Tailored Approaches to Reduce Distress and Improve Self-Management for Veterans with Diabetes (TARDIS) – Photo Elicitation and Intervention

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PROTOCOL TITLE: Tailored Approaches to Reduce Distress and Improve Self-Management for Veterans with Diabetes (TARDIS) – Photo Elicitation and Intervention

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Purpose

Veterans with type 2 diabetes (T2D) may become overwhelmed with the self-management behaviors needed to maintain optimal health. Veterans may experience diabetes distress (DD), a concept distinct from depression, due the amount and frequency of these behaviors. Diabetes distress negatively influences the Veteran's engagement in self-management and subsequent glycosylated hemoglobin (HbA1c) levels. Previous interventions aimed at improving T2D self-management and reducing DD do not tailor T2D self-management information to a Veteran's DD, which may be one reason interventions are ineffective at reducing DD.

The etiology of DD in Veterans may be different than non-Veterans due to the cumulative nature of Veteran-related comorbid psychosocial factors (e.g., post-traumatic stress disorder (PTSD), depression). Conceptually, DD, depression, and PTSD are unique and independent factors; however, in each individual, these factors may overlap and negatively impact a Veteran's engagement in self-management.

The purpose of this research study is to further understand DD by expanding on what we have learned thus far in cognitive and semi-structured interviews with Veterans. In Aim 3a, the photo elicitation study, the Veteran would be provided with a camera and instructed to take approximately 20 photos over two weeks. We would conduct two semi-structured interviews with the Veteran to discuss this experience. Visual-based qualitative methods will help us identify and more robustly describe DD in Veterans. Aim 3a will have its own consent documents that are separate from Aim 3b. In Aim 3b, we will conduct a feasibility and acceptability trial of a novel telemedicine intervention. Aim 3b will have its own consent documents that are separate from Aim 3a.

The TARDIS intervention (Aim 3b) will build off data collected in Aim 3a and provide tailored coaching to Veterans with type 2 diabetes mellitus. The TARDIS intervention includes coaching, self-management information and support, and referrals to VHA supportive services delivered via the telephone. TARDIS will augment current VHA care for patients with diabetes. All Veterans will continue to receive care from their primary clinicians during the study.

Aim 3a and Aim 3b will be performed entirely by our team at the Durham Center of Innovation to Accelerate Discovery and Practice Transformation (ADAPT). These data

collected will inform the development of an intervention that will provide tailored coaching and self-management information in conjunction with supportive services based upon a Veteran's DD. Aim 3b will be performed by our team, with assistance from the diabetes educator for the Durham VAMC catchment area. The purpose of Aim 3b is to understand the feasibility and acceptability of providing tailored diabetes self-management and support.

Background and Significance

An estimated 20-25% of Veterans are diagnosed with diabetes,[1] an incidence three times higher than the national rate. Treatment and management of poorly self-managed diabetes is costly as medical care costs are 2.3 times higher for individuals with diabetes than for those who do not have the disease.[2] Regular preventative care is essential to prevent comorbidities and maintain optimal health.

Individuals with T2D provide 99% of their own care; self-management of T2D is person-specific and ever-present.[3] Consistent and sustained self-management decreases comorbidity development, and positively influences quality of life and psychosocial outcomes.[4] Inconsistent self-management increases the risk of poor health outcomes including microvascular and/or macrovascular problems and psychosocial complications.[5] Yet rates of self-management remain sub-optimal.

T2D self-management is omnipresent, inescapable, and burdensome. A Veteran may become overwhelmed and/or frustrated because of the amount and frequency of T2D self-management behaviors, and these negative feelings may lead to inattention to critical self-management behaviors such as eating healthy or blood glucose checks.[6,7] Veterans often experience challenges to self-management despite knowing the importance of these behaviors.[3] Self-management challenges include limited access to a healthcare provider, unreliable transportation, limited knowledge of healthy food options, beliefs about T2D medications, or a lack of support.[6-9] Additionally, diabetes distress (DD)[10] and other psychosocial factors (i.e., depression, post-traumatic stress disorder)[11,12] negatively influence an individual's engagement in self-management and health outcomes. Due to the inherent complexity of T2D self-management, we propose that tailoring on DD is one way to focus the provision of tailored self-management information and connections to supportive services.

Diabetes distress encompasses the cognitive, physical, and affective experience of living with T2D. Diabetes distress occurs when an individual is overwhelmed with T2D, related self-management behaviors, and knowledge that T2D is progressive and uncurable.[10] Diabetes distress is subjective and person-specific; and while DD may fluctuate over time, DD may be continually present.[10,13-15] Undiagnosed and untreated DD, may be one cause of a Veteran's poor self-management, thus resulting in poor health outcomes.

Diabetes distress is commonly assessed via the *Diabetes Distress Scale*[14] or the *Problem Areas in Diabetes Scale.*[16] Research indicates both measures demonstrate the construct of DD is distinct from general anxiety, stress, and depression.[13,17-19] Both the *Diabetes Distress Scale* and *Problem Areas in Diabetes* scales assess DD in several domains, and each DD domain addresses a separate aspect of the burden of

T2D.[14,20,21] The *Diabetes Distress Scale* measures DD in four domains (i.e., regimen, emotional, interpersonal, healthcare provider),[14] and the *Problem Areas in Diabetes Scale* assesses DD using similar domains (i.e., emotional, diabetes management, treatment, and social support burden).[10,22] The *Diabetes Distress Scale* and *Problem Areas in Diabetes Scale* have demonstrated content validity in measuring an individual's perception of the resources available, or not available, for self-management.[13,19]

Diabetes distress is associated with more T2D complications, increased stress, being prescribed insulin by a healthcare provider, poor diet and exercise, inadequate support environments, and is more prevalent among women.[10,19,23-26] Diabetes distress levels correlate with self-management behaviors such as monitoring one's diet, engaging with providers, and monitoring one's blood glucose.[9,15,27-29] High to moderate levels of DD are related to poorer glucose regulation[15], higher HbA1c[20], lower medication adherence[30], and poorer quality of life.[31] Individuals with DD report diabetes-related physical burden, health care system distress, and distress with comorbid conditions.[9] In this proposal, we will further examine the Veteran's experience of DD.

The TARDIS grant and the prior work done for TARDIS was based upon the original Diabetes Distress Scale (DDS) and the four domains within that scale. Those domains include: regimen, provider, interpersonal, and emotional. In 2022, the authors of the Diabetes Distress Scale published an updated version of the DDS called the Type 2 Diabetes Distress Assessment System (T2D-DDAS). The T2D-DDAS contains core and source items that contribute to DD. The T2D-DDAS sources include: hypoglycemia, long-term health, health care provider, interpersonal issues, shame/stigma, healthcare access, and management demands. The sources or facets of DD we identified in the TARDIS foundational work are reflected in the T2D-DDAS. Of note, we identified several additional facets of DD in our work such as pain, military experience, living with comorbidities, and being a caregiver. The scoring for low, moderate, and high DD in the DDS and the T2D-DDAS is the same. For the TARDIS intervention, we will be focusing on the domains of DD as measured by the DDS and not the sources of DD as measured by the T2D-DDAS. The DDS is in the Cerner EHR and is being used in the VA and the foundational TARDIS work uses the DDS.

Aim 3a: Visual Based Qualitative Methods

Visual-based qualitative methods will help us identify and more robustly describe DD in Veterans and will expand on what we have learned thus far in cognitive and semi-structured interviews. Veterans will have the autonomy to select photos that impact, either positively or negatively, their DD and diabetes self-management behaviors. Veterans who participate in the project may want to share their experiences because this is their personal story which they want to share to help other people. The Veteran has the autonomy to decide what, and how much, information to share.

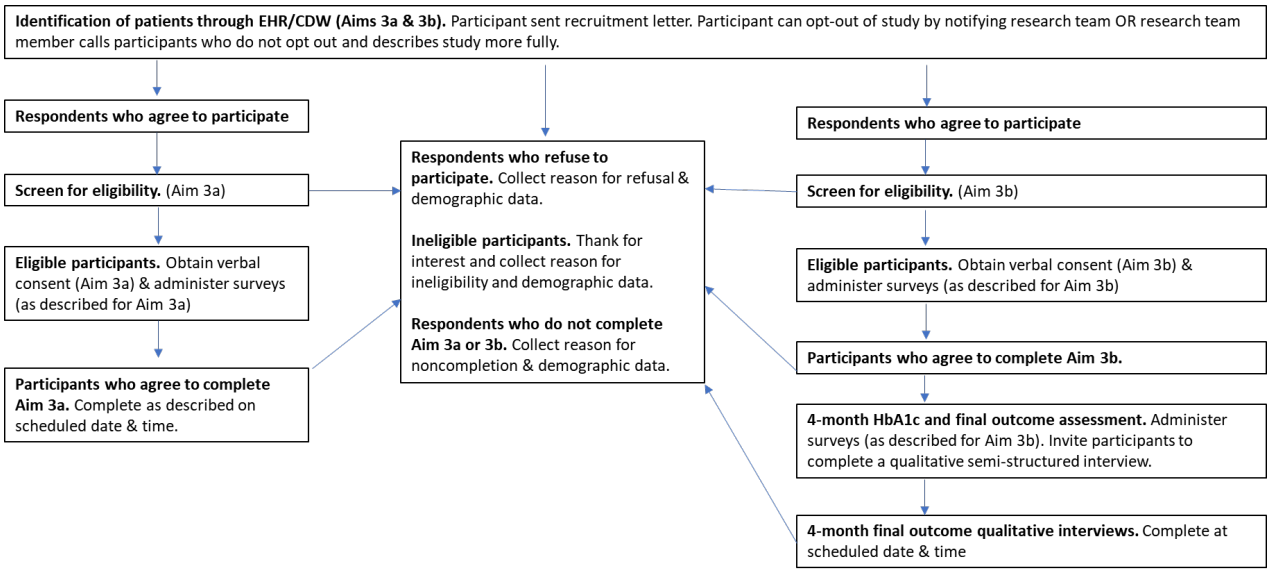
Aim 3b: TARDIS Intervention

The TARDIS intervention builds upon data collected in Aim 3a. Health coaching is a person-centered approach to identifying health goals, challenges to these goals, and then developing strategies to address these challenges. For the purposes of TARDIS, interactions are 1:1 between a 'coach', or someone who has received training in

