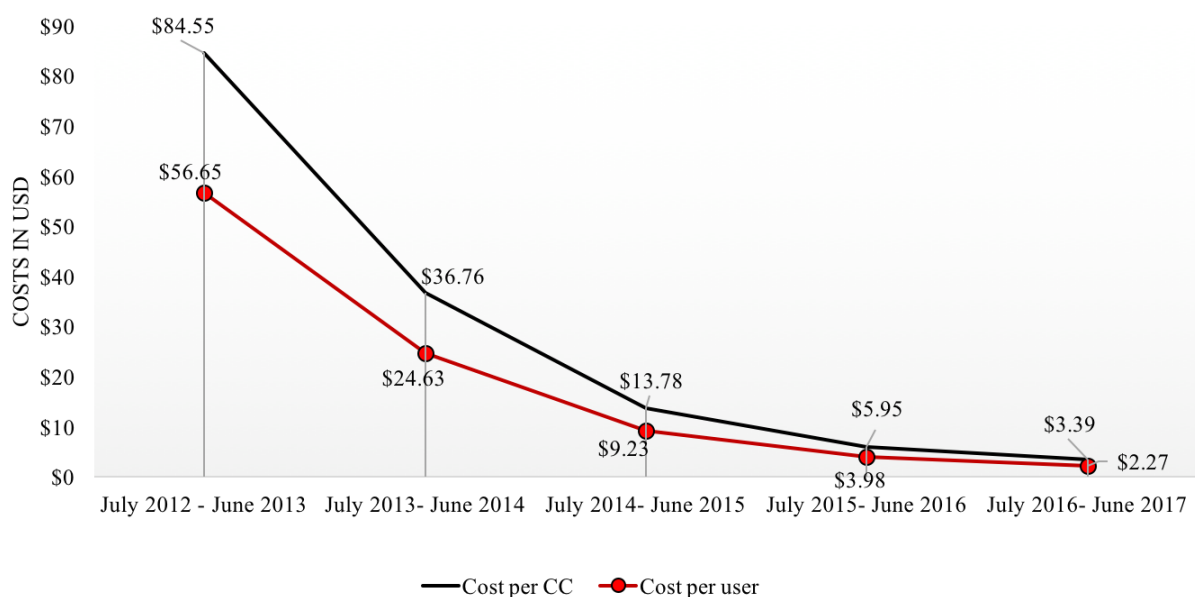


Table 1. Forecasted 5-year costs in 2015 US \$ for gradual rollout in Gauteng province, South Africa.

Category	Total program cost, July 2012 to June 2013	Total program cost, July 2013 to June 2014	Forecasted, July 2014 to June 2015	Forecasted, July 2015 to June 2016	Forecasted, July 2016 to June 2017	Total cost over 5 years (% of total cost)
Implementation support						
Development	37,353.42	38,474.03	39,628.25	39,628.25	42,041.61	197,125.55 (17)
Start-up	17,765.76	18,298.74	18,847.70	18,847.70	19,995.52	93,755.41 (8)
Training	149.73	—	73.86	—	80.51	304.10 (0)
Personnel	18,375.80	18,798.00	19,630.41	20,514.67	21,398.94	98,717.82 (8)
Buildings	5974.80	5644.53	5894.48	6160.00	6425.52	30,099.33 (3)
Transport	3223.16	3044.99	3179.83	3323.06	3466.30	16,237.34 (1)
Communication	537.19	507.50	529.97	553.84	577.72	2706.22 (0)
Subtotal implementation support	83,379.87	84,767.78	86,081.31	89,027.53	93,986.12	437,242.60 (37)
Technology costs						
Start-up/development	129.89	129.89	137.03	144.08	158.74	699.63 (0)
Content maintenance	10,478.75	12,876.98	9167.21	9442.22	9725.49	51,690.64 (4)
Technology maintenance	8279.94	36,864.04	18,509.92	19,333.07	20,156.87	103,143.84 (9)
Project management/personnel	25,697.90	30,970.64	15,588.69	16,625.15	17,709.78	106,592.15 (9)
Monitoring and evaluation	1842.36	1961.43	108.72	111.99	115.34	4139.84 (0)
Building/overhead	10,073.21	13,088.45	12,225.42	12,765.21	13,305.66	61,457.94 (5)
Travel	11,353.19	8606.91	3100.02	3237.30	3374.71	29,672.13 (3)
SMS text message delivery	5384.11	9857.96	23,233.68	75,421.98	246,909.46	360,807.20 (31)
SMS text message translation	1736.80	1855.87	1855.87	1855.87	1855.87	9160.28 (1)
Printing	4726.26	—	—	—	—	4726.26 (0)
Subtotal technology	79,702.40	116,212.16	83,926.55	138,936.88	313,311.93	732,089.92 (63)
Total	163,082.27	200,979.94	170,007.86	227,964.40	407,298.04	1,169,332.51 (100)

Figure 2. 5-year trends in the total program cost per registered user and per case of comprehensive care (CC) received among MAMA users over 60 months.

Estimates of service utilization were used to forecast the costs to the health system associated with registering pregnant women to MAMA as well as treating additional cases (Multimedia Appendix 2). Assuming a 3-minute registration time, provider costs to register each woman were estimated to be US \$0.08 (range of \$0.04-0.11), while ANC counseling service delivery costs were estimated to be US \$1.28 for ANC 1 and US \$1.03 for each of the remaining ANC 2-4 visits. PNC was estimated to cost US \$1.03 for PNC 1 and US \$0.51 for each of the remaining 5 visits. Adjusting for differentials in utilization across study arms, total ANC 4+ and PNC 5+ costs were \$1,101,947 in the MAMA study arm and \$857,070 in the comparison arm.

Mean costs to users for attending ANC and PNC were drawn from structured interviews and included food, wages lost, child care, and transport costs (Multimedia Appendix 2). The mean cost per visit was \$1.66 for ANC and \$1.48 for PNC. The largest proportion of costs were attributed to wages lost (90%), followed by transportation (5%), child care (4%), and food (1%). Multimedia Appendix 3 summarizes data on costs and consequences for years 1-5 by study arm. Deterministic estimates of the incremental cost per live saved from a societal perspective ranged from US \$56,011 in year 1 to US \$5652 in year 5. Estimates of the cost per DALY averted similarly

declined from US \$1985 in year 1 to US \$200 in year 5. Probabilistic estimates mirror this pattern.

Figure 3 presents the cost-effectiveness plane for each year, 1 through 5, whereas Figure 4 depicts incremental cost-effectiveness acceptability curves for each year of implementation. The cost per DALY averted falls beneath the 2015 Gross National Income (GNI) for South Africa of US \$6080 for each of the 5 years of implementation. At a lower willingness-to-pay threshold of \$250, the probability of achieving cost-effectiveness ranges from 0% in year 1 to 64% in year 5.

Using the South Africa's Gross National Income per capita for 2015 of US\$6080 as the threshold, program activities have a 100% probability of being cost-effective. At lower willingness-to-pay thresholds, the probability of MAMA being cost-effective increases over time as the number of users increases along with anticipated health effects.

To compliment probabilistic sensitivity analyses, we also conducted one-way sensitivity analyses to identify key drivers of the incremental cost per DALY averted (Figure 5). The leading driver of incremental cost-effectiveness is the number of lives saved and corresponding number of DALYs averted, followed by programmatic costs associated with SMS text message delivery costs.

Figure 3. Cost effectiveness plane of years 1-5 of MAMA implementation vs. Status quo in Gauteng, South Africa. Individual dots represent the incremental costs and incremental disability adjusted life years (DALYs) averted for each of 1,000 simulations conducted by year of implementation.



Figure 4. Incremental cost effectiveness acceptability curve of years 1-5 of MAMA implementation vs status quo in Gauteng, South Africa. Using the South Africa’s gross national income (GNI) per capita for 2015 of US \$6,080 as the threshold, program activities have a 100% probability of being cost effective. At lower willingness pay thresholds, the probability of MAMA being cost effective increases over time as the number of users increases along with anticipated health effects. DALY: Disability adjusted life years.

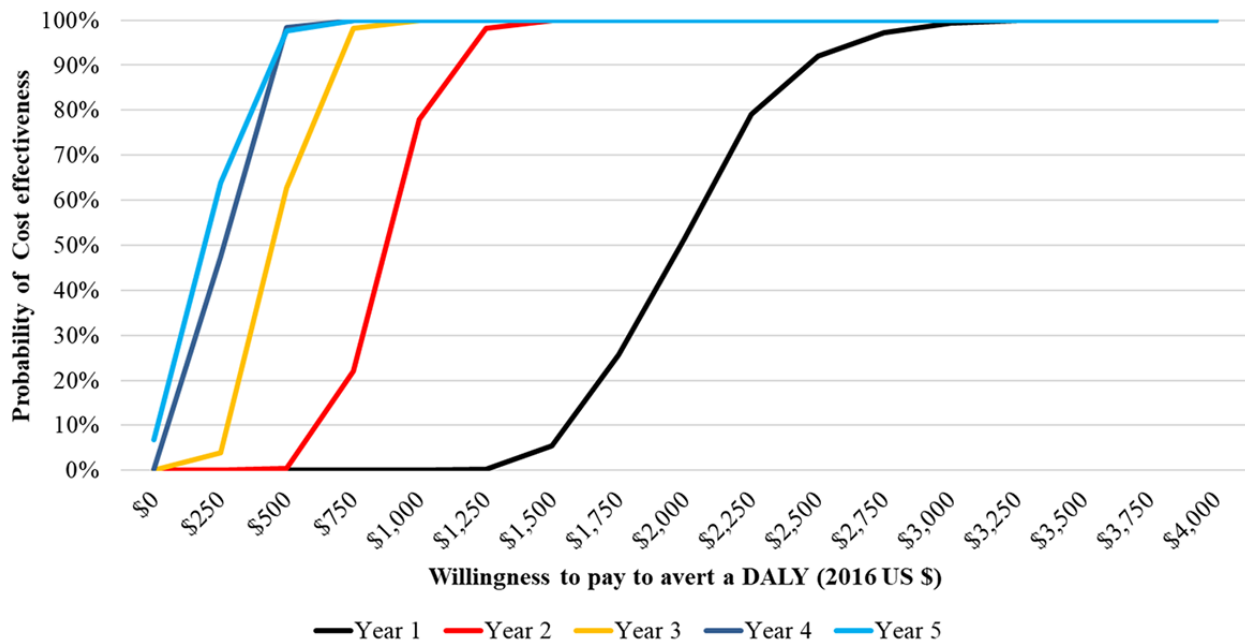
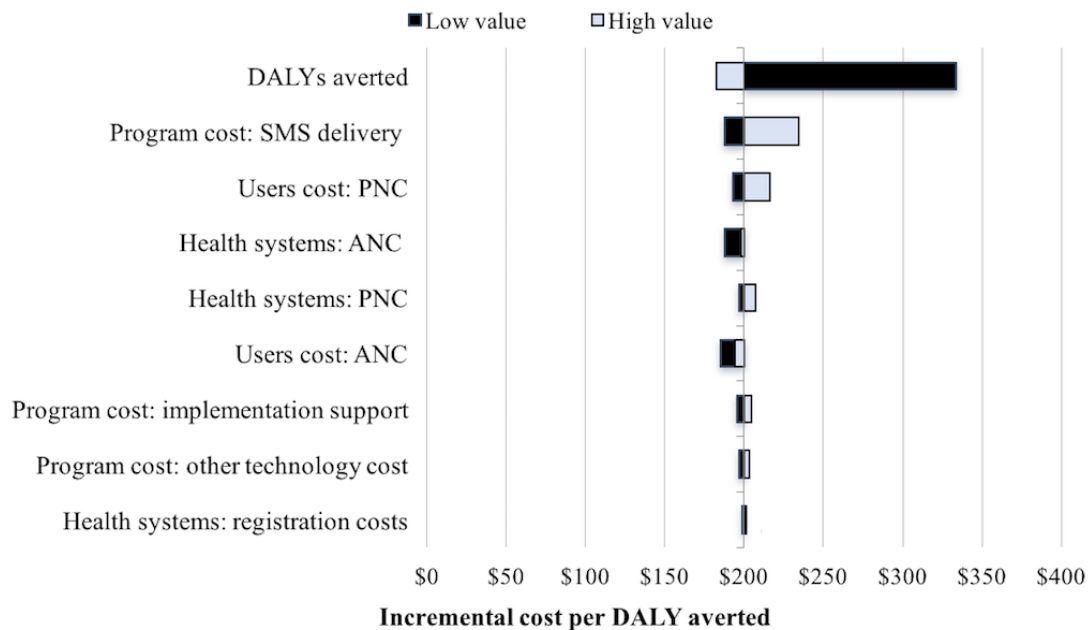


Figure 5. One way sensitivity analysis of key drivers of incremental cost per disability adjusted life year (DALY) averted for year 5 of program implementation (all costs in US \$). ANC: antenatal care; PNC: postnatal care; SMS: short message service.



Discussion

Summary of Key Findings

Study findings modeling the incremental cost-effectiveness of exposure to SMS text messages during delivery and postpartum on care-seeking and childhood immunizations suggest that the cost per DALY averted ranges from US \$1985 in year 1 when only 1% of pregnant women are registered to US \$200 in year 5 when 60% of pregnant women are included. Societal costs to implement MAMA in the 5th year of implementation were

estimated to be US \$3.6 million dollars, 59% of which represent costs borne by users to seek care for ANC and PNC, 30% costs to the health system, and 11% program costs. When considered against a status quo comparator, the incremental annual cost to implement MAMA at 60% coverage is US \$1.03 million.

To estimate the health effects of SMS text messaging exposure, we drew from sample data on changes in the utilization of services among MAMA users and nearby non-MAMA-using mother-infant pairs for ANC and childhood immunizations up to 9 months. Less than 100 complete records were available in each study arm. When coupled with the existing high rates of

service utilization, it meant that we were not powered to measure changes in the utilization rates for individual vaccines. However, we were powered to measure observed changes in the utilization for ANC and comprehensive care (defined as ANC 1-4 and full immunizations). Based on available data, 1%-4% increases in immunization rates were observed by vaccine type along with a 14% increase in all 4 ANC visits. The latter finding is consistent with changes in coverage observed in Zanzibar as part of the Wired Mothers Program [4] and with emerging findings from the mCare project in Bangladesh. However, it is noteworthy that the overall utilization of ANC is higher in South Africa than elsewhere in the region, including Zanzibar; thus, it is feasible that we have overestimated health effects. Efforts to account for this were made through one-way and probabilistic sensitivity analyses, which sought to explore the effects of changing individual parameters, including coverage, on overall cost-effectiveness.

In the 2 years since the MAMA program ended, the National Department of Health (NDOH) has developed and rapidly scaled a maternal SMS text messaging program called "MomConnect," which is based on MAMA but with less specific messages on the prevention of mother-to-child transmission of HIV. Like MAMA, MomConnect registers pregnancies and links expectant mothers to gestation age-specific pregnancy information, while also providing access to a help desk for reporting compliments or complaints on service delivery. Since its inception, MomConnect has grown to become one of the largest mHealth initiatives globally, registering >1 million pregnant women in >95% (3300) of health facilities in South Africa to receive SMS text messages on maternal health information [22]. While data on the cost-effectiveness of MomConnect are not available, trends in the number of registered users in this analysis mirror those attained. With many of the technology partners overlapping, it is feasible that costs and value for money estimates will be similar.

Elsewhere, data on the value for money of digital health programs are slowly emerging. However, to our knowledge, this is the first study to provide evidence on the value for money of maternal SMS text messaging programs. To date, a dozen peer-reviewed papers comprise the body of evidence on the value for money of mHealth solutions, including CEAs (6 studies) [23-26], cost-utility analyses (2 studies) [27,28], and cost-benefit analyses (4 studies) [29-32]. The distribution of digital health application types include 4 studies focused on client education and behavior change communication, 2 on electronic decision support, 2 on provider training and education, 2 on sensors and point-of-care diagnostics, and one on provider-to-provider communication [33]. Across disease areas, 42% of studies focus on general health, 25% on infectious diseases, 25% on chronic diseases, and 8% on women's health [33]. Efforts to compare these studies with MAMA are challenging, given the differences in the outcome measures used. None of the identified CEAs report outcome metrics in units comparable (eg, lives saved) to those reported here, and only one of the 2 cost-utility analyses used DALYs as the outcome measure. Where the latter is concerned, a 2012

cost-utility analysis of a tuberculosis control strategy in Thailand, wherein patients received daily SMS text messages from a village health volunteer reminding them to take their medication, was associated with a median ICER of 350 international dollars (or US \$4270) per DALY averted [27]. However, the uncertainty ranges around the health gain in DALYs were wide and crossed zero, suggesting that no distinction could be made in cost-effectiveness between mobile phone reminders and the comparator [27]. Findings from a 2013 cost-utility analysis of telemedicine to screen for diabetic retinopathy in India reported that screening once in a lifetime (US \$2692 per Quality Adjusted Life Year, QALY, gained), twice in a lifetime (US \$2475 per QALY gained), and every 5 years (US \$3134 per QALY gained) were cost-effective using the WHO threshold recommendations [28]. However, annual screenings and/or those every 3 years did not fall below the threshold for cost-effectiveness [28]. Collective consideration of this body of evidence, in conjunction with our study findings, suggests that mobile SMS text messaging interventions for maternal health may compare favorably with the handful of other cost-effectiveness studies of mHealth interventions emerging from lower- and middle-income countries.

Limitations

From the outset, we sought to base this analysis on primary data and focus only on the 2-year analytic time horizon of the program. However, primary data collection efforts were hampered by challenges in patient recruitment and data completeness. While we sought to obtain data on immunizations from the paper-based booklets provided by NDOH to mothers and completed by health workers at the time of service delivery, in practice, significant gaps in the completeness and quality of record keeping meant that a large proportion of interviewed participants were excluded from the final analyses. In shifting to a model-based analysis, we sought not only to more rigorously capture uncertainty but also consider the implications of service delivery at scale. Except for variable costs associated with SMS text message delivery, much of the technological costs associated with the MAMA program activities were fixed, irrespective of the scale of implementation. That said, our findings clearly suggest that greater value for money is attained with increasing scale. We hope that further analyses drawing from primary data of maternal SMS text messaging at scale through MomConnect and other initiatives will confirm this.

Conclusions

This is a first of its kind study to provide an evidence-informed model of the value for money of maternal SMS text messaging programs. Study findings suggest that SMS text messages to pregnant and postpartum women are cost-effective, according to the GNI per capita thresholds for South Africa. Cost-effectiveness improves with scale. Further efforts are needed to determine the value for money of maternal SMS text messaging under more robust study designs and in differing settings where technological (network coverage and access to mobile phones), epidemiological, and health systems profiles may differ.

Acknowledgments

The data underpinning this analysis were gathered through interviews with providers and mothers registered to receive MAMA messages in Gauteng. The authors are grateful to these individuals for their generosity, time, and insights. We additionally thank Dr Garrett Mehl and Dr Patty Mechael for their guidance and support to the project.

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Authors' Contributions

JC is the principal investigator. JC conceived the idea for this research with inputs from ALeFevre, and JE. ALeFevre, MCE, and JC designed the data collection instruments for patient interviews. JC oversaw the data collection and quantitative data entry with support from IB. DR, AN, and JC collected data on program costs. ALeFevre conducted the probabilistic sensitivity analysis with inputs from YJ. IB, DM, and JE provided critical inputs to the quantitative analyses and interpretation of results. ALeFevre conducted the analyses and wrote the first draft of the manuscript with inputs from JC, MCE and all other authors. All authors approved the final draft.

Conflicts of Interest

None declared

Multimedia Appendix 1

Eligibility and enrollment flow of study participants included.

[[PDF File \(Adobe PDF File\), 115KB - mhealth_v6i7e153_app1.pdf](#)]

Multimedia Appendix 2

Parameters for probabilistic sensitivity analysis drawing from Year 5 costs (All currency in US \$).

[[PDF File \(Adobe PDF File\), 193KB - mhealth_v6i7e153_app2.pdf](#)]

Multimedia Appendix 3

Year 1 Program costs in US \$ for gradual rollout in Gauteng province, South Africa.

[[PDF File \(Adobe PDF File\), 141KB - mhealth_v6i7e153_app3.pdf](#)]

Multimedia Appendix 7

Year 2 Program costs in US \$ for gradual rollout in Gauteng province, South Africa.

[[PDF File \(Adobe PDF File\), 141KB - mhealth_v6i7e153_app4.pdf](#)]

Multimedia Appendix 5

Year 3 Program costs in US \$ for gradual rollout in Gauteng province, South Africa.

[[PDF File \(Adobe PDF File\), 142KB - mhealth_v6i7e153_app5.pdf](#)]

Multimedia Appendix 6

Year 4 Program costs in US \$ for gradual rollout in Gauteng province, South Africa.

[[PDF File \(Adobe PDF File\), 141KB - mhealth_v6i7e153_app6.pdf](#)]

References

1. World Health Organization. Geneva: WHO; 2006. eHealth Tools & Services: Needs of the Member States: Report of the WHO Global Observatory for eHealth URL: <http://apps.who.int/medicinedocs/documents/s16468e/s16468e.pdf> [accessed 2018-06-15] [[WebCite Cache ID 70BoRK9Zb](#)]
2. Mehl G, Vasudevan L, Gonsalves L, Berg M, Seimon T, Temmerman M, et al. Harnessing mHealth in Low-Resource Settings to Overcome Health System Constraints and Achieve Universal Access to Healthcare. In: Marsch L, Lord S, Dallery J, editors. Behavioral Health Care and Technology: Using Science-Based Innovations to Transform Practice. New York, New York: Oxford University Press; Nov 2014:239-263.

3. Watterson J, Walsh J, Madeka I. Using mHealth to Improve Usage of Antenatal Care, Postnatal Care, and Immunization: A Systematic Review of the Literature. *Biomed Res Int* 2015;2015:153402 [FREE Full text] [doi: [10.1155/2015/153402](https://doi.org/10.1155/2015/153402)] [Medline: [26380263](https://pubmed.ncbi.nlm.nih.gov/26380263/)]
4. Lund S, Nielsen B, Hemed M, Boas I, Said A, Said K, et al. Mobile phones improve antenatal care attendance in Zanzibar: a cluster randomized controlled trial. *BMC Pregnancy Childbirth* 2014 Jan 17;14:29 [FREE Full text] [doi: [10.1186/1471-2393-14-29](https://doi.org/10.1186/1471-2393-14-29)] [Medline: [24438517](https://pubmed.ncbi.nlm.nih.gov/24438517/)]
5. Lund S, Hemed M, Nielsen B, Said A, Said K, Makungu M, et al. Mobile phones as a health communication tool to improve skilled attendance at delivery in Zanzibar: a cluster-randomised controlled trial. *BJOG* 2012 Sep;119(10):1256-1264 [FREE Full text] [doi: [10.1111/j.1471-0528.2012.03413.x](https://doi.org/10.1111/j.1471-0528.2012.03413.x)] [Medline: [22805598](https://pubmed.ncbi.nlm.nih.gov/22805598/)]
6. Lund S, Rasch V, Hemed M, Boas I, Said A, Said K, et al. Mobile phone intervention reduces perinatal mortality in zanzibar: secondary outcomes of a cluster randomized controlled trial. *JMIR Mhealth Uhealth* 2014 Mar 26;2(1):e15 [FREE Full text] [doi: [10.2196/mhealth.2941](https://doi.org/10.2196/mhealth.2941)] [Medline: [25098184](https://pubmed.ncbi.nlm.nih.gov/25098184/)]
7. Watkins SC, Robinson A, Dalious M. Village Reach/Invest in Knowledge Initiative. Malawi; 2013 Dec. Evaluation of the Information and Communications Technology for Maternal, Newborn and Child Health Project Known locally as “Chipatala Cha Pa Foni” (Health Center by Phone) A pilot project of the Concern Worldwide Innovations for Maternal, Newborn & Child Health Project URL: http://www.villagereach.org/wp-content/uploads/2017/07/ICT_for_MNCH_Report_131211md_FINAL.pdf [accessed 2018-06-15] [WebCite Cache ID 70BoXx1JO]
8. Rajan R, Raihan A, Alam M, Agarwal SA, Ahsan A, Ahsan R, et al. MAMA Bangladesh. 2013 Dec. MAMA “APONJON” Formative Research Report URL: <https://www.mhealthknowledge.org/sites/default/files/MAMA%20Bangladesh%20Formative%20Research%20Report.pdf> [accessed 2018-06-15] [WebCite Cache ID 70Bodw54m]
9. Coleman J, Bohlin K, Thorson A, Black V, Mechael P, Mangxaba J, et al. Effectiveness of an SMS-based maternal mHealth intervention to improve clinical outcomes of HIV-positive pregnant women. *AIDS Care* 2017 Dec;29(7):890-897. [doi: [10.1080/09540121.2017.1280126](https://doi.org/10.1080/09540121.2017.1280126)] [Medline: [28107805](https://pubmed.ncbi.nlm.nih.gov/28107805/)]
10. Coleman J, Lau Chan V, Black V, Thorson A, Eriksen J. Improving maternal and infant health using mHealth text messages in a low-resource urban setting in South Africa. Submitted 2018 (forthcoming).
11. LeFevre A, Shillcutt S, Broomhead S, Labrique A, Jones T. Defining a staged-based process for economic and financial evaluations of mHealth programs. *Cost Eff Resour Alloc* 2017;15:5 [FREE Full text] [doi: [10.1186/s12962-017-0067-6](https://doi.org/10.1186/s12962-017-0067-6)] [Medline: [28428734](https://pubmed.ncbi.nlm.nih.gov/28428734/)]
12. UNICEF/WHO/The World Bank/United Nations Population Division. Unicef. New York; 2015. Levels & Trends in Child Mortality URL: https://www.unicef.org/publications/files/Child_Mortality_Report_2015_Web_9_Sept_15.pdf [accessed 2018-06-15] [WebCite Cache ID 70Boi77JW]
13. WHO Africa. 2015. Trends in Maternal Mortality: 1990 to 2015 URL: <http://www.afro.who.int/sites/default/files/2017-05/trends-in-maternal-mortality-1990-to-2015.pdf> [accessed 2018-06-15] [WebCite Cache ID 70Bos2WeS]
14. Statistics South Africa. Statistics South Africa. 2016 Aug 25. Mid-year population estimates 2016 URL: <https://www.statssa.gov.za/publications/P0302/P03022016.pdf> [accessed 2018-06-15] [WebCite Cache ID 70BozTQsJ]
15. Shisana O, Rehle T, Simbayi I, Zuma K, Jooste S, Jungi N, et al. Human Sciences Research Council Press. 2014. South African National HIV Prevalence, Incidence and Behaviour Survey, 2012 URL: <http://www.hsrc.ac.za/en/research-outputs/ktree-doc/15031> [accessed 2018-06-15] [WebCite Cache ID 70BpAPkpi]
16. Health Systems Trust. 2015 Oct. District Health Barometer 2014/15 URL: https://www.health-e.org.za/wp-content/uploads/2015/10/Complete_DHB_2014_15_linked.pdf [accessed 2018-06-15] [WebCite Cache ID 70BpHJGP2]
17. Health Systems Trust. 2009. District Health Barometer 2008/2009 URL: <http://www.hst.org.za/publications/District%20Health%20Barometers/Complete%20dhb0809.pdf> [WebCite Cache ID 70BqIOPDm]
18. Johns Hopkins Bloomberg School of Public Health. The Lives Saved Tool – software that estimates survival of mothers and children. Baltimore URL: <http://www.livessavedtool.org/> [accessed 2018-05-31] [WebCite Cache ID 6zpa2pS6m]
19. World Health Organization. Country Profile: South Africa. Geneva: WHO URL: <http://www.who.int/countries/zaf/en/> [accessed 2018-05-30] [WebCite Cache ID 6zpaHcoUy]
20. International Monetary Fund. World Economic Outlook Database, October 2013. Washington, D.C: IMF URL: <http://www.imf.org/external/pubs/ft/weo/2013/02/weodata/weoselco.aspx?g=2603&sg=All+countries+%2F+Emerging+market+and+developing+economies+%2F+Sub-Saharan+Africa> [accessed 2018-05-30]
21. OANDA. Currency Converter Foreign Exchange Rates. URL: <http://www.oanda.com/currency/converter/> [accessed 2018-05-31] [WebCite Cache ID 6AREIkiPU]
22. Barron P, Pillay Y, Fernandes A, Sebidi J, Allen R. The MomConnect mHealth initiative in South Africa: Early impact on the supply side of MCH services. *J Public Health Policy* 2016 Nov;37(Suppl 2):201-212. [doi: [10.1057/s41271-016-0015-2](https://doi.org/10.1057/s41271-016-0015-2)] [Medline: [27899795](https://pubmed.ncbi.nlm.nih.gov/27899795/)]
23. Dodani S, Songer T, Ahmed Z, Laporte RE. Building research capacity in developing countries: cost-effectiveness of an epidemiology course taught by traditional and video-conferencing methods in Pakistan. *Telemed J E Health* 2012 Oct;18(8):621-628. [doi: [10.1089/tmj.2011.0262](https://doi.org/10.1089/tmj.2011.0262)] [Medline: [23061643](https://pubmed.ncbi.nlm.nih.gov/23061643/)]

24. White JS, Dow WH, Rungruanghiranya S. Commitment contracts and team incentives: a randomized controlled trial for smoking cessation in Thailand. *Am J Prev Med* 2013 Nov;45(5):533-542 [FREE Full text] [doi: [10.1016/j.amepre.2013.06.020](https://doi.org/10.1016/j.amepre.2013.06.020)] [Medline: [24139765](https://pubmed.ncbi.nlm.nih.gov/24139765/)]
25. Chen Z, Fang L, Chen L, Dai H. Comparison of an SMS text messaging and phone reminder to improve attendance at a health promotion center: A randomized controlled trial. *J. Zhejiang Univ. Sci. B* 2008 Jan;9(1):34-38. [doi: [10.1631/jzus.B071464](https://doi.org/10.1631/jzus.B071464)] [Medline: [18196610](https://pubmed.ncbi.nlm.nih.gov/18196610/)]
26. Rashid RM, Ramli S, John J, Dahlui M. Cost effective analysis of recall methods for cervical cancer screening in Selangor--results from a prospective randomized controlled trial. *Asian Pac J Cancer Prev* 2014;15(13):5143-5147 [FREE Full text] [Medline: [25040965](https://pubmed.ncbi.nlm.nih.gov/25040965/)]
27. Hunchangsith P, Barendregt JJ, Vos T, Bertram M. Cost-effectiveness of various tuberculosis control strategies in Thailand. *Value Health* 2012;15(1 Suppl):S50-S55 [FREE Full text] [doi: [10.1016/j.jval.2011.11.006](https://doi.org/10.1016/j.jval.2011.11.006)] [Medline: [22265067](https://pubmed.ncbi.nlm.nih.gov/22265067/)]
28. Rachapelle S, Legood R, Alavi Y, Lindfield R, Sharma T, Kuper H, et al. The cost-utility of telemedicine to screen for diabetic retinopathy in India. *Ophthalmology* 2013 Mar;120(3):566-573. [doi: [10.1016/j.ophtha.2012.09.002](https://doi.org/10.1016/j.ophtha.2012.09.002)] [Medline: [23211635](https://pubmed.ncbi.nlm.nih.gov/23211635/)]
29. Latifi K, Lecaj I, Bekteshi F, Dasho E, Doarn C, Merrell R, et al. Cost-benefit analysis on the use of telemedicine program of Kosova for continuous medical education: a sustainable and efficient model to rebuild medical systems in developing countries. *Telemed J E Health* 2011 Dec;17(10):757-762. [doi: [10.1089/tmj.2011.0102](https://doi.org/10.1089/tmj.2011.0102)] [Medline: [22011053](https://pubmed.ncbi.nlm.nih.gov/22011053/)]
30. Broomhead S, Mars M. Retrospective return on investment analysis of an electronic treatment adherence device piloted in the Northern Cape Province. *Telemed J E Health* 2012;18(1):24-31. [doi: [10.1089/tmj.2011.0143](https://doi.org/10.1089/tmj.2011.0143)] [Medline: [22150713](https://pubmed.ncbi.nlm.nih.gov/22150713/)]
31. Andrade M, Maia A, Cardoso C, Alkmim M, Ribeiro ALP. Cost-benefit of the telecardiology service in the state of Minas Gerais: Minas Telecardio Project. *Arq Bras Cardiol* 2011 Oct;97(4):307-316 [FREE Full text] [Medline: [21808852](https://pubmed.ncbi.nlm.nih.gov/21808852/)]
32. Bernal-Sánchez G, de LTJ, Robles-Bonilla C, Campos-Romero A, Otero-Meza C. [Cost/benefit and cost/effectiveness study: Anahuac telemedicine]. *Cirugia y cirujanos* 2007;75(3):227-235. [Medline: [17659176](https://pubmed.ncbi.nlm.nih.gov/17659176/)]
33. LeFevre A, Stauss N, Gross P, Jones T, Agarwal S, Broomhead S, et al. Systematic review of economic evaluations of eHealth and mHealth programs in low and middle income countries from 2005-2015. Unknown 2017 Submitted for publication.

Abbreviations

ANC: antenatal care
CC: comprehensive care
DALY: disability adjusted life year
GNI: gross national income
ICER: incremental cost-effectiveness ratio
LiST: Lives Saved Tool
MAMA: Mobile Alliance for Maternal Action
NDOH: National Department of Health
PNC: postnatal care
QALY: quality adjusted life year
RMNCH: reproductive, maternal, newborn, and child health
SBA: skilled birth attendance
SMS: short message service

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Original Paper

The Complexity of Mental Health App Privacy Policies: A Potential Barrier to Privacy

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Abstract

Background: In 2017, the Supreme Court of India ruled that privacy is a fundamental right of every citizen. Although mobile phone apps have the potential to help people with noncommunicable diseases, such as diabetes and mental illness, they often contain complex privacy policies, which consumers may not understand. This complexity may impede the ability of consumers to make decisions regarding privacy, a critical issue due to the stigma of mental illness.

Objective: Our objective is to determine whether mental health apps have more complex privacy policies than diabetes apps.

Methods: The study used privacy policies extracted from apps. The apps pertained to diabetes or mental health, and were all of Indian origin. Privacy policy reading complexity was compared between the two types of apps using a series of 15 readability measures. The universe of applicable apps on the Google Play store, as viewed between May and June 2017, was considered. The measures of readability were compared using chi-square tests.

Results: No significant difference was found between the privacy policy readability of the diabetes apps versus the mental health apps for each of the measures considered. The mean Flesch-Kincaid Grade Level was 13.9 for diabetes apps and 13.6 for mental health apps; therefore, the mean policy grade level for both types of apps was written at a college level. Privacy policies in the 25th percentile of complexity were also written at a college level for both types of apps.

Conclusions: Privacy policy complexity may be a barrier for informed decision making.

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KEYWORDS

apps; privacy; ethics; mobile phone

Introduction

The Supreme Court of India's August 2017 ruling that privacy is a fundamental right of every citizen underscores the need for greater attention to privacy rights in all contexts of Indian society [1]. Indians' rights to privacy are only truly protected if Indians are able to make conscious decisions about their privacy-related decisions in all contexts, including while surrendering rights in the process of agreeing to privacy policies. The issue of privacy is especially important for mHealth apps, which are showing strong potential for addressing

noncommunicable disease in developing nations such as India [2]. Although more than 40% of Americans believe that mental illness is similar to physical illness, less than 20% of Indians agree with this sentiment [3]. Due to this attitudinal difference, it is possible that there is a greater distinction between the privacy policies of apps for mental health versus physical health in India than in the United States.

Although privacy is an important issue for all users of mHealth apps, regardless of condition or location, in 2013, India lost more than 30 million disability-adjusted life years (DALYs) to mental, neurological, and substance abuse disorders—a 61%

increase over the quantity in 1990. By comparison, all developed countries combined lost 50 million DALYs [4]. Noncommunicable physical illnesses are also afflicting a substantial number of Indians. India has been named the diabetes capital of the world [5]. It had a population of more than 72 million citizens with diabetes in 2017 and is projected to have 151 million citizens with diabetes in 2045 [6]. Given the substantial and growing number of people experiencing mental illness and diabetes within India and the greater degree of stigma associated with mental illness in India than in the United States [3], the potential for users of both physical and mental health apps to make informed privacy decisions is important to assess. The recent declaration of a fundamental right to privacy in India has amplified the importance of assessing the potential difficulty that users of Indian mHealth apps may have while attempting to preserve their privacy.

Recent research has raised concerns that irrespective of health benefits, there are inadequate privacy protections within mobile phone apps. One study examining the privacy policies of 211 diabetes apps noted that of those apps investigated, 81% did not even offer a privacy policy [7]. Another study attempting to examine the privacy policies of 72 dementia apps found that more than 50% lacked a privacy policy [8]. Privacy policies are of central importance because the majority of health apps live outside of the jurisdiction of national or federal health care regulations, meaning that privacy of information collected by a mobile phone app is not guaranteed in the same way as information shared with a doctor [9]. The US Department of Health and Human Services acknowledged the scope of this problem in a recent report outlining the extent to which consumers may be unaware of what data they are disclosing when using health-related mobile phone apps, who is able to access their data, and how their data may be sold or bartered [10]. The recent misuse of personal data, including personality profiles, in the 2018 Facebook and Cambridge Analytica scandal highlights the potential magnitude of harm resulting from inappropriate access and the global nature of such risks [11]. Thus, health app privacy policies that consumers can access and understand are necessary for consumers to protect their privacy rights and control what happens to their personal data.

Even when a privacy policy is present, it may not be comprehended by vulnerable consumers, such as those with mental illnesses that impair cognition [12,13]. Prior studies have characterized app privacy policies as being lengthy, linguistically complex, and even absent [14,15]. They have been shown to be difficult to read even for people pursuing a graduate degree in law or policy [16]. Although it is already well established that online privacy policies are challenging to read [17-20], the problem is even more pronounced within apps; it has been demonstrated that privacy policies are more difficult to read on a mobile device than on a desktop [21]. One study suggested that those with lower health literacy might misjudge privacy policies and falsely assume more protections are in place than those who are more health literate [14]. However, little research has been done to examine the reading level required to understand mobile health app privacy policies. No studies have examined whether the complexity of privacy policies differs according to the condition apps are intended to

address. Furthermore, although much of the prior research on privacy policies has been conducted in the United States, there are national differences in privacy concerns, which reflect both differences in culture and values [22]. Thus, in this study we sought to characterize and compare the reading level of privacy policies for Indian apps intended to address issues related to diabetes and mental health.

Methods

Study Design and Data Sources

This study examined the complexity of privacy policies found within Indian apps for issues related to diabetes and mental health. The study used a novel dataset composed of privacy policies extracted from apps found on the Google Play app store for the Android operating system between May and June 2017 by a researcher based in India. Institutional Review Board approval was unnecessary because the subject of the research was software rather than people.

Sample Selection

The Google Play store was searched for Indian apps related to diabetes and mental health. The apps returned by queries for “Indian diabetes,” “Indian diabetic,” or “Indian diabetes help” were included in the set of diabetes apps. The apps returned by queries for “Indian mental health,” “Indian anxiety,” “Indian depression,” “Indian schizophrenia,” “Indian posttraumatic stress disorder,” “Indian mood disorder,” “Indian cognitive behavior therapy,” “Indian cognitive remediation,” “Indian dialectical behavior therapy,” “Indian dementia,” or “Indian Alzheimer” were included in the set of mental health apps. Apps were excluded from the analysis if they were unrelated to health, despite containing health-related keywords, if they contained keywords related to India, but were not of Indian origin, if they lacked a link to a privacy policy, if they contained a broken link to a privacy policy, if the privacy policy was not in English, or if the privacy policy could not be copied for analysis. Privacy policies not written in English could not be included because structural differences in languages would make the readability statistics not comparable.

Outcomes and Analyses

Apps were categorized according to whether they were interactive, noninteractive, or related to e-commerce, and then again categorized according to whether they were clinical, nonclinical, or related to e-commerce. (The same apps were placed in the e-commerce category under both categorizations.) Interactive apps were defined as apps that facilitate two-way discussions with a health expert (eg, doctors, therapists, nutritionists), apps which facilitate group chats, and apps with discussion forums. Apps involving interactions with supporting staff (eg, receptionists/customer care executives for online appointment booking) were categorized as noninteractive apps. A subset of the interactive apps was categorized as clinical if they involved interaction with a health expert; apps outside of the subset were categorized as nonclinical if they were not related to e-commerce.

Multiple metrics were used to evaluate the complexity of the app privacy policies: word count, sentences per paragraph,

words per sentence, characters per word, average number of sentences per 100 words, average words with six or more characters, average number of sentences per 100 words, Flesch Reading Ease, Flesch-Kincaid Grade Level, Gunning Fog Score, SMOG Index, Coleman Liau Index, Automated Readability Index, Fry Grade Level, and Raygor Estimate Graph Grade Level. The mean, standard deviation, median, and interquartile range were calculated for each metric, separately for the diabetes and mental health apps. Metrics for diabetes apps and mental health apps were compared using *t* tests and Wilcoxon rank sum tests to assess for significant differences in mean and median, with $P < .05$ used as an indicator of significance. Chi-square tests were used to assess whether diabetes and mental health apps were similarly distributed between the interactive, noninteractive, and e-commerce categories, as well as between the clinical, nonclinical, and e-commerce categories, with $P < .05$ again used as an indicator of a significant association. All statistical analyses were conducted using STATA software version 13.

Results

As is shown in [Figure 1](#), a total of 267 potential Indian diabetes apps were found by searching the Google Play store. Of these apps, only 41 (15.4%) were included after the various exclusions were applied (nearly half the apps were unrelated to health despite containing health-related keywords). A similar process, shown in [Figure 2](#), was applied to obtain the mental health app privacy policies. A total of 623 apps were returned by the initial searches of the Google Play store, but only 29 (4.7%) were included in the study after the exclusion criteria were applied. Of the total 70 apps included for analysis, eight apps (11%) were common for both diabetes and mental health.

The readability metrics for the app privacy are presented in [Table 1](#). There were no significant differences in the readability

of the privacy policies for apps for diabetes versus mental health. Similar results were found after excluding the common apps ($n=8$) from the analysis (data not shown). Overall, the metrics suggest that privacy policies may be difficult for people to read. A typical privacy policy is approximately as long as an article in an academic journal; a mean of 1875 words (SD 1448) for diabetes apps and 2421 words (SD 2102) for mental health apps. Although mental health app privacy policies had a higher mean and median word count, the difference was not statistically significant. Several of the metrics suggest that the privacy policies require a high degree of reading comprehension. The mean Flesch-Kincaid Grade Level for diabetes privacy policies was 13.9, and the mean for mental health privacy policies was 13.6. Furthermore, the 25th percentile of the interquartile range was 12.7 for diabetes apps and 12.4 for mental health apps. This suggests that understanding the majority of privacy policies requires reading at a college level. The Fry Grade Levels calculated—11.6 for diabetes apps and 12.4 for mental health apps—helps triangulate this finding. Although the mean Raygor Estimate Graph Grade Levels were lower (6.9 for diabetes and 7.4 for mental health), they also suggest that at least a middle school level of reading comprehension is required. In short, the privacy policies found in Indian apps for diabetes and mental health tend to be lengthy and difficult to read.

There were some differences in the nature of diabetes apps versus mental health apps, as shown in [Table 2](#). The vast majority of mental health apps (85%, 23/27) were interactive, whereas only a slight majority (23/39, 59%) of diabetes apps were interactive, a significant difference ($P=.04$). Mental health apps were likewise more likely to be clinical (82%) than diabetes apps (61%), although the distribution of apps between the clinical, nonclinical, and e-commerce categories was not significantly associated with app type ($P=.06$).

Figure 1. Selection of apps for diabetes.

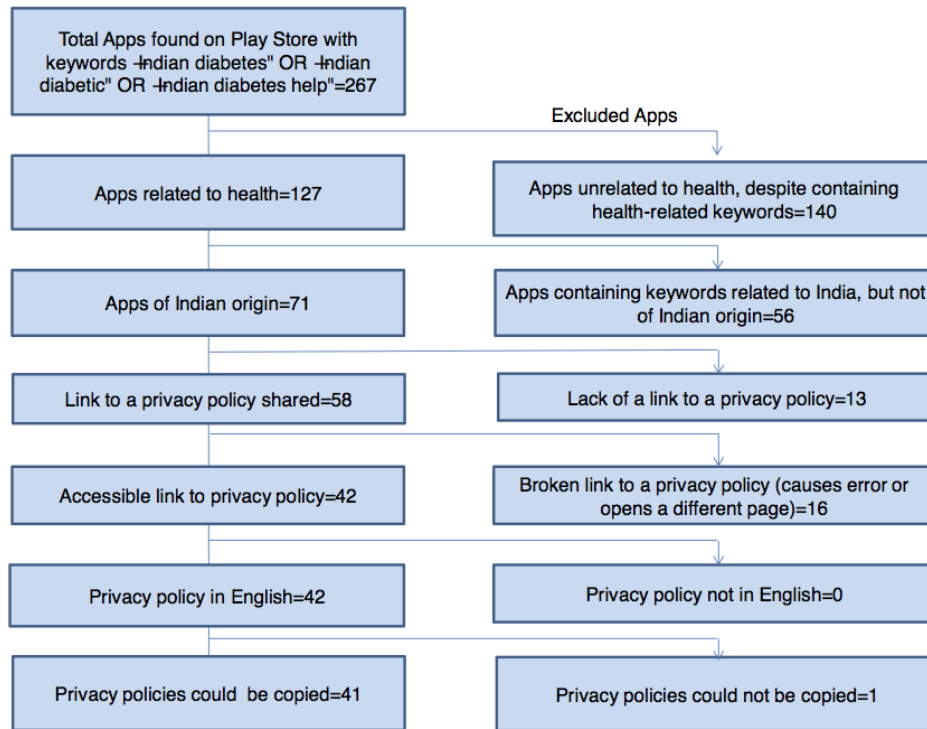


Figure 2. Selection of apps for mental health.

