AHRQ Grant Final Progress Report

Title of Project:

Diabetes and Depression Text Messaging Intervention (DIAMANTE)

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R01 HS25429 - Diabetes and Depression Text Messaging Intervention (DIAMANTE) - Final Report

Structured Abstract

Purpose: Improving Diabetes and Depression Self-Management via Adaptive Mobile Messaging (DIAMANTE) sought to develop and test a personalized motivational text messaging intervention to improve management of comorbid diabetes and depression with an emphasis on low-income populations (conducted in both English and Spanish).

Scope: The project implemented personalized motivational text messaging to improve management of comorbid diabetes and depression amongst patients from primary care clinics with the San Francisco Health Network (SFHN) and via online recruitment. The project focused on English and Spanish speaking low-income patients 18 years or older.

Methods: In a three-arm randomized controlled trial, we plan to examine the effect of a text-messaging smartphone application to encourage physical activity in low-income ethnic minority patients with comorbid diabetes and depression. The adaptive intervention group received messages chosen from different messaging banks by a reinforcement learning algorithm. The uniform random intervention group received the same messages but chosen from the messaging banks with equal probabilities. The control group received a weekly mood message. We will compare passively collected daily step counts, self-report PHQ-8 and most recent hemoglobin A1c from medical records at baseline and at intervention completion at 6-month follow-up.

Results:

The results of the primary question regarding differences in step counts are not yet available due to the study not ending until December 2022. Results will be forthcoming in early 2023 for the primary outcomes. We successfully enrolled a total of 196 participants, 72 from primary care clinics and 124 from social media recruitment.

Key Words: telemedicine, health informatics, depression & mood disorders, diabetes & endocrinology, digital literacy, underserved, digital divide, patient-centered, digital health, mhealth, intervention, telehealth, COVID-19

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Purpose

The main aim of the 'Diabetes and Mental Health Adaptive Notification Tracking and Evaluation' trial (DIAMANTE) was to test a smartphone intervention that generated adaptive messaging, learning from daily patient data to personalize the timing and type of text messages. We compared the adaptive content to (1) a uniform random messaging intervention, in which the messaging content and timing will be delivered with equal probabilities (ie, not adapted by a learning algorithm), (2) a control condition that only delivers a weekly mood message. The primary outcomes for this aim will be improvements in physical activity at 6-month follow-up defined by daily step counts.

We investigated the following specific aims in the study:

Aim 1: Conduct user testing of the DIAMANTE platform in English and Spanish.

We conducted three iterative phases of User Centered Design (UCD) testing with ten patients each (n=30).

The goal of the first UCD phase was to identify key messages that will motivate physical activity behavior change for diverse patient populations. Patients participated in 1.5-hour individual semi-structured interviews to identify barriers and facilitators to physical activity. They participated in a card sorting activity and provided feedback on messages they liked, those they disliked, and those they were neutral towards. Findings from phase 1 were used to inform content and information delivery decisions of the final intervention including selecting the thematic message categories and the design decisions.

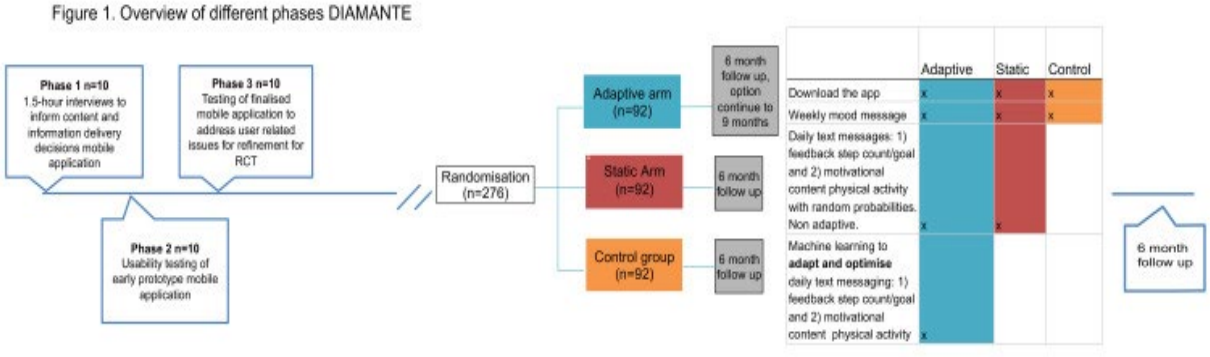
The second phase UCD aimed to evaluate the perceived ease of use and usefulness according to the Technology Acceptance Model (TAM), as these are two key determinants of eventual use of a technological system. In this phase, patients participated in receiving text messages for 2-weeks and providing feedback on the text messages and on their participation in the program.