motivational interviewing, and a Veteran with T2DM. This personalized approach can help elicit, understand, and address the experience of DD, and its impact on T2DM self-management, in Veterans with T2DM. With personalized, Veteran-centric information and support, a Veteran may be more equipped to implement self-management to overcome his/her personal modifiable challenges to engaging in T2DM self-management.

Design

For Aims 3a and 3b, only individuals officially assigned to the study team will have access to individually identifiable information about human subjects. This will include the principal investigator, mentors and consultants, statistician, computer programmer, research assistant, project coordinator, qualitative analyst, and interventionists. All of these individuals will have completed VA required human subjects training and will be included on a staff listing with the DVAHCS IRB. Some data described above (e.g., HbA1c, health conditions noted in medical records) will be accessed from information already collected as part of usual care. All additional data collected from subjects will be specifically for the proposed research project and not a part of clinical care. Specifically, for Aim 3b, we will use a single-arm feasibility and acceptability design. In order to evaluate the feasibility and acceptability of delivering TARDIS within a single VHA site, we will enroll from Veterans Affairs Medical Centers (VAMCs) in Durham, NC. We will consent up to ~40 Veterans in order to enroll ~30 Veterans with HbA1c ≥8.5% (type 2 diabetes only) to receive TARDIS in addition to standard VHA care (HT care coordination and telemonitoring; or standard VA diabetes care). All participants will receive TARDIS for 3 months, during which time they will also continue to receive usual VHA care. We will quantitatively and qualitatively examine DD and feasibility and acceptability of TARDIS. Study flow is described in the Figure below. Additionally, for Aim 3b we will conduct qualitative interviews to further understand the process of implementing TARDIS within the context of the Durham VAMC. In conducting this evaluation, study team members at ADAPT will speak with Veterans who participated in TARDIS, TARDIS study staff (HSR&D interventionist), and VA Durham staff at the participating VAMC. The data we are generating will inform future VA implementation of TARDIS, ultimately assuring that rural Veterans have access to effective, context-appropriate diabetes management options.



Risk/Benefit Assessment

Selection of Subjects

For Aims 3a and 3b, potentially eligible patients will initially be identified via VA CDW/electronic health records data extract. (ICD-10 codes: E11.9, E11.8, and other inclusionary criteria detailed below, as well as the absence of any exclusionary diagnoses).

We plan to conduct qualitative interviews with VAMC staff members at participating sites, to gather feedback on the process of implementing TARDIS. Staff members that we will approach will include the diabetes educator, HSR&D interventionists delivering the program, and other stakeholders (clinicians, clinical and administrative leadership). We anticipate contacting a maximum of 6 staff members in order to evaluate TARDIS.

Inclusion and Exclusion Criteria (for Aims 3a and 3b unless otherwise indicated)

Veterans must meet **all** inclusion criteria

- Diagnosis of type 2 diabetes (ICD-10 codes: E11.9, E11.8)
- Documentation of HbA1c drawn within the past 180 days
- Able to speak and read English
- Be able to provide informed consent to participate in the study.
- Own a smartphone or mobile

Veterans who meet **any** one of the exclusion criteria will be excluded.

- New diagnosis of T2D within the last 60 days
- Hospitalization for mental illness within the past 30 days
- Receiving active chemotherapy and/or radiation treatment
- Diagnosis for Metastatic Cancer
- Recent hospitalization within the past 60 days that would influence their diabetes

device to take photos (Aim 3a only)

- A1C ≥ 8.5 (Aim 3b only)
- Be prescribed insulin (Aim 3b only)

medication regimen (e.g., myocardial infarction, cerebrovascular accident, coronary artery bypass grafting, etc.)

- Currently receiving Kidney Dialysis
- Limited hearing or speech difficulties that influence the Veteran's ability to complete the survey and intervention
- Dementia, delirium, or other cognition issues that influence the Veteran's ability to provide consent and complete the survey.
- Not currently prescribed insulin (Aim 3b only)

Subject Recruitment

For the purposes of screening, recruiting, and determining eligibility information will be obtained through written communication with the prospective participant and/or identifiable private information will be obtained by accessing medical records. Potential participants will be identified utilizing the VA's Information and Computing Infrastructure (VINCI) Corporate Data Warehouse (CDW) and/or local electronic health record (EHR). With approval of a HIPAA waiver, we will initially conduct a data pull with real Social Security Numbers (SSNs) from VINCI. In order to identify potential participants, we will complete computer-based screening using the VA Corporate Database Warehouse and our established inclusion/exclusion criteria. For Aims 3a and 3b, based on protocol we will select the appropriate number of participants to be included in each letter batch and create the letters for each batch of potential participants. Multiple batches of letters will be sent until we reach our recruitment goal. We will send letters to all eligible potential participants. An IRB approved letter along with study information documents will be sent to the potential participant informing them of the study and providing a phone contact for study staff. The Durham, NC Center of Innovation (COIN) will be the site for this study. Durham is an appropriate setting for this study because of our COIN's extensive experience with research conduct, our racially and socioeconomically diverse patient population, and our use of telehealth interventions to improve diabetes health outcomes.

For Aims 3a and 3b, each week eligible participants will be mailed introductory letters that provide basic information about the study and let patients know that a study team member will call them to ask whether they are interested in participating. The letter will also provide patients with a telephone number they may call to leave a message saying they are not interested in participating and do not want to receive a call from the study team. Between 5-7 days after the letter is sent, the research assistant (RA), or another study team member, will call Veterans who do not opt out to assess interest in participation. Veterans who do not opt out will be screened for eligibility. Participants contacted will next complete a brief telephone-based screening questionnaire to assess eligibility criteria that are not captured in DVAHCS electronic medical records. We will only ask a limited number of questions that are needed to determine study eligibility.

Once the Veteran is deemed to be eligible for this study, they will be invited to set up a meeting to further discuss the project. When patients agree to participate in the TARDIS program (Aim 3b), they are asked if they would be amenable to being contacted by telephone for a future interview to register feedback regarding their participation in the program. We plan to contact only those patients who expressed such interest. We will contact potential staff members via telephone or email. Verbal consent will be obtained from patients and staff and will be documented prior to conducting the qualitative interviews via telephone.

For Aim 3a, the photo elicitation study will consist of 3 contacts:

Contact 1: A study team member will read consent the Veteran, introduce the study to the Veteran, and review all study procedures. We anticipate this meeting to last between ~60-75 minutes. The Veteran will also complete the Diabetes Distress Scale and demographic questions. This meeting will be conducted via telephone. At this meeting, the Veteran will be encouraged to email photos to an identified study email address prior to the second meeting. Veterans will be asked to take ~10 photos prior to the second meeting.

Contact 2: A study team member will meet with the Veteran via telephone or approved video-conferencing software, 10-14 days after the first contact. The study team member will discuss photos the Veteran emailed to the study team and the Veteran's experience thus far. We anticipate this meeting to last between ~60-75 minutes. Veterans will be encouraged to take additional photos and remit those to the research team via an identified study email address prior to the third meeting. Veterans will be asked to take ~10 photos prior to the second meeting.

Contact 3: A study team member will meet with the Veteran via telephone or approved video-conferencing software, 10-14 days after the second contact. The study team member will discuss photos the Veteran emailed to the study team and the Veteran's overall experience completing this research study. We anticipate this meeting to last between ~60-75 minutes.

For Aim 3b, the intervention will consist of up to 3 study contacts, and 3 TARDIS contacts (health coach), in addition to the Veteran's regularly scheduled health care:

Study Contacts.

Contact 1: A study team member will read the consent to the Veteran, introduce the study to the Veteran, and review all study procedures. We anticipate this meeting to last between ~60-75 minutes. The Veteran will also complete the baseline measures. This meeting will be conducted via telephone. We will obtain baseline data on psychosocial factors (depression, PTSD), environmental factors (finances, support), self-management behaviors, HbA1c and DD. Surveys will enable examination at the conclusion of the intervention. We will use the 17-item *Diabetes Distress Scale* due to its stronger associations than the *Problem Areas in Diabetes Scale* with self-management challenges, physician-related distress, and clinical outcomes.[17] *Diabetes Distress Scale* scores are reported as both a total score and as scores for each of the

four domains.[14,32] The *Diabetes Distress Scale* is reliable and valid in assessing DD in diverse populations, the factor structure is stable across sites and populations, the measure is parsimonious, and items are clear and readable.[8,34,37,38,40] The surveys will provide insight into potential facilitators and barriers to DD and T2D self-management such as symptom severity, minimal social support, and/or high chronic illness needs. We will use these surveys to understand DD, and facilitators and barriers to T2D self-management, in a sample of Veterans who receive care at Durham.