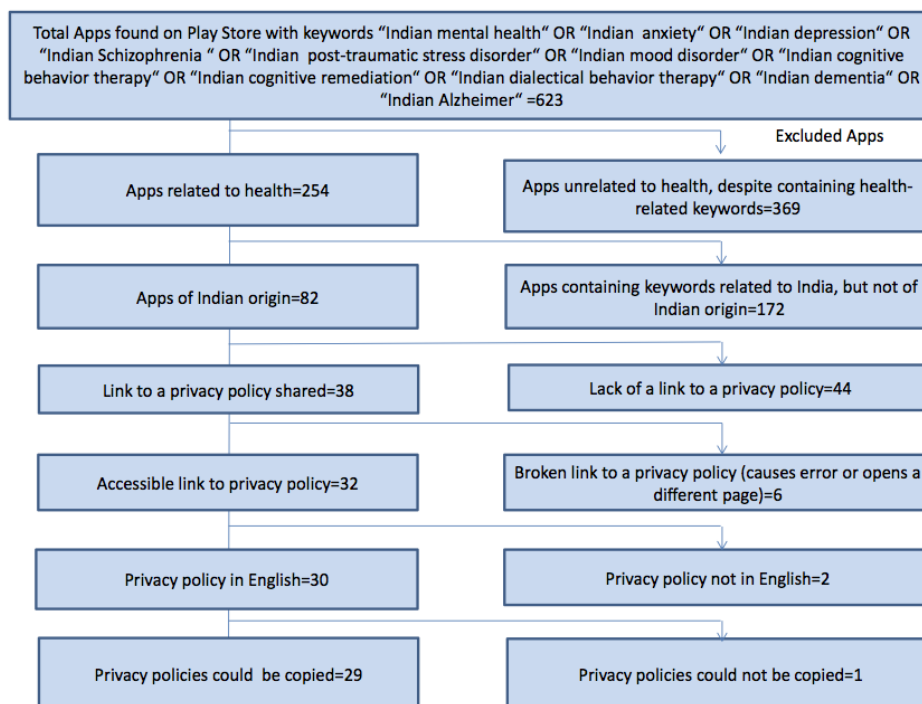


Table 1. Readability statistics of privacy policies of diabetes and mental health mobile apps (N=70).

Readability metric	Diabetes apps (n=41)	Mental health apps (n=29)	P value ^a
Word count			
Mean (SD)	1874.5 (1447.9)	2420.5 (2101.7)	.20
Median (IQR ^b)	1520 (733-2278)	1783 (1117-3049)	.35
Range	111-6010	163-9424	
Sentences per paragraph			
Mean (SD)	2.9 (1.9)	2.5 (1.0)	.29
Median (IQR)	2.6 (2.0-3.2)	2.2 (2.0-2.7)	.28
Range	1.4-12.8	1.3-6.7	
Words per sentence			
Mean (SD)	23.4 (4.9)	22.8 (5.2)	.60
Median (IQR)	24.1 (21.4-26.9)	23.7 (20.6-25.2)	.40
Range	11.7-32	8.5-37.5	
Characters per word			
Mean (SD)	5.1 (0.2)	5.0 (0.2)	.47
Median (IQR)	5.1 (5.0-5.2)	5.1 (5.0-5.1)	.54
Range	4.6-5.5	4.8-5.3	
Average number of sentences per 100 words^c			
Mean (SD)	5.9 (5.1)	4.8 (0.9)	.27
Median (IQR)	5 (4.2-5.8)	4.7 (4.2-5.3)	.34
Range	3.4-37	3.0-7.1	
Average words with ≥6 characters^d			
Mean (SD)	19.8 (2.5)	19.4 (2.5)	.52
Median (IQR)	20 (18.0-22.0)	20 (17.5-21)	.62
Range	14.0-26.0	14.0-23.0	
Average number of sentences per 100 words^d			
Mean (SD)	5.1 (1.3)	4.8 (0.9)	.33
Median (IQR)	5.0 (4.2-5.8)	4.7 (4.2-5.3)	.52
Range	3.4-7.7	3.0-7.1	
Flesch Reading Ease			
Mean (SD)	35.1 (8.8)	37.1 (8.6)	.36
Median (IQR)	36.5 (28.3-38.2)	37.3 (31.3-42.5)	.41
Range	18.5-50.6	21.9-55.0	
Flesch-Kincaid Grade Level			
Mean (SD)	13.9 (2.3)	13.6 (2.4)	.50
Median (IQR)	14 (12.7-15.1)	14 (12.4-15.0)	.51
Range	9.3-18	8.1-19	
Gunning Fog Score			
Mean (SD)	15.2 (2.2)	15.4 (1.8)	.72
Median (IQR)	15.0 (13.9-16.8)	15.3 (14.7-16.1)	.55
Range	11.5-20	11.5-19.9	

Readability metric	Diabetes apps (n=41)	Mental health apps (n=29)	P value ^a
SMOG Index			
Mean (SD)	12.1 (1.7)	12.1 (1.3)	.90
Median (IQR)	11.9 (10.7-13.1)	12.2 (11.7-12.5)	.66
Range	9.6-15.4	9.5-14.8	
Coleman Liau Index			
Mean (SD)	14.2 (0.8)	13.9 (0.9)	.18
Median (IQR)	14.5 (13.6-14.7)	14.2 (13.1-14.6)	.17
Range	12.3-15.8	11.3-15.6	
Automated Readability Index			
Mean (SD)	13.4 (2.8)	13.5 (2.2)	.86
Median (IQR)	13.3 (11.5-14.9)	13.3 (12.8-14.6)	.85
Range	8.8-18.4	8.5-18.6	
Fry Grade Level			
Mean (SD)	11.6 (3.1)	12.4 (1.5)	.20
Median (IQR)	12.0 (11.0-14.0)	13.0 (12.0-14.0)	.36
Range	5.0-15.0	10.0-15.0	
Raygor Estimate Graph Grade Level			
Mean (SD)	6.9 (1.1)	7.4 (2.2)	.25
Median (IQR)	7.0 (6.0-8.0)	7.0 (7.0-8.0)	.70
Range	4.0-9.0	4.0-18.0	

^aP values are from using *t* tests of significance for the means and Wilcoxon rank sum tests for the medians.

^bIQR: interquartile range.

^cFry word statistics.

^dRaygor estimate word statistics.

Table 2. Characteristics of diabetes and mental health mobile apps by Indian developers.

Strata	Diabetes apps, n (%)	Mental health apps, n (%)	P value ^a
Interactivity			.04
Interactive	23 (59.0)	23 (85.2)	
Noninteractive	6 (15.4)	3 (11.1)	
E-commerce	10 (25.6)	1 (3.7)	
Use case			.06
Clinical	25 (61.0)	23 (82.1)	
Nonclinical	6 (14.6)	4 (14.3)	
E-commerce	10 (24.4)	1 (3.6)	

^aP values are from chi-square tests of significance.

Discussion

Principal Findings

Although readability measures could be applied to any English-language privacy policies, there are a number of factors that make India a robust country to study. Because India is home to the world's second-largest population of English speakers (after the United States) [23], the world's second-largest base

of mobile phone users (after China) [24], and legally enforces privacy rights [1], it has a well-developed market for English-based mHealth apps containing privacy policies. Given that the 2011 Census found that only 6% of the Indian population has a college education [25], whereas 30% of United States adults have a college education [26], the impact of privacy policies written at a college level is even more acute in India than in the United States. Furthermore, there is a great need for

mHealth apps in India due to limited access to care in some parts of the country [27].

Lengthy, complex app privacy policies are not as likely to be read and understood as short, simple privacy policies. Depending on the metric used, the majority of app privacy policies evaluated may require a college education to comprehend. These findings are consistent with the prior finding by other researchers, who determined that the average grade level of the privacy policy of a mobile health app is grade 16 [15]. As mobile phones become more affordable to people of all incomes, the problems posed by complex privacy policies will likely intensify. In 2016, 25% of Indians had a mobile phone [28]. Among urban Indian mobile phone owners, the proportion who were less educated and earned a low income expanded from 38% to 45% between 2013 and 2015 [29].

Many other materials presented to the Indian public online are not this complex. Prior researchers have measured the Flesch-Kincaid Grade Level of a number of different websites administered by the Indian government and found their grade levels to be more moderate. For instance, the website of the Indian Air Force was written at an 8.4 grade level, whereas the website of the High Court of Bombay was written at a 6.6 grade level [30]. Although government-oriented websites may be inherently less complex than privacy policies, they do demonstrate that it is possible to convey information to the masses in a simple format.

Privacy policies incomprehensible to the majority of users are unfair because they do not allow users to make an informed choice between their desire for privacy and their desire to sacrifice some privacy to obtain the benefits of the app. As the Flesch-Kincaid Grade Level metrics suggest that some college education may be required to understand the privacy policies of three-quarters of apps, the majority of Indian diabetes and mental health app users are left with the choice between not using the majority of apps or agreeing to privacy policies that they may not fully understand. The potential for unfairness was highlighted when the provider of public Wi-Fi services, Purple, created a deliberately unreasonable privacy policy, requiring users to perform 1000 hours of community service on agreement and offering anyone who read to the end a prize if they contacted them. Of the 22,000 people who agreed to the policy, only one person contacted the company after having thoroughly read it [31].

Recommendations

Privacy policies do not need to be incomprehensible. Complex concepts can be explained graphically to make them more accessible to people with limited reading comprehension. For instance, Creative Commons has created a standardized set of logos that indicate the rights that the authors of media have reserved [32]. These logos can be understood at a glance by people informed of their meaning. A similar approach could be

applied to privacy policies if a standardized set of policies, with associated logos, were created.

Furthermore, standardized licenses like the GNU General Public License enable users to avoid the hassle of re-reading a long document each time they agree to use software by providing consistency across licenses [33]. Although users with lower levels of reading comprehension may not be able to understand standardized licenses, they too can benefit because more educated users have thoroughly vetted the policies to ensure that they are fair. When nonstandard policies are used, the likelihood of them being read by anyone (regardless of ability) is lower than when standardized policies are used. Furthermore, abstract concepts, such as deidentification and anonymization, can be explained with graphical representations so that they may be more widely understood. Finally, outreach efforts to help educate and explain the risk and benefits of digital technologies such as apps may be necessary to ensure individuals are equipped to make informed decisions regarding use. Already, online resources for digital technology ethics and privacy are emerging, such as the free-to-access and use Connected and Open Research Ethics Initiative [34].

Limitations

The results of this study reflect two categories of health apps, from one country, from one app store, examined at one period in time. It is possible that the findings from this study are not generalizable to other types of apps, to other app stores (eg, the iTunes App Store), or to apps that are not of Indian origin. It is also possible that the privacy policies of apps may evolve over time. Furthermore, although apps addressing a broad selection of mental illnesses were analyzed, only apps addressing a single physical illness (diabetes) was analyzed. It was necessary to analyze apps addressing multiple mental illnesses rather than a single mental illness due to the relative paucity of apps addressing each illness. Even after this accommodation, the sample of apps related to mental health was substantially smaller than the sample of diabetes apps. The findings of this study may have been impacted by the set of keywords used during the app sample selection process. The 2017 actions of the Indian Supreme Court [1], which occurred after the data collection for this study was complete, may cause India-based app developers to evaluate whether their privacy policies remain consistent with the needs of Indian users and with Indian law.

Conclusions

Although no differences were found between the complexity of the privacy policies of Indian apps for diabetes versus mental health, both were found to be complex. Some of the measures calculated suggested that a college level of reading comprehension is required to understand the typical privacy policy in an Indian app for diabetes or mental health. In order to ensure that the majority of India's citizens are able to willfully consent to privacy policies when using apps, an effort to simplify privacy policies is needed.

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Conflicts of Interest

AP reports employment at Payer+Provider Syndicate, scientific/medical advisory board member with the Mary Christie Foundation and PsyberGuide, and stock ownership of Payer+Provider Syndicate, Select Medical Holdings, Team Health Holdings, AmSurg Corp, Centene Corp, CVS Health Corp, Community Health Systems, HCA Holdings, Inc, Quorum Health Corporation, and Tenet Healthcare Corp. PS and JT have nothing to disclose. None of the authors have a direct conflict of interest with the study.

References

1. AP News. 2017 Aug 25. India's Supreme Court rules privacy is a fundamental right URL: <https://apnews.com/12c1222843d24573a74388c3f68d1f69> [accessed 2018-05-04] [WebCite Cache ID 6zAkIzVLq]
2. Peiris D, Praveen D, Johnson C, Mogulluru K. Use of mHealth systems and tools for non-communicable diseases in low- and middle-income countries: a systematic review. *J Cardiovasc Transl Res* 2014 Nov;7(8):677-691. [doi: [10.1007/s12265-014-9581-5](https://doi.org/10.1007/s12265-014-9581-5)] [Medline: [25209729](https://pubmed.ncbi.nlm.nih.gov/25209729/)]
3. Seeman N, Tang S, Brown A, Ing A. World survey of mental illness stigma. *J Affect Disord* 2016 Jan 15;190:115-121. [doi: [10.1016/j.jad.2015.10.011](https://doi.org/10.1016/j.jad.2015.10.011)] [Medline: [26496017](https://pubmed.ncbi.nlm.nih.gov/26496017/)]
4. Charlson FJ, Baxter AJ, Cheng HG, Shidhaye R, Whiteford HA. The burden of mental, neurological, and substance use disorders in China and India: a systematic analysis of community representative epidemiological studies. *Lancet* 2016 Jul 23;388(10042):376-389. [doi: [10.1016/S0140-6736\(16\)30590-6](https://doi.org/10.1016/S0140-6736(16)30590-6)] [Medline: [27209143](https://pubmed.ncbi.nlm.nih.gov/27209143/)]
5. Malik R. Times of India. 2016 Jan 28. India is the diabetes capital of the world! URL: <https://timesofindia.indiatimes.com/life-style/health-fitness/health-news/India-is-the-diabetes-capital-of-the-world/articleshow/50753461.cms> [accessed 2018-05-04] [WebCite Cache ID 6zAkMrUlv]
6. International Diabetes Foundation. 2018. IDF SEA Region URL: <https://www.idf.org/our-network/regions-members/south-east-asia/members/94-india.html> [accessed 2018-05-04] [WebCite Cache ID 6zAkPBsUo]
7. Blenner SR, Köllmer M, Rouse AJ, Daneshvar N, Williams C, Andrews LB. Privacy policies of android diabetes apps and sharing of health information. *JAMA* 2016 Mar 08;315(10):1051-1052. [doi: [10.1001/jama.2015.19426](https://doi.org/10.1001/jama.2015.19426)] [Medline: [26954415](https://pubmed.ncbi.nlm.nih.gov/26954415/)]
8. Rosenfeld L, Torous J, Vahia I. Data security and privacy in apps for dementia: an analysis of existing privacy policies. *Am J Geriatr Psychiatry* 2017 Aug;25(8):873-877. [doi: [10.1016/j.jagp.2017.04.009](https://doi.org/10.1016/j.jagp.2017.04.009)] [Medline: [28645535](https://pubmed.ncbi.nlm.nih.gov/28645535/)]
9. Glenn T, Monteith S. Privacy in the digital world: medical and health data outside of HIPAA protections. *Curr Psychiatry Rep* 2014 Nov;16(11):494. [doi: [10.1007/s11920-014-0494-4](https://doi.org/10.1007/s11920-014-0494-4)] [Medline: [25218603](https://pubmed.ncbi.nlm.nih.gov/25218603/)]
10. DeSalvo KB, Samuels J. Health IT Buzz. 2017 Jul 19. Examining oversight of the privacy & security of health data collected by entities not regulated by HIPAA URL: <https://www.healthit.gov/buzz-blog/privacy-and-security-of-ehrs/examining-oversight-privacy-security-health-data-collected-entities-not-regulated-hipaa/> [accessed 2018-05-04] [WebCite Cache ID 6zAkVCVYr]
11. Granville K. The New York Times. 2018 Mar 19. Facebook and Cambridge Analytica: what you need to know as fallout widens URL: <https://www.nytimes.com/2018/03/19/technology/facebook-cambridge-analytica-explained.html> [accessed 2018-05-03] [WebCite Cache ID 6zAkW70WH]
12. Marvel CL, Paradiso S. Cognitive and neurological impairment in mood disorders. *Psychiatr Clin North Am* 2004 Mar;27(1):19-36, vii [FREE Full text] [doi: [10.1016/S0193-953X\(03\)00106-0](https://doi.org/10.1016/S0193-953X(03)00106-0)] [Medline: [15062628](https://pubmed.ncbi.nlm.nih.gov/15062628/)]
13. Trivedi J. Cognitive deficits in psychiatric disorders: current status. *Indian J Psychiatry* 2006 Jan;48(1):10-20 [FREE Full text] [doi: [10.4103/0019-5545.31613](https://doi.org/10.4103/0019-5545.31613)] [Medline: [20703409](https://pubmed.ncbi.nlm.nih.gov/20703409/)]
14. Seeman N, Tang S, Brown AD, Ing A. World survey of mental illness stigma. *J Affect Disord* 2016 Jan 15;190:115-121. [doi: [10.1016/j.jad.2015.10.011](https://doi.org/10.1016/j.jad.2015.10.011)] [Medline: [26496017](https://pubmed.ncbi.nlm.nih.gov/26496017/)]
15. Sunyaev A, Dehling T, Taylor PL, Mandl KD. Availability and quality of mobile health app privacy policies. *J Am Med Inform Assoc* 2015 Apr;22(e1):e28-e33. [doi: [10.1136/amiajnl-2013-002605](https://doi.org/10.1136/amiajnl-2013-002605)] [Medline: [25147247](https://pubmed.ncbi.nlm.nih.gov/25147247/)]
16. Reidenberg J, Breaux T, Cranor L, French B. Disagreeable privacy policies: mismatches between meaning and users' understanding. *Berkeley Tech LJ* 2015;30(1):39. [doi: [10.15779/Z384K33](https://doi.org/10.15779/Z384K33)]
17. McDonald AM, Reeder RW, Kelley PG, Cranor LF. A comparative study of online privacy policies and formats. 2019 Aug 05 Presented at: International Symposium on Privacy Enhancing Technologies Symposium; Aug 5, 2009; Berlin p. 37-55. [doi: [10.1007/978-3-642-03168-7_3](https://doi.org/10.1007/978-3-642-03168-7_3)]
18. Graber MA, D'Alessandro DM, Johnson-West J. Reading level of privacy policies on Internet health Web sites. *J Fam Pract* 2002 Jul;51(7):642-645. [Medline: [12160504](https://pubmed.ncbi.nlm.nih.gov/12160504/)]
19. Ermakova T, Fabian B, Babina E. Readability of privacy policies of healthcare websites. 2015 Presented at: 12th International Conference on Wirtschaftsinformatik; Mar 4-5, 2015; Osnabrück, Germany p. 1085-1099.

20. Sheehan K. In poor health: an assessment of privacy policies at direct-to-consumer web sites. *J Public Policy Mark* 2005 Sep 01;24(2):1. [doi: [10.1509/jppm.2005.24.2.273](https://doi.org/10.1509/jppm.2005.24.2.273)]
21. Singh R, Sumeeth M, Miller J. Evaluating the readability of privacy policies in mobile environments. In: Lumsden J, editor. *Developments in Technologies for Human-Centric Mobile Computing and Applications*. Hershey, PA: IGI Global; 2012:56-78.
22. Bellman S, Johnson E, Kobrin S, Lohse G. International differences in information privacy concerns: a global survey of consumers. *The Information Society* 2004 Nov;20(5):313-324. [doi: [10.1080/01972240490507956](https://doi.org/10.1080/01972240490507956)]
23. Wikipedia. 2018. List of countries by English-speaking population URL: https://en.wikipedia.org/wiki/List_of_countries_by_English-speaking_population [accessed 2018-05-04] [WebCite Cache ID 6zAkXIHGo]
24. Wikipedia. 2018. List of countries by smartphone penetration URL: https://en.wikipedia.org/wiki/List_of_countries_by_smartphone_penetration [accessed 2018-05-04] [WebCite Cache ID 6zAkgLa2x]
25. Office of the Registrar General & Census Commissioner, India. 2017. Census of India URL: <http://www.censusindia.gov.in/2011census/C-series/C08.html> [accessed 2018-05-04] [WebCite Cache ID 6zAkhEBXp]
26. United States Census Bureau. 2017. American FactFinder URL: https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_15_5YR_S1501&src=pt [accessed 2017-09-24] [WebCite Cache ID 6zAki6Ch3]
27. Deogaonkar M. Socio-economic inequality and its effect on healthcare delivery in India: inequality and healthcare. *Electron J Sociol* 2004;11:e1.
28. Pew Research Center: Global Attitudes & Trends. 2017. Spring 2016 Survey Data URL: <http://www.pewglobal.org/datasets/> [accessed 2018-05-04] [WebCite Cache ID 6zAkiy7fs]
29. The Changing Mobile Broadband Landscape: Understanding the Diverse Behavior and Needs of Smartphone Mobile Internet Users in Urban India. Stockholm: Ericsson ConsumerLab; 2015 Apr. URL: <https://www.ericsson.com/assets/local/news/2015/4/ericsson-consumerlab-the-changing-mobile-broadband-landscape-india.pdf> [accessed 2017-10-23] [WebCite Cache ID 6zAl3PS5n]
30. Ismail A, Kuppusamy K, Kumar A, Ojha P. Connect the dots: accessibility, readability and site ranking – An investigation with reference to top ranked websites of Government of India. *J King Saud U Comp Inform Sci* 2017 May 22:A [FREE Full text] [doi: [10.1016/j.jksuci.2017.05.007](https://doi.org/10.1016/j.jksuci.2017.05.007)]
31. Jones R. Gizmodo. 2017 Jul 16. 22,000 People agree to clean toilets for WiFi because they didn't read the terms URL: <https://gizmodo.com/22-000-people-agree-to-clean-toilets-for-wifi-because-t-1796959482> [accessed 2018-05-04] [WebCite Cache ID 6zAkpMgq5]
32. Creative Commons. 2017. Licenses and examples URL: <https://creativecommons.org/share-your-work/licensing-types-examples/licensing-examples/> [accessed 2018-05-04] [WebCite Cache ID 6zAksNV0I]
33. GNU Operating System. 2017. Frequently asked questions about the GNU licenses URL: <http://www.gnu.org/licenses/gpl-faq.html> [accessed 2018-05-04] [WebCite Cache ID 6zAktBWLy]
34. CORE. 2017. Connected and Open Research Ethics URL: <https://thecore.ucsd.edu/> [accessed 2018-05-04] [WebCite Cache ID 6zAkp9Mr]

Abbreviations

DALY: disability-adjusted life years

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Original Paper

Mobile Apps for Caregivers of Older Adults: Quantitative Content Analysis

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Abstract

Background: Informal caregivers of older adults provide critical support for their loved ones but are subject to negative health outcomes because of burden and stress. Interventions to provide information and resources as well as social and emotional support reduce burden. Mobile apps featuring access to information, assistance with scheduling, and other features can automate support functions inexpensively and conveniently and reach a greater proportion of caregivers than otherwise possible.

Objective: The aim of this study was to identify mobile apps geared towards caregivers of older adults, catalog features, and suggest best practices for adoption based on empirical findings of beneficial interventions in the caregiving literature.

Methods: Search for apps focused on ones catered for caregivers of older adults in Google Play and iTunes, compiling their features, and identifying features reflecting categories of support identified in successful intervention studies to negative caregiver outcomes. Intervention research indicates that provision of information and resources, assistance in practical problem solving, coordinating care among multiple caregivers, and emotional support reduce caregiver burden.

Results: Despite approximately over 200,000 mobile health-related apps, the availability of mobile apps for caregivers is relatively sparse (n=44 apps) as of October 2017. Apps generally addressed specific categories of support, including information and resources, family communication, and caregiver-recipient interactions. Few apps were comprehensive. Only 8 out of 44 (18%) had features that addressed three or more categories. Few apps provided specific stress reduction exercises for caregivers, which is important for reducing burden.

Conclusions: Mobile apps have the potential to provide resources, just-in-time information for problem-solving, and stress reduction strategies for caregivers. Many apps offer functions that have been shown to reduce burden and improve health outcomes in caregivers, but few provide emotional support. Using an evidence-based practice approach, mobile apps for caregivers can provide multiple beneficial support functions. Apps can serve a much larger proportion of this highly underserved population in their mobile form than more traditional means, improving their health and quality of life.

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KEYWORDS

mobile apps; aged; elderly; caregivers; family caregivers; carers; adult children; quality of life; dementia

Introduction

The rapid increase in longevity and the post-World War II baby boom have produced major demographic changes in the United States. The number of adults over the age of 65 in the US is expected to be 89 million by 2050, more than double the number of older adults in the US in 2010 [1]. Critical developments

associated with the increase in longevity are the reduction of acute diseases associated with mortality and the rise in chronic diseases as leading causes of disability, and death [1]. Indeed, the majority of adults over 65 years of age have one or more chronic conditions such as arthritis or hypertension. Importantly, the quality of life also declines with an increasing number of chronic conditions. The ability to perform Instrumental Activities of Daily Living (IADL), such as grocery shopping

or housework is likely to be affected by chronic disease. As frailty increases, the ability to engage successfully in basic Activities of Daily Living (ADL), such as toileting, feeding, or bathing may also be compromised. This leads to a loss of independence, and a greater reliance on others for assistance in daily tasks [1]. Because the US health care system is designed to focus on acute care (treating curable illness), the responsibility of managing more chronic or long-term conditions typically falls upon family members, who have been called the “backbone” of this type of care [2].

According to the National Alliance for Caregiving (NAC) and the American Association of Retired Persons (AARP) Caregiving in the US 2015 report [3], an estimated 34.2 million adults in the US provided unpaid care to an adult aged 50 years or older in 2014. The majority of these caregivers provided care for a relative, with 49% caring for a parent or a parent-in-law and 10% providing care for a spouse or partner. The top 3 reported reasons for care were (1) old age, (2) Alzheimer disease or another type of dementia, and (3) surgery or wounds. Family caregivers spend, on average, 24.4 hours a week providing care for their loved ones, and this amount of time is almost doubled to 44.6 hours a week for those providing care for a spouse or partner. Much of caregiving efforts are spent assisting with ADLs, and on average, 4.2 out of 7 IADLs. Also, caregivers often engage in other activities on behalf of their care recipients to coordinate care, such as communicating with care providers, and other agencies [3]. Furthermore, a growing number of family caregivers are members of the so-called “sandwich generation,” balancing care for dependent children and aging parents simultaneously, adding to the complexity and stress of care responsibilities [4].

Researchers have thoroughly documented that high demands of caregiving often lead caregivers to experience stress in physical, mental, and social health. This is a phenomenon commonly referred to as caregiver burden. Although there is no medical diagnosis code for caregiver burden, Zarit et al [5] define it as “the extent to which caregivers perceive that caregiving has had an adverse effect on their emotional, social, financial, physical, and spiritual functioning.” Indeed, as a meta-analysis revealed, in comparison to noncaregivers, caregivers fare worse across 5 indicators of health, including depression, stress, subjective well-being, self-efficacy, and physical health [6]. Risk factors for experiencing caregiver burden include being female, having low education, living with the care recipient, higher number of hours spent providing care, depression, social isolation, financial stress, and the lack of choice in being a caregiver [3,7]. Unfortunately, the amount of caregiver burden continues to rise with the aging population, as individuals are living longer but not necessarily healthier, as evidenced by the continued prevalence of chronic disease [8].

For those providing care for individuals with dementia, the risk of caregiver burden is especially high. Caregivers of individuals diagnosed with moderate to severe dementia, with the inability to perform most IADLs and the presence of behavioral disturbances, tend to experience higher levels of caregiver burden [9]. Higher caregiver burden correlated with dementia severity is seen more in women and older caregivers [10]. In caregivers of individuals with dementia, greater psychological

distress, including depression, anxiety, and hostility, tends to occur with increased caregiver burden [11].

One theoretical framework that has played a particularly prominent role in shaping the development of interventions is the stress process framework [12]. The stress process framework combines prior research by Pearlin et al [13] and the transactional model of stress and coping [14]. The theoretical framework asserts that factors in the care context can influence the types of stressors that caregivers tend to experience, the way they appraise and cope with that stress, and caregiving outcomes. The stress framework has been extremely influential in the design of caregiver support services in several ways. First, it demonstrated that caregiver stress involves more than the burden of providing physical care. Instead, as the caregiver experience is influenced by variables across multiple domains, it is not likely that one single intervention will effectively reduce caregiver stress. Thus, the stress framework underscored the need for programs to target multiple domains for intervention. It also led to the development of a wide range of psychosocial interventions. Before the stress process framework, the primary focus of caregiver support programs was providing respite or chore services, which proved to be relatively ineffective on their own [15]. However, the stress process framework has led to a vast increase in psychoeducational programs, two of which are the Savvy Caregiver Program [16] and Powerful Tools for Caregivers [17]. Both of these programs are influenced by the stress and coping framework [14] and have been identified as best practice models for caregiver intervention.

Many intervention studies have focused on reducing caregiver burden among caregivers of older adults with dementia (ie, those with highest burden levels). Interventions that have been found to be most successful have provided them with information about dementia, trained practical problem-solving skills, improved family communication and other social support, and increased caregivers’ sense of self-efficacy [18,19]. Recent studies have delivered such interventions, grounded in stress and coping theory, using forms of remote communication. For example, in the Miami REACH (Resources for Enhancing Alzheimer’s Caregiver Health) program, Cuban American caregivers who were provided with in-person family therapy, access to information databases, and conference calls in conjunction with a Computer-Telephone Integrated System. For example, telephones with monitors that allowed remote visual communication with therapists, showed the most significant reduction in caregiver depression after 6 months. Benefits were sustained at 18 months relative to conventional family therapy or only minimal support [20]. Bank et al [21] also demonstrated the generalization of telephone support groups for ethnically diverse caregivers of individuals with dementia, with similar patterns of benefit from the different features of the intervention.

Although there have been some mixed findings, Web-based caregiving programs have strong potential to increase access to social support from other caregivers and new social contacts, access to relevant information, and support from care professionals. These types of programs have also been shown to lead to improvements in coping skills, confidence, and self-efficacy and significant reductions in caregiver depression,

anxiety, stress, and strain [22-26]. A recent review study on Web-based technologies for caregivers of individuals with chronic illness supported these findings that internet-based interventions can improve mental health, physical health, and general caregiving outcomes [27].

The ubiquity of mobile technology also has great potential for reducing caregiver burden. Technology already plays a pivotal role in many aspects of everyday life. According to Nielsen, 71.4% of adults living in the US own a mobile phone [28], and 89% of mobile media time is spent using a mobile app [29]. TechCrunch reported that many users believe apps to be more convenient (55%), faster (48%), and easier to browse (40%) than mobile websites [30]. Also, whereas adoption of traditional computer use has declined or stalled, the adoption of mobile devices such as smartphones continues to grow among Americans over 50 years of age. Over half of this group now owns a smartphone, and this number continues to grow [31].

Mobile app programs are easily accessible, generally inexpensive, and provide a repository for information, which they can integrate from multiple sources [32]. This makes them promising tools for assisting with important health-related activities. For example, Wang et al [33] found that smartphone interventions were effective in helping individuals manage chronic diseases including diabetes, obesity, depression, and cancer. With the help of mobile app programs, patients with chronic conditions participated in their health management more effectively, felt more secure in the knowledge that their illnesses were closely monitored, and felt more connected to their doctors. Although we could find no published study examining the effect of app programs on reducing caregiver burden, it is very likely that mobile technology has vast potential to support caregiving by providing convenient tools and resources to coordinate the demanding tasks and the complex networks of relationships involved in caring for others. Also, Schulz et al [34] found that caregivers are willing to pay for technologies to help their loved ones but unwilling to pay significant amounts, making inexpensive mobile apps an acceptable solution.

In an online survey of 1000 technology using caregivers conducted by the NAC and United Healthcare [35], 7 in 10 respondents reported they would be somewhat or very receptive to using a smartphone for apps to help them with caregiving (69%). Younger caregivers were twice as likely to report being very receptive (43% versus 21% of caregivers 50 years of age or older) to using smartphone apps to help with caregiving needs. Also, those employed full time are more receptive than caregivers who are not employed to using a smartphone to help with caregiving (78% versus 57% very or somewhat receptive), even when controlling for the caregiver's age. A larger proportion of medium- to high-burden caregivers report being very receptive to using caregiving apps (34%) relative to low-burden caregivers (25%), likely reflecting their greater need for assistance. Furthermore, a recent NAC report featuring results from a roundtable of experts from government, Silicon Valley entrepreneurs, caregiving advocates, and researchers identifies the need for and recommends the development of mobile technology to better support family caregiving [36].

It is estimated that the number of mobile health (mHealth) apps available to consumers exceeds 259,000 [37,38]. A small subset of these apps is designed to assist family caregivers with the specific challenges associated with providing care to older adults with dementia and other chronic diseases. We surveyed and reviewed the types of apps available for caregivers of older adults in October 2017. We identified these apps to determine whether they reflected aspects of support shown to be the most effective in the caregiving literature and could in principle reduce levels of burden, providing much needed, uniquely accessible support to this valuable population.

Methods

During October 2017, apps in English that self-identified or advertised themselves as tools or aids for caregiving were identified in the iTunes App Store and Google Play, the most prevalent operating systems in use by smartphones, by searching the keywords "caregiving," "caregiver," and "elder care." The internet was also used to identify caregiving apps using the search phrase, "caregiving apps," in Google Search. Only apps that specifically addressed family or informal caregivers of older adults were included.

Apps developed for professional caregiving provider organizations or apps that help locate professional caregiving services were excluded. Apps that were designed for those living with specific conditions or health issues (eg, stroke or cancer patients) were also excluded from this study, but it is important to acknowledge that these may also be used by caregivers. All apps were classified on their platform availability. This included the Apple iOS or Android and both phone and tablet, cost, and features as described on their iTunes App store or Google Play store page.

Results

Census of Relevant Apps

Relative to general mHealth apps, availability of mobile apps geared towards caregivers of older adults is relatively sparse with 44 apps as of October 2017. Nevertheless, this number has been steadily on the rise. Existing caregiving apps generally addressed specific aspects of the caregiving experience. Few apps were comprehensive, with only 7/44 (16%) apps with features that addressed 3 functions, and 1 (2%) app addressing 4 or more (Table 1).

Content Analysis

The 44 app programs (Multimedia Appendix 1) were categorized separately by two coders (authors MG and DZ) and the differences were resolved by discussion. The categories were not mutually exclusive (Table 2). They represented functions served by successful caregiver burden reduction interventions: (1) information and resources, (2) practical problem-solving involving behavioral solutions, medication management, safety, and personal health record tracking, (3) memory aids, (4) family communication, including coordinating care, calendars for appointments and sharing, medical and emergency contact lists, ability to share important information, photos, and messages among caregivers and family members, and (5) caregiver support

(ie, care for the caregiver), and comprehensive apps that integrated multiple functions [18,19]. Of the 44 apps, 22 (50%) were specifically designed for caregivers of individuals with dementia.

Information and Resources

Fifteen (34%) apps met criteria for providing caregivers with *Information and Resources*. These apps provide medical information and expert advice on topics in aging or elder care. Some include searchable databases on a wide variety of medical conditions, with features that include videos, symptom tracking, personalized reports, and first aid essentials. Of these 15, 9 (60%) apps were designed specifically for caregivers of individuals with Alzheimer disease or other forms of dementia, offering information and helpful solutions for difficult dementia-related behaviors. The remaining 6 (40%) were for caregivers of older adults, providing important information on more general eldercare topics.

Practical Problem Solving

A total of 21 app programs addressed practical problem-solving needs that many caregivers share. Practical problem solving was defined as addressing medication management, safety, personal health record tracking, or behavioral solutions. Three of the 21 (14%) apps contained tools for *Medication Management*. Common features for these apps include medication schedule and reminder programs, missed dose alerts,

refill reminders, searchable drug databases with drug information such as dosage, indication, side effects, and drug interactions. While many other medication management apps exist, they are not geared toward caregivers of older adults, and thus were excluded from the search.

One serious concern for caregivers of family members with Alzheimer disease or other types of dementia is wandering by the care recipient. For example, 60% of the individuals with dementia will wander, and this can lead to dangerous consequences [39,40]. Five (24%) apps contained tools to address the *Safety* of loved ones by monitoring their movements. Two (10%) of these apps used GPS to inform caregivers of the location of their care recipients and relied on their having a GPS-enabled phone on their person. Of these, 1 (5%) app was available in iOS only and the other was available in both iOS, and Android. Both were free, and 1 was designed to improve the autonomy of individuals with Alzheimer disease in the early stages of the disease. Walking has been found to be beneficial in the early stages of this disease, and these apps might make it more likely for individuals with Alzheimer disease to go for walks on their own, supporting an also critical sense of autonomy. The remaining 3 (14%) apps featured wearable technology or home sensors at an added cost that allow family caregivers to monitor their loved ones' whereabouts. These apps were designed specifically as a tool for caregivers of persons with dementia.

Table 1. Number of functions associated with caregiving apps (N=44).

Number of functions	n (%)
1	25 (57)
2	11 (25)
3	7 (16)
4	1 (2)

Table 2. Apps meeting the criteria for each category of features (N=44). Note that some apps meet the criteria for more than one category.

Category	Examples and features	Platforms, n (%)			
		iOS	Android	Both	Total
Information and resources	Tips and advice; information about dementia, other diseases; searchable databases; videos; symptom tracking	4 (9)	3 (7)	8 (18)	15 (44)
Family communication	Care coordination among family; instant messaging; calendar sharing; to-do lists	3 (7)	2 (5)	10 (23)	15 (44)
Memory aids	Activities for care recipient; conversation starters; tools for memory support and reminiscence	5 (11)	4 (9)	3 (7)	12 (27)
Care for caregiver	Support/chat groups Burden assessments; words of encouragement	2 (5)	4 (9)	4 (9)	10 (23)
Behavior solutions	Tips and information to manage problem behaviors (eg, agitation, wandering)	3 (7)	2 (5)	3 (7)	8 (18)
Medication management	Medication reminders; dosage information; drug-interaction databases	—	—	3 (7)	3 (7)
Safety	GPS ^a /motion sensor tracking; automated check-in calls; alarms and reminders	1 (2)	1 (2)	3 (7)	5 (11)
Personal health record tracking	Doctors' appointment reminders	1 (2)	—	4 (9)	5 (11)

^aGPS: Global Positioning System.

Personal Health Record Tracking apps allow caregivers to collect, track and share past and current health information about a care recipient. They often accommodate multiple user profiles with emergency contact information, health insurance, doctors' contact information, and reminders for doctors' appointments, and other upcoming medical appointments on a calendar. Five of the 21 (24%) practical problem-solving apps were identified that provided specific health record tracking tools to assist caregivers with managing their loved one's health.

In addition, 8 apps (38%) provided suggested solutions for dealing with behavioral problems that can arise in the care recipient. All of these apps were specifically designed for those caring for individuals with Alzheimer disease or other forms of dementia, as behavioral disturbances are often present in the middle and later stages of the disease and can be challenging for family members to handle. Examples of behavioral solutions or tips provided by these apps include how to address sleep disturbances, delusions, hallucinations, wandering, and catastrophic responses to stressors later in the day possibly associated with light changes towards sundown ("sundowning").

Family Communication

Our search yielded 15 apps that facilitate better communication for coordinating care among family members. These apps were designed as communication tools to allow family, friends, neighbors, and colleagues to coordinate care needs for the care recipient. The apps allow caregivers to create profiles of their loved one containing health information pertinent to care, such as medical condition, medication list, and emergency contacts. An important feature of many of these apps is a shared calendar to coordinate the efforts of multiple family members or caregivers to assure recipient's needs are addressed. With features such as instant messaging, sharing of photos and videos and other updates, they also provide a much-needed support network for caregivers. Only 2/15 (13%) of these apps were specifically designed for caregivers of persons with dementia, though the others were all designed for elder care.

Memory Aids

Importantly, some apps aim to reduce caregiver burden by stimulating or supporting the needs of the care recipient. There has been a recent influx of care recipient focused *Memory Aid* apps (currently numbering 12 apps), designed to assist individuals with Alzheimer disease and other types of dementia by supporting enhanced cognitive function, communication, and quality of life. Two of these 12 (17%) apps serve as tools for memory assistance, providing cues and reminders for a list of tasks for people with dementia, traumatic brain injury, or other memory disorders. Nine (75%) apps aim to improve the quality of life for people with dementia and their caregivers through shared activities such as making an interactive life storybook, or providing story starters, memory games, and music and videos. Additionally, 1 (8%) app provides a picture-based communication tool for caregivers of individuals with little to no verbal communication ability, including those in the later stages of dementia.

Care for Caregiver

Caregivers are providing a significant service managing their loved ones' health, but occasionally the stressful nature of this role can become detrimental to their own health. A total of 10/44 (23%) apps contained components to address caring for the caregiver, in the sense of providing emotional or social support or forms of stress relief, and respite. Apps in this category contain features such as chats or app-based support groups or social networks, assessments to track stress and burden level to be aware of one's condition, suggestions for supporting one's own health and quality of life and encouraging words, and advice from other caregivers.

Comprehensive

Comprehensive app programs combine some of the functions described thus far including: symptom tracking and journaling, medication management with refill reminders, calendars for appointments and coordinating care, medical record profiles with emergency contact lists, and features that enable sharing of information, photos, messages among caregivers and other family members. While no apps in our October 2017 search addressed all empirically-derived components of necessary caregiver support, 1/44 (2%) app was found that addressed at least half (4 out of 8) of these components and thus was deemed comprehensive in nature.

The *Balance: For Alzheimer Caregivers* app allows caregivers to coordinate care among multiple family members by tracking physical, behavioral, and emotional changes in the care recipient and sharing the information with other caregivers and doctors in real time using a chat feature. It also enables multiple caregivers to manage caregiving tasks and provides a newsfeed with the latest Alzheimer disease and caregiving findings and information. Additionally, the app includes a one-click button to connect to a free 24-hour helpline, available in a range of languages, and a "doctor diary" which caregivers can use to communicate with doctors about changes in symptoms and behaviors in "real time." This app is created by RiverSpring Health, a senior health care organization, and CaringKind, a dementia non-profit which was formally the New York City chapter of the Alzheimer's Association. CaringKind professionals manage the 24-hour helpline, lending support to its credibility (Note that these are the features as described in 2017, and apps frequently undergo changes and updates.)

Cost and Platform Availability

The apps meeting our search criteria varied in cost and platform availability. Most were available for free, although some required or encouraged supplemental in-app purchases. Of those that did cost to download, the fee ranged from US \$0.99 to US \$29.99 making them relatively affordable. The only exceptions were the safety apps requiring additional GPS or sensor technologies. While the apps themselves were free, 2 required wearable sensors and hardware kits that start at US \$249.99, and 1 offered home-based sensor technology at subscription rate ranging from approximately US \$60 to US \$170 per month, depending on the number of sensors needed.

Most apps (23/44, 52%) were available for both iOS and Android devices. However, of those available in only 1 platform,

slightly more were available for download for iOS than for Android devices.

Discussion

Principal Findings

In summary, over the last few years, there has been growth in the number of mobile apps targeted at caregivers of older adults and designed to help them manage caregiving responsibilities and reduce levels of burden. However, in comparison to the large number of mHealth apps and caregiving apps available more generally, there are still relatively few apps catering specifically to the unique needs of caregivers of older adults. As the baby boomer generation is aging, this country is bracing to deal with the largest proportion of older adults our population has ever seen. For the first time in the US and globally, adults 60 years of age and older will soon outnumber children aged 5 years and under. [41]. The primary responsibility to care for this growing number of older adults, along with their chronic health conditions, is poised to fall upon family caregivers. However, because of other simultaneously occurring demographic changes, such as lower birth rate and greater geographic dispersion of family members, the number of available family caregivers is decreasing, leaving an unfortunate imbalance between those available to provide care and those who need it [42].

Alzheimer disease and other types of dementia are projected to increase drastically with the aging of the population. Currently, Alzheimer disease affects over 5 million Americans, and it is projected that this number will triple by 2050 [43,44]. The majority of individuals with dementia are cared for at home by family members. Fortunately, our review showed an increase in recent development of mobile apps targeted at Alzheimer disease and other forms of dementia, with a particularly large number of apps addressing the domains of information and resources for caregivers and memory aids and enrichment for care recipients. This development is encouraging, and it is important that apps in this area continue to grow, as there is still no cure for Alzheimer disease, an illness that takes a huge toll on both the caregiver and recipient. For this reason, it is also a positive development to see apps directed at the care recipient as well as the caregiver. For example, certain apps were designed to help those with dementia maintain feelings of autonomy and independence for as long as possible. Others aim to foster improved interaction and communication between the caregiver and care recipient, a relationship that can sometimes become tense on both sides. A focus on individuals with dementia and their family members as care partners, rather than as patient and caregiver, is promising and in line with research on the increasingly recognized value of person-centered care [45,46].

Another finding revealed by this study is that caregiving apps still have room for improvement regarding their comprehensiveness. For instance, 25/44 (57%) of the apps surveyed provided only 1 service to caregivers. Only 8 (17%) of the 44 apps provided 3 or more services. Caregivers are already balancing various daily tasks, medical appointments, jobs, and more. Thus, it might be ideal to combine as many

useful features as possible into 1 easy-to-use app. The goal of mobile apps to support caregivers should be to reduce their load to help their productivity rather than hinder it. Also, as mentioned previously, the stress process framework suggests that caregivers experience stress in a larger context and targeting just one problem or fulfilling a single need will likely be less effective than an intervention targeting multiple needs [15].

In addition, most of the caregiving apps currently on the market do not seem to have been developed with the guidance of caregiving researchers. Therefore, there may be gaps between app features and empirical findings regarding caregiver burden and effective means of intervention. Future developers should collaborate with academic researchers to ensure that their apps are designed with the current empirical evidence in mind. For example, one crucial area particularly overlooked by most existing apps is caring for the caregiver. While 10 (23%) apps provided some form of limited caregiver support, most of the apps focused on providing solutions to concrete problems (eg, tracking a wandering loved one, dealing with problematic behaviors, communicating with other family members, or keeping a health record). Though these are pressing needs, there is still an imperative demand for resources focusing on supporting the caregiver's emotional well-being, including coping with stress, anxiety, and depression. Our search yielded many general meditation and stress relief apps, but none were found to be directed toward caregivers of older adults and their unique stressors and experiences.