In the third phase of UCD, patients received the entire platform for an "in the wild" evaluation for a 2-week period. Data collected during this phase was used for the reinforcement learning algorithm to begin "training". After this brief initial collection of data, the algorithm began sending individual messages that took into consideration previous outcomes. Patients were contacted after 1 week throughout this evaluation and completed an interview that addresses components of the TAM as well as usability. Additionally, we met with 3 groups consisting of 2 to 3 clinicians to obtain

feedback on the DIAMANTE intervention. We showed clinicians the existing website and dashboard as well as mock-ups and low fidelity prototypes of future iterations.

The third phase tested out the final DIAMANTE intervention including thematic message content and finalized application in order to address any user-related issues prior to launching the randomized control trial (see figure 1 for an overview of the different UCD phases and the RCT).

Figure 1. Overview of different phases DIAMANTE



Aim 2: Evaluate the effectiveness of adaptive vs. static messaging intervention. The first goal of the randomized trial was to study the influence of personalized text messaging on both glycemic control and depressive symptoms. For the randomized trial, we recruited 196 adults from primary care clinics within the San Francisco Health Network and through social media recruitment. (Note, we are still collecting data until December 2022).

During the randomized control trial, we investigated the following hypothesis:

Primary hypothesis: We expected that the group receiving adaptive messaging had a statistically significant higher increase in step counts over the 6-month intervention period, compared with both the group receiving the uniform random messaging and the control group receiving only a weekly mood message. We expected that both the adaptive and the uniform random messaging groups had a higher increase in step counts than the control group.

Secondary hypotheses

- We expected that the group receiving adaptive, personalized messages had a significant reduction in hemoglobin A1c (HbA1c) levels, depression scores, weekly mood ratings, higher behavioral activation, lower rumination and anxiety, more positive attitudes about PA and higher self-efficacy to manage chronic diseases at 6 months, compared with the group that received the uniform random messaging intervention and the control group.

- Exploratory: because of the unique nature of the patient population enrolled in our study, we expected to find differences by language (English vs Spanish). Language has been shown to be especially influential in mobile technology uptake and effectiveness in our previous work.[1] Spanish speakers may engage more in the mobile intervention and might have different motivations for becoming physically active, which might result in differences in effectiveness of the various messages.

Aim 3: Evaluate the effectiveness of phone outreach for non-responsive participants. The secondary goal of the trial is to evaluate the influence of phone outreach on glycemic control and depressive symptoms for participants who are non-responsive to the text messaging approaches used in this study.

Scope

Background

Both depression and diabetes are highly prevalent, often co-occurring diseases that are among the major causes of global disability. [2-4] Comorbid diabetes and depression are associated with a worse prognosis of both diseases, including a higher rate of complications of diabetes, greater disability and an increased risk of mortality.[5] Vulnerable populations, including low-income, low health literacy and ethnic minority individuals experience higher prevalences and worse outcomes for both diabetes and depression. [6 7] There is a great need for the development of treatments that can target overlapping risk factors for diabetes and depression. A growing body of evidence suggests that physical activity (PA) is such a risk factor: it is linked to both mental health and diabetic outcomes. [8 - 12]

Mobile applications have been found effective in helping patients engage in healthy behaviors including PA. For instance, a recent meta-analysis of nine RCTs concluded that smartphone apps that focus on PA have a moderate positive effect on increasing PA levels, and another meta-analysis including 18 studies moderate-to-large effect in daily step changes.[13 14] These effect sizes are similar to 'face-to-face' interventions.[15] However, because around 70% of lower income Americans (including Latinos) currently own smartphones, [16] and the ownership of smartphones is expected to increase in low-income populations globally,[17] mobile apps have great potential to reach individuals that normally do not have access to care. Further, mobile technology can help overcome existing barriers in access to care for vulnerable populations, including lower availability of psychological treatment in primary care settings, language and literacy barriers, stigma, cost and inflexible

employment schedules.[18] Latinos in the USA in particular show higher underutilisation rates of mental health treatment than non-Latino whites.[19] Deploying effective mobile applications can therefore decrease existing decrease disparities in health.

