FAMS Mobile Health Intervention for Diabetes Self-care Support
NCT02481596
4-9-2018

Study Type and Performance Site Information

Type of study:

[**x**] **Standard or Expedited**
[ ] Exempt
[ ] Grant Review/Umbrella Review for funds release
[ ] Comparative Effectiveness Research
[ ] Non-Human Subject Determination
[ ] Quality Improvement/Non-Research Determination
[ ] Study reviewed by another IRB
[ ] Coordinating Center ONLY

Please indicate which Committee is most appropriate to review your project:

[**x**] **Social and Behavioral Sciences**
[ ] Health Sciences

Are there sites in this study in which the PI is responsible other than Vanderbilt University or Vanderbilt University Medical Center, including all VUMC clinics and hospitals?

[**x**] **Yes**
[ ] No

Are there any international sites involved?

[ ] Yes
[**x**] **No**

Are the sites "Engaged in the Research"?

[ ] yes
[**x**] **no**
[ ] both engaged sites and not engaged sties

Please list all Performance Sites "Not Engaged" in the research:

Faith Family Medical Clinic
The Clinic at Mercury Courts
Vine Hill Community Clinic
Priest Lake Family & Women's Health Center
Neighborhood Health
Shade Tree Clinic

Are any of these sites international?

[ ] Yes
[**x**] **No**

Is this project cancer-related?

[ ] Yes
[**x**] **No**

Study Purpose and Description

Provide a brief abstract of the study in lay language. The IRB Committees are comprised of scientists with varied backgrounds, non-scientists, and community members.

This IRB application addresses the second of three aims for our overall research plan: to evaluate a mobile-phone delivered medication adherence intervention (called REACH; Rapid Education/Encouragement And Communications for Health) and test intervention effects on adherence and glycemic control among low income adults with type 2 diabetes mellitus (T2DM) receiving primary care at Federally Qualified Health Centers (FQHCs) or VUMC. In addition, family-focused components (called FAMS; Family-focused Add-on to Motivate Self-care) are integrated with the larger REACH intervention, and include diabetes coaching, goal-focused text messages delivered to the patient, and supplemental text messages delivered to an identified adult family member. We will evaluate the effects of the supplemental, family-focused intervention on family members' supportive and obstructive behaviors, patients' diabetes self-efficacy, and patients' adherence to diet and exercise. (Aim 1, to improve the content and functionality of an existing mobile phone-delivered medication adherence promotion intervention for consistency with the Information-Motivation-Behavioral skills model and clear health communication strategies, and test for usability and acceptability with patients, received approval [see IRB #140562] in April 2014.)

Expected duration of the study.

We expect to complete data collection by the end of 2019, but the study will remain open for analyses and manuscript writing/submissions for an additional five years.

The IRB needs to understand how this study adds to the knowledge on this topic in order to be able to judge the risks and benefits to the research participants.

BACKGROUND

Medication nonadherence is a major public health problem with few solutions for patients with diabetes. Approximately 1 in 3 persons with T2DM are suboptimally adherent [1-3], and this rate is higher among low income racial/ethnic minorities with diabetes [4-7]. Medication nonadherence undermines treatment effectiveness, and in doing so, contributes to suboptimal glycemic control [4-6, 8], hospitalizations [3, 9-11], premature death, and considerable costs to the U.S. healthcare system [11, 12]. In our prior work with 314 diverse patients with low socioeconomic status [13], 79% reported less than perfect medication adherence and 66% had a hemoglobin A1c (A1c) ≥7.0%. Moreover, medication adherence was the only self-care behavior associated with glycemic control when adjusted for other self-care behaviors (e.g., diet, exercise, self-monitoring of blood glucose (SMBG)), highlighting the need to improve medication adherence in order to achieve glycemic control in low SES patient populations [13].

Recent evidence suggests African Americans (AAs) with diabetes are more likely than non-Hispanic Whites (NHW) to report lacking adherence-related information (e.g., not knowing the number of doses to take or what each medication is for) [14], motivation (e.g., believing medications do more harm than good and lacking social support for adherence) [14-16], and behavioral skills (e.g., forgetting doses and having difficulty obtaining refills) [14, 17, 18]. These barriers map onto a well-validated conceptualization of adherence behavior, the Information--Motivation--Behavioral skills (IMB) model [19], which informed effective medication adherence interventions among patients with other chronic conditions [20-23]. Yet of published intervention studies addressing medication adherence among patients with T2DM [24-41], only one [29] is theory-based, and there are no studies, to our knowledge, that used a theory with empirical support for the theory's tenants in a target population and/or pertaining to that population's medication adherence behavior, specifically. The IMB model of adherence [19] is validated in cross-sectional [42, 43] and intervention outcome research with patients with HIV and, separately, with patients who underwent heart surgery [20-23], and incorporates central components of other theoretical models (e.g., Social Cognitive Theory [44], Theory of Planned Behavior [45]).

Given increased rates of T2DM-related complications and mortality among minority groups and patients with low SES [46, 47], it is particularly critical to focus family interventions on at-risk patient populations who may need more support to maintain self-care and glycemic control [48, 49]. Such populations have higher rates of limited health literacy [50], life stressors [51-53], and depression [54, 55], making them more vulnerable to the detrimental effects of obstructive family behaviors on self-care and A1C [48, 49]. Interventions simply educating and/or involving families without working to reduce obstructive family behaviors may actually evoke less patient adherence [56-59]. We explored cross-sectional associations between diabetes-specific supportive and obstructive family behaviors and adults' T2DM self-care behaviors and A1C in the target population and found that family members' supportive and obstructive behaviors were each independently associated with more and less adherence to self-care, respectively [56].

