INcreasing Veteran EngagemeNT to Prevent Diabetes (INVENT)

NCT Number: NCT03403231

March 15, 2021

Protocol/Human Subjects Application

1. Human experiment to be done:

a) Briefly describe the purpose of this study.

- To determine the effects of 5 innovative strategies from behavioral economics and health psychology on weight and HbA1c among Veterans with prediabetes;
- To determine the effects of 5 innovative strategies from behavioral economics and health psychology on behaviors to prevent T2DM and mediators of these behaviors among Veterans with prediabetes;
- To evaluate the acceptability to and feasibility among patients of strategies from behavioral economics and health psychology that aim to increase engagement in behaviors to prevent T2DM among Veterans with prediabetes.

Given our limited funding timeline, we strongly feel that this is the best solution to complete our study at our target date and thus ensure support staff are funded throughout the end of the study.

b) Briefly describe the scholarly or scientific rationale

There is tremendous national enthusiasm for translating and disseminating efficacious strategies to prevent type 2 diabetes mellitus (T2DM). Yet, little attention has been devoted to how we can better leverage the processes through which patients receive information about prevention of T2DM to better engage them in such prevention. Further, despite efforts to disseminate structured programs, many patients at high risk for developing T2DM may still be unable or unwilling to access them. In these cases, increasing patient engagement in individually directed lifestyle change or pharmacotherapy is critical. Strategies developed in the fields of behavioral economics and health psychology hold significant promise for improving Veteran engagement in each of these approaches. To date, however, these strategies have rarely been translated into real-world settings where they could benefit Veterans. This novel work will address this critical gap and could transform communication with Veterans about prevention in ways that will improve their health outcomes.

The following 5 strategies will be implemented in the weekly messages that study participants will receive: (1) tailoring to aspirations in life; (2) implementation intentions; (3) preference checklists; (4) urgency framing; (5) social norms. We will implement these strategies alone and in combination in a 16-arm fractional factorial design experiment (i.e., a full factorial design).

Each of these 5 strategies has been developed and examined in other decision contexts as a way to increase engagement in recommended behaviors that have potential long-term benefits but suboptimal levels of engagement. Therefore, each of these 5 strategies has great promise to increase at-risk Veterans' engagement in behaviors to prevent diabetes, for which there are similarly potential long-term benefits but suboptimal levels of engagement in VA. For example, tailoring messages to aspirations in life is an approach our team has developed that aims to help individuals perceive behaviors as being congruent with their life goals, values, and aspirations. Such congruence is termed *integrated regulation*, which produces a more autonomous form of motivation that is more likely than other forms of extrinsic motivation to yield sustained healthy behaviors. We recently pilot tested the acceptability, feasibility, and preliminary efficacy of this type of tailored messaging among obese University of Michigan employees who want to lose weight. Implementation intentions ask individuals to craft "if-then" statements that specify the when, where, and how of goal striving in advance. This approach has successfully increased goal attainment in a variety of contexts, including for health-related decisions such as uptake of influenza vaccinations.[9] Preference checklists are a choice architecture modification in which individuals are asked to consider a list of choice-relevant factors that individuals in their situation might want to consider, but often do not. This strategy aims to "frame the future first" and has been shown to increase savings for retirement. Urgency framing is a messaging strategy that seeks to make the future feel more proximal, thus prompting immediate

action and minimizing procrastination. Making messages more urgent has been shown to prompt action around pro-social behaviors such as reducing adverse environmental impacts or donating to a charity. Social norms aims to encourage individuals to focus on what they think someone important to them would say they should do at a decision point. Based on existing behavioral economic literature, we anticipate such focusing on a pro-social norm will prompt preventive action.

Because these 5 approaches have great promise to increase engagement in recommended behaviors that have potential long-term benefits but have not been translated into the context of diabetes prevention among Veterans, a main goal of this project will be to measure the acceptability, feasibility, and preliminary efficacy of using VA Secure Messaging to deliver these strategies to Veterans at risk for diabetes.

c) Describe the site(s) and setting where the research will take place.

