ForgIng New Paths to Prevent DIabeTes (FINDIT)

NCT Number: NCT02747108

March 25, 2019

FINDIT Protocol and Updated Narrative

Note: This document has been created to accurately show the most recent protocol for this project. Language has been borrowed from our R&D and Human Subjects applications.

Background

Study Objectives

The objectives of this study are:

- To describe perception of risk for T2DM among Veterans at risk for T2DM;
- To describe motivation to prevent T2DM among Veterans at risk for T2DM;
- To describe awareness of and preferences for strategies to prevent T2DM among Veterans at risk for T2DM;
- To describe engagement in behaviors to prevent T2DM among Veterans at risk for T2DM.
- To determine the effects of a prediabetes diagnosis and brief counseling on weight change;
- To determine the effects of a prediabetes diagnosis and brief counseling on engagement in behaviors to prevent T2DM and mediators of these behaviors;
- To gain deep insights into the effects of a prediabetes diagnosis and brief counseling on engagement in behaviors to prevent T2DM and mediators of this engagement;

Scientific rationale

An essential step in designing effective strategies to improve patient engagement in behavior change is to better understand their current levels of engagement in these behaviors and determine which factors most influence their engagement. However, within and outside the VHA, little is known about how patients with risk factors for T2DM view their risk of developing T2DM, what these patients understand about strategies to reduce this risk, and to what degree at-risk patients are currently engaging in behaviors to prevent T2DM. This project will generate important data on key health behaviors and their mediators in our target population, as well information about the effects of a prediabetes diagnosis and brief counseling on engagement in behaviors to prevent T2DM and mediators of these behaviors.

Setting/Study Criteria

During the course of the study we encountered a small, but significant number of patients who have consented into the study, but subsequently develop exclusion criteria such as the completion of an HbA1C test prior to enrollment into the intervention. Thus, we amended our protocol to consent a greater number of patients in order to meet our enrollment goal of 315 randomized patients. Thus, we requested the ability to consent up to 400 patients to enroll our

goal of 315. In addition, we also clarified that "consented" patients will refer to those who completed the informed consent process and "enrolled" will refer to those who completed the baseline requirements and have been randomized into a study group.

We will consent up to 400 patients to ensure we can enroll 315 non-diabetic Veterans receiving primary care in the VA Ann Arbor Healthcare System or the John D. Dingell VA Medical Center, who meet the following inclusion criteria: willing to complete a HIPAA authorization form, no HbA1c results in previous 12 months, due for VA Primary Care appointment approximately 12 weeks of sending the recruitment letter and BMI ≥ 30.0 kg/m^2, or a BMI of 25.0-30.0 kg/m^2 with ≥ 1 obesity-related conditions, such as:

- Hypertension
- Hyperlipidemia
- Hypoalphalipoproteinemia
- Coronary Artery Disease
- Hypertriglycederidemia
- Past hemoglobin A1c (HbA1c) of 5.7 – 6.4
- Past diagnosis of Impaired Fasting Glucose (IFG) or Impaired Glucose Tolerance (IGT)
- Polycystic Ovary Syndrome (PCOS)

We chose these inclusion criteria because they would merit screening for T2DM within the VHA, are readily attainable from VHA electronic records, are based on the VA/DOD and ADA guidelines, and represent the MOVE!-eligible population on which our estimates of the prevalence of prediabetes are based. We estimate that over 19,000 VAAAHS patients will meet these criteria.