SIGNIFICANCE

Approximately 91% of U.S. adults are mobile phone users, with 45% using feature phones (i.e., basic mobile phones used for voice communications and short message service (SMS) text messaging and 56% using smartphones (i.e., mobile phones that include feature phone functionality coupled with Internet access) [60]. Smartphone users can access online health information and health applications ('apps'). However, persons with low SES are less likely than persons with high SES to have a smartphone and are subsequently less likely to use their mobile phone for health-related reasons [60, 61]. Feature phone functionality (e.g., SMS and voice communications) is used equally across race/ethnic and socioeconomic groups [62, 63], providing the broadest access to mobile phone users. Our prior work with the target population found that 88% use a mobile phone, but only 23% accessed the Internet from their phone, whereas twice as many used SMS. We also found no income or racial differences in having a mobile phone, or comfort with using SMS or a phone's voice/call features [62]. More recently, in 2013, we sampled 179 patients from the target population, and found that 96% used a mobile phone and, of these patients, 89% used SMS.

Intervention content delivered via basic mobile phone technology can deliver targeted and tailored health information to support the hardest-to-reach and most vulnerable patients and, in turn, improve health outcomes [64-66]. Studies involving feature phone functionality have improved medication adherence and clinical outcomes among persons with chronic conditions in third world countries [62, 67, 68], and have improved medication adherence among racially diverse

and homeless persons in the U.S. [69]. However, more research is needed to understand the health benefits of basic mobile phone interventions for racial/ethnic minorities and/or persons with low SES in general, particularly those persons with chronic conditions such as diabetes [70, 71] and the sustainability of such interventions in routine clinical care. Therefore, we will test whether our intervention improves adherence-related information, motivation, and behavioral skills and whether improving these mechanisms drives improvements in adherence and, in turn, glycemic control. Intervention trials are notoriously concerned with establishing efficacy without understanding the mechanisms through which an intervention achieves its effect. The former is important for practice, but the latter tells us how to intervene more effectively, informing future research, practice, and policy [72, 73]. Our approach includes both; and for the latter, we will assess valid measures of adherence-related information, motivation, and behavioral skills to test (a) whether our intervention improved the IMB mechanisms; (b) whether such improvements are what produced improvements in adherence and, in turn, glycemic control; and (c) whether adherence improvements caused improvements in glycemic control.
We hypothesize that our SMS intervention will effectively improve medication adherence and glycemic control. We base this on our prior work and that of others. For instance, a 2012 study reported that patients with HIV who used an SMS intervention for 6 months were more optimally adherent even after intervention discontinuation [74]. In addition, in an SMS intervention with adults with T2DM, 100% of participants said they would recommend the program to family/friends with diabetes [75] and many actually did so [76], but to date no study has explored adult patients' receptivity to engaging their family members in SMS interventions about their own health and/or the potential benefits of doing so [77-79]. This is an important first step in expanding the reach of mHealth interventions to family members, who are at-risk for T2DM [80-82]. Rather than trying to change family members' behaviors directly, the supplemental family-focused intervention will target patients' ability to identify family behaviors that support or impede their self-care goals and enhance skills to ask for needed support and manage obstructive behaviors.

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Research, Activities, Procedures, and Schedule of Events for Study Participants

Please check all that apply to your study and describe each below.

[ ] Behavioral Observation
[**x**] **Randomization**
[**x**] **Blinding**
[**x**] **Surveys, Interviews, Questionnaires**
[**x**] **Document and Artifact Collection**
[ ] Deception, Withholding or Postponing Medications/Treatments, or Imposing other Restrictions
[**x**] **Audio/Video Recording**
[ ] Sham Procedure
[**x**] **Specimen/Data Collection and/or Storage**

DATA COLLECTION, STORAGE OF DATA/SPECIMENS, AND/OR ISSUES OF CONFIDENTIALITY - Describe the procedures that will be utilized to protect the privacy of the research participant. Include who will have access to the research information (for example, video/audio recordings, discovering information about the participant that could be harmful if released such as mental illness, genetic information, sexual preference, drug abuse, etc.) and where it will be stored.

Only KSP, approved by the IRB, will have access to participant data. Original paper copies of signed informed consent documents will be filed in a locked file cabinet in the Center for Health Behavior and Health Education (The Center also requires key card access.). Participant information used to contact or follow-up with participants will be stored without any health information, and be password-protected. Participant information will be retained on a secure Vanderbilt University Medical Center (VUMC) server until the close of the study, at which point it will be destroyed. KSP will record and store survey data electronically via REDCap (Research Electronic Data Capture; see below), separate from identifiable information used to contact or follow-up with participants. Additionally, participant identifiers will be retained for financial and regulatory research purposes, and to contact those participants who agree to let us contact them for future studies. Such information will be password-protected and stored separately from any study-related data. Any voicemails left on the REACH Helpline will be stored on a secure, HIPAA-compliant server, and only KSP can access recordings via password. Participant responses to two-way text messages will be collected by MEMOTEXT, and never associated with any identifiable information, but rather only with the participant's unique study ID. MEMOTEXT will provide reports of such de-identified data to KSP, which will be password protected and stored electronically on a secure VUMC server for at least ten years after the close of the study (see Reach Memotext Reporting).

Neighborhood Health participants sign an RoI as part of clinic processes. Once signed, the hard copy of the document will be scanned for the clinic to store in their EMR. We will store a scanned copy on our secure VUMC shared drive until the end of the study. We will store hard copies with the date of birth and Social Security Number (an optional field for the participant to fill out) redacted in our locked file cabinet separate from study data until the end of the study.

Describe how the confidentiality of participants' data will be assured. Include a description of any issues specific to the study that might increase the risk of breach of confidentiality. Describe how codes will be generated if codes are used to protect identities, and who will have access to such codes. If a certificate of confidentiality will be provided, include the name of the person holding the certificate. Describe the final disposition of research data when the study is concluded (e.g., will information be destroyed, will the PI maintain the information indefinitely, etc.).