Contact 2: A study team member will meet with the Veteran at the conclusion of TARDIS and complete the end-of-TARDIS surveys. The surveys will include all surveys completed in Contact 1. We anticipate this meeting to last between ~60-75 minutes. This meeting will be conducted via telephone. The RA will invite the Veteran to complete a qualitative interview to discuss the Veteran's experience. For those Veterans who decline to participate in the qualitative interview no further contact will be made. For those Veterans who accept to participate in the qualitative interview, the RA will, based on patient and interviewer availability, schedule the interview to take place within the next 2 weeks.

Contact 3. Prior to beginning the qualitative interview, a verbal consent script will be reviewed with the participant and verbal willingness to continue participation will be captured at the beginning of the audio recording. Recording and transcription of the qualitative interviews will be conducted utilizing VA approved software installed and configured by VA OI&T personnel. Audio recordings will be captured using WebEx or Microsoft Teams the software to record the audio portion of the patient interviews. WebEx or Microsoft Teams recordings will be saved directly to the restricted study folder on the R drive. We will use the approved version of Audacity software (http://trm.oit.va.gov/ToolPage.aspx?tid =5566#) to edit the audio file in the study folder on the HSRD VA project server. We anticipate this meeting to last ~30-45 minutes.

TARDIS Health Coaching Contacts

After enrollment to the study, a TARDIS study team member (HSR&D interventionist) will deliver the health coaching to the Veteran. The interventionist will have training and experience in motivational interviewing and health coaching. A total of 3 contacts will occur over 3 months. The first health coach visit will be scheduled to take place within two weeks following enrollment and completion of the baseline surveys.

Health Coach Contact #1: Within 2 weeks after enrollment & completion of baseline surveys (Duration = ~30 minutes)

- Discussion around DD and T2DM self-management. Preliminary discussion will first focus on the highest, or most prominent, domain of diabetes distress to identify key issues related to, or that impact, adherence to T2DM self-management. The highest domain will be identified by the highest domain score for the domain in the survey. If the Veteran has multiple domains of DD with high scores (e.g., 'high' or 'moderate' distress in more than one domain), the

interventionist will work with the Veteran to determine which area to prioritize. The interventionist will then inquire about any other pressing issues that may impact or influence the DD score, or engagement in T2DM self-management.
- Identification of a SMART goal

Health Coach Contact #2: Within 1 month post contact #1 (Duration = ~30 minutes)
- Discuss Veteran's concerns or thoughts regarding recommendations, interaction with the diabetes educator, and goal made

Health Coach Contact #3: Within 1 month post contact #2 (Duration = ~20 minutes)
- Identify if issue was addressed and if Veteran has any continued concerns or thoughts regarding recommendations made
- Discuss Veteran's concerns or thoughts regarding recommendations, interaction with the diabetes educator, and goal made

Consent Process

For both Aims 3a and 3b, we will request a waiver of written consent, waiver of consent documentation and waiver of HIPAA authorization from the IRB to conduct recruitment activities described above. Because these interviews represent minimal risk to participants and are being conducted remotely by the Durham VAHCS team with participating VAMC site patients and staff, we are also requesting a waiver/alteration of documentation of written consent and HIPAA Authorization for the conduct of the qualitative interviews. Every effort will be made to talk via telephone with participants in privacy of their own home when completing the consent and questionnaires for data collection. Participants will be able to indicate to study staff if they are in a private environment or if they would like to be called at another time. This will ensure privacy and protect against embarrassment of sensitive survey questions and interview details. When we speak with patients and staff by telephone, we will obtain verbal consent for study participation and to record the qualitative interview. The consent will be documented at the beginning of the recording within the study files (audio recording and tracking). We will not document the verbal informed consent in the electronic health record (EHR).

Prior to beginning recruitment, the PI will meet with key personnel to review the protocol, the informed consent process, and the collection of questionnaires. Research study staff will demonstrate the essential steps in how to implement the protocol to ensure proper technique is communicated to participants. PI will ensure all study staff are up-to-date with required VA security and privacy training. PI will also ensure research study data are no longer accessible to study personnel when they are no longer part of the research team.

Study Procedures

For Aim 3a, all participants will participate in the photo elicitation study, there is no randomization or groups. For Aim 3b, there is no randomization or groups. After the consent process, Veterans will complete a battery of survey questions administered by

the RA. These surveys will be collected in the study RedCAP survey. In anticipation of recruitment challenges, we will use methods: (1) flexible staffing of the PC and RA, to recruit and enroll Veterans who have varying work and life commitments; (2) clear language in the initial recruitment letter, to indicate the time commitment for the survey; (3) using a call schedule developed by the Durham COIN PCs, we will make three calls on three different days, at three different times, and leave two messages. We will offer Veterans the option of completing the surveys via telephone.

Variables and data collection methods for the baseline survey.

Variable	Measure	Source
HbA1c	Most recent value in the past 180 days	EHR/CDW
Diabetes Distress	Diabetes Distress Scale. 17-items that use a 6-point Likert scale that measures diabetes distress in 4 domains: emotional, interpersonal, healthcare provider, regimen.[14,18,32] Scores indicate low, moderate, or high diabetes distress.[14] Internal reliabilities of 0.92 - 0.93 demonstrated.[14,18]	PRO
Demographics	Age, sex, gender, race/ethnicity, etc.	EHR/CDW
Comorbidities	Current medical diagnoses during the past 180 days	EHR/CDW
Medications	Currently prescribed medications during the past 180 days	EHR/CDW
Depression	The Patient Health Questionnaire-2 (PHQ-2). A two-item measure that uses a Likert scale to assess for depression.[33] Established reliability and specificity for assessing depression in adults with diabetes.[33]	PRO
PTSD	Primary Care PTSD Screen for DSM-5. 5-items that identify respondents with probable PTSD in primary care settings. Scores "yes" to 3 or more questions is considered *positive* for PTSD. Established reliability and specificity.[34]	PRO
Social Needs	Health Related Social Needs Survey. 10-items to assess unmet, health-related social needs in 5 domains: housing instability, food insecurity, transportation needs, utility needs, and interpersonal safety.[35]	PRO
Self-Efficacy	Diabetes Empowerment Scale-Short Form (DES-SF). 8-items to assess diabetes related self-efficacy. Demonstrated validity and reliability.[36,37]	PRO
Self-Management Behaviors	We will use either one of these scales to assess self-care activities: Summary of Diabetes Self-Care Activities. We will use the core 11-items that measure completion of T2D self-care behaviors in the past seven days. Validity and reliability have been demonstrated.[38] Self-Care Inventory-Revised Version (SCI-R). We will	PRO

	use the core 15-items that measure completion of T2DM self-care behaviors in the last 1-2 months. Validity and reliability have been demonstrated.[39]	
Stigma, shame	PROMIS Neuro Quality of Life Short Form Stigma. We will use the 8-item stigma short form. Validity and reliability have been demonstrated.[40]	PRO
Pain and physical activity	PROMIS Pain Interference – (Short Form 6a). We will use the 6-item scale to examine pain interreference on daily life. Validity and reliability have been demonstrated.[41]	PRO
Life stresses	Confusion, Hubbub, and Order Scale[42]. We will use the core 15-items that measure life chaos. Validity and reliability have been demonstrated in Veteran populations.[43,44]	PRO
Note: EHR/CDW=electronic health record/corporate data warehouse, data will be obtained by the RA upon study enrollment prior to the survey completion; PRO=patient reported outcome, data will be obtained via survey/interview.		

For both Aims, those identified for the studies will be invited to complete the semi-structured interviews. If patients decline to participate in the study no further contact will be made. For both aims, for those who, accept the invitation, the RA will, based on patient and interviewer availability, schedule the interview to take place within the next 2 weeks. For aim 3a, prior to beginning the first meeting, a verbal consent script will be reviewed with the participant and verbal willingness to continue participation will be captured at the beginning of the audio recording. For aim 3a, at the conclusion of meeting 1, the qualitative analyst will schedule an appointment for meeting number 2. For aim 3a, at the conclusion of meeting 2, the qualitative analyst will schedule an appointment for meeting number 3. For aim 3a, at the beginning of meetings 2 and 3, the qualitative analyst will review the verbal consent script with the participant and verbal willingness to continue participation will be captured at the beginning of the audio recording. For aim 3b, at the end of the intervention, a verbal consent script will be reviewed with the participant and verbal willingness to continue participation will be captured at the beginning of the audio recording. Recording and transcription of the qualitative interviews will be conducted utilizing VA approved software installed and configured by VA OI&T personnel. Audio recordings will be captured using WebEx as the software to record the audio portion of the patient interviews. WebEx recordings will be saved directly to the restricted study folder on the R drive. We will use the approved version of Audacity software (http://trm.oit.va.gov/ToolPage.aspx?tid =5566#) to edit the audio file in the study folder on the HSRD VA project server.

