Protocol

A Pharmacist and Health Coach–Delivered Mobile Health Intervention for Type 2 Diabetes: Protocol for a Randomized Controlled Crossover Study

Lisa Kay Sharp[1], BSc, MA, PhD; Alana Biggers[2], MD, MPH; Rosanne Perez[2], BSc; Julia Henkins[2], BA, MPH; Jessica Tilton[3], PharmD; Ben S Gerber[2], BSc, MPH, MD

[1]Department of Pharmacy Systems, Outcomes & Policy, College of Pharmacy, University of Illinois at Chicago, Chicago, IL, United States

[2]Department of Medicine, Section of Academic Internal Medicine & Geriatrics, University of Illinois at Chicago, Chicago, IL, United States

[3]Department of Pharmacy Practice, College of Pharmacy, University of Illinois at Chicago, Chicago, IL, United States

Corresponding Author:
Lisa Kay Sharp, BSc, MA, PhD
Department of Pharmacy Systems, Outcomes & Policy, College of Pharmacy
University of Illinois at Chicago
833 S Wood St
Chicago, IL, 60611
United States
Phone: 1 3123553569
Email: sharpl@uic.edu

Abstract

Background: Aggressive management of blood glucose, blood pressure, and cholesterol through medication and lifestyle adherence is necessary to minimize the adverse health outcomes of type 2 diabetes. However, numerous psychosocial and environmental barriers to adherence prevent low-income, urban, and ethnic minority populations from achieving their management goals, resulting in diabetes complications. Health coaches working with clinical pharmacists represent a promising strategy for addressing common diabetes management barriers. Mobile health (mHealth) tools may further enhance their ability to support vulnerable minority populations in diabetes management.

Objective: The aim of this study is to evaluate the impact of an mHealth clinical pharmacist and health coach–delivered intervention on hemoglobin A_{1c} (HbA_{1c}, primary outcome), blood pressure, and low-density lipoprotein (secondary outcomes) in African-Americans and Latinos with poorly controlled type 2 diabetes.

Methods: A 2-year, randomized controlled crossover study will evaluate the effectiveness of an mHealth diabetes intervention delivered by a health coach and clinical pharmacist team compared with usual care. All patients will receive 1 year of team intervention, including lifestyle and medication support delivered in the home with videoconferencing and text messages. All patients will also receive 1 year of usual care without team intervention and no home visits. The order of the conditions received will be randomized. Our recruitment goal is 220 urban African-American or Latino adults with uncontrolled type 2 diabetes ($HbA_{1c} \geq 8\%$) receiving care from a largely minority-serving, urban academic medical center. The intervention includes the following: health coaches supporting patients through home visits, phone calls, and text messaging and clinical pharmacists supporting patients through videoconferences facilitated by health coaches. Data collection includes physiologic (HbA_{1c}, blood pressure, weight, and lipid profile) and survey measures (medication adherence, diabetes-related behaviors, and quality of life). Data collection during the second year of study will determine the maintenance of any physiological improvement among participants receiving the intervention during the first year.

Results: Participant enrollment began in March 2017. We have recruited 221 patients. Intervention delivery and data collection will continue until November 2021. The results are expected to be published by May 2022.

Conclusions: This is among the first trials to incorporate health coaches, clinical pharmacists, and mHealth technologies to increase access to diabetes support among urban African-Americans and Latinos to achieve therapeutic goals.

International Registered Report Identifier (IRRID): DERR1-10.2196/17170

XSL•FO
RenderX

KEYWORDS

mHealth; type 2 diabetes mellitus; community health workers; clinical pharmacists

Introduction

Background

Diabetes disproportionately affects African-American and Latino adults in the United States compared with Whites [1]. Not only is the prevalence of type 2 diabetes approximately 1.5 times greater, but diabetes-related outcomes are consistently worse. Aggressive management of blood glucose, blood pressure, and cholesterol through medication and lifestyle adherence is necessary to minimize adverse health outcomes [2,3]. However, fewer than 20% of African-Americans and Latinos reach all therapeutic goals [4-11]. Adherence to medication is generally poor [12]: 20%-30% of prescriptions are never filled (due to cost or concerns of side effects), and 50% of medications for chronic disease are not taken as prescribed [13-15]. Additional barriers to physical activity [16] and healthy eating [17] behaviors are common within urban neighborhoods where low-income African-Americans and Latinos reside. Access to healthy foods and safe areas for physical activity are often limited. As a result, adherence to the recommended diet and physical activity is low for a majority of minorities with type 2 diabetes [18,19]. Additional barriers to self-management among low-income, minority populations include low health literacy, depression, lack of social support, poor patient-clinician communication, limited access to health care, and language (particularly Latinos who prefer Spanish for communication with providers) [20-27].

Four large systematic reviews of intervention studies aimed at improving medication adherence have concluded that few existing interventions improved clinical outcomes beyond adherence alone [13,14,28,29]. In addition, the reviews highlighted concerns regarding the abundance of studies with small sample sizes and the underrepresentation of ethnic minorities, especially Latinos. Components of the most effective interventions often included behavioral strategies and incorporated pharmacists [30]. Pharmacist-led interventions enhance adherence to chronic disease medication and health behaviors through patient education, use of adherence aids, and addressing medication-related issues (eg, drug interactions and cost) [14,31-36]. Clinical pharmacists have expertise in medication management and the ability to adjust therapy in collaboration with providers [37-42]. Within the United States, most state boards of pharmacy authorize collaborative drug therapy management protocols between clinical pharmacists and prescribers [42-45].

More recently, 2 pragmatic studies of chronic disease management employed multifaceted interventions delivered by clinical pharmacists using telephone-based brief negotiated interviewing, a variant of motivational interviewing [46,47]. First, Choudhry et al [46] studied patients within a large multispecialty medical group including 488 patients with diabetes and others with hypertension or hyperlipidemia that were poorly controlled. A statistically significant improvement in medication adherence failed to translate into any significant improvement in clinical outcomes for patients with diabetes or the other chronic conditions. In the second study, Lauffenburger et al [47] enrolled members of the largest health insurer in New Jersey with similar results. However, in a secondary analysis of 196 participants with diabetes who completed at least one telephone pharmacy consultation, hemoglobin A_{1c} (HbA_{1c}) decreased (difference between intervention and propensity score matched comparison group: mean decrease in HbA_{1c} –0.48 with a 95% CI of –0.91, –0.05). Although both studies included ethnic minorities, subgroup analyses to explore the impact of the intervention based on ethnicity were not reported.

Health coaches (HCs) may extend the ability of clinical pharmacists to support medication adherence in low-income minority populations. HCs alone have been shown to contribute to improvements in diabetes self-management and HbA_{1c} levels [48-55]. Trained HCs are trusted by patients, understand sociocultural barriers, and can help increase the relevancy of disease self-management to individuals who manage competing priorities. Our previous research demonstrated that HCs can successfully collaborate with clinical pharmacists in addressing lifestyle and medication adherence [56], with unclear evidence of improved clinical outcomes [15]. In our initial efficacy trial of African-American and Latino patients with uncontrolled type 2 diabetes, we demonstrated a modest reduction in HbA_{1c} with pharmacist support alone (mean decrease in HbA_{1c} –0.45%; with a 95% CI –0.96, 0.05), which was similar to the change observed with HC-augmented pharmacist support (mean decrease in HbA_{1c} -0.42% with a 95% CI –0.93, 0.08). However, many participants did not fully engage with the pharmacists, which required transportation to the clinic for in-person visits. Importantly, 80.4% (152/189) of our study sample surveyed expressed interest in participating in a mobile health (mHealth) approach with pharmacists and HCs.

To address patients' feedback and enhance our clinical pharmacist and HC support, we designed this study, which incorporates mHealth (text messaging and videoconferencing) combined with in-person HC support. Videoconferencing in diabetes care is practical, potentially cost-effective, and reliable for disease management [46,57,58]. Despite the heterogeneity found in studies conducted in various countries with diverse patient populations, telemedicine interventions produce significantly better glycemic outcomes than usual care [59]. Videoconferencing with clinical pharmacists to promote medication adherence is a growing model in practice but is not well studied, particularly with mobile devices or involving urban, low-income minority patients [60,61]. Our inclusion of HCs to assist pharmacists in the delivery of videoconferencing services is further aimed at supporting adherence efforts and improving outcomes. In addition, HCs use text messaging to provide social support and improve self-efficacy and adherence. Text messaging interventions in diabetes management have shown encouraging results, targeting both medication adherence and lifestyle modification with a reduction in HbA_{1c} [60-64]. Although no specific text messaging components have been

linked to improved outcomes, follow-up contact, individualized frequency, and tailored content are likely important components [65,66].

Drawing upon the need to develop new models of care that address the needs of those most adversely impacted by diabetes, our team has developed an innovative clinical pharmacist and HC mHealth model to improve HbA$_{1c}$ (primary outcome). This model targets African-Americans and Latinos (both English- and Spanish-speaking) with uncontrolled diabetes [20,56]. This paper describes our currently implemented mHealth study protocol and includes a crossover randomized controlled trial.