KSP will assign participants a unique subject ID associated with their identifiable information in REDCap. Family member participant information is linked to the patient participant. All transcripts, surveys, message response data, and audio-recordings will be de-identified. KSP will use REDCap to record and electronically store survey data. REDCap is developed specifically around HIPAA security guidelines and is a secure, web-based application housed in a local data center at Vanderbilt. All de-identified data will be stored in password-protected files and retained on a secure VUMC server for at least ten years after the close of the study.

RANDOMIZATION - Describe the randomization process (who will randomize, how will randomization be determined, etc.)

After completing informed consent and enrolling in the study, participants are randomized to one of three study groups: REACH, FAMS, or control (see Research Study Design). Randomization is determined with a statistical script developed in R, and run by a member of KSP. (This feature is not yet integrated into REDCap. Once available, this will occur in REDCap). Unblinded KSP calls each participant prior to the Sunday in which they will begin the program to communicate what they can expect based on their study group assignment (see REACH, FAMS, and Control Condition Explanations).

All participants will receive a welcome text message to begin the program (see Stand Alone Text Content). All participants will be provided with access to the REACH Helpline for technology-related (e.g., inquiries about sending or receiving text messages), research-related (e.g., inquiries about participant compensation), and medication-related (e.g., inquiries about medication side effects) questions (see Helpline Recording Script). The latter will be addressed by a clinical pharmacist on our team who can provide medication management support, if needed (see Clinic Helpline Agreements). All participants will also receive a text message notification when their A1c results are ready (see section below on Specimen Collection).

Participants assigned to REACH or FAMS will receive a one-way text message each day addressing individual barriers to medication adherence and medication regimen, diet, exercise, or self-monitoring of blood glucose (SMBG) (see REACH One Way SMS Content and FAMS Patient User SMS Content). Each day, they will also receive a two-way text message before bedtime that asks about their medication adherence that day (see Stand Alone Text Content). These daily responses are used to provide adherence feedback sent via one-way text message at the end of each week (See REACH Weekly SMS Feedback). Additionally, FAMS participants will receive a weekly two-way text message that solicits a response about their adherence to their diet/exercise goal for the week (see FAMS Weekly SMS Content). FAMS family member participants will receive one-way text messages 3-4 times per week, for up to six months (see FAMS Family Member SMS Content).

At six month assessment, participants are given the option to receive less text messages. Participants who choose this "low dose" option will then receive one-way text messages every third day addressing individual barriers to medication adherence and medication regimen, diet, exercise, or self-monitoring of blood glucose, and will receive a two-way weekly medication adherence text with associated feedback (see REACH Weekly SMS Feedback Low Dose) .

BLINDING - Describe who will be blinded and if/when research results or previously blinded treatment assignments will be made available to participants. Include the provisions for breaking the blind (e.g., emergency situations, participant's request, etc.).

Individuals blinded to participants' group assignment include the PI and Co-Is. We will not tell participants that they are in a control or intervention group, but we will tell them what they can expect in terms of what intervention components they will receive (see REACH, FAMS, and Control Condition Explanations).

SURVEYS, INTERVIEWS, AND QUESTIONNAIRES - If surveys, interviews or questionnaires will be used as part of this study, indicate who will conduct the survey, interview or questionnaire and his/her qualifications. In addition, describe the setting and mode of administering the instrument (e.g., by telephone, one-on-one, group, etc.) and attach a copy of the instrument.

Participants will complete an in-person survey administered by a trained RA (using REDCap) in a private room at their clinic. Participants complete a baseline survey, and then follow-up survey assessments are conducted at 3-, 6-, 12-, and 15-months (see REACH RCT Survey). For eligible participants who are interested but unable to enroll in the study in-person at the clinic (e.g., work schedule or transportation constraints) will have the option of being sent the baseline survey via mail or e-mailed link to online survey to complete on their own and send back (RAs will give them this option, and we would send them the survey or link, which do not have any identifiers, and will include return postage paid for mailed surveys). During the in-person assessment, RAs will have the option of completing the demographic information on their own, filling in their answers on a paper survey. RAs will ask whether they want to complete this on their own, or the RA can walk them through each question aloud (see Paper Survey Demographic and Contact Information). For follow-up assessments, those participants with high health literacy (based on our survey measure) and/or are unable to complete assessments in person (e.g., due to work schedule or transportation constraints) will have the option of being sent the follow-up survey via mail or e-mailed link to online survey to complete on their own and send back (RAs will give them this option, and we would send them the survey or link, which do not have any identifiers, and will include return postage paid for mailed surveys) (see Cover Email, Cover Letter, Protocol for Sending REACH Survey, Paper Survey. RCT Eligibility, and Online Survey).

For participants randomized to receive FAMS, a trained RA will deliver diabetes coaching via telephone once per month. Following each diabetes coaching session, the RA will complete the coaching assessment in REDCap (see FAMS Diabetes Coaching Protocol).

A trained RA will conduct a telephone survey with family members at enrollment and a follow-up assessment at six months (see FAMS Family Member Recruitment and Enrollment and FAMS Follow-up Survey and Script Family Member). The family member can also complete the enrollment and follow-up survey online if they prefer.

DOCUMENT AND ARTIFACT COLLECTION - Describe any documents or other artifacts (e.g., student written assignments, EKG report, x-rays, etc.) that are to be collected and used as part of the research study.

Trained RAs will access patient participants' electronic medical record (EMR) for information collected as part of their regular care, including medical diagnoses, vitals, recent A1c results, and medication (see REACH RCT Survey). During the course of their enrollment, if a participant begins to receive diabetes care at a site other than one of the participating clinics, KSP will get participants' authorization to retrieve their medical information (see VUMC Authorization).

Neighborhood Health Clinic now requests that all patients sign an additional Release of Information (RoI) form. To accommodate their new process, we will mail the form along with a cover letter to those participants who are not scheduled to meet with us in the next month for a study follow up appointment. All other participants from Neighborhood Health will sign the form at their next appointment with a research staff member at their clinic.