For aim 3a, in order to participate in this study, the Veteran will email photos taken on their personal device to a VHA study email address. The project coordinator, qualitative

analyst, research fellow (Dr. Roman Jones), and study PI (Dr. Lewinski) will have access to this email address. They will follow these procedures to ensure data safety and accuracy: (1) the project coordinator will check the email box each day; (2) if there is an email from a participant, the project coordinator will save the photos into a folder with the participant's study ID; (3) the project coordinator will notify Dr. Lewinski; Dr. Lewinski will then verify the photos are saved into the correct participant's folder on the R drive; (4) Dr. Lewinski will notify the project coordinator with a final result. The qualitative analyst and the research fellow will have the ability to email participants directions to log into the video conference call or for other study matters relating to viewing photos to discuss during the qualitative interviews.

For aim 3b, each intervention component will be administered by an HSR&D interventionist, as would be the case in real-world practice. TARDIS interventionists will complete training during a single session, which will be led by the study PI, with follow-up/refresher sessions as needed. The interventionists will receive an email or hardcopy (depending on their preference) of the TARDIS intervention manual containing study materials and procedures and will use online software to track intervention activities (e.g., attempted/ completed phone calls, modules delivered, medication changes). TARDIS research staff will not participate in intervention delivery, but will manage only study-specific tasks like enrollment, randomization, and outcome assessment. Of note, while receiving TARDIS, study participants will continue to receive care from primary care and other VHA providers.

The TARDIS interventionist will deliver the intervention components during telephone encounters according to a schedule (see intervention schedule). Each encounter will be documented in an intervention database, and/or in the EHR. We will allow for flexibility in the encounter schedule for patients based upon the Veteran's response to introduction questions at the beginning of each contact. Examples of the introduction questions are listed below; however, the wording of these questions may differ slightly based upon the conversation and interaction with the Veteran:

1. How is your diabetes routine going?
2. In general, is your diabetes routine changing or limiting your life activities?
    a. If yes: what makes you get thrown off your routine? How do you handle that when it happens?
3. Are there any questions you have, or things you want to discuss, in regards to your diabetes self-management?

At the end of the encounter, the interventionist will ask one question and provide one comment. Examples of the question and comment are listed below; however, the wording of these may differ slightly based upon the conversation and interaction with the Veteran:

1. Do you have questions about anything we have covered as part of today's session?
2. Now, I would like to share a [resource, encouragement, tip] based on something we discussed today.

In response to question #1, the interventionist will review the goal setting process as requested by the Veteran. In response to question #2, the interventionist will share either a resource, encouragement, or tip based on material discussed during the encounter.

The standard encounter frequency will be approximately every 30 days. Intervention components are described below:

1. **Identifying the Domain of Distress.** We will identify the DD domain to target for the TARDIS intervention using the *Diabetes Distress Scale (DDS).* We will then identify, for that domain, the specific area of the Veteran's DD to target the intervention. In that discussion we will identify barriers to adherence/engagement to T2DM self-management and discuss ways to address this specific domain of distress using a person-centered approach.
2. **Goal Setting & Connecting to Reduce Distress.** Identify a SMART goal that addresses the Veteran's DD (or other barriers to engagement in T2DM self-management) to address during TARDIS and connect the Veteran to the diabetes educator and resources that may support the Veteran's goal. The TARDIS Interventionist will refer the Veteran to resources and referrals (as able within scope).
3. **Assessment.** Determine completion of goals and acceptability of information and resources shared with Veteran. If the Veteran needs additional support or information, the TARDIS interventionist will contact the diabetes educator via secure VA approved software (Microsoft Teams and/or encrypted email) and/or make a note in the patient's EHR.

The TARDIS interventionist's actions after the 1st and 2nd Visits with Veteran include:

1. Create order within electronic health record (as able within scope): refer Veteran to appropriate VA resources
2. Document the encounter in an intervention database and/or the EHR: summarize discussion with the Veteran, describe the SMART goal set, follow-up plans, and resources provided.
3. Contact the diabetes educator: Using secure VA approved software and/or add the diabetes educator and Veteran's PACT RN to the note.

The TARDIS interventionist's actions after the 3rd Visit with Veteran include:

1. Create order within electronic health record (as able within scope): refer Veteran to appropriate VA resources

2. Document the encounter in an intervention database and/or the EHR: summarize discussion with the Veteran, describe the SMART goal set, follow-up plans, and resources provided.
3. Contact the diabetes educator: Using secure VA approved software and/or add the diabetes educator and Veteran's PACT RN to the note.

Aim 3b. TARDIS Intervention Follow-Up

Veterans will receive their assigned intervention for 3 months. Within one month after (by 4 months), the Veteran will complete a battery of follow-up surveys. The estimated time required for the 4-month visit is ~60-75 minutes. At study completion, the TARDIS study team will obtain HbA1c data from the EHR.

Participants that agreed to a future interview at the outset of their participation in the TARDIS program will be contacted via telephone, as will participating staff. At a minimum, we will include a brief summary of the study at all points of contact. Prior to beginning the qualitative interview, a verbal consent script will be reviewed with the participant and verbal willingness to participate will be captured at the beginning of the audio recording. The verbal consent will also be documented in the local study files. A study team member will put a consent note into the EHR to document that the patient has been consented and enrolled in a research study. If patients decline to participate in the qualitative interview no further contact will be made. Those who agree to be audio recorded will be recorded. Recording and transcription of the qualitative interviews will be conducted utilizing VA approved software installed and configured by VA OI&T personnel. Audio recordings will be captured using WebEx or Microsoft Teams as the software to record the audio portion of the patient interviews. When available, WebEx or Microsoft Teams interviews will be auto-transcribed verbatim by the software's auto-captioning process. WebEx or Microsoft Teams recordings will be saved directly to the restricted study folder on the R drive. We will use the approved version of Audacity software (http://trm.oit.va.gov/ToolPage.aspx?tid =5566#) to edit the audio file in the study folder on the HSRD VA project server. As is the case with any research subject, patients may decline to answer any individual questions during the interview. It is also anticipated that the participant may miss a scheduled telephone call or may need to reschedule the interview at a more convenient time. We will not consider these to be protocol deviations since schedule changes will not impact participant's healthcare or impose any risks. We anticipate that conduct of each patient and staff interview will last ~30-45 minutes for patients, and ~25 minutes for staff. For patients, interviews will address their experiences with the program (see Appendix 1 for our patient interview guide). For staff, interviews will address their experiences with the program (see Appendix 2 for our staff interview guides).

Adverse Events

Risks to participants will not exceed those associated with usual care. There are no hazards associated with the study protocol; however, there are several hazards that could potentially occur to the adult population with type 2 diabetes and include sickness or infection, hospital admissions, falls, etc. Dr. Lewinski is a licensed registered nurse and will be involved in every aspect of the study. Any concern about patient health status will be communicated to Dr. Lewinski by study staff. Dr. Lewinski will maintain close contact with Dr. Crowley (a licensed VA-credentialed endocrinologist) to discuss and obtain guidance on clinical matters and concerns. Dr. Lewinski will maintain close contact with Dr. Bosworth to discuss and obtain guidance on intervention implementation. The PI will work closely with the research coordinator throughout the study to identify individual hazards, if any occur. The PI will be notified of any hazard that occurs and will determine if the participant should be removed from the study. If it is agreed that the subject be removed, the PI and research coordinator will explain to the participant why it is in her best interest to withdraw from the study. The participants will be assured that nothing related to her during the study will affect any medical care in the future.

For Aim 3a, Veteran photos could potentially include images that indicate the Veteran is in personal distress and there is a concern for their safety. Given that we propose contacting a small group of patients for this photo elicitation study, we will not utilize a Data Safety Monitoring Board. All adverse events will be reported per Durham VAMC requirements. All Serious, Unanticipated and Related adverse events will be reported to IRB within 5 business days of hearing of the event. All other adverse events will be reported at continuing review.

For Aim 3b, because TARDIS is a self-management and support intervention that utilizes approaches that are common in standard practice, we anticipate that adverse events will be similar to standard care in quality and rate. Veterans in TARDIS will maintain regular participation in their routine VHA health care and the interventionist and will be encouraged to report all adverse events (e.g., hypoglycemia, reactions to commonly-used diabetes medications) to their VHA healthcare team. Due to the age and comorbidities of our study cohort (e.g., risk of vascular disease, existing depression), hospitalizations and other health events (e.g., development of new medical conditions, surgeries, ER visits, MI, stroke, falls and death) unrelated to the study are expected. Any events that fall into one of these categories will be reported at continuing review/per the current SOP. Participants may miss study encounters or follow-up assessments during the conduct of the project. We will not consider such events to be protocol deviations, as they will not impact participants' healthcare or impose any additional risks. At study outset, Veterans will be instructed to seek immediate emergency services for any adverse events that require urgent in-person evaluation. As some recruited patients may have diagnosed or undiagnosed depression, all patients will be given the national suicide hotline number at study outset for use as needed. Given that we propose contacting a small group of patients for a telephone interview, we will not utilize a Data Safety Monitoring Board nor will we ask patients about adverse events that do not pertain to their study participation. The primary risk in this study is a loss of confidentiality. Protection of patients' privacy is addressed in the "Privacy,

Confidentiality, and Information Security" section. All adverse events will be reported per Durham VAMC requirements. All Serious, Unanticipated and Related adverse events will be reported to IRB within 5 business days of hearing of the event. All other adverse events will be reported at continuing review.