We may consent up to 200 patients to ensure we can randomize 144 VA Ann Arbor Healthcare System patients into our intervention. Consenting extra patients will ensure that those who do not complete the baseline survey or for some reason cannot be randomized are not included in our final study sample of 144. Patients who meet preliminary eligibility criteria consist of MyHealtheVet Secure Messaging users or those willing to sign up for Secure Messaging, and have had a HbA1c test result approximately 6 months prior to recruitment in the prediabetes range according to ADA/CDC guidelines. Ann Arbor will be the only participating site and patient contact will typically occur through telephone, mail, and VA MyHealtheVet Secure Messaging.

d) How will you identify and recruit participants for the research study?

VA staff may not retain individually identifiable patient records for a research study before receiving final approval by VA R&D and IRB.

(Explain if you will be using recruitment letters, flyers, brochures, e-mail. The VA does not allow cold-calling by telephone call to VA patients without a prior mailed letter.)

At the start of each month or beginning of each week, during the recruitment period, we will pull a random patient sample from the VA Medical SAS Inpatient & Outpatient Files, Corporate Data Warehouse (CDW), and Local (Ann Arbor) Vista System of Veterans currently using MyHealtheVet secure messaging (or are willing to sign up) and have had a HbA1c test in the past 6 months that meets the ADA/CDC classification for prediabetes. Veterans will be excluded from the generated sample if they have recently completed a weight loss program (e.g., MOVE!), are trying to lose weight and are very physically active, are >75 years of age, pregnant, taking metformin, have participated in the FINDIT study (the preceding sister study under the same grant funding), have been hospitalized or received rehab for stroke or myocardial infarction within past 6 months, are receiving chemotherapy for cancer, or have any International Classification of Diseases (ICD-9/10) codes for T2DM, dementia, major functional limitations, cirrhosis, Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage 4 chronic obstructive pulmonary disease (COPD), or end stage renal disease (ESRD).

We will use CPRS to confirm up-to-date patient information at any point after we pull patient samples from CDW. 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.

Typically, we will generate and send recruitment packets within 1-2 business days of extracting our patient sample. Potentially eligible Veterans will be mailed a letter that describes the study and asks them to call or email study staff in the next 7 days if they are not interested in being contacted about the study. If no call is received after 7 days, study staff will call the patient to screen for and exclude

Veterans who are actively engaged in a lifestyle change programs, have major functional limitations, New York Heart Association (NYHA) class III or IV congestive heart failure (CHF), or any other exclusion criteria that cannot be confirmed via CDW or CPRS. If the patient is eligible and agrees to participate, the patient will provide documented informed consent.

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 200 Veterans to ensure we can randomize 144 patients who complete the requirements for randomization. Eligible patients include those who are currently using MyHealtheVet secure messaging (or are willing to sign up), meet inclusion/exclusion criteria, and have received an HbA1c test within the last 6 months that meets the ADA/CDC classification for prediabetes. Study participants will be surveyed about their engagement in behaviors to prevent TDM2 and mediators of this engagement. After completing a baseline survey, participants will be randomly assigned to receive different novel presentations of information about ways to prevent T2DM through both Secure Messaging and US Mail. We will test the 5 presentations that each: (1) represent an innovative approach from behavioral economics or health psychology with great promise to increase engagement in behaviors to prevent T2DM among patients with prediabetes; and (2) have not been tested in this setting. While there are other approaches from these fields we could test, we feel these 5 strategies constitute an exceptional blend of innovation, scalability, and feasibility within the contexts of a CDA and existing VHA care systems.

CDW Sample: Our sample will consist of Veterans who received an HbA1c test between 5.7 and 6.4 in the past 6 months and who meet preliminary eligibility criteria. Preliminary eligibility criteria will be defined as inclusion/exclusion criteria that can be confirmed through CDW data extraction (e.g., recent HbA1c test, diagnoses, age, engagement in VA MOVE!, and medication). Other eligibility criteria that are more difficult to confirm via CDW will be asked during the recruitment and screening process. For example, we will exclude those who have had 4 or more MOVE! visits in the last year from CDW, but will find out if patients have recently participated in other weight loss programs when they are screened for eligibility over the phone. We have included an eligibility screener with this IRB amendment.

Depending on our recruitment demand, the number of patients who meet preliminary study criteria, and our available resources, we will generate a random sample of up to 50 Veterans weekly, or 200 Veterans monthly.