Objectives

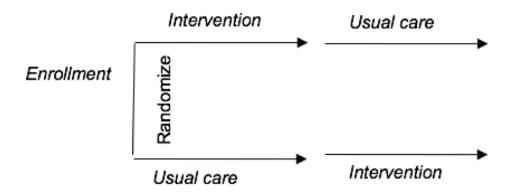The aim of this study is to evaluate the impact of an mHealth clinical pharmacist and HC intervention in African-Americans and Latinos with poorly controlled type 2 diabetes. We hypothesize that the mHealth intervention will improve HbA$_{1c}$, blood pressure, and low-density lipoprotein (LDL) as well as medication and lifestyle behavior adherence compared with usual care. In addition, the crossover design will test the hypothesis that improvements in outcomes resulting from the intervention in year 1 will be maintained during the maintenance period (usual care) in year 2.

Methods

Study Design

As shown in Figure 1, a randomized controlled crossover study will evaluate the effectiveness of an mHealth intervention delivered by a clinical pharmacist and HC versus a usual care group.

Figure 1. Randomized crossover study design.

The primary outcome is the change in HbA$_{1c}$ level. Secondary outcomes include changes in blood pressure and LDL cholesterol levels. Using a 1:1 ratio, we will randomize 220 patients to either (1) a mHealth intervention delivered by a clinical pharmacist and HC for 1 year, followed by usual care for 1 year, or (2) usual care for 1 year, followed by the mHealth intervention for 1 year. Both groups will crossover at the end of year 1, such that those receiving the mHealth intervention during the first year will receive usual care during the second year (to evaluate potential maintenance of outcome improvement). Similarly, those with usual care in year 1 will crossover to receive the intervention in year 2 (to ensure that all subjects are able to receive the intervention). Of note, we do not consider HbA$_{1c}$ levels collected at the end of year 1 when crossover occurs. The treatment received by patients (intervention or usual care) will change at the end of year 1, independent of HbA$_{1c}$ levels.

Separate randomization schedules generated in REDCap will be used for each of the 4 main clinical sites with stratification for ethnic group (African-American and Latino) and gender to balance the proportion of participants across randomized conditions. All study procedures have been approved by the University of Illinois at Chicago Institutional Review Board (IRB 2016-0380).

Setting and Recruitment

The study will be conducted at the University of Illinois Hospital and Health Sciences System (UI Health), which includes both inpatient and outpatient facilities serving an urban, largely minority population in Chicago. All outpatient sites share access to the electronic medical record (EMR), Cerner Powerchart.

An initial pool of potential patient participants will be identified through EMR queries and include all patients registered in 4 UI Health internal medicine or family practice clinics. Patients with a documented diagnosis of type 2 diabetes and HbA$_{1c}$≥8 in the last year will be targeted for recruitment. The study team will mail study introductory letters by post to those patients identified from the EMR queries meeting the two initial criteria. The letter explains that if the patient is not interested in being contacted by telephone regarding the study, they should either mail back the enclosed prepaid card or call the telephone number provided to indicate that they are not interested in being contacted further (*opt-out*). Individuals who do not *opt out* are called by a research assistant (RA) to determine study interest and assess eligibility. Eligible and interested patients are scheduled to complete written consent, Health Information Portability and Accountability Act (HIPAA) authorizations, and baseline data collection with a data collector at the Clinical Research Center at UI Health. Additional recruitment is completed by RAs present within the clinics who receive referrals directly from the staff. A study physician reviews patients' EMR to confirm eligibility (Textbox 1).

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria:

- Self-identified as Latino or Hispanic or African-American

- Verbal fluency in English or Spanish

- Latest hemoglobin A_{1c} ≥8.0% (within 6 months)

- History of type 2 diabetes (>1 year)

- Aged between 21 and 75 years

- Mobile phone or text messaging plan

- Agrees to home visits by health coach

- Receives primary care at clinical site (>1 year)

Exclusion criteria:

- Unable to verbalize comprehension of study or impaired decision making (eg, dementia)

- Lives outside Chicago (≥3 months/year)

- Household member already participating in same study

- Plans to move from the Chicago area within the next year

- Pregnant or trying to get pregnant

- Unable to send or read text message on mobile phone

- History or planned gastric bypass or transplant surgery

---

mHealth Intervention

Clinical Pharmacist

During the intervention year, patients receive pharmacist videoconferences facilitated by an HC who is in the patient's home with a tablet (iPad with cellular plan). The initial pharmacist encounter is scheduled after the HC has already conducted 1-2 home visits and lasts 60 minutes. The pharmacist initially reconciles medications via videoconferencing with HC assistance. Subsequent pharmacist encounters vary in frequency based on patient needs and range in length from 30 to 60 minutes. HCs schedule videoconference appointments during dedicated days or times when pharmacists are available. Videoconferences are conducted using VSee software. VSee transmits personal health information securely and is available for use on desktop computers and mobile devices providing real-time person-to-person audio and video communications. However, it is most suitable for health-related communication, as it is Food and Drug Administration registered and HIPAA compliant (using FIPS 140-2 certified 256-bit Advanced Encryption Standard). Finally, it uses *peer-to-peer* sessions so that information is not stored on a server.

Pharmacist services are based on a standardized pharmacist management protocol. After the initial medication reconciliation, follow-up pharmacist activities include reviewing home glucose and/or blood pressure, monitoring log data obtained by the HC during home visits, identifying therapeutic goals for HbA_{1c} and blood pressure collaboratively with patients' primary care providers (PCPs), formulating an approved plan of care, assessing changes in medications, and documenting the plan in the EMR. In addition, pharmacists provide education related to medication (name and purpose of medications and time, strength, and method of administration); drug interactions and side effects; goals of therapy; basic lifestyle modifications; and use of pillboxes, low-literacy visual medication lists, or other adherence aids. Pharmacists educate and encourage lifestyle changes, consistent with the published guidelines [67-69]. They propose medication changes based on algorithms and protocols derived from national guidelines under physician guidance [70-72]. Pharmacists routinely monitor hypoglycemic events, address prevention, and review treatments. This includes 3 steps: (1) addressing hypoglycemia with every patient contact, (2) applying principles of appropriate therapy (education, empowerment, frequent glucose self-monitoring, flexible medication regimen, individualized goals, and professional guidance), and (3) considering risk factors for hypoglycemia. Overall, there is mixed evidence regarding the benefits of aggressive glycemic control [73-75]. In the proposed study, PCPs and pharmacists adopt the American Diabetes Association approach to individualized care, where the general goal for nonpregnant adults is HbA_{1c} less than 7%. They may decide upon less stringent goals for those with a history of severe hypoglycemia, limited life expectancy, advanced complications, or extensive comorbid conditions [76]. In addition, pharmacists follow the 2018 American College of Cardiology or American Heart Association guidelines for lipid management (eg, calculating 10 year atherosclerotic cardiovascular risk to determine statin intensity) [77].

EMR Documentation and PCP Communication

PCPs and pharmacists communicate routinely regarding patient care and are located in the same area within the medical setting. Pharmacists review EMRs, including blood test results, clinical progress notes, problem and medication lists, drug allergies, hospitalization records, and emergency room reports. Nonurgent

communication and electronic progress notes from each pharmacist encounter will be sent to the PCP through inbox messaging and note forwarding within the EMR. Pharmacist progress notes include a detailed list of medications, estimated adherence levels, and home glucose or blood pressure monitoring log information.

Videoconference Training

Videoconferencing procedures in the intervention follow the American Telemedicine Association practice guidelines [68]: (1) pharmacist and patient/HC identity verification, (2) informed consent, (3) appropriate physical environment (privacy, lighting, and noise), (4) education and training (pharmacist and HC), (5) alternate communication (eg, telephone contact in case of disruption of service), and (6) documentation in UI Health EMR (by pharmacist and HC). All study pharmacists and HCs receive standardized training on the use of videoconferencing, which includes scheduling, preparing the environment (home or pharmacist office), patient education on telehealth, and documentation. All encounters have contingency plans in place for technology problems (eg, inadequate signal for video streaming through iPads), including the use of mobile phones for all HCs.

HC

HCs will introduce themselves to the patients in person at the data collection visit that aligns with the beginning of the patients' intervention year (ie, baseline visit or crossover visit at the beginning of year 2 depending on randomization). When possible, the first home visit will be scheduled at the initial introductory meeting. If this is not possible, the HC will follow up by telephone within 1 week to schedule the first home visit. All HCs are either African-American or bilingual or bicultural Latino and work with patients who are concordant for race or ethnicity and language. The HCs have an undergraduate college degree in or related to community health with experience conducting home visits. Specific training for the research study includes 80 hours of standardized HC training or retraining. As outlined in Textbox 2, training begins with an overview of the research protocol and discussion of the HC goals. The

fundamental components of providing health support to marginalized populations are addressed with the required reading materials, didactic presentations, and discussions [78].

HC training highlights the unique qualification of HCs to provide culturally sensitive support, tailor visits based on the personal preferences of participants, and assist patients in navigating the health care system [79,80]. Diabetes education follows the Diabetes Education Empowerment Program, which targets literacy and cultural awareness [81], and the Training Curriculum for Health Coaches [52,82]. Training includes shadowing a clinical pharmacist to understand medication use, adherence, glucose and blood pressure monitoring, insulin injection, and medication reconciliation. The study investigators provide training in videoconferencing (eg, scheduling and practice encounters), text messaging (eg, practice with the custom text messaging platform and standardized safety procedures), and conducting home visits in a culturally sensitive manner. Ongoing training is provided periodically on topics that reinforce and expand the initial training (eg, motivational interviewing and insulin management). HCs receive routine orientation to clinical operations and staff at their primary care locations. Standardized safety procedures related to text messaging and home visits are also addressed. To evaluate clinical skills, the HCs demonstrate reliable measurement of blood sugar, blood pressure, and administration of insulin (though HCs do not administer insulin to patients).