Costs and/or Payments to Subjects
There will be no cost to participants for care they receive as a participant in the VA research project.

For Aim 3a, we will compensate participants for their time. Veterans will receive a direct deposit /check by mail from the VA for $30 four to six weeks after completing the consent and introduction process to the study. If participants complete the second discussion to discuss photos, they will receive a direct deposit/check by mail from the VA for $30 four to six weeks after completion. If participants complete the final interview to discuss photos, they will receive an additional $40. The total amount participants can receive through the study is $100. If participants withdraw from the study early, they will be paid for the interviews they have completed. We will use the current established process for providing compensation to patients at this facility.

For Aim 3b, we will compensate participants for their time. Within four to six weeks after completing the activities below, Veterans will receive a direct deposit /check by mail from the VA. The total amount participants can receive through the study is $135.

- Completion of Baseline Surveys: $45
- [*if agreed to participate*] Completion of Qualitative Interview: $45
- Completion of Surveys at 4 months: $45

If participants withdraw from the study early, they will be paid for the study contacts they have completed. We will use the current established process for providing compensation to patients at this facility.

Data and Safety Monitoring
For Aim 3a, because risks to subjects will not exceed usual care, and all subject contact takes place within the context of discrete qualitative interviews, no Data Safety Monitoring Board will be utilized. The PI assumes responsibility for monitoring all data and safety information collected during the conduct of the program evaluation described in this research proposal.

For Aim 3b, medical risks associated with study participation is similar to standard diabetes care. TARDIS will include health coaching, which is available as part of standard VHA care for Veterans. It is possible that health coaching may increase the risk of negative psychosocial outcomes (e.g., distress, depression). However, all Veterans will continue to receive their normal VHA care, so risks will not exceed standard care. Of note, patients will be referred to the diabetes educator. Because the diabetes educator is uniquely suited to identifying and managing hypoglycemia and other therapeutic risks in Veterans with diabetes, overall detection and amelioration of

medical risks could actually be enhanced relative to standard care. Further, all Veterans will continue to receive their regular VHA care with PCPs and other providers during the study, which will provide an added layer of risk protection. At study outset, Veterans will also be instructed to seek immediate emergency services for any adverse events that require urgent in-person evaluation. Risks specifically associated with study procedures, such as completing surveys and qualitative interviews, are minimal. As with any study, risk exists for breach of confidentiality and loss of protected health information (PHI), but steps will be taken to minimize this risk as per the "Privacy and Confidentiality/Information Security" section below. Direct benefits associated with study participation may include improved diabetes control. Improved control could translate to reduced rates of future complications (which are particularly common for Veterans with poorly controlled T2DM). Veterans may also experience reduction in distress and improved control of depressive symptoms. Potential benefits to study subjects include improved glycemic control and avoidance of future diabetic complications. Benefits for Veterans not enrolled in this study may include the development of an effective, practical treatment option for Veterans with diabetes distress and poorly controlled T2DM, which is currently not available within or beyond VHA.

For Aim 3b, because risks to subjects will not exceed usual care, the proposed qualitative study is small and limited to program participants, and all subject contact takes place within the context of discrete qualitative interviews, no Data Safety Monitoring Board will be utilized. The PI assumes responsibility for monitoring all data and safety information collected during the conduct of the pilot trial described in this research proposal.

For both Aims 3a and 3b, one aspect of our data and safety monitoring plan will involve reporting to the principal investigator and DVAHCS IRB. Study team members who become aware of any adverse event related to the study (who can include the research assistant, project coordinator, and qualitative analyst) will notify the principal investigator, Dr. Lewinski, immediately. Safety monitoring for adverse events (AEs) will be conducted in real time by Dr. Lewinski and/or the project coordinator. Dr. Lewinski will report all adverse events to Drs. Bosworth and Crowley. The following information about AEs will be collected: 1) the onset and resolution of the AE, 2) an assessment of the severity or intensity (use existing grading scales whenever possible), 3) an assessment of the relationship of the event to the study (definitely, probably, possibly or not related), and 4) action taken (e.g., none, referral to physician). The PI, in consultation with Dr. Bosworth (primary mentor) and Dr. Crowley (secondary mentor) will determine the severity of the event, will assign attribution to the event, and will monitor the event until its resolution. Any adverse events will be reported to the IRB in accordance with the local Human Research Protection Program's Standards of Practice. Reports of non-serious AEs are required as part of these progress reports.

For both Aims 3a and 3b, study team members will have contact information for Dr. Lewinski for evening/weekend hours. (Most study activities will occur during regular business hours, but some participants may request to be contacted for a screening interview during evening or weekend hours.) If Dr. Lewinski is not available for contact when a study team member becomes aware of a study-related AE, Dr. Bosworth (Dr.

Lewinski's primary mentor) or Dr. Crowley (Dr. Lewinski's co-mentor), will be contacted. Once Dr. Lewinski (or Dr. Bosworth or Dr. Crowley) is contacted about the AE, she/he will decide about the reporting requirements in accordance with the DVAHCS IRB guidelines.

For both Aims 3a and 3b, Dr. Lewinski will meet at least weekly with study personnel to discuss participants' reactions to the survey/interviews and any AEs or unanticipated problems. Dr. Lewinski will also meet weekly with Dr. Bosworth (primary mentor) and biweekly with Dr. Crowley (co-mentor). Monthly meetings between the investigators and the project coordinator will allow for ongoing progress reports, including the number of participants currently involved in the study, attrition rates, and scheduled data collection from participants, as well as notification and review of any AEs. All individuals involved in the study will develop and implement methods of verifying entered data and of quality control.

Data management

Study tracking data will be entered into an intervention database and stored electronically using VA REDCap (Research Electronic Data Capture) which is a web-based application hosted on the VA Enterprise Cloud and is available only on the VA network. This database will allow us to track: patient study status (i.e., eligible, enrolled, refused); the results of screening interviews; intervention tasks due for each participant; and encounter-specific data (e.g., attempted/completed phone calls, duration of phone encounters, modules delivered, medication changes). Screening and outcome measures will also be entered directly into the study database using RedCAP. RedCAP will be hosted on the VINCI servers. Data will be stored in a restricted folder on a secure VHA server.

Integrity of study data

Accuracy and integrity of study data will be ensured in two ways. First, the Durham VHA COIN conducts computer operations in a secure Centralized Computing Facility managed by VHA network and server administrators. Within this computing facility, all research data are stored on VHA-Administered servers, which are physically secured in the Durham VAMC computer room. VHA network access to research data is controlled in accordance with the COIN's standard operating procedures and VHA policies. In addition, standard COIN procedures ensure that servers, workstations and portable computers are kept up-to-date with virus filters, security patches, software updates and firmware updates.

Future Data Use

For Aims 3a and 3b, we may want to run secondary data qualitative and quantitative analyses related to the original aims of the grant (e.g., mediator/moderator analyses, analyses of baseline data, etc.). We will also track referrals (number, type, etc.) in CPRS and/or CDW that each participant has completed at 3 and 6 months subsequent to the final session of their intervention. It is also possible that data collection under this

proposal might be used to inform future surveys, interviews, and/or intervention development among patients with diabetes. We may also want to review the patient's A1C value approximately 3 months after the completion of the patient's involvement in TARDIS to inform future studies, interviews, or intervention development. Data would only be used from patients who agreed that their data could be stored and used for future analysis. A de-identified data set from the variables obtained for the project will be created. A separate protocol, defining the possible new project(s) would be submitted to the Durham VA IRB. These future studies would request either a waiver/alteration to the ICF/HIPAA requirements or a consent form and updated HIPAA Authorization, as appropriate.

Withdrawal of Participants

VA Patients who no longer want to participate in Aims 3a or 3b may inform the staff. The staff will document that change in status, so they are not prompted to contact the patient in the future. For Aim 3b, patients who do not wish to continue TARDIS may inform the interventionist and/or the TARDIS study staff. Study staff will remove document the change in status. Veterans who choose to withdraw from TARDIS will continue to receive care as normal.

For Aims 3a and 3b, patients may be withdrawn from the research study without their consent under the following conditions (also previously listed as exclusion reasons):

1. Inability to communicate by telephone
2. New diagnosis of dementia or psychosis
3. Active alcohol or substance disorder
4. Current report of new pregnancy during study
5. New instance of hypoglycemic seizure or coma
6. HbA1c value < 8.5% at baseline study assessment

Patients who choose to withdraw from the study after enrolling will be asked to provide written documentation of the request to the study team. If a patient withdraws, no new data will be collected about him/her, other than a possible reason for withdrawal. All data collected prior to the date of withdrawal will remain with the study files and may be used for analysis.

Data Analysis and Statistical Considerations

Aim 3a – Photo Elicitation Interviews.