However, in the US, low-income minority patients frequently receive their care in safety net settings (services in the public sector for those unable to attain private health insurance), where novel mobile technologies are not often designed, developed or implemented.[20] This translational gap increases the probability that these interventions will ultimately fail when implemented in actual clinical settings that serve vulnerable populations.

Further, most mobile applications that target behavioral changes are not personalized,[21] which could contribute to lower effect sizes of these interventions for trials with longer study durations (eg, over 3 months).[13] Smartphone interventions allow for data collection by passive sensing technologies, which offer an opportunity for tailoring and personalizing interventions to users' behaviors, preferences and needs. Personalisation can be achieved by computer tailoring: tailoring interventions to observed behavior and characteristics of the participant. This can include feedback, goal setting or user targeting (ie, conveying that communication is designed specifically for the user).[22] However, more complex forms of personalisation might be needed to increase and maintain engagement with PA interventions,[23] a requirement for a digital intervention to be effective.

One promising approach is to use adaptive learning, which allows the prediction of which content might be effective for users, learning from its previous actions and participant data collected by mobile phones.[24] For instance, an adaptive learning algorithm might be more effective as it can match motivation needs for each participant. Some intervention studies have attempted cultural tailoring to large groups of people. However, most tailoring approaches occur at the group level whereas we are bringing the tailoring down to the individual level.[25] Research on the efficacy of these adaptive treatments is still in its early stages.

Population

Patients were recruited within Zuckerberg San Francisco General hospital (ZSFG) and various clinics, including the Richard Fine People's Clinic, the Family Health Center, in the San Francisco Health Network which is operated by the Department of Public Health in San Francisco, California that served as the study sites for this trial. Several clinicians and endocrinologist providers at ZSFG

helped identify patients. These clinics serve a diverse, chronically ill population and, as in many public hospital settings, they employ multiple part-time providers, creating the risk for lack of continuity of care that mobile health programs may be able to supplement. Social media and online recruitment methods were added in December 2020 as a result of recruitment complications due to COVID-19. Ads targeted various cities within the United States.

Inclusion criteria

Patients aged 18–75 years who have been diagnosed with diabetes and documented depression and/or depressive symptoms with a score >5 on the PHQ-9, as determined by their medical health records, were eligible for this study. Eligible patients needed to use text messaging and have an iPhone or Android smartphone in order to download the pedometer app onto their phones, but they did not need to be proficient in using mobile phone applications. Concomitant care and interventions were permitted during the trial.

Exclusion criteria

We excluded patients with an inability to exercise due to physical disability; active psychosis or mania; active suicidal ideation; severe cognitive impairment; inability to read and write in English or Spanish; current pregnancy; planned to leave the country for extended periods of time during the 6-month trial.

Methods

Design

This study is a randomized, controlled trial with three groups and a primary endpoint of increase in daily number of steps during a 6-month intervention delivered by a smartphone app. Randomization was performed as block randomization with a 1:1:1 allocation. Patients were automatically randomized into groups through our secure server during onboarding of the app, thereby ensuring allocation concealment. Patients were informed of the nature and frequency of the messages they would be receiving and were allowed to discuss this with investigators during the course of the study. Further, if messages were not being sent out appropriately, research assistants contacted the app developer to address errors within 24 hours. If PA data did not come in, research assistants contacted participants to ensure that the app was actively running on their phone and assisted participants with redownloading the app if necessary. The necessity of these steps made it unfeasible to blind the researchers. We used the Standard Protocol Items: Recommendations for Interventional Trials checklist when writing our report.