The HC component involves monthly home visits with ongoing telephone support, including the facilitation of all pharmacist videoconferences. The HCs work with the pharmacist to evaluate adherence (eg, check label instructions and fill and expiration dates of pill bottles), assist in medication reconciliation, review home glucose and/or blood pressure monitoring data, and provide reinforcement of proper medication use. Finally, HCs debrief patients after pharmacist encounters to reinforce and clarify recommendations and plans. HCs and pharmacists communicate with each other between videoconference encounters by phone or secure email, as needed, to coordinate efforts.

Textbox 2. Summary of health coach training.

Introduction to research study

- Project history and overview

- Study protocol

- Institutional Review Board and human subjects research training

Role of health coaches (HCs)

- Core competencies and roles of HCs

- Role of HCs in addressing health disparities

- Understanding trauma and supporting survivors

Navigating the health care system

- Primary care clinic workflow

- Navigating electronic medical record and encounter documentation

- Patient advocacy and empowerment

- "Closing the loop," connecting patients to care

Diabetes education

- Understanding diabetes and risk factors

- Disease pathophysiology, complications

Disease management

- Blood glucose monitoring

- Medication therapies for diabetes

- Medication reconciliation, adherence

- Treating hypoglycemic events

- Nutrition and physical activity education

Health coaching strategies

- Patient-centered collaboration

- Motivational interviewing

- Specific, measurable, achievable, relevant, and time-specific goals

- Stress reduction, coping with depression

Home visits and safety

- Ethical considerations, boundary setting

- Cultural humanity

- Safety guidelines and self-defense

Mobile health technology

- Videoconferencing software (VSee)

- MyTapp text messaging system

- Best practices for telehealth encounters

Home visits include the HC and patient. Family members are permitted by patient requests. Through open discussion and reflective listening, HCs encourage patients to explore their emotions and share their concerns [83]. Overall, HCs provide diabetes self-management education and support (DSME/S), consistent with the recommendations of the American Diabetes Association's position statement [83]. Specifically, HCs provide DSME/S that includes the following over the course of the 1-year intervention: engagement, information sharing, psychosocial and behavioral support, integration with other therapies, and coordination of care. Initial HC encounters focus on relationship building and gaining an understanding of the

patient's individualized diabetes education needs. HCs provide diabetes education and consider realistic and achievable food choices, portion sizes, and cooking preparation; discuss relationships between medications, meals, and glucose levels; and help patients integrate movement into their daily lifestyles. Diabetes education is facilitated by our culturally appropriate multimedia education iBook, *Living Well with Diabetes/Viviendo Bien con Diabetes* [84]. This iBook (available in English and Spanish) provides patients with video testimonials and various interactive educational experiences. HCs present specific chapters on an iPad to reinforce specific diabetes self-management concepts [84]. To promote behavioral change, HCs use motivational interviewing techniques to assist patients in setting specific health behavior change goals. Goals set jointly by HCs and patients follow the specific, measurable, achievable, relevant, and time-specific (SMART) framework [85]. Providing social support while helping patients engage with their existing support systems offers the potential of long-term behavior change beyond the duration of the research period. Educating patients on how to effectively navigate the health care system and use existing resources promotes continued self-efficacy. In summary, HC interactions are culturally tailored to individual needs, preferences, and resources to provide DSME/S [86].

By the end of the second month, HCs will facilitate a videoconference encounter with a pharmacist and patient to conduct a complete medication reconciliation. HCs work with patients to identify adherence barriers and assist in problem solving or referrals for resources aimed at overcoming recognized challenges in medication use. Finally, HCs document summaries of each encounter (with or without videoconferencing) in the EMR and forward notes electronically to PCPs and pharmacists.

Text Messaging

Between home visits, HCs will communicate with patients through telephone calls and text messaging. All text messages will be tailored by HCs and sent through a custom software app (*mytapp*). We developed *mytapp* for community-based health behavior research. *mytapp* sends messages immediately or at a scheduled date or time, recurrent messages (daily, weekly, or weekdays), group messages, or multiple question surveys. HCs receive training on *mytapp* and schedule messages for their patients regarding appointments and medications. HCs send messages to maintain motivation, elicit feedback on progress, and screen for barriers that may reduce the chance of success (Table 1). For example, a morning text message may ask a patient how they did on their goal the previous day.

No more than 7 messages are delivered weekly, except for optional medication reminders. For safety, patients are reminded that text messages are sent in an automated fashion by a computer. Furthermore, they are reminded that urgent health questions should be directed to their PCP and not sent in a text message. HCs monitor patient responses through their study phones.

Texts are monitored by the HCs with additional oversight by the project coordinator.

Table 1. Example text message templates.

Message type	Example
Medication reminder	"Hi, Ms. Brown, just checking to see if you took your morning pills."
Refill reminder	"Make sure you don't run out. Check to see when a pill refill is due."
Appointment reminder	"Just a reminder that you have a doc's appointment today."
Goal monitoring	"Remember your goal. Did you take your meds last night?"
Glucose monitoring	"Hello, Mr. Marquez, have you had time to check your sugar today?"
Self-efficacy	"Taking your meds is within your control. You can do it."
Motivation	"You have come a long way! Keep up the good work!"

Usual Care

All participants spend 1 year in the usual care condition, either year 1 or 2, depending on the randomization. During receipt of usual care, they receive health care from their usual providers without the support of a pharmacist or HC. There are no home visits or pharmacist telehealth videoconferencing encounters with usual care. In addition, participants receive a 1-page list of clinic resources with names and direct telephone numbers (eg, social worker or clinical pharmacist) along with a low-literacy, paper-based diabetes education pamphlet [87]. Usual care reflects the type of health care that patients receive outside of any participation in research.

Intervention Fidelity

To continuously evaluate the fidelity of both conditions, we review logs maintained by the HCs weekly, including visit dates, length of visits, visit content, and disposition (eg, visit completed, and patient unreachable). Weekly group meetings with HCs and the research team provide an opportunity to monitor intervention delivery. Monthly lunch meetings with clinical pharmacists, HCs, and investigators ensure active collaboration between HCs and pharmacists. All technology-related difficulties are reported to the coordinator immediately and discussed in weekly meetings with the investigators. One investigator, a health psychologist, maintains weekly contact with HCs to provide emotional support and incorporate structured training opportunities. Text messages sent and received via *mytapp* are reviewed monthly.

Data Collection

Trained, blinded RAs collect physiological and self-report data through interview administration within the clinical research center at UI Health at 5 time points: baseline and every 6 months

for 2 years. RAs are matched to patient language preferences in English or Spanish. Laminated cards with Likert-type scale responses are provided as a visual reference to the patients. Interview data are entered directly into laptop computers using Research Electronic Data Capture (Vanderbilt University) electronic data capture web application [88]. The baseline survey requires an average duration of 60 minutes with subsequent follow-up visits lasting 30 minutes. Subjects receive US $30 as compensation for travel and time at each of the 5 data collection points (plus US $50 if at least one videoconference is completed in the prior 6 months during the intervention period). Public transit cards and parking passes are provided when needed. Participants are informed of their randomization assignment at the end of the baseline data collection.

Sociodemographics include age, gender, self-reported race and ethnicity, country of origin, income, highest level of education, employment status, global health status [89], and insurance. Diabetes and medical history include self-reported time since diabetes diagnosis, prior receipt of diabetes education, current therapy, known diabetes complications, and comorbid conditions. Health literacy is assessed using 3 screening questions with high discriminatory power among English- and Spanish-speaking populations [67,90,91]. Mobile phone use and comfort sending text messages is also assessed using 5 items [68].

Intermediate variables are also collected at each of the 5 time points. Perceived severity of diabetes and perceived susceptibility are assessed using 2 items adapted from the study by Bradley et al [92]. The perceived benefits of therapy are measured by a 5-item survey related to the benefits of therapy [71]. Diabetes distress is measured using the brief Diabetes Distress Scale [73]. Depression is measured using the Patient Health Questionnaire [75,76]. Social support is measured using an assessment of the amount of total support received and satisfaction with support from family, friends, and the health care team [93]. Self-efficacy is measured using the Stanford 8-item self-efficacy for diabetes survey [94]. Contextual data include an environmental survey that addresses loneliness, social cohesion, and neighborhood safety as well as the identification of stressful life events [95-97].

HCs record the dates of patient contacts in REDCap (eg, phone calls and home encounters). Clinical progress notes are completed in the EMR after every participant contact (by phone if longer than 15 minutes and in-person). Information includes mode, time, location (home vs clinic), content of contact, results of glucose or blood pressure self-monitoring, goals, life events, pharmacist interactions, and interventions. Intensification of therapy will be defined as the number of dosage increases of antihypertensive, hypoglycemic agent, or insulin or the addition of a new agent since the baseline visit [98-100]. Chart review will define the number of PCP visits and pharmacist videoconferences as well as the number of pharmacist- or physician-initiated medication changes.