Audio recordings will be transcribed by the DVAHCS staff or VA approved transcription service. When transcribed, names and other identifying information will be redacted. Transcripts will be saved in the secured VA project drive (\\v06.med.va.gov\DUR\HSRD\TARDIS-Photo). We will use a convenience sampling plan to recruit ~12 Veterans with T2D who receive care at the Durham VA. The preferred method of data collection will be: (1) telephone or video-conferencing software (E.g., WebEx). Interviewing Veterans via the telephone may decrease barriers to participation (e.g., access, time, transportation); and (2) patient-generated health data in

the form of photographs taken by the Veteran on their personal device and emailed to a study email address.

Photo elicitation guided semi-structured interviews will enable us to further understand DD in the context of T2DM self-management. Interviews will be conducted by a qualitative analyst, will last 45-60 minutes, and will be recorded as permitted by the Veteran. If the Veteran does not consent to being recorded, the qualitative analyst will take detailed notes throughout the interview. We will use an interview guide to elicit Veterans' photos in the context of DD and T2DM self-management. Prior to meetings 2 and 3, the qualitative analyst will review the photos taken by that participant. The qualitative analyst will then open these photos to guide the discussion with the Veteran.

We will use verbal probes as a way to elicit Veteran's answers.[45-47] The use of *concurrent* (e.g., to assess real-time thoughts and feelings about DD and their photos) and *retrospective* (e.g., to assess thoughts of taking photos at interview completion) probes will enable us to obtain specific and global feedback on DD and the photo elicitation method.[45] During the interview, we will encourage the Veteran to describe the context depicted in the photo, what prompted them to take the photo, and any thoughts about the images in the photo.

Analysis Plan.

Aim 3a

We will begin analysis after the first three interviews and preliminary analysis will guide future data collection.[48] Each interview will be transcribed and identifying information will be removed. Limited demographic information (e.g., gender, medication) will be noted within the transcript to facilitate consideration of the Veteran's responses. We will use thematic analysis with the software NVivo for this study.[49]

A coding team consisting of Dr. Lewinski and the qualitative analyst will code these data. They will meet weekly during interviewing, coding, and analysis to identify emerging areas, refine the interview guide, and address emergent questions. The coding team will independently read all transcripts to become familiar with these data; the coding unit for each *a priori* code will be a response to an item. The coding team will independently create examples from the transcripts for the *a priori* codes, and any emergent codes, for 20% of the transcripts, and then meet to discuss codes and coding units. We will compare examples and discuss findings until agreement is reached on coding definitions and application of the definitions to these data. The coding team will repeat the described process until we have total agreement on the first level coding; following discussions, the coding team will re-code transcripts using any new codes. The coding team will identify and create higher level codes based upon created and agreed upon codes after the completion of first level coding and discussion of preliminary findings with the co-mentors. Second level coding will mirror the first level coding approach in that the coding team will independently code 20% of the transcripts and meet to discuss emerging patterns. To ensure reliability and validity of the coding process and the creation of these descriptive summaries, the coding team will meet

weekly to compare coding and resolve disagreements. All findings will be discussed and reviewed with other study team members to ensure reliability and validity.

Primary outcome: Interviews and photos will provide insight into how the Veteran interprets DD, T2DM self-management, and the associated challenges/strategies with self-management.

Aim 3b

TARDIS is a pilot study to assess feasibility and acceptability; thus, the most critical endpoints are related to recruitment, retention, feasibility, and acceptability of the intervention. Collection of detailed process data (e.g., phone calls attempted and completed, length of calls, number of services utilized via EHR and Veteran self-report) is critical. Additionally, we will collect outcomes that we anticipate using in a future application such as HbA1c, diabetes distress score, self-efficacy for diabetes self-management, and self-management behaviors. A formative evaluation will enable us to make modifications to TARDIS prior to the implementation of the intervention in a larger, randomized trial.

Feasibility. We operationalize feasibility as demand for, and practicality of, TARDIS.[50] We will assess the feasibility using: (1) recruitment data (e.g., number of Veterans eligible, approached, and enrolled in TARDIS); (2) process data specific to Veterans (e.g., phone calls attempted and completed, length of phone calls, number of services utilized via EHR and Veteran self-report, participation and retention during TARDIS); and (3) process data specific to TARDIS (e.g., methods of delivery, nurse interventionist time/effort). Length and duration of TARDIS calls and interactions with interventionist (number of contacts suggested, number of contacts completed). Length and duration of TARDIS calls with diabetes educator (number of contacts suggested, number of contacts completed). Process measures (length of time between interactions). Referrals (referrals made, referrals completed, mean time to referral completion). Semi-structured interviews will enable us to obtain data on the amount and type of resources needed; perceived negative/positive effects, and perceived demand for TARDIS.

Acceptability. Semi-structured interviews with Veterans will elicit responses about: (1) intervention components and delivery; (2) participation challenges; (3) suggestions regarding future iterations of TARDIS; (4) quality of referrals made during TARDIS. Semi-structured interviews with the TARDIS intervention staff will elicit responses about: (1) intervention components; (2) delivering TARDIS via telephone; (3) interactions with the Veterans; (4) overall impression of the intervention; (5) suggestions for changes to TARDIS; and (6) appropriateness and fit of TARDIS within VA organizational structure. We will then present the TARDIS findings and TARDIS staff responses to our local and national stakeholders to obtain further insight into acceptability of TARDIS at VA. The

review of TARDIS summary notes from Veteran's EHR and interventionist debrief notes will provide insight into the content of the TARDIS sessions.

Statistical analysis. These data to examine feasibility and acceptability will be primarily descriptive and qualitative. Feasibility measures will be assessed as proportion of Veterans meeting a retention rate of 80% of all sessions and completing 80% of the suggested connections to supportive services. We will also calculate descriptive statistics on the process data. For the outcome variables to be used in a future study, we will calculate descriptive statistics at each time point and the difference between baseline and 4-months. Finally, we will calculate the effect size of the difference between baseline and 4 months, with corresponding 95% confidence intervals to provide information about the possible range of effect sizes and to compare magnitude of changes across different measures.[51] Acceptability data of semi-structured interviews with the Veterans and the TARDIS nurse will be analyzed using methods described below.

Sample size considerations. Our target enrollment is 20 Veterans, over 12 months. A power calculation will not be performed given that we are not evaluating statistical significance in the TARDIS pilot study. Rather, we are seeking an indication of feasibility and acceptability to evaluate our TARDIS pilot protocol. A sample size of 20 Veterans will provide sufficient input to inform intervention refinement and improvement for a larger RCT under the limitations of a time period and funding resources.

Potential problems and solutions. Potential problems include retention of Veterans and maintaining up-to-date supportive materials. We will keep detailed notes on each Veteran encounter during TARDIS. We will keep a logbook of actions the interventionist and diabetes educator have taken, so that if the interventionist or diabetes educator changes mid-intervention, we can maintain continuity of care. To ensure that the information we provide to Veterans is correct, we will work to maintain an up-to-date listing of resources in VA and community. To decrease attrition, we will use successful retention strategies previously used by our team.

Qualitative Interviews:

The preferred method of data collection will be via telephone. Interviewing Veterans and staff via the telephone may decrease barriers to participation (e.g., access, time). Semi-structured interviews will be completed by a Qualitative Analyst. We will develop an operating manual for the interviews, review interviewing techniques that encourage openness, and review active listening techniques.[52,53] Prior to the first Veteran and staff interview, we will practice interviewing to ensure the qualitative analyst is familiar with the interview guide and purpose of the interviews. We will observe the qualitative analyst for the first 2 interviews to ensure she is using the interview guide correctly, and

then we will listen to recordings of every fourth interview to ensure that the qualitative analyst is following the interview guide.

Analysis Plan. We will begin analysis after the first two interviews and preliminary analysis will guide future data collection.[48] The analysis process will be iterative, as initial analysis will inform interview guide questions.[48] A coding team consisting of Dr. Lewinski and qualitative analyst will code these data. They will meet weekly during interviewing, coding, and analysis to identify emerging areas, refine the interview guide, and address emergent questions. All transcripts will be de-identified and will not contain information about Veteran's engagement in TARDIS, HbA1c level, or DD score to ensure objectivity during coding and analysis. Throughout coding and analysis, findings will be discussed with the study team and mentors to ensure reliability and validity of the interpretation. The coding team will use thematic analysis with the software NVivo. The analysis plan will occur in two steps. First, the transcribed text from the interviews will be coded and analyzed for aggregate themes specific to DD and T2D self-management. Then, using matrices, we will identify similarities and differences between levels of DD, engagement in TARDIS, and participant characteristics. While we will code and analyze the patient and staff interviews separately, we will follow the procedures described below for analysis.