Recommendations for Outreach and Research

Family caregivers are providing an indispensable service to society, saving the health care system billions of dollars annually. Often, they do so to the detriment of their health and well-being. Furthermore, studies suggest that when the caregivers' mental health is strained, their care recipients may suffer as well, regarding worsened health and shortened longevity [47]. Therefore, it is vital to invest time and energy into developing technology with the potential to vastly improve the lives of caregivers and their loved ones receiving care.

Importantly, though they may be the ones who have the most to gain from this technology, family caregivers have been found to be less likely to use mobile apps than the general public [48]. This imbalance suggests that greater efforts need to be made to reach this population and show them the value of this burgeoning technology. Caregivers need to be made aware that these types of resources exist at their fingertips. Another potential barrier is that many family caregivers do not identify as care partners, sometimes for many years, and therefore may not search for resources like mobile apps. Policymakers and insurance providers should consider policies promoting the use of mHealth apps that have been shown to be effective at improving health outcomes via subsidies or other incentives [48]. Health professionals might also consider providing their patients and family caregivers with information on mobile apps available to them as a means of additional support, and can guide them in terms of selecting apps with evidence-based content.

Models of technology acceptance suggest that users, including older adults, are willing to invest in new technologies if they

perceive enough usefulness and ease of use [49-51]. Therefore, it is critical that apps reflect features that users find most beneficial. It is also critical that apps focus on being intuitive and easy to operate. One study examined mHealth app use among research participants, including those managing diabetes, depression, or caregiving, and found that many highly rated apps were still too difficult for participants to use [52]. Furthermore, caregivers are a group of people for whom time is typically strained, thus underscoring the value of simple, clear, and easy to operate technologies and interfaces.

For reasons such as these, user experience studies are needed to customize apps to the needs, desires, and abilities of the targeted users. For instance, it may prove useful to develop adaptive material for caregivers whose care recipients are experiencing different stages of dementia. A strategy that works to calm or stir memories in a person with dementia may work well initially but lose its effectiveness as the disease progresses. Dementia is a progressive disease, meaning that symptoms will change and worsen over time. Therefore, a one-size-fits-all approach may not be appropriate for dementia caregivers, at least not without addressing the diversity of caregivers and the evolving needs of their care recipients. Additionally, many caregivers of older adults are over 65 years of age themselves, caring for a spouse or other loved one. As such, app designers should involve older adults in the design process as much as possible, as opposed to simply testing with younger demographics. Apps that are user-friendly for younger adults may not be user-friendly for older users.

Another consideration that will be important as the field of mHealth continues to move forward is that of security and privacy, for example with video monitoring of care recipients. Of course, with the advent of these new technologies comes the great potential for increased supervision, safety, and support. However, these developments also give rise to important questions regarding the invasion of privacy and security of information [53,54]. Privacy concerns may be especially relevant to older adults, who voice the most concern over the privacy and security of their information online (AARP, 2017). To address these concerns, it has been argued that mHealth apps especially need to focus on standard app development guidelines and security authentication measures, such as device and app

passwords, strong encryption mechanisms, and informative privacy policies [55].

Another question worth considering is whether 1 app can, or should, actually “do it all.” While it is our opinion that simplicity, by way of fewer apps, will be preferred by caregivers, we must recognize that this may not be the case. Perhaps well-developed apps, each with a different focus, will be equally useful and preferred for the sake of compartmentalization. However, during our review, 6 caregiving apps that were included in an early count in December 2016 disappeared by October 2017, each of which had provided a singular service. This turnover pattern might provide support for the futility and limited appeal of single function apps for caregivers. Lastly, it is essential to take into account the frequency and duration of app use. If an app’s sole purpose is to provide information and resources, will caregivers continue usage after they have acquired the specific information they sought? For this reason, an app offering multiple features may be favored by caregivers and used more regularly.

Conclusions

In conclusion, the findings discussed in this paper should inform future work to develop more evidence-based, comprehensive apps to support caregivers’ needs and reduce caregiver burden. Apps may be an easy, accessible, and relatively inexpensive way to help this population manage and navigate the day-to-day challenges of the caregiving role, especially for those who do not have the time or means to seek out in-person support. More research is needed on effective mobile app interventions and resources for caregivers, including piloting with and surveying caregivers themselves to see how this technology can best suit their needs and preferences. It is extremely encouraging to see the number of relatively new apps supporting family caregivers of older adults. However, taking into account the input of caregivers themselves and incorporating the most up-to-date evidence emerging from research will likely be critical to the success and effectiveness of these apps. With the rapid growth of mobile phone use in our population and the simultaneous growing number of older adults, a golden opportunity exists to utilize mobile phone technologies to help manage their caregiving needs.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Catalog of caregiving apps and their features.

[[PDF File \(Adobe PDF File\), 42KB - mhealth_v6i7e162_app1.pdf](#)]

References

1. The state of aging and health in America 2013. Centers for Disease Control and Prevention. 2013. URL: <https://www.cdc.gov/aging/pdf/state-aging-health-in-america-2013.pdf>
2. Kane R. Meeting the challenge of chronic illness. Baltimore: Johns Hopkins University Press; 2005.
3. AARP, National AFC. Caregiving in the US; NAC and AARP Public Publishing Institute. AARP 2015:2015.
4. Boyczuk AM, Fletcher PC. The Ebbs and Flows: Stresses of Sandwich Generation Caregivers. *J Adult Dev* 2015 Oct 6;23(1):51-61. [doi: [10.1007/s10804-015-9221-6](https://doi.org/10.1007/s10804-015-9221-6)]
5. Zarit SH, Todd PA, Zarit JM. Subjective Burden of Husbands and Wives as Caregivers: A Longitudinal Study. *The Gerontologist* 1986 Jun 01;26(3):260-266. [doi: [10.1093/geront/26.3.260](https://doi.org/10.1093/geront/26.3.260)]
6. Pinquart M, Sörensen S. Differences between caregivers and noncaregivers in psychological health and physical health: A meta-analysis. *Psychology and Aging* 2003;18(2):250-267. [doi: [10.1037/0882-7974.18.2.250](https://doi.org/10.1037/0882-7974.18.2.250)]
7. Adelman RD, Tmanova LL, Delgado D, Dion S, Lachs MS. Caregiver burden: a clinical review. *JAMA* 2014 Mar 12;311(10):1052-1060. [doi: [10.1001/jama.2014.304](https://doi.org/10.1001/jama.2014.304)] [Medline: [24618967](https://pubmed.ncbi.nlm.nih.gov/24618967/)]
8. Crimmins EM, Beltrán-Sánchez H. Mortality and morbidity trends: is there compression of morbidity? *J Gerontol B Psychol Sci Soc Sci* 2011 Jan;66(1):75-86 [FREE Full text] [doi: [10.1093/geronb/gbq088](https://doi.org/10.1093/geronb/gbq088)] [Medline: [21135070](https://pubmed.ncbi.nlm.nih.gov/21135070/)]
9. Hall D, Wilkerson J, Lovato J, Sink K, Chamberlain D, Alli R, et al. Variables Associated with High Caregiver Stress in Patients with Mild Cognitive Impairment or Alzheimer's Disease: Implications for Providers in a Co-Located Memory Assessment Clinic. *Journal of Mental Health Counseling* 2014 Apr;36(2):145-159. [doi: [10.17744/mehc.36.2.l880r8h860071414](https://doi.org/10.17744/mehc.36.2.l880r8h860071414)]
10. Ziello A, Pastore F, Fasanaro AM, Poderico C, Iavarone A. Caregiver burden and coping strategies in caregivers of patients with Alzheimer's disease. *NDT* 2014 Jul;1407. [doi: [10.2147/NDT.S58063](https://doi.org/10.2147/NDT.S58063)]
11. Razani J, Corona R, Quilici J, Matevosyan A, Funes C, Larco A, et al. The Effects of Declining Functional Abilities in Dementia Patients and Increases in Psychological Distress on Caregiver Burden Over a One-Year Period. *Clinical Gerontologist* 2014 Apr 09;37(3):235-252. [doi: [10.1080/07317115.2014.885920](https://doi.org/10.1080/07317115.2014.885920)]
12. Pearlin LI, Mullan JT, Semple SJ, Skaff MM. Caregiving and the stress process: an overview of concepts and their measures. *Gerontologist* 1990 Oct;30(5):583-594. [Medline: [2276631](https://pubmed.ncbi.nlm.nih.gov/2276631/)]
13. Pearlin L, Menaghan E, Lieberman M, Mullan J. The Stress Process. *Journal of Health and Social Behavior* 1981;22(4):337-356 [FREE Full text]
14. Lazarus R, Folkman S. Coping and Adaptation. In: Gentry WD, editor. *The Handbook of Behavioral Medicine*. New York: Guilford; 1984:282-325.
15. Montgomery, Kwak, Kosloski. Theories Guiding Support Services for Family Caregivers. In: Bengtson VL, Settersten Jr R, editors. *Handbook of Theories of Aging*. New York: Springer Publishing Company; 2016:443-459.
16. Cleland M, Schmall VL, Studervant M, Congleton L, Kirkbride K, McFalls J, et al. *The caregiver helpbook: Powerful tools for caregivers*. Portland, OR: Legacy Caregiver Services; 2006.
17. Hepburn KW, Lewis M, Sherman CW, Tornatore J. The savvy caregiver program: developing and testing a transportable dementia family caregiver training program. *Gerontologist* 2003 Dec;43(6):908-915. [Medline: [14704391](https://pubmed.ncbi.nlm.nih.gov/14704391/)]
18. Ostwald SK, Hepburn KW, Caron W, Burns T, Mantell R. Reducing Caregiver Burden: A Randomized Psychoeducational Intervention for Caregivers of Persons With Dementia. *The Gerontologist* 1999 Jun 01;39(3):299-309. [doi: [10.1093/geront/39.3.299](https://doi.org/10.1093/geront/39.3.299)]
19. Chen H, Huang M, Yeh Y, Huang W, Chen C. Effectiveness of coping strategies intervention on caregiver burden among caregivers of elderly patients with dementia. *Psychogeriatrics* 2014 Dec 17;15(1):20-25. [doi: [10.1111/psyg.12071](https://doi.org/10.1111/psyg.12071)]
20. Eisdorfer C, Czaja SJ, Loewenstein DA, Rubert MP, Arguelles S, Mitrani VB, et al. The Effect of a Family Therapy and Technology-Based Intervention on Caregiver Depression. *The Gerontologist* 2003 Aug 01;43(4):521-531. [doi: [10.1093/geront/43.4.521](https://doi.org/10.1093/geront/43.4.521)]
21. Bank AL, Argüelles S, Rubert M, Eisdorfer C, Czaja SJ. The value of telephone support groups among ethnically diverse caregivers of persons with dementia. *Gerontologist* 2006 Feb;46(1):134-138. [Medline: [16452294](https://pubmed.ncbi.nlm.nih.gov/16452294/)]
22. Topo P. Technology Studies to Meet the Needs of People With Dementia and Their Caregivers: A Literature Review. *Journal of Applied Gerontology* 2008 Oct 01;28(1):5-37. [doi: [10.1177/0733464808324019](https://doi.org/10.1177/0733464808324019)]
23. Chiu T, Marziali E, Colantonio A, Carswell A, Gruneir M, Tang M, et al. Internet-based caregiver support for Chinese Canadians taking care of a family member with alzheimer disease and related dementia. *Can J Aging* 2009 Dec;28(4):323-336. [doi: [10.1017/S0714980809990158](https://doi.org/10.1017/S0714980809990158)] [Medline: [19925698](https://pubmed.ncbi.nlm.nih.gov/19925698/)]
24. Godwin KM, Mills WL, Anderson JA, Kunik ME. Technology-driven interventions for caregivers of persons with dementia: a systematic review. *Am J Alzheimers Dis Other Demen* 2013 May;28(3):216-222. [doi: [10.1177/1533317513481091](https://doi.org/10.1177/1533317513481091)] [Medline: [23528881](https://pubmed.ncbi.nlm.nih.gov/23528881/)]
25. Boots L, Vugt M, Knippenberg R, Kempen G, Verhey F. A systematic review of internetbased supportive interventions for caregivers of patients with dementia. *International Journal of Geriatric Psychiatry* 2014;29(4):331-344. [Medline: [23963684](https://pubmed.ncbi.nlm.nih.gov/23963684/)]
26. Lundberg S. The results from a two-year case study of an information and communication technology support system for family caregivers. *Disabil Rehabil Assist Technol* 2014 Jul;9(4):353-358. [doi: [10.3109/17483107.2013.814170](https://doi.org/10.3109/17483107.2013.814170)] [Medline: [23855387](https://pubmed.ncbi.nlm.nih.gov/23855387/)]

27. Ploeg J, Markle-Reid M, Valaitis R, McAiney C, Duggleby W, Bartholomew A, et al. Web-based interventions to improve mental health, general caregiving outcomes, and general health for informal caregivers of adults with chronic conditions living in the community: Rapid evidence review. *Journal of Medical Internet Research* 2017;19(7):e263.
28. Mobile millennials: Over 85% of generation y owns smartphones. 2014. URL: <http://www.nielsen.com/us/en/insights/news/2014/mobile-millennials-over-85-percent-of-generation-y-owns-smartphones.html> [accessed 2017-12-05] [WebCite Cache ID 6snH4soDE]
29. An era of growth: The cross-platform report Q4. 2013. 2014 URL: <http://www.nielsen.com/us/en/insights/reports/2014/an-era-of-growth-the-cross-platform-report.html> [accessed 2017-12-05] [WebCite Cache ID 6snHHVFMU]
30. Perez S. Users have low tolerance for buggy apps- only 16% will try a failing app more than twice. 2013. URL: [http://techcrunch.com/2013/03/12/users-have-low-tolerance-for-buggy-apps-only-16-will-try-a-failing-app-more-than-twice/?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed:+Techcrunch+\(TechCrunch\)](http://techcrunch.com/2013/03/12/users-have-low-tolerance-for-buggy-apps-only-16-will-try-a-failing-app-more-than-twice/?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed:+Techcrunch+(TechCrunch)) [accessed 2017-11-30] [WebCite Cache ID 6snHRmfVV]
31. Anderson G. Technology trends among mid-life and older Americans. AARP Research 2016 [FREE Full text]
32. Dayer L, Heldenbrand S, Anderson P, Gubbins PO, Martin BC. Smartphone medication adherence apps: Potential benefits to patients and providers. *Journal of the American Pharmacists Association* 2013 Mar;53(2):172-181. [doi: [10.1331/JAPhA.2013.12202](https://doi.org/10.1331/JAPhA.2013.12202)]
33. Wang J, Wang Y, Wei C, Yao NA, Yuan A, Shan Y, et al. Smartphone interventions for long-term health management of chronic diseases: an integrative review. *Telemed J E Health* 2014 Jun;20(6):570-583. [doi: [10.1089/tmj.2013.0243](https://doi.org/10.1089/tmj.2013.0243)] [Medline: [24787747](https://pubmed.ncbi.nlm.nih.gov/24787747/)]
34. National Alliance for Caregiving and United Healthcare. eConnected family caregiver: Bringing caregiving into the 21st century URL: https://www.caregiving.org/data/FINAL_eConnected_Family_Caregiver_Study_Jan%202011.pdf [accessed 2018-07-20] [WebCite Cache ID 713pwYBrg]
35. Schulz R, Beach SR, Matthews JT, Courtney K, De VDA, Mecca LP. Caregivers' Willingness to Pay for Technologies to Support Caregiving. *Gerontologist* 2016 Oct;56(5):817-829 [FREE Full text] [doi: [10.1093/geront/gnv033](https://doi.org/10.1093/geront/gnv033)] [Medline: [26035899](https://pubmed.ncbi.nlm.nih.gov/26035899/)]
36. Adler R, Mehta R. Catalyzing technology to support family caregiving. National Alliance for Caregiving. 2014. URL: http://www.caregiving.org/wp-content/uploads/2010/01/Catalyzing-Technology-to-Support-Family-Caregiving_FINAL.pdf
37. Murray A, Lyle J. Patient adoption of mHealth: Use, evidence and remaining barriers of mainstream acceptance. IMS Institute for Healthcare Informatics. 2015. URL: http://moodle.univ-lille2.fr/pluginfile.php/215343/mod_resource/content/0/IIHI_Patient_Adoption_of_mHealth.pdf
38. Research2Guidance. mHealth App Developer Economics. 2016. 2016 URL: <https://research2guidance.com/r2g/r2g-mHealth-App-Developer-Economics-2016.pdf> [accessed 2017-08-17] [WebCite Cache ID 6snBuzqC5]
39. Alzheimer's Association. Chicago, IL URL: <http://www.alz.org/care/alzheimers-dementia-wandering.asp> [accessed 2017-08-17] [WebCite Cache ID 6snCXCvp9]
40. Gergerich E, Davis L. Silver Alerts: A Notification System for Communities with Missing Adults. *J Gerontol Soc Work* 2017 Apr;60(3):232-244. [doi: [10.1080/01634372.2017.1293757](https://doi.org/10.1080/01634372.2017.1293757)] [Medline: [28409711](https://pubmed.ncbi.nlm.nih.gov/28409711/)]
41. World Health Organization. 2015. Ageing and health fact sheet no 404 URL: <http://www.who.int/mediacentre/factsheets/fs404/en/> [accessed 2017-11-30] [WebCite Cache ID 6snHW4Avs]
42. Wolff JL, Feder J, Schulz R. Supporting Family Caregivers of Older Americans. *N Engl J Med* 2016 Dec 29;375(26):2513-2515. [doi: [10.1056/NEJMp1612351](https://doi.org/10.1056/NEJMp1612351)] [Medline: [28029922](https://pubmed.ncbi.nlm.nih.gov/28029922/)]
43. Hebert LE, Weuve J, Scherr PA, Evans DA. Alzheimer disease in the United States (2010-2050) estimated using the 2010 census. *Neurology* 2013 May 07;80(19):1778-1783 [FREE Full text] [doi: [10.1212/WNL.0b013e31828726f5](https://doi.org/10.1212/WNL.0b013e31828726f5)] [Medline: [23390181](https://pubmed.ncbi.nlm.nih.gov/23390181/)]
44. Hung Y, Kadziola Z, Brnabic AJ, Yeh J, Fuh J, Hwang J, et al. The epidemiology and burden of Alzheimer's disease in Taiwan utilizing data from the National Health Insurance Research Database. *Clinicoecon Outcomes Res* 2016 Aug;8:387-395 [FREE Full text] [doi: [10.2147/CEOR.S93323](https://doi.org/10.2147/CEOR.S93323)] [Medline: [27536149](https://pubmed.ncbi.nlm.nih.gov/27536149/)]
45. Kogan AC, Wilber K, Mosqueda L. Person-Centered Care for Older Adults with Chronic Conditions and Functional Impairment: A Systematic Literature Review. *J Am Geriatr Soc* 2016 Jan;64(1):e1-e7. [doi: [10.1111/jgs.13873](https://doi.org/10.1111/jgs.13873)] [Medline: [26626408](https://pubmed.ncbi.nlm.nih.gov/26626408/)]
46. Love K, Pinkowitz J. Person-centered care for people with dementia: A theoretical and conceptual framework. *Generations* 2013;37(3):23-29 [FREE Full text]
47. Lwi SJ, Ford BQ, Casey JJ, Miller BL, Levenson RW. Poor caregiver mental health predicts mortality of patients with neurodegenerative disease. In: *Proc Natl Acad Sci U S A*. 2017 Jul 11 Presented at: Proceedings of the National Academy of Sciences of the United States of America. ;114(28); 2017; New York p. 7319-7324. [doi: [10.1073/pnas.1701597114](https://doi.org/10.1073/pnas.1701597114)]
48. Kim H, Paige PM, Bhuyan SS, Bhuyan SS. Seeking Medical Information Using Mobile Apps and the Internet: Are Family Caregivers Different from the General Public? *J Med Syst* 2017 Mar;41(3):38. [doi: [10.1007/s10916-017-0684-9](https://doi.org/10.1007/s10916-017-0684-9)] [Medline: [28101781](https://pubmed.ncbi.nlm.nih.gov/28101781/)]
49. Eggermont S, Vandebosch H, Steyaert S. Towards the desired future of the elderly and ICT: policy recommendations based on a dialogue with senior citizens. *Poiesis Prax* 2006 May 25;4(3):199-217. [doi: [10.1007/s10202-005-0017-9](https://doi.org/10.1007/s10202-005-0017-9)]

50. Ijsselsteijn W, Nap H, de Kort Y, Poels K. Digital game design for elderly users. 2007 Presented at: Proceedings of the conference of Future Play; 2007; Toronto, ON p. 17-22. [doi: [10.1145/1328202.1328206](https://doi.org/10.1145/1328202.1328206)]
51. Melenhorst A. Adopting communication technology in later life: the decisive role of benefits (PhD). Eindhoven, Netherlands: Technische Universiteit Eindhoven; 2002.
52. Sarkar U, Gourley GI, Lyles CR, Tieu L, Clarity C, Newmark L, et al. Usability of Commercially Available Mobile Applications for Diverse Patients. *J Gen Intern Med* 2016 Dec;31(12):1417-1426. [doi: [10.1007/s11606-016-3771-6](https://doi.org/10.1007/s11606-016-3771-6)] [Medline: [27418347](https://pubmed.ncbi.nlm.nih.gov/27418347/)]
53. Faudree B, Ford M. *CIO Journal*. 2013. Security and Privacy in Mobile Health URL: <http://deloitte.wsj.com/cio/2013/08/06/security-and-privacy-in-mobile-health/melenho> [WebCite Cache ID 6tp8fjE01]
54. Kharrazi H, Chisholm R, VanNasdale D, Thompson B. Mobile personal health records: an evaluation of features and functionality. *Int J Med Inform* 2012 Sep;81(9):579-593. [doi: [10.1016/j.ijmedinf.2012.04.007](https://doi.org/10.1016/j.ijmedinf.2012.04.007)] [Medline: [22809779](https://pubmed.ncbi.nlm.nih.gov/22809779/)]
55. Adhikari R, Richards D, Scott K. Security and privacy issues related to the use of mobile health apps. 2014 Presented at: 25th Australian Conference on Information Systems; 2014; Auckland, New Zealand.

Abbreviations

AARP: American Association of Retired Persons

ADL: Activities of Daily Living

GPS: Global Positioning System

IADL: Instrumental Activities of Daily Living

mHealth: mobile health

NAC: National Alliance for Caregiving

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Original Paper

Health Care Provider Utilization and Cost of an mHealth Intervention in Vulnerable People Living With HIV in Vancouver, Canada: Prospective Study

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Abstract

Background: Improving adherence to combined antiretroviral therapy (cART) can be challenging, especially among vulnerable populations living with HIV. Even where cART is available free of charge, social determinants of health act as barriers to optimal adherence rates. Patient-centered approaches exploiting mobile phone communications (mHealth) have been shown to improve adherence to cART and promote achievement of suppressed HIV plasma viral loads. However, data are scarce on the health care provider (HCP) time commitments and health care costs associated with such interventions. This knowledge is needed to inform policy and programmatic implementation.

Objective: The purpose of this study was to approximate the resources required and to provide an estimate of the costs associated with running an mHealth intervention program to improve medication adherence in people living with HIV (PLWH).

Methods: This prospective study of HCP utilization and costs was embedded within a repeated measures effectiveness study of the WelTel short-message service (SMS) mHealth program. The study included 85 vulnerable, nonadherent PLWH in Vancouver, Canada, and resulted in improved medication adherence and HIV plasma viral load among participants. Study participants were provided mobile phones with unlimited texting (where required) and received weekly bidirectional text messages to inquire on their status for one year. A clinic nurse triaged and managed participants' responses, immediately logging all patient interactions by topic, HCP involvement, and time dedicated to addressing issues raised by participants. Interaction costs were determined in Canadian dollars based on HCP type, median salary within our health authority, and their time utilized as part of the intervention.

Results: Participant-identified problems within text responses included health-related, social, and logistical issues. Taken together, management of problems required a median of 43 minutes (interquartile range, IQR 17-99) of HCP time per participant per year, for a median yearly cost of Can \$36.72 (IQR 15.50-81.60) per participant who responded with at least one problem. The clinic nurse who monitored the texts solved or managed 65% of these issues, and the remaining were referred to a variety of other HCPs. The total intervention costs, including mobile phones, plans, and staffing were a median Can \$347.74/highly

vulnerable participant per year for all participants or Can \$383.18/highly vulnerable participant per year for those who responded with at least one problem.

Conclusions: Bidirectional mHealth programs improve HIV care and treatment outcomes for PLWH. Knowledge about the HCP cost associated, here less than Can \$50/year, provides stakeholders and decision makers with information relevant to determining the feasibility and sustainability of mHealth programs in a real-world setting.

Trial Registration: ClinicalTrials.gov NCT02603536; <https://clinicaltrials.gov/ct2/show/NCT02603536> (Archived by WebCite at <http://www.webcitation.org/70IYqKUjV>).

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KEYWORDS

HIV; mHealth; health care provider; cost; health care utilization; adherence

Introduction

With the success of combined antiretroviral therapy (cART), the health of people living with HIV (PLWH) has greatly improved [1], and life expectancies are now approaching those of the general population [2]. However, cART effectiveness is dependent on high rates of medication adherence. Among vulnerable populations such as individuals at high risk for disengagement from treatment due to various social determinants of health (eg, housing or food insecurity, substance use issues, and advanced HIV infection), being adherent is often a challenge [3-5]. This can be due to a combination of demographic, structural, and psychosocial barriers, and it results in PLWHs' engagement being lost along the cascade of care continuum [4,6]. Adherence is also crucial at the population level, as nonadherence can result in high HIV viremia, which places others at higher risk of acquiring the virus [7,8]. Consequently, tools to help cART adherence and engagement in care bring value for both personal and population health. It is known that patients' improved connection to health care providers (HCPs) can enhance their engagement in care [9-13]. This can be achieved through the use of mobile health (mHealth) technology, whereby a mobile phone is used to connect a patient with an HCP [14-16]. When provided in a bidirectional fashion, mHealth provides a patient with the ability to request and receive assistance when not physically present at clinic. This allows a variety of "problems" related to physical, emotional and mental health, housing, food security, and medication use to be managed in timely fashion, as they arise [17,18]. In addition, mHealth enables HCPs to connect with patients and monitor their wellness between clinic visits [18].

Communication through mHealth technology with PLWH was first shown to significantly improve adherence to cART and plasma viral load (pVL) suppression in a text-messaging intervention study conducted in Kenya (WelTelKenya1) [14]. This bidirectional outpatient management service was then tested for acceptability and feasibility at Oak Tree Clinic, Vancouver, British Columbia, in a prospective mixed methods pilot study (WelTelBC1) [18,19]. HCPs involved with the pilot reported that, although workload increased initially, intervention benefits went beyond improving pVL and addressed the social determinants of health that act as barriers to engagement in care and to medication adherence [18,19]. This pilot was followed by the study presented here, WelTel OakTree, which examined the effectiveness of this weekly text-messaging intervention

over one year, with 85 highly vulnerable and nonadherent PLWH, who experience many social determinants of health as barriers to care [20]. Before the study, communication with patients was likely to be only around their scheduled appointments, with the main method of communication being in person or perhaps over the phone on an intermittent basis. Efficacy results of WelTel OakTree demonstrated an improvement in cART adherence and HIV pVL among PLWH who received the intervention, so that 47.5% of participants achieved undetectable pVL by study end [20].

While the benefits of mHealth are clear, little is known regarding HCP time utilization and the costs involved in enacting such an intervention. Detailing the types of problems and time required by HCPs to provide the service would allow visualization for what is involved in providing this efficacious program, as a program that is very time intensive for providers may not be feasible or sustainable in busy clinics. Assessing the true financial and personnel costs to the health care system is crucial to the translation of this research into clinical care and is necessary information for health care system officials who may elect to provide such a service to their population. Prospectively and throughout the WelTel OakTree study [20], detailed data were collected on all HCP-participant interactions. Here we report the estimated HCP utilization and cost of providing an mHealth intervention for vulnerable PLWH in Canada.

Methods

Study Setting

The Oak Tree Clinic (OTC), located in Vancouver, Canada, is a provincial referral center for women and families living with HIV throughout British Columbia, many of whom have multiple demographic, structural, and psychosocial barriers to engagement in care. The OTC hosts an interdisciplinary team that provides holistic care for the health needs of women and their families in a single setting. The PLWH receiving care at OTC span all HIV-acquisition risk factor groups.

Study Participants

Details of the WelTel OakTree study, its participants, and results were reported elsewhere [20]. Briefly, 85 participants were recruited between April 2013 and May 2014 at OTC and were enrolled in a repeated measures cohort study, with the 12 months

prior to initiation of the study used retrospectively as the control year.

Patients were eligible for study participation if they met the following inclusion criteria: attendance at OTC for at least one year prior to study entry (with the one year prior to study start representing the control year), an indication for cART, detectable HIV pVL (≥ 200 copies/mL) in the control year, age ≥ 14 years, and being “vulnerable.” The latter was defined as being high-risk or vulnerable for disengagement from treatment according to a list of predetermined criteria. High-risk individuals were identified based on consensus by the care team where at least one of the following was present: intimate partner violence, unstable housing, advanced HIV infection/AIDS, mental health illness, cART nonadherence, difficulty to contact, poor appointment attendance, substance use, long distance from care, and recent incarceration. All candidates were reviewed by the multidisciplinary care team who decided on applicable vulnerabilities by manner of consensus. We excluded those not meeting the above criteria, living in an area with no mobile phone service, or otherwise unable to communicate via the text-messaging system.

Participants were provided with a basic mobile phone with unlimited text-messaging capability if they did not have one. Where required, participants received instruction on how to use text messaging for communication. In addition to the intervention, participants continued to receive their regular care through the interdisciplinary OTC team. This included follow-up appointments every 1-4 months, as clinically indicated by overall health status and HIV pVL. In British Columbia, cART for PLWH is fully covered through the provincial drug treatment program and was prescribed according to published provincial therapeutic guidelines [21]. The study was reviewed and approved by the University of British Columbia Research Ethics Board (H12-03002).

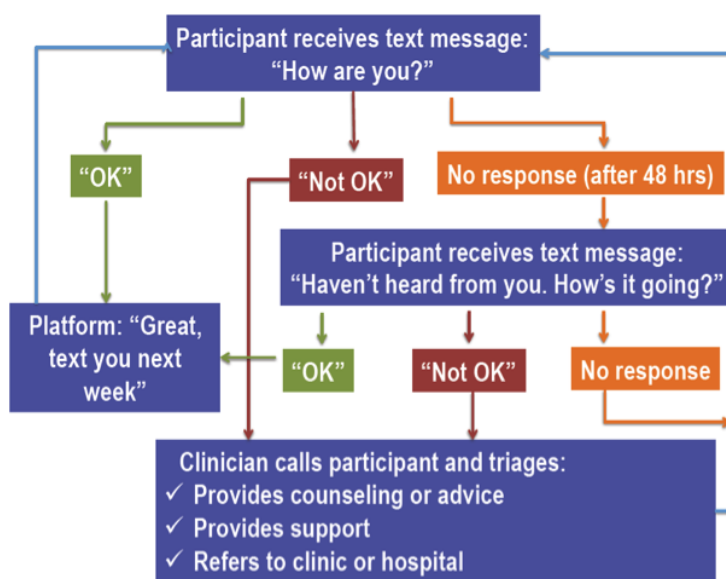
WelTel Program

Participants received a weekly interactive text message of “How are you?” to check in on their health status for one year. An automated software platform sent the text every Monday at noon from a number not traceable to the clinic. Participants were asked to respond each week within 48 hours if they were “OK” or had a “problem.” A study nurse monitored responses daily (except weekends) and responded to all “problem” texts from participants during working hours, as shown in Figure 1. The study nurse triaged “problem” responses and involved additional HCP as required. Participants who did not respond to the initial text were sent a second message on Wednesday, “Haven’t heard from you. How’s it going?” If there was still no response, the clinic nurse called participants who had not responded by Thursday. If there was again no response, participants were texted as per usual the following Monday. HCPs never texted information relating to HIV status or the clinic unless asked explicitly to do so by the participant.

Data Collection and Analysis

All communications related to the program were recorded and encoded prospectively by participant ID in an electronic study log maintained exclusively by the single study nurse. The number of minutes required to triage and solve each “problem” response was also recorded in the log. At the time of the interaction, the study nurse thematically coded all problems based on the nature of each interaction and the classification of the HCP involved with the interaction. Where multiple providers were consulted, time taken and theme of interaction was recorded for each one. The cost of each interaction was then determined based on HCP time utilized and the mean salary of each HCP type, within our health authority (British Columbia’s Provincial Health Services Authority) [22]. Clinical data, including HIV pVL, CD4 (cluster of differentiation 4) counts, appointment attendance, and medication adherence, are reported elsewhere [20].

Figure 1. Weekly text-messaging structure.



Results

Participant Characteristics

Of the 85 participants recruited, 80 remained enrolled for the entire duration of the study, and five withdrew for personal reasons. Baseline demographics of these 85 participants are shown in [Table 1](#). Of the participants, 44 had their own mobile phone at study start, and 41 were given phones with unlimited text-messaging capability.

Text-Messaging Responses

Over the intervention year, a total of 3764 “How are you?” texts were sent to participants, fewer than the predicted total of 4420 texts. Texts were not sent either due to planned participant absences (n=125), participants losing their phone (n=366), or participant withdrawal (n=165). At the participant level, a wide range of individual response rates to text messages were observed (0%-98%). The mean response rate was 50% (median 52%) among participants continuing to study completion. Of text messages sent, 46.68% (1757/3764) resulted in an initial “OK” response, 9.62% (362/3764) indicated a “problem,” and 43.70% (1645/3764) returned no response. While 362 “problem” responses were received in response to the Monday text message, an additional 203 “problem” responses were received later in the week, either as a second “problem,” or as a new problem after an initial “OK” response. Thus, at study completion, there were a total of 565 “problem” responses received.

As more than one HCP was often required to address an issue, a total of 761 distinct HCP interactions resulted from the 565 problem responses. We illustrate the number of HCP-participant interactions by HCP type ([Figure 2](#)), mean time of each interaction ([Figure 3](#)), and total time per HCP ([Figure 4](#)) over the study period. The study nurse managed 64.9% (494/761) of problem interactions and spent the most time (2443/4533 minutes, 53.9%) on problem solving overall, among all HCPs. The counselor spent the greatest amount of time per interaction, averaging 27 minutes. Overall, managing “problem” responses required a total of 75.5 hours, with a median (interquartile range, IQR) of 43 (17-99) minutes of HCP time per year for participants who responded with problems ([Table 2](#)). Additionally, approximately 78 hours (55 minutes/participant/year) of HCP time was required for sending unscheduled text messages, weekday monitoring of the platform, and making phone calls to participants who did not respond to text messages.

WelTel participants reported a great breadth of “problems,” encompassing medical problems, as well as issues related to social determinants of health. [Figure 5](#) depicts the nature and frequency of these “problem”-related interactions between HCPs and participants. The most common “problem” responses involved the participant seeking medical advice (199/761, 26.1%). The study nurse solved majority of these issues (153/199, 76.9%). Other common problem responses were related to counseling (71/761, 9.3%), antiretrovirals refill/pick-up (72/761, 9.5%), appointment reminders/rescheduling (103/761, 13.5%), check-in/making contact (75/761, 9.8%), and phone/study support (49/761, 6.4%).

Table 1. Baseline demographics of a high-risk Canadian HIV-positive cohort (N=80).

Demographics	Participants
Gender, n (%)	
Female	72 (90)
Male	6 (8)
Transgender	2 (3)
Age in years, median (range)	38 (15-61)
Ethnicity, n (%)	
White	30 (38)
First Nations	27 (34)
African Canadian	18 (22)
South Asian	5 (6)
Income source, n (%)	
Disability	57 (71)
Welfare	6 (8)
Employed	4 (5)
Other	13 (16)
Cell phone ownership, n (%)	
Yes	43 (54)
No	37 (46)

Figure 2. Total number of interactions with participants per health care provider over study year.

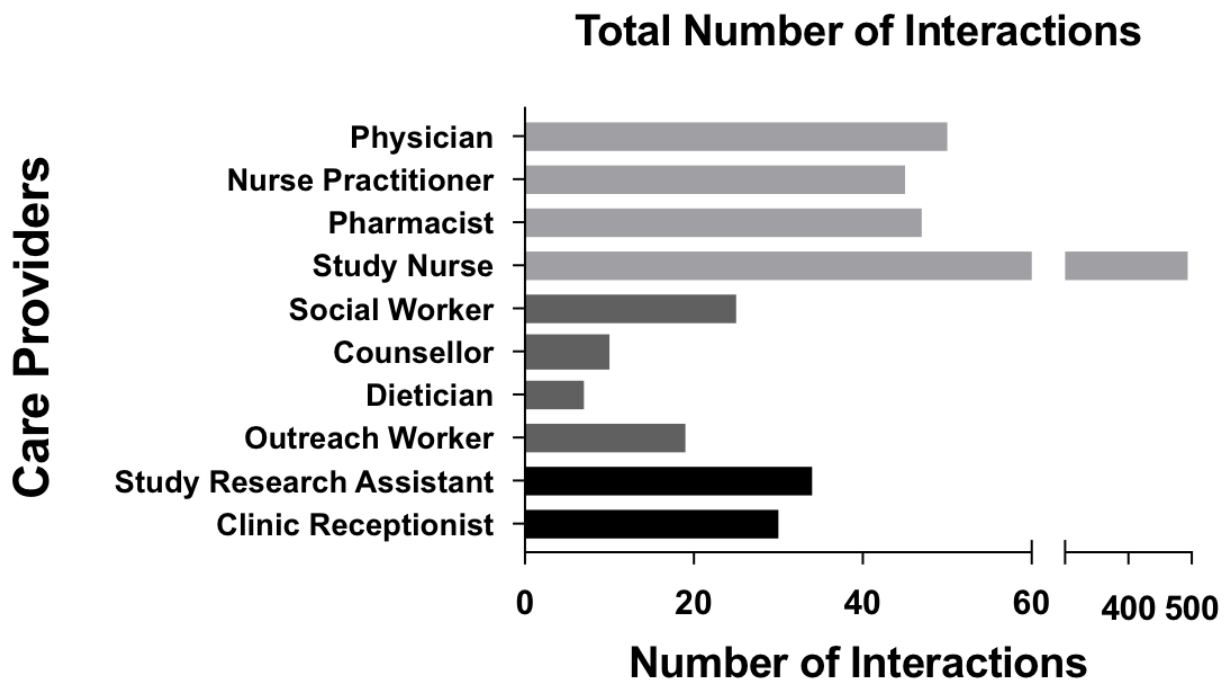


Figure 3. Total amount of health care provider time per interaction.

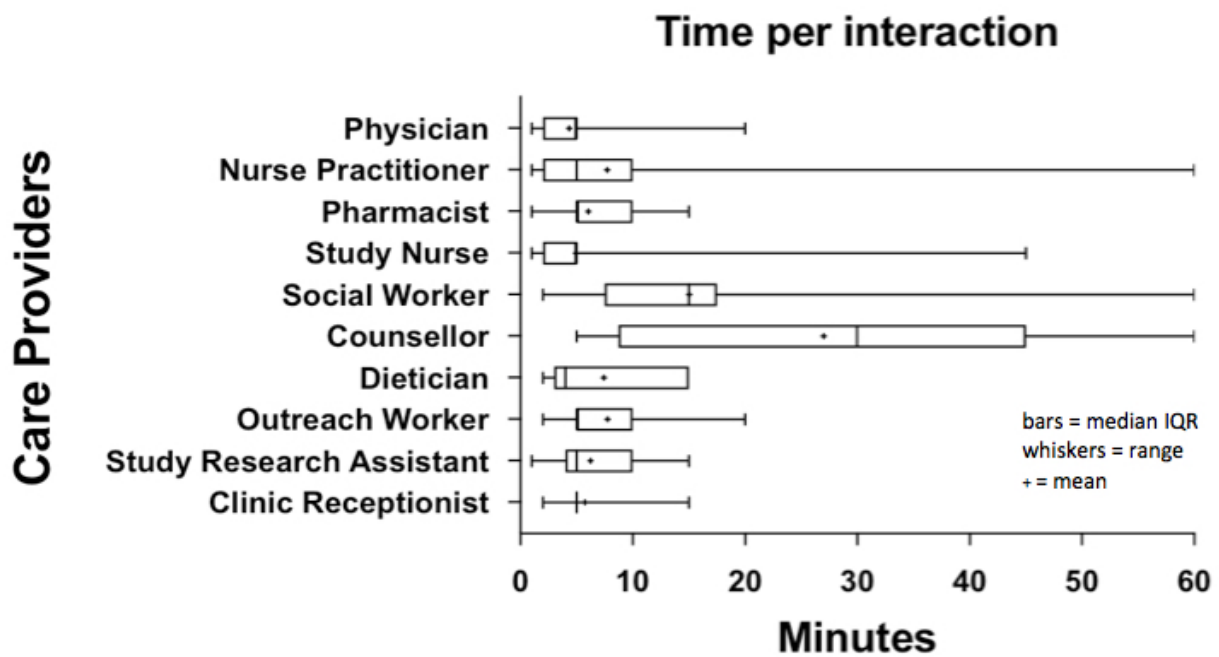
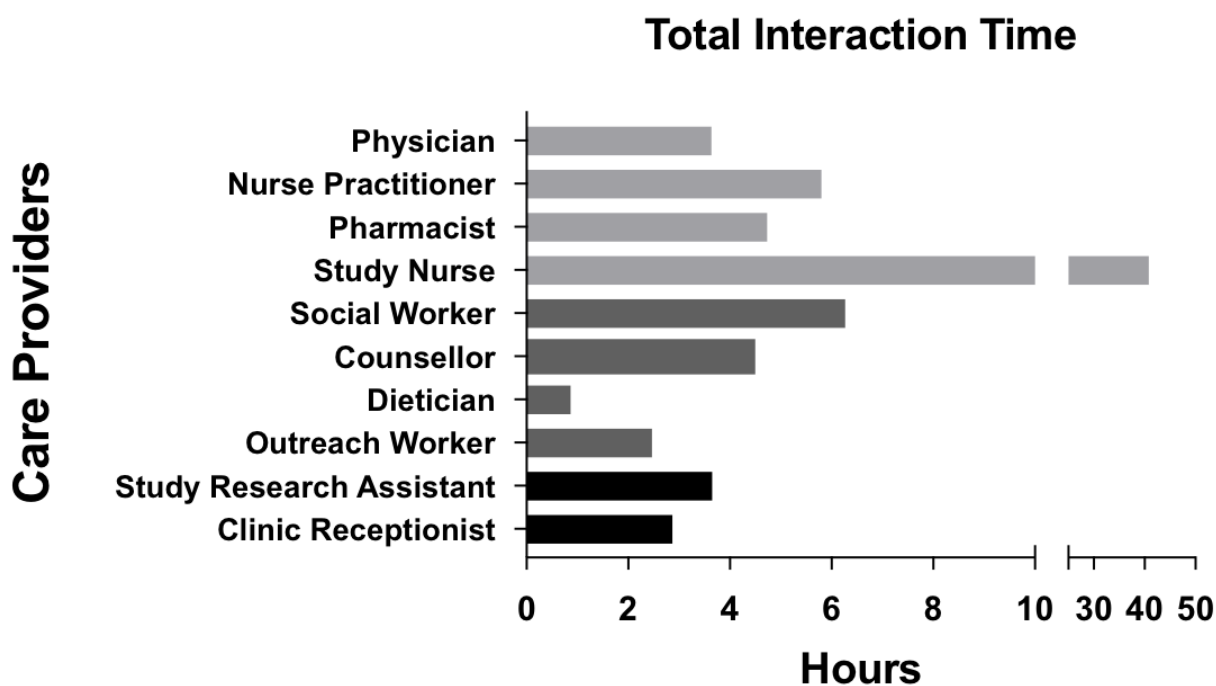


Figure 4. Total interaction time per health care provider over study year.**Table 2.** Median time and cost per problem and per year for all participants and problem responders during WeTel intervention.

Times and costs	All participants (n=85)	Problem responders (n=65)
Median time/problem, minutes	5	5
Time/year, minutes		
Median	22	43
Interquartile range	3-85	17-99
Range	0-335	2-335
Median cost/problem, Can \$	4.08	4.08
Cost/year, Can \$		
Median	17.95	36.72
Interquartile range	2.45-71.40	15.50-81.60
Range	0-273.37	1.63-273.37

Figure 5. Nature and frequency of problem-response interactions that health care providers solved over intervention year.

	Physician	Nurse Practitioner	Pharmacist	Study Nurse	Social Work Counselor	Dietician	Outreach Worker	Research Assistant	Clinic Receptionist	Totals	
Medical Advice				153			1	3		199	26.1%
Outside referral					1		1			20	2.6%
Referral coordination										16	2.0%
Test results	19				9		3			29	3.8%
ARV refill / pick-up		27									
Medication interactions, side effects				19.5							
Medication related - other			34	11.5							
Housing	5			20						72	9.5%
Disability / forms				31	9					41	5.4%
Finances/Employment				21	6		1	28		21	2.8%
Child care	7			19						24	3.1%
Counseling		3		11.5						11	1.4%
Food Support/Diet	8			8.5							
Outreach pick-ups				52.5	4		6			71	9.3%
Phone/Study Support	1			20.5						49	6.4%
Appointment reminders/scheduling	3	7									
Check-in / making contact	7		12	60.5	5		1			103	13.5%
Totals	50	45	47	494	25	107	19	34	30	761	Grand total:
	6.6%	5.9%	6.2%	64.9%	3.3%	14.25%	4.5%	3.9%			

Text-Messaging Costs

Figure 6 displays the cost per interaction and Figure 7 shows total costs (in Canadian dollars), over the study period for each HCP in managing “problem” responses. Interactions involving the counselor carried the greatest cost, averaging Can \$19.11 per interaction, due to their length. However, these interactions were few (total cost Can \$191.13). In contrast, interactions with the study nurse carried an average cost of Can \$3.63 per interaction, for a total cost of Can \$1791.70. The median cost of all HCP time for managing all “problem” responses in the study was Can \$36.72 (IQR 15.50-81.60) per participant who had replied with “problem” responses, and the median cost of HCP time was Can \$17.95 (IQR 2.45-71.40) per highly vulnerable participant for 1 year of service (Table 2).