Recruitment

Patients were recruited by direct provider referrals, in-person clinic recruitment timed to eligible patient visits and through social media advertisements. To identify potentially eligible patients, we asked for permission from known providers to pull patient lists, and review and identify patients with diagnosis of diabetes and depression that fit our inclusion criteria (eg, is able to walk and is not pregnant).

Baseline visit

A researcher asked patients if they are interested in joining a study to increase PA and help manage their mood using their mobile phone. Interested individuals were invited into our offices at ZSFG for a baseline study visit and to obtain informed consent in Spanish or English. Thereafter, we collected all baseline survey measures of interests as well as patient demographics and information about current mobile technology familiarity and utilization. All patients received assistance in downloading a pedometer application onto their phone and sent test text messages back to our system. The researcher constructed a plan for PA goals with the patient and instructed patients to have the app open at all times. Thereafter, users were automatically randomized by the secure server, using a block randomization with block size 3 to allocate individuals into either the uniform random, adaptive or control group.

Partial patient and public involvement

Patients worked with us to design the text messages, mobile app user interface and were asked to assess the burden and time commitment of the study, as part of our user-centered design approach. We did not involve patients in other areas of the study design.

Measures

Our primary outcome, change in daily step counts, was passively collected by a mobile phone application during the time that patients remain in the intervention. For secondary outcomes, we derived HbA1c, the average plasma glucose over the previous eight to 12 weeks, recommended as a means to diagnose diabetes,[26] from patients' electronic health records (EHR). We used the most recent, available measurement from a maximum of 12 months before participating in the study. After 6 months, we again assessed the most recent HbA1c (pulling from patients' EHR), ensuring that at least 3 months elapsed between baseline and follow-up HbA1c levels. For additional secondary outcomes, we administered a survey at baseline and 6-month follow-up.

The project coordinator and research assistants were responsible for managing patient data collection. Data was stored on UCSF Qualtrics and the HealthySMS platform. Once data from all patients are collected, it will be stored on UCSF's Secure Box, a secure cloud-hosted platform.

Engagement measures

In addition to PA and the measures mentioned above, we also examined engagement measures, such as (1) times that the app was opened (2) time spent reading the messages (3) usability data, assessed by the Systems Usability Scale [27] and open-ended qualitative questions about their opinions of the app.

Interventions

We employed a mobile phone app, 'DIAMANTE' developed by Audacious Software (https://diamante.healthysms.org/). This application tracks step counts by pooling from Google Fit, Apple HealthKit or the built-in pedometer on patients' phones. We used a text-messaging platform HealthySMS, previously developed by Dr. Aguilera and Audacious Software, to send text messages and manage patient responses back to our system. The app only needed to be installed once, but had to remain open consistently. The app is designed in English and Spanish versions and is freely available as a download from the Apple App Store and Android Google Play application.

Figure 1 shows the different intervention groups during the trial period. Briefly, both the adaptive and uniform random group received the same types of messages: feedback (four active categories plus no message) and motivation (three active categories plus no message). However, the message categories, timing and frequency were optimized by a reinforcement learning (RL) algorithm in the adaptive group, and were delivered with equal probabilities in the uniform random group (following a uniform random distribution). The control group did not receive these messages (only a weekly mood check-in message). All groups had the app downloaded on their phone and their steps were passively tracked within the app. See figure 1 for an overview.

Control condition

Control patients only installed the app on their phone and did not receive any feedback messages. They received one message a week, on a fixed day, asking them to assess their mood in the previous week on a scale of 1–9. The message was sent weekly at 10:00. Non-responders received reminders to submit their mood self-assessments in 2 hours intervals.

Uniform random message arm

We sent patients up to two messages per day within four randomly selected time intervals. These

messages are based on the COM-B framework (examples shown in table 2A,B). In addition, they received one message, on the seventh day, which asked patients to rate their mood on a scale from 1 to 9. PA (step-count/day) was passively monitored via the app on their smartphone.

Table 2 - Daily motivational and feedback messages DIAMANTE study

A: Different categories with feedback messages that the algorithm chooses from	
Feedback Messages	Examples
0: No feedback message	
1: Reaching goal	"Yesterday, you did not reach your goal"
2: Steps waled yesterday	"Yesterday, you walked 3824 steps"
3: Walked more/less today than yesterday	"Yesterday, you waled more than your goal"
4: Steps waled yesterday, plus a positive/negative motivational message	"You walked 8000 steps yesterday. Great job!"