Analysis Plan: Step 1. First, we will upload the transcripts into NVivo and then begin coding. First level coding will be guided by *a priori* codes based upon how Veterans describe DD and feasibility and acceptability of TARDIS. Emergent codes about DD, T2D self-management, and engagement in TARDIS will be identified in relation to observations of self-management unique to Veterans. Codes will be examined in the context of DD and self-management of T2D to focus the analysis.[54] The coding team will independently read all transcripts to become familiar with these data, and then identify appropriate coding units for each *a priori* code prior to beginning coding. The coding team will independently create examples from the transcripts for the *a priori* codes, and any emergent codes, for 20% of the transcripts, and then meet to discuss codes and coding units. We will compare examples and discuss findings until agreement is reached on coding definitions and application of the definitions to these data. The coding team will repeat the described process until we have total agreement on the first level coding; following discussions, the coding team will re-code transcripts using any new codes. The coding team will identify and create higher level codes based upon created and agreed upon codes after the completion of first level coding and discussion of preliminary findings with the co-mentors. Second level coding will mirror the first level coding approach in that the coding team will independently code 20% of the transcripts and meet to discuss emerging patterns. We anticipate that a multidimensional structure will be present in these data, thus no limit will be placed upon codes to which a coding unit can be assigned.

Analysis Plan: Step 2. We will begin Step 2 once we identify the overall themes for the entire data corpus. We will use the co-occurrence feature in NVivo and explore the findings in matrices to identify patterns of similarities and differences. To enable the analysis in Step 2, we will first label each transcript in NVivo with the Veteran's HbA1c

level, engagement, and Diabetes Distress Scale score. Dr. Lewinski has previously used the co-occurrence feature to identify points of similarities and differences.[55]

Validity and reliability. Validity and reliability of findings and the iterative generation of codes will be ensured by working closely with qualitative analyst and the research team.[54] The coding team will: provide rich descriptions of all codes and themes; discuss coding until consensus is reached for each code and theme; triangulate data from quantitative and qualitative sources; and present any discrepant information.[54] The codebook will describe the codes and emerging themes and serve as an audit trail. Regular meetings with the study team will ensure validity and reliability, higher level code development, and discussion of emerging findings.

Privacy and Confidentiality/Information Security

For Aims 3a and 3b, our experienced team has a strong understanding of research-associated risks and will take all necessary measures to protect patients at both study sites. Data security for this project will be overseen by the Durham COIN Computer Science specialist. The Durham COIN has developed standard operating procedures for data acquisition and data management, which are designed to protect against data loss and maintain patient confidentiality. These procedures have been used in many studies and we will adhere to these procedures at both sites for the proposed study.

All participant information collected in the context of this research study, even the fact that an individual is participating in the study, will be considered confidential, and the study team will take steps to ensure the participant's confidentiality is protected at each step of the research process:

- Each participant will be assigned a study identification number (ID), which links all computerized research records; all research data files are organized by study ID, with no names or other identification attached.
- All PHI will be housed on a secure server behind the Durham VAMC firewall at both sites, and access will be restricted. Computerized study data will be maintained on VHA network servers which are secured behind a firewall (as well as through controlled physical access). Server access is controlled by the computer specialist at the Durham COIN, and staff members will only be allowed access to data pertinent and authorized for their role. All study forms and paper records that contain participant information will be kept in secured, locked areas when not in use, accessible only to appropriate personnel; when in use, these materials will be kept from public view.
- For qualitative interviews, staff will use a VHA encrypted laptop in conjunction with WebEx audio recording device to record interviews, which will then be saved on the encrypted computer, immediately uploaded to a restricted folder on the VHA server network, and then removed from the laptop. We will remove identifiers from the file names and interview notes.
- All study personnel will maintain IRB research certification, with special training in research ethics. This training includes detailed instruction on confidentiality.

- Participants will not be identified by name in any reports or publications, nor will data be presented in such a way that the identity of individual participants can be inferred. All information obtained in the course of the study that identifies an individual will be treated as confidential in accordance with section 903C of the Public Health Service Act (42 U.S.C.299a-1). We will strip all identifiers from analytic data sets after data merging, and keep all personal identifiers in a separate location from the analytic data. Database files needed to generate mailing labels will contain no research data.

Privacy, Confidentiality, and Information Security

1. Lists of Data Reviewed and/or Collected for Screening/Recruitment and Conduction of Study:

The Personal Health Information that will be obtained, used, and/or shared for this study includes:

Identifier(s)	Source(s) of Health Information
☒ Names	☒ Medical history & physical exam information
☒ All geographic subdivisions smaller than a State, including street address, city, county, precinct, and zip code. Describe: street address, City, Zip, County	☒ Photographs, videotapes, audiotapes, or digital or other images
☒ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, visit or treatment dates, etc.; and all ages over 89, Describe: birth date, dx dates, admission date, discharge date, visit or treatment dates, RX dates, lab dates, survey dates	☐ Biologic specimens (e.g., blood, tissue, urine, saliva). Describe:
☒ Telephone numbers	☒ Progress notes
☐ Fax numbers	☒ Diagnostic / Laboratory test results
☒ Electronic mail addresses	☐ Operative reports
☒ Social Security Numbers	☐ Imaging (x-ray, CT, MRI, etc.)
☐ Medical record numbers	☒ Discharge summaries
☐ Health plan beneficiary numbers	☒ Survey / Questionnaire responses
☐ Account numbers	☐ Billing records
☐ Certificate and/or license numbers	☐ HIV testing or infection records
☐ Vehicle identifiers and serial numbers, including license plate numbers	☐ Sickle cell anemia information
☐ Device identifiers and serial numbers	☐ Alcoholism or alcohol use information
☐ Web Universal Resource Locators	☐ Drug abuse information

Identifier(s)	Source(s) of Health Information
(URLs)	
☒ Internet Protocol (IP) address numbers	☐ Mental health (not psychotherapy) notes
☐ Biometric identifiers, including finger & voice prints	☐ Psychological test results
☐ Full-face photographic images and any comparable images	☐ Genetic testing
☒ Any other unique identifying number, characteristic, or code, describe : Anonymous/Randomly assigned study ID# **Note: This is not the unique code assigned to otherwise de-identified health information for re-identification purposes.*	☐ Other, describe:

2. Data and/or Specimen Acquisition:

Data for this study will be collected through (*check all that apply*):

☒ Prospective data and/or specimen collection obtained from participants. Provide description of processes: We will collect information from patients using telephonic survey collection methods, patient generated photographs, and WebEx conference communications. Patients will email patient generated photographs to the study email address. The study team will check the study email daily and immediately save the patient generated photos to the study folder.

☒ Retrospective data collection and/or specimens obtained from medical chart review/data access. Describe how data will be obtained (e.g., fileman, CDW, etc.):

We will use the current VA CDW/VINCI resources to identify the necessary participants with the requested inclusion/exclusion criteria. Using the real SSNs from that subset, we will retrieve current mailing addresses, telephone number, as well as the specific medical record data (using approved VA data bases) via the VHA Corporate Data Warehouse (CDW) dataset via the VINCI or another secure platform.

☐ Retrospective data collection and/or specimens obtained from an IRB-approved data and/or specimen repository. Indicate the repository source including name, VA location, and IRB number: .

Note: for data and/or specimens obtained from a VA approved data repository, a Data Use Agreement (DUA) must be executed prior to obtaining data and/or specimens. See VHA Handbook 1200.12 for further information.

3. Level of Data:

The following level(s) of data will be acquired/maintained for this study (*check all that apply*):

☒ Identifiable—Data contains direct identifiers.
☒ Coded—Data linked to a specific by a code rather than a direct identifier for re-identification purposes. Only someone possessing the key to the code can link the data to a particular participant.
☒ De-Identified (all 18 HIPAA identifiers removed
- ☐ Verified Statistically
  OR
- ☒ Verified by Absence or Removal of 18 HIPAA identifiers

☐ Limited Data Set
☐ Other: Describe:

4. Location of Data and/or Specimens, and Data Retention Plan:

A. Data and/or Specimen Location: All survey data will be collected and stored on VA secure server for the Study RedCap survey located on VINCI.

For Aim 3a and Aim 3b, data will be stored electronically in R:\TARDIS_Photo_IRB1650875. Data that will be stored electronically include electronic versions of recruitment letters, scanned copies of completed surveys, hard copy surveys, database with study cohort criteria. Paper records of data include hard copy of telephone screening documents, and surveys, etc., will be stored at Legacy tower, suite 700, cubical 716B and office 605.

☒ Data will be also be placed at the VA Informatics and Computing Interface (VINCI; http://vaww.vinci.med.va.gov/vincicentral/VINCIWorkspace.aspx). The VA Informatics and Computing Infrastructure is a partnership between the VA Office of Information Technology and the Veterans' Health Administration Office of Research and Development. Researchers and operations staff can use VINCI to access data and statistical analysis tools in a virtual working environment through a certified VHA network computer using the VA Intranet or Virtual Private Network (VPN).

B. Data Retention Plan

☒ Research records will be maintained and destroyed according to the National Archives and Records Administration, Records Schedule Number: DAA-0015-2015-0004. Records destruction, when authorized, will be accomplished using the then current requirements for the secure disposal of paper and electronic records. Currently, destruction of research records (see DAA-0015-2015-0004, section 7.6 "Research Investigator Files" for materials included in research records) is scheduled for 6 years after the cut-off (the cut-off is the completion of the research project) and may be retained longer if required by other federal agencies. Records will not be destroyed without pre-notification to the facility records manager. .