The study nurse spent approximately 90 minutes each week monitoring participant responses, for a total cost of Can \$3432.31 (including 20% benefits cost). The automated software platform cost for this study was Can \$5000. Where a phone and phone plan were given to participants (n=50 over course of

study), basic phone cost was Can \$50, and cost of phone plans was Can \$28.50 per person per month (including taxes). The total cost of providing phones and plans to 50 participants (of 85) was Can \$392 per person per year, or a total cost of Can \$19,600/year. Study cost per participant when a basic phone and unlimited texting plan were included was therefore Can \$509.15 per person per year for all participants or Can \$527.92 per person per year for problem responders. Study cost for participants who used their own phone was Can \$117.15 per person per year for all participants or Can \$135.92 per person per year for problem responders. Therefore, the intervention overall cost Can \$347.74 per highly vulnerable participant per year for all participants or Can \$383.18 per highly vulnerable participant per year for those who responded with at least one problem (Table 3).

At study end, nearly half (38/80, 47.5%) of participants had undetectable pVL (previously published [20]). Thus, WeITel program and HCP cost per undetectable pVL achieved was Can \$835.03/year.

Figure 6. Cost per interaction per health care provider.

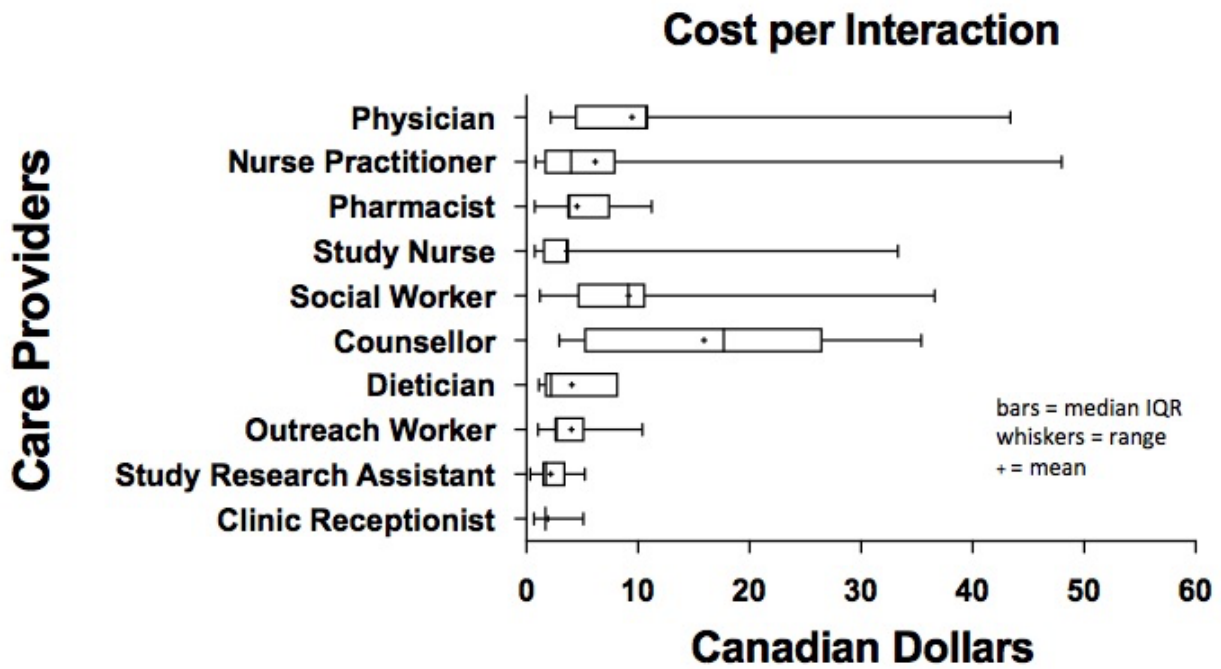


Figure 7. Total cost per health care provider over study year.

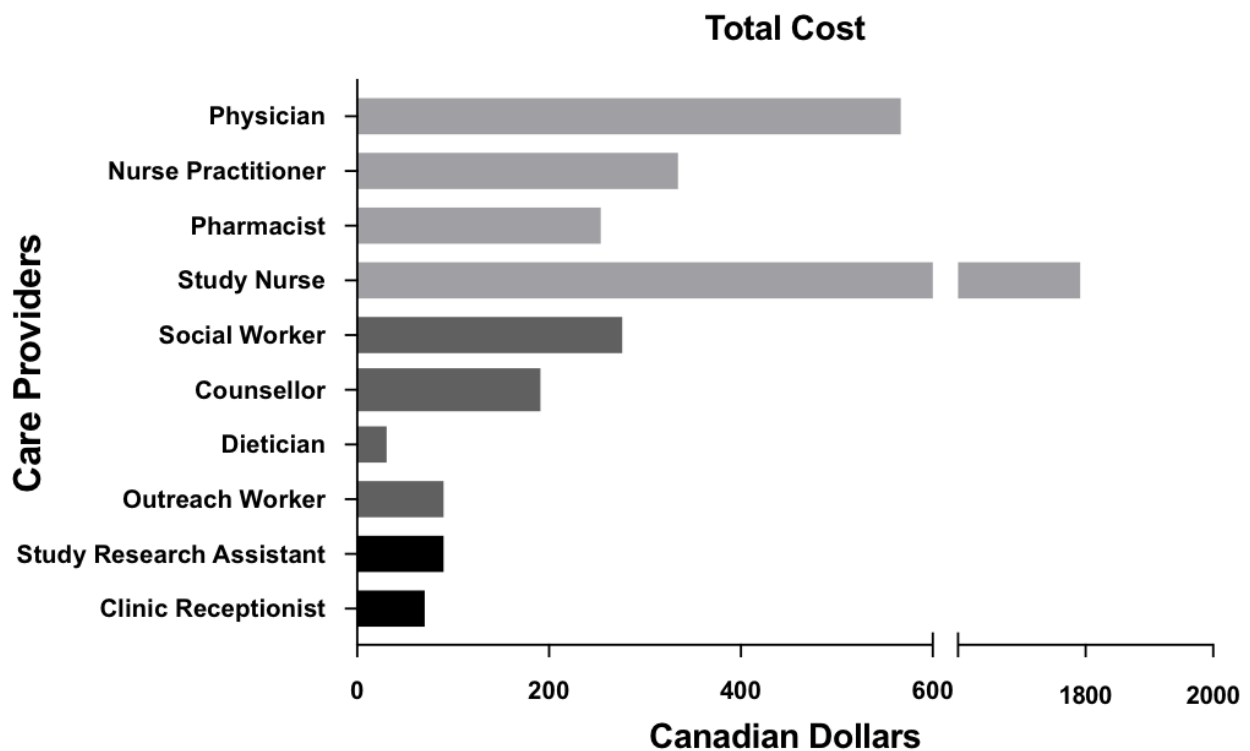


Table 3. Deconstructed costs of WelTel OakTree Study during intervention year (in Canadian dollars).

Item	Median cost per participant (n=85)	Median cost per problem responder (n=65)	Total cost (n=85) ^a
Automated software platform	\$58.82	\$58.82	\$5000 ^b
Study nurse checking responses	\$40.38	\$40.38	\$3432.31
Managing “problem” responses	\$17.95	\$36.72	\$3699.20
Phones (n=50)	\$50.00	\$50.00	\$2500.00
Phone plans (n=50)	\$342.00	\$342.00	\$17,100.00
Own phone, total	\$117.15	\$135.92	\$31,731.20
Given phone and plan, total	\$509.15 ^c	\$527.92 ^d	\$31,731.20
All	\$347.74	\$383.18	\$31,731.20

^a50 participants were provided with a phone.

^bFixed cost: does not change with enrollment and is subject to change.

^c50 participants were provided with phones and plans.

^d41 participants were provided with phones and plans.

Discussion

Principal Findings

Mobile health interventions, such as WelTel, are effective at improving cART adherence and pVL in PLWH [14,15,20]. However, translating this program from research to clinical care requires the buy-in and support of decision makers and payers. This study provides policy makers with the real-world cost and staff requirements to roll out such a program as a part of care for PWLH who are vulnerable to disengagement in care in a Canadian setting.

Data were captured at the time of each event; hence, results presented here precisely reflect the nature of “problems” and time utilization for each HCP-participant interaction in the study. The study nurse was able to address the majority (64.9%) of “problem” responses without referral to a secondary HCP. Many of these responses were medically related. Thus, when implementing bidirectional mHealth interventions in the real-world setting, it would be advantageous to employ HCPs capable of giving basic medical advice when answering text messages. Other “problems” were related to social determinants of health, reflecting the vulnerability of our study population. These were managed through a variety of OTC care providers. In the case of a limited resource setting, however, many of these issues could be managed by a skilled nurse, with the aid of a social worker in some instances. A situation with fewer care providers, though providing a less specialized service, may provide the added benefit of further strengthening patient-HCP relationships through increased interaction. This could be beneficial, as enhancing patient-provider relationships has been associated with improved adherence self-efficacy [23], as well as improvement in cART adherence [9,11], viral suppression [24], and overall health outcomes [25]. The possible downside of a small team, however, may include a larger effect on participants if and when a staffing change occurs.

The total HCP time for managing “problem” responses was 75.5 hours, or 43 minutes per participant per year. It should be noted that the highly vulnerable and complex nature of the study

participants might have resulted in more problems, inflating HCP time above what may be expected in a more mixed cohort. An additional 78 hours (55 minutes per participant per year) was required for sending unscheduled text messages, weekday checking of the platform, and making phone calls to participants who did not respond to text messages. However, phoning nonresponders later in the week was time consuming with low yield and is not recommended going forward. Without these calls, considerable savings (30–60 minutes/week) could be achieved. Overall, the time spent by HCPs per participant over the study year was lower than anticipated, amounting to a cost similar to that of a single physician visit (Can \$130/hour) [22]. This small time investment may be worthwhile, since mitigating problems as they arise can prevent progression of illness and decrease morbidity, thus reducing costs of health care over time [26,27].

Indeed, it is known that PLWH with sustained viral suppression have considerably lower non-cART direct medical costs [28]. As complications involving medication tolerance and adherence are solved, adherent individuals become healthier over time [1], requiring less frequent medical appointments and fewer hospital admissions [28,29]. These costs would add up, as the average cost of a hospital stay in British Columbia is approximately Can \$6000 [30]. Furthermore, stable, virally suppressed individuals could use the WelTel program for viral-load-informed differentiated care, where text messaging would be sufficient to follow stable patients and allow less frequent patient-provider visits [31]. Thus, the WelTel intervention could potentially avoid some of these costs.

Through improved cART adherence and HIV viral suppression, the WelTel mHealth program can also be expected to lower risk of HIV transmission from participants to others, an important public health consideration [28,32–34]. The cost of treatment for individuals newly diagnosed with HIV in Canada is estimated at Can \$250,000 over their lifetime [35]. When also including quality of life years (Can \$380,000) and productivity loss (Can \$670,000), the estimated lifetime cost of those newly diagnosed increases to Can \$1.3 million [35]. Consequently, fewer HIV transmissions and therefore fewer new cases of HIV

per year would result in a lower cost of HIV care [36]. These cost reductions would likely offset the cost of our mHealth intervention, making the cost of Can \$835.03 per newly undetectable PLWH/year a seemingly worthwhile investment.

Importantly, the clinical and economical information from our intervention can be applied to other aspects of health care, such as diabetes care [37,38], eldercare [39], and many other chronic diseases where patient treatment fatigue is a known barrier [15,40-43]. As bidirectional mHealth offers patients real-time advice from HCPs and improves self-management of chronic diseases, the benefits may extend beyond what we are able to quantify. Implementing a triage system could be beneficial, such that the WelTel service is provided to our most vulnerable patients, but also more selectively to those most likely to use it and benefit from it, optimizing usage of health care funds. Mobile health is an accessible and practical method of communication, as the majority of Canadians have mobile phones. In our study, approximately half of participants had phones at baseline, speaking to the vulnerability of our cohort. This increased the costs of our service and would thus likely overestimate the costs of implementing mHealth programs into health care practices where a higher percentage of individuals had a mobile phone. Taken together, information on the costs and time required by HCPs to provide the WelTel service gives

valuable insight into what implementation would mean in our and other settings.

Limitations

Since HCP resource usage data were not collected during the control year, we cannot comment on any change in HCP resource utilization relative to the past or future if the program were extended. Identified participant vulnerabilities were not measured at study end, so potential change or improvement cannot be determined. In addition, this study was carried out by engaging the most vulnerable patients in our clinic; thus, resource use for a more stable population may be different than that presented here.

Conclusion

To our knowledge, this is the first study detailing HCP time and resource utilization for an mHealth intervention in Canada. While further studies should address the question of change in resource utilization over time, both prior to and in the context of providing an mHealth intervention (eg, less time needed for social work/outreach, fewer clinical appointments), our study shows that weekly patient contact does not require a considerable amount of HCP time. When compared to the cost of a physician visit or hospital admission, it carries only a modest cost per participant for PLWH who are most vulnerable to morbidity and death.

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Authors' Contributions

All authors contributed significantly to the manuscript. ARC was responsible for literature search, data analysis, data interpretation, formation of figures, and writing of the manuscript. KK did all of the data collection involved in the study, including collection of health care provider time and recording and thematically coding interaction data, and reviewed and commented on the manuscript. HCFC assisted in data analysis and designing figures and has reviewed and extensively edited the manuscript. RTL aided in study design and data interpretation and reviewed and commented on the manuscript. RTL also invented the WelTel computer-based program used in the study. AQQ was involved in ethics submission, participant recruitment, study design, and reviewed and commented on the manuscript. EJM was involved in ethics submission, participant recruitment, study design, and reviewed and commented on the manuscript. AA was involved with study design and reviewed and commented on the manuscript. NP was involved with study design and reviewed and commented on the manuscript. MCMM designed the study, including setting up the initial thematic coding framework for interaction data, led statistical analysis, data interpretation, and helped with figures in the paper, as well as overseeing and significantly helping with the writing of the manuscript.

Conflicts of Interest

RTL is the founder of WelTel. This technology platform has been developed by a nonprofit organization and a private company. RTL has financial as well as professional interests in both organizations.

References

1. Montaner JSG, Hogg R, Wood E, Kerr T, Tyndall M, Levy AR, et al. The case for expanding access to highly active antiretroviral therapy to curb the growth of the HIV epidemic. *Lancet* 2006 Aug 05;368(9534):531-536. [doi: [10.1016/S0140-6736\(06\)69162-9](https://doi.org/10.1016/S0140-6736(06)69162-9)] [Medline: [16890841](https://pubmed.ncbi.nlm.nih.gov/16890841/)]
2. Patterson S, Cescon A, Samji H, Chan K, Zhang W, Raboud J, CANOC collaboration. Life expectancy of HIV-positive individuals on combination antiretroviral therapy in Canada. *BMC Infect Dis* 2015 Jul 17;15:274. [doi: [10.1186/s12879-015-0969-x](https://doi.org/10.1186/s12879-015-0969-x)] [Medline: [26183704](https://pubmed.ncbi.nlm.nih.gov/26183704/)]
3. Bangsberg DR, Perry S, Charlebois ED, Clark RA, Roberston M, Zolopa AR, et al. Non-adherence to highly active antiretroviral therapy predicts progression to AIDS. *AIDS* 2001 Jun 15;15(9):1181-1183. [Medline: [11416722](https://pubmed.ncbi.nlm.nih.gov/11416722/)]

4. British Columbia Centre for Excellence in HIV/AIDS. 2016. HIV Monitoring Quarterly Report for British Columbia, Second Quarter 2016 URL: http://www.cfenet.ubc.ca/sites/default/files/uploads/publications/centredocs/bc_monitoring_report_16q2_final_aug19.pdf [WebCite Cache ID 6yQAT1XCx]
5. Joseph B, Kerr T, Puskas CM, Montaner J, Wood E, Milloy M. Factors linked to transitions in adherence to antiretroviral therapy among HIV-infected illicit drug users in a Canadian setting. *AIDS Care* 2015;27(9):1128-1136 [FREE Full text] [doi: [10.1080/09540121.2015.1032205](https://doi.org/10.1080/09540121.2015.1032205)] [Medline: [25915438](https://pubmed.ncbi.nlm.nih.gov/25915438/)]
6. Kilmarx PH, Mutasa-Apollo T. Patching a leaky pipe: the cascade of HIV care. *Curr Opin HIV AIDS* 2013 Jan;8(1):59-64. [doi: [10.1097/COH.0b013e32835b806e](https://doi.org/10.1097/COH.0b013e32835b806e)] [Medline: [23211779](https://pubmed.ncbi.nlm.nih.gov/23211779/)]
7. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, HPTN 052 Study Team. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med* 2011 Aug 11;365(6):493-505 [FREE Full text] [doi: [10.1056/NEJMoa1105243](https://doi.org/10.1056/NEJMoa1105243)] [Medline: [21767103](https://pubmed.ncbi.nlm.nih.gov/21767103/)]
8. Dube S, Boily M, Mugurungi O, Mahomva A, Chikhata F, Gregson S. Estimating vertically acquired HIV infections and the impact of the prevention of mother-to-child transmission program in Zimbabwe: insights from decision analysis models. *J Acquir Immune Defic Syndr* 2008 May 01;48(1):72-81. [doi: [10.1097/QAI.0b013e31816bcdbb](https://doi.org/10.1097/QAI.0b013e31816bcdbb)] [Medline: [18317229](https://pubmed.ncbi.nlm.nih.gov/18317229/)]
9. Beach MC, Duggan PS, Moore RD. Is patients' preferred involvement in health decisions related to outcomes for patients with HIV? *J Gen Intern Med* 2007 Aug;22(8):1119-1124 [FREE Full text] [doi: [10.1007/s11606-007-0241-1](https://doi.org/10.1007/s11606-007-0241-1)] [Medline: [17514382](https://pubmed.ncbi.nlm.nih.gov/17514382/)]
10. Bofill LM, Lopez M, Dorigo A, Bordato A, Lucas M, Cabanillas GF, et al. Patient-provider perceptions on engagement in HIV care in Argentina. *AIDS Care* 2014;26(5):602-607 [FREE Full text] [doi: [10.1080/09540121.2013.844767](https://doi.org/10.1080/09540121.2013.844767)] [Medline: [24138788](https://pubmed.ncbi.nlm.nih.gov/24138788/)]
11. Brion J. The patient-provider relationship as experienced by a diverse sample of highly adherent HIV-infected people. *J Assoc Nurses AIDS Care* 2014;25(2):123-134. [doi: [10.1016/j.jana.2013.01.006](https://doi.org/10.1016/j.jana.2013.01.006)] [Medline: [23809659](https://pubmed.ncbi.nlm.nih.gov/23809659/)]
12. Knowlton AR, Arnsten JH, Eldred LJ, Wilkinson JD, Shade SB, Bohnert AS, et al. Antiretroviral use among active injection-drug users: the role of patient-provider engagement and structural factors. *AIDS Patient Care STDS* 2010 Jul;24(7):421-428 [FREE Full text] [doi: [10.1089/apc.2009.0240](https://doi.org/10.1089/apc.2009.0240)] [Medline: [20578910](https://pubmed.ncbi.nlm.nih.gov/20578910/)]
13. Schneider J, Kaplan SH, Greenfield S, Li W, Wilson IB. Better physician-patient relationships are associated with higher reported adherence to antiretroviral therapy in patients with HIV infection. *J Gen Intern Med* 2004 Nov;19(11):1096-1103 [FREE Full text] [doi: [10.1111/j.1525-1497.2004.30418.x](https://doi.org/10.1111/j.1525-1497.2004.30418.x)] [Medline: [15566438](https://pubmed.ncbi.nlm.nih.gov/15566438/)]
14. Lester RT, Ritvo P, Mills EJ, Kariri A, Karanja S, Chung MH, et al. Effects of a mobile phone short message service on antiretroviral treatment adherence in Kenya (WelTel Kenya1): a randomised trial. *Lancet* 2010 Nov 27;376(9755):1838-1845. [doi: [10.1016/S0140-6736\(10\)61997-6](https://doi.org/10.1016/S0140-6736(10)61997-6)] [Medline: [21071074](https://pubmed.ncbi.nlm.nih.gov/21071074/)]
15. Wei J, Hollin I, Kachnowski S. A review of the use of mobile phone text messaging in clinical and healthy behaviour interventions. *J Telemed Telecare* 2011;17(1):41-48. [doi: [10.1258/jtt.2010.100322](https://doi.org/10.1258/jtt.2010.100322)] [Medline: [21097565](https://pubmed.ncbi.nlm.nih.gov/21097565/)]
16. Chiang N, Guo M, Amico KR, Atkins L, Lester RT. Interactive Two-Way mHealth Interventions for Improving Medication Adherence: An Evaluation Using The Behaviour Change Wheel Framework. *JMIR Mhealth Uhealth* 2018 Apr 12;6(4):e87 [FREE Full text] [doi: [10.2196/mhealth.9187](https://doi.org/10.2196/mhealth.9187)] [Medline: [29650504](https://pubmed.ncbi.nlm.nih.gov/29650504/)]
17. Ingersoll KS, Dillingham RA, Hetteema JE, Conaway M, Freeman J, Reynolds G, et al. Pilot RCT of bidirectional text messaging for ART adherence among nonurban substance users with HIV. *Health Psychol* 2015 Dec;34S:1305-1315 [FREE Full text] [doi: [10.1037/hea0000295](https://doi.org/10.1037/hea0000295)] [Medline: [26651472](https://pubmed.ncbi.nlm.nih.gov/26651472/)]
18. Murray MCM, O'Shaughnessy S, Smillie K, Van BN, Graham R, Maan EJ, et al. Health care providers' perspectives on a weekly text-messaging intervention to engage HIV-positive persons in care (WelTel BC1). *AIDS Behav* 2015 Oct;19(10):1875-1887. [doi: [10.1007/s10461-015-1151-6](https://doi.org/10.1007/s10461-015-1151-6)] [Medline: [26297567](https://pubmed.ncbi.nlm.nih.gov/26297567/)]
19. Smillie K, Van BN, Abaki J, Pick N, Maan EJ, Friesen K, et al. A qualitative study investigating the use of a mobile phone short message service designed to improve HIV adherence and retention in care in Canada (WelTel BC1). *J Assoc Nurses AIDS Care* 2014;25(6):614-625 [FREE Full text] [doi: [10.1016/j.jana.2014.01.008](https://doi.org/10.1016/j.jana.2014.01.008)] [Medline: [24768442](https://pubmed.ncbi.nlm.nih.gov/24768442/)]
20. King E, Kinvig K, Steif J, Qiu AQ, Maan EJ, Albert AY, et al. Mobile Text Messaging to Improve Medication Adherence and Viral Load in a Vulnerable Canadian Population Living With Human Immunodeficiency Virus: A Repeated Measures Study. *J Med Internet Res* 2017 Jun 01;19(6):e190 [FREE Full text] [doi: [10.2196/jmir.6631](https://doi.org/10.2196/jmir.6631)] [Medline: [28572079](https://pubmed.ncbi.nlm.nih.gov/28572079/)]
21. Montaner J, Guillemi S, Harris M. Therapeutic Guidelines for Antiretroviral Treatment of Adult HIV Infection. 2015. URL: http://www.cfenet.ubc.ca/sites/default/files/uploads/Guidelines/bc-cfe-art-guidelines-Oct_14_2015.pdf [WebCite Cache ID 6yQAg6LON]
22. Provincial Health Services Authority. 2015. Provincial Health Services Authority Salaries URL: https://www.glassdoor.ca/Salary/Provincial-Health-Services-Authority-Salaries-E304646_P3.htm [accessed 2018-06-27] [WebCite Cache ID 70UU3jHAM]
23. Johnson MO, Chesney MA, Goldstein RB, Remien RH, Catz S, Gore-Felton C, NIMH Healthy Living Project Team. Positive provider interactions, adherence self-efficacy, and adherence to antiretroviral medications among HIV-infected adults: A mediation model. *AIDS Patient Care STDS* 2006 Apr;20(4):258-268 [FREE Full text] [doi: [10.1089/apc.2006.20.258](https://doi.org/10.1089/apc.2006.20.258)] [Medline: [16623624](https://pubmed.ncbi.nlm.nih.gov/16623624/)]

24. Dombrowski JC, Kent JB, Buskin SE, Stekler JD, Golden MR. Population-based metrics for the timing of HIV diagnosis, engagement in HIV care, and virologic suppression. *AIDS* 2012 Jan 02;26(1):77-86 [FREE Full text] [doi: [10.1097/QAD.0b013e32834dcee9](https://doi.org/10.1097/QAD.0b013e32834dcee9)] [Medline: [22008656](https://pubmed.ncbi.nlm.nih.gov/22008656/)]
25. Bankoff SM, McCullough MB, Pantalone DW. Patient-provider relationship predicts mental and physical health indicators for HIV-positive men who have sex with men. *J Health Psychol* 2013 Jun;18(6):762-772. [doi: [10.1177/1359105313475896](https://doi.org/10.1177/1359105313475896)] [Medline: [23449678](https://pubmed.ncbi.nlm.nih.gov/23449678/)]
26. Montaner JS, Lima VD, Harrigan PR, Lourenço L, Yip B, Nosyk B, et al. Expansion of HAART coverage is associated with sustained decreases in HIV/AIDS morbidity, mortality and HIV transmission: the “HIV Treatment as Prevention” experience in a Canadian setting. *PLoS One* 2014;9(2):e87872 [FREE Full text] [doi: [10.1371/journal.pone.0087872](https://doi.org/10.1371/journal.pone.0087872)] [Medline: [24533061](https://pubmed.ncbi.nlm.nih.gov/24533061/)]
27. Nosyk B, Min JE, Lima VD, Hogg RS, Montaner JSG. Cost-effectiveness of population-level expansion of highly active antiretroviral treatment for HIV in British Columbia, Canada: a modelling study. *The Lancet HIV* 2015 Sep;2(9):e393-e400. [doi: [10.1016/S2352-3018\(15\)00127-7](https://doi.org/10.1016/S2352-3018(15)00127-7)]
28. Nosyk B, Lima V, Colley G, Yip B, Hogg RS, Montaner JS. Costs of health resource utilization among HIV-positive individuals in British Columbia, Canada: results from a population-level study. *Pharmacoeconomics* 2015 Mar;33(3):243-253 [FREE Full text] [doi: [10.1007/s40273-014-0229-8](https://doi.org/10.1007/s40273-014-0229-8)] [Medline: [25404425](https://pubmed.ncbi.nlm.nih.gov/25404425/)]
29. Sutton SS, Hardin JW, Bramley TJ, D'Souza AO, Bennett CL. Single- versus multiple-tablet HIV regimens: adherence and hospitalization risks. *Am J Manag Care* 2016 Apr;22(4):242-248 [FREE Full text] [Medline: [27143289](https://pubmed.ncbi.nlm.nih.gov/27143289/)]
30. Canadian Institute for Health Information. 2016. Cost of a Standard Hospital Stay URL: <https://yourhealthsystem.cihi.ca/hsp/inbrief?lang=en> [accessed 2018-04-04] [WebCite Cache ID 6yQAzAG9E]
31. Working Group on Modelling of Antiretroviral Therapy Monitoring Strategies in Sub-Saharan Africa, Phillips A, Shroufi A, Vojnov L, Cohn J, Roberts T, et al. Sustainable HIV treatment in Africa through viral-load-informed differentiated care. *Nature* 2015 Dec 03;528(7580):S68-S76 [FREE Full text] [doi: [10.1038/nature16046](https://doi.org/10.1038/nature16046)] [Medline: [26633768](https://pubmed.ncbi.nlm.nih.gov/26633768/)]
32. Quinn TC, Wawer MJ, Sewankambo N, Serwadda D, Li C, Wabwire-Mangen F, et al. Viral load and heterosexual transmission of human immunodeficiency virus type 1. Rakai Project Study Group. *N Engl J Med* 2000 Mar 30;342(13):921-929. [doi: [10.1056/NEJM200003303421303](https://doi.org/10.1056/NEJM200003303421303)] [Medline: [10738050](https://pubmed.ncbi.nlm.nih.gov/10738050/)]
33. Montaner JSG, Lima VD, Barrios R, Yip B, Wood E, Kerr T, et al. Association of highly active antiretroviral therapy coverage, population viral load, and yearly new HIV diagnoses in British Columbia, Canada: a population-based study. *Lancet* 2010 Aug 14;376(9740):532-539 [FREE Full text] [doi: [10.1016/S0140-6736\(10\)60936-1](https://doi.org/10.1016/S0140-6736(10)60936-1)] [Medline: [20638713](https://pubmed.ncbi.nlm.nih.gov/20638713/)]
34. Nosyk B, Zang X, Min JE, Krebs E, Lima VD, Milloy M, et al. Relative effects of antiretroviral therapy and harm reduction initiatives on HIV incidence in British Columbia, Canada, 1996-2013: a modelling study. *Lancet HIV* 2017 Dec;4(7):e303-e310 [FREE Full text] [doi: [10.1016/S2352-3018\(17\)30045-0](https://doi.org/10.1016/S2352-3018(17)30045-0)] [Medline: [28366707](https://pubmed.ncbi.nlm.nih.gov/28366707/)]
35. Kingston-Riechers J. The economic cost of HIV/AIDS in Canada. Edmonton, Alberta: Canadian AIDS Society; 2011:1-19.
36. Johnston KM, Levy AR, Lima VD, Hogg RS, Tyndall MW, Gustafson P, et al. Expanding access to HAART: a cost-effective approach for treating and preventing HIV. *AIDS* 2010 Jul 31;24(12):1929-1935. [doi: [10.1097/QAD.0b013e32833af85d](https://doi.org/10.1097/QAD.0b013e32833af85d)] [Medline: [20588171](https://pubmed.ncbi.nlm.nih.gov/20588171/)]
37. Franklin VL, Waller A, Pagliari C, Greene SA. A randomized controlled trial of Sweet Talk, a text-messaging system to support young people with diabetes. *Diabet Med* 2006 Dec;23(12):1332-1338. [doi: [10.1111/j.1464-5491.2006.01989.x](https://doi.org/10.1111/j.1464-5491.2006.01989.x)] [Medline: [17116184](https://pubmed.ncbi.nlm.nih.gov/17116184/)]
38. Wagner DV, Barry SA, Stoeckel M, Teplitsky L, Harris MA. NICH at Its Best for Diabetes at Its Worst: Texting Teens and Their Caregivers for Better Outcomes. *J Diabetes Sci Technol* 2017 Dec;11(3):468-475 [FREE Full text] [doi: [10.1177/1932296817695337](https://doi.org/10.1177/1932296817695337)] [Medline: [28745094](https://pubmed.ncbi.nlm.nih.gov/28745094/)]
39. Gellis ZD, Kenaley B, McGinty J, Bardelli E, Davitt J, Ten HT. Outcomes of a telehealth intervention for homebound older adults with heart or chronic respiratory failure: a randomized controlled trial. *Gerontologist* 2012 Aug;52(4):541-552. [doi: [10.1093/geront/gnr134](https://doi.org/10.1093/geront/gnr134)] [Medline: [22241810](https://pubmed.ncbi.nlm.nih.gov/22241810/)]
40. Spoelstra SL, Given CW, Sikorskii A, Coursaris CK, Majumder A, DeKoekkoek T, et al. Proof of Concept of a Mobile Health Short Message Service Text Message Intervention That Promotes Adherence to Oral Anticancer Agent Medications: A Randomized Controlled Trial. *Telemed J E Health* 2016 Dec;22(6):497-506 [FREE Full text] [doi: [10.1089/tmj.2015.0126](https://doi.org/10.1089/tmj.2015.0126)] [Medline: [26716365](https://pubmed.ncbi.nlm.nih.gov/26716365/)]
41. Chow CK, Redfern J, Hillis GS, Thakkar J, Santo K, Hackett ML, et al. Effect of Lifestyle-Focused Text Messaging on Risk Factor Modification in Patients With Coronary Heart Disease: A Randomized Clinical Trial. *JAMA* 2015;314(12):1255-1263. [doi: [10.1001/jama.2015.10945](https://doi.org/10.1001/jama.2015.10945)] [Medline: [26393848](https://pubmed.ncbi.nlm.nih.gov/26393848/)]
42. Badawy SM, Barrera L, Sinno MG, Kaviany S, O'Dwyer LC, Kuhns LM. Text Messaging and Mobile Phone Apps as Interventions to Improve Adherence in Adolescents With Chronic Health Conditions: A Systematic Review. *JMIR Mhealth Uhealth* 2017 May 15;5(5):e66 [FREE Full text] [doi: [10.2196/mhealth.7798](https://doi.org/10.2196/mhealth.7798)] [Medline: [28506955](https://pubmed.ncbi.nlm.nih.gov/28506955/)]
43. Pandey A, Krumme A, Patel T, Choudhry N. The Impact of Text Messaging on Medication Adherence and Exercise Among Postmyocardial Infarction Patients: Randomized Controlled Pilot Trial. *JMIR Mhealth Uhealth* 2017 Aug 03;5(8):e110 [FREE Full text] [doi: [10.2196/mhealth.7144](https://doi.org/10.2196/mhealth.7144)] [Medline: [28778843](https://pubmed.ncbi.nlm.nih.gov/28778843/)]

Abbreviations

cART: combined antiretroviral therapy

HCP: health care provider

HIV: human immunodeficiency virus

mHealth: mobile health

OTC: Oak Tree Clinic

PLWH: people living with HIV

pVL: plasma viral load

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Original Paper

A Realistic Talking Human Embodied Agent Mobile Phone Intervention to Promote HIV Medication Adherence and Retention in Care in Young HIV-Positive African American Men Who Have Sex With Men: Qualitative Study

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Abstract

Background: Avatars and embodied agents are a promising innovation for human health intervention because they may serve as a relational agent that might augment user engagement in a behavioral change intervention and motivate behavioral change such as antiretroviral adherence and retention in care.

Objective: This study aimed to develop a theory-driven talking avatar-like embodied agent mobile phone intervention guided by the information-motivation-behavioral skills model to promote HIV medication adherence and retention in care in young African American men who have sex with men (MSM).

Methods: We performed 5 iterative focus groups in Chicago with HIV-positive African American MSM aged 18-34 years to inform the ongoing development of a mobile phone app. Participants for the focus groups were recruited from 4 University of Illinois at Chicago Community Outreach Intervention Project sites located in different high HIV incidence areas of the city and the University of Illinois at Chicago HIV clinic using fliers and word of mouth. The focus group data analysis included developing an ongoing list of priorities for app changes and discussion between two of the investigators based on the project timeline, resources, and to what extent they served the app's objectives.

Results: In this study, 16 men participated, including 3 who participated in two groups. The acceptability for an embodied agent app was universal in all 5 focus groups. The app included the embodied agent response to questions and antiretroviral regimen information, adherence tracking, CD4 count and viral load tracking, motivational spoken messages, and customizability. Concerns that were identified and responded to in the development process included privacy, stigma, avoiding the harsh or commanding tone of voice, avoiding negative motivational statements, and making reminder functions for a variety of health care interactions.

Conclusions: An avatar-like embodied agent mHealth approach was acceptable to young HIV-positive African American MSM. Its relational nature may make it an effective method of informing, motivating, and promoting health behavioral skills. Furthermore,

the app's ease of access, stigma-free environment, and audiovisual format may help overcome some adherence barriers reported in this population.

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KEYWORDS

adherence; mHealth; HIV; African American; men who have sex with men; avatar, embodied agent

Introduction

Young HIV-positive men who have sex with men (MSM) are an important population who may benefit from intervention on the HIV Continuum of Care. MSM account for 82% of new HIV diagnoses among men [1]. The largest subgroup within this population comprises African American MSM. In a national study of HIV-positive MSM reported by the Centers for Disease Control and Prevention, both young MSM (aged 18-34 years) and African American MSM had the lowest viral suppression and retention in care compared with MSM in other age or racial or ethnic groups [2]. Although African Americans represent 13% of the US population, they account for >50% of deaths from HIV or AIDS [3]. African Americans have lower proficient health literacy than Caucasians [4], which is especially important because health literacy is associated with the antiretroviral adherence [5].

An avatar is an animated computerized character designed to look like a person. It may be cartoonish and simplistic or remarkably realistic in its resemblance to an actual person. While avatars are commonly used in computer games, their application to the promotion of human health is new and actively emerging [6-10]. In fact, an avatar is most often used as an embodiment of an online user (as in a computer game); the term embodied agent (or embodied conversational agent) refers to a computer-generated character that provides a feeling of human verbal or nonverbal interaction to the user. Avatars and embodied agents are promising innovative tools for human health intervention because they may serve as a relational agent, a computerized image to which a person may react as if they are in a relationship; this relational aspect might augment user engagement in a behavioral change intervention and thus motivate behavioral change [11]. Avatars and embodied agents offer certain advantages. They may overcome some barriers to care, especially for minority groups, who may be challenged by difficulty traveling to a clinic, have concerns about experiencing stigma in the health care setting, and have other issues such as low literacy and subsequent discomfort clarifying instructions spoken or written above their literacy level.

Avatars and embodied agents can be customized to a user's preferences, engaging the user in a personal manner. They can engage the user with multiple modalities, such as audio, graphics, text, and interactivity, which may motivate behavior, educate, and encourage repeated use. They also can raise the user's health literacy by explaining terminology and improving their understanding of the rationale for healthy behavior. Furthermore, encouraging the user with simple engaging speech, hand gestures, facial cues, and other nonverbal behaviors may augment comprehension and impact [12].

Evidence suggests that a mobile avatar health intervention might be effective in African American MSM. Reportedly, African Americans (72%) have high mobile phone ownership [13]. A national survey reported that lesbian, gay, and bisexual persons have higher mobile phone use than heterosexuals [14]. A randomized controlled trial examined a "virtual agent nurse" providing discharge instructions to 764 hospital patients, among whom approximately half were minorities and half had low health literacy [15,16]. The nurse was randomly provided either an African American or a white avatar, and patients exhibited very high satisfaction with the agent. A larger number of patients stated that they preferred talking to the agent compared with a human. Moreover, patients with lower health literacy reported feeling more cared for by the agent than patients with higher health literacy [15,16].

As low health literacy is a factor associated with the antiretroviral therapy (ART) adherence and retention in care [17-22], avatar-based technologies may be a useful vehicle to promote healthy HIV-related behaviors. However, to the best of our knowledge, this is the first study to develop a mobile-delivered, avatar-based intervention addressing retention in HIV care.

We developed a theory-driven, avatar-based embodied agent mobile phone intervention (hereafter referred to as an avatar) to promote HIV medication adherence and retention in care in young African American MSM. This embodied agent was created using an avatar framework from the image of a young African American male volunteer. This mobile phone app was informed by an iterative process of focus groups with young African American MSM that provided feedback on serial versions. The theoretical backdrop for the app design was the information-motivation-behavioral skills model of antiretroviral adherence [23]. Therefore, the app was designed to remedy knowledge gaps (information), improve self-efficacy (motivation), and include functions, such as reminder alerts and calendar functions, which may help improve adherence (behavioral skills). This study aimed to describe the development of this app and lessons learned.

Methods

Participants

We conducted 5 focus groups, with 3-4 participants in each group, in Chicago from January to May 2016. Participants for the focus groups were recruited from 4 University of Illinois at Chicago Community Outreach Intervention Project sites located in different high HIV incidence areas of the city and the University of Illinois at Chicago HIV clinic using fliers and word of mouth. In this study, 3 men who participated in the first

group returned for the second group, and the other 13 participants were present only one time ($N=16$ participants).

The inclusion criteria for the study were self-reported age of 18-34 years, African American race, MSM, HIV-positive, on ART for at least 3 months by self-report, and owning a mobile phone.

Procedures

All procedures were approved by the Institutional Review Board of the University of Illinois at Chicago School of Public Health. Before starting each focus group, we obtained informed consent, and participants were provided with a short questionnaire to determine their age, number of ART doses missed in the past 2 weeks, and the main reason for missing doses, if relevant. Of note, focus groups were performed in a confidential setting led by one of the investigators (MD) and an experienced focus group moderator. Focus group locations included Community Outreach Intervention Project sites and the University of Illinois at Chicago's School of Public Health. Participants were encouraged not to share what was discussed within the room or disclose anyone else's participation, and their names were not used. Focus groups lasted approximately 90 minutes. Feedback from participants was immediately transcribed for review by the research team and discussion with the computer scientist (SL) as developmental drafts emerged. The analysis of the transcribed data was performed by one of the investigators (MD) throughout the project duration. The avatar dialogue was created and edited in response to participants' recommendations and feedback, and a list of new functions or changes to functions that were explained or demonstrated to participants was created. Then, this list was discussed with the computer scientist (SL), including after each focus group. These two investigators made a decision of which changes to prioritize regarding the feasibility of making each change based on the project timeline, resources needed, and to what extent the change might enhance the efficacy of the app. Examples of app enhancement taken into consideration were would it encourage use, encourage repeat use, and serve the app's objectives of providing knowledge, motivation, and promoting behavioral skills.

Focus groups began by showing the current form of the app. Then, we asked questions regarding app engagement and each of its proposed functions, which included their opinions about the app symbol, each function in general, and the language used by the avatar. Participants' likes and dislikes were specifically sought. Then, we asked participants about the proposed functions that might motivate the long-term use and why they had this opinion. Next, we asked them about their perception of the avatar (Figure 1), including its gender, casual or formal appearance, other physical characteristics they sought, and desires for customizability. The discussion progressed to explore what they would like the app to do specifically with respect to helping them take their medication and stay in care. Next, we asked what motivates them to stay in care and what things they

would like the avatar to say to motivate them to take their medication without missing doses and stay in care. Furthermore, they were asked whether they wanted the avatar to say anything that acknowledges their dual identity of being both African American and MSM, such as issues of racism, homophobia, beliefs about masculinity, social isolation related to being gay, and HIV status; however, they did not seek such acknowledgment from the app. Finally, they were asked whether they preferred the avatar speaking or did they want to read avatar-provided information. The focus group feedback was categorized as follows to inform the development of the app: acceptability of the intervention (including privacy concerns derived from stigma), avatar customization and content preferences, information, motivation, and behavioral skills that impact HIV care retention. As a dialogue for the avatar was developed (a script), participants were read the dialogue (such as questions that the avatar might say and answer) and then asked about the relevance of the question, comprehension, and reaction to the response. We also asked about other questions they wanted to be addressed. Relational language (ie, language that may promote a social-emotional relationship with the user) was purposively inserted into the dialogue. For example, phrases spoken by participants were inserted into the avatar's dialogue like "Just keepin' it real" or referring to something as "nasty." Similarly, the person chosen to voice the avatar dialogue was an African American man, and his diction was left unaltered when it differed slightly from the written version. Next, new components and content that augmented the avatar's functionality were developed on the basis of participants' input and shared with the next focus group for feedback in an iterative way. Initially, participants were shown storyboard images of planned functions and graphics. By the third focus group, the participants were shown the evolving app on a mobile phone, which included both visual and audio components. Although we refer to these gatherings as focus groups, they were not used for identifying themes, and so, no qualitative analyses were performed. Rather, this iterative process was similar to product development by a company that wants to ensure the target population will find the product acceptable. As the purpose of these focus groups was to primarily guide real-time image and function app edits, the data did not require formal qualitative analysis.

Proposed Mobile Phone App

Entry into the app is password protected. The initially proposed and final version of the mobile phone app includes 4 tabs.

Home Screen

Tapping on the first tab delivers the user to the home screen. The avatar greets users on the home screen and provides an audio orientation to the tabs. Later, we added another interaction (inviting the user to hear the motivational messages described below) to the home screen.

Figure 1. Proposed initial appearance of the avatar shown to focus group participants at the first focus group.



Let Me Explain

Tapping on the second tab opens the “Let Me Explain” function, which displays the avatar and a scroll bar of questions. Tapping on the question causes the avatar to read and respond. The educational content includes a basic explanation of key concepts relevant to adherence and retention in care such as understanding viral load, CD4 count, routinely obtained blood tests and their rationale as well as what is AIDS, how AIDS differs from HIV, and how often they should see their health care provider. We showed participants draft illustrations that could augment educational content, such as an animation of an x-ray developing an infiltrate, while the avatar explains *Pneumocystis pneumonia* in response to the question, “What can happen if I get AIDS?”

Medication Manager

Tapping on the third tab opens the “Medication Manager” function, which includes several tap and click components. Clicking on “Enter Medicine” displays ART and allows users to select their regimen, which the app can display if they click on “My Regimen.” Additional ART information, including generic and commercial names, common side effects, doses per day, and food restrictions, are available by clicking on the image of each medication. Each day the app is opened, the user is prompted on the home screen to record whether they took their ART doses that day. If they respond no, the app asks the reason for missing the dose by providing a list of common reasons to check which applied. If none of the listed responses is applicable, the user can enter a free text response as “Other.” These data results are available to view in a calendar screen available within the “Medication Manager” that shows the image of a pill on the dates with medication taken and an “X” for dates they responded no. “Medication Manager” includes the ability

to enter the current and past viral load and CD4 counts to populate a trends curve for each. Later in the iterative process, we added the ability to enter side effects daily.

Settings

Tapping on the fourth tab opens “Settings,” where users can create multiple simultaneous personalized reminders for medication and care or lab appointments that can be set as recurring reminders. They may also customize their avatar appearance (such as, hair, glasses, clothes, and background), enter phone numbers of key contacts (health care provider, case manager, and pharmacy) for touch and click calling, and read the “Let Me Explain” and ART information without activating the avatar audio. Within any function, users may pause and silence the avatar with a button located on all screens. When the pause screen is not used, the avatar has a slight head motion and blinking to appear lifelike.

As the app development progressed, participants in the last 3 focus groups were shown the app demonstration on the phone. The avatar’s dialogue included both motivational and empathetic statements (to promote the relationship with the avatar) and phrasing derived from focus group discussions. The avatar dialogue was recorded, not synthetic, and the avatar’s animation included minimal head movement, eye blinking, and mouth movement. By the final focus group, the app offered users with opportunities to respond to questions posed by the avatar, such as whether they wanted to hear the avatar’s (or his friend’s) thoughts on a subject (eg, depression), which would allow the avatar (or his friends in the form of audiorecordings) to provide the additional motivational dialogue that was derived from focus group participant thoughts or recommendations.

