Protocol and Data Analysis Plan

NCT04041375

Using Peer Navigators to Increase Access to VA and Community Resources for Veterans With Diabetes-related Distress

11/22/2022

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Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

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Status: Approved
Initial Submit Date: 9/20/2018
Approval Period: 3/1/2021 - 3/1/2026

Section Aa: Title & PI

A1. Main Title

USING PEER NAVIGATORS TO INCREASE ACCESS TO VA AND COMMUNITY RESOURCES FOR VETERANS WITH DIABETES-RELATED DISTRESS (INSPIRED)

A2. Principal Investigator

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

Organization: VA HSR&D

A6a. Institution(s) where work will be performed:

Michael E. DeBakey Veterans Affairs Medical Center

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
Yes

A9. ClinicalTrials.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?
Yes

Who will be responsible for registering and maintaining the registration of this Applicable Clinical Trial?
The non-BCM lead site of this multicenter trial will register the trial.

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Diabetes and mental heath

Diabetes-related distress increases the risk of poor diabetes self-care and adverse diabetes outcomes. Diabetes-related distress, which is ¿the negative emotional impact of living with diabetes,¿ affects about a quarter of adults with diabetes mellitus (DM). At any given time point, they experience elevated levels of DM-related distress, and over longer periods, one third to one half of adults with DM experience moderate to severe diabetes-related distress. Higher levels of diabetes-related distress are reliably associated with objective parameters of glycemic control (e.g., hemoglobin A1c [HbA1c]), self-

management behaviors, and diabetes-related self-efficacy. In a longitudinal study, a high level of diabetes-related distress at 1 time point significantly predicted deterioration in DM status 1 year later.

Though DM is a chronic disease known for its mental health comorbidities, diabetes-related distress is related to, but conceptually distinct from, other mental phenomena, such as depression, anxiety, and psychological stress. Unique and specific aspects of diabetes-related distress include concerns about adhering to a treatment and self-management regimen, anxiety about diabetes-related complications and interference, concerns about health care quality and costs, and perceived stigmatization related to DM. Although depression and anxiety are common in people with DM, diabetes-related distress appears to be a stronger and more proximal predictor of problems with treatment adherence, self-management behaviors, and disease status. Studies suggest, for instance, that diabetes-related distress mediates the relationship between depression and disease status and that diabetes-related distress is correlated with disease status, even after adjusting for depression history. Accordingly, the 2016 American Diabetes Association (ADA) guidelines distinguish diabetes-related distress from mental health comorbidity and recommend that health care providers specifically screen and address diabetes-related distress to improve overall functioning and DM self-management behaviors.

Diabetes-related distress is modifiable through intervention. Diabetes self-management and education (DSME) is a fundamental component of DM care shown to improve diabetes-specific outcomes, including diabetes-related distress. Core components of DSME address nutrition, physical activity, medication use, problem-solving, risk reduction, and stress management. DSME interventions in a variety of formats, led by professionals, patients themselves, and peers, reduce diabetes-related distress. In particular, health coaching improves glycemic control and diabetes-related distress, particularly for those who present with high diabetes-related distress. Furthermore, health promotion and self-management interventions reduce diabetes-related distress.

Psychological comorbidities, particularly depression, increase risk for diabetes-related distress and vice versa.20,21 Accordingly, mental health interventions also have the potential to reduce diabetes-related distress. An Internet-based self-help intervention aimed at reducing symptoms of depression in people with DM was found, for example, also to improve diabetes-related distress and glycemic control.22 Most studies of psychological interventions for people with DM have targeted people with significant symptoms of depression, rather than diabetes-related distress per se, and have not measured diabetes-related distress. However, for people with comorbid diabetes-related distress and psychological diagnoses, behavioral interventions are an appropriate option to reduce distress and thereby promote better disease-specific outcomes.

Interventions for diabetes-related distress are underused. Peer coaching, DSME, and mental health interventions have been proven to decrease diabetes-related distress. Resources to provide DSME vary greatly and are limited at some Veterans Health Administration (VHA) facilities because of inadequate staffing or lack of trained personnel, reflected by the 40% of Veterans who report receiving no DM education. A recent systematic review traces low engagement in DSME to 2 themes: problems with access (e.g., logistical, financial, and other barriers to participation) and lack of perceived benefit (e.g., perception that no problem exists and a negativity toward self-management programs). We know tailoring DSME and mental health interventions to individual preferences and goals tends to improve outcomes, yet further examining the impact of tailoring health coaching and improving access and delivery modes is a vital need, one highlighted by the 2017 VA/DoD Practice Guideline for Management for DM. Whereas changes in service organization and delivery may address access problems, low patient activation and negative attitudes about self-management present more complex challenges. Thus, we must consider how resources and delivery mechanisms outside the confines of a health system can facilitate innovative health-promotion interventions by prompting program redesign and adopting a socioecological approach that helps overcome negativity.

Community engagement and peer support Community engagement leverages VHA health care. Patients, practitioners, and community stakeholders emphasize the potential of peer support and facilitated, tailored sharing of information for advancing DSME and use of clinical and self-help resources. A growing literature has demonstrated benefits of community-engaged approaches to health interventions, including improved physical and mental health and increased community capacity for care. The VHA has invested substantial resources in the MyVA Communities model, with the goal of engaging Veterans, families, and other key community stakeholders in developing local solutions and improving health. Leveraging and improving access to community resources for DM is consistent with the chronic care model, which promotes effective use and development of disease management resources through coordination of patients, health systems, and community resources and programs. To date, however, little research has addressed facilitating use of community resources for people with DM; and a recent systematic review of 12 trials based on the chronic care model for type 2 DM found that consideration of community resources was absent from all 12 studies. Thus, interventions to promote greater coordination of community resources between health systems and patients are a relatively untapped area of opportunity for improving the care of Veterans and are one of the Under Secretary¿s highest priorities.

Veteran peer-support specialists are ideal navigators for Veterans with DM and mental health¿related comorbidity. In the peer support model, patients ¿in recovery¿ or successfully managing an illness provide emotional, instrumental, and informational support to patients struggling with the disease. Although peer-support providers are like community health workers, peers differ in that, in addition to being members of the same community, they more often have prior personal experience with the illness of the patients they are serving. VHA peer-support specialists share cultural, economic, linguistic, and other characteristics with the Veterans with whom they work and are able to build close, trusting relationships with communities because of a deep knowledge of that community. Their competencies include elements of community outreach (advocacy organizations), modeling of health behaviors, care coordination, education, coaching, and navigation. Current efforts seek to expand peer-support services from the current workforce of 1100, largely employed in mental health services, into primary care services and community settings using new pilot programs. Peer specialists may

overcome barriers to DM self-management by modeling effective skills, changing negative attitudes about self-management, and providing emotional and problem-solving support. VHA peer-support specialists, by normalizing the difficulty of living with DM, sharing their own stories of improving DM self-management, and sharing the same background, are ideal for linking Veterans to community and VHA resources and addressing low motivation.