Study Flow

Identification of Sample and Recruitment

At the start of each month during the recruitment period (T0), we will use data from the VA Medical SAS Inpatient & Outpatient Files, Corporate Data Warehouse (CDW), and SAS Inpatient and Outpatient Files or locally through Vista System to generate a random sample of Veterans who have an upcoming primary care appointment at the VA Ann Arbor Healthcare System or the John D. Dingell VA Medical Center in T0 + 12 weeks, do not have any International Classification of Diseases (ICD-9 or ICD-10) code for T2DM, and meet inclusion criteria. From this list, study staff will either filter out via CDW or review the Computerized Patient Record System (CPRS) to exclude patients who are >75 years of age or have diabetes, dementia, end stage renal disease (ESRD), severe chronic obstructive pulmonary disease (COPD) and using home supplemental oxygen, New York Heart Association Class III or IV congestive heart failure, pregnancy, or cirrhosis, are receiving chemotherapy for cancer (within 6 months of call) or have been hospitalized or received rehab for stroke or myocardial infarction within past 6 months. Note: Some of this information will need to be confirmed with patients during recruitment calls. See *eligibility script* for more details. Since CPRS contains the most up-to-date patient information we will also use this system to confirm eligibility for the study prior to contact with potential participants. This will minimize burden on patients, providers and study staff and will ensure study staff are aware of diagnosis changes between the date the sample was pulled and the date patients are considered for the study.

At the beginning of the study, we will notify the facility primary care providers about the study so that they are aware that some of their patients may be enrolling.

HbA1c results will be communicated to PACT primary care providers and PACT RN Case Managers via CPRS before the study team shares these results with patients so that to give providers have the opportunity to communicate HbA1c these test results to their patients first if they so choose.

e) Briefly describe the research procedures of this study that are not part of the standard therapeutic care of the subject. (Are the procedures inpatient or outpatient?) (Will there be audio, video records?) (if retrospective study, please summarize planned data analysis).

Summary: We will consent up to 400 patients to ensure we can enroll 315 non-diabetic Veterans in the VA Ann Arbor Healthcare System who have a body-mass index (BMI) ≥ 30 kg/m2, or BMI ≥ 25 kg/m^2 and an obesity-related comorbidity. Study participants will be surveyed about their engagement in behaviors to prevent TDM2 and mediators of this engagement. After completing a baseline survey and HIPAA authorization form, 252 Veterans will be randomally assigned to undergo screening for T2DM using a hemoglobin A1c (HbA1c) test. The 63 Veterans whom we project will have HbA1c values in the prediabetes range will receive brief standard counseling about this. All 315 Veterans will have their weight tracked over the next year and will be surveyed immediately after the screening and brief counseling process, at 3 months, and at 1 year. Among the 63 Veterans with prediabetes, we will conduct 20 semi-structured interviews to gain insights into the effects of a prediabetes diagnosis and brief counseling.

Recruitment

Recruitment Mailing: After receiving the patient sample frame, we will mail to each potential patient a recruitment packet that will include a recruitment letter, business reply envelope (BRE), informed consent document and a HIPAA authorization form. These documents will explain the study, allow for a quick response for eligible and interested patients, and provide contact information for inquiries or to opt-out of further consideration. Patients may opt-out by telephone or by using the enclosed BRE to mail back the recruitment letter with the opt-out box checked.

For patients that are interested in participating in our study, we will allow them to meet us at the VAMC to return the consent, HIPAA or any other study-related documents if it is more convenient for them. If a patient expresses interest to participate, but is unable to receive the recruitment packet or any other study materials by mail or MyHealtheVet, then we issue these in-person at the VAMC.

Recruitment Calls: We will contact patients approximately 10 days after we send the recruitment packet, provided that they haven't opted out of study participation. Our study will be equipped with an advanced database that will filter out those who opt-out in our calling lists. This database will also detect duplicate SSN's entered into the database from different CDW data pulls to prevent the same patient from being added to the database from separate data pulls.

Study staff will not leave more than three consecutive telephone messages for potential participants without a callback.

Study staff will assess by phone each patient's interest and suitability for study participation. For those that are interested in enrolling, study staff will use an eligibility screener to ensure

each patient meets all inclusion/exclusion criteria. We will maintain the records of all potential and actual study participants to ensure those that are uninterested, ineligible, or deceased are not called again after we've made a disposition.

Baseline Data Collection - First Survey: After providing informed consent, we will mail patients an enrollment packet which will include a letter with instructions for completing the survey (including the study website and Qualtrics code), a paper version of the survey (for patients who indicate a preference to complete the survey in this format), and a BRE for mailing back the paper survey if applicable. We anticipate that this survey will take 20 minutes to complete.