If at any point we cannot consistently identify enough Veterans who meet all preliminary eligibility criteria, we will consider extracting a list of patients who meet all criteria with the exception of the HbA1c requirement. In this situation, we will generate a list of patients who are due for HbA1c tests per the VA/DoD Guidelines and can satisfy this requirement before enrolling in the intervention. Similarly if needed, we will also consider extracting a sample of patients who meet all requirements with the exception of enrollment in MyHealtheVet Secure Messaging and elicit their willingness to sign up per our eligibility criteria. Only those who are willing to sign up and eventually do will be fully enrolled into the study.

Recruitment

Recruitment Summary: We would like to design our recruitment process using the same model we used for the FINDIT study. Typically, consent and HIPAA forms were filled out and sent back to us via mail; however we found that giving the patient the option to meet study staff in person at the VAMC increased the chances of Veterans completing the full consent process. For FINDIT, we did not initially provide the opportunity for Veterans to meet us in person at the VAMC, however due to

the number of requests by Veterans we submitted an IRB amendment to provide this accommodation.

Given our recruitment timeline and personnel resources it would not be feasible to require all Veterans to meet us in person at the VAMC to enroll into our study. In addition, given that all aspects of the study can be completed remotely, it would be an unnecessary burden to require all Veterans to meet us in-person at the VAMC. We are simply allowing Veterans to meet us at the VAMC at their request.

Recruitment Sample/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. However, we will typically correspond with patients via phone, mail, or MyHealtheVet Secure Messaging.

Given the low risk nature of this study and the fact that Veterans will have an opportunity to address any questions or concerns during recruitment calls, we did not provide detailed descriptions of each arm in our informed consent form. Our concern was that presenting 16 different descriptions, all of which have just slight variations, would cause confusion or create misconceptions. 8% of consented FINDIT patients initially sent back their opt-out form, but after discussing the study with study staff (staff contacted patients before the opt-out form was received in the mail) were able to ask questions and address their concerns about the study over the phone. Thus, we would like to learn from our previous experience and provide a more Veteran-centered approach to discussing the study arms with Veterans. We would like to provide more explicit details during the phone consent process so as to allow Veterans the opportunity to ask questions and allow study staff to address confusion or misconceptions.

Recruitment Calls: We will contact patients approximately 7 days after we send the recruitment packet, provided that they haven't opted out of study participation. 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.

First Survey: After providing informed consent, the patient will complete the First (Baseline) survey. This survey will include questions on demographic characteristics, patient activation, health literacy, perception of risk for T2DM, motivation to prevent T2DM, knowledge of strategies to prevent T2DM, self-efficacy to engage in behaviors to prevent T2DM, preferences for strategies to prevent T2DM, physical activity, eating behaviors, and engagement in key health behaviors related to T2DM prevention.

We will mail participants a survey packet that includes a letter with instructions for completing the survey and a paper version of the survey . We anticipate this survey will take approximately 30 minutes to complete. Patients will be given the option to complete the survey by mail or by phone.

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 First 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.

Randomization: Immediately after completion of the baseline survey, study participants will be randomly assigned to a study arm. We will test 5 presentations that represent innovative messaging strategies from behavioral economics or health psychology with great promise to increase engagement in behaviors to prevent T2DM among patients with prediabetes. Study participants will be assigned to 1 of 16 different study arms based on different combinations of the 5 different strategies. We will contact patients by phone, letter, or secure message to inform them that their study group and intervention start date have been selected.

Strategy 1 - Preference Checklists: Preference checklists are lists of choice-relevant factors that individuals might theoretically want to consider when making a decision about prevention, but may not due to time pressure, lack of knowledge or information, or competing priorities. In such checklists, individuals read lists of choice-relevant thoughts that would favor taking preventive action and then indicate which they would consider in their decision making. Evidence from the marketing literature suggests this strategy can encourage individuals to be more discerning about decisions with major future implications.

Strategy 2 – Urgency Framing: In urgency framing, messages take a valence that encourages more immediate action around preventive behaviors that can be vulnerable to procrastination.

Strategy 3 – Implementation Intentions: Implementation intentions are a self-regulatory strategy in which individuals use "if-then" planning for achieving goals. Evidence from the behavioral economics literature suggests this approach can support well habit and behavior modifications because in the "if-then" statements individuals are asked to specify the when, where and how portions of goal-directed behavior.