B: Different categories with motivational messages that the algorithm chooses from	
Motivational Messages	Examples
0: No message	
1: Capability, describes the physical and psychological benefits of walking and exercise	"Doing more physical activity can help reduce feelings of fatigue"
2: Motivation, meant to increase self-confidence and the belief that one is capable of walking even in the face of challenges	"You have made changes to improve your health before, you can do it again"
3: Opportunity, physical and social environment cues that make it more likely to engage in walking	"Is there a local park you have been waiting to visit? Use it as an opportunity to get out of the house and do more steps!"

The algorithm can also choose not to send a message (category no feedback).
The algorithm can also choose not to send a message (category no motivation).

Adaptive message arm

Patients in the adaptive messaging arm received the daily COM-B messages (equal to the uniform random arm, examples shown in table 2A,B), but the message categories, timing and frequency, were not chosen randomly, but by using an RL algorithm. This allowed us to adequately assess whether differences in effects are driven by the use of the RL algorithm. In addition, they received one message, on the seventh day, which asked patients to rate their mood on a scale from 1 to 9. PA (step-count/day) was actively monitored via the app on their smartphone.

Patients in all groups received reminders to open the app if no data are being transmitted. Additionally, patients in all groups could reply 'STOP' or 'PARAR' if they wished to stop receiving messages. Finally, the researchers monitored the incoming step data. The researchers contacted the patients by phone for troubleshooting if patients' phones were not transmitting data for more than 3 days.

Adaptive learning algorithm

We developed an RL algorithm (an area of machine learning) based on previous work.[28] On a daily basis, this algorithm assessed (1) which feedback message (table 2A), (2) which motivational message (table 2B) and (3) which time period of the day (in intervals of 2.5 hours from 09:00 to 19:00) is predicted to maximize the number of steps walked the next day. We used algorithms for contextual multi armed bandit (MAB) problems, as these have been employed in different domains (including mobile health) and show promise to maximize cumulative rewards in sequential decision tasks (here, which sequences of messages optimally promote PA).[29] A contextual MAB problem is an RL setting in which the algorithm chooses between different treatment options which all have different reward functions. The reward functions depend on contextual variables.

We used Thompson Sampling, a Bayesian method, which allowed us to continuously learn which feedback and motivational messages were effective for a user, based on contextual features like their previous PA, demographic and clinical characteristics (such as age, gender and PHQ-8 scores). Thompson sampling effectively dealt with small amounts of data and addressed the exploration/exploitation tradeoff. [30] As such, it frequently picked out from the most rewarding messages and occasionally explored the messages with uncertainty in their reward.

More specifically, each morning, the algorithm evaluated which messages would likely increase the PA for every participant in the upcoming day, and at which time period the messages should be delivered. The algorithm training data consisted of the historical data of all participants (contextual variables), which included which messages were sent previously and within which time periods, and select clinical/demographic data (such as age, language and depression scores) to improve prediction abilities.

During the trial, patients received messages for 6 months. After 6 months, provided patients the possibility to remain receiving messages for up to 9 months.

Results

SA - 1 User Centered Design

We completed the UCD in Aim 1 by the second year of the grant and published two manuscripts. Our application was "live" in both the App Store and Google Play for download. A manuscript on the design process, given that we were able to use participant feedback, crowdsourced data from mTurk, and health behavior theory to finalize the text-messages in English and Spanish for our RCT.

SA 2 - Randomized control trial

We also published our RCT study protocol in BMJ Open (https://bmjopen.bmj.com/content/10/8/e034723). The manuscript provides a detailed account of the hypotheses, rationale, and methodology of the study at the launch of the trial in January 2020.

Reinforcement learning model

We developed another scientific paper detailing the scientific decisions encountered when finalizing our reinforcement learning algorithm used in this study. This was published in JAMIA in February 2021: https://pubmed.ncbi.nlm.nih.gov/33657217/. In summary, our final reinforcement learning algorithm personalized feedback and motivational text messages to send for the adaptive arm of our RCT. On a daily basis, this algorithm assesses 1) which feedback message, 2) which motivational message, and 3) which time period of the day (in intervals of 2.5 hours from 9am to 7pm) is predicted to maximize the number of steps walked the next day.