Peer navigation improves access and outcomes. Because telephone-based peer coaching is acceptable¿and sometimes preferable¿to face-to-face coaching, peer coaching can add little to no additional burden related to access. Additionally, peers can facilitate choice and access by linking Veterans to community resources and VHA resources. Most peer navigation has focused on patients with cancer, showing strong evidence for improving quality of care and patient support and satisfaction but weak evidence for improving cancer outcomes. Recently, reports are endorsing peer navigators for chronic illnesses, including not only DM but also such mental health conditions as posttraumatic stress disorder (PTSD) and depression. Peer navigation in DM care improves important diabetes-related outcomes, including primary care appointment adherence, physical activity, self-efficacy, and HbA1c level. Peer coaching may be especially helpful for baseline poor medication adherence and self-care, and it does not appear to be less effective for people with comorbid depression. Although peer coaching for mental illness is new, the VHA has

Significance We propose a peer-based intervention for diabetes-related distress that facilitates access to and use of VHA and community resources and provides social and emotional support from the peer to increase patient activation and self-efficacy. No peer interventions have emphasized utilization and coordination of both VHA and non-VHA resources to improve disease self-management, and we expand this innovation by offering outreach to non-VHA users and by widening its range to encompass mental health concerns associated with DM (i.e., No Research Overlap). Nearly 25% of US Veterans and 33% of VHA users have type 1 or type 2 DM, a percentage that has grown over the past decade and remains dramatically higher than that of the general US population (12.2%). Despite DM initiatives to help Veterans, only 20% with DM achieve recommended physical activity levels, and only 40% meet nutrition guidelines. Thus, effective DM interventions remain a critical need for Veterans. Moreover, the 50% prevalence rate of diabetes-related distress and the elevated prevalence of mental disorders and psychological distress in the Veteran population demand action to ensure that DM is proactively addressed, its negative health consequences avoided, and diabetes-related distress minimized or eliminated.

The VA National Center for Health Promotion and Disease Prevention champions the expansion and improvement of clinical, research, and educational activities of VHA with respect to services such as health coaching and disease self-management. Concurrently, VA/Department of Defense Diabetes Guidelines emphasize the identification and management of comorbid psychologic illness to facilitate DM treatment. Despite increased attention, recognition and treatment of psychologic distress in persons with DM is low. Collaborative care interventions show promise but are clinic based and seldom used. Furthermore, collaborative-care approaches that primarily target improved mental health care have modest mental health outcomes but have high patient refusal rates and disappointing DM outcomes. Based on these findings, recommendations suggest tailoring interventions, adapting delivery modes, and including a social care component. For these reasons, we propose iNSPiRED (VeteraN SuPport and REsources for Diabetes), an intervention tailored to individual Veterans¿ needs, mindful of their preferences, and responsive (and not addressed in currently funded grants) to the 2016 VHA Health Services Research and Development (HSR&D) high-priority domain of Patient-centered Care, Care Management, and Health Promotion.

Incorporating an approach that engages the community addresses these gaps. First, involving community partners at the earliest stages of the intervention enhances acceptability of the program and the research design and ensures that measured outcomes are meaningful to Veterans. Second, including VHA peer-support specialists prioritizes social contexts of DM self-management and bridges VHA resources and community-based resources. Finally, partnering with community-based organizations (CBOs) to recruit participants and engage in non-VHA settings improves our reach to non-VHA users and Veterans who use the VHA only for some services (e.g., medication) but prefer community settings for others. Focusing on Veterans within and outside the VHA system ensures this work will have a broad audience, including VHA health providers, Veteran peer-support organizations, and non-VHA CBOs. Engagement of Veterans, community organizations, and other stakeholders in developing the research design and implementation and use of VHA peer-support specialists responds to the 2016 HSR&D high-priority domain of Health Care Systems Change and the 2017 VA Under Secretary¿s priorities of Greater Choice (offering community and VHA resources), Efficiency (community and VHA coordination), and Timeliness (telephone delivery).

Section D: Purpose and Objectives

We propose a community-VHA partnership and peer-led navigation intervention (iNSPiRED, or VeteraN SuPport and REsources for Diabetes) to improve access to Diabetes Self-Management and Education (DSME) and mental healthcare in the VHA or the community for Veterans who have DM and diabetes-related distress. iNSPiRED uses peer coaches/navigators to help Veterans access VHA and community resources, including self-management tools, education, and clinical care for mental health and DM. The format, intensity and location of support will be tailored to each Veteran's motivation and preferences. The VHA¿s growing use of Veteran peer-support specialists offers an opportunity to employ them to improve DM management and mental health outcomes. Innovative aspects of this proposal include (1) recruitment of Veterans outside the healthcare system, where they are less likely to access or engage in care; (2) use of Veteran peer-support specialists to address DM and mental health through navigation and coaching; and (3) integration of a community-VHA partnership, including reaching out to Veterans not obtaining care in the VHA and providing options for care outside the VHA. Our proposed intervention aligns with the chronic care model by promoting coordinating healthcare delivery

mechanisms, self-management support and community-based resources and is unique among diabetes-related interventions in its explicit inclusion of community resources and partnerships.

Goal The goal of this intervention is to determine if Veteran peer coaches can decrease diabetes-related distress by facilitating use of VHA and non-VHA medical and health-promotion resources and providing support. The 3-month intervention is enhanced by a robust community-engaged partnership developed by Dr. Kunik and his team between VHA researchers and United Way, Area Agency on Aging, Veteran service organizations, and Veteran-serving community-based organizations.

Aims/Objectives We will evaluate the following outcomes in Veterans with diabetes distress with a randomized trial comparing the iNSPiRED intervention to usual care (print-based referral information and resources):

PRIMARY OUTCOME a. iNSPiRED Veterans will improve more in diabetes-related distress (17-item Diabetes Distress Scale). SECONDARY OUTCOMES b. iNSPiRED Veterans will improve more in diabetes self-management (Diabetes Self-Management Scale). c. iNSPiRED Veterans will improve more in depression symptoms (Patient Health Questionnaire¿8 [PHQ-8]) and anxiety symptoms (Generalized Anxiety Disorder scale [GAD-7]). d. iNSPiRED Veterans will be more likely to use health-promotion programs and clinical care and be more likely to newly choose VHA or community health-promotion programs or clinical care.