We will send these documents via MyHealtheVet Secure Messaging if we are unable to find a current address or if patients indicate a preference to receive information through this channel. For their convenience, patients will also be given the option to use MyHealtheVet Secure Messaging to send any documents that need to be returned to study staff.

During the telephone consent process, we will elicit the survey completion preference for each patient. Patients will be given the option to complete the survey online, via a paper mailed survey, or over the phone.

Online – Study staff will provide patients with the study website, www.finditstudy.com, which includes a URL that will redirect them to the secure Qualtrics survey. Study staff will provide by phone and mail (in the enrollment packet) a unique survey code for study participants to enter into Qualtrics when prompted.

The primary reason for the website is to provide a simple redirect hyperlink to the secure online survey in Qualtrics. This will prevent patients from having the burden of manually typing in a long URL such as https://www.qualtrics.com/clients/thisstudy/cg-fjfjk22n4n5/thesurveypage-StudyID_189374.html. The website will also summarize the research study and provide contact information for study staff.

No research data will be collected from the study website itself.

Phone: Study staff will offer to administer the survey to patients over the phone with patients. This may occur either immediately after the phone consent process or at a later mutually agreed upon time.

Paper: Patients who prefer to complete the survey on paper will be mailed a survey in their enrollment packet. Approximately 7 days after we send the enrollment packet, we will call these patients to remind them to complete the survey. Those who do not complete the First Survey will not fulfill the requirements for the study enrollment process and will no longer be further considered for the study.

For patients that are enrolled in our study, we will allow them to meet us at the VAMC to return the paper survey or any other study-related documents if it is more convenient for them. If an enrolled patient is unable to receive the survey packet or any other study materials by mail or MyHealtheVet, then we issue these materials in-person at the VAMC. Please note that this also includes gift cards.

First Survey Incentive: We will require patients to return the First Survey in order to receive the $10 incentive. Following the completion of the First Survey, study staff will send a First Survey incentive packet which will include a $10 gift card and a letter that will thank the patient for completing the survey.

To track surveys completed online, we will frequently download completed surveys from the Qualtrics server and import these responses into our secure study database which will be housed behind the VA firewall. Our study database will notify us of patients who complete the survey online in Qualtrics, but have not yet been sent a gift card.

Randomization to screening for T2DM: Approximately 2 weeks before their Primary Care appointment, we will randomize participants into one of the two study groups: 1) Blood Test Group and 2) Brochure Group. 252 study participants will be randomly assigned to undergo screening for T2DM using an HbA1c test at the laboratory of their respective VA primary care clinic. Participants will have a 4/5 (80%) chance of being selected for the Blood Test Group and 1/5 (20%) chance of being selected for the Brochure Group. Our database will use a programmed algorithm that will give all participants the same chances of being randomized into these two groups.

Following randomization, study staff will contact patients by phone and mail to notify them of the arm to which they were randomized. For those that are randomized to the Blood Test Group, we will obtain a preferred date for patients to complete the HbA1c blood draw and study staff will accordingly enter this order date in CPRS.

Baseline Data Collection – HbA1c lab order and talking points

Blood Test Group: Following the randomization process, for patients randomized to the Blood Test Group, study staff will enter an HbA1c blood test order into CPRS. Study staff will aim to set up the blood draw order on the same day as the patient's upcoming Primary Care appointment for convenience.

Information about HbA1c results: Once we obtain the HbA1c results, we will store the results in our study database and deliver to the patient and their primary care provider information about these results. We will then use the following categories based on American Diabetes Association and National Diabetes Prevention Program guidelines to interpret HbA1c results:

- Normoglycemia: If results are < 5.6 then participants will be given the "normoglycemia information"
- Prediabetes: If results are 5.7 – 6.4 then participants will be given the "prediabetes information"
- Diabetes: If results > 6.5 then participants will be given the "diabetes information"

HbA1c results and information will be immediately communicated to primary care providers via CPRS to give providers the opportunity to communicate HbA1c test results to their patients before the study team shares these results with the patients. Trained study staff will deliver the applicable information by phone approximately 1 week after the test results are available.