Strategy 4 – Tailored Information: Tailored communications use information about an individual to determine the specific content he or she will receive and the frames surrounding the content. One promising way to tailor information is to link health behaviors directly to individuals' core aspirations. Research from the Self-Determination Theory literature suggests this approach can facilitate integrated regulation for behavior change, which is the most autonomous form of extrinsic motivation and thus the most likely type of extrinsic motivator to lead to sustained healthy behaviors.

Strategy 5 – Social Norms: This strategy aims to encourage individuals to focus on what they think someone important to them would say they should do at a decision point. Based on existing behavioral economic literature, we anticipate such focusing on a pro-social norm will prompt preventive action.

We will test these 5 strategies in isolation and in combination through a full factorial design **(**FFD) experiment with 16 messaging combinations. This design will allow us to measure the independent effects of each strategy as well as look for interactions between strategies.

Self-determination theory (SDT) is an approach to modifying human behavior that builds on the importance of internalized forms of behavioral regulation for achieving long-term maintenance. SDT further postulates that humans have 3 innate psychological needs: autonomy, competence, and relatedness.[3] Satisfaction of these essential needs promotes internalization of behavioral regulation, personal development, and well-being. As such, interventions that support the satisfaction of these needs are most likely to yield long-term healthy behaviors.

Another major contribution of SDT has been illuminating different types of motivation, each with a different likelihood of producing sustained engagement in behaviors. In this typology, different forms of motivation and regulation lie on a continuum based on the degree to which they support autonomy and are thus likely to support the initiation and maintenance of healthy behaviors.[16] *Integrated regulation* is the most autonomy-supportive type of extrinsic motivation and occurs when a behavior is congruent with what an individual values and is aspiring to accomplish. Because integrated regulation facilitates an internal locus of causality, once established and reinforced it is more likely to promote sustained behaviors. Further, integrated regulation may be more realistic to achieve in behavioral interventions than intrinsic motivation because, while many individuals at risk for diabetes may never find behaviors to prevent diabetes to be inherently enjoyable,[17] all individuals have aspirations in life that could be facilitated by preventing diabetes (e.g., community contributions could be facilitated by improved physical functioning, and personal growth could be supported by greater self-control).

Our team recently translated these insights[1,2] into a tailored messaging intervention that we pilot tested among obese U-M employees. We first developed a novel system for linking weight loss to employees' aspirations in life as measured by items from the Aspiration Index (AI).[18–20] The AI is a 105-item survey scale used in psychology research that is valid and reliable across cultures.[21] The AI asks about 5 life goals related to each of 7 categories of aspirations: (1) wealth, (2) fame, (3) image, (4) meaningful relationships, (5) personal growth, (6) community contributions, and (7) good health. Our system used the 35 AI items that ask individuals to rate the importance on a 1 to 7 scale of each of the 35 goals. For each individual we computed scores for the importance of each aspiration (ranging from 5 to 35) to identify the 3 aspirations with the highest scores as an individual's main aspirations. We then pre-tested this system with 2 focus groups of obese U-M employees and refined it based on their feedback.

After developing and refining our approach, we conducted a 12-week pilot RCT to test the acceptability to participants, feasibility to deliver, and preliminary effects of this novel way to tailor messages among 62 obese U-M employees. In the beginning of the tailored messaging intervention, participants were informed of the 3 main aspirations in life we identified from their responses to the AI items in their baseline survey and invited to respond to an online writing prompt in which participants typed into a text box at least 1 way in which achieving their weight loss goals could help them achieve 1 or more of these aspirations, or something else important to them. This aimed to help individuals perceive weight loss as being concordant with their main aspirations so as to promote greater autonomous motivation for weight loss.[4,22] Here is an example of a writing prompt that was sent to a participant whose main aspirations were **good relationships**, **feeling healthy**, and **personal growth**:

*From your responses to the survey you took at the beginning of this program, we learned that **good relationships**, **feeling healthy**, and **personal growth** are important to you. In order to stay motivated to lose weight and keep it off, it can help to think about how the program could help you achieve these and other life goals that are important to you.*

How could losing weight help you achieve good relationships, feeling healthy, personal growth, or something else important to you?

Please take a moment to think about these questions and type your answers here:

We will test these 5 strategies in isolation and in combination through a full factorial design **(**FFD) experiment with 16 messaging combinations. This design will allow us to measure the independent effects of each strategy as well as look for interactions between strategies.