Results

Participants

The reported ages of 16 participants ranged between 21 and 34 (median 29.5) years. As per the inclusion criteria, all were African American MSM. Of all, 7 had missed at least 3 ART doses, 4 had missed 2 doses, 4 had missed 1 one, and only 1 participant did not miss any ART dose in the past 2 weeks. The main reason for missing a dose was forgetting (n=8), being away from home (n=4), avoiding side effects (n=2), and both being away from home and forgetting (n=2).

Acceptability

The acceptability for the concept was universal in all 5 focus groups. Participants affirmed that the idea of a talking instructional avatar was a welcome innovation:

He looks so real, and he's a nice attractive man, and I'm going to ask him a lot of questions about medication! This is genius idea! Thank you! People can go on their phone. People say, I'm afraid to take my meds. This thing can talk back to say, "It's okay." Here's why to take your meds. [Focus group 1]

I think it will work. I'm sure it will. [Focus group 2]

It's good that it can explain the side effects. It's a good idea that there's a picture of the medicine. [Focus group 3]

Participants also provided feedback about the content, suggesting which dialogue should be changed to facilitate better understanding; this informed changes that were tested in a subsequent group that were much better received. For example, although participants accepted the use of the word AIDS in a question such as "Is AIDS the same thing as HIV?", they reacted negatively to its use as an explanation of the CD4 count by stating, "It's pretty low if it's under 200. That's AIDS if it's under 200." A participant asserted that if he had a CD4 count below 200 and was told by the app that he had AIDS as it was stated in this response, it would make him not want to use the app. He stated,

Like I'm gonna keep it real, like if my doctor told me that, I'm not going back to the doctor. [Focus group 4]

Another participant said, in response,

I think that in the black community, we are not comfortable with that word, AIDS. Instead, don't have it say below 200 you got AIDS. Have it say if you less than 200, you got to see the doctor. Don't say, "That's AIDS!" Say, "That means your risk of infection is much higher, and it's so important to take your medication to get healthy." [Focus group 4]

While participants generally welcomed the use of images to complement the dialogue, images portraying sickness or negative consequences of having HIV were less well received. Originally, an illustration of an avatar on a ventilator appeared during the explanation of the complications of AIDS in part to provide a rationale and motivation for healthy behavior. Some participants felt that negative images were upsetting and not

motivating. However, illustrations that explained the body and HIV were welcomed such as an image of an x-ray that revealed and explained *Pneumocystis pneumonia* as a complication for AIDS that required taking an antibiotic to prevent it when the CD4 count is low. One participant from focus group 5 stated, "It's interesting to know what's going on in the body."

As a result of the above feedback, the explanation of AIDS was softened to one accepted by the group, "Under 200 means your immune system doesn't fight infections so good." Similarly, any image that repelled a participant from wanting to use the app was removed. When no participants agreed that a language or an image was unacceptable, a language that they all could agree was acceptable was offered. A new language was selected when all agreed it was preferable and met the objective of that function (such as clear and educational or motivating). For example, the original wording of the response to the question, "Why do I need my blood drawn?" included the statement, "And some benefits plans that pay for your medication, they need to see your blood test results too." This was intended to remind them that to keep the benefits of programs, like the AIDS Drug Assistance Program (ADAP), they need to have had their blood drawn, as it is a requirement for every 6-month renewal. However, there were reactions such as, "I just don't get it," and another participant said, "That was a distraction, the benefits part." Subsequently, participants found the following lengthier but more explanatory language acceptable:

"And some benefits plans that pay for your medication, they need to see your blood test results too. Have you heard of ADAP or CHIC? The AIDS Drug Assistance Plan or CHIC Premium assistance? Every 6 months they have to receive your blood results, or they expire and then so does getting medication for free! So to keep certain benefits like ADAP from expiring, you get the blood drawn so the results can get sent in with the renewal application."

Stigma and Privacy

Stigma emerged as an important issue in the first 4 focus groups. Specifically, participants were very sensitive to no one knowing their sexual or HIV-related identity through an association with the app. Participants voiced no concerns related to the app by the fifth group, after it had been edited in response to previously voiced issues. Participants sought privacy features that protected anonymity concerning their MSM identity, HIV status, and their health in general. They stated that it was common to have someone looking at or holding their phone. For example, they wanted to minimize the unwanted attention from alerts or reminders to take medicine. Furthermore, they expressed reluctance to ask questions from health care providers or to disclose problems when not asked about them. They suggested a feature that would allow them to instantly change the app screen image to an image that hides their activity to mislead people who are trying to figure out what they are looking at. Notably, images of a game, Facebook, or other culturally appropriate graphics were suggested. A screen hiding function was added by the fourth focus group.

What would be nice, they trying to be nosy and he can change into a game image. Only we know that he's a puzzle now. [Focus group 1]

I wouldn't want it to pop up saying take your meds. [Focus group 1]

The "Did you take your medicine notification" is a problem. "Did you take your medication?" Anybody in their right mind is going be, "What do you mean you take medication?" It lets them know your sick. You could be hiding it from your family. [Focus group 3]

In response to the feedback, the avatar tells the user about these privacy features during the orientation while acknowledging an understanding of these privacy concerns in a relational statement: "People are always getting up in my business. How about you?" A relational dialogue, such as this example, may help build trust and credibility as it introduces the avatar as an ally who has some understanding of their world. Specifically, we built a function that allows the user to select among multiple images that would instantly disguise the screen. We also made the reminder alert customizable so the user can decide if they want it to say "take your meds" or a cryptic message only they understand instead.

Customizability

Nearly all participants found the male avatar acceptable, but 4 stated they would like to be able to choose a female version (specifically a white nurse). They enjoyed the concept of the avatar and desired customization that sometimes reached beyond

the budget and timeline for the project. For example, in the fifth focus group, a participant recommended that the avatar have his (the user's) own face and voice.

Make him functionable like I can brush his hair or take his medicine, drink water, get rest. Have the alarm clock to be aware of his medicine. [Focus group 1]

Have everybody create the avatar that they like. That way everybody's can be distinct. They don't say, "Hey you got that thing on your phone." [Focus group 3]

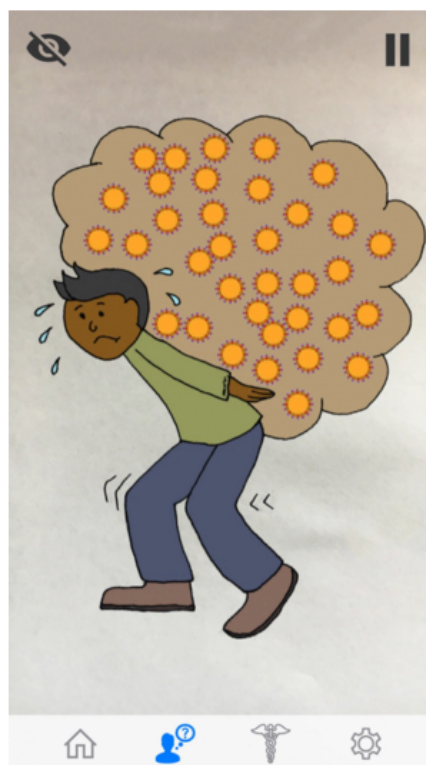
Throw a lady in there as a choice. [Focus group 4]

Although we considered these recommendations, not all were feasible, given the budget and timeline of the project. Changing the avatar's clothing, accessorizing him (such as with glasses or a stethoscope), modifying his background (such as office setting), and adding or subtracting hair were built into the app in response to requests.

Information

Participants were read a dialogue from the "Let Me Explain" component and provided feedback that led to the development of additional content (eg, signs and symptoms of syphilis, taking ART with alcohol, ART side effects, and additional basic HIV and ART adherence information), as well as overall improvements in the dialogue to improve comprehension and relevance. Participants suggested that the avatar dialogue should be combined with imagery to reinforce complicated topics (eg, the meaning of an elevated vs undetectable viral load and affirmed or offered ideas for images).

Figure 2. An illustration that appears during the answer to "What is a viral load?" Responding to the question, the avatar explains in a relational way, "You can think of the viral load as the load of virus you're carrying around. You don't want to carry around a big load of this virus. Right? So you want the doctor to tell you that your viral load is low."



The illustrations are a better way of explaining it. Sometimes I still get confused, the CD4 confused with the viral load. [Focus group 2]

As a result of this feedback, illustrations were incorporated into several answers (Figure 2).

Motivation

Participants were enthusiastic about the inclusion of motivational messages that appeared throughout the app, which addressed ART adherence, retention in care, advocating for their needs during appointments, and app function use, including the “Let Me Explain” function’s questions and answers. However, they varied on their preference for positive versus negative encouragement. Some felt that HIV was “like a dog that is barking at you” and can be locked up in a cage by taking medication regularly and that this was a good way to motivate adherence and retention in care. However, others rejected it and favored positive imagery. One participant recommended that taking medication could be thought of like keeping one’s hands on a steering wheel to maintain control, and this language was adopted and found acceptable to the subsequent focus group. Participants also discouraged any intonation in the avatar’s voice that sounded harsh or commanding. They welcomed that the avatar acknowledged their concerns and used “straight talk” to motivate like a friend or relative would. These concerns included advocating for their needs during a medical visit, struggling with adherence, being afraid to take medication, getting help with depression, and asking for re-explanation of health information they did not understand. Furthermore, one participant gave an example of having got clarification about his neuropathy that led to his doctor addressing his problem.

I have neuropathy too. I asked the doctor. He said it come from the disease, not the medicine. If I wouldn’t have asked, I kept going along like it’s ok...I advocated for myself. [Focus group 1]

Some people need that push from your parent. My mother said, “boy if you don’t take your medicine I’m not coming to your funeral.” [Focus group 1]

“Have avatar tell to take a walk in the park or other motivating language” when depressed. “Some people shuts down.” “See a family member, tell somebody that’s on the same level as me.” [Focus group 1]

“When I get any depression, I don’t want to take any medicine.” Regarding avatar dialogue recommending avoiding isolation and activities to try when depressed: “That’ll keep me more motivated. I like that.” [Focus group 2]

When someone jumps on my back about something, I get rebellious. Better with a smooth voice, as if they have love for you. My doctor at first irritated me too bad so we almost got in a fist fight. I got up and left. [Focus group 4]

Keep your hand on the steering wheel. You got to go straight. You can control your own choice. Its gonna eventually turn. But if you keep your hand on the wheel, you got control. [Focus group 4]

In response to the feedback, the avatar specifically motivates the user to advocate for himself. However, it was not clear whether harsh language (referring to one’s funeral) delivered by the avatar (as opposed to a loved trusted person like one’s mother) would be received well so no such language was included. Similarly, the language was edited to be soft, positive, or affirming, and the activities the avatar suggested in response to feelings of depression were those offered by the participants.

In the fifth focus group, participants approved of avatar-spoken motivational statements that would initiate upon entering the app (after its first-time use). The avatar would greet the user with a question such as, “Do you know what I think?” or “Do you want to hear me talk about depression?” If the user clicked yes, the avatar provided a brief statement derived from the focus group discussion such as how social support from a trusted person can help with adherence. In the fifth group, users supported the concept of adding audiorecordings of real people (young HIV-positive African American MSM and health care professionals) giving a brief motivational message. In this study, we recorded 11 people (5 young African American MSM and 6 health care professionals, including 2 doctors, 1 nurse, 1 nurse assistant, 1 pharmacist, and 1 mental health provider) who spoke for 1-2 minutes each. To hear one of these real people recordings, the user would respond to the avatar asking, “Do you want to hear what a friend of mine says?”

Motivational messaging was integrated with many of the “Let Me Explain” responses. For example, when the avatar explains the viral load, language affirming adherence self-efficacy is included. The response to a question about how often to see a health care provider emphasizes the importance of keeping appointments. Similarly, in the final version, an explanation of the benefit of taking HIV medication expresses that “you can handle” the twists and turns of the road of life “by keeping your hands on the wheel,” and an optimistic closing statement follows: “Good luck with your personal goals. Enjoy that full life! You’ll get there.” Participants voiced and offered some of these incorporated motivational phrases or sentences.

Behavioral Skills

Participants provided suggestions for how the app could address needed behavioral skills to adhere to ART and stay in care. Some participants thought that the ability to track and observe trends in CD4 counts and viral load was “a good idea” but advised that the avatar should “explain how to read the graph.” Participants also approved of reminder functions. However, they encouraged that reminders should be available for other health care events such as blood draws. In response to their feedback, explanatory dialogue concerning the trends and reminder functions for medication taking, appointments, and blood draws were added to the app as choices on a scroll bar, as well as an option of “Other” to accommodate other potential events. A participant recommended a dictation-like function to record concerns to be shared at future health care appointments; this capability was placed on a list for the future work because it was not accomplishable within the 1-year timeframe available for development.

Alarm is a good thing to alert—or to pick up medication too—or to make your appointments, like

getting blood work. Have avatar ask about "I'm wondering what's causing my low platelets." It could take notes and tell to ask the doctor about this. [Focus Group 1]

Discussion

Principal Findings

These focus group data demonstrate the value of the iterative development of technology-based health interventions. Enthusiasm for a theory-based mobile phone app that used a talking realistic human avatar-like embodied agent was strong across all five focus groups conducted with young African American MSM. Their feedback helped to design and refine the app for closer alignment with their preferences for the receipt of app-based information, motivation, and skills. By the final focus group, much of the discussion was an affirmation of the more fully developed app and a unanimous request to download the app onto their mobile phones. These findings would help to move the field of adherence research forward. For example, young African American MSM living with HIV liked the idea of a mobile phone avatar-based app approach to adherence and retention in care. While negative messages and images were not welcomed by some young African American MSM, positive messages and images were welcomed by all. In addition, this study revealed that the design of a health app for this population must consider stigma at many levels of interaction (eg, icon, tab appearance, reminders, and password protection).

Many participants described the role HIV- and sexual identity-related stigma plays in their lives and how an app-based intervention should not contribute to this problem. They explained how having an HIV-related app on their phone could place them in situations that could inadvertently result in the disclosure of their HIV status or sexuality. App features, such as an HIV-related icon, reminders, and notifications for the ART use, may draw unwelcome attention. Similarly, if they were to store private information, such as viral load, CD4 count, and medication data, access to the app must be password protected, and time-out features after a period of nonuse were expected. Participants' input helped to modify the app and strengthen its acceptability, as the icon was made to appear uninteresting, reminders and notifications were designed to be customizable, password entry was required for use, and password entry was required for re-entry after the app automatically closes when the nonuse time reaches 5 minutes. Goldenberg et al conducted focus groups to help develop an app for the HIV prevention in MSM [24]; similar to our study, they found that an app for MSM needed to make them feel safe and was trustworthy. Liu, in a focus group study of patients with chronic diseases in Beijing, reported that worrying about the privacy of personal information was the main reason for not using a health-related app [24,25]. These studies support the prioritization of privacy when designing a mobile phone health app for young African American MSM living with HIV.

A critical part of the development of an avatar or embodied agent intervention is the dialogue. Participants expressed universal enthusiasm for positive motivational statements, whereas the use of negative motivational statements was

controversial. Hence, we chose to edit the dialogue to remove negative statements and images that participants could not all agree were acceptable to maximize the acceptability. Accordingly, we replaced these statements with participants' suggested language and images. While, all participants found educational images of disease acceptable to view (such as a tongue with thrush or an x-ray with pneumonia), images of an ill avatar or statements that allowed one to be directly reminded that they have AIDS were strongly rejected by several participants. Furthermore, negative images can overwhelm users and make them want to turn off the app and not return to it.

An advantage of our approach was that the motivational language could be inserted throughout the app. In the context of the information-motivation-behavioral skills model, motivation is a key component that can drive behavioral change, especially ART adherence [16,26]. Similar to the practice of motivational interviewing, the avatar's dialogue was intended to move the users away from indecision and toward adherence and retention in care [26]; this kind of language contributes to the relational aspect of the avatar and may allow users to feel that the avatar cares about them.

Among the behavioral skills that mobile phone apps can promote are reminder and notification functions, especially when combined with other interventions and delivered weekly rather than daily [27,28]. Such functions are typically available on mobile phones such as calendar alerts. However, while such capability was already on their phones, participants did not report the common use and welcomed these functions in this app. Although the avatar announces that such functions are available during the initial interaction, it is uncertain whether having the functions in the app will lead to their use or will they be effective. It is possible that encouragement to use reminders in persons who are receptive to them will be most effective if it comes from a health care provider or case manager who may introduce the app to them. Such an interaction might include setting reminders as part of the appointment where the app is used as an intervention. Future research piloting the app will determine the frequency of the use of this function independent from such human assistance. While a notification by itself might be insufficient in producing ART adherence change, this app allows for user customization of the message, and this function was integrated into a broader experience.

Previously, low health literacy has been associated with poor ART adherence and retention in care [17-22]. A talking avatar may help overcome this barrier by providing information in an audiovisual format allowing for an instruction that goes beyond the usual practice in outpatient settings where providers may have limited time for instruction, patients might be reluctant to ask for an explanation, and medical jargon may be used that patients do not understand. Another advantage of a mobile phone avatar app is that information can be replayed to overcome the distraction or emotional impact when a provider says something upsetting and the patient cannot concentrate on the information provided immediately after. In this study, the participants in the focus groups were eager to learn new information and acknowledged that they had learned from the avatar dialogue.

The avatar's appearance was important to them to ensure he appeared credible. Although they welcomed customizability with casual clothing, they expected him to be dressed in a professional manner as a default. Furthermore, there was a white racial preference by some participants for a female dressed as a nurse. The future app development will offer this option.

Limitations

The limitations of this study include the generalizability. The focus groups included only 16 participants and were performed in only one city. We focused on young African American MSM because of their relatively high HIV incidence and poorer adherence and retention in care [1,28]. In addition, participants had to own a mobile phone. While the intervention can be modified for delivery on a computer, we do not know whether this broadening of the audience would influence preferences.

Conclusions

We developed a theory-based, relational realistic talking human avatar-like embodied agent mobile phone intervention to promote HIV medication adherence and retention in care in young HIV-positive African American MSM. We used an iterative approach that helped to ensure that the app development considered the desires and concerns of users. An avatar mHealth approach was acceptable to this population, and its relational nature may make it an effective method of informing, motivating, and promoting health behavioral skills. We propose that this app may be especially helpful if recommended and initially overseen by a case manager or health care provider when a patient is initiating ART or is recognized to be struggling with adherence or retention in care. The next step for this work is a pilot study to determine the preliminary efficacy.

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Conflicts of Interest

None declared.

References

1. Centers for Disease Control and Prevention. HIV in the united states: At A glance URL: <https://www.cdc.gov/hiv/statistics/overview/ataglance.html> [accessed 2018-02-21] [WebCite Cache ID 6xRD5L6RC]
2. Singh S, Bradley H, Hu X, Skarbinski J, Hall HI, Lansky A, Centers for Disease ControlPrevention (CDC). Men living with diagnosed HIV who have sex with men: progress along the continuum of HIV care--United States, 2010. *MMWR Morb Mortal Wkly Rep* 2014 Sep 26;63(38):829-833. [Medline: 25254559]
3. Centers for Disease Control and Prevention. HIV among african americans URL: <https://www.cdc.gov/hiv/group/raciaethnic/africanamericans/> [accessed 2018-02-22] [WebCite Cache ID 6xRDVsthp]
4. National Center for Education Statistics. The health literacy of america's adults: Results from the 2003 national assessment of adult literacy URL: <https://nces.ed.gov/pubs2006/2006483.pdf> [accessed 2018-02-23] [WebCite Cache ID 6xRK6PN9J]
5. Drainoni M, Rajabiun S, Rumptz M, Welles SL, Relf M, Rebholz C, et al. Health literacy of HIV-positive individuals enrolled in an outreach intervention: results of a cross-site analysis. *J Health Commun* 2008;13(3):287-302. [doi: 10.1080/10810730801985442] [Medline: 18569359]
6. Fox J, Bailenson JN, Tricase L. The embodiment of sexualized virtual selves: The Proteus effect and experiences of self-objectification via avatars. *Computers in Human Behavior* 2013 May;29(3):930-938. [doi: 10.1016/j.chb.2012.12.027]
7. Napolitano MA, Hayes S, Russo G, Muresu D, Giordano A, Foster GD. Using avatars to model weight loss behaviors: participant attitudes and technology development. *J Diabetes Sci Technol* 2013 Jul 01;7(4):1057-1065 [FREE Full text] [Medline: 23911189]
8. Lyles AA, Amresh A, Huberty J, Todd M, Lee RE. A Mobile, Avatar-Based App for Improving Body Perceptions Among Adolescents: A Pilot Test. *JMIR Serious Games* 2017 Mar 02;5(1):e4 [FREE Full text] [doi: 10.2196/games.6354] [Medline: 28254737]
9. Bickmore T, Mitchell S, Jack B, Paasche-Orlow M, Pfeifer L, Odonnell J. Response to a Relational Agent by Hospital Patients with Depressive Symptoms. *Interact Comput* 2010 Jul 01;22(4):289-298 [FREE Full text] [doi: 10.1016/j.intcom.2009.12.001] [Medline: 20628581]
10. Wells KJ, Vázquez-Otero C, Bredice M, Meade CD, Chaet A, Rivera MI, et al. Acceptability of a Virtual Patient Educator for Hispanic Women. *Hisp Health Care Int* 2015;13(4):179-185 [FREE Full text] [doi: 10.1891/1540-4153.13.4.179] [Medline: 26671558]
11. Baylor AL. Promoting motivation with virtual agents and avatars: role of visual presence and appearance. *Philos Trans R Soc Lond B Biol Sci* 2009 Dec 12;364(1535):3559-3565 [FREE Full text] [doi: 10.1098/rstb.2009.0148] [Medline: 19884150]

12. Bickmore TW, Caruso L, Clough-Gorr K, Heeren T. 'It's just like you talk to a friend' relational agents for older adults. *Interacting with Computers* 2005 Dec;17(6):711-735. [doi: [10.1016/j.intcom.2005.09.002](https://doi.org/10.1016/j.intcom.2005.09.002)]
13. Pew Research Center. 2018. Mobile Fact Sheet URL: <http://www.pewinternet.org/fact-sheet/mobile/> [accessed 2018-02-23] [[WebCite Cache ID 6xRDomOV2](#)]
14. Seidenberg AB, Jo CL, Ribisl KM, Lee JGL, Buchting FO, Kim Y, et al. A National Study of Social Media, Television, Radio, and Internet Usage of Adults by Sexual Orientation and Smoking Status: Implications for Campaign Design. *Int J Environ Res Public Health* 2017 Dec 21;14(4) [[FREE Full text](#)] [doi: [10.3390/ijerph14040450](https://doi.org/10.3390/ijerph14040450)] [Medline: [28430161](#)]
15. Bickmore T, Pfeifer L, Jack B. Taking the time to careempowering low health literacy hospital patients with virtual nurse agents. 2000 Presented at: Proceedings of the SIGCHI conference on human factors in computing systems; 2009; - p. -. [doi: [10.1145/1518701.1518891](https://doi.org/10.1145/1518701.1518891)]
16. Zhou S, Bickmore T, Paasche-Orlow M, Jack B. Agent-user concordance and satisfaction with a virtual hospital discharge nurse. 2000 Presented at: International Conference on Intelligent Virtual Agents; 2014; - p. 528-541. [doi: [10.1007/978-3-319-09767-1_63](https://doi.org/10.1007/978-3-319-09767-1_63)]
17. Jones D, Cook R, Rodriguez A, Waldrop-Valverde D. Personal HIV knowledge, appointment adherence and HIV outcomes. *AIDS Behav* 2013 Jan;17(1):242-249 [[FREE Full text](#)] [doi: [10.1007/s10461-012-0367-y](https://doi.org/10.1007/s10461-012-0367-y)] [Medline: [23143751](#)]
18. Kalichman SC, Ramachandran B, Catz S. Adherence to combination antiretroviral therapies in HIV patients of low health literacy. *J Gen Intern Med* 1999 May;14(5):267-273 [[FREE Full text](#)] [Medline: [10337035](#)]
19. Kalichman SC, Pope H, White D, Cherry C, Amaral CM, Swetzes C, et al. Association between health literacy and HIV treatment adherence: further evidence from objectively measured medication adherence. *J Int Assoc Physicians AIDS Care (Chic)* 2008;7(6):317-323 [[FREE Full text](#)] [doi: [10.1177/1545109708328130](https://doi.org/10.1177/1545109708328130)] [Medline: [19056866](#)]
20. Kalichman SC, Rompa D. Functional health literacy is associated with health status and health-related knowledge in people living with HIV-AIDS. *J Acquir Immune Defic Syndr* 2000 Dec 01;25(4):337-344. [Medline: [11114834](#)]
21. Osborn CY, Paasche-Orlow MK, Davis TC, Wolf MS. Health literacy: an overlooked factor in understanding HIV health disparities. *Am J Prev Med* 2007 Nov;33(5):374-378. [doi: [10.1016/j.amepre.2007.07.022](https://doi.org/10.1016/j.amepre.2007.07.022)] [Medline: [17950402](#)]
22. Wolf MS, Davis TC, Tilson HH, Bass PF, Parker RM. Misunderstanding of prescription drug warning labels among patients with low literacy. *Am J Health Syst Pharm* 2006 Jun 01;63(11):1048-1055. [doi: [10.2146/ajhp050469](https://doi.org/10.2146/ajhp050469)] [Medline: [16709891](#)]
23. Fisher JD, Amico KR, Fisher WA, Harman JJ. The information-motivation-behavioral skills model of antiretroviral adherence and its applications. *Curr HIV/AIDS Rep* 2008 Nov;5(4):193-203. [Medline: [18838059](#)]
24. Goldenberg T, McDougal SJ, Sullivan PS, Stekler JD, Stephenson R. Preferences for a Mobile HIV Prevention App for Men Who Have Sex With Men. *JMIR Mhealth Uhealth* 2014;2(4):e47 [[FREE Full text](#)] [doi: [10.2196/mhealth.3745](https://doi.org/10.2196/mhealth.3745)] [Medline: [25355249](#)]
25. Liu Y, Wang L, Chang P, Lamb KV, Cui Y, Wu Y. What Features of Smartphone Medication Applications Are Patients with Chronic Diseases and Caregivers Looking for? *Stud Health Technol Inform* 2016;225:515-519. [Medline: [27332254](#)]
26. Miller W, Rollnick S. *Motivational Interviewing: Helping People Change*, 3rd Edition (Applications of Motivational Interviewing). New York, NY: The Guilford Press; 2012.
27. Pop-Eleches C, Thirumurthy H, Habyarimana JP, Zivin JG, Goldstein MP, de WD, et al. Mobile phone technologies improve adherence to antiretroviral treatment in a resource-limited setting: a randomized controlled trial of text message reminders. *AIDS* 2011 Mar 27;25(6):825-834 [[FREE Full text](#)] [doi: [10.1097/QAD.0b013e32834380c1](https://doi.org/10.1097/QAD.0b013e32834380c1)] [Medline: [21252632](#)]
28. Horvath T, Azman H, Kennedy GE, Rutherford GW. Mobile phone text messaging for promoting adherence to antiretroviral therapy in patients with HIV infection. *Cochrane Database Syst Rev* 2012;3:CD009756. [doi: [10.1002/14651858.CD009756](https://doi.org/10.1002/14651858.CD009756)] [Medline: [22419345](#)]

Abbreviations

ADAP: AIDS Drug Assistance Program

ART: antiretroviral therapy

MSM: men who have sex with men

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Original Paper

Evaluating the Implementation of a Mobile Phone–Based Telemonitoring Program: Longitudinal Study Guided by the Consolidated Framework for Implementation Research

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Abstract

Background: Telemonitoring has shown promise for alleviating the burden of heart failure on individuals and health systems. However, real-world implementation of sustained programs is rare.

Objective: The objective of this study was to evaluate the implementation of a mobile phone–based telemonitoring program, which has been implemented as part of standard care in a specialty heart function clinic by answering two research questions: (1) To what extent was the telemonitoring program successfully implemented? (2) What were the barriers and facilitators to implementing the telemonitoring program?

Methods: We conducted a longitudinal single case study. The implementation success was evaluated using the following four implementation outcomes: adoption, penetration, feasibility, and fidelity. Semistructured interviews based on the Consolidated Framework for Implementation Research (CFIR) were conducted at 0, 4, and 12 months with 12 program staff members to identify the barriers and facilitators of the implementation.

Results: One year after the implementation, 98 patients and 8 clinicians were enrolled in the program. Despite minor technical issues, the intervention was used as intended. We obtained qualitative data from clinicians (n=8) and implementation staff members (n=4) for 24 CFIR constructs. A total of 12 constructs were facilitators clustered in the CFIR domains of inner setting (culture, tension for change, compatibility, relative priority, learning climate, leadership engagement, and available resources), characteristics of individuals (knowledge and beliefs about the intervention and self-efficacy), and process (engaging and reflecting and evaluating). In addition, we identified other notable facilitators from the characteristics of the intervention domain (relative advantage and adaptability) and the outer setting (patient needs and resources). Four constructs were perceived as minor barriers—the complexity of the intervention, cost, inadequate communication among high-level stakeholders, and the absence of a formal implementation plan. The remaining CFIR constructs had a neutral impact on the overall implementation.

Conclusions: This is the first comprehensive evaluation of the implementation of a mobile phone–based telemonitoring program. Although the acceptability of the telemonitoring system was high, the strongest facilitators to the implementation success were

related to the implementation context. By identifying what works and what does not in a real-world clinical context using a framework-guided approach, this work will inform the design of telemonitoring services and implementation strategies of similar telemonitoring interventions.

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KEYWORDS

Consolidated Framework for Implementation Research; eHealth; heart failure; implementation; telemonitoring

Introduction

Heart failure telemonitoring systems are developed with the objective of reducing mortality and hospitalizations and improving patients' quality of life [1]. However, despite patient acceptance [2-4], the diffusion of these services is lagging [5]. Meta-analyses tend to support claims of the positive impact on heart failure outcomes [1,6-9]; however, important inconsistencies in the evidence persist [10]. Inconsistencies are believed to result from the heterogeneity of the intervention and patient populations used in primary studies and the lack of consistency with which interventions are used (ie, fidelity) in clinical trials [10]. Much remains to be learned on how to best implement telemonitoring interventions such that true effectiveness can be measured and their benefits be fully realized.

Systematic reviews present extensive lists of various barriers and facilitators to telemonitoring implementation [11-13]. External barriers include the lack of a clear business model in single-payer health systems [14] and the lack of acceptable reimbursement methods for clinician users [15]. Furthermore, clinician adoption is influenced by the quality and usability of the technology, compatibility of the intervention with existing work processes, and intrinsic clinician motivation to adopt telemonitoring as part of their practice [11-13]. In fact, a recent review found that the challenge presented by new and often ill-defined clinician roles within changing workflows was a key factor in leading to the failure of eHealth interventions [16]. One multisite qualitative study similarly highlights the importance of contextual factors for clinician adoption, including the degree of support clinicians receive in their new roles and alignment with organization objectives [17]. However, most telemonitoring implementation studies have been conducted retrospectively, which does not allow for a robust analysis of how these barriers and facilitators exert their influence over the entire implementation period. In addition, few studies report on quantitative outcomes to justify judgments of the implementation success or failure.

A mobile phone-based telemonitoring program called *Medly* was implemented as part of the standard of care at a specialty heart function (HF) clinic in Toronto, Canada. This program features a system that has previously demonstrated improvements in clinical outcomes, patient self-care, and quality of life [18]. The objective of this study was to evaluate the implementation of the *Medly* program by answering two research questions: (1) To what extent was the *Medly* program successfully implemented? (2) What were the barriers and facilitators to implementing the *Medly* program?

Methods

Study Design

This study used a longitudinal single case study design. The case was defined as the telemonitoring intervention and the implementation site as described below for one year following the enrollment of the first patient (August 23, 2016). The units of analysis for this evaluation were the Ted Rogers Centre of Excellence for Heart Function (HF clinic) and program staff with data for determining the implementation success being collected through a document review. In addition, barriers and facilitators were assessed using semistructured interviews with program staff guided by the Consolidated Framework for Implementation Research (CFIR) [19]. Notably, the patient perspective, including reasons for use, adherence, and withdrawal will feature in an upcoming publication. In this study, data collection was conducted within the context of a larger quality improvement program evaluation [20], which has been approved by the University Health Network (UHN) Research Ethics Board (16-5789).

Intervention

The *Medly* program consists of two components: (1) the technology (hardware and software) and (2) the human-dependent interactions and services.

Medly Technology

The patient-facing technology includes the *Medly* mobile phone app, which works by allowing patients with heart failure to record the following three parameters: (1) weight; (2) blood pressure; and (3) symptoms. Based on these data inputs by patients at home, the *Medly* app, which contains a rule-based algorithm customized according to patient-specific target ranges, displays self-care messages and generates alerts that are automatically relayed to a clinician when signs of clinically significant health status deterioration occur. Patients were instructed to record the three parameters daily, and they would receive an automated phone call if they had not done so before 10 am; this was intended to assist with compliance. For the launch of the program, each patient was provided with all the required equipment, which includes a mobile phone with a data plan, a Bluetooth-enabled weight scale, and a Bluetooth-enabled blood pressure monitor.

The clinician-facing technology seeks to support the management of the patient alerts; this is primarily conducted through a Web-based interface (ie, the dashboard) containing a list of patient alerts, graphs showing patient-level trends of the three clinical parameters monitored, and heart failure-specific lab results. In addition, clinicians have the option

of receiving alerts through automated emails, which contain the latest weight, blood pressure, and symptoms. Furthermore, the email contains the patients' current medication list, heart failure-related laboratory results, and contact information.

Medly Services

Enrollment into the program was based on clinical judgment. After discussing the program with patients, a clinician, ie, a cardiologist, a nurse practitioner (NP), or a resident, fills out a form to indicate the desired target ranges needed to customize the algorithm. Then, a telehealth analyst (THA) provides patients with the *Medly* technology and training on how to use it. When alerts are triggered, they are viewable by patients' treating cardiologist and NPs. The clinicians might act independently or communicate among themselves by email or in person to determine the best course of action. If required, a clinician will follow up with patients either by phone or email, documenting all actions and decisions in the hospital electronic medical record (EMR). Furthermore, patients and clinicians are instructed to contact the THA to receive the technical support, if required.

Implementation Site

The HF clinic, part of UHN, is a high-volume specialty care clinic for patients with heart failure in Toronto. The intervention was developed by UHN's Centre for Global eHealth Innovation (eHI) in close collaboration with clinicians from the HF clinic. The THA is employed by the UHN Telehealth Department with 25% of their time dedicated to supporting the *Medly* program. The HF clinic, UHN telehealth services, and eHI are physically located in the same building.

Implementation Strategy

Preparations for the program launch included the development of training materials for patients (user manual and training checklist). In addition, clinician users were provided with a user guide and a training session lasting approximately 1 hour. Moreover, members of the eHI team followed a service design methodology, consisting of mapping clinic workflows and producing a service blueprint for the *Medly* program, which sought to minimize the disruption to existing HF clinic processes.

Implementation Outcomes

We selected 4 implementation outcomes from Proctor et al's Implementation Outcomes Framework as measures of the implementation success [21]. In addition, data on the outcomes, defined below, were collected after 4 and 12 months of the launch through a document review process and semistructured interviews.

- *Adoption*: The number of clinicians deciding to monitor patients using the *Medly* system.
- *Penetration*: The level of integration of the *Medly* program within the existing services of the HF clinic.
- *Feasibility*: The extent to which the *Medly* program can be successfully used by patients.
- *Fidelity*: The extent to which the *Medly* program is being used as initially intended.

Barriers and Facilitators to Implementation

Semistructured interviews were developed based on the constructs of the CFIR, which provides a pragmatic organization of theory-informed constructs known to impact the implementation success across the following 5 domains: (1) intervention characteristics; (2) outer setting (eg, patient needs and resources, external policy and incentives, etc); (3) inner setting (networks and communication, implementation climate, readiness for implementation, etc); (4) characteristics of individuals; and (5) process [18]. Further interview probes were developed to explain the quantitative implementation outcome indicators. Moreover, interviews were conducted prior to the program launch, and again after 4 and 12 months, each session lasting 30-60 minutes. Of note, all adopting clinicians and eHI *Medly* program staff were invited for participation. In addition, clinicians who had not adopted the system by 12 months were also invited to participate. All interviews were recorded and transcribed for later qualitative analysis.

Data Analysis

The interview transcripts were analyzed by two independent investigators (PW and KG) using the Framework Method [22]; this involved a largely deductive thematic analysis using a codebook based on the CFIR constructs [19]. PW and KG independently coded the transcripts and then met to discuss contradictory codes and passages. The management of source documents and coding was done with the help of NVivo version 11 (QSR International, Doncaster, Victoria, Australia). To determine the degree to which the barriers and facilitators impacted the implementation, valence ratings were attributed by PW and KG to each construct according to the criteria outlined by Damschroder et al [23]. Qualitative findings and valence ratings were validated during a meeting with key members of the clinician and eHI program staff (n=6).

Results

Study Participants

In this study, 8 clinicians participated. One cardiologist, who was the only clinician who had not adopted the technology before the end of the study period, did not respond to requests to be interviewed prior to completion of the manuscript. [Table 1](#) shows the interview schedule and the role of each participant.

Implementation Outcomes

[Table 2](#) presents the results of implementation outcomes, which are discussed below.

Adoption and Penetration

The program was launched with 3 clinician users (1 cardiologist and 2 NPs). By the 12-month time point, 5 additional cardiologists were monitoring patients using *Medly*, representing an increase in the penetration of the *Medly* program in the HF clinic from 38% to 89%, a diffusion pattern that is explained in the interviews.

Table 1. Study participants and timing of interviews. An "X" indicates an interview was conducted at the specified time point.

Study identifier	Role in the program	Role descriptor	Baseline	4 months	12 months
Clinician 1	Cardiologist and clinical lead of the Ted Rogers Centre of Excellence for Heart Function	Early adopter		X	X
Clinician 2	Nurse practitioner	Early adopter	X	X	X
Clinician 3	Nurse practitioner	Early adopter	X	X	X
Clinician 4	Cardiologist	Late adopter (9 months)			X
Clinician 5	Cardiologist	Late adopter (11 months)			X
Clinician 6	Cardiologist	Late adopter (11 months)			X
Clinician 7	Cardiologist	Late adopter (11 months)			X
Clinician 8	Cardiologist	Late adopter (11 months)			X
eHealth 1	Project manager	Left on maternity leave after 4 months	X		
eHealth 2	Project manager	Replaced original project manager		X	X
eHealth 3	Program operations lead	New position was created after 3 months		X	X
eHealth 4	Telehealth analyst			X	X

Table 2. Implementation outcomes indicators.

Implementation outcome ^a and indicator	4 months	12 months
Adoption		
Number of clinicians having decided to use <i>Medly</i> to monitor patients	3	8
Penetration		
Percentage of clinicians using <i>Medly</i> over the total number of potential clinician users in the Ted Rogers Centre of Excellence for Heart Function	38	89
Feasibility		
Cumulative number of patients enrolled in the <i>Medly</i> program	42	98
Cumulative number of patients removed from the <i>Medly</i> program for clinical reasons (eg, received a heart transplant)	0	8
Cumulative number of patients having chosen to leave the <i>Medly</i> program	0	5
Number of deaths (all unrelated to the program)	1	5
Fidelity		
Cumulative number of calls or emails made to the telehealth analyst for technical assistance	56	195
Cumulative number of requests for changes to the <i>Medly</i> technology	15	72

^aImplementation outcomes are defined in the framework by Proctor et al [21].

All participants described how the *Medly* program was initially only open to the 3 clinicians who were most actively involved in its development. By the 11th month of the program, the clinical lead of the HF clinic decided to open its availability as a resource to other cardiologists. Many of the later adopting clinicians had always expected to be involved and were simply waiting to be invited.

I had no involvement a year ago, I was aware of it, and very supportive of it... [The request] probably came through [Clinician 1] finally saying "we're at a mature point, Medly is really working, we have good capacity, let's let the others in...I was just waiting to see when it would happen. [Clinician 7]

Although all cardiologists who adopted *Medly* after the initial launch had a similar perspective, some were concerned about

the time it would add to their workday. They ultimately decided to participate because they felt a responsibility to share in the workload being taken on by their colleagues. Another important factor swaying their decision was a concern that they could be excluded from their patients' circle of care.

I'd like to be more involved but I also like to know that I have the time... I think [the reason I decided to participate is] just a sense of fairness. I think it's just not fair for one person to take over the ownership of it. Again, that speaks to the sustainability. It's not sustainable for one physician or one nurse or one healthcare professional to be remote monitoring all the data and all the patients all the time... In this case, it's a cardiologist that I know and trust very well... But again, you don't want to be left outside the circle of

care for a patient that is your patient and your responsibility. [Clinician 5]

Feasibility

By 12 months, 98 patients were enrolled in the *Medly* program; this was a lower number than initially anticipated and is partially explained by a low initial penetration within the clinic. In addition, throughout the implementation, clinicians began to realize that patients benefited differently depending on their disease severity, ability to use the technology, ability to adhere to taking measures, and receptivity to self-care messages, which led to clinicians becoming more selective of which patients were enrolled.

I also think and I respect that they're doing their due diligence...about actually finding the right patients. The clinicians need to make sure they're only targeting patients that would benefit and not someone that they'll just take off after a week...So of course, it's a little difficult on their side. They have to do a lot, you have to think a lot more about it. But I feel like they're being more mindful about it. [eHealth 4]

Feasibility is also demonstrated by the relatively low number of patients who chose to stop using the system (n=5). Additionally, 5 patients passed away during the evaluation period. These deaths were determined to be unrelated to the *Medly* program and were explained by clinicians as being reflective of the severe disease state of the patient population.

Fidelity

Overall, the intervention is generally being used as intended with clinicians reviewing all alerts generated by *Medly*, following up with patients when necessary, and documenting all actions in EMR. The *Medly* program was launched with the idea that both the system and the service would continue to improve and evolve over time. Throughout the implementation, the THA received 159 calls from patients and 36 calls from clinicians related to problems with the system (eg, receiving adherence calls when they had taken their readings, usability issues, and general connectivity problems between the phone and the peripheral Bluetooth equipment), all representing examples of when the system was not working as intended. However, these, as well as the 72 documented feature requests by patients and clinicians, are evidence of a properly functioning quality improvement mechanism.

Barriers and Facilitators of Implementation

Table 3 describes the barriers and facilitators of the implementation along with a valence rating signifying the degree to which it had an impact on the implementation of the *Medly* program. Unless otherwise discussed, valences were relatively consistent throughout the entire 12-month implementation period.

Intervention Characteristics Domain

Evidence Strength and Quality

Clinician participants acknowledged ambiguity in the literature of the impact of telemonitoring for heart failure. However, this

did not impact the implementation for reasons identified in the construct *knowledge and beliefs about the intervention*.

Relative Advantage

The *Medly* program was perceived as having a relative advantage over alternative telemonitoring options. Unlike many telemonitoring systems, *Medly* measures multiple clinical parameters and offers algorithm-based self-care instructions with structured telephone support when necessary.

It's another version of what other people have tried. It has more elements than just daily weight because I think we know that daily weights are inadequate for measuring the state of somebody's heart failure. It can [also] be used with other things, structured telephone follow up as needed. I think the interactions with the nursing staff are an important value add related to Medly. [Clinician 5]

Adaptability

Many statements revealed the adaptability of both the technology and service components of the *Medly* program, giving this a strong positive valence. Examples include flexibility in how clinicians perform program-related tasks (eg, documentation), workflow adaptations to make more efficient use of the THA's time, and changes to the *Medly* algorithm.

Pulling us out [of the clinic] was a good change. That's more to the workflow...When it comes to the actual product, there have been changes, well a lot of feature requests to change the algorithm or to change some copy of the alert and things like that... There are multiple examples of how algorithm changes have already been made and that has helped. [eHealth 4]

Complexity

Several statements revealed the complex nature of the *Medly* program, giving this construct a negative valence in the early stages of the implementation. Examples of complexity include (1) need for extensive documentation, (2) relying on engagement from patients, (3) challenges in identifying program candidates, (4) communicating patient information between *Medly* clinicians, and (5) setting algorithm parameters.

The biggest time for me is having to create all these communication notes in [the EMR] to document my conversations with people. [Clinician 3]

The patient also has an almost 50/50 responsibility. They don't have to be there when I call, but if I leave a message and if I leave a call back number...I expect that someone is going to call me back. [Clinician 3]

There is no literature out there to clearly say who's the right person...I mean people that I've learned are more challenging are people with cognitive impairment and people who, for a variety of reasons, aren't engaged enough to respond when we contact them. [Clinician 3]

Table 3. Valence ratings assigned to Consolidated Framework for Implementation Research constructs.

Domains and constructs ^a	Operational definition ^a	Rating assigned to construct ^b
I. Intervention characteristics		
Evidence strength and quality	Perception of the quality and validity of the evidence supporting the use of telemonitoring for heart failure.	0
Relative advantage	Perception of the advantage of implementing the <i>Medly</i> program versus an alternative solution.	+2
Adaptability	The degree to which the <i>Medly</i> program can be adapted to meet the needs of the HF clinic ^c .	+2
Complexity (reverse rated)	Perceived complexity of the <i>Medly</i> program as reflected by the degree of disruptiveness to existing workflows and number of steps involved in using the intervention as intended.	-1
Design quality and packaging	Perceived quality of the <i>Medly</i> program (technology and service components) and how well these components are bundled and work together.	0
Cost	Financial and opportunity costs of implementing the <i>Medly</i> program.	-1
II. Outer setting		
Patient needs and resources	The degree to which heart failure patients' needs are known and prioritized by the HF clinic (ie, patient-centeredness).	+2
External policy and incentives	Policies and incentives that support or hinder the implementation of telemonitoring programs.	0
III. Inner setting		
Networks and communications	The quality of the communication networks that support the implementation and daily operations of the <i>Medly</i> program.	-1
Culture	Norms and values of the HF clinic and UHN ^d .	+2
Implementation climate		
Tension for change	The degree to which stakeholders perceive a need for change in the clinical management of patients in the HF clinic.	+2
Compatibility	The degree of fit between the <i>Medly</i> program and the HF clinic's values, norms, needs, and existing workflows and systems.	+1
Relative priority	Stakeholders' perception of the importance of implementing the <i>Medly</i> program.	+2
Learning climate	The degree to which the HF clinic and UHN have a climate that provides time and space for reflective thinking and that allows team members to feel essential, valued, and safe to try new methods.	+2
Readiness for implementation		
Leadership engagement	Commitment, involvement, and accountability of the HF clinic lead.	+2
Available resources	The level of resources dedicated for the implementation and ongoing operations of the <i>Medly</i> program.	+2
Access to knowledge and information	Ease of access to digestible information and knowledge about the <i>Medly</i> program and how to incorporate it within existing HF clinic workflows.	0
IV. Characteristics of individuals		
Knowledge and beliefs about the intervention	Clinicians' attitudes toward and value placed on the <i>Medly</i> program.	+2
Self-efficacy	Clinicians' and telehealth analyst's belief in their own capabilities to execute their role within the <i>Medly</i> program and achieve implementation goals.	+2
V. Process		
Planning	The degree to which a plan for implementing the <i>Medly</i> program was developed in advance and the quality of that plan.	-1
Engaging		
Opinion leaders	Individuals in the HF clinic who have a formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the <i>Medly</i> program.	+1

Domains and constructs ^a	Operational definition ^a	Rating assigned to construct ^b
Champions	Individuals who dedicate themselves to supporting and overcoming barriers to the implementation of the <i>Medly</i> program.	+2
Executing	Carrying out or accomplishing the tasks needed to support the implementation of the <i>Medly</i> program.	0
Reflecting and evaluating	Feedback about the progress and quality of the implementation along with regular debriefing about progress and experience.	+2

^aThe constructs and operational definitions are adapted from the Consolidated Framework for Implementation Research [19].