Recruitment

To date, we recruited San Francisco Health Network patients from an active list of over 600 patients with diabetes and depression that speak English or Spanish, and over 40 providers review their own patients from this list to facilitate our study recruitment.

During the second week of February 2020, our research staff began to actively recruit patients to participate in the randomized trial, using detailed verification of eligibility criteria and meticulous training of all research assistants. We recruited a total of 15 participants during the first four weeks of in-person RCT recruitment prior to the COVID pandemic.

We then had to pause recruitment after the COVID-19 social distancing orders in the California Bay Area in early March of 2020 and get IRB approval to switch all recruitment steps to remote processes via phone and Zoom. This process was challenging given the digital literacy barriers of our patient population, who were no longer able to receive our in-person assistance with downloading our DIAMANTE app onto their smartphones. To circumvent these challenges, we reformatted all

onboarding processes to add remote assistance for our patients in learning to use Zoom and download apps onto their smartphones themselves. We also created a new recruitment protocol to emphasize one-on-one staff-patient partnerships to provide this specialized technical assistance personalized to each patient's digital skills. Using research staff's expertise and training, along with patient insight, we increased access to the intervention and created the infrastructure to offer technical assistance.

The adaptation of previous in-person study procedures to remote practices took place from March to April 2020. As an initial step, we analyzed the digital profiles—including digital literacy and device or broadband access—of patients who participated in our previous pre–COVID-19 in-person sessions (hereafter referred to as the pre–COVID-19 cohort). Following the analysis, research staff met to discuss personal experiences encountered during previous in-person onboarding sessions. Analysis and feedback allowed us to address the most relevant barriers to and facilitators of an internet-based remote visit. The results led us to alter our study procedures to orient patients to download the digital health application being studied via an internet-based remote visit (ie, by using the Zoom video conferencing software or during a phone call). The project coordinator conducted several educational meetings to introduce and share the rough outlines of the new study procedures with the entire research team. Several amendments were made to these outlines based on onboarding research staff's feedback and internal piloting efforts.

The final versions were then used to enroll eligible patients into a complete, digitized version of the clinical trial during the period of social distancing in the context of the COVID-19 pandemic (hereafter referred to as the COVID-19 cohort), from April 2020 to June 2021. Enrolled patients who were able to attend a remote onboarding visit were asked about the new remote recruitment processes, and their feedback was both audio-recorded and documented with detailed field notes. Following California's lift of all stay-at-home orders in June 2021, along with changes in university policies that allowed for in-person research activities. We offered a hybrid model, where patients could choose to complete in-person and/ or remote enrollment. This also allowed research staff to recruit from clinics in-person.

Finally, in December 2020, we added additional online-only recruitment methods that allow for the self-enrollment of eligible participants that meet our existing DIAMANTE study criteria. Using Craigslist, Facebook, Google Ads we were able to enroll 125 additional participants nationwide.

Our final recruitment totals for the DIAMANTE RCT, combining SFHN patients and online participants, is n=197.

Discussion

In this randomized controlled trial, we aimed to examine the effect of a smartphone app that uses RL to predict the most effective messages for increasing PA in 196 low-income, ethnic and racial minority patients with diabetes and depression in urban public sector primary care clinics. We compared this intervention to uniform random messages, delivered with equal and unchanging probabilities, and a control group that only receives a weekly mood message.

Decreasing health disparities

Though the numbers of mHealth pilot studies are increasing in vulnerable populations, many of these fail to follow through with an implementation component to the study design.[31] Here, we used a blended design: while the intervention is in addition to current care, there are ways we are attempting to make it more a part of patients' clinical care. For instance, patients are mainly approached through primary care health providers, which recommend eligible patients whom they think are directly interested in a PA intervention. In addition, we will make patients' data available to providers: a summary of the step increase for that patient at the conclusion of the study and updated PHQ-8 and GAD scores entered into the record. Our study therefore is the first step to addressing this gap because of its integration in primary care clinics that serve low-income patients. Future work should focus more specifically on implementation of the app as part of routine clinical care.