AUDIO/VIDEO RECORDING - Describe how the audio/video recordings will be stored, as well as how they will be disposed of when this research is complete. Describe how the participant's confidentiality will be maintained.

Messages left on the REACH Helpline will be recorded. Only trained KSP can access the messages through a password protected website hosted on MEMOTEXT's secure, HIPAA-compliant server. Audio files will then be stored on a secure VUMC server separate from other participant data. These files will be deleted upon study closure.

For those randomized to FAMS, diabetes coaching sessions will be audio recorded, and audio files will be stored using the unique subject ID on a secure VUMC server. Coaching sessions will be transcribed, de-identified, and stored on a secure VUMC server (separate from other participant data) for at least ten years after the close of the study. Audio files will be deleted upon completion of the research study.

SPECIMEN COLLECTION - Describe all procedures used for specimen collection.

Patients will receive a laboratory A1c blood test upon enrollment/baseline and at each 3-, 6-, 12-, and 15-month assessment. Clinic nurses or phlebotomists will collect a small amount of blood (7ml) at each draw, which is then sent to the lab used by each clinic. Results will be forwarded to our research team and KSP will enter them into participant's data record in REDCap. Once a value is entered, participants will be informed via text message that their A1c result is available. The text message instructs them to either log on to a secure website or call the REACH Helpline to receive their A1c result (see Stand Alone Text Content and A1c Website and Script).

Participants who are unable to complete an A1c blood draw in their clinic (e.g., work schedule or transportation constraints) will have the option of receiving a mail-in A1c kit to complete on their own. The kit includes no identifying information, as we de-identify each kit and link it to a secure barcode before sending it the participant. The return envelop is prepaid for the participant to send their kit to the lab. We then receive the results from Coremedica through a secure portal, listed by barcode number--with no identifiable information. Those participants using the mail-in kit also receive a letter and instructions, an informational insert, and they can also call the REACH team with any questions (see Mail-in A1c Letter, HemaSpot Instructions, A1c Insert, and Mail-in A1c Script).

Will you be performing a blood draw(s)?

[**x**] **Yes**
[ ] No

Indicate ml over unit of time.

Participants have a small amount of blood (7ml) collected at enrollment/baseline, and at the 3-, 6-, 12-, and 15-month assessment.

The mail-in kit uses approximately 2-3 drops of blood.

Will specimens be obtained for genetic testing?

[ ] Yes
[**x**] **No**

Will the PI create a repository at VU/VUMC with any of the specimens and/or data for future use?

[ ] Yes
[**x**] **No**

Please indicate all procedures and activities performed for research purposes only and the frequency at which they occur in the study (e.g., skin biopsy, 3 times).

[]

If all of your study is minimal risk, please indicate the categories that it fits 45 CFR 46.110 or 21 CFR 56.110:

[ ] N/A: Study is greater than minimal risk or Standard
[ ] (F)(1) Drugs or devices where no IND/IDE is required
[ ] (F)(2) Collection of blood by stick or venipuncture
[ ] (F)(3) Prospective collection of specimens by non invasive means
[ ] (F)(4) Collection of noninvasive data through routine clinical practice
[**x**] **(F)(5) Research on materials that have been collected for non research**
[**x**] **(F)(6) Collection of data from voice, video, digital or image recordings**
[**x**] **(F)(7) Research on individual or group characteristics (surveys)**

Please indicate what materials have been or will be collected.

Medication, Diagnoses, Vitals, A1c results

Please indicate the type of data collected.

Voice recordings from diabetes coaching and voicemails left on the REACH Helpline

Please describe type of survey or focus group, evaluation methods used.

A trained RA will administer a self-report survey at enrollment/baseline as well as at the follow-up assessments at 3-, 6-, 12-, and 15-months. These surveys will be administered face-to-face in a private room at the patient's clinic, and the RA will enter data into REDCap. In the event a participant is unable to complete the survey during a face-to-face appointment (e.g., due to repeated scheduling conflicts), an RA may administer the survey via telephone. The enrollment/baseline survey process will take approximately one hour, and follow-up assessments will take 30-45 minutes each (see REACH RCT Survey). Additionally, participants who are unable to complete the surveys in-person at their clinic (e.g., work schedule or transportation constraints) have the option to complete the assessment via mailed survey or e-mailed link to online REDCap survey.

For family member participants, a trained RA will administer a survey at enrollment and at a follow-up assessment at six months. These surveys will be administered via telephone (see FAMS Family Member Recruitment and Enrollment and FAMS Follow-up Survey and Script Family Member).

All participants will be given a "debriefing" letter in-person or via mail after the 15 month timepoint as part of ending their participation (see RCT Debriefing Letter).

Data and Safety

Describe how the risks to participants are minimized (e.g., screening to assure appropriate selection of participants, identify standard of care procedures, sound research design, safety monitoring and reporting).

Risks to participants are minimized through study procedures, including screening to assure appropriate selection of participants, the use of standard of care procedures (e.g., routine A1c laboratory testing), and safety monitoring and reporting. KSP will screen all patients for eligibility. Trained RAs will review patients' electronic medical record (EMR) to confirm age (18 years or older), a diagnosis of T2DM, and a prescription for daily diabetes medication, defined as a daily medication to control blood sugar. In addition, trained RAs will ensure risks are minimized by confirming patients are able to provide written informed consent, do not have certain impairments (e.g., visual, hearing, speech) that may effect their ability to participate in this research, and are able to receive, read, and respond to text following RA instruction (see REACH RCT Eligibility and Consent).