Physiologic outcomes will be collected at 5 time points (0, 6, 12, 18, and 24 months). The research staff will perform phlebotomy, blood pressure, weight, and height recordings. HbA_{1c} and fasting lipid profile (total cholesterol, high-density lipoprotein, LDL, and triglycerides) are obtained via phlebotomy. A calibrated digital scale measures weight. A height stadiometer measures height, with subjects removing their shoes (for BMI assessment). Blood pressure is assessed in subjects sitting down for at least 5 minutes, following a standard procedure. Health-related quality of life is measured using the EuroQol Group 5D and Diabetes Distress Scale [73].

The revised Summary of Diabetes Self-Care Activities Measure captures basic diet, exercise, blood sugar testing, foot care, and smoking with 11 core items [101]. Additional questions address skipping medications and insulin injections to evaluate adherence, as well as taking aspirin regularly. Alcohol misuse is assessed using the Alcohol Use Disorder Identification Test—Concise [102].

Sample Size Justification

The sample size calculation is powered to detect the primary outcome, which is the change in HbA_{1c}. Reviews of published studies suggest that successful education programs lower A_{1c} levels by 0.4% to 1.7% [3,103]. On the basis of our previous experience with the patient population, we estimated a mean baseline HbA_{1c} level of 10% with a SD of 1.8 and an effect size of 0.56 for aim 1. The cross-time correlation was estimated to be 0.30, with a compound symmetry structure. We adjusted for clustering and assumed an intraclass correlation coefficient of 0.01, with 5 clusters. This yielded a design effect of 1.34. Two-sided alpha of .05 and 80% power were assumed. Allowing for a 20% dropout rate, 220 patients were required [104].

Data Management and Analysis

To address missing data, we will examine the data for patterns of missingness and potential bias in missingness. If data are not missing at random, we will apply one of several available imputation methods in a sensitivity analysis based on the nature and extent of missing data [105]. We will determine effectiveness using intention-to-treat principles with actual imputation of missing data [106-109]. This will allow us to appreciate the potential biases inherent in a *real-world* setting due to dropout and poor adherence to study procedures.

Patients who share a single PCP might exhibit similarities that are not shared with patients cared for by other PCPs. To address this, we will include random effects in the model for clinic site, PCP, and HC (though the small numbers of HCs may call for a fixed effect approach or *insufficient replication*) [110]. To examine a stricter examination of effect, we will also do a *per-protocol* analysis of complete cases. Completed cases will not be dependent on intermediate time point data collections (6 and 18 months). Potential selection bias will be corrected by including model covariates that are differentially related to study participation.

Univariate comparisons between the 2 study groups for outcomes and covariates at baseline will be conducted using chi-square tests for categorical variables, Kruskal-Wallis tests for ordinal variables, and *t* tests for continuous variables. All tests will be two-sided. Nonnormal continuous data will be transformed before the analysis. To provide a comprehensive analysis of our primary hypothesis, we will extend the usual

analysis of crossover designs [111] by including a longitudinal trend component in the first year. Thus, we can examine the time course (0, 6, and 12 months) as linear or quadratic over the first 3 measurements. This will allow us to investigate whether changes are made early and at what rate they continue throughout the rest of the period. This analysis permits a comparison of the trends between the 2 conditions. In addition, we will regard subjects as a random effect and will use Gaussian mixed model estimation. We can then substitute treatment by period interactions for the carry-over effects, and the model can be reduced in a recommended sequence (first omit carry-over, then omit treatment, and finally omit period) [111]. We will also explore patterned covariance structures such as compound symmetry and autoregression along with incorporating time-constant and time-varying covariates, such as health literacy or diabetes distress.

The primary analysis of all physiological outcomes jointly in the repeated measures design will be conducted using a general linear model framework. Repeated measures multivariate analysis of variance will be used to explore the simultaneous impact of the treatment on multiple correlated dependent variables, including the use of Roy-Bargmann stepdown F tests and discriminant function analysis as post hoc tests to identify subsets of outcome measures affected [112]. Multivariate analysis of variance (MANOVA) secondary analyses will explore the impact of inhomogeneous baseline variables on the results. Group by time-trend interaction contrasts will be used to explore different group trajectories of change. The potential consequences of medication intensification (eg, initiation of insulin) will be explored by evaluating changes in BMI and quality of life.

Exploratory subgroup analyses will follow a heterogeneity in treatment effects framework [113,114]. We will determine which subjects in the intervention group had the greatest improvement in outcomes, based on multiple prespecified patient characteristics, including race (African-American or Latino), depression, comorbidities, baseline behaviors, health literacy, continuity of care, and social support. These analyses will also consider additional comparisons between subjects above and below the median levels of videoconferencing and text messaging activity. Statistical tests will be implemented as interactions within the full data set.

If the intervention results in improved HbA_{1c} more than that in the usual care, we will examine whether changes in self-efficacy, health beliefs, or social support serve as mediators for improved outcomes. In addition, we will explore diabetes-related behaviors as well as medication treatment intensification as mediators using MPlus [115-118]. To further identify the relative contributions of videoconferencing and/or text messaging, we will conduct meditational modeling with videoconferencing time, number of text messages, and HC contact time as mediating variables. This may describe any dose-response relationship between mHealth utilization and outcomes. We will compute bias-corrected bootstrap standard errors using MPlus. This offers accurate confidence intervals for mediation coefficients [119]. Due to anticipated relationships between HC activity level and mHealth delivery, we plan to inspect correlations between mediators and incorporate any significant findings in model development. This analysis will demonstrate whether the intervention effects are sensitive to mediators. Finally, given the sample size, observed (rather than latent) variables will be used in the mediation models. To enhance the power of mediation modeling, we adopt an $\alpha=.10$ type I error criterion to improve the chances of finding promising mediators for future studies.

We expect a limited amount of decline in physiologic outcomes with the transition back to usual care. We will test the hypothesis that improvements in HbA_{1c} (primary outcome), blood pressure, and LDL cholesterol (secondary outcomes) will be maintained during the maintenance period. The analyses will be conducted in a manner similar to our primary hypothesis and will evaluate changes in the initial intervention group 1 year after intervention completion.
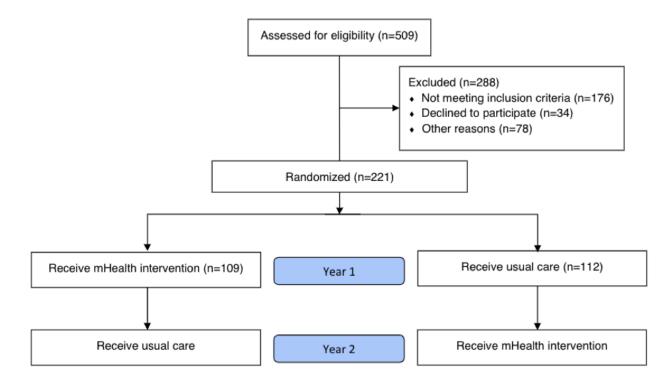
Results

The study was initiated in July 2016, and enrollment began in March 2017. Figure 2 shows the Consolidated Standards of Reporting Trials diagram for recruitment.

Figure 2. Consolidated Standards of Reporting Trials flow diagram. mHealth: mobile health.

As shown in Table 2, 221 patients have been enrolled, exceeding our goal of 220 patients. A total of 112 patients have been randomized to usual care for their first year, and 109 patients have been randomized to the mHealth intervention.

The retention rate is currently 90% for subjects completing the first year of the study. We anticipate that data collection will be completed in November 2021. Following data analyses, the manuscript will be developed with primary results by May 2022 for peer-reviewed publication.

Table 2. Demographic characteristics of study population.

Characteristic	Usual care (n=112)	Intervention (n=109)
Age (years), mean (SD)	54.5 (9.6)	56.0 (9.3)
Diabetes duration (years), mean (SD)	12.3 (7.9)	13.1 (7.7)
Ethnicity, n (%)		
Latino or Hispanic	36 (32.1)	37 (33.9)
African-American	76 (67.9)	72 (66.1)
Gender, n (%)		
Male	35 (31.2)	32 (29.4)
Female	77 (68.7)	77 (70.6)
Language preference, n (%)		
English	97 (86.6)	87 (79.8)
Spanish	15 (13.4)	22 (20.2)
Income (US $), n (%)		
Less than 10,000	38 (33.9)	36 (33.0)
10,000-19,999	19 (17.0)	26 (23.8)
20,000-29,999	12 (10.7)	16 (14.7)
30,000-39,999	7 (6.2)	10 (9.2)
40,000-49,999	12 (10.7)	0 (0)
50,000-59,999	6 (5.4)	8 (7.3)
60,000-69,999	2 (1.8)	3 (2.8)
70,000 or more	14 (12.5)	8 (7.3)
Refused to answer	2 (1.8)	2 (1.8)
Education, n (%)		
Less than high school	26 (23.6)	29 (26.6)
High school diploma or equivalent	22 (19.6)	33 (30.3)
Some college, 2-year certificate, or associates degree	41 (36.6)	26 (23.8)
College graduate (4 year)	11 (9.8)	13 (11.9)
Some graduate school	3 (2.7)	3 (2.8)
Graduate degree	8 (7.1)	5 (4.6)
Other	1 (0.9)	0 (0)
Health status, n (%)		
Excellent	2 (1.8)	0 (0)
Very good	4 (3.6)	5 (4.6)
Good	42 (37.5)	38 (34.9)
Fair	47 (42.0)	58 (53.2)
Poor	17 (15.2)	8 (7.3)
Insurance, n (%)		
None	5 (4.5)	8 (7.3)
Public	69 (61.6)	70 (64.2)
Private	36 (32.1)	30 (27.5)
Other	2 (1.8)	1 (0.9)

Discussion

This study assesses the effectiveness of a novel mHealth approach for improving diabetes self-management in an underserved, minority population with type 2 diabetes. The study will provide further evidence of the use of mHealth in both clinical and community environments, with tools to support clinical pharmacists and HCs in their patient-oriented activities. If effective, this intervention can be considered for implementation in low-resource settings where pharmacist services are not readily available, and HCs can extend the reach of providers targeting patients with limited access to care.