To guarantee that all participants receive some form of information related to their HbA1c results, we

will mail a brief one page sheet summarizing the applicable information with the letter for their Second Survey; patients should receive this around the time of the aforementioned phone call.

We will send this information via MyHealtheVet Secure Messaging if we are unable to find a current
address or if patients prefer this mode of communication. Given that this information is the heart of our research study, it is imperative that patients receive this information. Thus, we need as many modes of providing this information to patients as possible.

Randomization to Brochure Group: The 63 participants randomized to the Brochure Group will not receive study ordered HbA1c blood tests. We will mail to Brochure Group participants general health promotion information developed by the VA National Center for Health Promotion and Disease Prevention. We will ask these patients to review this information prior to completing the Second Survey.

Second Survey: Participants in both study groups will be issued a Second Survey packet immediately after their HbA1c test results are available (Blood Test Group) or at the time of their primary care appointment and/or appointment recall date (Brochure Group). This packet will include a letter with instructions for completing the survey using the same mode as the First Survey, a paper version of the survey (if applicable) and (if applicable) a paper version of the aforementioned information about HbA1c results. We anticipate this survey will take approximately 20 minutes to complete.

We will send these documents via MyHealtheVet Secure Messaging if we are unable to find a current address or if patients indicate a preference to receive information through this channel. For their convenience, patients will also be given the option to use MyHealtheVet Secure Messaging to send any documents that need to be returned to study staff.

Upon completion of the Second Survey, we will mail to patients an incentive packet which will include a thank you letter and a $10 gift card for completing the survey.

Third Survey: We will issue a Third Survey packet approximately 2 1/2 months after participants complete the First Survey. This survey will take approximately 20 minutes to complete. This packet will include a letter with instructions for completing the survey in the same mode they used to complete the preceding surveys.

We will send these documents via MyHealtheVet Secure Messaging if we are unable to find a current address or if patients indicate a preference to receive information through this channel. For their convenience, patients will also be given the option to use MyHealtheVet Secure Messaging to send any documents that need to be returned to study staff.

Upon completion of the Third Survey, we will mail an incentive packet which will include a thank you letter and $10 gift card.

Final Survey: We will issue a Final Survey packet approximately 11 months after participants complete the First Survey. This packet will include a letter with instructions for completing the survey in the same mode they used to complete the preceding surveys. This survey will take approximately 20 minutes to complete.

We will send these documents via MyHealtheVet Secure Messaging if we are unable to find a current address or if patients indicate a preference to receive information through this channel.

For their convenience, patients will also be given the option to use MyHealtheVet Secure Messaging to send any documents that need to be returned to study staff.

Upon completion of the Final Survey, we will mail an incentive packet, which will include a thank you letter and $10 gift card.

12-month Weights: Patients routinely have their weights measured at each Primary Care visit. Thus participants will have weight measurements at the time of their scheduled Primary Care appointment or around the time of their recall appointment date. We anticipate that through usual care many participants will have another weight measurement 12 months (±1 month) later.

Prior to the first Final Survey follow-up call, study staff will identify those who do not have a 12 month (±1 month) weight measurement in CPRS and encourage these participants to go to their Primary Care clinic for a weight measurement.

Interviews among Participants with Prediabetes about Their Perceptions of a Prediabetes Diagnosis: To gain deeper understanding of patient perceptions of a prediabetes diagnosis and brief counseling, we will conduct approximately 30 semi-structured telephone interviews among a maximum variation purposive sample of patients who are newly diagnosed with prediabetes and have different levels of health literacy. We will focus on health literacy because of its strong relationship to patients' self-care behaviors, receipt of recommended preventive services, understanding of health information, and health outcomes. We will conduct the interviews by phone to minimize participant burdens and maximize the response rate. These participants will be invited to participate in the interview after the completion of the 3rd Survey, which we anticipate for most participants will be approximately 6 months after their HbA1c test. Interviews will consist of open-ended questions to elicit information on feelings about receiving a prediabetes diagnosis, understanding of prediabetes and behavioral recommendations, facilitators of and barriers to behavior change, uncertainties about prediabetes. We anticipate each interview will take 30 minutes. Interviews will be audio recorded and transcribed. Consent to audio record interviews will be obtained during the initial informed consent process, though participants may choose to participate without agreeing to be recorded. We will conduct data analysis concurrently with data collection and will stop conducting interviews once we have reached thematic saturation. *Prior to any contact with participants we will submit the interview guide for IRB approval. (Note: This has been approved by the IRB)*