STAKEHOLDER OUTCOMES We will employ stakeholder engagement activities to increase development and sustainability of VHA-community partnerships, trust, communication and capacity building. A mixed-methods process evaluation will be used to evaluate this aim.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adult (18-64 yrs), Geriatric (65+ yrs)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:
Asymptomatic patients with chronic conditions, healthy; Patients

Which if any of the following vulnerable populations will be recruited as subjects?
Employees or lab personnel, Mentally ill

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

Although this study involves minimal risk, particular attention will be given to being sure that participants understand that refusing to consent will not affect eligibility to receive any services or benefits from the VA and that confidentiality will be maintained except as allowed by law or as described in the consent document.

Study staff will contact all referrals by phone for initial screening within 48 hours of the initial contact for those referred by community agencies and Veterans Service Organizations and within 10 days for those recruited through opt out letters. For all patients, a telephone script will be used to obtain verbal consent to administer the initial protocol screening. At the initial screen, the study staff will confirm eligibility criteria. Veterans will be screened for distress using the 2-item screening version of the Diabetes Distress Scale (DDS2). Veterans with a mean score of 3 or more will be eligible for the baseline assessment.

Veterans who are eligible and wish to participate further will be scheduled for a telephone baseline assessment. They will receive a cover letter, informed consent document without signature lines, and copies of the baseline assessment instruments. A member of the study team will then call and review the consent documents before final enrollment and completion of the baseline assessment. Given the intervention and research assessments are non-invasive in nature and almost exclusively involve monitoring and assessment of patient functioning, we have established telephone-based contact methods to decrease participant burden. To further improve this process, we will verbally consent participants to afford us greater opportunities to increase our outreach to patients and decrease participant burden. If there is any

confusion, RAs will continue the discussion until the consent form is clarified. Participants will be informed that if they do not wish to answer specific questions or wish to terminate the session, they will be able to do so.

Subjects with suicidal ideation will not be enrolled. However, given that this is a study of treatment for distress, a plan for addressing suicidal behavior during the study was developed. At the start of the study, all Veterans who are enrolled will be asked to provide an emergency contact number of a family member or friend or their PCP. Any increases in distress will be captured during the regular assessments incorporated in the study protocol and appropriate measures will be taken. If participants express thoughts of hurting or killing themselves during intervention or research assessment, staff will complete the Suicide Risk Protocol attached in Section S and provide the Veteran with the phone number to a crisis hotline. Responses will be discussed with a supervisor, who is a licensed mental health provider. The staff member and the supervisor will then decide in collaboration the next steps necessary for the Veteran¿s safety, which may include contacting the Veteran¿s emergency contact and referral for further evaluation and treatment, including hospitalization if necessary.

Stakeholder and researcher engagement will be measured with a survey and process diary. Some researchers and stakeholders are VA employees. Surveys will be anonymized prior to data analysis. We will emphasize that participation is voluntary and will not affect their employment.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

z.r) Randomized, Efficacy Study -- Surgical Techniques/Interventions

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

Overview. The goal of the study is to conduct and evaluate a time-limited, Veteran peer-support specialist-led navigation intervention on diabetes-specific outcomes, mental health outcomes, and use VHA or community care in Veterans with DM and clinically significant diabetes-related distress. We will evaluate the outcomes of the intervention in a randomized trial comparing the intervention to usual care. The proposed work is informed by an established and ongoing partnership between VHA researchers and clinicians, individual Veterans, and representatives of Veteran Service Organizations (VSOs)Community Based Organizations (CBOs) serving Veterans. These key partners have been working together for more than a year, as described above, and will collaborate on all aspects of the research, as detailed below. Study design. This is a single-blind, parallel group, randomized trial of a 3-month peer-navigation intervention for Veterans with DM and elevated levels of diabetes-related distress. Participants will be assigned at random (see below) to the intervention (peer navigation with follow-up) or usual care (print materials and encouragement to continue follow-up with health care providers). Assessment of primary, secondary and intermediate end points will occur preintervention at baseline and postintervention at 3 and 6 months.

Participants. We plan to recruit 218 participants (1:1 allocation) over 31 months (7/month). Central to the design of this trial is the recruitment of Veterans who are VHA users and Veterans who are not. We will screen at our local VHA medical center (MEDVAMC) and established community partnerships, including government agencies, CBOs, and VSOs as described above.

Inclusion Criteria:

Patients will be eligible to participate in the study if they meet the following criteria:

(1) Veteran (2) Diagnosis of type 2 diabetes mellitus, per self-report (3) Moderate diabetes-related distress (Diabetes Distress Scale [DDS2] mean score of 3 or greater)

Exclusion Criteria:

(1) Lack of reliable access to a telephone (2) Cognitive, sensory, or other impairment that prevents use of a telephone (3) Current participation in another diabetes-related counseling or self-management program

F2. Procedure

Upon providing informed consent, participants will be randomized in blocks of 6 or 8, based on referral source (MEDVAMC and non-MEDVAMC). At the initial screen, the study staff will confirm eligibility.Veterans will be screened for distress using the 2-item screening version of the Diabetes Distress Scale. Veterans with a mean score of 3 or more will be eligible to continue. Veterans who are eligible and wish to participate further will be scheduled for a telephone baseline assessment.They will be mailed a cover letter, informed consent document without signature lines, and copies of baseline assessment instruments.A member of the study team will call and review the consent documents before final enrollment and completion of the baseline assessment.

Usual care.Veterans randomized to the usual care condition will be encouraged to follow-up with their primary care provider and/or specialty providers for management of their health conditions. They will receive a packet of printed information that includes a list of self-management support resources in the VHA and the local community, but no specific recommendations or referrals.The list will be updated periodically with similar resources as needed.