Intervention:

The FINDIT study, the sister study of INVENT was approved to conduct secure message pre-testing drafts with patients to collect feedback and inform the development of the INVENT intervention. We have collected feedback from Veterans about the content and have modified our drafts accordingly.

Participants in all study arms will receive a series of Secure Messages through MyHealtheVet and monthly printouts by mail. We chose Secure Messaging because of the growing number of Veterans that use technology to manage their healthcare, the large percentage of Ann Arbor VA Veterans signed up for MyHealtheVet and Secure Messaging, and the number of previous VA research studies that are currently using Secure Messaging. Given that emails and text-messages (with the exception of the VA ANNIE project, which is not currently accepting new sites) are not permitted to communicate with Veterans, secure messaging allows for a simple, convenient, scalable yet patient-centered approach to delivering our intervention.

We are proposing a 3 month schedule of weekly Secure Messages and monthly mailings for this intervention. The intervention materials and the delivery schedule are provided in this IRB amendment. In total, there will be two monthly mailings that will be mailed respectively near Weeks 4 and 8.

The following 5 strategies will be implemented in the weekly messages that study participants will receive over the course of the 3-month active intervention phase: (1) tailoring to aspirations in life; (2) implementation intentions; (3) preference checklists; (4) urgency framing; (5) social norms. We will implement these strategies alone and in combination in a 16-arm fractional factorial design experiment (i.e., a full factorial design). The initial messages will be based on a text template that will vary based on the arm an individual is randomized to; for participants who are randomized to an arm that will receive messages tailored to aspirations this initial message will be tailored to their responses to the baseline survey. The weekly messages will be based on a text template that will vary based on the arm an individual is randomized to as well as their previous replies to the initial message (e.g., what an individual wrote in response to the writing prompt tailored to their aspirations, or in response to the implementation intention prompt).

The messages will encourage the following behaviors that have been shown in previous research to reduce individuals' risk for diabetes:

- Losing at least 7% of one's body weight
- Getting at least 30 minutes of moderate physical activity (e.g., brisk walking, biking, or gardening) 5 times each week
- Participating in a weight loss program such as the VA MOVE! program or a Diabetes Prevention Program
- Asking one's VA Primary Care Team about pharmacotherapy to prevent diabetes

We have included with our amendment, a color-coded key that illustrates the timeline and aspects of the template text that will vary depending on the messaging strategies that will be implemented in the arm to which a participant is randomized.

Final Survey: We will issue a Final Survey packet approximately 3 months after participants receive their first intervention message. This packet will include a letter with instructions for completing the survey in the same mode they used to complete the preceding survey. This survey will take approximately 20 minutes to complete. Patients will be given the option to complete the survey by mail or by phone.

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.

Update April 2018: We made some slight changes to our Final Survey that help ensure we are capturing the most meaningful follow-up data.

Follow-Up Data from CDW: While we are only collecting 3 months of survey data, we will collect data from the CDW on participants' weights, HbA1c tests, prescriptions, and MOVE! visits for the 12 months after the end of the intervention.

We will explicitly explain the time period that we are requesting in our informed consent and HIPAA documents.

f) Briefly describe the usual healthcare procedures already being performed for diagnostic or treatment purposes that will be used for research data collection; or N.A.

We will collect data such as weights, HbA1c tests, and diagnoses that are typically collected at primary care visits.

g) Please list and attach all research questionnaires and/or research surveys that will be administered to the subjects.
(All questionnaires and surveys must be approved by the IRB.)

We are planning to issue surveys at two different points:

(1) Baseline

(2) Approximately 3 months after receiving first intervention message

We will be conducting semi-structured interviews by phone with approximately 20 study participants to evaluate their experience with the interventions.

We will sample patients with varying levels of participation in both the interactive message arms (i.e., the arms that include questions in the secure messages intended to engage participants) and static message arms (i.e., the control arms that do not ask questions in the secure messages).

Participants will be mailed a letter with a $10 gift card for completing an interview. Interviews are voluntary and even those who agree to complete an interview can stop at any time or refuse to answer any question. For those that refuse to have the interview recorded, we will instead write detailed notes. Interviews will be recorded using a VA-approved DVR device and will be removed from the device within 24 hours. The interviews will be stored on the secure INVENT study folder on HSR&D's servers behind the VA firewall. Access to the interviews will be exclusive to study staff.

At this time, we are not planning to transcribe these interviews.