Strengths and Limitations

The study is innovative in several ways. The proposed study will be the first randomized controlled trial to evaluate an mHealth intervention to improve diabetes management in low-income African-Americans and Latinos with type 2 diabetes delivered through HCs. This study builds upon prior work and is responsive to patient feedback in offering remotely delivered videoconferencing with clinical pharmacists who collaborate with HCs to improve diabetes outcomes [56]. Pharmacist videoconferencing overcomes the transportation barriers commonly experienced by individuals with limited income. We currently use scalable, inexpensive mHealth tools (VSee and

mytapp) to promote adoption in low-resource clinical organizations, including Federally Qualified Health Centers.

A number of limitations and challenges have been identified. First, there is the potential for contamination across groups, as randomization was not clustered. Intervention and usual care patients may share the same provider and clinical site. In addition, we recruited patients from a single urban health care system, which may limit generalizability. Additional studies in practice networks would require the availability of clinical pharmacists and HCs. Finally, our intervention integrates multiple components: clinical pharmacists, HCs, videoconferencing, and text messaging, so we are unable to determine the impact of each component individually.

In conclusion, despite the widespread use of mobile devices, little is known about the effectiveness of the technology in improving health care delivery or outcomes. Although systematic reviews show the preliminary value of text messaging, patient education apps, and videoconferencing in chronic disease management, most studies have been small in size, underpowered, and low in quality and include motivated, nonminority subjects. This study will provide the evidence needed on the impact of mHealth diabetes adherence support delivered to low-income minority patients with uncontrolled type 2 diabetes.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Peer-review report by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).
[PDF File (Adobe PDF File), 167 KB-Multimedia Appendix 1]

References

1. Centers for Disease Control and Prevention. National Diabetes Statistics Report. U.S. Department of Health and Human Services. 2017. URL: https://www.cdc.gov/diabetes/pdfs/library/diabetesreportcard2017-508.pdf [accessed 2021-02-21]
2. Chatterjee S, Davies MJ, Heller S, Speight J, Snoek FJ, Khunti K. Diabetes structured self-management education programmes: a narrative review and current innovations. Lancet Diabetes Endocrinol 2018 Feb;6(2):130-142. [doi: 10.1016/s2213-8587(17)30239-5]
3. Murphy SL, Xu J, Kochanek KD, Arias E. Mortality in the United States, 2017. NCHS Data Brief 2018 Nov(328):1-8 [FREE Full text] [Medline: 30500322]
4. Glantz NM, Duncan I, Ahmed T, Fan L, Reed BL, Kalirai S, et al. Racial and ethnic disparities in the burden and cost of diabetes for US medicare beneficiaries. Health Equity 2019 May;3(1):211-218 [FREE Full text] [doi: 10.1089/heq.2019.0004] [Medline: 31289781]
5. Smalls BL, Ritchwood TD, Bishu KG, Egede LE. Racial/ethnic differences in glycemic control in older adults with type 2 diabetes: United States 2003-2014. Int J Environ Res Public Health 2020 Feb 04;17(3):950 [FREE Full text] [doi: 10.3390/ijerph17030950] [Medline: 32033032]

XSL•FO

RenderX

6. Preston SH, Choi D, Elo IT, Stokes A. Effect of diabetes on life expectancy in the United States by race and ethnicity. Biodemography Soc Biol 2018 Dec 20;64(2):139-151 [FREE Full text] [doi: 10.1080/19485565.2018.1542291] [Medline: 31178981]

7. Kirk JK, Passmore LV, Bell RA, Narayan KV, D'Agostino RB, Arcury TA, et al. Disparities in A1C levels between Hispanic and non-Hispanic white adults with diabetes: a meta-analysis. Diabetes Care 2008 Feb 31;31(2):240-246. [doi: 10.2337/dc07-0382] [Medline: 17977939]

8. Casagrande SS, Fradkin JE, Saydah SH, Rust KF, Cowie CC. The prevalence of meeting A1C, blood pressure, and LDL goals among people with diabetes, 1988-2010. Diabetes Care 2013 Aug 15;36(8):2271-2279 [FREE Full text] [doi: 10.2337/dc12-2258] [Medline: 23418368]

9. Shah BM, Mezzio DJ, Ho J, Ip EJ. Association of ABC (HbA1c, blood pressure, LDL-cholesterol) goal attainment with depression and health-related quality of life among adults with type 2 diabetes. J Diabetes Complications 2015 Aug;29(6):794-800. [doi: 10.1016/j.jdiacomp.2015.04.009] [Medline: 25976863]

10. Casagrande SS, Aviles-Santa L, Corsino L, Daviglus ML, Gallo LC, Espinoza Giacinto RA, et al. Hemoglobin A1C, blood pressure, and LDL-cholesterol control among Hispanic/Latino adults with diabetes: results from the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). Endocrine Practice 2017 Oct;23(10):1232-1253. [doi: 10.4158/ep171765.or]

11. American Diabetes Association. Improving Care and Promoting Health in Populations:. Dia Care 2018 Dec 17;42(Supplement 1):S7-S12. [doi: 10.2337/dc19-s001]

12. Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005 Aug 04;353(5):487-497. [doi: 10.1056/nejmra050100]

13. Haynes RB, Ackloo E, Sahota N, McDonald H, Yao X. Interventions for enhancing medication adherence. Cochrane Database Syst Rev 2008;2. [doi: 10.1002/14651858.cd000011.pub3]

14. Viswanathan M, Golin CE, Jones CD, Ashok M, Blalock SJ, Wines RC, et al. Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review. Ann Intern Med 2012 Dec 04;157(11):785-795 [FREE Full text] [doi: 10.7326/0003-4819-157-11-201212040-00538] [Medline: 22964778]

15. Fischer MA, Stedman MR, Lii J, Vogeli C, Shrank WH, Brookhart MA, et al. Primary medication non-adherence: analysis of 195,930 electronic prescriptions. J Gen Intern Med 2010 Apr 4;25(4):284-290 [FREE Full text] [doi: 10.1007/s11606-010-1253-9] [Medline: 20131023]

16. Wanko NS, Brazier CW, Young-Rogers D, Dunbar VG, Boyd B, George CD, et al. Exercise preferences and barriers in urban African Americans with type 2 diabetes. Diabetes Educ 2004 Sep 04;30(3):502-513. [doi: 10.1177/014572170403000322] [Medline: 15208848]

17. Marcy TR, Britton ML, Harrison D. Identification of barriers to appropriate dietary behavior in low-income patients with type 2 diabetes mellitus. Diabetes Ther 2011 Mar 21;2(1):9-19 [FREE Full text] [doi: 10.1007/s13300-010-0012-6] [Medline: 22127765]

18. Bazargan-Hejazi S, Arroyo JS, Hsia S, Brojeni NR, Pan D. A racial comparison of differences between self-reported and objectively measured physical activity among US adults with diabetes. Ethn Dis 2017 Dec 07;27(4):403-410 [FREE Full text] [doi: 10.18865/ed.27.4.403] [Medline: 29225441]

19. Vaccaro JA, Huffman FG. Sex and race/ethnicity differences in following dietary and exercise recommendations for U.S. representative sample of adults with type 2 diabetes. Am J Mens Health 2017 Mar 07;11(2):380-391 [FREE Full text] [doi: 10.1177/1557988316681126] [Medline: 27932589]

20. Dahal PK, Hosseinzadeh H. Association of health literacy and diabetes self-management: a systematic review. Aust J Prim Health 2019;25(6):526. [doi: 10.1071/py19007]

21. Thornton PL, Kumanyika SK, Gregg EW, Araneta MR, Baskin ML, Chin MH, et al. New research directions on disparities in obesity and type 2 diabetes. Ann N Y Acad Sci 2020 Feb 03;1461(1):5-24 [FREE Full text] [doi: 10.1111/nyas.14270] [Medline: 31793006]

22. Huang ES, Brown SE, Thakur N, Carlisle L, Foley E, Ewigman B, et al. Racial/ethnic differences in concerns about current and future medications among patients with type 2 diabetes. Diabetes Care 2009 Feb 18;32(2):311-316 [FREE Full text] [doi: 10.2337/dc08-1307] [Medline: 19017766]