Peer intervention. The peer intervention will include approximately 5-6 contacts over a 3-month period. Peer coaches are responsible for providing emotional and social support, normalizing the difficulty of living with DM, modeling help-seeking behaviors, and connecting patients with VHA and/or Community-based Organizations (CBOs) to address mental health and DM self-management needs. Peer coaches are not responsible for health education directly, but will encourage patients to use appropriate programs in which mental health and DM self-management services are provided.They will be trained to offer encouragement and basic assistance with problem-solving, activation, achieving self-efficacy, and setting goals. As Veterans with DM or other chronic medical/mental health conditions, peer coaches are ideal guides who help uniquely by sharing their personal stories and modeling. After making an initial introduction by telephone, the peer coach will arrange to meet with the Veteran in person at a mutually suitable place (e.g. a coffee shop, a community agency, a VHA facility) or by telephone, Facetime, GoogleDuo, Zoom or Microsoft Teams with a VA cell phone. Home visits may be allowed for home-bound Veterans pending an evaluation of safety and approval of the PI/his designee. During this meeting, the peer coach will orient the Veteran to his or her role, exchange contact information and preferences for contact, and conduct a needs assessment to identify opportunities to recommend specific resources. Potential mental health resources include counseling and medication referrals, online or in-person support groups, and education materials about distress and mental health conditions. Potential DM resources include online education materials from the ADA, cooking and recipe information, referrals to DM education and dietitians, free and low-cost exercise classes and gyms, and local food banks that have DM-friendly foods. Specific resources for related issues--low-cost primary care clinics, help with sleep problems, and transportation resources for medical appointments--are included. Peer coaches will be trained to probe for additional information as needed and to identify specific unmet needs or experiences of securing help. For instance, a Veteran who reports feeling overwhelmed with a DM regimen may be asked other questions to identify whether he or she has obtained help from a health professional and what solutions have already been tried. As peer coaches come to understand the Veteran's priorities, preferences, and barriers better, they will provide validation and support, offer suggestions for a few applicable community programs, and facilitate goal setting to help the Veteran choose and follow through on recommendations. The peer coach will follow up by phone approximately every 2-3 weeks, based on Veteran needs and preferences. Information and education on DM self-management and psychological well-being may be provided verbally or through the mail and will be tailored to the patient's needs and preferences. Participants will also be provided with a study workbook and goal-setting worksheet. The intervention will end at 3 months, when the Veteran chooses to terminate or after 5 consecutive unsuccessful attempts at contact.To ensure fidelity to the intervention, peers will complete semi-structured session notes after each interaction with a Veteran that will be reviewed by the peer supervisor each week. Session notes will include which resources were provided, whether problem-solving or coaching was used, and progress towards goals.

Peer coach selection and training. We will recruit two Veterans through referral from partner agencies and the VHA to serve as peer coaches. Recruitment, hiring, and interviewing will be based on the VHA's peer hiring toolkit. Peer coaches will not have other employment relationships with the VHA. Study investigators will provide 40 hours of training that will cover the role of a peer support provider, general principles of self-management, DM self-management, motivational techniques, goal setting, communication, safety issues and boundaries, and tracking and follow-up procedures. Included will be 8 hours of Military Veteran Peer Network Basic training provided by Mental Health America of Houston, which equips peer coaches with frontline intervention tools (e.g. modes of peer support; assessment skills; skills in handling suicide prevention, stress, and addictive behaviors). Peers will also be oriented to VHA and community DM and mental health resources. A study investigator-clinician readily accessible by phone will supervise coaches, meeting with each one at least weekly. Peers will be provided an intervention manual that includes safety guidelines.

Patient assessments will be measured by telephone by an independent evaluator without access to group assignments at baseline, M3 and M6: -Background and Demographics (baseline) -DM-related distress score, as measured using the DDS17 -Summary of Diabetes Self-care Activities Questionnaire (SDSCA) -The Patient Health Questionnaire-8 (PHQ-8) -The Generalized Anxiety Disorder-7 (GAD-7) -Veteran's self-report of use of community-based or VHA resources (baseline and M6) -Patient Activation Measure (PAM-13) -Patient-Reported Outcomes Measurement Information System (PCORI) instruments: Self-Efficacy for Managing Social Interactions, Emotions, and Daily Activities Participants will be asked if they would like to be mailed a summary of the study results after the study is completed.

Exit interview. We will administer a semistructured exit interview at M6 to intervention group participants to elicit patient-level barriers/facilitators to engagement and views on how to improve the intervention. Questions are designed to elicit

brief responses. Responses will be entered verbatim into the database.

With the subject's permission, study staff may communicate with subjects about appointments via text messages from VA cell phones (e.g. appointment reminders), in order to facilitate retention. Links to information and resources that do not contain sensitive information may also be sent via text message from VA cell phones. This will be explained during the informed consent process and is included in the consent document. No PHI/PII/sensitive information will be included in the messages. Creating and maintaining community-VHA partnerships Partners for the proposed research include representatives from the community agencies already engaged in developing the current proposal, including local government agencies, CBOs that serve Veterans, and Veteran Service Organizations (VSOs); an individual Veteran with DM with experience and expertise in use of VHA and community resources; the MEDVAMC DM educator; and leadership from the VHA research team. These partners will meet twice a year in person or online during the project to discuss progress and study updates and provide input on key aspects of study implementation, data collection and analysis, and dissemination of findings. All members of the partnership who are not VHA employees will be compensated $150 per meeting in recognition of their time and expertise. These meetings will be run according to principles of Community-Based Participatory Research (CPBR), as informed by best practices set forth by PCORI and other leaders in CBPR: sharing authority, acknowledging different areas of knowledge and expertise, building trust through safe communication, and creating knowledge with partners from different backgrounds and perspectives. A co-Investigator, with expertise and experience in this approach, will advise leadership on best practices for organizing, preparing for, and executing these meetings. A team member will be designated to record observations for the process diary, including who attends, who provides input, areas of agreement and disagreement, and how disagreements are resolved. The VHA team will communicate with partners via e-mail, phone, and in person to address any issues about study implementation. Topics discussed and actions taken will become part of the study diary. Stakeholder and researcher engagement. At baseline and 1-year intervals throughout the project, we will measure engagement from the community partner and research perspective using the PCORI Ways of Engaging-Engagement Activity Tool (WE-ENACT). The Patient and Stakeholder Survey will be administered to 1-2 key representatives from each CBO. The Researcher Survey (modified version) will be completed by the PI with team input. Surveys will be self-administered via Survey Monkey (non-VA employees) or on paper and will be anonymized prior to data analysis. Process diary. A qualitative process diary will be kept by the project manager and updated weekly, with a focus on intervention delivery and community engagement. Domains of the process diary will include recruitment and data collection challenges, strategies, and outcomes; recruitment/refusal rates and loss to follow-up rates for VHA vs. community sites; challenges and successes related to community engagement in all phases of the study; most common problems encountered during peer coaching.

We will develop a brief Memorandum of Understanding between the VA leadership team and each partner outlining: 1. The purpose/goals of the partnership, 2. What they can expect from the VA research team, and 3. What will be asked of them during the course of the project including activities, meetings, and surveys they will be asked to complete as part of the engagement process. Protection Against Risk: Questionnaires. Participants will be informed that if they do not wish to answer specific questions or wish to terminate the session, they will be able to do so.

Adverse Events. In addition to the subject's request, criteria for discontinuing a subject's participation may include, as determined by the Primary Investigator in discussion with the study team, any life-threatening or potentially disabling event, or hospitalization for acute medical or psychological illness. These serious adverse events (SAEs) will be recorded and included in the database. SAEs will be reviewed by the PI and reported to the IRB in accord with VAMC policy. Any subject who develops an SAE during the conduct of study protocols will be referred for immediate medical care at the VAMC or outside medical facility and referred to their physician for ongoing care. Management of Suicidal Ideation (SI) or Behavior. SI with intent or plan is an exclusion for this study. However, given that this is a study of treatment for distress, a plan for addressing suicidal behavior at any time during the study was developed (see section E2).