PA measure

We chose passively collected daily step count from patients' preowned digital devices as a measure of PA. Although there are many different ways to measure PA, daily step count seems to be a particularly relevant measure because of: (1) its relative ease to measure, and (2) the clinical importance of individuals' walking behavior. Low number of daily step counts have been associated with all-cause mortality in some longitudinal studies[32] and results from pooled population studies show clear dose–response effects of PA to overall mortality.[33] In patients with type 2 diabetes, several studies have now shown that increasing step counts can significantly decrease HbA1c levels. For instance, a 10 000 steps per day walking prescription increased steps and decreased HbA1c in patients with type 2 diabetes.[34] Further, Manjoo *et al* found that each SD increase in daily steps was associated with a 0.21% decrease in HbA1c.[35] However, negative findings have also been reported. For instance, a meta-analysis by Qiu *et al* found that step-counter use was associated with increased

steps per day (over 1800 more steps compared with a control group) among people with diabetes, but not with lowering of HbA1c.[36]

In exploratory post hoc analyses, we will also be able to examine the more immediate effect of PA messages, for example, on hourly steps in addition to daily steps, which will help to improve future PA interventions (eg, deliver messages at the right times). For instance, it is possible that one could receive a message in the morning and make plans to walk in the afternoon or evening, or messages could have more of an immediate impact. This information is currently unknown.

Personalization of intervention

The results of this RCT will help us understand if adaptive mHealth interventions for depression and diabetes are more beneficial than interventions that do not use learning algorithms. If mHealth interventions are not personalized, their efficacy might be low, due to low engagement and high drop-out rates.[21] The use of machine learning to adapt interventions according to users' characteristics and behaviors is still in its early stages, but shows promise.[37] For instance, Yov-Tom *et al* using an adaptive learning algorithm found that adaptive feedback messages were more effective in increasing the amount and speed of PA and also reduced HbA1c in sedentary patients with type 2 diabetes. [40] Further, Zhou *et al* showed short-term efficacy of using adaptive weekly step goals determined by RL in healthy patients.[38] The current study, with a relatively large group of patients, will further increase our understanding of the potential of machine-learning-driven text-messaging interventions.

Limitations

First, the results of this study might be specific to this population of low-income ethnic minority patients and might therefore not be generalisable to other populations. However, the inclusion of vulnerable patients in a primary care setting increases the likelihood that this intervention will be effective for other underserved populations. Further, our study procedures do not allow a double-blind design, as researchers and patients need to be made aware of the nature and frequency of messages they are receiving. Additionally, as with all digital interventions, technical issues might arise leading to unreliable step-count data and reduced ability for the algorithm to predict the most effective messages.

Strengths

Diabetes and depression are among the top 10 causes of disability in the USA.[39] Developing cost-effective and scalable models of care for patients with common chronic conditions has been

postulated as of key importance in improving the performance of healthcare systems.[40] If mHealth apps that target diabetes and depression through their common risk-factor physical inactivity are effective, they can have a major public health impact. Further, because the learning algorithm that we apply in this study is automated and delivers adaptive messages based on patients' behaviors, it can potentially be applied in other patient populations with a wide range of conditions.

To conclude, the outcome of this trial will provide information on the effectiveness of a text-message-based smartphone app that uses machine learning to increase PA in low-income ethnic minority patients in primary care settings. The results will provide key information on the effectiveness of adaptive mobile applications, compared with more traditional static digital interventions. If effective, this application has the ability to decrease healthcare disparities by providing a type of personalized care to a diverse and traditionally hard to reach group of underserved patients.

List of Publications and Products

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Results from A Multi-Level Micro-Randomized Trial. Manuscript Accepted in Annals of Behavioral Medicine.

- Figueroa CA, Aguilera A, Chakraborty B, Modiri A, Aggarwal J, Deliu N, Sarkar U, Jay Williams J, Lyles CR. Adaptive learning algorithms to optimize mobile applications for behavioral health: guidelines for design decisions. J Am Med Inform Assoc. 2021 Feb 28:ocab001. doi: 10.1093/jamia/ocab001. Epub ahead of print. PMID: 33657217.
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