23. Baghikar S, Benitez A, Fernandez Piñeros P, Gao Y, Baig AA. Factors impacting adherence to diabetes medication among urban, low income Mexican-Americans with diabetes. J Immigr Minor Health 2019 Dec 23;21(6):1334-1341 [FREE Full text] [doi: 10.1007/s10903-019-00867-9] [Medline: 30798408]

24. Gonzalez JS, Tanenbaum ML, Commissariat PV. Psychosocial factors in medication adherence and diabetes self-management: implications for research and practice. Am Psychol 2016 Oct;71(7):539-551 [FREE Full text] [doi: 10.1037/a0040388] [Medline: 27690483]

25. Walker RJ, Strom Williams J, Egede LE. Influence of race, ethnicity and social determinants of health on diabetes outcomes. Am J Med Sci 2016 Apr;351(4):366-373 [FREE Full text] [doi: 10.1016/j.amjms.2016.01.008] [Medline: 27079342]

26. Lewey J, Shrank WH, Avorn J, Liu J, Choudhry NK. Medication adherence and healthcare disparities: impact of statin co-payment reduction. Am J Manag Care 2015 Oct;21(10):696-704 [FREE Full text] [Medline: 26633094]

27. Pawaskar MD, Xu L, Tang Y, Puckrein GA, Rajpathak SN, Stuart B. Effect of medication copayment on adherence and discontinuation in medicare beneficiaries with type 2 diabetes: a retrospective administrative claims database analysis. Diabetes Ther 2018 Aug 24;9(5):1979-1993. [doi: 10.1007/s13300-018-0489-y]

28. Kripalani S, Yao X, Haynes RB. Interventions to enhance medication adherence in chronic medical conditions: a systematic review. Arch Intern Med 2007 Mar 26;167(6):540-550. [doi: 10.1001/archinte.167.6.540] [Medline: 17389285]

29. Bogner HR, de Vries HF. Integrating type 2 diabetes mellitus and depression treatment among African Americans: a randomized controlled pilot trial. Diabetes Educ 2010 Dec 29;36(2):284-292 [FREE Full text] [doi: 10.1177/0145721709356115] [Medline: 20040705]

30. Conn VS, Ruppar TM. Medication adherence outcomes of 771 intervention trials: Systematic review and meta-analysis. Prev Med 2017 Jun;99:269-276 [FREE Full text] [doi: 10.1016/j.ypmed.2017.03.008] [Medline: 28315760]

31. Milosavljevic A, Aspden T, Harrison J. Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: a systematic review. Int J Pharm Pract 2018 Oct;26(5):387-397. [doi: 10.1111/ijpp.12462] [Medline: 29927005]

32. Doggrell SA. A review of interventions ≥ 6 months by pharmacists on adherence to medicines in cardiovascular disease: Characteristics of what works and what doesn't. Res Social Adm Pharm 2019 Feb;15(2):119-129. [doi: 10.1016/j.sapharm.2018.04.003] [Medline: 29656935]

33. Community Preventive Services Task Force. Team-based care to improve blood pressure control: recommendation of the Community Preventive Services Task Force. Am J Prev Med 2014 Jul;47(1):100-102. [doi: 10.1016/j.amepre.2014.03.003] [Medline: 24933493]

34. Margolis KL, Asche SE, Bergdall AR, Dehmer SP, Groen SE, Kadrmas HM, et al. Effect of home blood pressure telemonitoring and pharmacist management on blood pressure control: a cluster randomized clinical trial. J Am Med Assoc 2013 Jul 03;310(1):46-56 [FREE Full text] [doi: 10.1001/jama.2013.6549] [Medline: 23821088]

35. Antoine SL, Pieper D, Mathes T, Eikermann M. Improving the adherence of type 2 diabetes mellitus patients with pharmacy care: a systematic review of randomized controlled trials. BMC Endocr Disord 2014 Jul 7;14(1). [doi: 10.1186/1472-6823-14-53]

36. Deters MA, Laven A, Castejon A, Doucette WR, Ev LS, Krass I, et al. Effective interventions for diabetes patients by community pharmacists: a meta-analysis of pharmaceutical care components. Ann Pharmacother 2018 Feb 26;52(2):198-211. [doi: 10.1177/1060028017733272] [Medline: 28948839]

37. Iyer R, Coderre P, McKelvey T, Cooper J, Berger J, Moore E, et al. An employer-based, pharmacist intervention model for patients with type 2 diabetes. Am J Health Syst Pharm 2010 Feb 15;67(4):312-316. [doi: 10.2146/ajhp090047] [Medline: 20133537]

38. Rochester CD, Leon N, Dombrowski R, Haines ST. Collaborative drug therapy management for initiating and adjusting insulin therapy in patients with type 2 diabetes mellitus. Am J Health Syst Pharm 2010 Jan 01;67(1):42-48. [doi: 10.2146/ajhp080706] [Medline: 20044368]

39. Taveira TH, Friedmann PD, Cohen LB, Dooley AG, Khatana SAM, Pirraglia PA, et al. Pharmacist-led group medical appointment model in type 2 diabetes. Diabetes Educ 2010 Dec 04;36(1):109-117. [doi: 10.1177/0145721709352383] [Medline: 19966072]

40. Nieuwlaat R, Wilczynski N, Navarro T, Hobson N, Jeffery R, Keepanasseril A. Interventions for enhancing medication adherence. Cochrane Database Syst Rev 2014;11. [doi: 10.1002/14651858.cd000011.pub4]

41. Viswanathan M, Kahwati LC, Golin CE, Blalock SJ, Coker-Schwimmer E, Posey R, et al. Medication therapy management interventions in outpatient settings: a systematic review and meta-analysis. JAMA Intern Med 2015 Jan 01;175(1):76-87. [doi: 10.1001/jamainternmed.2014.5841] [Medline: 25401788]

42. Chung N, Rascati K, Lopez D, Jokerst J, Garza A. Impact of a clinical pharmacy program on changes in hemoglobin A1c, diabetes-related hospitalizations, and diabetes-related emergency department visits for patients with diabetes in an underserved population. J Manag Care Spec Pharm 2014 Sep;20(9):914-919. [doi: 10.18553/jmcp.2014.20.9.914] [Medline: 25166290]

43. Fazel MT, Bagalagel A, Lee JK, Martin JR, Slack MK. Impact of diabetes care by pharmacists as part of health care team in ambulatory settings: a systematic review and meta-analysis. Ann Pharmacother 2017 Oct 02;51(10):890-907. [doi: 10.1177/1060028017711454] [Medline: 28573873]

44. Skinner JS, Poe B, Hopper R, Boyer A, Wilkins CH. Assessing the effectiveness of pharmacist-directed medication therapy management in improving diabetes outcomes in patients with poorly controlled diabetes. Diabetes Educ 2015 Aug 25;41(4):459-465 [FREE Full text] [doi: 10.1177/0145721715587563] [Medline: 26009557]

45. Bluml BM, Watson LL, Skelton JB, Manolakis PG, Brock KA. Improving outcomes for diverse populations disproportionately affected by diabetes: Final results of Project IMPACT: Diabetes. J Am Pharm Assoc 2014 Sep;54(5):477-485. [doi: 10.1331/japha.2014.13240]

46. Choudhry NK, Isaac T, Lauffenburger JC, Gopalakrishnan C, Lee M, Vachon A, et al. Effect of a remotely delivered tailored multicomponent approach to enhance medication taking for patients with hyperlipidemia, hypertension, and diabetes. JAMA Intern Med 2018 Sep 01;178(9):1182. [doi: 10.1001/jamainternmed.2018.3189]

47. Lauffenburger JC, Ghazinouri R, Jan S, Makanji S, Ferro CA, Lewey J, et al. Impact of a novel pharmacist-delivered behavioral intervention for patients with poorly-controlled diabetes: The ENhancing outcomes through Goal Assessment and Generating Engagement in Diabetes Mellitus (ENGAGE-DM) pragmatic randomized trial. PLoS One 2019 Apr 2;14(4):e0214754 [FREE Full text] [doi: 10.1371/journal.pone.0214754] [Medline: 30939143]

48.   Gary TL, Batts-Turner M, Yeh H, Hill-Briggs F, Bone LR, Wang N, et al. The effects of a nurse case manager and a community health worker team on diabetic control, emergency department visits, and hospitalizations among urban African Americans with type 2 diabetes mellitus: a randomized controlled trial. Arch Intern Med 2009 Oct 26;169(19):1788-1794 [FREE Full text] [doi: 10.1001/archinternmed.2009.338] [Medline: 19858437]

49.   Sherifali D, Viscardi V, Bai J, Ali RMU. Evaluating the Effect of a Diabetes Health Coach in Individuals with Type 2 Diabetes. Can J Diabetes 2016 Feb;40(1):84-94. [doi: 10.1016/j.jcjd.2015.10.006] [Medline: 26827684]

50.   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] [Medline: 26441467]

51.   Rothschild SK, Martin MA, Swider SM, Tumialán Lynas CM, Janssen I, Avery EF, et al. Mexican American trial of community health workers: a randomized controlled trial of a community health worker intervention for Mexican Americans with type 2 diabetes mellitus. Am J Public Health 2014 Aug;104(8):1540-1548. [doi: 10.2105/ajph.2013.301439]