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 218 Worldwide: 218

Please indicate why you chose the sample size proposed:

In determining the sample size of 218 needed to recruit for the study, we examined the number of patients needed to have adequate power to detect differences between the intervention and usual care groups using the mean DDS17 score as the primary outcome. The sample size was initially based on testing for a medium effect size (d = .50) between the intervention and usual care groups at a single time point, using a two-group t test with a 0.05 2-sided significance level and power of 80%. Because we will assess participants at three time points (baseline, posttreatment, and 6 months), this estimate was then adjusted to account for the correlation among the repeated measurements, using the adjustment factor [1 + (T-1)ñ]/T, where T is the number of follow-up measurements and ñ is the correlation coefficient of the repeated measurement. In our study, T = 2 follow-up measurements after baseline, and ñ is estimated using the relatively high value of 0.5. The sample size determined for the primary outcome was inflated to account for attrition of 30% at 6 months. In a VHA-funded investigator-initiated grant (Behavioral Activation Therapy for Rural Veterans with Diabetes and Depression; PI: A. Naik), on which members of the research team are co-investigators, attrition at 6 months was 16.9%. Because this study will include Veterans from VHA and non-VHA settings, we estimated attrition to be somewhat higher than what we

found in the study of patients from VHA settings only. Thus, a sample size of 134 patients would need to be recruited (67 in the intervention group and 67 in usual care) for 80% power to find important differences in the DDS17 measures.

However, to have power to address the secondary outcomes and because only a portion of the recruited Veterans will have anxiety and depression, we increased the sample size of 134 by 62.7% as described below, resulting in 218 Veterans to be recruited. Although all eligible participants will have diabetes-related distress, we expect depression and anxiety to be prevalent in 25% or more of participating Veterans. Fisher et al. found that 22.5% of those with high diabetes-related distress were clinically depressed. For these secondary outcomes, we initially calculated the sample size based on testing for a large effect size (d = .80) between the intervention and usual care groups at a single time point, using a two-group t test with a 0.05 two-sided significance level and power of 80%. Adjusting this to account for correlation among repeated measures results in 18.4 participants per group. Finally, adjustment for 30% attrition at 6 months results in a total needed of 27 per group. Therefore, we need to recruit 218 Veterans, of whom we expect 25% (54) to have anxiety and depression. Thus, we will have 80% power to detect a large effect size of .80 for the secondary outcomes of PHQ-8 and GAD-7. If we based the sample size for the secondary outcomes on detecting a medium effect size of .50, the required sample size of 134 patients would mean increasing the total to 536 patients, a number not feasible for this grant (25% of 536 patients = 134 with anxiety and depression).

In our prior work involving similar recruitment methods, we expect that approximately 7% of those referred to the study from VHA patient databases or community partners will be enrolled in the study (i.e. contact made, interested and eligible for the study). Therefore, we estimate that we will need to attempt to contact approximately 3,114 potential subjects in order to enroll 218 patients in the study.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

Outcomes: Primary outcome. We will compare participants in the 2 study arms on baseline characteristics, including sociodemographic characteristics and clinical variables. Based on the Consolidated Standards of Reporting Trials recommendations, we will not provide tests of significance or adjust subsequent analyses for variables found to differ because adjustment may bias the estimated treatment effect. However, because socioeconomic status (SES) and race/ethnicity might impact the mechanism of navigation/coaching, we will include the SES (income and education) and race/ethnicity variables as a priori covariates in our regression analyses. We will examine distributions of the primary outcome (DDS17) and consider transformations, if necessary. We will test for differences between the active intervention and usual care groups using continuous dependent measures (either untransformed or transformed if needed). The random coefficient model will allow us to fit a line for each participant using his/her available data, including participants with missing values, and will maximize the power to detect differences because participants are not removed from the analysis if any time period is missing. Analyses will contain a variable indicating the treatment group, a variable representing the referral source (MEDVAMC and non-MEDVAMC [community social service agencies, or VSOs]), SES and race/ethnicity variables, a variable indicating time (baseline, 3 months, or 6 months), and a term for the interaction of time and treatment. The time-by-treatment interaction is of most interest in this repeated measures analysis because a significant value will indicate a difference between groups over 6 months.

The treatment effect will measure differences between the groups at baseline, and the time effect will measure outcome change over time. By dichotomizing the outcome, we will determine whether the groups differed proportionally in clinically significant improvement on the DDS17. A value of 2.9 or less for the DDS17 will be considered as indicating little or no distress to moderate distress; a value of 3.0 or more will represent high distress. We will test this difference using a logistic regression model in which the dichotomous outcome is the dependent variable. Independent variables will be those for the linear regression models.

Outcomes: Secondary outcomes. Analyses of the secondary clinical outcomes will be similar to those used for the continuous primary outcomes. We will test assumptions of normality and make transformations as needed. We will then run linear regression models separately for each secondary outcome. The models will include terms for the intervention, time period, time-by-period interaction, the a priori SES and race/ethnicity variables, and the referral source. Significant values for the time-by-treatment interaction will indicate that there were significant differences over time in the secondary outcome. In addition, by dichotomizing the outcomes, we will determine whether the groups differed in having or not having clinically significant changes in PHQ-8 and GAD-7 scores. A 5.0-point decrease in the value of PHQ-8 will be considered a minimally clinically important change94 and coded as such; decreases of less than 5.0 points from baseline will be coded as not having achieved clinically significant change. For GAD-7, a score of less than 10 will be considered as having clinical improvement, with scores of 10 or higher representing clinically elevated anxiety symptoms. We willtest whether the two groups (clinically significant change vs. no clinical change) differed using a logistic regression model in which the dichotomous outcomes are the dependent variable. The independent variables will be those described above for the linear regression models.

For the secondary outcomes of use of printed/web-based resources, health promotion programs, and clinical care, we will run logistic regression analyses of dichotomized variables (i.e., whether or not the patient used printed/web resources, whether or not he/she used health promotion programs, and whether or not he/she used clinical care during the 6-month follow-up). The models will include terms for the intervention, the a priori SES and race/ethnicity variables, and the referral source. Significant values for the treatment term will indicate that there were significant differences between the iNSPiRED and usual care groups.

In examining responses to the Formal Care and Service Utilization questionnaire to determine if iNSPiRED Veterans are more likely to choose VHA or community health care, we will use subsets of the data set. In examining beginning to use care, we will use the subset of participants who did not use VHA services at baseline and completed the 6-month questionnaire. We will determine if each participant did or did not use VHA care at 6 months. A continuity-corrected chi-square test will find any significant differences between the groups in the proportions of users at 6 months. Also, we will run a logistic regression with the outcome of whether or not the Veteran newly used VHA care at 6 months with terms for the intervention, SES, race/ethnicity, and referral source. Then a subset not using community care at baseline will be similarly analyzed.