☐ Other data retention plan, describe:

5. **Data Access and Data Recipients:**

Only members of our DVAHCS research team will have access to identifiers and coded data. All VA research personnel who have access to VHA records are instructed, in accordance with VA policy, on the requirements of Federal privacy and information laws and regulations, VA regulations and policies, and VHA policy. All study personnel who are VA employees working within the VA system have fulfilled all required HIPAA and other VA security and privacy policy training requirements and have agreed to follow guidelines pertaining to the protection of patient data. All research staff sign VA Rules of Behavior, and all study staff are up-to-date with VHA Privacy Policy Training and the VA Office of Cyber and Information Security Awareness Training Course. The data security and privacy procedures summarized in that course include logging off or locking the computer when walking away from it; no sharing of access codes, verify codes or passwords; not allowing anyone else to use the computer under one's password; and disposing of sensitive information using VA-approved methods (e.g., shredder bins). Access to study data will be removed for all study personnel when they are no longer part of the research team.

6. Data and/or Specimen Transportation and/or Transmission for all data and/or specimens involved in the study:

I. ☐ Data and/or specimens will not be transported or transmitted outside of Durham VAMC environment.

II. ☐ Data and/or specimens will be transported BETWEEN sites that are under the auspices of the Durham VA Medical Center.

III. ☒ Data and/or specimens will be transmitted to other VA sites using the following method(s):

A. Data

☒ Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted disk (encryption is optional).

☐ Data are coded or contain identifiers and thus will be sent

☐ Other, describe:

B. Specimens

☐ Specimens are de-identified and thus will be sent via standard carrier (tracking is optional).

☐ Specimens are coded or contain identifiers and thus will be sent via VA-authorized carrier with tracking.

☐ Other, describe:

IV. ☒ Data and/or specimens will be transported to non-VA/VHA sites (e.g., academic affiliates, laboratories, etc.) using the following method(s):

A. Data

☒ Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted CD.

☐ Data are coded or-contain identifiers and thus will be sent via using VA—approved carrier with tracking.

☐ Data are coded or identified and will be sent using Azure RMS encryption via a VA email account.

☐ Data are coded or identified and will be uploaded to sponsor website using electronic case report form (eCRF)

☐ Other, describe:

B. Specimens

☐ Specimens are de-identified and thus will be sent via standard carrier (tracking is optional) or will be hand-delivered by research study personnel. Specify method of delivery:

☐ Specimens are coded and thus will be sent via VA-approved carrier with tracking or will be hand-delivered by research study personnel. Specify method of delivery:

In accordance with the HIPAA and the Privacy Act, for any coded or identifiable data or specimens released from the Durham VAMC (with the exception of Limited Data Sets), an Accounting of Disclosure (AOD) will be maintained (e.g., in a database or spreadsheet) that includes the participant's name, date of the disclosure, description of the nature of the Individually Identifiable Information (III) disclosed, purpose of each disclosure, and the name and address of the person/agency to whom the disclosure was made.

C. ☐ Local DVAMC memorandum "Authorization to Use, Process, Store, or Transmit VA Sensitive Information Outside VA Owned or Managed Facilities" has been pre-filled out for each study team member who may transport the data and/or specimens off-site. This (these) forms are included with the IRB materials.

D. ☐ Containers (e.g., briefcase, bin) are labeled with the following notice (label placed on the outside of container) in accordance with VHA Directive 6609:

NOTICE!!!

Access to these records is limited to: AUTHORIZED PERSONS ONLY. Information may not be disclosed from this file unless permitted by all applicable legal authorities, which may include the Privacy Act; 38 U.S.C. §§ 5701, 5705, 7332; the Health Insurance Portability and Accountability Act; and regulations implementing those provisions, at 38 C.F.R. §§ 1.460 – 1.599 and 45 C.F.R. Parts 160 and 164. Anyone who discloses information in violation of the above provisions may subject to civil and criminal penalties.

V. ☐ We will communicate with veterans enrolled as participants in this research study through MyHealtheVet.

7. Risk Mitigation Strategies:

Participant's identifying information (name and last 4 of social security number) will be linked to a study code to be used for all data sets. There will be one key of the last 4SS#/Name and study code, on the secure computer server. The VA server will only be accessible to study personnel with rights to the folder. These data will be entered into the database on the secure VA server. Any paper form will be kept in a secure, locked file cabinet in a locked research office in the ADAPT HSRD at Legacy Tower, suite 700, office 602 or cubical 716B. They will be identified only by a study code. All data will be retained in accordance to the Records Control Schedule, the Records Management Officer will be contacted for the current policy, prior to any destruction.

☒ Data are fully de-identified (stripped of HIPAA 18 and study ID/code) before being shared outside of Durham VAMC.

☐ Specimens are fully de-identified (stripped of HIPAA 18 and study ID/code before being shared outside of Durham VAMC.

☒ Data or specimens are coded and the code is not related to, or derived from, information about the individual and that code is not otherwise capable of being translated as to the identify the individual. Only someone possessing the key to code can link the data to a particular participant.
☐ Other, specify:

8. Suspected Loss of VA Information:
Should any incident such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls occur it will be immediately reported according to VA policy. All incidents regarding information security/privacy incidents will be

reported to the ISO and PO within 1 hour of acknowledgement of issue and done so using the VHADUR Research Events Report e-mail group (VHADURResearchEventReport@va.gov).

9. Reporting of Results:

☒ Reporting of results, such as in scientific papers and presentations, will never identify individual subjects. Data will be presented in aggregate and individual-level data will not be published.

☐ Other results reporting plan, describe:

10. Future Use of Data:

X Data will be retained for future use. This is described elsewhere in the protocol and is noted in the HIPAA authorization.

☐ Future Use of data is optional (i.e., not required by the research subject).

☐ Future Use of data is required for participation in the study.

☒ No future use of data is currently planned.

11. Use of Mail Merge Technology

☐ Mail merge programs will be used to generate letters and/or address labels for mailings to potential or already enrolled research subjects. The study team is aware that to reduce risk of mail merge related privacy incidents, use of mail merge programs requires a 25% accuracy check to verify that (potential) research subject name and mailing address are properly "matched". If discrepancies are found, a 100% accuracy check is required before letters may be mailed.

12. Use of Non-Standard Software

☐ I do NOT intend to use any new specialized software (i.e. Software that's not already approved OR installed) in this study.

☐ I intend to use specialized software that has not already been installed and it has been approved for use by the VA Technical Reference Model (TRM) Group.
(Note: All new software must be approved by TRM before it can be installed on VA systems.)

☒ I intend to use previously installed software on my VA computer.

13. Use of Cloud Computing Services

☒ Cloud computing services will NOT be used in this study.

☐ Cloud computing services WILL be used in this study as described below and have been approved nationally by the VA Chief Information Officer (CIO). (Note: ONLY cloud computing services that have been approved nationally may be used.)

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Provide references, if applicable.

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Appendix A: Expedited Review of Research

The categories of research that may be reviewed by the IRB through the expedited review procedure include research activities that present no more than minimal risk to human subjects **AND** involve procedures listed in one or more of the specific categories listed below.

The expedited review procedure is not to be used when identification of the subjects or their responses would reasonably place them at risk of criminal or civil liability; be damaging to the subjects' financial standing, employability, insurability, or reputation; or be stigmatizing, unless reasonable and appropriate protections are implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. The IRB must apply the standard requirements for informed consent (or its waiver, alteration, or exception) to all studies that undergo expedited review.

EXPEDITE CATEGORIES
1-Drugs and Devices: One of the following must be met: (1) The research is on drugs for which an IND application is not required. (2) The research is on medical devices for which an investigational device exemption (IDE) application is not required; or the medical device is cleared or approved for marketing, and the medical device is being used in accordance with its cleared or approved labeling.
2-Blood Samples: Collected by finger / heel / ear stick or venipuncture: (1) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 milliliters (ml) in an 8-week period, and collection may not occur more frequently than two times per week; or (2) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kilogram (kg) in an 8-week period, and collection may not occur more frequently than two times per week.
3-Noninvasive Collection of Biological Specimens: Collected prospectively for research purposes by noninvasive means: (1) Hair and nail clippings in a non-disfiguring manner. (2) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction. (3) Permanent teeth if routine patient care indicates a need for extraction. (4) Excreta and external secretions (including sweat). (5) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue. (6) Placenta removed at delivery. (7) Amniotic fluid obtained at the time of rupture of the membrane prior to, or during, labor. (8) Supra- and subgingival dental plaque and calculus, provided the collection

EXPEDITE CATEGORIES
procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques. (9) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings. (10) Sputum collected after saline mist nebulization.
4-Noninvasive Collection of Data: Data must be collected through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. (1) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy. (2) Weighing the subject. (3) Testing sensory acuity. (4) Magnetic resonance imaging (MRI). (5) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography. (6) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing, where appropriate, given the age, weight, and health of the individual.
5-Collected Material: Research involves: (1) Materials (data, documents, records, or specimens) that have been collected for any purpose, including previous research; or (2) Materials (data, documents, records, or specimens) that will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
6-Collection of Data From Voice, Video, or Photographs: Research involves collection of data from voice, video, or photographs.
7-Group Characteristics, Surveys, Interviews, and Quality Assurance: Research must be on individual or group characteristics or behavior (including, but not limited to: research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or will employ survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. ***NOTE****: Some research in this category may be exempt from the VA regulations for the protection of human subjects (38 CFR 16.101(b)(2) and (b)(3)). This listing refers only to research that is not exempt.*