Participants will receive an A1c blood test at enrollment/baseline, 3-, 6-, 12-, and 15-month assessments. The testing of A1c on a 3-month interval basis is the current standard of care. RAs will work with clinics and patient participants to schedule assessments in line with routine clinic visits to minimize unnecessary patient or provider burden. Participants may experience pain, discomfort, and bruising as a result of the A1c blood test; however these are the risks of this test, which are conducted routinely for patients with uncontrolled diabetes. During the informed consent process, patients will be told they may experience discomfort from thinking about, reporting, and/or discussing how they manage their diabetes, and certain health information will be sent to their cell phones via text message, which may include medication names or information about how to access their A1c test results. If they share or lose their phone, they risk disclosing this information to someone else. Family member participants will not be provided with any health information, but the patient's name will be disclosed along with health-related language that may implicate the patient.

Although adverse events (AE) are not anticipated given the nature of this study, any reported AE will be documented by the PI and handled according to our AE protocol (see section below describing reporting of adverse events).

Describe how the risks to participants are reasonable in relation to anticipated benefits (e.g., includes benefits to the individual as well as to human kind, indicate how the risks are justified in this population).

We anticipate a highly favorable overall risk/benefit ratio for participants. There is minimal risk to participants, with potential risks including 1) the time and inconvenience associated with completing self-report measures; 2) the time, inconvenience, and potential frustration associated with completing a diabetes coaching session; and 3) experiencing discomfort, embarrassment, and frustration associated with a.) using technology generally; b.) annoyance by a technical glitch or "bug" requiring time to resolve; and c.) the inconvenience associated with receiving/responding to a text message. The A1c blood tests may provide discomfort to participants; however, participants are provided with these lab results and at no cost. Test results will inform patients of how well their diabetes is controlled.

Is there a data safety monitor or board/committee to review this study for safety and adherence to the study protocol?

[**x**] **Yes**
[ ] No

Describe the composition of the committee and their qualifications.

An independent data safety monitoring board (DSMB) will review adverse events in a timely fashion and ensure appropriate management is initiated and completed. The DSMB directly communicates with the PI and will follow study events on an ongoing basis. The DSMB includes a Vanderbilt health services researcher (Dr. Kerri Cavanaugh), a practicing primary care physician at Vanderbilt (Dr. Russell Rothman), and an external behavioral diabetes researcher (Dr. Jeffrey Gonzalez), all of whom are not involved with this research. Dr. Cavanaugh is an Assistant Professor and practicing physician at Vanderbilt who performs behavioral research in diabetes. Dr. Rothman is an Associate Professor and a practicing primary care physician at Vanderbilt. Dr. Gonzalez is an Associate Professor of Psychology at Yeshiva University and performs behavioral research in diabetes, including research on medication adherence.

Provide a general description of the data and safety monitoring plan.

This study involves gathering survey data, extracting information from participants' medical record (e.g., medication, vitals, other medical conditions), recording A1c lab results, collecting cell phone user data, and audio-recorded data from diabetes coaching and voicemails left on the REACH Helpline. KSP will comply with all federal, state, and local laws, and maintain complete confidentiality of all data.The risks to participants in this study are minimal. We will follow inclusion/exclusion criteria, and only enroll individuals eligible and capable of participating. RAs are trained to respect patients' self-esteem and privacy. The PI will monitor adherence to these procedures, and ensure participant confidentiality is protected and maintained.

Describe plans for monitoring the progress of trials and the safety of participants (e.g., timing of DSM reviews and reports, planned interim analysis, etc.).

Throughout the study, the PI and/or KSP will monitor participants for unanticipated problems involving risks to themselves or others. Such events will be reviewed and reported by the PI to the DSMB and IRB within 10 working days. Study progress and events will also be reported to the IRB at the time of continuing review. Study staff will regularly monitor user reporting from MEMOTEXT (see REACH Memotext Reporting) to review SMS delivery and responses. Data collection and management, including that from REDCap, MEMOTEXT, the REACH Helpline, and diabetes coaching will be discussed in regular research meetings. We will routinely our data and our ongoing processes, and ensure its success.

Describe plans for assuring compliance with requirements regarding the reporting of adverse events (AEs), including plans for reporting of AEs to the IRB and appropriate regulatory agencies.

Although unanticipated given the nature of this study, KSP will notify the PI of any AE. The PI will then notify additional KSP and DSMB. The DSMB will assist the PI in determining any necessary protocol changes as result of AEs. If protocol changes are needed, the PI will submit an amendment request to the IRB. Protocol changes will not be implemented prior to IRB approval unless necessary, in which case the IRB will be promptly informed of the change following implementation (within 10 working days).

Describe plans for assuring that any action resulting in a temporary or permanent suspension of a federally funded research project is reported to the grant program director responsible for the grant.

The PI and KSP will review our data each week. Any serious, unanticipated events will be promptly reported to the IRB and the grant program director (within 10 working days).

Describe plans for assuring data accuracy and protocol compliance.

The PI trains all research assistants on protocol compliance and about the process of informed consent, and checks for RAs' ability to comply with all protocols before enrolling any participants. The PI and KSP will ensure quality control by conducting regular data verification, reporting reviews, and protocol compliance checks. The PI will complete annual reports detailing the study progress.

Is Vanderbilt going to be the Coordinating Center?

[ ] Yes
[**x**] **No**

Please select the phase of study.

[ ] Phase I
[ ] Phase I/II combined
[ ] Phase II
[ ] Phase III,
[ ] Phase IV
[**x**] **N/A**

Does this study require registration with clinicaltrials.gov?

[**x**] **Yes**
[ ] No

Subject Population(s)

Is this a study in which you will have interaction with individuals? NOTE: Please check "yes" if you need to report accrual goals for participant engagement.

[**x**] **Yes**
[ ] No

Accrual Goal: What is your total accrual goal?

525

Does this study target one gender or specific social/ethnic group(s)?

[ ] Yes
[**x**] **No**

Is the population being enrolled in this study at high risk for incarceration?