52.   Thom DH, Ghorob A, Hessler D, De Vore D, Chen E, Bodenheimer TA. Impact of peer health coaching on glycemic control in low-income patients with diabetes: a randomized controlled trial. Ann Fam Med 2013 Mar 18;11(2):137-144 [FREE Full text] [doi: 10.1370/afm.1443] [Medline: 23508600]

53.   Hughes MM, Yang E, Ramanathan D, Benjamins MR. Community-based diabetes community health worker intervention in an underserved Chicago population. J Community Health 2016 Dec 10;41(6):1249-1256. [doi: 10.1007/s10900-016-0212-8] [Medline: 27286843]

54.   Pirbaglou M, Katz J, Motamed M, Pludwinski S, Walker K, Ritvo P. Personal health coaching as a type 2 diabetes mellitus self-management strategy: a systematic review and meta-analysis of randomized controlled trials. Am J Health Promot 2018 Sep 15;32(7):1613-1626. [doi: 10.1177/0890117118758234] [Medline: 29658286]

55.   DePue JD, Dunsiger S, Seiden AD, Blume J, Rosen RK, Goldstein MG, et al. Nurse-community health worker team improves diabetes care in American Samoa: results of a randomized controlled trial. Diabetes Care 2013 Jul 07;36(7):1947-1953 [FREE Full text] [doi: 10.2337/dc12-1969] [Medline: 23393217]

56.   Sharp LK, Tilton JJ, Touchette DR, Xia Y, Mihailescu D, Berbaum ML, et al. Community health workers supporting clinical pharmacists in diabetes management: a randomized controlled trial. Pharmacotherapy 2018 Jan 30;38(1):58-68 [FREE Full text] [doi: 10.1002/phar.2058] [Medline: 29121408]

57.   Zhai Y, Zhu W, Cai Y, Sun D, Zhao J. Clinical- and cost-effectiveness of telemedicine in type 2 diabetes mellitus. Medicine 2014;93(28):e312. [doi: 10.1097/md.0000000000000312]

58.   Verhoeven F, van Gemert-Pijnen L, Dijkstra K, Nijland N, Seydel E, Steehouder M. The contribution of teleconsultation and videoconferencing to diabetes care: a systematic literature review. J Med Internet Res 2007 Dec 14;9(5):e37 [FREE Full text] [doi: 10.2196/jmir.9.5.e37] [Medline: 18093904]

59.   Lee SWH, Chan CKY, Chua SS, Chaiyakunapruk N. Comparative effectiveness of telemedicine strategies on type 2 diabetes management: a systematic review and network meta-analysis. Sci Rep 2017 Oct 4;7(1). [doi: 10.1038/s41598-017-12987-z]

60.   Dick JJ, Nundy S, Solomon MC, Bishop KN, Chin MH, Peek ME. Feasibility and usability of a text message-based program for diabetes self-management in an urban African-American population. J Diabetes Sci Technol 2011 Sep 01;5(5):1246-1254 [FREE Full text] [doi: 10.1177/193229681100500534] [Medline: 22027326]

61.   Carpenter R, DiChiacchio T, Barker K. Interventions for self-management of type 2 diabetes: an integrative review. Int J Nurs Sci 2019 Jan 10;6(1):70-91 [FREE Full text] [doi: 10.1016/j.ijnss.2018.12.002] [Medline: 31406872]

62.   Baron JS, Hirani SP, Newman SP. Investigating the behavioural effects of a mobile-phone based home telehealth intervention in people with insulin-requiring diabetes: Results of a randomized controlled trial with patient interviews. J Telemed Telecare 2016 Jul 03;23(5):503-512. [doi: 10.1177/1357633x16655911]

63.   Lee PA, Greenfield G, Pappas Y. The impact of telehealth remote patient monitoring on glycemic control in type 2 diabetes: a systematic review and meta-analysis of systematic reviews of randomised controlled trials. BMC Health Serv Res 2018 Jun 26;18(1):495 [FREE Full text] [doi: 10.1186/s12913-018-3274-8] [Medline: 29940936]

64.   Hartz J, Yingling L, Powell-Wiley TM. Use of mobile health technology in the prevention and management of diabetes mellitus. Curr Cardiol Rep 2016 Dec 8;18(12):130. [doi: 10.1007/s11886-016-0796-8] [Medline: 27826901]

65.   Tomlinson M, Rotheram-Borus MJ, Swartz L, Tsai AC. Scaling up mHealth: where is the evidence? PLoS Med 2013;10(2):e1001382 [FREE Full text] [doi: 10.1371/journal.pmed.1001382] [Medline: 23424286]

66.   Head KJ, Noar SM, Iannarino NT, Harrington NG. Efficacy of text messaging-based interventions for health promotion: a meta-analysis. Soc Sci Med 2013 Nov;97:41-48. [doi: 10.1016/j.socscimed.2013.08.003] [Medline: 24161087]

67.   Wallace LS, Rogers ES, Roskos SE, Holiday DB, Weiss BD. Brief report: screening items to identify patients with limited health literacy skills. J Gen Intern Med 2006 Aug;21(8):874-877 [FREE Full text] [doi: 10.1111/j.1525-1497.2006.00532.x] [Medline: 16881950]

68.   Nundy S, Razi RR, Dick JJ, Smith B, Mayo A, O'Connor A, et al. A text messaging intervention to improve heart failure self-management after hospital discharge in a largely African-American population: before-after study. J Med Internet Res 2013 Mar 11;15(3):e53 [FREE Full text] [doi: 10.2196/jmir.2317] [Medline: 23478028]

69.   Recommendations for managing type 2 diabetes in primary care. International Diabetes Federation. 2017. URL: www.idf.org/managing-type2-diabetes [accessed 2021-02-10]

70. American Diabetes Association, Bantle JP, Wylie-Rosett J, Albright AL, Apovian CM, Clark NG, et al. Nutrition recommendations and interventions for diabetes: a position statement of the American Diabetes Association. Diabetes Care 2008 Jan;31 Suppl 1:S61-S78 [FREE Full text] [doi: 10.2337/dc08-S061] [Medline: 18165339]

71. Sigal RJ, Kenny GP, Wasserman DH, Castaneda-Sceppa C, White DL. Physical activity/exercise and type 2 diabetes: a consensus statement from the American Diabetes Association. Diabetes Care 2006 Jun;29(6):1433-1438 [FREE Full text] [doi: 10.2337/dc06-9910] [Medline: 16732040]

72. Cryer PE, Davis SN, Shamoon H. Hypoglycemia in diabetes. Diabetes Care 2003 Jun;26(6):1902-1912 [FREE Full text] [doi: 10.2337/diacare.26.6.1902] [Medline: 12766131]

73. Fisher L, Glasgow RE, Mullan JT, Skaff MM, Polonsky WH. Development of a brief diabetes distress screening instrument. Ann Fam Med 2008;6(3):246-252 [FREE Full text] [doi: 10.1370/afm.842] [Medline: 18474888]

74. Levis B, Benedetti A, Thombs BD, DEPRESsion Screening Data (DEPRESSD) Collaboration. Accuracy of Patient Health Questionnaire-9 (PHQ-9) for screening to detect major depression: individual participant data meta-analysis. Br Med J 2019 Apr 09;365:l1476 [FREE Full text] [doi: 10.1136/bmj.l1476] [Medline: 30967483]

75. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001 Sep;16(9):606-613 [FREE Full text] [doi: 10.1046/j.1525-1497.2001.016009606.x] [Medline: 11556941]

76. Kroenke K, Strine TW, Spitzer RL, Williams JB, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. J Affect Disord 2009 Apr;114(1-3):163-173. [doi: 10.1016/j.jad.2008.06.026] [Medline: 18752852]

77. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Cholestrol Clinical Practice Guidelines. URL: https://www.ahajournals.org/doi/pdf/10.1161/CIR.0000000000000625 [accessed 2021-02-11]

78. Berthold T. Foundations of community health workers, 2nd ed. U.S: Bookbyte; 2016.

79. Sherifali D. Diabetes coaching for individuals with type 2 diabetes: a state-of-the-science review and rationale for a coaching model. J Diabetes 2017 Jun;9(6):547-554. [doi: 10.1111/1753-0407.12528] [Medline: 28084681]

80. Islam N, Shapiro E, Wyatt L, Riley L, Zanowiak J, Ursua R, et al. Evaluating community health workers' attributes, roles, and pathways of action in immigrant communities. Prev Med 2017 Oct;103:1-7 [FREE Full text] [doi: 10.1016/j.ypmed.2017.07.020] [Medline: 28735724]

81. Midwest LHRTC. Diabetes Education and Empowerment Program (DEEP) - 3rd ed. Midwest Latino Health Research Training Policy Center. URL: https://mwlatino.uic.edu/deep-program-2/) [accessed 2020-12-13]

82. Ghorob A, Vivas MM, De Vore D, Ngo V, Bodenheimer T, Chen E, et al. The effectiveness of peer health coaching in improving glycemic control among low-income patients with diabetes: protocol for a randomized controlled trial. BMC Public Health 2011 Apr 01;11:208 [FREE Full text] [doi: 10.1186/1471-2458-11-208] [Medline: 21457567]

83. Powers MA, Bardsley J, Cypress M, Duker P, Funnell MM, Fischl AH, et al. Diabetes self-management education and support in type 2 diabetes: a joint position statement of the american diabetes association, the american association of diabetes educators, and the academy of nutrition and dietetics. Clin Diabetes 2016 Apr;34(2):70-80 [FREE Full text] [doi: 10.2337/diaclin.34.2.70] [Medline: 27092016]

84. Gerber BS, Brodsky IG, Lawless KA, Smolin LI, Arozullah AM, Smith EV, et al. Implementation and evaluation of a low-literacy diabetes education computer multimedia application. Diabetes Care 2005 Jul;28(7):1574-1580. [doi: 10.2337/diacare.28.7.1574] [Medline: 15983303]

85. Locke EA, Latham GP. New developments in goal setting and task performance. New York: Routledge; 2013.

86. Goldman ML, Ghorob A, Hessler D, Yamamoto R, Thom DH, Bodenheimer T. Are low-income peer health coaches able to master and utilize evidence-based health coaching? Ann Fam Med 2015 Aug;13 Suppl 1:S36-S41 [FREE Full text] [doi: 10.1370/afm.1756] [Medline: 26304970]

87. Living with diabetes: an everyday guide for you and your family. In: American College of Physicians. Chicago: American College of Physicians; 2017.

88. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, REDCap Consortium. The REDCap consortium: building an international community of software platform partners. J Biomed Inform 2019 Jul;95:103208 [FREE Full text] [doi: 10.1016/j.jbi.2019.103208] [Medline: 31078660]

89. Krause NM, Jay GM. What do global self-rated health items measure? Med Care 1994 Sep;32(9):930-942. [doi: 10.1097/00005650-199409000-00004] [Medline: 8090045]

90. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. Fam Med 2004 Sep;36(8):588-594 [FREE Full text] [Medline: 15343421]

91. Sarkar U, Schillinger D, López A, Sudore R. Validation of self-reported health literacy questions among diverse English and Spanishspeaking populations. J Gen Intern Med 2011 Mar;26(3):265-271 [FREE Full text] [doi: 10.1007/s11606-010-1552-1] [Medline: 21057882]

92. Bradley C, Brewin C, Gamsu D, Moses J. Development of scales to measure perceived control of diabetes mellitus and diabetes-related health beliefs. Diabet Med September 01 1984;1(3):213-218. [doi: 10.1111/j.1464-5491.1984.tb01955.x]

93. Tang TS, Brown MB, Funnell MM, Anderson RM. Social support, quality of life, and self-care behaviors amongAfrican Americans with type 2 diabetes. Diabetes Educ 2008;34(2):266-276. [doi: 10.1177/0145721708315680] [Medline: 18375776]

94. Lorig K, Ritter PL, Villa FJ, Armas J. Community-based peer-led diabetes self-management: a randomized trial. Diabetes Educ 2009;35(4):641-651. [doi: 10.1177/0145721709335006] [Medline: 19407333]

95. Hughes ME, Waite LJ, Hawkley LC, Cacioppo JT. A short scale for measuring loneliness in large surveys: results from two population-based studies. Res Aging 2004;26(6):655-672 [FREE Full text] [doi: 10.1177/0164027504268574] [Medline: 18504506]

96. York Cornwell E, Cagney KA. Assessment of neighborhood context in a nationally representative study. J Gerontol B Psychol Sci Soc Sci 2014 Nov;69 Suppl 2:S51-S63 [FREE Full text] [doi: 10.1093/geronb/gbu052] [Medline: 24875376]

97. Kowitt SD, Donahue KE, Fisher EB, Mitchell M, Young LA. How is neighborhood social disorganization associated with diabetes outcomes? A multilevel investigation of glycemic control and self-reported use of acute or emergency health care services. Clin Diabetes Endocrinol 2018;4:19 [FREE Full text] [doi: 10.1186/s40842-018-0069-0] [Medline: 30377539]

98. Anderson TS, Jing B, Auerbach A, Wray CM, Lee S, Boscardin WJ, et al. Clinical outcomes after intensifying antihypertensive medication regimens among older adults at hospital discharge. JAMA Intern Med 2019 Aug 19 [FREE Full text] [doi: 10.1001/jamainternmed.2019.3007] [Medline: 31424475]

99. Giugliano D, Maiorino MI, Bellastella G, Esposito K. Clinical inertia, reverse clinical inertia, and medication non-adherence in type 2 diabetes. J Endocrinol Invest 2019 May;42(5):495-503. [doi: 10.1007/s40618-018-0951-8] [Medline: 30291589]

100. Billue KL, Safford MM, Salanitro AH, Houston TK, Curry W, Kim Y, et al. Medication intensification in diabetes in rural primary care: a cluster-randomised effectiveness trial. BMJ Open 2012;2(5) [FREE Full text] [doi: 10.1136/bmjopen-2012-000959] [Medline: 22991217]

101. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. Diabetes Care 2000 Jul;23(7):943-950 [FREE Full text] [doi: 10.2337/diacare.23.7.943] [Medline: 10895844]

102. Bradley KA, DeBenedetti AF, Volk RJ, Williams EC, Frank D, Kivlahan DR. AUDIT-C as a brief screen for alcohol misuse in primary care. Alcohol Clin Exp Res 2007 Jul;31(7):1208-1217. [doi: 10.1111/j.1530-0277.2007.00403.x] [Medline: 17451397]

103. Vas A, Devi ES, Vidyasagar S, Acharya R, Rau NR, George A, et al. Effectiveness of self-management programmes in diabetes management: a systematic review. Int J Nurs Pract 2017 Oct;23(5). [doi: 10.1111/ijn.12571] [Medline: 28758701]

104. Rochon J. Sample size calculations for two-group repeated-measures experiments. Biometrics 1991 Dec;47(4):1383. [doi: 10.2307/2532393]

105. Little RJA, Rubin DB. Statistical analysis with missing data, 2nd Edition. Hoboken, NJ: John Wiley & Sons, Inc; 2014.

106. Little R, Yau L. Intent-to-treat analysis for longitudinal studies with drop-outs. Biometrics 1996 Dec;52(4):1324. [doi: 10.2307/2532847]

107. Hollis S, Campbell F. What is meant by intention to treat analysis? Survey of published randomised controlled trials. Br Med J 1999 Sep 11;319(7211):670-674 [FREE Full text] [doi: 10.1136/bmj.319.7211.670] [Medline: 10480822]

108. Lachin JM. Statistical considerations in the intent-to-treat principle. Controlled Clinical Trials 2000 Jun;21(3):167-189. [doi: 10.1016/s0197-2456(00)00046-5]

109. Kahn SE, Haffner SM, Heise MA, Herman WH, Holman RR, Jones NP, et al. Glycemic durability of rosiglitazone, metformin, or glyburide monotherapy. N Engl J Med 2006 Dec 07;355(23):2427-2443. [doi: 10.1056/nejmoa066224]

110. Donner A, Klar N. Design and analysis of cluster randomization trials in health research. New York: Oxford University Press; 2000:A.

111. Jones B, Kenward MG. Design and analysis of cross-over trials. London: Chapman and Hall; 1989.

112. Tabachnick BG, Fidell LS. Using multivariate statistics (5th Edition). US: Allyn & Bacon, Inc; 2007.

113. Kent DM, Rothwell PM, Ioannidis JP, Altman DG, Hayward RA. Assessing and reporting heterogeneity in treatment effects in clinical trials: a proposal. Trials 2010 Aug 12;11:85 [FREE Full text] [doi: 10.1186/1745-6215-11-85] [Medline: 20704705]

114. Kaplan SH, Billimek J, Sorkin DH, Ngo-Metzger Q, Greenfield S. Who can respond to treatment? Medical Care 2010;48:S9-S16. [doi: 10.1097/mlr.0b013e3181d99161]

115. Baron RM, Kenny DA. The moderator–mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. J Pers Soc Psychol 1986;51(6):1173-1182. [doi: 10.1037/0022-3514.51.6.1173]

116. Fairchild AJ, MacKinnon DP. A general model for testing mediation and moderation effects. Prev Sci 2009 Jun;10(2):87-99 [FREE Full text] [doi: 10.1007/s11121-008-0109-6] [Medline: 19003535]

117. Muthén LK, Muthén BO. Mplus User's Guide. Sixth edition ed. Los Angeles, CA: Muthén & Muthén; 2010. URL: https://socialwork.wayne.edu/research/pdf/mplus-users-guide.pdf [accessed 2021-02-21]

118. MacKinnon D. Introduction to statistical mediation analysis. New York: Lawrence Erlbaum Associates; 2008.

119. Efron B. Better bootstrap confidence intervals. J Am Stat Assoc 1987 Mar;82(397):171-185. [doi: 10.1080/01621459.1987.10478410]

Abbreviations

DSME/S: diabetes self-management education and support
EMR: electronic medical record
HbA1c: hemoglobin A1c

XSL•FO

RenderX

HC: health coach
HIPAA: Health Information Portability and Accountability Act
LDL: low-density lipoprotein
MANOVA: multivariate analysis of variance
mHealth: mobile health
PCP: primary care provider
RA: research assistant
UI Health: University of Illinois Hospital and Health Sciences System

XSL•FO
RenderX