Exploratory mediator analysis. As noted by Kraemer et al., the mediator must measure change occurring during treatment, must correlate with the intervention, and should have a main or interactive effect on the outcome. The exploratory analysis for examining activation and self-efficacy as possible mediators will include calculation of the correlation between the mediators and treatment. Separate linear models for the primary and secondary outcomes will be run in which the independent variables are the treatment (intervention versus usual care), the potential mediators, and the treatment-by-mediator interactions. Once mediators are identified, a subsequent randomized trial could be designed to help establish if a mediator is indeed a mechanism.

Exit interview qualitative data. Responses to exit interview questions will be entered verbatim into a template-based Word document and imported into Atlas.ti software to facilitate coding and analysis. Using a directed content analysis approach, an experienced co-Investigator will lead development of coding for patient perceptions of barriers and facilitators to engaging in the intervention, including setting goals, accessing resources, and coaching peers. Using a list of a priori codes based on the interview questions and concepts previously identified in the literature on barriers and facilitators to peer support¿focused interventions, the team will conduct open coding of 10 randomly selected Veteran responses identifying and defining emerging concepts related to barriers and facilitators. They will do the same for concepts of overall perceptions and suggestions for improving the intervention. The lead co-Investigator, who will develop a codebook of code labels and definitions and collect exemplar quotes, will train and supervise research assistants. Through regular phone meetings, he/she and the coders will resolve any problems with the coding process and the emergence of new concepts. If new codes are identified, previously coded data will be reviewed for recoding. The lead co-Investigator will summarize the final coding and identify patterns in the data, focusing on elements of the study's conceptual model (e.g., they may consider how patient-identified barriers and facilitators could explain use of VHA and community resources). The lead co-Investigator will present preliminary qualitative findings to the research team, community partners, and other key stakeholders. Feedback will be included in the qualitative report.

Stakeholder quantitative and qualitative data. As part of the mixed methods process evaluation, the lead co-Investigator will analyze quantitative and qualitative responses to the WE-ENACT survey as it is collected (every 6 months) and at study conclusion so that quality of engagement at different stages of the research can be described to provide insight into community engagement at the project level. Responses to open-ended questions (qualitative data) will be used to understand responses to closed-ended questions (quantitative) better and to posit possible explanations for quantitative findings. We do not have a formal hypothesis concerning how domains of engagement will change over time; however, the literature suggests that domains such as trust may vary over time but improve overall. Data collected through the process diary and peer coach weekly reflections will be analyzed in the same manner as is qualitative data from the exit interviews and summarized by the lead co-Investigator and the research team to characterize barriers and facilitators to implementation of the peer navigation and community engagement components of the study from the perspective of peer coaches and other study team members. Findings will be used to inform future studies of implementation and the spread of peer coaching and CBPR interventions to improve access to and engagement in DM self-care strategies.

Missing data. We will conduct sensitivity analyses using tests for data missing completely at random and tests for nonrandom missingness. For nonrandom missing data, the Markov chain Monte Carlo imputation method will be used. We will also follow guidance by Sterne et al. In imputation, we will assess nonnormality of the data and transform variables as needed to approximate normality before imputation and then transform the imputed values back to the original scale. We will attempt to avoid bias in the imputation analyses by including all variables in the substantive analyses and, when computationally feasible, all variables predictive of the missing values and all variables influencing the cause of the missing data, even if they are not of interest in the substantive analysis. We will conduct both complete case analyses and multiple imputation analyses, and if the results differ, we will seek possible reasons and report them publicly. Sensitivity analyses will investigate the robustness of the findings to assumed missing-not-at-random mechanism.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

Overall, this study poses low risks to the Veterans. No deception is involved in any phase of the study, including the assessments and the intervention. Potential risks for the patients include 1) discomfort or negative response to the peer-led coaching and navigation intervention, 2) exacerbation of negative emotions at any point during the study period, 3) the disclosure of confidential material, and 4) fatigue or boredom related to the assessments.

a) Discomfort or negative response to the peer-led coaching and navigation intervention: The intervention will include scheduled breaks, during which the trained providers will discuss their assessments of individual participant's needs. Efforts will be made to engage all participants in a positive manner. Being in the study is optional thus all participants will be given the opportunity not to participate, stop the study at any time he/she likes, and ask questions at any time. Importantly, previous research has shown that similar interventions are effective at decreasing distress and enhancing quality of life.

b) Exacerbation of negative emotions: Some participants may not improve with the intervention or control condition or may experience an increase of distress-based symptoms that requires professional help. Those assigned to the control group may also experience an increase of distress-based symptoms. Alternative treatments are available to participants in the VA and community. These would include psychotropic medications and psychotherapy. Appropriate referrals will be made for participants who request it. In fact, all participants regardless of assignment will have resource and referral lists of clinical and non-clinical resources in the VA and community.

c) Disclosure of confidential material: Questionnaires and data will be labeled only with a participant identification number. Names will not be tied directly to the data. Patients will be informed that they do not need to answer any questions that they do not feel comfortable answering. Research staff will respect any requests by patients to not answer questions for the study.

d) Fatigue or boredom related to the assessments: Participants will be allowed to either skip any questions that they would prefer not to answer or not complete any task at their request. The research team member administering the assessments will provide breaks or will allow testing to cease if necessary.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

The benefits to Veterans include an assessment that might uncover symptoms of distress, depression, or anxiety that might benefit from treatment regardless of whether the participant elects to, or is found to be eligible to, participate in the study.

Patients may also experience benefit from the intervention or from the resources provided to those in the control condition. Finally, participants may experience benefit from contributing to knowledge through participation in research.

Describe potential benefit(s) to society of the planned work.

Findings will also provide helpful insights into the effectiveness of a peer led coaching and navigation intervention for veterans with distress. If effective, this intervention has the potential of improving outcomes for veterans with diabetes-related distress. It will also provide important information on the impact and value of engaging community partners in reaching Veterans who may not otherwise seek help.

Although diabetes-related distress is common and important to diabetes and mental health outcomes, there are limited interventions for Veterans that seek to primarily address it. This peer led intervention is tailored to the needs and preferences of the Veteran and delivered in a feasible format. By addressing both physical and mental health, providing peer and community support, and endorsing self-care and disease self-management while introducing resources, we believe this intervention can change the DM trajectory, reduce diabetes-related distress, and engage Veterans in support systems within and outside the VA that can improve outcomes.

Innovative aspects of this proposal include: (1) recruitment of Veterans outside the healthcare system where they are less likely to access or be engaged in care, (2) use of Veteran peer support specialists to address DM and mental health through navigation and coaching, and (3) integration of a community-VA partnership including outreach to Veterans not obtaining care in the VHA and providing options for care outside of the VHA.