^bDefinitions of valence ratings are adapted from Damschroder et al's study [23]: -2, the construct had a strong negative influence on the implementation effort; -1, the construct had a minor negative influence on the implementation effort; 0, the construct had a neutral influence on the implementation effort. Alternatively, different aspects of the construct had a positive influence, while others had negative influence: +1, the construct had a minor positive influence on the implementation effort; +2, the construct is a strong positive influence on the implementation effort.

^cHF clinic: Ted Rogers Centre of Excellence for Heart Function.

^dUHN: University Health Network.

If [another clinician], for example, has had to deal with several alert-related issues for a particular patient, how is that information then communicated over to me...if there's some issue I have to follow up on? [Clinician 2]

[Another challenge] is this idea of trying to guess what your range of variation is going to be for each patient [when setting parameter thresholds for the algorithm]. I think there are probably more accurate mathematical models to try to come up with that rather than me sort of flipping a coin and deciding, "Okay, it's going to be 3 pounds + or -, or 2.5 pounds." [Clinician 6]

As these challenges were identified and solutions to mitigate their impact implemented, the complexity of the program was no longer viewed as negatively impacting the program's continued growth.

Design Quality and Packaging

General satisfaction with the *Medly* program and its design were a pervasive theme throughout the interviews. However, some design-related factors were perceived as barriers to continued growth of the program and sustainability even if they did not significantly impact clinician adoption. For example, clinicians expressed a desire for a more seamless integration with existing technologies and workflows by (1) integrating the dashboard with the hospital EMR to facilitate documentation, (2) making the dashboard available on mobile devices, (3) providing more patient details in the dashboard, and (4) allowing for multiple patient-clinician communication modalities (eg, short message service text messaging).

I really wish it worked on my iPhone or my iPad, particularly in the odd time where [Clinician 1] has been away and I've had to do it on the weekend, you know, or [when] I needed to check something when I was trapped in New York and I couldn't work remotely because I can't get it on my phone. [Clinician 3]

I find dashboard right now is very intuitive. I think the part that I find really challenging is that I have to usually have [the EMR] open with Dashboard and

so it would be nice to have some patient information in the Dashboard so that you're not having to go back all the time between those two platforms. The other thing I would say, they're minor things but you know, contact information for patients. Not simply just one phone number but also an email at the top or the ability to text a patient or do something like that that's good for you to kind of manage clinical alerts. [Clinician 2]

Cost

Most of the costs associated with implementing the *Medly* program were related to the equipment, which were perceived as high and unsustainable. However, plans are being made to reduce costs by having patients use their own devices. The other major cost involved the THA's time, which was higher than initially anticipated.

Currently the system is CAD \$2200 a pop for the phone, the data plan, the weight scale and the cuff so obviously, we don't yet have a mechanism to pay for that and thankfully through [philanthropy] we'll be able to cover the costs of the program. [Clinician 1]

I think with time, we can drive the cost of [equipment] down. As we move to "bring your own device," the phone costs [will] matter less... Where I think we've gone over budget [is that] we had anticipated that [telehealth] support would cost 25% of a person's time and I think it's coming closer to 50-75% of their time...and that overflows into the rest of the teams. [eHealth 2]

This construct received a ranking of -1 because although the equipment cost was not a large initial barrier due to philanthropic funding, it was a barrier to program sustainability that would need to be addressed. Furthermore, although the additional THA time requirements did not significantly impact the *Medly* implementation, it did have important opportunity costs related to that individual's ability to work on other projects. A formal economic evaluation of the impact of the *Medly* program from the perspectives of patients, HF clinic, and public payer will be published subsequently.

Outer Setting Domain

Patient Needs and Resources

This construct represents the idea that the implementation site comprehends and seeks to address patients' needs. Numerous examples of the HF clinic's patient-centered approach to care made this a strong facilitator.

It's a very supportive environment for patients and families, and that is something that I repeatedly hear in clinic, especially patients who have been in the clinic for a long period of time, how thankful and how grateful they are for the care that they receive. You hear this a lot, people just...they don't want to go somewhere else. [Clinician 2]

External Policy and Incentives

This construct had a neutral impact because although the program was perceived as compatible with government policies seeking to encourage more comprehensive chronic disease care outside of the hospital, factors like regulation, funding, and clinician reimbursement were flagged as crucial barriers to the program's sustainability.

Any tool that we can develop that will actually improve patient-centred care...and potentially impact communication between different members of the team, which is the ultimate goal of Medly...are all in line with where the ministry of health is taking us. [Clinician 1]

Inner Setting Domain

Networks and Communication

Three networks of communication were identified as having an influence on the implementation success. First, communication within the HF clinic was described as generally good and had a positive influence. Second, communication between clinicians and the THA involved in the day-to-day operations of the *Medly* program was also perceived as positive for the implementation. Finally, communication among high-level stakeholders was described as an early barrier to the implementation, particularly as it is related to decision making about the program and having clear channels to operationalize those decisions. This barrier was identified and notable improvements were made by the 4-month time point.

In the past, I think it was every possible channel...There were emails [that] didn't always go to the same people...Everyone knows what happens in the meetings, but it's what happened outside of those meetings where I think things were a lot more confusing. In addition to that, there was a lot of back-channel communication happening, and by that I don't mean between us, but I think between the stakeholders themselves...and then the rest of us eventually figure it out. So it was all over the place. And right now, I think it's consolidated a lot better. [eHealth 2]

Culture

The HF clinic's culture of teamwork was perceived as having facilitated both the implementation and the daily operations of the *Medly* program.

This hospital is like working in a 5-star hospital...we are a multidisciplinary team, so there are many people taking care of our patients, it's not just us. It's fantastic, it's excellent. We are very patient-centred. In general, the environment or the mood in the clinic is positive and constructive. [Clinician 8]

Implementation Climate

Tension for Change

Clinician participants were proud of the quality of care they offered to patients. However, a perceived gap existed between the current and ideal state. Coupled with a busy clinic with limited staff and space resources, this created a tension for change.

[Clinic capacity] is an ongoing concern for me and I think we're at a bit of a crux where we couldn't handle somebody not coming to work and we can't handle any more volume. [Clinician 1]

Compatibility

The *Medly* program was perceived as compatible with the values of the organization and complimentary to existing services offered in the HF clinic.

Offering patients something different and unique that is more based on technology that they can use at home, I think totally fits with UHN's goals and vision with advancing patient care...I don't see anything else that we're doing that overlaps with what Medly's doing. I mean, one of the things that we want to try and do a lot more of is education in the clinic environment for patients and I think, if anything, Medly just completely supports those messages that we give to patients about why salt restrictions are important and those kinds of things. So I don't see it as a duplication, I think it just kind of nicely fits together in terms of more comprehensive care for patients. [Clinician 2]

Early apprehension about increased clinician workloads speaks of the incompatibility of the telemonitoring program with existing clinic workflows. However, by the end of the first year, evidence exists that a new normal has been created such that this initial incompatibility did not significantly impact the overall implementation success.

I organize my time differently now...I've changed the way I do things because I can't be in clinic doing clinic and trying to run back and forth because that's challenging. So, I try to carve out like at least the first half an hour or hour of my day to deal with Medly and then I go [to clinic]. [Clinician 3]

Relative Priority

The implementation of the *Medly* program was perceived as having a high priority by all participants.

My understanding is that Medly is a fairly high priority...A lot of the other [initiatives] are still important and they're going on simultaneously, but I would say [Medly]'s up there. [Clinician 3]

Learning Climate

Participants describe a work environment that values ongoing quality improvement. They feel the climate offers a safe space for learning and trying new things, making this construct a strong positive influence on implementation success.

I work with a great staff, very closely with a few heart failure physicians who have been fantastic in advancing my knowledge and teaching me along the last one year. [Clinician 2]

Readiness for Implementation

Available resources

Important to the success of this implementation was the availability of financial and human resources. No new clinicians were employed; rather, existing NPs were expected to perform Medly-related tasks within their salaried hours. Although this was possible, the added NP workload should not be underestimated.

[I am] not complaining about [responding to alerts] because that is part of why I'm hired. It's just that there needs to be, in order for Medly to work, you have to have a clinician who is devoting time to do all of that, to answer alerts, to document, and to see patients that are unwell in clinic. [Clinician 3]

The THA was an additional resource that was hired to support this program. Flexibility with respect to this resource, both in terms of quantity of time and time during the day, was an important facilitator that might not be realistic in other sites.

It makes it a lot easier when they call me down to the clinic or they have a patient come to the clinic and I am available and I can just run down and be there in five minutes. My worry would be if it was a different site and they need that kind of instant support. It may be difficult getting someone there. [eHealth 4]

Funding for the equipment came from philanthropic donations, thereby mitigating the potential barrier of nonavailability of funds common in many real-world implementations.

The cost, although improved, is still an issue, because right now Medly is being funded [by philanthropy] and obviously, we're not here to fund it for the province. [Clinician 1]

Finally, insufficient physical space is a challenge for the HF clinic and was likely an indirect barrier as clinic rooms are required for patient onboarding.

What hasn't been solved is the fact that there aren't enough resources in terms of rooms, in terms of workflow around patients getting seen and into the rooms, we're limited by the physical space. [Clinician 7]

Access to Knowledge and Information

The availability of the THA to provide on-call and personalized information about how to use the intervention was an important facilitator. However, although clinicians perceive the training they received to be sufficient, some felt that more comprehensive training around understanding the algorithm was required. In addition, the novelty of this program meant that no clear medical-legal guidelines existed on exactly what information needed to be documented. Therefore, this is a challenge that clinician users needed to navigate on their own.

That was a little bit confusing maybe [for us], what should be documented in terms of alerts and what should not. So that's kind of just been teased out as we've been going through it for the last four months. [Clinician 2]

Characteristics of Individuals Domain

Knowledge and Beliefs About the Intervention

Clinician knowledge and positive beliefs about the Medly program likely helped overcome the potentially negative influence of the equivocal scientific evidence.

I don't know if I'm just being an optimist. I actually think [the Medly program] is going to show reduced hospital length of stay and admissions. And so I think that if the system has proven to do this, I think it's going to be useful across the board because heart failure is everywhere. [Clinician 4]

Self-Efficacy

Despite initial apprehensions about increased workload, the clinician and eHI teams were confident that they would be successful in implementing the program.

I don't think that there's any doubt that we will be implementing it I think as intended. While I may be apprehensive, it doesn't mean that I don't think that we still actually need to try and actually see. [Clinician 3]

Process Domain

Planning

Despite user training being planned and the initial service design work leading up to the program launch, an overarching implementation plan was never explicitly developed at the outset; this was perceived as having a negative impact during the initial months of the implementation. However, after realizing this deficiency, ongoing plans were formalized by the team; this was perceived as having a positive influence on the current and future program.

Since the four-month, we regrouped as an op[eration]s team...I think we have a much better strategy for what we're trying to do and we actually now have people dedicated to that...I think there's a much more coherent strategy and a much more coherent plan. [eHealth 2]

Engaging Champions and Opinion Leaders

The presence of a clinician champion or opinion leader was an important facilitator for both the development and implementation of the *Medly* program. Importantly, the fact that this champion and opinion leader set a positive example appears to have had more of an impact on the implementation success than this individual's role as a formal leader.

I think certainly that from the clinic side, that [Clinician 1] is the champion of this. She's pushed very hard for its development and rollout and by far I think she's certainly enrolled the largest number of patients onto the system. [Clinician 3]

Executing

Although no formalized implementation plan existed, overall, there is a perception that the eHI team has been effective in doing what was necessary to support the implementation. However, the team's inability to deliver rapid technology adaptations was perceived as a barrier by all participants.

I think there have been some deviations, but overall, I think the team is doing a relatively good job with meeting the expectations. I think some of the deviations are reasons outside of our control or some of them are just because of delays in development. I know a lot of the things we want to do with the program around streamlining it involve adapting the technology and we haven't been able to fully do that. But on the process side, we've been responding pretty well. [eHealth 2]

Reflecting and Evaluating

Embedded within the *Medly* program was a mechanism to facilitate the ongoing quality improvement. All participants spoke positively of the benefits of being able to quickly identify and evaluate problems and implement solutions when possible.

[We meet] every two weeks to discuss the recruitment in the program, how things are going, any issues or problems that people have faced. And then we discuss those issues, identify solutions and come up with a plan for how we want to address them. We also talk about achievements that have happened, so recruitment milestones, things like that. [eHealth 2]

Discussion

Principal Findings

This longitudinal implementation evaluation found that the *Medly* program had been successfully implemented, as demonstrated by the steady growth in patient enrollment and clinician adoption and the fidelity with which the intervention was being used in clinical practice. Costs were relatively high because of the decision to initially supply patients with all the telemonitoring equipment. That said, these costs were not estimated to have significantly impacted the implementation and are expected to dramatically decrease, as the program shifts to a bring your own device (BYOD) model. This study also identified 24 CFIR constructs that explain these measures of implementation success. Fifteen constructs were facilitators

predominately clustered in the domains of *inner setting* and *characteristics of individuals*. Four CFIR constructs were minor barriers in the earlier phases of implementation—*complexity*, *cost*, *networks and communication*, and *planning*. Five additional constructs had a mixed valence and therefore were determined to have a neutral impact on the implementation.

Comparison with Prior Work

The implementation barriers and facilitators identified in this study are very much in line with results from other telemonitoring implementation studies. Systematic reviews have concluded the importance of characteristics of the technology, people involved, extraorganizational environment, and implementation setting [11-13]. In addition, the literature suggests that having undefined roles in the context of new workflows is a common barrier to eHealth implementations [16]. This study provides concrete examples of these barriers as they relate to the CFIR constructs of *complexity* and *compatibility*. For example, in the absence of clear guidelines for documentation, identifying ideal patient candidates and setting parameter thresholds needed for the algorithm, clinicians are forced to develop experiential knowledge to be able to perform these tasks. The development of this tacit knowledge can often only happen over time and might be challenging in a fast-paced clinic environment. The learning climate in this study was perceived as being an important facilitator, which likely helped overcome this challenge. However, clear guidelines for clinician staff roles will likely be required to ensure implementation success where learning climates might not be as favorable.

In addition to providing a framework that allows for the easier transferability of study results, using CFIR-guided methods allowed this research to make two additional contributions to the field of implementation science. To the best of our knowledge, this is the first study to demonstrate the feasibility of using the CFIR for evaluating complex telehealth interventions [24]. However, the CFIR lacks granularity for identifying factors that might be unique to health information systems. Researchers wanting an in-depth understanding of the impact of the technology (as opposed to the full intervention) should consider informing their methods using an additional framework that will help open the black box of *design quality and packaging*. For example, the Clinical Adoption Framework could be useful for designing probes around the quality of the system, quality of the information within the system, and quality of the services supporting the system [25]. Another limitation of the CFIR is that we consider most software updates to be an inherent quality of software-based health interventions. As such, we do not think that a technology's capacity to iterate is adequately captured in the CFIR construct of *adaptability*, which relates more to the components of an intervention that can be adapted or tailored.

Unlike studies that present a list of barriers and facilitators, the CFIR guides the classification of these factors into broader domains. For example, the strongest influencing factors on the *Medly* program were in the CFIR domains of *inner setting*, *characteristics of individuals*, and *process*. This is not to say that the characteristics of the intervention were not important,

but it makes the point that the implementation context cannot be ignored.

Limitations

This study was conducted at a single implementation site. Therefore, we acknowledge that the characteristics of the HF clinic might differ compared with other settings in terms of the availability of resources, structure of care delivery, and characteristics of the individuals involved. In addition, we acknowledge the absence of the patients' perspective in this study. That said, a mixed method study of factors that influence patient adoption, use, and adherence to the *Medly* program will feature in a future publication. Finally, one cardiologist did not agree to participate in an interview; therefore, barriers to adoption for this individual are unknown.

Recommendations

We offer the following recommendations based on key study findings to facilitate the transferability of results to other implementation settings:

1. Evaluate contextual barriers: This study highlights the importance of contextual factors. Early identification of potential barriers as part of a readiness assessment would allow for the development of mitigating strategies. Using a framework such as the CFIR could facilitate this task; our results provide an example of how the CFIR constructs can be operationalized for telehealth interventions.
2. Define all components of the intervention: Complexity is an important barrier for the successful implementation of eHealth interventions [16]. However, this negative influence can be mitigated by an explicit definition of each intervention component. In this study, contextual facilitators helped overcome the lack of protocolized clinician roles; however, better definition of nontechnology program

components and roles could facilitate clinician adoption in future implementations.

3. Plan and document the implementation strategy: The lack of clearly defined implementation plan was identified as an early barrier in this study, which was moderated by contextual facilitators and other *process* factors, including the presence of a strong clinical champion and a robust mechanism for ongoing reflecting and evaluation. The Quality Implementation Framework [26] offers a prescriptive approach that can help formulate an implementation strategy that incorporates an assessment of many of the constructs outlined in the CFIR [19].

Conclusions

This study presents results from the real-world implementation evaluation of a mobile phone-based telemonitoring program for patients with heart failure. The overall success of the implementation, as determined by the four implementation outcomes, was explained by the presence of several facilitators and relatively few barriers. Although the results are consistent with other telemonitoring implementation studies, this study also demonstrates how barriers and facilitators are dynamic and can influence the implementation success differently over time. Finally, we highlight a previously undescribed challenge—telemonitoring interventions often rely on clinicians' ability to build experiential knowledge to use the system as intended. The results from this research can inform the development of telemonitoring programs and their implementation strategies. Hence, evidence-based implementation is important to ensure the success of real-world telemonitoring deployments as well as for ensuring that telemonitoring studies can yield unambiguous evidence of effectiveness, which will be required for the wider diffusion of telemonitoring.

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Authors' Contributions

PW led the overall design, data collection, data analysis, and write-up of this study. HJR, AL, JAC, and ES contributed to the design. KG contributed to the analysis and interpretation of the qualitative data. All authors reviewed and edited the manuscript. All authors read and approved the final version of the manuscript.

Conflicts of Interest

HJR, JAC, and ES hold intellectual property in the *Medly* system and may profit from future commercialization of the technology.

References

1. Kitsiou S, Paré G, Jaana M. Effects of home telemonitoring interventions on patients with chronic heart failure: an overview of systematic reviews. *J Med Internet Res* 2015;17(3):e63 [FREE Full text] [doi: [10.2196/jmir.4174](https://doi.org/10.2196/jmir.4174)] [Medline: [25768664](https://pubmed.ncbi.nlm.nih.gov/25768664/)]
2. Fairbrother P, Ure J, Hanley J, McCloughan L, Denvir M, Sheikh A, et al. Telemonitoring for chronic heart failure: the views of patients and healthcare professionals - a qualitative study. *J Clin Nurs* 2014 Jan;23(1-2):132-144. [doi: [10.1111/jocn.12137](https://doi.org/10.1111/jocn.12137)] [Medline: [23451899](https://pubmed.ncbi.nlm.nih.gov/23451899/)]
3. Prescher S, Deckwart O, Winkler S, Koehler K, Honold M, Koehler F. Telemedical care: feasibility and perception of the patients and physicians: a survey-based acceptance analysis of the Telemedical Interventional Monitoring in Heart Failure (TIM-HF) trial. *Eur J Prev Cardiol* 2013 Jun;20(2 Suppl):18-24. [doi: [10.1177/2047487313487483e](https://doi.org/10.1177/2047487313487483e)] [Medline: [23702987](https://pubmed.ncbi.nlm.nih.gov/23702987/)]

4. Seto E, Leonard KJ, Cafazzo JA, Barnsley J, Masino C, Ross HJ. Perceptions and experiences of heart failure patients and clinicians on the use of mobile phone-based telemonitoring. *J Med Internet Res* 2012;14(1):e25 [FREE Full text] [doi: [10.2196/jmir.1912](https://doi.org/10.2196/jmir.1912)] [Medline: [22328237](https://pubmed.ncbi.nlm.nih.gov/22328237/)]
5. Canada Health Infoway. Connecting Patients with Providers: A Pan-Canadian Study on Remote Patient Monitoring. 2014. Connecting Patients with Providers: A Pan-Canadian Study on Remote Patient Monitoring URL: <https://www.infoway-inforoute.ca/en/component/edocman/1918-rpm-benefits-evaluation-study-full-report-final/view-document?Itemid=0> [accessed 2018-07-20] [WebCite Cache ID 713CsT5GW]
6. Inglis SC, Clark RA, Dierckx R, Prieto-Merino D, Cleland JGF. Structured telephone support or non-invasive telemonitoring for patients with heart failure. *Cochrane Database Syst Rev* 2015(10):CD007228. [doi: [10.1002/14651858.CD007228.pub3](https://doi.org/10.1002/14651858.CD007228.pub3)] [Medline: [26517969](https://pubmed.ncbi.nlm.nih.gov/26517969/)]
7. Kotb A, Cameron C, Hsieh S, Wells G. Comparative Effectiveness of Different Forms of Telemedicine for Individuals with Heart Failure (HF): A Systematic Review and Network Meta-Analysis. *PLoS ONE* 2015 Feb 25;10(2):e0118681. [doi: [10.1371/journal.pone.0118681](https://doi.org/10.1371/journal.pone.0118681)]
8. Lin M, Yuan W, Huang T, Zhang H, Mai J, Wang J. Clinical effectiveness of telemedicine for chronic heart failure: a systematic review and meta-analysis. *J Investig Med* 2017 Mar 22;65(5):899-911. [doi: [10.1136/jim-2016-000199](https://doi.org/10.1136/jim-2016-000199)] [Medline: [28330835](https://pubmed.ncbi.nlm.nih.gov/28330835/)]
9. Yun JE, Park J, Park H, Lee H, Park D. Comparative Effectiveness of Telemonitoring Versus Usual Care for Heart Failure: A Systematic Review and Meta-analysis. *J Card Fail* 2018 Jan;24(1):19-28. [doi: [10.1016/j.cardfail.2017.09.006](https://doi.org/10.1016/j.cardfail.2017.09.006)] [Medline: [28939459](https://pubmed.ncbi.nlm.nih.gov/28939459/)]
10. Greenhalgh T, A'Court C, Shaw S. Understanding heart failure; explaining telehealth - a hermeneutic systematic review. *BMC Cardiovasc Disord* 2017 Jun 14;17(1):156 [FREE Full text] [doi: [10.1186/s12872-017-0594-2](https://doi.org/10.1186/s12872-017-0594-2)] [Medline: [28615004](https://pubmed.ncbi.nlm.nih.gov/28615004/)]
11. Brewster L, Mountain G, Wessels B, Kelly C, Hawley M. Factors affecting front line staff acceptance of telehealth technologies: a mixed-method systematic review. *J Adv Nurs* 2014 Jan;70(1):21-33. [doi: [10.1111/jan.12196](https://doi.org/10.1111/jan.12196)] [Medline: [23786584](https://pubmed.ncbi.nlm.nih.gov/23786584/)]
12. Gagnon M, Ngangue P, Payne-Gagnon J, Desmartis M. m-Health adoption by healthcare professionals: a systematic review. *J Am Med Inform Assoc* 2016 Jan;23(1):212-220. [doi: [10.1093/jamia/ocv052](https://doi.org/10.1093/jamia/ocv052)] [Medline: [26078410](https://pubmed.ncbi.nlm.nih.gov/26078410/)]
13. Radhakrishnan K, Xie B, Berkley A, Kim M. Barriers and Facilitators for Sustainability of Tele-Homecare Programs: A Systematic Review. *Health Serv Res* 2016 Feb;51(1):48-75 [FREE Full text] [doi: [10.1111/1475-6773.12327](https://doi.org/10.1111/1475-6773.12327)] [Medline: [26119048](https://pubmed.ncbi.nlm.nih.gov/26119048/)]
14. Lehoux P, Daudelin G, Williams-Jones B, Denis J, Longo C. How do business model and health technology design influence each other? Insights from a longitudinal case study of three academic spin-offs. *Research Policy* 2014 Jul;43(6):1025-1038 [FREE Full text] [doi: [10.1016/j.respol.2014.02.001](https://doi.org/10.1016/j.respol.2014.02.001)] [Medline: [25904163](https://pubmed.ncbi.nlm.nih.gov/25904163/)]
15. Meystre S. The current state of telemonitoring: a comment on the literature. *Telemed J E Health* 2005 Feb;11(1):63-69. [doi: [10.1089/tmj.2005.11.63](https://doi.org/10.1089/tmj.2005.11.63)] [Medline: [15785222](https://pubmed.ncbi.nlm.nih.gov/15785222/)]
16. Granja C, Janssen W, Johansen MA. Factors Determining the Success and Failure of eHealth Interventions: Systematic Review of the Literature. *J Med Internet Res* 2018 May 01;20(5):e10235 [FREE Full text] [doi: [10.2196/10235](https://doi.org/10.2196/10235)] [Medline: [29716883](https://pubmed.ncbi.nlm.nih.gov/29716883/)]
17. Hunting G, Shahid N, Sahakyan Y, Fan I, Money Penny CR, Stanimirovic A, et al. A multi-level qualitative analysis of Telehomecare in Ontario: challenges and opportunities. *BMC Health Serv Res* 2015 Dec 09;15:544 [FREE Full text] [doi: [10.1186/s12913-015-1196-2](https://doi.org/10.1186/s12913-015-1196-2)] [Medline: [26645639](https://pubmed.ncbi.nlm.nih.gov/26645639/)]
18. Seto E, Leonard KJ, Cafazzo JA, Barnsley J, Masino C, Ross HJ. Mobile phone-based telemonitoring for heart failure management: a randomized controlled trial. *J Med Internet Res* 2012;14(1):e31 [FREE Full text] [doi: [10.2196/jmir.1909](https://doi.org/10.2196/jmir.1909)] [Medline: [22356799](https://pubmed.ncbi.nlm.nih.gov/22356799/)]
19. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009;4:50 [FREE Full text] [doi: [10.1186/1748-5908-4-50](https://doi.org/10.1186/1748-5908-4-50)] [Medline: [19664226](https://pubmed.ncbi.nlm.nih.gov/19664226/)]
20. Ware P, Ross HJ, Cafazzo JA, Laporte A, Seto E. Implementation and Evaluation of a Smartphone-Based Telemonitoring Program for Patients With Heart Failure: Mixed-Methods Study Protocol. *JMIR Res Protoc* 2018 May 03;7(5):e121 [FREE Full text] [doi: [10.2196/resprot.9911](https://doi.org/10.2196/resprot.9911)] [Medline: [29724704](https://pubmed.ncbi.nlm.nih.gov/29724704/)]
21. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda. *Adm Policy Ment Health* 2010 Oct 19;38(2):65-76. [doi: [10.1007/s10488-010-0319-7](https://doi.org/10.1007/s10488-010-0319-7)]
22. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol* 2013;13:117 [FREE Full text] [doi: [10.1186/1471-2288-13-117](https://doi.org/10.1186/1471-2288-13-117)] [Medline: [24047204](https://pubmed.ncbi.nlm.nih.gov/24047204/)]
23. Damschroder LJ, Lowery JC. Evaluation of a large-scale weight management program using the consolidated framework for implementation research (CFIR). *Implement Sci* 2013;8:51 [FREE Full text] [doi: [10.1186/1748-5908-8-51](https://doi.org/10.1186/1748-5908-8-51)] [Medline: [23663819](https://pubmed.ncbi.nlm.nih.gov/23663819/)]

24. Kirk MA, Kelley C, Yankey N, Birken SA, Abadie B, Damschroder L. A systematic review of the use of the Consolidated Framework for Implementation Research. *Implement Sci* 2016 May 17;11:72 [[FREE Full text](#)] [doi: [10.1186/s13012-016-0437-z](https://doi.org/10.1186/s13012-016-0437-z)] [Medline: [27189233](#)]
25. Lau F, Price M, Keshavjee K. From benefits evaluation to clinical adoption: making sense of health information system success in Canada. *Healthc Q* 2011;14(1):39-45. [Medline: [21301238](#)]
26. Meyers DC, Durlak JA, Wandersman A. The quality implementation framework: a synthesis of critical steps in the implementation process. *Am J Community Psychol* 2012 Dec;50(3-4):462-480. [doi: [10.1007/s10464-012-9522-x](https://doi.org/10.1007/s10464-012-9522-x)] [Medline: [22644083](#)]

Abbreviations

BYOD: bring your own device
CFIR: Consolidated Framework for Implementation Research
eHI: Centre for Global eHealth Innovation
EMR: electronic medical record
HF: heart function
NP: nurse practitioner
TM: telemonitoring
THA: telehealth analyst
UHN: University Health Network

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Original Paper

An Assessment Framework for e-Mental Health Apps in Canada: Results of a Modified Delphi Process

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Abstract

Background: The number of e-mental health apps is increasing rapidly. Studies have shown that the use of some apps is beneficial, whereas others are ineffective or do not meet users' privacy expectations. Individuals and organizations that curate, recommend, host, use, or pay for apps have an interest in categorizing apps according to the consensus criteria of usability and effectiveness. Others have previously published recommendations for assessing health-related apps; however, the extent to which these recommendations can be generalized across different population groups (eg, culture, gender, and language) remains unclear. This study describes an attempt by Canadian stakeholders to develop an e-mental health assessment framework that responds to the unique needs of people living in Canada in an evidence-based manner.

Objective: The objective of our study was to achieve consensus from a broad group of Canadian stakeholders on guiding principles and criteria for a framework to assess e-mental health apps in Canada.

Methods: We developed an initial set of guiding principles and criteria from a rapid review and environmental scan of pre-existing app assessment frameworks. The initial list was refined through a two-round modified Delphi process. Participants (N=25) included app developers and users, health care providers, mental health advocates, people with lived experience of a mental health problem or mental illness, policy makers, and researchers. Consensus on each guideline or criterion was defined a priori as at least 70% agreement. The first round of voting was conducted electronically. Prior to Round 2 voting, in-person presentations from experts and a persona empathy mapping process were used to explore the perspectives of diverse stakeholders.

Results: Of all respondents, 68% (17/25) in Round 1 and 100% (13/13) in Round 2 agreed that a framework for evaluating health apps is needed to help Canadian consumers identify high-quality apps. Consensus was reached on 9 guiding principles: evidence based, gender responsive, culturally appropriate, user centered, risk based, internationally aligned, enabling innovation, transparent and fair, and based on ethical norms. In addition, 15 informative and evaluative criteria were defined to assess the effectiveness, functionality, clinical applicability, interoperability, usability, transparency regarding security and privacy, security or privacy standards, supported platforms, targeted users, developers' transparency, funding transparency, price, user desirability, user inclusion, and meaningful inclusion of a diverse range of communities.

Conclusions: Canadian mental health stakeholders reached the consensus on a framework of 9 guiding principles and 15 criteria important in assessing e-mental health apps. What differentiates the Canadian framework from other scales is explicit attention to user inclusion at all stages of the development, gender responsiveness, and cultural appropriateness. Furthermore, an empathy

mapping process markedly influenced the development of the framework. This framework may be used to inform future mental health policies and programs.

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KEYWORDS

mental health; mobile phone apps; consensus; Delphi process; evaluation framework; telemedicine

Introduction

The number and range of electronic health apps, including those targeting mental health, continues to expand [1,2]. Studies indicate that the use of some apps can be beneficial to mental health and many improve accessibility to mental health services [3]. According to a recent meta-analysis, mobile phone-based mental health apps can have positive effects on depressive symptoms, anxiety, and other mental health conditions [4]. Digital solutions, including mobile phone apps, can also help address some traditional barriers—cost, capacity, geography, and stigma—to mental health services [5]. However, research suggests that some apps are unsafe, ineffective, poorly documented, or do not meet users' privacy and security expectations [6-8].

In Canada, supporting mental health and resilience through appropriate mobile health solutions is an area of growing policy interest, particularly given the rising rates of common mental health conditions [9] and unmet needs for services [10]. For example, *Changing Directions, Changing Lives*, the Mental Health Strategy for Canada, recommends increasing the use of e-mental health to reach more Canadians in need of support [11]. Accordingly, the Mental Health Commission of Canada has explored the use of these solutions in Canada and has also explored the associated opportunities and barriers to their use [5]. Likewise, the *Healthy and Productive Work Signature Initiative* of the Canadian Institutes of Health Research, which aims to support evidence-based interventions that foster healthy, meaningful, and productive work for all workers, recognizes e-mental health as a potential direction for improving the wellness of workers across the mental health continuum [12,13].

Currently, it can be time-consuming and difficult for potential users to assess the quality, safety, and evidence base of available health apps [3,14,15]. The private sector, government, academics, consumer groups, and others are trialing a range of strategies to tap into the benefits of eHealth while also addressing its attendant challenges. Regulatory, accreditation, market influence, educational, informational, and financial interventions are among the approaches that have been explored. For example, the United States Food and Drug Administration has established and updated regulatory guidance for mobile medical apps [16]. The Ontario Telemedicine Network has launched the public-facing Practical Apps website, which presents reviews of various health care apps; primary care providers can use this app to support their patients to better understand and manage their disease [17]. The National Health Service in the United Kingdom established a curated Apps Library, with apps assessed against a defined set of criteria, which was later rolled back following research that showed privacy and security gaps in a large proportion of the included

apps [18]. However, this service has since been relaunched through a beta site [19]. Researchers in Canada and beyond are testing techniques to engage app users in the development process [20,21]. Likewise, Apple Inc. introduced specific requirements for medical apps that are made available through their App Store [22].

Several formal development strategies, rating scales, or assessment frameworks have been published to help raise standards on app quality, and efforts are underway to develop others [1,14,20,23-28]. At their core, most of these efforts depend on a structured assessment of apps against defined criteria. While there is some convergence on the technical criteria considered, there are also important differences between the approaches. The aims, scope, purpose, target audiences, and methods of assessment vary considerably. For instance, some initiatives consider factors such as the characteristics of the app developer or funder; their policies; and features of the app, its performance characteristics, and ongoing maintenance or updating requirements, while others do not. While these efforts have provided information and direction for this study, the authors were not able to find a single scale or framework that addressed the unique combination of cultural and political factors required for the Canadian context.

The well-documented variation in the app quality and safety requires a consistent and transparent assessment framework for apps applied at an organizational level or as a self-assessment for app developers. Results must be meaningful and trustworthy for potential app users with a wide variety of needs and perspectives. In Canada, improving and expanding ready access to—and use of—effective and appropriate e-mental health solutions, including mental health apps, holds promise as a key enabler for addressing mental health. The purpose of this study was to achieve consensus among a broad group of Canadian stakeholders on a comprehensive set of principles to guide the development of a framework for assessing e-mental health apps in Canada as well as future processes to implement such a framework. A secondary objective was to achieve consensus on a complementary set criteria to support and ground these guiding principles by providing informative and evaluative measures that could be applied as part of an assessment process. Methods and results are reported in alignment with the guidance for reporting results from Delphi processes developed by Boulkedid et al [29].

Methods

Study Design

We used a modified Delphi process in a three-stage process with two voting rounds to reach consensus on guiding principles

and criteria for a Canadian e-mental health app assessment framework (Figure 1).

Unlike the open-ended initial phase of a traditional Delphi process [30,31], a modified Delphi process provides a starting point for discussion. Experts are polled for their views on this starting point individually and anonymously through two or more rounds of voting. Results are provided to participants between rounds. The process concludes when predefined stopping points—usually a specified level of consensus—are reached. The mini-Delphi or estimate-talk-estimate approach adapts this technique for face-to-face meetings, allowing experts to interact between iterations of anonymous votes [32]. Figure 1 illustrates this approach as applied to this study. Ethics approval was not required for this study as it falls under an exemption for research conducted by faculty and staff as an outside professional activity (see exemption #8 on the University of Victoria website, the first author’s institution) [33].

Participant Recruitment

We used a heterogeneous purposive recruitment strategy to seek diversity on the following three key variables: (1) the breadth of perspective with relevant expertise recognized by the Institute of Gender and Health at the Canadian Institutes of Health Research or the Mental Health Commission of Canada (app developers, app users, health care providers, mental health advocates, lived experience of mental health problems or illnesses either personally or as a family member, policy makers, researchers, and workplace or workforce expertise); (2) sex and gender; and (3) geographic distribution across Canada.

The project steering committee reviewed the distribution of potential participants against a structured template that showed distribution based on the abovementioned criteria. Relevant expertise was loosely defined as a characteristic of individuals

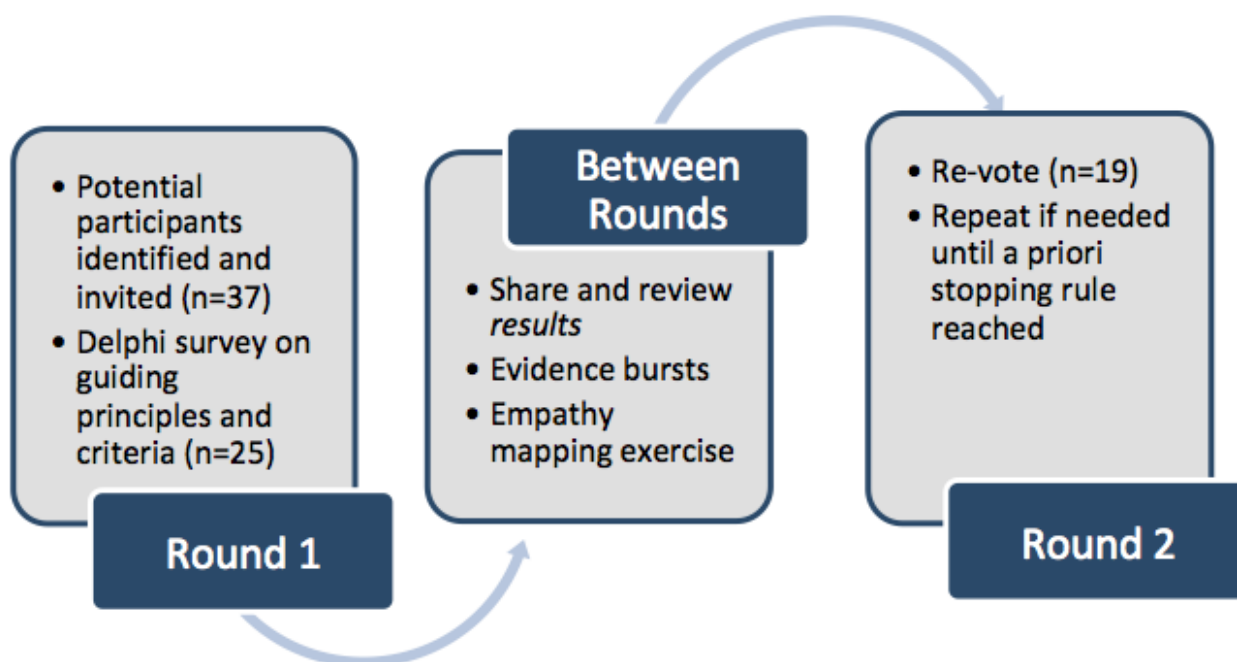
recognized by their peers as having competence and experience in specific areas relevant to this project. For instance, researchers were selected on the basis of having received scientific funding or research productivity in the area of e-mental health; individuals with lived experience were part of a volunteer group that advises the Mental Health Commission of Canada.

Then, we purposefully selected and recruited potential participants via invitations from the Institute of Gender and Health at the Canadian Institutes of Health Research and the Mental Health Commission of Canada to maximize the breadth and depth of experience and expertise available from the participant group [34]. Invitations were distributed via emails, with follow-up by telephone or in-person as required. Those who indicated an interest in taking part then received an email with a link to the website hosting the first round of the Delphi study. This email included the rationale for seeking consensus on an assessment framework for e-mental health apps. Voluntary participation implied consent.

Development of the Initial Set of Draft Principles and Criteria

First, we conducted a rapid review and environmental scan of pre-existing e-mental health app assessment frameworks found in the published and gray literature. Additional resources were identified and supplied by the modified Delphi participants. Alignment with Canadian culture and policies was considered. Gender responsiveness and cultural appropriateness were deemed to be two foundational and nonnegotiable elements, given Canada’s strong commitment to gender equality and cultural inclusiveness, particularly of indigenous people [35-37]. Delphi process organizers and the authors of this study felt it was an ethical imperative to include an app’s evidence base as a third foundational element of the framework in order to avoid the potential for harm from low-quality e-mental health apps.

Figure 1. The modified Delphi process.



Based on the findings, one of the authors (JZ) constructed a draft list of six other potential principles to guide the development and implementation of an e-mental health app assessment framework. Furthermore, 14 potential criteria were also identified, which aligned with the guiding principles and could be used as part of an app assessment process. The initial list was vetted by the steering committee (MN, MS, and KvH) for the project.

Round 1 of the Modified Delphi Process

In Round 1 of the modified Delphi process, which took place between November 15 and 28, 2016, 25 stakeholders agreed to participate. The survey questions used to assess the initial list of principles and criteria were modeled after an app evaluation Delphi process led by researchers at the Imperial College in England [38] and pre-existing formats extracted from the rapid review and environmental scan of eHealth and e-mental health app assessment frameworks.

The survey was prefaced with three contextual questions:

1. Confirmation of the perspectives that the participant brought to the consensus process, as per the list above (participants could self-identify with multiple perspectives).
2. How they would rate currently available health apps in terms of overall quality, usability or user engagement, use of high-quality evidence from credible sources, and information security or privacy. Respondents were asked to endorse the applicability of each of these criteria using a 4-point scale (poor, fair, good, and excellent) plus a “don’t know” option.
3. Whether a framework for evaluating health apps is needed for consumers to identify apps of higher quality using a 5-point Likert scale (strongly disagree, disagree, neither agree nor disagree, agree, and strongly agree).

While gender and geographic diversity were considered in recruitment, we did not ask questions about these dimensions as part of the survey. This decision was taken to preserve the anonymity of responses, an important feature of a Delphi process. Inclusion of demographic variables in the survey would have made it possible to connect votes with the identity of at least some participants, which we sought to avoid. Likewise, we did not undertake a separate participant demographic survey to reduce the respondent burden.

The remaining survey questions assessed the initial list of 6 potential principles to guide the development of an e-mental health app assessment framework and the 14 potential criteria that might be included in such a framework. Criteria were classified as informative or evaluative. Informative criteria were defined as those where one answer is not “better” than another, but the information could be helpful to a user. Informative criteria would usually not be scored or have a minimum threshold for inclusion. Evaluative criteria were defined as those where directionality is clear (eg, whether more or less, presence or absence, is better). Evaluative criteria may have a minimum threshold for inclusion or be scored. We asked participants to rate the principles using a 5-point Likert scale (strongly disagree, disagree, neither agree nor disagree, agree, and strongly agree) and the criteria using a different 3-point scale (not necessary,

desirable, and essential). Participants also had the opportunity to provide comments on and suggest additions to the guiding principles and criteria.

Between Round Discussions, Evidence Presentations, and Empathy Mapping

A face-to-face meeting was held on November 28, 2016, at the Centre for Addiction and Mental Health (Toronto, Canada). Overall, 19 participants of the first modified Delphi process and all authors were in attendance. The event was facilitated by JZ, an experienced health services researcher with expertise in eHealth and a PhD in economics. She has previously led similar consensus-building exercises. Field notes were recorded by a research assistant.

At the beginning of the session, representatives from the Institute of Gender and Health of the Canadian Institutes of Health Research and the Mental Health Commission of Canada provided an overview of the policy context and rationale for this initiative. They specified that while a variety of approaches can be used for e-mental health app assessment, most depend on identifying a set of principles to guide the assessment process. The presenters reinforced that the scope of the exercise should be relevant to apps targeted at individuals and families seeking support to manage their own health, excluding apps targeted specifically at health professionals. Furthermore, clarification was provided that the framework could either be implemented by one or several organizations or as a self-assessment for app developers. Either way, the results of the assessment framework, once implemented, would be aimed at supporting the needs of members of the public as potential app users. App developers were considered a second important audience. Participants agreed that evidence base, gender responsiveness, and cultural appropriateness should be included as 3 foundational guiding principles of any Canadian assessment scale and need not be included in the consensus-building exercise.

Results from Round 1 of the modified Delphi process were presented using frequency distributions to summarize answers to survey questions with ordinal response scales. It was determined *a priori* that only principles and criteria from Round 1 voting with less than 80% agreement would be discussed during the meeting. Agreement was defined as endorsement of “strongly agree” or “agree” for the guiding principles and endorsement of “essential” or “desirable” for the criteria. Summaries of open-ended questions, including suggestions for changes or additions to principles or criteria, were also presented using quotes illustrative of the comments received. A facilitated iterative discussion led to modification, adaptation, removal, and addition to principles and criteria that did not initially secure 80% or greater agreement.

Furthermore, time was allocated for brief evidence presentations or “evidence bursts” from participant experts on opportunities for research related to eHealth apps, existing eHealth app assessment frameworks, and the digital health ecosystem. The purpose of the evidence bursts was to provide additional context and information to all participants on key considerations that might influence the selection of the guiding principles and criteria. Participants were allowed to ask questions after each

presentation and discuss the relevance to the app assessment framework.