[ ] Yes
[**x**] **No**

Check all that apply (*Complete the appropriate supplemental information as applicable):

[**x**] **N/A**
[ ] Children/minors*
[ ] Cognitively impaired - comatose/traumatized*
[ ] Pregnant women/fetal tissue/placenta*
[ ] Prisoners*

Recruitment

Describe the specific steps to be used to identify and/or contact prospective participants. (If applicable, also describe how you have access to lists of potential participants.)

Recruitment methods will include the use of interest cards, flyers and brochure, and referrals from healthcare providers and clinic staff, and in-person contact with patients in the clinic waiting room or at clinic and community events (see RCT Interest Cards, RCT Study Contact Cards, Recruitment Flyer with Tabs, and RCT Appointment Reminder Cards).

We will also contact potential participants through a letter via postal mail and e-mail. This also will allow us to contact patients who aren't in the clinic as often (e.g., every six months) so thus would be unlikely to to come in contact with KSP on-site or fill out an interest card. Our partnered clinics will provide a listing of potential participants based on their EMR queries (e.g., with parameters related to our inclusion criteria such as patients with Type 2 diabetes and on at least one daily diabetes medication). Potential participants will be sent a letter via postal mail (see Participant Recruitment Letters). We are no longer pursuing recruitment via e-mail at Neighborhood Health. For our other partnering clinics, those potential participants who have an e-mail listed as a contact in their EMR will be sent an e-mail (see Participant Recruitment Email). E-mails will be sent from REACH@vanderbilt.edu (which is only accessible to KSP) or a clinic e-mail address, if preferred by the clinic.

Each clinic reviewed and approved the letter and e-mail for use with their patients. Per the request of Neighborhood Health, the mailed recruitment letter is now using an opt-in approach. The letter describes the research, and explains how to call the REACH Helpline to opt-in. Only those Neighborhood Health patients that opt-in are contacted further by KSP. For our other partnering clinics, the letter also briefly describes the research opportunity, and then explains that a KSP will contact them about participating in the study. For those who are not interested and do not want to be contacted by KSP, we provide instructions on how they can opt-out using the REACH Helpline. Those participants who opt out will not be further contacted for study participation by KSP.

We will also use a brief recruitment text (see Recruitment Text) to send participants identified from clinic lists so they can respond with a time that is convenient for them for us to call and tell t hem more about the study. This will help reduce the amount of attempts and back and forth calls in trying to speak with the potential participant.

We may use text messages to correspond with participants who are enrolled in the study. Typically, we use phone calls to communicate with participants about study information (e.g., remind them about upcoming study appointments, confirm receipt of a mailed survey). We will use text messages as a back-up method of communication in our attempts to reach participants about relevant study information.

For potential participants at Faith Family Medical Center, clinic pharmacists will also give patients a half-page insert when they pick up their diabetes medication at the clinic pharmacy. Additionally, we will recruit participants from our previous research studies who indicated they would like us to contact them for future research studies. These individuals will be contacted by their preferred method (e.g, cell phone), and invited to participate.

Patients can also contact research staff via the REACH Helpline if they are interested in participating after learning about REACH at their clinic (see REACH Recruitment Script).

VUMC patient recruitment: We will also locate potential participants meeting eligibility criteria at Vanderbilt locations through specific tools including subject locator, my research at vanderbilt (MRAV), and research derivative. Subject Locator will be used as a recruitment tool to identify potential research subjects based on available in VU clinical systems (e.g. STAR Panel, WizOrder, Clinic Scheduling). The Subject Locator program is part of a toolset available through VICTR that enables teams to specify inclusion/exclusion criteria for a specific study. The inclusion/exclusion criteria are codified for computable use and combined with data coming through VU Clinical Systems to proactively identify individuals who might qualify for a study. KSP will use Subject Locator to identify patients who met eligibility criteria. KSP will then conduct EHR review to confirm the patient met eligibility criteria. We then e-mail or mail all identified patients an

IRB-approved letter from Dr. Tom Elasy stating that research staff will contact them about the study unless they respond via e-mail or phone to opt-out. 7-10 days after the e-mails and letters are sent, KSP will call patients who did not opt-out to tell them about the study. We have approval to contact these patients from the Medical Director of Vanderbilt Primary care, and the primary care physicians at the clinics we are recruiting from.

Once enrolled, any participants randomized to FAMS will be asked if they want to invite an adult family member to participate. They can elect to invite a family member by providing the person's name and mobile phone number. KSP will then contact the family member to describe the study and formally invite them to participate (see also FAMS Recruitment and Enrollment Script Family Members).

Those participants who complete a follow-up survey electronically or via mailed paper copy will receive their materials along with a cover letter that explains the study components. KSP will fill out the information needed. Because this is a long study with several components, this letter and figure help to reiterate key points of the study, and we hope, also contribute to better retention. KSP will use to appropriate form based on how the participant will be completing the survey (e.g., online, mailed paper survey) and which items are needed for the timepoint (e.g., A1c, survey, both), fill it out with the applicable information, and these letters will be included when sending the online or paper follow-up survey materials.

Identify the criteria for inclusion and exclusion and explain the procedures that will be used to determine eligibility. If psychiatric/psychological assessments will be conducted (e.g., depression or suicidal ideation screenings), state who will administer, his/her experience, and how risks will be managed.

Patient inclusion criteria includes adults aged 18 years and older (per participant report and confirmed by a trained RA following informed consent); individuals with a diagnosis of T2DM; patient at a participating health center (Faith Family Medical Clinic, The Clinic at Mercury Courts, Vine Hill Community Clinic, Priest Lake Family & Women's Health Center, Neighborhood Health Clinics, and VUMC; see Faith Family, Ketel, and UCHS Letters of Support); and current treatment with oral and/or injectable daily diabetes medication.