This project will also provide important information about the value of partnering with community-based organizations serving Veterans in order to recruit Veterans who may not go to the VAMC. If shown to be effective, trained therapists in

the VA system can develop relationships with community organizations in order to provide an effective intervention for Veterans who prefer to go to a community-based organization versus the VAMC.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

This study involves minimal potential risks to subjects, and measures are in place to minimize these risks. The potential benefits to subjects and society are substantial. Therefore, the potential benefits outweigh the potential risks.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

Yes

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)

A waiver of consent and authorization is being requested for the recruitment portion of the study:

We will request from the VA Corporate Data Warehouse a list of patients of MEDVAMC who have had at least one visit in the past year with an ICD 10 code for Type 2 DM (E11.x). We will also request a list of patients with an ICD 10 code for Type 2 DM (E11.x) with at least one visit in the past 3 years but no visits in the past year. Variables requested will be name, address, phone numbers, E11x diagnosis code, Scrambled SSN and Real SSN. Real SSN is needed in order to search for updated contact information in CPRS if needed. These subjects will be mailed a letter that describes the purpose of the study, provides contact information for study staff, and invites them to opt-out (a toll-free number will be provided) to the study. Veterans who do not opt out will be called by study staff for screening and consent. This query will be repeated every six months during the recruitment period as needed.

In addition, we will mail opt-out letters to clients of our community partner, Harris County Area Agency on Aging (HCAAA), who they have identified has being Veterans with diabetes. These Veterans will be contacted for recruitment using the method described above.

An additional waiver of HIPAA authorization is being requested for the entire study for the following reason:

To reduce participant burden, verbal consent is being obtained for study participation (see request to waive written documentation of consent in J1a.). Therefore, we request a waiver of the requirement for HIPAA authorization for study participation.

Explain why the research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.

The intervention and research assessments are non-invasive in nature and almost exclusively involve monitoring and assessment of patient functioning. Significant protections are in place to minimize the risk of breach of privacy. All PHI will be kept secure and not shared. Only the study team will be able to see research records, questionnaires, and other identifying information. All information will be stored in a locked file cabinet in a locked storage room at the MEDVAMC. We will store information collected on a secure computer server behind the MEDVAMC firewall. This means that the information will be in a computer that no one outside the VA/ BCM can get into. A number will be assigned to each patient and caregiver, which will be kept separate from all identifying information, except for a master list stored in a folder that can only be accessed by the study team on a secure server behind the MEDVAMC firewall. Information from the VA Corporate Data Warehouse will also be stored on VINCI project servers maintained by OI&T personnel.

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.

PHI will be combined with information from other people in the study. We will write about the combined information and not about any person individually. We will not share any records unless the law requires us to. PHI will not be reused or disclosed to or shared with any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the privacy rule. Any data shared outside the study team will be de-identified/anonymized and care will be taken to ensure that individuals cannot be re-identified using publicly available information.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted without access to and use of the protected health information.

We would not be able to conduct the study without access to PHI due to the need to re-contact and interact with the subjects during the intervention and for assessments. In prior studies recruiting veterans,we have not been able to reach target recruitment without use of reaching out to Veterans through identifying them through VA administrative databases and sending them opt out letters. In addition, this allows us to recruit a more representative sample. We have established telephone-based contact methods to decrease participant burden and increase generalizability in this minimal risk study. To further improve this process we are requesting to verbally consent participants by telephone and to waive HIPPA authorization to afford us greater opportunities to increase our outreach to patients and decrease participant burden.

Describe how the research could not practicably be carried out without using the collected identifiable biospecimens in an identifiable format.

NA

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.

PHI will not be reused or disclosed to or shared with any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

The PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

No

Specific information concerning drug abuse:

No

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

No

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

Yes

Partial Social Security # (Last four digits):

No

Billing or financial records:

No

Photographs, videotapes, and/or audiotapes of you:

No

Other:

Yes, as described:
address and telephone number

Will additional pertinent information be provided to subjects after participation?

Yes

If Yes, explain how subjects will be provided additional pertinent information after participation.

At enrollment, Veteran participants will be asked if they would like to receive a brief report on study findings and/or be invited to an in-person presentation of findings at a community-based location. A study brief will be mailed according to each Veteran's indicated preferences and/or the Veteran will be invited to a presentation of study findings at a partner organization.

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

Yes

Explain how the research involves no more than minimal risk to the participants, and the specifics demonstrating that the research does not involve procedures for which written consent is normally required outside of the research context.

We are requesting permission to verbally consent patient participants to this study by telephone. Given the intervention and research assessments are non-invasive in nature and almost exclusively involve monitoring and assessment of patient functioning, we have established telephone-based contact methods to decrease participant burden. To further improve this process we are requesting to verbally consent participants to afford us greater opportunities to increase our outreach to patients and decrease participant burden. Patients will be initially introduced to the study and screened by telephone. If the initial screen indicates the patient may be eligible for the study, the patient will be mailed detailed information about the study procedures and an informed consent document (without signature lines) for their review. The study coordinator or other research staff will then follow up with the patient by telephone. Telephone consent will occur before administering baseline measures. Our protections for confidentiality are described below. The telephone screening will be conducted using a structured script (attached in section S).

We are also requesting permission to waive written documentation of consent for stakeholder and research survey participation. The survey is a 28-item measure that includes items to describe engagement in the research process from the stakeholder point of view. The survey also asks for some basic demographic information including age, race, ethnicity, and gender. A cover page will include a description of the survey, potential risks, and a statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefit. Survey responses will be anonymized prior to data analysis. Subjects can indicate with a check box if they consent or would like to opt out of participation. Details of stakeholder participation will also be explained in a brief Memorandum of Understanding.

J2. Consent Procedures

Who will recruit subjects for this study?