We used a facilitated persona empathy mapping exercise to ensure that a broad range of end users' needs and perspectives were considered in the process [39,40]. Four personas were identified in advance, and participants added four more at the meeting (see [Appendix 1](#)). The eight personas represented a range of ages, sexes, genders, identities, cultures, geographic locations, and spectrum or severity of mental health conditions found across Canada. For each persona, meeting participants were encouraged to reflect and share the reasons why that individual might use an e-mental health app and what they imagined the use of such an app might achieve for each, according to individualized goals and needs. There was considerable discussion among meeting participants on these topics, including about how they might influence the principles and criteria. Consequently, several changes or additions were made to the text of the principles and criteria.

Round 2 of the Modified Delphi Process

Following the presentations, evidence bursts, and empathy mapping exercise, the participants at the face-to-face meeting re-rated the principles and criteria (in some cases with changes or additions based on the discussion) using the same scales as used in Round 1. Voting was anonymous and took place using electronic tools and on paper. Participants did not have access to each other's votes.

For Round 2 of the modified Delphi process, consensus was defined as 70% agreement, consistent with other studies of this type [41-43]. The intent was for items that did not achieve this consensus threshold to be included in a third postmeeting round of the Delphi process. This round, if required, would be conducted in the same manner as Round 1.

After Round 2 voting, participants shared key advice with policy makers on the directions ahead and provided feedback on the modified Delphi process. Following the session, a summary of the outcomes of the conversation was circulated to participants for review. We received no suggestions for amendments.

Results

Round 1 of the Modified Delphi Process

Participants in Round 1 of the modified Delphi self-identified as one or more of the following: app developers (5/24, 21%), app users (8/24, 33%), health care providers (8/24, 33%), mental health advocates (12/24, 50%), having lived experience of mental health problems as an individual living with such a problem or as a family member (8/24, 33%), policy makers (4/24, 17%), researchers (9/24, 38%), having workplace or workforce expertise (6/24, 25%), or having other relevant roles (6/24, 25%). There was one nonresponder. While participants could self-identify as having more than one role, many of them

were explicitly recruited because of their lived experience of mental health problems.

In response to the contextual questions posed in Round 1, almost half of the participants (12/25, 48%) rated the overall quality of currently available health apps as poor or fair, whereas 24% (6/25) gave a good or excellent rating. The remainder of participants (7/25, 28%) indicated that they were uncertain of the overall quality of currently available health apps.

Guiding Principles

[Figure 2](#) illustrates the consensus ratings from the 6 guiding principles assessed during Round 1 voting. As 3 principles received "agree or strongly agree" ratings of at least 80% after Round 1, these were not discussed in detail prior to Round 2 voting; these included the principles that criteria should be user centered; processes should be open, transparent, and fair; and the research undertaken should reflect ethical norms. In addition, 2 principles representing the concepts that the apps enable innovation and be risk based received ratings of at least 70% but not 80%. Furthermore, the principle of international alignment received a rating of less than 70%.

Criteria

Round 1 voting included 14 potential criteria. [Figure 3](#) lists the initial criteria assessed in Round 1 of the modified Delphi process and their endorsement by Delphi participants. All except one criterion met the essential or desirable inclusion consensus threshold. Only 2 of these—utility and transparency on information security or privacy policies—were endorsed as essential by at least 80% of participants. All participants voted on all criteria in this round, except one. There was one nonresponse for the "utility" criterion. The criterion of "awards that an app has received" was the only one that did not meet the consensus threshold for inclusion and was specifically discussed at the in-person meeting.

Between Round Discussion, Evidence Presentations, and Empathy Mapping

Discussion: Guiding Principles

As per *a priori* decision rules, between rounds at the in-person meeting, participants discussed the 3 guiding principles that did not receive "agree or strongly agree" ratings of at least 80% in Round 1. In addition to the comments received as part of Round 1 open-ended questions, suggestions for revisions to the wording of these principles and the framework emerged throughout the discussion. One suggestion that was endorsed by all was to change the terminology from "evaluation framework" to "assessment framework" to reflect the breadth of the agreed-upon guiding principles and criteria. In addition, participants suggested that the 3 foundational criteria (evidence base, gender responsiveness, and cultural appropriateness) should be explicitly stated and added to the list of guiding principles.

Figure 2. Rating of the initial guiding principles in Round 1.

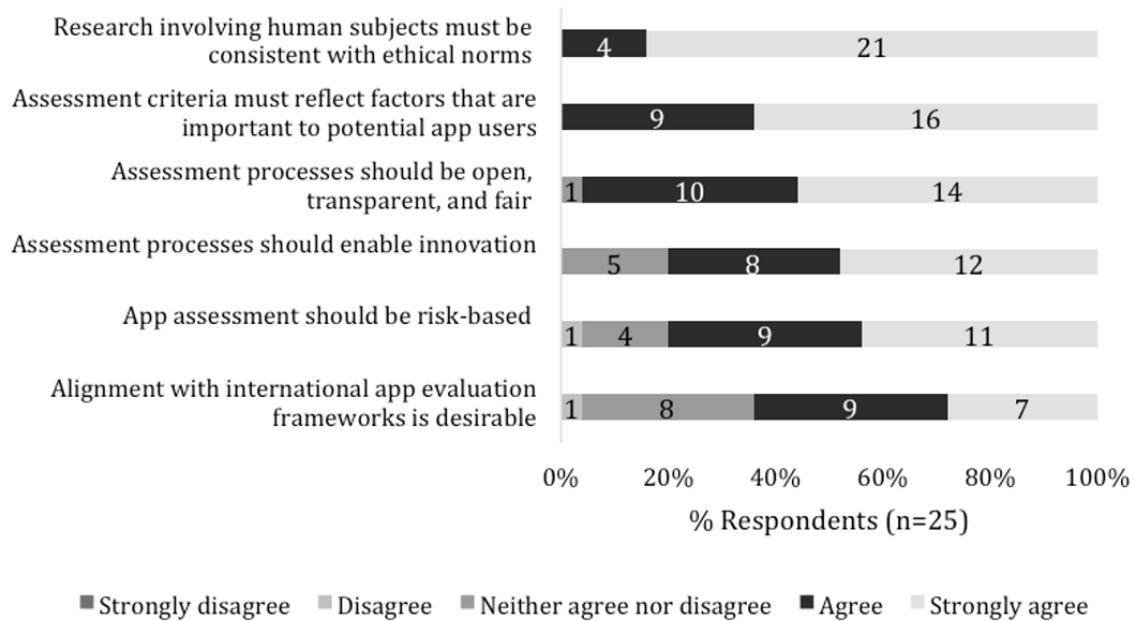
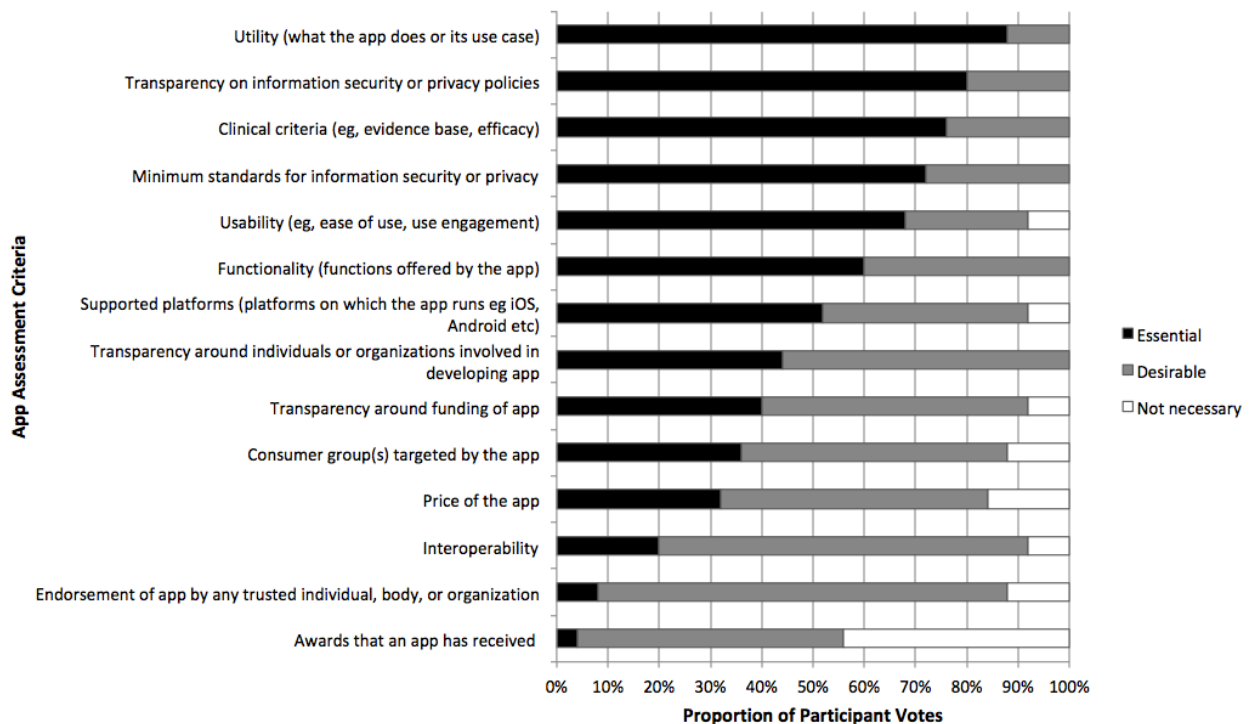


Figure 3. Round 1 rating of criteria for an e-mental health evaluation framework.



Discussion: Criteria

Three additional criteria emerged through discussions among participants about the important perspectives and expertise that different stakeholders bring. These 3 additional criteria were added prior to Round 2 voting based on the feedback from participants. These potential criteria included user desirability, ideally presented in a way that can be stratified by the type of user; user inclusion in the development of the apps; and

meaningful inclusion of a diverse range of communities in the testing of the apps. Participants underscored that user views must be sought, considered, and reflected throughout the app development process to ensure app quality and relevance. There was general agreement among participants that, at a minimum, stakeholder engagement in the development, implementation, and assessment of e-mental health apps should be expected.

Participants also discussed the appropriateness of the labels used for the list of criteria. There was general agreement that

the “utility” criteria label should be replaced with the word “effectiveness” to clarify its meaning; this change was applied to the criteria list prior to Round 2 voting.

Round 2 of the Modified Delphi Process

Guiding Principles

Following discussion, participants were asked to re-rate the relevant principles, with updated wording applied. All guiding principles reached at least 70% consensus in Round 2 (77%-100% agreed or strongly agreed). As a result, a third round of voting was not required.

A total of 9 guiding principles for an e-mental health app assessment framework were retained ([Textbox 1](#)). These included the 3 initial foundational principles: evidence base, gender responsiveness, and cultural appropriateness; 6 principles from the Round 1 list (3 with modifications based on participant input); and 1 new principle introduced on the basis of participant input at the in-person meeting.

Criteria

We asked participants to re-rate the relevant criteria, with updated wording applied. [Table 1](#) shows the distribution of votes endorsing criteria as “essential,” “desirable,” or “not

necessary” as well as the distribution of votes indicating how criteria should be approached—as either informative or evaluative. All criteria, except 2, reached at least 70% consensus, so a third round of voting was not required. The 2 criteria that were removed were “awards that an app has received” and “endorsement of the app by any trusted individual or body or organization” because participants expressed concern regarding the potential for bias in these criteria. The final criteria to be included in a Canadian e-mental health app assessment framework are listed in [Textbox 2](#).

Reaching Consensus on the Need for a Canadian e-Mental Health App Assessment Framework

In Round 1 and at the end of Round 2, we asked participants about the need for an app assessment framework to help consumers identify e-mental health apps of higher quality. Participants’ attitudes changed throughout the process. About two-thirds (17/25, 68%) of respondents in Round 1 agreed or strongly agreed with the need for the abovementioned framework. This number rose to 100% of participants after the in-person meeting, as assessed in Round 2 voting. For logistical reasons, some participants had to leave the in-person meeting prior to voting on this question, which resulted in n=13 for the Round 2 voting on this question.

Textbox 1. The final guiding principles for a Canadian e-mental health app assessment framework.

1. Evidence Based (*foundational principle*)

- Consideration must be given to the apps’ evidence base and effectiveness

2. Gender Responsive (*foundational principle*)

- Apps must take into account sex and gender considerations

3. Culturally Appropriate (*foundational principle*)

- Appealing to and inclusive of Canada’s diverse population

4. User Centered

- Assessment criteria must reflect the needs and expectations of potential app users

5. Risk Based

- App assessment should be risk based
- More detailed assessment is required for interventional apps, for example, drug dosing calculations or Web-based cognitive behavioral therapy, than for those focusing on general wellness support, for example, fitness trackers

6. Internationally Aligned

- App assessment framework should be informed by international experience or frameworks

7. Allows for Development and Continual Improvement

- The app assessment process should not impede the development or continual improvement of available apps

8. Open, Transparent, and Fair

- Assessment processes should be open, transparent, and fair

9. Human Research Consistent with Ethical Norms

- Research involving human subjects must be consistent with ethical norms
- Where an app is provided as part of a research study, Tri-Council Guidelines regarding Ethical Conduct for Research Involving Humans [37] must be followed.

Table 1. Round 2 criteria voting results.

Criteria	Distribution of endorsement			Approach to inclusion	
	Essential	Desirable	Not necessary	Informative	Evaluative
Effectiveness	18	0	0	4	19
Functionality	15	3	1	14	9
Clinical criteria	14	5	0	4	19
Interoperability	3	11	3	11	9
Usability	15	1	2	7	15
Information security transparency	18	1	0	4	19
Information security	16	2	0	4	17
Supported platforms	6	10	1	18	3
Audience	8	8	1	12	7
Developer transparency	9	6	0	18	5
Funding transparency	9	6	1	16	4
App price	6	10	2	19	2
User desirability	9	7	1	9	12
User inclusion	9	6	1	12	9
Meaningful inclusion	5	6	4	14	7
Endorsement of app ^a	3	8	7	6	4
Awards ^b	0	0	17	N/A ^c	N/A

^aDid not meet the consensus threshold in Round 2.

^bDid not meet the consensus threshold in Round 1; thus, omitted from informative versus evaluative criteria vote in Round 2.

^cN/A: not applicable.

Textbox 2. The final criteria to be included in a Canadian e-mental health app assessment framework.

1. Effectiveness

- What does the app do? What is its use case?

2. Transparency of Information Security

- Are the app's security and privacy policies transparent and easy to find?

3. Information Security

- Does the app meet minimal standards for information security and privacy?

4. Functionality

- What are the functions offered by the app?

5. Usability

- Is the app easy to use? Do its intended users find it engaging?

6. Clinical Criteria

- What is the app's evidence base? Is there evidence of its efficacy?

7. Developer Transparency

- Is there readily available information regarding the individuals and organizations involved in the development of the app?

8. Funding Transparency

- Is there readily available information regarding who funded the development of the app?

9. User Inclusion

- Were potential users involved in the development of the app?

10. User Desirability

- Have the intended users expressed a desire for the functionality provided by the app?

11. Audience

- Is it clear who the intended consumer group(s) is and what issues the app aims to address?

12. Supported Platforms

- What platforms does the app run on? (eg, iOS, Android, etc)

13. App Price

- How much does it cost to use the app? If it is not free, is it a one-time cost, subscription-based, or other?

14. Meaningful Inclusion

- Is information available on to what extent and how potential end users were involved in the development of the app?

15. Interoperability

- To what extent do users have the ability to move across different platforms (mobile and desktop) while maintaining profile preferences and information?

Discussion

Principal Findings

The Delphi process described in this study demonstrates that consensus was reached on a Canadian set of guiding principles and criteria for assessing the quality, effectiveness, and usability of evidence-informed e-mental health apps that adhere to ethical

standards. The purpose of this study is to render transparent the process through which this framework was developed. Specifically, two rounds of a modified Delphi process, including the use of presentations, evidence bursts, and empathy mapping between the two rounds, led to an assessment framework incorporating 9 guiding principles and 15 supporting criteria.

These principles and criteria make up a framework that reflects Canadian priorities associated with the need for evidence-based solutions, transparency, gender responsiveness, cultural appropriateness, and user engagement at all levels of e-mental health app development and testing. Furthermore, iterative and interactive discussions solidified the perception that a framework is essential for meeting the promise and potential of using e-mental health apps as part of a broader strategy to improve mental health in Canada.

While the framework described here was developed with particular attention to the Canadian context and national priorities, the principles and results of our consensus process are generally consistent with other efforts and findings in this area. For example, a 2016 systematic review of methods used to assess mobile health apps found that researchers evaluated the app quality in 6 domains: scientific or clinical basis, functionality, usability, accountability, impact, and popularity; 80% (73/91) participants used measures drawn from one or more of these domains [14]. Table 2 illustrates how we see our framework as mapping onto these domains.

Given the potential global reach of apps and the growing evidence that many apps available today do not conform to the established guidelines or best practices [1], the need for an assessment framework is increasingly salient. Potential users and health care professionals who intend to recommend e-mental health apps will want a simple way of knowing the quality and other characteristics of apps available to them. Assessment frameworks are an important first step in addressing this need, but many challenges exist in achieving a widespread implementation and scale-up.

For instance, the Canadian framework described in this study was designed so that it could be applied at an organizational

level or as a self-assessment for app developers. In the former case, a minimal standard of critical appraisal and the resources to undertake the analysis would be needed to research and assess the evidence base for an app, establish the characteristics of an app's developers, and evaluate other criteria, such as cultural appropriateness. Indeed, even defining the process through which evidence base and clinical criteria will be assessed requires further investigation. In addition, an independent accreditation body could be tasked with this process to ensure quality and sustainability. While some Canadian organizations have assumed the aspects of this role (eg, via Canada Health Infoway's certification program for privacy, security, and interoperability of digital health solutions), no organization has undertaken the full scope of assessment involved.

The Mental Health Commission of Canada is working on a fact sheet to disseminate the results of this consensus process broadly to those who might be able to use the information to affect change in a way that mental health apps are developed, recommended, and taken up. Given that health is provincially and territorially regulated in Canada, there is a potential for provincial and territorial health authorities to implement the framework, or an adapted version of it, within their jurisdictions as mental health apps become a more mainstream option to address barriers like affordability and lack of access in remote communities. The 2017 Canadian federal budget included Can \$11 billion over 10 years aimed at supporting provinces and territories in improving mental health and home care services [44]. This investment, as well as the spotlight it has put on mental health services, creates an opportune moment to promote this framework as a tool to make e-mental health an effective part of evolving provincial and territorial strategies.

Table 2. How the Canadian framework maps onto 6 domains commonly used by researchers to evaluate the app quality.

Six domains	Canadian framework guiding principles	Canadian framework criteria
Scientific or clinical basis	<ul style="list-style-type: none"> Evidence based Human research consistent with ethical norms 	<ul style="list-style-type: none"> Clinical criteria Meaningful inclusion
Functionality	<ul style="list-style-type: none"> Allows for development and continual improvement 	<ul style="list-style-type: none"> Functionality Supported platforms Interoperability
Usability	<ul style="list-style-type: none"> Gender responsive Culturally appropriate User centered 	<ul style="list-style-type: none"> Usability User inclusion
Accountability	<ul style="list-style-type: none"> Risk based Open, transparent, and fair 	<ul style="list-style-type: none"> Transparency of information security Information security Developer transparency Funding transparency
Impact	<ul style="list-style-type: none"> Internationally aligned 	<ul style="list-style-type: none"> Effectiveness App price
Popularity	N/A ^a	<ul style="list-style-type: none"> User desirability Audience

^aN/A: not applicable.

Another question that must be addressed is how the assessment results would be presented. For instance, a key decision is whether evaluative criteria should be used to calculate an overall summary score for each app or there should be minimum acceptable thresholds for certain criteria. The *Mobile App Rating Scale* (MARS), developed in Australia and one of the most developed examples of an app evaluation tool, weighs all criteria equally [27]. MARS ratings average the mean scores from the following 5 subscales: engagement, functionality, esthetics, information, and subjective quality. Given that *evidence base* is only 1 of 7 items listed under the information subscale, an app could potentially receive a very high rating on the MARS scale without having a strong evidence base. This method does not appear to be consistent with the findings from our Canadian Delphi process, which highlighted the significance that stakeholders attach to factors such as evidence base, gender responsiveness, and cultural appropriateness. Thus, further research could be helpful in addressing these and related questions regarding how best to obtain assessment results that accurately and appropriately reflect the guiding principles of the framework.

Research could also help inform a number of other practical implementation challenges. For example, the landscape of global mental health apps is evolving rapidly. Participants in the Delphi process emphasized that an assessment framework and process should not impede the development or continual improvement of apps. In this context, one needs to consider factors such as the timeline and criteria for re-assessing apps as they evolve. Likewise, if apps that have been assessed can be accessed via an integrated listing or shared repository, who would curate the collection and how would need to be determined, as would how to encourage its use by the public and health professionals.

Many other countries around the world are grappling with similar issues related to the endorsement of e-mental health apps. Some countries have published recommendations for

assessing health-related—including mental health-related—apps, but the extent to which they can be generalized across a variety of populations and their characteristics (eg, culture, gender, and language) remains unclear. This is one of the reasons why we used a process focused on the needs of stakeholders across Canada. While the diversity of our participants is a strength of this study, we solicited their feedback within a defined Canadian scope and perspective. Furthermore, there was a 20% attrition of participants who voted in the first (Web-based) and second (in-person) round of the Delphi process. This may have introduced selection bias for some of the principles and criteria retained in the final framework.

While the methods used in this study can be replicated readily, the outcomes that we obtained by consulting stakeholders from across Canada may or may not be transferable to other countries or contexts. As several of the factors considered in our process were aligned with a related process simultaneously underway in the United Kingdom, it may be possible to explore this question in the future when their results are available.

Conclusions

Improving health gains and reducing risks from the use of e-mental health apps depends on tilting the balance toward solutions that are of higher quality and are more acceptable to potential users. To inform the efforts to achieve this goal, we used an innovative structured Delphi process that incorporated evidence bursts and empathy mapping to ask a diverse group of Canadian stakeholders about what factors were important in assessing e-mental health apps. The group reached consensus on 9 guiding principles and 15 criteria for an e-mental health app assessment framework that could be applied at an individual or organizational level to support them in meeting the needs and expectations of potential app users and other key stakeholders. This consensus has the potential to inform future research, policy, and programs at a still relatively early stage in the evolution of e-mental health solutions.

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The views expressed are those of the authors and should not be regarded as stating an official position of any organization that contributed to this work. All coauthors provided input to the Delphi process and participated in the mini-Delphi session. JZ drafted the paper, with material contributions, critical review, and final validation from all coauthors.

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Conflicts of Interest

JZ received consulting fees from the project funders to plan and facilitate the modified Delphi process described herein, as well as to prepare a summary of the meeting outcomes. TvM is the CEO & Founder of Evolution Health Systems Inc, a company that owns and manages digital health interventions. He is also the acting CSO of VeggieCake LLC, a company developing mental health interventions targeting millennials. The views expressed in this paper are those of the authors and do not necessarily reflect those of the Canadian Institutes of Health Research (CIHR) or the Government of Canada.

Multimedia Appendix 1

Personas for empathy mapping.

[\[PDF File \(Adobe PDF File\), 25 KB - mhealth_v6i7e10016_app1.pdf \]](#)**References**

1. Bakker D, Kazantzis N, Rickwood D, Rickard N. Mental Health Smartphone Apps: Review and Evidence-Based Recommendations for Future Developments. *JMIR Ment Health* 2016 Mar 01;3(1):e7 [FREE Full text] [doi: [10.2196/mental.4984](https://doi.org/10.2196/mental.4984)] [Medline: [26932350](https://pubmed.ncbi.nlm.nih.gov/26932350/)]
2. Research2Guidance. mHealth App Developer Economics 2016: The current status and trends of the mHealth app market, 6th annual study on mHealth app publishing. 2016 Oct. URL: <http://research2guidance.com/r2g/r2g-mHealth-App-Developer-Economics-2016.pdf> [accessed 2018-02-01] [WebCite Cache ID 6wt2batXa]
3. Donker T, Petrie K, Proudfoot J, Clarke J, Birch M, Christensen H. Smartphones for smarter delivery of mental health programs: a systematic review. *J Med Internet Res* 2013 Nov 15;15(11):e247 [FREE Full text] [doi: [10.2196/jmir.2791](https://doi.org/10.2196/jmir.2791)] [Medline: [24240579](https://pubmed.ncbi.nlm.nih.gov/24240579/)]
4. Firth J, Torous J, Nicholas J, Carney R, Prasad A, Rosenbaum S, et al. The efficacy of smartphone-based mental health interventions for depressive symptoms: a meta-analysis of randomized controlled trials. *World Psychiatry* 2017 Oct;16(3):287-298 [FREE Full text] [doi: [10.1002/wps.20472](https://doi.org/10.1002/wps.20472)] [Medline: [28941113](https://pubmed.ncbi.nlm.nih.gov/28941113/)]
5. Mental Health Commission of Canada. Ottawa: Mental Health Commission of Canada; 2014. E-mental health in Canada: transforming the mental health system using technology - A briefing document URL: http://www.mentalhealthcommission.ca/sites/default/files/MHCC_E-Mental_Health-Briefing_Document_ENG_0.pdf [WebCite Cache ID 6wt2lu1yr]
6. S. Bhuyan S, Kim H, Isehunwa O, Kumar N, Bhatt J, Wyant D, et al. Privacy and security issues in mobile health: Current research and future directions. *Health Policy and Technology* 2017 Jun;6(2):188-191. [doi: [10.1016/j.hlpt.2017.01.004](https://doi.org/10.1016/j.hlpt.2017.01.004)]
7. Nicholas J, Larsen M, Proudfoot J, Christensen H. Mobile Apps for Bipolar Disorder: A Systematic Review of Features and Content Quality. *J Med Internet Res* 2015 Aug 17;17(8):e198 [FREE Full text] [doi: [10.2196/jmir.4581](https://doi.org/10.2196/jmir.4581)] [Medline: [26283290](https://pubmed.ncbi.nlm.nih.gov/26283290/)]
8. Larsen ME, Nicholas J, Christensen H. A Systematic Assessment of Smartphone Tools for Suicide Prevention. *PLoS One* 2016;11(4):e0152285 [FREE Full text] [doi: [10.1371/journal.pone.0152285](https://doi.org/10.1371/journal.pone.0152285)] [Medline: [27073900](https://pubmed.ncbi.nlm.nih.gov/27073900/)]
9. Statistics Canada. Ottawa: Statistics Canada; 2016. Table 13-10-0802-01 Mental health characteristics: Ability to handle stress and sources of stress URL: <http://www5.statcan.gc.ca/cansim/a26> [WebCite Cache ID 6wt64rl37]
10. Sunderland A, Findlay LC. Perceived need for mental health care in Canada: Results from the 2012 Canadian Community Health Survey-Mental Health. *Health Rep* 2013 Sep;24(9):3-9 [FREE Full text] [Medline: [24258361](https://pubmed.ncbi.nlm.nih.gov/24258361/)]
11. Mental Health Commission of Canada. Calgary; 2012. Changing Directions, Changing Lives: The Mental Health Strategy for Canada URL: <http://strategy.mentalhealthcommission.ca/pdf/strategy-images-en.pdf> [WebCite Cache ID 6wt6B7oqt]
12. Tannenbaum C, Voss P, El-Gabalawy H, Joannette Y. Gender, Work, and Aging. *Can J Aging* 2016 Dec;35(3):405-411. [doi: [10.1017/S0714980816000416](https://doi.org/10.1017/S0714980816000416)] [Medline: [27418079](https://pubmed.ncbi.nlm.nih.gov/27418079/)]
13. Canadian Institutes of Health Research. 2015 Dec 20. Healthy and Productive Work URL: <http://www.cihr-irsc.gc.ca/e/47706.html> [accessed 2018-01-31] [WebCite Cache ID 6wt6PQioG]
14. Grundy Q, Wang Z, Bero L. Challenges in Assessing Mobile Health App Quality: A Systematic Review of Prevalent and Innovative Methods. *Am J Prev Med* 2016 Dec;51(6):1051-1059. [doi: [10.1016/j.amepre.2016.07.009](https://doi.org/10.1016/j.amepre.2016.07.009)] [Medline: [27659122](https://pubmed.ncbi.nlm.nih.gov/27659122/)]
15. Shen N, Levitan M, Johnson A, Bender J, Hamilton-Page M, Jadad A, et al. Finding a Depression App: A Review and Content Analysis of the Depression App Marketplace. *JMIR mHealth uHealth* 2015 Feb 16;3(1):e16. [doi: [10.2196/mhealth.3713](https://doi.org/10.2196/mhealth.3713)]
16. U.S. Food and Drug Administration. 2015 Sep 02. Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff URL: <https://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf> [accessed 2018-02-01] [WebCite Cache ID 6wt3j99XI]
17. Ontario Telemedicine Network. The Practical Apps Approach. 2016. URL: <https://practicalapps.ca/approach/> [accessed 2018-01-31] [WebCite Cache ID 6wt43XEWO]
18. Huckvale K, Prieto J, Tilney M, Benghozi P, Car J. Unaddressed privacy risks in accredited health and wellness apps: a cross-sectional systematic assessment. *BMC Med* 2015 Sep 25;13(1):A. [doi: [10.1186/s12916-015-0444-y](https://doi.org/10.1186/s12916-015-0444-y)]
19. National Health Service, UK. Apps Library Beta URL: <https://apps.beta.nhs.uk/> [accessed 2018-04-04] [WebCite Cache ID 6yQkOJJ3]
20. Grindrod KL, Li M, Gates A. Evaluating user perceptions of mobile medication management applications with older adults: a usability study. *JMIR Mhealth Uhealth* 2014 Mar 14;2(1):e11 [FREE Full text] [doi: [10.2196/mhealth.3048](https://doi.org/10.2196/mhealth.3048)] [Medline: [25099993](https://pubmed.ncbi.nlm.nih.gov/25099993/)]
21. Avis JV, van MT, Fournier R, Ball GD. Lessons Learned From Using Focus Groups to Refine Digital Interventions. *JMIR Res Protoc* 2015 Jul 31;4(3):e95 [FREE Full text] [doi: [10.2196/resprot.4404](https://doi.org/10.2196/resprot.4404)] [Medline: [26232313](https://pubmed.ncbi.nlm.nih.gov/26232313/)]
22. Apple Inc. Apple Developer. App Store Review Guidelines URL: <https://developer.apple.com/app-store/review/guidelines/> [accessed 2018-01-31] [WebCite Cache ID 6wt4GcGJh]

23. Fiore P. How to Evaluate Mobile Health Applications: A Scoping Review - Studies in Health Technology Informatics. In: Building Capacity for Health Informatics in the Future. Amsterdam: IOS Press; 2017:109-114.
24. Chindalo P, Karim A, Brahmabhatt R, Saha N, Keshavjee K. Health Apps by Design: A Reference Architecture for Mobile Engagement. *International Journal of Handheld Computing Research* 2016;7(2):34-43. [doi: [10.4018/IJHCR.2016040103](https://doi.org/10.4018/IJHCR.2016040103)]
25. Albrecht U. Transparency of health-apps for trust and decision making. In: *J Med Internet Res*. Hershey, PA: IGI Global; Dec 30, 2013:e277-e108.
26. Hanrahan C, Dy Aungst T, Cole S. Evaluating Mobile Medical Applications. Bethesda, MD: American Society of Health-System Pharmacists, Inc; 2014.
27. Stoyanov S, Hides L, Kavanagh D, Zelenko O, Tjondronegoro D, Mani M. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. *JMIR Mhealth Uhealth* 2015 Mar 11;3(1):e27 [FREE Full text] [doi: [10.2196/mhealth.3422](https://doi.org/10.2196/mhealth.3422)] [Medline: [25760773](https://pubmed.ncbi.nlm.nih.gov/25760773/)]
28. Singh K, Drouin K, Newmark LP, Rozenblum R, Lee J, Landman A, et al. Developing a Framework for Evaluating the Patient Engagement, Quality, and Safety of Mobile Health Applications. *Issue Brief (Commonw Fund)* 2016 Feb;5:1-11. [Medline: [26934758](https://pubmed.ncbi.nlm.nih.gov/26934758/)]
29. Boulkedid R, Abdoul H, Loustau M, Sibony O, Alberti C. Using and Reporting the Delphi Method for Selecting Healthcare Quality Indicators: A Systematic Review. *PLoS ONE* 2011 Jun 9;6(6):e20476. [doi: [10.1371/journal.pone.0020476](https://doi.org/10.1371/journal.pone.0020476)]
30. Dalkey N, Helmer O. An Experimental Application of the DELPHI Method to the Use of Experts. *Management Science* 1963 Apr;9(3):458-467. [doi: [10.1287/mnsc.9.3.458](https://doi.org/10.1287/mnsc.9.3.458)]
31. Fink A, Koscoff J, Chassin M, Brook RH. Consensus methods: characteristics and guidelines for use. *Am J Public Health* 1984 Sep;74(9):979-983. [Medline: [6380323](https://pubmed.ncbi.nlm.nih.gov/6380323/)]
32. Gustafson D, Shukla R, Delbecq A, Walster G. A comparative study of differences in subjective likelihood estimates made by individuals, interacting groups, Delphi groups, and nominal groups. *Organizational Behavior and Human Performance* 1973 Apr;9(2):280-291. [doi: [10.1016/0030-5073\(73\)90052-4](https://doi.org/10.1016/0030-5073(73)90052-4)]
33. University of Victoria. Human Research Ethics. 2018. URL: <https://www.uvic.ca/research/conduct/home/regapproval/humanethics/index.php> [accessed 2018-02-10] [WebCite Cache ID 70W0yuUCn]
34. Mathison S. Purposeful sampling. In: *Encyclopedia of Evaluation*. Thousand Oaks, CA: Sage Publications, Inc; 2004.
35. Status of Women Canada. 2017 Oct 03. Government of Canada's Approach: Gender-Based Analysis Plus URL: <http://www.swc-cfc.gc.ca/gba-acs/approach-approche-en.html> [accessed 2018-02-01] [WebCite Cache ID 6wtBJzQvm]
36. Government of Canada. 2017 Jun 27. Health Portfolio Sex and Gender-Based Analysis Policy URL: <https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/health-portfolio-sex-gender-based-analysis-policy.html> [accessed 2018-02-01] [WebCite Cache ID 6wtC0qH02]
37. Department of Justice. 2018 Feb 14. Principles respecting the Government of Canada's relationship with Indigenous peoples URL: <http://www.justice.gc.ca/eng/csj-sjc/principles-principes.html> [accessed 2018-02-01] [WebCite Cache ID 6wtCaNT49]
38. Mobasheri M. Personal communication with Jennifer Zelmer. E-mail 2016 Oct 25.
39. Ferreira B, Williamson S, Oliveira EAJ, Conte T. Designing Personas with Empathy Map. 2015 Presented at: SEKE; July 6-8, 2015; Pittsburgh p. 501-505.
40. Williams I, Brereton M, Donovan J, McDonald K, Millard T, Tam A, et al. A Collaborative Rapid Persona-Building Workshop: Creating Design Personas with Health Researchers. *International Journal of Sociotechnology and Knowledge Development* 2014 Apr;6(2):17-35. [doi: [10.4018/ijskd.2014040102](https://doi.org/10.4018/ijskd.2014040102)]
41. Hasson F, Keeney S, McKenna H. Research Guidelines for the Delphi Survey Technique. *Journal of Advanced Nursing* 2008 Jun 28;32(4). [doi: [10.1046/j.1365-2648.2000.t01-1-01567.x](https://doi.org/10.1046/j.1365-2648.2000.t01-1-01567.x)] [Medline: [11095242](https://pubmed.ncbi.nlm.nih.gov/11095242/)]
42. Kleyne M, Braun S, Bleijlevens M, Lexis M, Rasquin S, Halfens J, et al. Using a Delphi technique to seek consensus regarding definitions, descriptions and classification of terms related to implicit and explicit forms of motor learning. *PLoS One* 2014;9(6):e100227 [FREE Full text] [doi: [10.1371/journal.pone.0100227](https://doi.org/10.1371/journal.pone.0100227)] [Medline: [24968228](https://pubmed.ncbi.nlm.nih.gov/24968228/)]
43. Zafar SY, Currow DC, Cherny N, Strasser F, Fowler R, Abernethy AP. Consensus-based standards for best supportive care in clinical trials in advanced cancer. *Lancet Oncol* 2012 Feb;13(2):e77-e82. [doi: [10.1016/S1470-2045\(11\)70215-7](https://doi.org/10.1016/S1470-2045(11)70215-7)] [Medline: [22300862](https://pubmed.ncbi.nlm.nih.gov/22300862/)]
44. Health Canada. 2018 May 14. Shared Health Priorities URL: <https://www.canada.ca/en/health-canada/corporate/transparency/health-agreements/shared-health-priorities.html> [WebCite Cache ID 6z4mS5tUq]
45. Greenspun H, Coughlin S. mHealth in an mWorld: How mobile technology is transforming health care. Washington, DC: Deloitte Center for Health Solutions; 2012. URL: <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lhsc-mhealth-in-an-mworld-103014.pdf> [WebCite Cache ID 6p25Cf7Da]
46. World HO. mHealth New horizons for health through mobile technologies: Based on the findings of the second global survey on eHealth - Global Observatory for. Geneva: World Health Organization; 2011.
47. Philbrick WC. mHealth and MNCH - State of the Evidence.: mHealth Alliance, UN Foundation; 2013. URL: http://www.mhealthknowledge.org/sites/default/files/15_un_007_evidencegapreport_digital_aaa.pdf [accessed 2017-03-17] [WebCite Cache ID 6p25nq3nf]
48. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. Tri-Council Policy Statement: Ethical Conduct for Research Involving

- Humans. Ottawa: Government of Canada; 2014. URL: http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf [accessed 2018-06-28] [[WebCite Cache ID 70WB9cjG9](#)]
49. Stoyanov S, Hides L, Kavanagh D, Zelenko O, Tjondronegoro D, Mani M. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. *JMIR Mhealth Uhealth* 2015 Mar 11;3(1):e27 [[FREE Full text](#)] [doi: [10.2196/mhealth.3422](https://doi.org/10.2196/mhealth.3422)] [Medline: [25760773](#)]
50. Chan S, Torous J, Hinton L, Yellowlees P. Towards a Framework for Evaluating Mobile Mental Health Apps. *Telemed J E Health* 2015 Dec;21(12):1038-1041. [doi: [10.1089/tmj.2015.0002](https://doi.org/10.1089/tmj.2015.0002)] [Medline: [26171663](#)]
51. Cuhls K. Delphi Method in Delphi Surveys: Teaching Material for UNIDO Foresight Seminars. Internet. Wien: UNIDO; 2005. URL: http://www.unido.org/fileadmin/import/16959_DelphiMethod.pdf [accessed 2017-02-08] [[WebCite Cache ID 6o8CYJIFB](#)]

Abbreviations

CIHR: Canadian Institutes of Health Research

MARS: Mobile App Rating Scale

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Original Paper

Clinical Feasibility of Monitoring Resting Heart Rate Using a Wearable Activity Tracker in Patients With Thyrotoxicosis: Prospective Longitudinal Observational Study

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Abstract

Background: Symptoms and signs of thyrotoxicosis are nonspecific and assessing its clinical status is difficult with conventional physical examinations and history taking. Increased heart rate (HR) is one of the easiest signs to quantify this, and current wearable devices can monitor HR.

Objective: We assessed the association between thyroid function and resting HR measured by a wearable activity tracker (WD-rHR) and evaluated the clinical feasibility of using this method in patients with thyrotoxicosis.

Methods: Thirty patients with thyrotoxicosis and 10 controls were included in the study. Participants were instructed to use the wearable activity tracker during the study period so that activity and HR data could be collected. The primary study outcomes were verification of changes in WD-rHR during thyrotoxicosis treatment and associations between WD-rHR and thyroid function. Linear and logistic model generalized estimating equation analyses were performed and the results were compared to conventionally obtained resting HR during clinic visits (on-site resting HR) and the Hyperthyroidism Symptom Scale.

Results: WD-rHR was higher in thyrotoxic patients than in the control groups and decreased in association with improvement of thyrotoxicosis. A one standard deviation-increase of WD-rHR of about 11 beats per minute (bpm) was associated with the increase of serum free T4 levels (beta=-.492, 95% CI 0.367-0.616, $P<.001$) and thyrotoxicosis risk (odds ratio [OR] 3.840, 95% CI 2.113-6.978, $P<.001$). Although the Hyperthyroidism Symptom Scale showed similar results with WD-rHR, a 1 SD-increase of on-site rHR (about 16 beats per minute) showed a relatively lower beta and OR (beta=-.396, 95% CI 0.204-0.588, $P<.001$; OR 2.114, 95% CI 1.365-3.273, $P<.001$) compared with WD-rHR.

Conclusions: Heart rate data measured by a wearable device showed reasonable predictability of thyroid function. This simple, easy-to-measure parameter is clinically feasible and has the potential to manage thyroid dysfunction.

Trial Registration: ClinicalTrials.gov NCT03009357; <https://clinicaltrials.gov/ct2/show/NCT03009357> (Archived by WebCite at <http://www.webcitation.org/70h55Llyg>)

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KEYWORDS

activity tracker; wearable device; heart rate; thyrotoxicosis; hyperthyroidism; Graves' disease

Introduction

Thyrotoxicosis is a clinical syndrome resulting from the high concentration of free thyroxine (T4) and free triiodothyronine (T3). The prevalence of thyrotoxicosis is approximately 2%, and its most common cause (ie, 60%-90%) is Graves' disease (GD) which is an autoimmune disease that stimulates the thyroid gland to produce and release thyroid hormone [1-3]. Thyrotoxicosis results in various symptoms and signs, including fatigue, anxiety, palpitations, sweating, heat intolerance, disturbed sleep, and weight loss because the thyroid hormone affects many different organs [4]. These clinical manifestations are relatively nonspecific and vary depending on factors such as patient age and sex, disease duration, and etiology [5,6]. Although palpitation and increased heart rate (HR) are among the most frequent symptoms and signs [7], and the easiest to quantify, HR can easily be affected by other factors such as the patient's emotional state, body position, and physical activities. Therefore, it is difficult to assess disease status based solely on patient HR that is either self-reported or obtained conventionally in the clinic during a specific moment. Although researchers have developed assessment tools that use parameters associated with symptoms and signs of thyrotoxicosis, most are questionnaire-based scoring systems that require time and educated scorers [8,9]. Thyrotoxicosis is diagnosed when a thyroid function test (TFT) shows increased serum thyroid hormone levels. This test is often delayed because patients tend to visit the clinic in severe status due to the nonspecific symptoms of thyrotoxicosis. Therefore, a simple, easy-to-measure parameter to predict thyroid status would be useful for thyrotoxicosis management.

The popularity of wearable activity trackers has grown considerably in recent years. The American College of Sports Medicine survey of fitness trends reported that wearable technology was the top-rated trend in 2016 [10]. Forecasts indicate that wearable activity tracker sales will exceed 82 million by the end of 2019, 2.5 times the expected sales volume in 2016 [11]. These devices are typically worn on the wrist or hip and provide the user with information about their physical activity, such as steps taken, vertical and horizontal moving distance, and sleep patterns. Recently developed devices can measure HR using photoplethysmography, which measures a differential reflection of light from the skin, based on the pulsatility of superficial blood vessels [12]. Many studies on the accuracy of these wrist-worn HR monitors have been published, showing relatively accurate HR during the resting state [13,14]. It is easy to collect detailed longitudinal HR data and physical activity with these wearable devices, and these data can provide more information than intermittently measured HR. This makes it now possible to collect and analyze more detailed and precise HR data, which is a crucial parameter changed in thyrotoxicosis. However, few trials have evaluated wearable devices for use in assessing thyroid dysfunction.

Therefore, the objectives of the present study were to investigate whether and how well HR data collected by commercially available activity trackers reflect thyroid function across the

clinical course of thyrotoxicosis. Using this approach, the clinical feasibility of wearable devices for the management of thyroid dysfunction was evaluated.

Methods

Study Design and Participants

This was a single-center prospective observational study. Subjects were recruited from the outpatient clinic of the endocrinology department at Seoul National University Bundang Hospital (SNUBH).