Data Analysis

Weights: Patients of the VAAAHS primary care clinics routinely have their weights measured at each primary care visit. Thus all participants will have a weight measurement in CPRS when they undergo brief counseling or review of health promotion literature. We anticipate that through usual care many participants will have another weight measurement 12 months (±1 month) later. Participants who do not have a weight measurement in CPRS 12 months (±1 month) later will be asked to come to the VAAAHS primary care clinic for a weight measurement.

8/10/2018 Update: We would like the ability to extract weight data, our primary outcome, for enrolled participants who have collected weights from other VA medical centers. We have identified a number of enrolled patients that either receive care at other VA medical centers during the winter or have moved out of state during the course of the study. Unfortunately, if either of these occur during the follow-up period, we are unable to collect weight data. While we have been able to still send and receive survey data from these participants, because our current medical record data (i.e., weight) data access is limited to the Ann Arbor VA Healthcare System, we are unable to collect weights that may have been collected at other facilities. By having the ability to expand our data queries to any VA facility from which our

participants may have received a weight, we will be able to achieve a greater percentage of study participants with baseline and FU data.

We will extract these data from VA CDW data queries.
12/19/2018 Update: We would also like to expand our previous amendment to also allow us to extract data for our secondary outcome analysis, which will include MOVE visits, metformin use, and HbA1c labs.

2/25/2019 Update: We would like to update the date range (March 2015 – December 2017) that was originally provided in our VA Research Data Privacy and Security Assessment form to coincide with our first and last randomization dates. Our first randomization occurred on 1/27/2016 and our final randomization occurred on 3/31/2017. Thus, we would like to update our data date range from 1/27/2015 – 7/1/2018. We strongly feel data one year prior to randomization and 15 months post randomization is sufficient for collecting data for all four timepoints and is consistent with what other similar projects (e.g., the VA DPP projects) have done. (Added 3/20/2019) Given that pre/post medical data (primarily lab and weight data, but also MOVE participation and metformin use) are not always assessed consistently for veterans, we are requesting to change the range of baseline and follow-up observation dates so that we can increase the probability of obtaining these data."

Analyses: The primary outcome will be weight change 12 months after brief counseling or review of health promotion literature. For this analysis, we will use a two-sample t test to evaluate the difference between the 2 arms. For any missing weight data, we will use multiple imputation. The main secondary outcomes will be changes in attempting weight loss, taking medication to prevent T2DM, or participating in a weight-related wellness program (e.g., MOVE! or DPP). For these outcomes, we will estimate mixed-effects regression models in which we will use data from the baseline, 3 month, and 12 month surveys for each participant to model individual change over time. Other secondary outcomes will be changes in mediators of engagement in behaviors to prevent T2DM such as risk perception, knowledge, motivation, and self-efficacy. For these outcomes we will also estimate mixed-effects regression models in which we will use data from the baseline, immediate follow-up, 3 month, and 12 month surveys to model individual change over time.

Interviews among participants with prediabetes will be audio-recorded and transcribed verbatim. We will conduct analyses concurrently with interviews, so early insights can inform subsequent data collection and analysis. We will code transcripts using a template analysis approach. Dr. Kullgren and study staff will independently review a subset of transcripts using modified grounded theory to identify salient themes. We will discuss the themes, refine them, and achieve consensus on codes and definitions. Dr. Kullgren and study staff will then independently code transcripts in NVivo software. First, they will independently code the same 20% subset of the transcripts. The unweighted Cohen's Kappa will then be calculated for each response and averaged to provide a single index of inter-rater reliability. Once excellent agreement is achieved, Dr. Kullgren and study staff will divide the remaining interview transcripts evenly and code these transcripts separately. Dr. Kullgren and study staff will meet regularly to discuss code summaries and memos.