Patient exclusion criteria includes non-English speakers; individuals reporting they do not have a cell phone; individuals unwilling and/or not able to give informed consent; individuals whose most recent A1c value, within 12 months, is <6.8%; individuals with unintelligible speech, a severe hearing impairment, or visual impairment; individuals reporting that a caregiver administers their diabetes medication; individuals unable to pass cognitive screening for eligibility; and individuals who cannot receive, read, and respond to a text message after instruction from a trained RA.

Upon recruitment, KSP will ask participants questions to pre-screen for eligibility either via telephone or in-person. If an individual meets those criteria and is interested in participating, KSP then schedule a time to complete eligibility screening and, if eligible, proceed to enrollment. Eligibility screening includes: a brief cognitive screening measure and a series of text message exchanges to ensure the participant is able understand, send, and receive text messages (see REACH Eligibility and Consent).

Family member inclusion criteria includes adults aged 18 years and older (per participant report and confirmed by a trained RA following informed consent); someone identified by the participant as part of their family (biologically or legally, or a close friend or roommate who is involved in the patients' daily routine).

Family member exclusion criteria includes non-English speakers; individuals reporting they do not have a cell phone; individuals unwilling and/or unable to give informed consent; and individuals with unintelligible speech, a severe hearing impairment, or visual impairment.

We will use several items we will use as part of our retention efforts with participants over the course of the 15 month trial. These include a t-shirt, water bottle, magnet, and birthday card with the REACH logo, and a brief seasonal newsletter. KSP will offer the magnet and t-shirt or water bottle over the course of the study in person at an upcoming survey assessment. If the participant completes their surveys via e-mail or a mailed survey, KSP will mail the item with the study materials. Our team will mail the birthday card during the month of the participants' birthday which is signed by the team members. The newsletter will be mailed to participants or e-mailed for those with whom e-mail is the preferred contact method. The newsletters offer information about community events, updates from our team, and recipe ideas. We will also e-mail a brief seasonal newsletter to a liaison at our partnering clinics to share with staff. This newsletter will have updates from our team and study progress.

Describe how the selection of participants is equitable in relation to the research purpose and setting.

Given our study aims, this research does not require systematic procedures to ensure equitable selection. We will enroll adults with T2DM that are diverse with respect to age, gender, race, and ethnicity.

Please indicate whether you plan to enroll any of the populations indicated below:

[ ] VU Medical Students/trainees
[ ] Students
[ ] Elderly/Aged - targeted
[ ] Subordinates/Employees
[ ] Females of childbearing potential
[ ] Terminally ill participants
[ ] Healthy Volunteers
[**x**] **Other**
[ ] Minorities

Please specify 'Other' populations:

Adults with T2DM and their adult family members

Please identify ALL applicable recruitment methods:

[ ] N/A
[**x**] **Flyers**
[ ] Internet
[**x**] **Letter**
[ ] Departmental Research Boards,
[ ] Mass E-mail Solicitation/Research Notifications Email Distribution List
[ ] Newspaper
[ ] Posters
[ ] ResearchMatch (IRB 090207)
[ ] Radio
[**x**] **Telephone**
[ ] Television
[ ] Social Media
[**x**] **Other**

Please describe other:

We will use Subject Locator to identify patients prior to upcoming appointments at Vanderbilt Primary Care clinics and send an opt-out letter or email. We may also contact patients via e-mail if indicated as a preferred method of contact on an interest card (see REACH Recruitment Email). We will send a recruitment e-mail (see Clinic Recruitment Letters) for those potential participants identified by one of our partnered clinics based on their EMR queries who have an e-mail contact listed in their EMR. Additionally, we will recruit patients through face-to-face communication in the waiting rooms of participating clinics, as well as at clinic or community events. Providers at participating clinics may also refer patients to the study, and patients can call the REACH Helpline to receive more information about participation (see REACH Recruitment Script).

Will the study provide compensation to research participants?

[**x**] **Yes**
[ ] No

Please specify the method of compensation.

Money

Please include information describing the payment amount and schedule.

Over the course of 15 months, participants can receive up to $210 for completing five assessments and A1c tests. Payment is broken down as follows:

Baseline: $20 Total ($10 survey; $10 A1c)
3 months: $35 Total ($15 survey; $20 A1c)
6 months: $50 Total ($20 survey; $30 A1c)
12 months: $65 Total ($25 survey; $40 A1c)
15 months: $40 Total ($20 survey; $20 A1c)

If participants complete screening but are ineligible to participate, they will receive $10 as compensation for their time.

Additionally, FAMS participants will receive $10 for their participation in diabetes coaching--for a total of up to $60 (Phone coaching is offered once per month for six months). Family member participants will receive up to $50--$25 for the initial assessment and $25 for the follow-up assessment at 6 months.

Participants receive payment via mailed Comdata cards. KSP submit payment information to our departmental budgets administration and then the VUMC card office, and the cards are pre-loaded and mailed to the participant. We will use mailed checks as a back-up method for participants who prefer to continue to receive a mailed check instead of the Comdata card.

Are you requesting a waiver for the collection of Social Security numbers?

[**x**] **Yes**
[ ] No

Do you agree to release study information to Vanderbilt-approved list services, web sites or publications? NOTE: Vanderbilt has a variety of list services and publications, such as the Clinical Trials Website. Posting research protocol information on research-related websites and other listing services, allows potential participants to search and find studies related to their condition or interest.

[ ] Yes, this information may be released as described in the lay summary.
[**x**] **No, do not release information to research-related web sites and other listing services.**

Does this study include a certificate of confidentiality or sensitive research information that must be hidden in the medical record?

[ ] Yes
[**x**] **No**

Radiation Procedures and Radioactive Drugs

Does this study involve any radiation ionizing procedures for research?