PI
PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Participants will be recruited through the Michael DeBakey Veterans Affairs Hospital, as well as Veterans who primarily use care outside the VA system. Non-VA users will include Veterans identified through our community partners (United Way of Greater Houston, Area Agency on Aging, Veterans Service Organizations and additional community partners to be named), and through word-of-mouth. Inclusion of Veterans who are non-VA will enable us to enroll distressed Veterans who may not be accessing care. All recruitment and consent procedures will follow VA and HIPAA regulations.

a) Recruitment through community Call lines: We will recruit participants through the United Way's 2-1-1 HELPLINE, the Harris County Area Agency on Aging (HCAAA) Call Connection, and BakerRipley Homeless Veteran Program. These call lines are staffed by referral specialists with training in Veteran benefits and services. Specialists provide information and referrals for a variety of health and social services in the Houston metropolitan area. Callers are routinely asked about their Veteran status. For the purpose of this proposal, Veterans will be asked whether they have DM and are interested in a study aimed at helping them to address and cope with their diabetes (see script in Section S). Community partners may also use this script when in-person visits are replaced by phone/video calls during the pandemic. They will first ask if the client is a Veteran. Contact information for those interested are securely sent to the study team (they will first ask if the client is a Veteran with DM).

b) Recruitment through community-based organizations. Several Veterans Service Organizations (e.g. U.S. Vets, Combined Arms) and other Community-based Organizations that serve Veterans (e.g. United Way) will provide venues for diabetes- and mental health-related talks, recruitment opportunities, and posting of flyers. The City of Houston Diabetes Awareness Network has diabetes programs across the City and has agreed to host community talks and post flyers for interested Veterans to contact the study team for more information. Vet Centers have also agreed to post flyers. Flyers will also be distributed through local reserve units, colleges and universities, transitional living centers, independent and assisted living facilities, outpatient clinics, other community groups, at resource fairs, and the Harris County and City Jails (to unincarcerated Veterans only). In some cases, flyers will be made available directly to Veterans and in other cases through a case manager. The United Way will also send a text blast to Veterans in their program (see text message in Section S).

c) Opt-out letters. We will request from the VA Corporate Data Warehouse a list of patients of MEDVAMC who have had at least one visit in the past year with an ICD 10 code for Type 2 DM (E11.x). We will also request a list of patients with an ICD 10 code for Type 2 DM (E11.x) with at least one visit in the past 3 years but no visits in the past year. Variables requested will be name, address, phone numbers, E11.x diagnosis code, Scrambled SSN and Real SSN. Real SSN is needed in order to search for updated contact information if needed. These subjects will be mailed a letter that describes the purpose of the study, provides contact information for study staff, and invites them to opt-out (a toll-free number will be provided) to the study (opt-out letters). Veterans who do not opt out will be called by study staff for screening and consent.

This query will be repeated every six months during the recruitment period. In addition, flyers will be posted at MEDVAMC and providers in the Primary Care and Specialty Clinics and the pharmacy will be provided flyers and asked to refer interested patients to the study.

CONTINUED IN SECTION S

Are foreign language consent forms required for this protocol?
No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?
No

J4. Children

Will children be enrolled in the research?
No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?
No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?
No

J7. Prisoners

Will Prisoners be enrolled in the research?
No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?
Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
Yes

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
Yes

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
No

Identifiable biospecimens
No

Other:
Yes, as described:
address and phone number

At what institution will the physical research data be kept?
Paper data will be stored in room 121 located at: Michael E. DeBakey VA Medical Center Health Services Research & Development Center for Innovations in Quality, Effectiveness and Safety (HSR&D IQuESt) Nabisco Building 2450 Holcombe Blvd., Suite 01Y Houston, TX 77021

How will such physical research data be secured?
All research materials, raw data, and other identifying information will be stored in a locked file cabinet in a locked storage room. An identification number will be assigned to each patient and will be kept separately from the patient's name, with the exception of the master list, also to be kept in a secured location.

At what institution will the electronic research data be kept?
Electronic data will be stored at the Michael E. DeBakey VA Medical Center. The location of the data is Mdrive\Research\Kunik_M_iNSPiRED Study_H-43140

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
No

Such electronic research data will be secured via Other:
Yes, (describe below):
The PI and the Project Coordinator will maintain a master link list of the unique study ID number and the patient name in a file on the VA secure computer server that can only be accessed by the research team. Study personnel with access to the unique study ID include the study PI (Kunik), Project Coordinator, RA, biostatistician, and study statistical programmer. Access to drives requires a VA login (username, strong password, and VHA domain). The system administrator restricts the study folders on the Mdrive to be accessed by designated study personnel only.

The location of the data is Mdrive\Research\Kunik_M_iNSPiRED Study_H-43140

Information from the VA Corporate Data Warehouse will also be stored on VINCI project servers maintained by OI&T personnel.

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?
Yes, identify the classes of the persons:
Dr. Kunik, co-investigators, and authorized research assistants under the supervision of Dr. Kunik. People who ensure quality from the institutions where the research is being done, federal and other regulatory agencies will have access to all of the research data. Data will not leave the MEDVAMC.

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.
All investigators and study staff will have VA clearance to view research data on the secure VA drive where it is stored.

Will you obtain a Certificate of Confidentiality for this study?
No

Please further discuss any potential confidentiality issues related to this study.
The iNSPiRED arm of this study involves research staff (Veteran Peers) meeting participants for an initial in-person counseling visit at a mutually agreed upon location outside the VA in order to establish rapport. All other visits will be conducted by telephone. The in-person visit will require sensitive data to temporarily leave the VA in the form of the participant's paper research record and contact information (name, telephone, and home or alternate meeting location address). The patient's contact information is required for purposes of direction and safety. The research record will contain the participant's ID number as well as a summary of the participants baseline needs and brief notes made during the visit to assist the Veteran Peer in helping the Veteran set goals, access resources, overcome barriers, and monitor progress on goals pertaining to their management of their diabetes and and mental health. To help ensure confidentiality, the research record and contact information will be stored separately from each other and will remain with the Veteran Peer at all times while outside the VA (hand carried).

A de-identified, anonymized data set underlying publications from this research will be created and made publicly available upon request of the principal investigator. All 18 HIPAA identifiers will be removed prior to sending outside the VA. Notices advising the public of the availability of the data set will appear in the acknowledgment sections of all publications along with contact information.

Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

To the best of our knowledge, there are no other potential confidentiality issues related to this study.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

Subjects will not be responsible for any research related costs.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

175

Distribution Plan:

Concern about depleting cell-phone minutes was identified as a barrier to completing telephone assessments in the pilot study. To make attendance possible for low-income participants, subjects will be compensated for both their time and cell phone minutes for each completed assessment. Each will receive $50 at baseline, $50 at 3 months, and $75 at 6 months (maximum of $175).

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

No

Section Q. Consent Form(s)

None

Section R: Advertisements

Mode of Advertising: Internet

Exact language of Advertisement:

Combined Arms, a Veteran Service Organization, and other partners will post the blog attached in Section S on their website and social media sites.

Mode of Advertising: Other: Flyer and Study Information Sheet

Exact language of Advertisement:

The flyer and information sheet attached in Section S will be used to advertise locally at VSOs, CBOs, MEDVAMC, colleges and universities, reserve units, transitional living centers, and the Harris County and city jails (unincarcerated Veterans only). In some cases the flyer will be made directly available to potential participants and in other cases it may be given to the participant by a case manager, provider, or other representative at the organization. They will also be used at community events and resource fairs and may be mailed to Veterans who request study information. They may also be displayed on partner websites and social media sites.