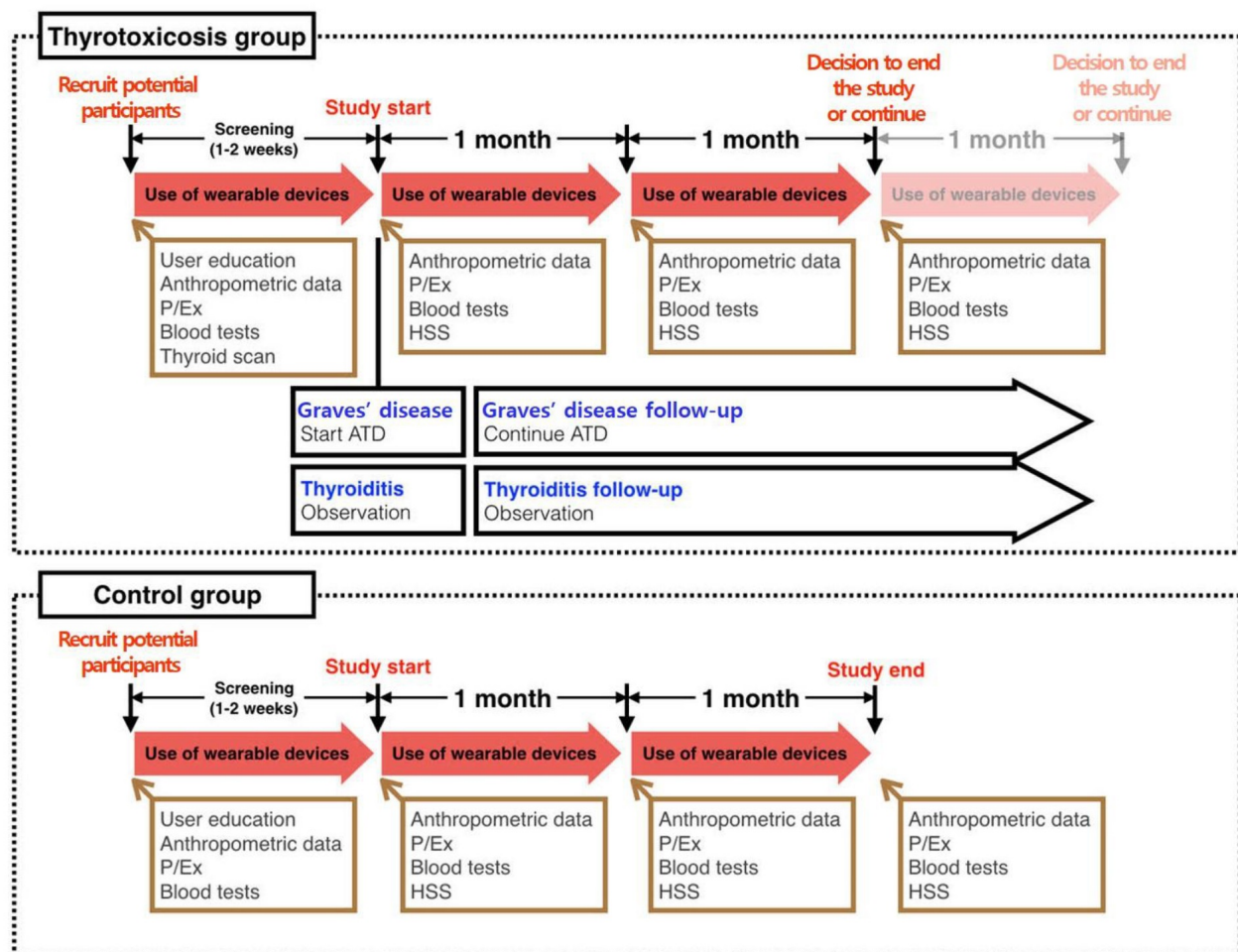
For the thyrotoxicosis group, patients 15-60 years of age who had been diagnosed with newly developed or recurrent thyrotoxicosis were eligible to participate. Participants needed to own a mobile phone and to be able to use a wearable device and its mobile application. Among those for whom the etiology of thyrotoxicosis was GD, only patients who had planned treatment with antithyroid drugs (ATD) were included so that their clinical course could be followed during medical treatment. We prescribed methimazole as the first choice ATD unless the subjects were contraindicated. No subject had a contraindication for methimazole or adverse events during the administration of methimazole. Inclusion and exclusion criteria are listed in [Multimedia Appendix 1](#). Prescribing beta blockers is a standard treatment for relief of thyrotoxicosis symptoms; we prescribed short-acting beta blocker propranolol to symptomatic patients to minimize its impact on the study. A total of 37 patients were screened for participation. A total of 30 patients were finally enrolled, and 2 withdrew during the study. One participant withdrew because of a skin reaction to the device (ie, Fitbit Charge HR) on their wrist; the investigators withdrew the second because of poor adherence to using the device. There were 25 and 3 patients diagnosed with GD and thyroiditis for the etiology of thyrotoxicosis, respectively, who completed the study.

Healthy adults without a history of thyroid disease were included in the control group. Consistent with the thyrotoxicosis group, participants needed to be able to use a wearable device and the mobile application. These participants were screened to ensure they were not taking medications affecting HR, including beta blockers. There were 13 potential participants screened, and 10 were enrolled in the control group. All participants were informed about the study and provided written informed consent. This study was approved by the SNUBH Institutional Review Board (IRB #B-1609-363-004) and registered on ClinicalTrials.gov (trial registration #NCT03009357).

Procedures

The study design is shown in [Figure 1](#). On the first visit, potential candidates were provided with a device and brief on-site instructions for its use. They were instructed to wear the device as much as possible throughout the day and during sleep. We also explained that if they did not wear the device or synchronize it with the application for more than five consecutive days, they could be withdrawn from the study due to poor adherence.

Figure 1. Study design and flow. Blood tests included a thyroid function test, serum levels of antithyroid-stimulating hormone receptor antibody, and other biochemical tests. Tc-99m is used in the thyroid scan. ATD: antithyroid drug, HSS: Hyperthyroidism Symptom Scale, P/Ex: physical examination.



After a one- to two-week screening period, patients visited the clinic to confirm the results of the TFT and other tests to determine the etiology (eg, autoantibodies, thyroid scan) and to start appropriate treatment. At this visit, those who met the inclusion criteria were enrolled. Patients with GD were prescribed a specific ATD dose, as determined by the endocrinologist. Patients with thyrotoxicosis caused by thyroiditis were reassured that their symptoms and signs were benign and self-limited. Patients taking propranolol were instructed to take the medication when their symptoms were severe and to inform the investigator of their dosing times, which were recorded in the case report form (CRF). Regardless of the etiology of thyrotoxicosis, all patients had monthly follow-ups, during which time they underwent blood tests, including TFT. Their ATD dose was adjusted as necessary. The study ended after each patient's third visit; however, the study duration could be extended at the discretion of the investigator with the patient's consent if their TFT was not fully restored. At each visit, anthropometric data were collected, and vital signs were measured.

Healthy adults were recruited into the control group through an official SNUBH announcement. Control participants visited the hospital on the same schedule as the thyrotoxic patients. They were given the same instruction about using the device and mobile application, and they were also instructed to wear the

device all day and to inform to the investigator of any medication changes, which were recorded in the CRF. Control participants' visit schedules and blood tests were consistent with those of thyrotoxic patients, but the duration of their study participation was not extended.

Wearable Devices and Applications

We used the Fitbit Charge HR or Fitbit Charge 2 (Fitbit, San Francisco, CA) and the Fitbit application for iOS (Apple, Cupertino, CA) or Android (Google, Mountain View, CA). The firmware versions of these devices were 18.128 for Fitbit Charge HR and 22.53.4 for Fitbit Charge 2 at the end of the study, and the latest version was maintained continuously over the study period. Although we started the study with Fitbit Charge HR, when Fitbit released Fitbit Charge 2, they discontinued production of the former device. Therefore, we used Fitbit Charge 2 with study participants enrolled after March 2017 ($n=7$ in the control group). However, these 2 models share a common sensor and data processing algorithm for both activity tracking and HR measurement. Activity and HR data are collected by the 3-axis accelerometer and plethysmography sensor, respectively. These sensors are equipped with the device. During the study period, each participant's Fitbit account information, including identification and password, were shared with researchers, allowing us to access their online Fitbit account [15] to monitor their synchronization status between the Fitbit

data server and tracking device. After the end of their participation, we separated the account from the device, and each participant retained their account.

Hyperthyroidism Symptom Scale

To assess their hyperthyroidism clinical status at each clinic visit, the endocrinologist overseeing this study evaluated the patients using the Hyperthyroidism Symptom Scale (HSS) [16,17]. The HSS consists of 10 items, including 1 psychometric item (ie, nervousness) and 9 items about physical response in the thyrotoxic state. A total of 8 items were evaluated through history taking: nervousness, sweating, heat intolerance, hyperactivity, weakness, diarrhea, appetite, and assessment of daily function. Physical examination evaluated the remaining 2 items: tremor and hyperdynamic precordium. Item scores were totaled to obtain an overall HSS score, which could range from 0-40 points.

Definition of Resting Heart Rate

The American Heart Association defines the resting heart rate (rHR) as the heart beats per minute (bpm) pumping the lowest amount of blood someone needs when they are in a resting position. The rHR can be changed by emotional state, medication, or current disease. In this study, we focused on rHR because we expected thyrotoxicosis to affect rHR significantly. We used 3 different rHR parameters according to the measurement method and calculating algorithm as follows. On-site rHR is the heart rate measured manually on the right wrist (ie, radial pulse) in a seated position after at least 10 minutes of resting. To calculate rHR from the HR log generated by the wearable device, we downloaded daily summary and detailed HR and activity data from the Fitbit database in JavaScript object notation (JSON) format using the application programming interface provided by Fitbit [18]. The process of data extraction to JSON has been described in detail in a previous paper [19]. From the HR log collected each day, we extracted HR data within time windows based on the absence of physical activity during the preceding 15 or more minutes and designated the median value of the extracted HR as the rHR of each day. In this study, rHR measured by a wearable device was defined as the mean 5-day rHR value extracted from the HR log collected by the wearable device before each TFT visit. The term WD-rHR-own refers to rHR data calculated by the above-described algorithm. Fitbit has an algorithm for generating rHR data from the HR and activity logs obtained from the tracking device. In a similar way, the term WD-rHR-Fitbit refers to rHR data based on the Fitbit algorithm. On-site rHR is consistent with the conventional definition of rHR, but the concept of WD-rHR does not guarantee that the participant is in a resting position during the measurement. This is because a lack of physical activity as detected by the device does not necessarily mean they are in a resting position. Although the exclusion criteria could control medication and other diseases, the emotional state was not controlled or evaluated in this study.

Anthropometric and Biochemical Measurements

We measured the subjects' height and weight while wearing light clothing and without shoes to the nearest 0.1 cm and 0.1

kg, respectively. Body mass index was calculated by determining the ratio between weight and the square of the height and expressed in kilograms per square meter. Right arm blood pressure was measured with the subject in a seated position after at least 10 minutes of resting. Biochemical measurements including TFT are listed in the [Multimedia Appendix 1](#). The free T4 assay had an analytic sensitivity of 0.05 nanograms per deciliter (ng/dL), and TSH had an analytical sensitivity of 0.04 milli-international units per liter (mIU/L) and functional sensitivity of 0.07 mIU/L. The reference ranges for free T4 and TSH were 0.89-1.79 ng/dl and 0.3-4.0 mIU/L, respectively. Thyrotoxicosis was defined based on the results of the TFT (ie, overt thyrotoxicosis was defined as higher free T4 and lower TSH levels than respective reference ranges; subclinical thyrotoxicosis was defined as normal free T4 and lower TSH levels). All subjects were examined for the presence of anti-TSH receptor antibody by radioimmunoassay (Cis Bio International), and the cutoff for positivity was greater than 1.0 units per milliliter (U/mL).

Data Analysis

Data were expressed as the mean (SD) or median (interquartile range). To compare variables between the patient and control groups, we used Student *t* test or the Mann Whitney *U* test for continuous variables and the chi-square test or Fisher exact probability test for categorical variables. Repeated measures analysis of variance (ANOVA) or Friedman test were used to analyze changes in thyroid hormone levels and associated parameters (HSS, on-site rHR, and WD-rHR) during the study period. The relationship between thyroid hormone levels and each associated parameter was determined by linear model generalized estimating equation (GEE) analyses. The relationship between thyrotoxicosis, defined as 1.8 ng/dL or more of free T4, and each associated parameter was assessed using binary logistic model GEE analyses. Odds ratios (OR) and 95% CI were computed per one standard deviation increase in these variables to the risk of thyrotoxicosis. A two-tailed $P < .05$ was considered statistically significant. All statistical analyses and data preparation were performed using IBM SPSS Statistics (version 20.0; IBM Corp, Armonk, NY, USA) and R (version 3.3.3; The R Foundation for Statistical Computing, Vienna, Austria).

Results

Participant Baseline Characteristics

Participant baseline characteristics are summarized in [Table 1](#). There were no differences in age, sex ratio, or body mass index between the 28 patients with thyrotoxicosis (ie, 25 diagnosed with GD, 3 with thyroiditis) and the 10 controls. As expected, on-site rHR in the thyrotoxicosis group was significantly higher than that in the control group. Blood pressure did not differ between the groups. There was a significantly higher HSS score and free T4, and lower TSH, in the thyrotoxic patients compared with the controls. Also, there were significant differences between the 2 groups on several parameters known to be related to thyrotoxicosis, including total cholesterol, serum creatinine, platelets, and liver enzymes. The mean duration of observation

was 3.27 (SD 1.21) months for all subjects, which was longer in thyrotoxic patients than in controls.

Changes in Thyroid Function and Associated Parameters

In thyrotoxic patients, thyrotoxicosis improved with treatment, as shown by decreased serum free T4 levels through the third visit. Serum TSH levels remained unchanged during the observation period (Table 2). Thyroid function was not fully restored in all patients by the end of the study, at which time 6 patients improved to a euthyroid state, 17 remained sub-clinically thyrotoxic, and 5 were still overtly thyrotoxic

(data not shown). HSS, on-site rHR, and WD-rHRs also decreased with treatment in the thyrotoxicosis group through the third visit (Table 2 and Figure 2). This study was scheduled to terminate after the third visit but was extended, with patient consent, in those whose thyroid function was not restored. Thus, increased free T4, HSS, and WD-rHRs were apparent after the fourth visit because only patients whose thyroid function had not yet recovered were retained in the study through a fifth visit. The control group completed the study at the third visit, and none of their thyroid hormone levels or associated parameters differed between visits.

Table 1. Baseline characteristics.

Characteristics	Thyrotoxicosis (n=28)	Control (n=10)	P value
Age (years), mean (SD)	34.9 (10.9)	34.1 (5.9)	.78 ^a
Gender, n (%)			
Male	10 (36)	3 (30)	
Female	18 (64)	7 (70)	.53 ^b
Body mass index (kg/m ²), mean (SD)	20.6 (4.7)	20.7 (1.6)	.93 ^a
Blood pressure (mmHg), mean (SD)			
Systolic blood pressure	130.2 (14.3)	124.6 (11.4)	.27 ^a
Diastolic blood pressure	78.1 (10.6)	70.6 (9.6)	.06 ^a
On-site resting heart rate (bpm ^c), mean (SD)	101.6 (14.5)	81.9 (14.8)	.001 ^a
Hyperthyroid symptom scale, mean (SD)	12.5 (10.0)	0.5 (2.8)	<.001 ^d
Thyroid function test			
Free thyroxine (ng/dL), mean (SD)	3.08 (1.09)	1.36 (0.12)	<.001 ^a
Thyroid stimulating hormone (mIU/L), median (IQR ^e)	0.01 (0.00)	1.33 (1.19)	<.001 ^d
Thyrotropin-binding inhibitory immunoglobulin (IU/L), median (IQR)	4.2 (10.3)	—	—
Glucose (mg/dL), mean (SD)	105.8 (18.6)	96.6 (23.1)	.24 ^a
Blood urea nitrogen (mg/dL), mean (SD)	13.0 (2.9)	11.7 (2.4)	.20 ^a
Creatinine (mg/dL), mean (SD)	0.50 (0.20)	0.69 (0.19)	.01 ^a
Total cholesterol (mg/dL), mean (SD)	141.7 (22.1)	180.2 (22.8)	<.001 ^a
Total protein (g/dL), mean (SD)	7.1 (0.5)	7.2 (0.4)	.37 ^a
Albumin (g/dL), mean (SD)	4.3 (0.3)	4.4 (0.3)	.17 ^a
Total bilirubin (mg/dL), mean (SD)	0.69 (0.30)	0.65 (0.26)	.69 ^a
Aspartate aminotransferase (mg/dL), mean (SD)	26.4 (10.4)	18.3 (3.1)	.001 ^a
Alanine aminotransferase (mg/dL), mean (SD)	33.1 (22.0)	15.1 (7.9)	.02 ^a
White blood count (no/mm ³), mean (SD)	5347.3 (1980.1)	5857.0 (1397.6)	.46 ^a
Hemoglobin (mg/dL), mean (SD)	14.0 (1.44)	13.6 (1.4)	.42 ^a
Platelet (no/mm ³), mean (SD)	182,200 (118,600)	276,600 (59,100)	.02 ^a

^aDerived from Student *t* test.^bDerived from Fisher exact probability test.^cbpm: beats per minute.^dDerived from Mann Whitney *U* test.^eIQR: interquartile range.

Table 2. Change of thyroid function and associating parameters during the study period in thyrotoxicosis and control groups.

Thyroid function test results and associated parameters	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	P value ^a
Thyrotoxicosis group, n	28	28	28	23	5	—
Free thyroxine (ng/dL), mean (SD)	3.08 (1.09)	2.02 (0.61)	1.66 (0.64)	1.60 (0.59)	1.96 (0.39)	<.001 ^b
Thyroid stimulating hormone (mIU/L), median (IQR) ^c	0.01 (0.00)	0.01 (0.00)	0.01 (0.13)	0.01 (0.10)	0.01 (0.10)	.114 ^d
Hyperthyroid Symptom Scale, median (IQR)	12.5 (10.0)	5.5 (7.8)	4.0 (8.8)	3.5 (4.5)	7.0 (4.5)	<.001 ^d
On-site resting heart rate (bpm) ^e , mean (SD)	101.6 (14.5)	94.4 (15.4)	90.1 (17.6)	85.5 (12.0)	83.5 (4.0)	.015 ^b
WD-rHR-own ^f (bpm), mean (SD)	88.0 (11.5)	82.9 (10.9)	75.9 (8.8)	76.2 (8.0)	72.7 (7.2)	<.001 ^b
WD-rHR-Fitbit ^g (bpm), mean (SD)	82.2 (12.5)	76.8 (9.5)	70.8 (8.4)	71.4 (7.8)	74.7 (9.8)	<.001 ^b
Control group, n	10	10	10	—	—	—
Free thyroxine (ng/dL), mean (SD)	1.36 (0.12)	1.37 (0.13)	1.35 (0.10)	—	—	.285 ^b
Thyroid stimulating hormone (mIU/L), median (IQR)	1.33 (1.19)	1.62 (2.21)	2.06 (1.21)	—	—	.236 ^d
Hyperthyroid Symptom Scale, median (IQR)	0.5 (2.8)	0.0 (2.0)	0.0 (2.0)	—	—	.504 ^d
On-site resting heart rate (bpm), mean (SD)	81.9 (14.8)	81.0 (13.2)	76.4 (11.2)	—	—	.250 ^b
WD-rHR-own (bpm), mean (SD)	65.8 (8.0)	63.2 (7.4)	64.5 (9.2)	—	—	.374 ^b
WD-rHR-Fitbit (bpm), mean (SD)	66.5 (8.2)	64.3 (7.3)	64.3 (7.7)	—	—	.101 ^b

^aVisit 1 to 3 were compared both in thyrotoxicosis and control groups.

^bDerived from ANOVA with repeated measures with a Greenhouse-Geisser correction.

^cIQR: interquartile range.

^dDerived from Friedman test.

^ebpm: beats per minute.

^fWD-rHR-own: the resting heart rate from wearable device derived by own algorithm.

^gWD-rHR-Fitbit: the resting heart rate from wearable device derived by Fitbit algorithm.

Association Between Serum Free Thyroxine Levels and Each Associated Parameter

Linear model GEE analyses were performed to verify the relationship between serum free T4 levels and each associated parameter (ie, HSS, on-site rHR, WD-rHR-own, and WD-rHR-Fitbit). In these analyses, the mean (SD) of each parameter were standardized to 0 and 1, respectively, to compare each parameter's relationship with free T4 levels and with each other. Before standardization, the 1SD of HSS, on-site rHR, WD-rHR-own, and WD-rHR-Fitbit were 6.3, 15.8, 11.4, and 11.2, respectively in thyrotoxic patients and 6.3, 16.2, 11.4, and 11.4 in all study participants. Although all parameters analyzed were significantly associated with serum free T4 levels in thyrotoxicosis patients and in all study participants, unstandardized beta for serum free T4 level by an increase of 1 SD of on-site rHR was relatively lower than those of other parameters (Table 3). To control thyrotoxicosis symptoms, some patients took a beta blocker intermittently. We performed the

same analysis, dividing the patient group into beta blocker users (n=13) and nonbeta blocker users (n=15), which did not change the interpretation of the results (Multimedia Appendix 1).

Odds Ratio of Each Associated Parameter for Thyrotoxicosis

The relationship between thyrotoxicosis, defined as 1.8 ng/dL or more of free T4, and each associated parameter was assessed with binary logistic model GEE analyses. All parameters analyzed were significant for predicting thyrotoxicosis (Table 4). Also, in this analysis, OR for thyrotoxicosis by a 1 SD increase in on-site rHR was relatively lower than those of other parameters, HSS, WD-rHR-own, and WD-rHR-Fitbit, which showed similar ORs (Table 4). These findings were consistent when analyzing beta blocker users and nonusers separately, except that on-site rHR was nonsignificant for predicting thyrotoxicosis in the nonbeta blocker users (Multimedia Appendix 1).

Figure 2. Change of serum free thyroxine (T4) levels (A), hyperthyroid symptom scale (B), on-site heart rate (C), and resting heart rate from wearable device (D) during the study period. HSS: Hyperthyroid Symptom Scale, rHR: resting heart rate, WD-rHR-own: rHR from wearable device derived by own algorithm, WD-rHR-Fitbit: derived by Fitbit algorithm. Error bars represent 95% CI of the means.

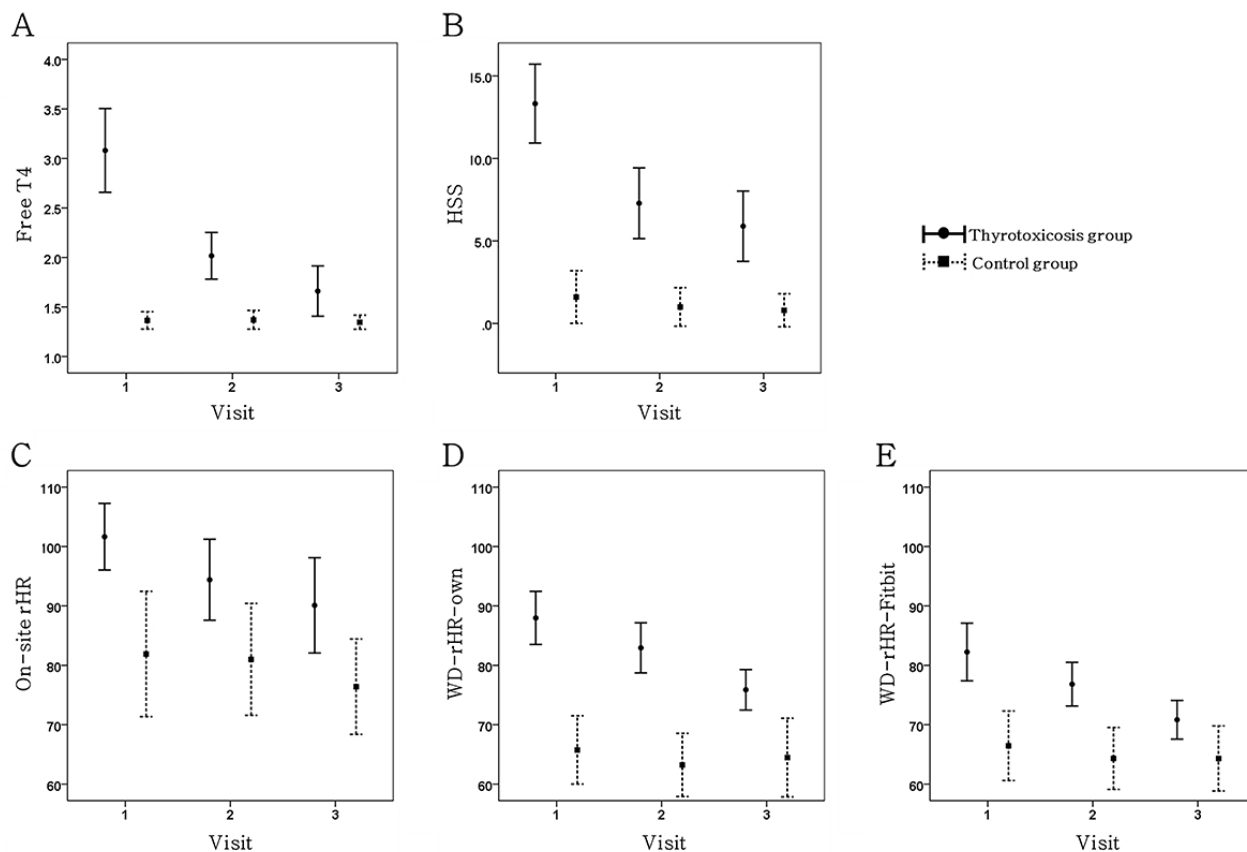


Table 3. Linear model generalized estimating equations analyses for the association between free thyroxine and associating parameters. Parameters standardized to the same mean and SD (mean 0, SD 1.0) for comparison and analyzed separately.

Association between free thyroxine and parameters	Unstandardized beta	95% CI	P value
Thyrotoxicosis group only			
Hyperthyroid Symptom Scale	.504	0.333-0.674	<.001
On-site resting heart rate	.362	0.122-0.602	.003
WD-rHR-own ^a	.465	0.300-0.630	<.001
WD-rHR-Fitbit ^b	.513	0.331-0.694	<.001
All groups			
Hyperthyroid Symptom Scale	.541	0.394-0.687	<.001
On-site resting heart rate	.396	0.204-0.588	<.001
WD-rHR-own	.492	0.367-0.616	<.001
WD-rHR-Fitbit	.515	0.375-0.656	<.001

^aWD-rHR-own: resting heart rate from wearable device derived by own algorithm.

^bWD-rHR-Fitbit: resting heart rate from wearable device derived by Fitbit algorithm.

Table 4. Binary logistic model generalized estimating equations analyses for the association between thyrotoxicosis and associating parameters. Parameters are standardized to have same mean and SD (mean 0, SD 1.0) for comparison and analyzed separately.

Association between free thyroxine and parameters	Odds ratio	95% CI	P value
Thyrotoxicosis group only			
Hyperthyroid Symptom Scale	2.614	1.612-4.238	<.001
On-site resting heart rate	1.648	1.047-2.594	.031
WD-rHR-own ^a	2.475	1.470-4.166	<.001
WD-rHR-Fitbit ^b	2.863	1.649-4.970	<.001
All groups			
Hyperthyroid Symptom Scale	3.601	2.190-5.923	<.001
On-site resting heart rate	2.114	1.365-3.273	<.001
WD-rHR-own	3.840	2.113-6.978	<.001
WD-rHR-Fitbit	3.843	2.067-7.144	<.001

^aWD-rHR-own: resting heart rate from wearable device derived by own algorithm.

^bWD-rHR-Fitbit: resting heart rate from wearable device derived by Fitbit algorithm.

Discussion

Principal Findings

To evaluate the clinical feasibility of wearable device generated data for the management of thyrotoxicosis, we investigated the association between HR data collected by activity trackers and thyroid function across the clinical course of thyrotoxicosis. Our results demonstrated that both rHR measured by a wearable device and HSS were significantly associated with thyroid function.

It is well known that the thyroid hormone has a positive chronotropic, inotropic effect, meaning that it stimulates the rate and force of systolic contraction and the rate of diastolic relaxation [7]. Therefore, thyrotoxicosis increases systolic blood pressure and HR and widens pulse pressure [20]. In this study, the thyrotoxicosis group showed elevated on-site rHR compared with the control group. Mean values for systolic and diastolic blood pressures were higher in the thyrotoxicosis group, but this difference was not statistically significant. Also, several parameters known to be associated with thyroid function differed between the thyrotoxicosis and control groups. Many studies have reported that the thyrotoxic condition decreases serum creatinine levels [21,22] and improves lipid profiles, including total cholesterol [23,24]. Thyrotoxicosis increases liver enzyme levels owing to relative hypoxia in the hepatic perivenular regions [25,26]. Although reports have conflicted, relatively low platelet counts in thyrotoxic patients have also been reported [27,28]. Our baseline results were consistent with these previous reports.

HSS, on-site rHR, WD-rHR-own, and WD-rHR-Fitbit were decreased as thyrotoxicosis improved and these variables were all associated with serum free T4 levels and thyrotoxicosis in linear and binary logistic model GEE analyses, respectively. Interestingly, standardized on-site rHR showed relatively lower beta for serum free T4 level and a lower OR for thyrotoxicosis compared with other standardized parameters in the GEE analyses. On-site rHR is a one-time measurement of one clinical

aspect, while HSS is a one-time measurement of several clinical aspects and WD-rHR is calculated from continuously monitored data for one clinical aspect. These differences can explain on-site rHR's relatively weak correlation with thyroid function compared with HSS or WD-rHR. Similar beta and ORs and their 95% CIs between standardized HSS and WD-rHR suggest that WD-rHR calculated from continuously collected, detailed data by wearable devices may be used to assess thyroid function status with similar accuracy and precision with HSS, a validated assessment tool known to reflect thyroid function, but which also requires time and an educated scorer [29,30]. Considering the time and effort required for evaluating HSS, WD-rHR, a simple parameter based on a large volume of detailed HR and activity data, could be a better predictor because the patient could get the results only by wearing the device. Even if patients measure their rHR manually between clinic visits, they still need to maintain a resting position without activity for 10 to 15 minutes. This makes it challenging to measure rHR manually several times daily. Taken together, WD-rHR is not only as accurate as a multi-dimensional assessment tool developed for evaluating thyrotoxic status, but also easier to measure compared with other assessment tools or conventional methods of measuring rHR.

Current wearable devices allow highly detailed, longitudinal measurement of physical indices. This large volume of clinical information (ie, "high definition data") may provide more accurate and objective information than subjective symptoms or physical signs recorded at clinic visits, which can be influenced by diurnal variation, emotional state, and other factors [31]. In this study, we calculated rHR from continuously monitored HR and physical activity data. Similar to manually measured HR, HR measured by wearable devices can also be affected by various factors, such as body position or emotional state. This influence cannot be selectively removed in the process of extracting rHR from collected HR data because these factors cannot be detected by the device we used. With the algorithm we used to calculate rHR, we could remove only the influence of physical activity, which can be detected by the

device. However, continuously monitored high definition data could blunt the influence of other factors. As mentioned above, we selected rHR as a median HR value from data collected within a given time window without physical activity during the day. This algorithm might minimize the effect of daily repeated short-term factors such as emotional state or body position. However, long-term and continuous factors, such as disease status, still influence the data. Therefore, WD-rHR-own might reflect the disease state of thyrotoxicosis more accurately than on-site rHR. Although the algorithm for extracting resting HR provided by Fitbit is proprietary and undisclosed, the basic concept is not different from ours, and WD-rHR-Fitbit showed a similar association with thyroid function compared with WD-rHR-own. Based on the results of the present study, we suggest that WD-rHR shows reasonable a prediction of thyroid function in thyrotoxic patients. Also, the development of a wearable device capable of measuring other parameters such as sweating, tremor, or respiration rate would further improve accurate prediction of thyroid function status. Therefore, “high-definition medicine”, through wearable devices, shows current capability and future potential in its clinical application in this field.

This study has some significant clinical implications. Although monitoring thyroid function using wearable devices cannot replace TFT, it could aid the management of thyrotoxicosis. During the treatment of GD, most patients are expected to repeat the TFT every one to two months regardless of their response to ATDs, and the interventions including dose adjustment of ATDs are provided with the same time interval. Monitoring thyroid function using wearable devices may provide patients with individualized, flexible, and more accurate interventions during treatment and follow-up, minimizing inconvenience and costs. Moreover, about 50% of patients have been reported to relapse within two years after discontinuing ATD, even if they were treated according to the recommended guidelines [32]. Monitoring during everyday life using wearable devices may enable early detection of disease recurrence in patients who are in remission after treatment. Although further studies are needed, these results may be applied to the monitoring of drug-induced subclinical thyrotoxicosis in patients with differentiated thyroid cancer (DTC) who are undergoing TSH-suppressive therapy (ie, maintaining iatrogenic subclinical thyrotoxic status using thyroid hormone over-replacement). TSH suppressive therapy is recommended to prevent the growth of DTC [33], but over-suppression of TSH increases risks of fracture and cardiovascular disease [34-36]. Therefore, a simple monitoring tool during TSH-suppressive therapy, such as a wearable device in everyday life, might help maintain appropriate intensities of TSH suppression. We have developed a web application to

predict thyrotoxicosis using rHR data from wearable devices [37] based on the results of this study. Since the present study was a small, observational, preliminary study, additional studies are planned to investigate the clinical usefulness of this application for thyrotoxic patients and DTC patients undergoing TSH suppressive therapy.

The primary strength of the study was that it contributes to the literature by monitoring HR throughout the day using wearable devices, for the first time, in patients with thyrotoxicosis. The clinical evidence provided herein may inspire further investigations and clinical applications of biosignals monitored by wearable devices in thyroid dysfunction. The other strength is that we used commercially available wearable devices and mobile applications. Thus, our results can be immediately applied to the management of thyrotoxic patients and provide a ready-to-use algorithm for making Web-based or mobile applications for managing thyrotoxicosis.

This study also has some limitations, which should be considered when interpreting the results. First, it was likely easier for younger people, who are adept at using mobile phones and wearable devices, to participate in the study, although the participants' ranged from 18 to 60 years of age. Also, signs such as increased HR owing to thyrotoxicosis may not be as evident in the elderly [5]. Therefore, it may be difficult to apply the results of this study to those aged over 65 years. However, the ages of the participants in this study were similar to the population in which thyrotoxicosis is most prevalent, and the results of this study can likely be applied to those who can use mobile phones and wearable devices. Second, this study has a small sample size and imbalance between patient and control group sizes, as well as the single-center based design. Among the 30 thyrotoxic patients, only 3 patients were diagnosed as thyroiditis, and we could not perform statistical analyses in these three patients separately. We analyzed the patients with GD only, and the results showed the same tendency as those in all patients (Multimedia Appendix 1). Despite the imbalance between patient and control group sizes, all statistical powers of the analyses in Table 1 and 2 were over 90%. Further investigations, including more participants and study sites, are needed to confirm the results of this study.

Conclusion

In conclusion, our results indicate that rHR data from wearable devices show reasonable predictability of thyroid function in patients with thyrotoxicosis. This parameter can be measured relatively simply and may be useful as well as clinically feasible for the management of thyroid dysfunction. This study is a starting point for the clinical application of high-definition medicine in the management of thyroid disease.

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Authors' Contributions

JHM was responsible for conception and design of the work. JHM, JEL, KMK, and TJO collected the data. JHM and JEL analyzed the data and drafted the manuscript. JHM, JEL, DHL, SHC, SL, YJP, DJP, and HCJ contributed data interpretation. JHM and JEL approved the final version of the manuscript. All authors agreed on the final content of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Inclusion and exclusion criteria, biochemical measurements, and generalized estimating equations analyses.

[PDF File (Adobe PDF File), 53KB - [mhealth_v6i7e159_app1.pdf](#)]

References

1. Cho BY. Clinical Thyroidology. In: 4th ed. Seoul, South Korea: Korea Medical Book Publishing Company; 2014.
2. Laurberg P, Pedersen KM, Vestergaard H, Sigurdsson G. High incidence of multinodular toxic goitre in the elderly population in a low iodine intake area vs. high incidence of Graves' disease in the young in a high iodine intake area: comparative surveys of thyrotoxicosis epidemiology in East-Jutland Denmark and Iceland. *J Intern Med* 1991 May;229(5):415-420. [Medline: [2040867](#)]
3. Moon JH, Yi KH. The diagnosis and management of hyperthyroidism in Korea: consensus report of the Korean thyroid association. *Endocrinol Metab (Seoul)* 2013 Dec;28(4):275-279 [FREE Full text] [doi: [10.3803/EnM.2013.28.4.275](#)] [Medline: [24396691](#)]
4. Devereaux D, Tewelde SZ. Hyperthyroidism and thyrotoxicosis. *Emerg Med Clin North Am* 2014 May;32(2):277-292. [doi: [10.1016/j.emc.2013.12.001](#)] [Medline: [24766932](#)]
5. Boelaert K, Torlinska B, Holder RL, Franklyn JA. Older subjects with hyperthyroidism present with a paucity of symptoms and signs: a large cross-sectional study. *J Clin Endocrinol Metab* 2010 Jun;95(6):2715-2726. [doi: [10.1210/jc.2009-2495](#)] [Medline: [20392869](#)]
6. Goichot B, Caron P, Landron F, Bouée S. Clinical presentation of hyperthyroidism in a large representative sample of outpatients in France: relationships with age, aetiology and hormonal parameters. *Clin Endocrinol (Oxf)* 2016 Mar;84(3):445-451. [doi: [10.1111/cen.12816](#)] [Medline: [25959282](#)]
7. Kahaly GJ, Dillmann WH. Thyroid hormone action in the heart. *Endocr Rev* 2005 Aug;26(5):704-728. [doi: [10.1210/er.2003-0033](#)] [Medline: [15632316](#)]
8. Crooks J, Marray IP, Wayne EJ. Statistical methods applied to the clinical diagnosis of thyrotoxicosis. *Q J Med* 1959 Apr;28(110):211-234. [Medline: [13658351](#)]
9. Kalra S, Khandelwal SK, Goyal A. Clinical scoring scales in thyroidology: A compendium. *Indian J Endocrinol Metab* 2011 Jul;15(Suppl 2):S89-S94 [FREE Full text] [doi: [10.4103/2230-8210.83332](#)] [Medline: [21966660](#)]
10. Thompson W. Worldwide Survey of Fitness Trends for 2016; 10th Anniversary Edition. *ACSM's Health & Fitness Journal* 2015;19(6):9-18. [doi: [10.1249/FIT.0000000000000164](#)]
11. Park Associates global sales of connected digital fitness trackers will exceed 82 million in 2019 from? Investing in the Connected Health Market? At Connected Health Summit database on the Internet. 2015 URL: <https://globenewswire.com/news> [accessed 2018-07-04] [WebCite Cache ID 70f6o2rJS]
12. Tamura T, Maeda Y, Sekine M, Yoshida M. Wearable Photoplethysmographic Sensors—Past and Present. *Electronics* 2014 Apr 23;3(2):282-302. [doi: [10.3390/electronics3020282](#)]
13. Dooley EE, Golaszewski NM, Bartholomew JB. Estimating Accuracy at Exercise Intensities: A Comparative Study of Self-Monitoring Heart Rate and Physical Activity Wearable Devices. *JMIR Mhealth Uhealth* 2017 Mar 16;5(3):e34 [FREE Full text] [doi: [10.2196/mhealth.7043](#)] [Medline: [28302596](#)]
14. Wang R, Blackburn G, Desai M, Phelan D, Gillinov L, Houghtaling P, et al. Accuracy of Wrist-Worn Heart Rate Monitors. *JAMA Cardiol* 2016 Oct 12. [doi: [10.1001/jamacardio.2016.3340](#)] [Medline: [27732703](#)]
15. Fitbit. URL: <https://www.fitbit.com/home> [accessed 2017-05-29] [WebCite Cache ID 6qp1DYZq5]
16. Klein I, Trzepacz P, Roberts M, Levey G. Symptom rating scale for assessing hyperthyroidism. *Arch Intern Med* 1988;148(2):4776-4790. [doi: [10.1001/archinte.1988.00380020131018](#)]
17. Lee JE, Lee DH, Oh TJ, Kim KM, Choi SH, Lim S, et al. Validity and Reliability of the Korean Version of the Hyperthyroidism Symptom Scale. *Endocrinol Metab (Seoul)* 2018 Mar;33(1):70-78 [FREE Full text] [doi: [10.3803/EnM.2018.33.1.70](#)] [Medline: [29589389](#)]
18. Fitbit. URL: <http://dev.fitbit.com> [accessed 2017-11-07] [WebCite Cache ID 6unGRzA5T]
19. Lee JE, Lee DH, Oh TJ, Kim KM, Choi SH, Lim S, et al. Clinical Feasibility of Continuously Monitored Data for Heart Rate, Physical Activity, and Sleeping by Wearable Activity Trackers in Patients with Thyrotoxicosis: Protocol for a

- Prospective Longitudinal Observational Study. *JMIR Res Protoc* 2018 Feb 21;7(2):e49 [FREE Full text] [doi: [10.2196/resprot.8119](https://doi.org/10.2196/resprot.8119)] [Medline: [29467121](https://pubmed.ncbi.nlm.nih.gov/29467121/)]
20. Klein I, Danzi S. Thyroid disease and the heart. *Circulation* 2007 Oct 09;116(15):1725-1735 [FREE Full text] [doi: [10.1161/CIRCULATIONAHA.106.678326](https://doi.org/10.1161/CIRCULATIONAHA.106.678326)] [Medline: [17923583](https://pubmed.ncbi.nlm.nih.gov/17923583/)]
 21. Basu G, Mohapatra A. Interactions between thyroid disorders and kidney disease. *Indian J Endocrinol Metab* 2012;16(2):204-213. [doi: [10.4103/2230-8210.93737](https://doi.org/10.4103/2230-8210.93737)]
 22. den Hollander JG, Wulkan RW, Mantel MJ, Berghout A. Correlation between severity of thyroid dysfunction and renal function. *Clin Endocrinol (Oxf)* 2005 Apr;62(4):423-427. [doi: [10.1111/j.1365-2265.2005.02236.x](https://doi.org/10.1111/j.1365-2265.2005.02236.x)] [Medline: [15807872](https://pubmed.ncbi.nlm.nih.gov/15807872/)]
 23. Duntas LH, Brenta G. The effect of thyroid disorders on lipid levels and metabolism. *Med Clin North Am* 2012 Mar;96(2):269-281. [doi: [10.1016/j.mcna.2012.01.012](https://doi.org/10.1016/j.mcna.2012.01.012)] [Medline: [22443975](https://pubmed.ncbi.nlm.nih.gov/22443975/)]
 24. Heimberg M, Olubadewo JO, Wilcox HG. Plasma lipoproteins and regulation of hepatic metabolism of fatty acids in altered thyroid states. *Endocr Rev* 1985;6(4):590-607. [doi: [10.1210/edrv-6-4-590](https://doi.org/10.1210/edrv-6-4-590)] [Medline: [3908084](https://pubmed.ncbi.nlm.nih.gov/3908084/)]
 25. Kyriacou A, McLaughlin J, Syed AA. Thyroid disorders and gastrointestinal and liver dysfunction: A state of the art review. *Eur J Intern Med* 2015 Oct;26(8):563-571. [doi: [10.1016/j.ejim.2015.07.017](https://doi.org/10.1016/j.ejim.2015.07.017)] [Medline: [26260744](https://pubmed.ncbi.nlm.nih.gov/26260744/)]
 26. Malik R, Hodgson H. The relationship between the thyroid gland and the liver. *QJM* 2002 Sep;95(9):559-569. [Medline: [12205333](https://pubmed.ncbi.nlm.nih.gov/12205333/)]
 27. Dorgalaleh A, Mahmoodi M, Varmaghani B, et al. Effect of thyroid dysfunctions on blood cell count and red blood cell indice. *Iran J Ped Hematol Oncol* 2013;3(2):73-77 [FREE Full text] [Medline: [24575274](https://pubmed.ncbi.nlm.nih.gov/24575274/)]
 28. Kurata Y, Nishioeda Y, Tsubakio T, Kitani T. Thrombocytopenia in Graves' disease: effect of T3 on platelet kinetics. *Acta Haematol* 1980;63(4):185-190. [Medline: [6771949](https://pubmed.ncbi.nlm.nih.gov/6771949/)]
 29. Kolawole BA, Ikem RT, Lawal OO. Relationship between thyroid hormone levels and hyperthyroid signs and symptoms. *Nig J Clinical Practice* 2002;5(1):29-31 [FREE Full text]
 30. Trzepak PT, Klein I, Roberts M, Greenhouse J, Levey GS. Graves' disease: an analysis of thyroid hormone levels and hyperthyroid signs and symptoms. *Am J Med* 1989 Nov;87(5):558-561. [Medline: [2816972](https://pubmed.ncbi.nlm.nih.gov/2816972/)]
 31. Torkamani A, Andersen KG, Steinhubl SR, Topol EJ. High-Definition Medicine. *Cell* 2017 Aug 24;170(5):828-843. [doi: [10.1016/j.cell.2017.08.007](https://doi.org/10.1016/j.cell.2017.08.007)] [Medline: [28841416](https://pubmed.ncbi.nlm.nih.gov/28841416/)]
 32. Kim YA, Cho SW, Choi HS, Moon S, Moon JH, Kim KW, et al. The Second Antithyroid Drug Treatment Is Effective in Relapsed Graves' Disease Patients: A Median 11-Year Follow-Up Study. *Thyroid* 2017 Dec;27(4):491-496. [doi: [10.1089/thy.2016.0056](https://doi.org/10.1089/thy.2016.0056)] [Medline: [28001121](https://pubmed.ncbi.nlm.nih.gov/28001121/)]
 33. Haugen BR, Alexander EK, Bible KC. 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer. *Thyroid* 2016;26(1):1-133. [doi: [10.1089/thy.2015.0020](https://doi.org/10.1089/thy.2015.0020)]
 34. Cho SW. Effects of Thyroid Stimulating Hormone on Bone Metabolism. *Int J Thyroidol* 2016;9(2):127-130. [doi: [10.11106/ijt.2016.9.2.127](https://doi.org/10.11106/ijt.2016.9.2.127)]
 35. Flynn RW, Bonellie SR, Jung RT, MacDonald TM, Morris AD, Leese GP. Serum thyroid-stimulating hormone concentration and morbidity from cardiovascular disease and fractures in patients on long-term thyroxine therapy. *J Clin Endocrinol Metab* 2010 Jan;95(1):186-193. [doi: [10.1210/jc.2009-1625](https://doi.org/10.1210/jc.2009-1625)] [Medline: [19906785](https://pubmed.ncbi.nlm.nih.gov/19906785/)]
 36. Klein HEN, Klein HMS, de BGH, et al. Long-term cardiovascular mortality in patients with differentiated thyroid carcinoma: an observational study. *J Clin Oncol* 2013 Nov 10;31(32):4046-4053. [doi: [10.1200/JCO.2013.49.1043](https://doi.org/10.1200/JCO.2013.49.1043)] [Medline: [24101052](https://pubmed.ncbi.nlm.nih.gov/24101052/)]
 37. Detect thyroid disease by your biosignals. URL: <http://thyroscope.org> [accessed 2018-07-04] [WebCite Cache ID 70fA8bi71]

Abbreviations

ANOVA: analysis of variance

ATD: antithyroid drug

CRF: case report form

DTC: differentiated thyroid cancer

GD: Graves' disease

GEE: generalized estimating equation

HR: heart rate

HSS: Hyperthyroidism Symptom Scale

IQR: interquartile range

JSON: JavaScript object notation

OR: odds ratio

SNUBH: Seoul National University Bundang Hospital

T3: triiodothyronine

T4: thyroxine

TFT: thyroid function test

TSH: thyroid hormone stimulating hormone

WD-rHR-Fitbit: resting heart rate from wearable device derived by Fitbit algorithm

WD-rHR-own: resting heart rate from wearable device derived by own algorithm

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