[ ] Yes
[**x**] **No**

Drugs, Devices, Biologics

Please check all that apply:

[**x**] **N/A**
[ ] Drug(s)/Biologic(s) or Placebo (inactive substance) Used for Research that HAVE an IND
[ ] Drug(s)/Biologic(s) or Placebo (inactive substance) used for Research that DO NOT have an IND [only include drugs that are being used outside of package insert labeling for indication, route of administration, dose, dosing frequency, dosage form, and/or population in which the drug is being used (i.e. children)]
[ ] IBC Review for Live, Recombinant, and/or Attenuated Microorganisms for Vaccination, Gene Transfer or Botox
[ ] Device(s) Used for Research (devices may also include computer software, in vitro diagnostics, etc.)

PHI/Consent

Please indicate what you plan to do with regard to consent (check all that apply):

[**x**] **Consent**
[**x**] **Waiver of Consent**
[ ] Consent was obtained in another study
[ ] Consenting not required (e.g., exempt project, non-human project)

Please describe the specific steps for obtaining informed consent and the procedures that will be utilized to protect the privacy of individuals.

Following recruitment, a member of the research team will schedule each patient for an enrollment appointment at the clinic where they receive care. During this time, a trained RA will go through the process of informed consent, reviewing the consent document verbally (see REACH ICD and REACH RCT Survey), allowing the patient to review the informed consent document, and then obtaining informed consent for participation in this research. The patient can ask questions at any point during the consent process. As part of the informed consent process, the RA will explain the procedures in place to protect the privacy and confidentiality of participants.

Patient participants randomly assigned to FAMS will have the option to invite a family member by providing that person's name and phone number. A trained RA will then call the family member to screen them for eligibility, tell this person more about the study, including the benefits and risks of participation, and ask if they are willing to participate (see FAMS Recruitment and Enrollment Script Family Members). Family members can also receive this information they agree to over the phone regarding their participation via mail or e-mail for their records (see FAMS Family Member Informed Consent).

Does the person obtaining consent have an existing relationship with the participant(s)?

[ ] Yes
[**x**] **No**

Please describe any waiting periods between informing potential participants of the research and obtaining consent, if applicable.

Some patients may learn about the study from their provider or by viewing a flyer in the clinic waiting room. Such participants can fill out an interest card and a trained RA will contact them to describe the study, screen for eligibility, and complete an enrollment survey. We anticipate the time between the completion of an interest card and RA contact to be less than one week. For some patients, there will be no waiting period because they learn of the study from an RA in the clinic waiting room and then, if interested and eligible, enrollment/baseline processes are completed on the same day.

Will surrogate consent be requested?

[ ] Yes
[**x**] **No**

How will non-English speaking participants be consented?

[ ] A translated written informed consent document in a language understandable to the participant. This should be an accurate translation of the full informed consent document (consider having a translator present during the consenting process should the participant have any questions).
[ ] Orally, using a qualified translator to translate the English informed consent document to the participant, and a translated short form in a language understandable to the participant. (See "Documentation of Informed Consent" at IRB Policy IV.B for details).
[**x**] **Enrolling only English speaking participants.**

Please provide a justification for only enrolling English speaking participants.

At this time, the study content (delivered via SMS) is available only in English.

Which type of waiver is being selected (check all that apply):

[**x**] **Waiver of Documentation**
[ ] Alteration of Informed Consent Process
[ ] Waiver of Informed Consent Process/Waiver of Authorization

The IRB may waive the requirement to obtain a signed informed consent document for some or all of the participants. This is a waiver of signatures only. With this option, all of the other basic elements of informed consent are still present and are provided to participants.

[ ] The only record linking the participant to the research is the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Under this condition, each participant must be asked whether he/she wants to sign a consent document. The IRB must review and approve the consent document.
[**x**] **The research is minimal risk and involves no procedures for which written consent is normally required outside of the research context (e.g. phone surveys, collection of de-identified data from medical record or other chart review). The IRB must review and approve the consent document or script.**

Are you requesting a waiver of authorization to access (use) Protected Health Information (PHI)?

[ ] Yes
[**x**] **No**

Please describe the plan to protect the identifiers from improper use and disclosure.

Participants will be assigned a unique subject ID associated with their identifiable information. Family member participants' information is linked to the patient participant. Original paper copies of informed consent documents and completed interest cards will be filed in a locked cabinet in the Center for Health Behavior and Health Education (CHBHE). All transcripts, surveys, text message response data, and audio-recordings will be de-identified. Survey data will be recorded and stored electronically (via REDCap), separate from identifiable information used to contact or follow-up with participants. All identifiable information used to contact or follow-up with participants will be stored without any health information, and is password protected and retained on a secure VUMC server until the close of the study, at which point it will be destroyed. Participants' responses to two-way text messages are never associated with identifiable information, but will be associated with participants' unique subject ID. Participant identifiers will be retained only for financial or regulatory research purposes, and are password-protected and stored separately from any associated data. Only trained KSP will have access to participant data.

Will Protected Health Information (PHI) be accessed (used) in the course of screening/recruiting for this research?

[**x**] **Yes**
[ ] No

Does this research use or disclose Protected Health Information (PHI)?

[**x**] **Yes**
[ ] No

Please indicate the source of the PHI to be collected.

Medical records and data previously collected for research purposes.

Please indicate when PHI will no longer be accessed.

Closure of the study

Please describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Participant identifiers will be retained only for financial or regulatory research purposes. All identifiable information used to contact or follow-up with participants will be stored without any health information, and will be password protected and retained on a secure VUMC server until the close of the study, at which point this information will be destroyed.

Conflict of Interest Disclosure

Is there a potential conflict of interest for the Principal Investigator or key personnel? • The PI is responsible for assuring that no arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research and no arrangement has been entered into where the amount of compensation will be affected by the outcome of the research. • Assessment should include anyone listed as Principal Investigator, or other research personnel on page 1 of this application. Please note that ownership described below apply to the aggregate ownership of an individual investigator, his/her spouse, domestic partner and dependent children). Do not consider the combined ownership of all investigators.

[ ] Yes
[**x**] **No**