Diabetes Disparities: Texting to Extend Treatment (DD-TXT)

NCT04227379

April 5, 2024

Information Sheet Template (Waiver of Documentation of Informed Consent)

VA Central IRB
VA Institutional Review Board for Multisite Studies

INFORMATION SHEET FOR Diabetes Disparities: Texting to Extend Treatment (ANNIE-DM) IIR 17-087, aka "VA Annie Texting Study for Diabetes", Annie Texting Program Trial

You are being asked to participate in a VA research study conducted by SITE NAME in CITY, STATE. We are conducting a study to help develop ANNIE-DM (Annie for Diabetes Mellitus), a new, customizable, interactive texting program that allows Veterans to choose what kinds of diabetes self-management support they need, and when.

Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time. Your withdrawal from this study will not affect benefits or care you receive

WHY IS THIS STUDY BEING DONE?

One way to help Veterans improve their diabetes control is through the use of technology to help provide information, motivation, and reminders necessary to support diabetes self-management. We are conducting a study to help develop and test ANNIE-DM, a new texting program to provide patients with the diabetes self-management support they need. We will be comparing two different texting protocols to support diabetes self-management at your facility. These texts will be sent to you through VA's texting program called "Annie." Veterans with diabetes will receive and respond to texts about their diabetes over a six-month period.

By doing this study, we hope to improve future useof Annie-based self-management support throughout VA. Your participation in this research will last about 6 months.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

If you decide to take part in this study, this is what will happen:

- **Baseline Visit:**
  - The Baseline visit should take between 60-90 minutes to complete.
  - You will be meeting with a study coordinator in person (if currently allowed due to COVID) or by video conferencing (program such as Zoom, Microsoft Teams, or WebEX), or over the telephone if preferred.
  - You will be asked to complete a baseline survey about your use of technology, how comfortable you are using technology, and some basic information about you. We can email you a link to an online survey, or you can answer the questions over the telephone or in person if you do not have access to a computer.
  - You may be asked to fill out a module customization form.
  - The study coordinator will stress that the Annie portal is not checked by your providers. The study coordinator will sign you up to receive Annie text messages and will help you practice receiving and responding to different messages.

- For women Veterans: If you are a woman of childbearing age, the study coordinator will ask if you are currently pregnant. Women cannot enroll in the trial if they are currently pregnant. Because of the risks of uncontrolled diabetes during pregnancy it will be extremely important for you to let the study team and your doctors know right away if you were to become pregnant (or if there were another major change to your health status).
- You will receive written instructions on how Annie works and how to contact the project coordinators for guidance if problems arise.

- **Text messages for 6 months:**
  - Everyone in this study will have text messages sent to their mobile phone for 6 months, beginning after the Baseline visit.
  - Text messages will be sent at minimum once a day and up to 4 times per day (on one of the protocols, the patient can request more messages).
  - Sometimes you will be invited to respond to a question sent through the text message. You may be asked about your blood pressure, blood sugar, daily exercise or diet depending on the modules you have chosen to receive
  - Some of the text messages you receive will be different for the two study groups.
  - The project coordinator may check in with you via phone to see whether you need help.
  - You may receive a monthly administrative message asking whether you would like to receive a call from the project coordinator for support or to modify your settings.
  - For women Veterans: If you do become pregnant during the trial, we may need to change what text messages you receive. You could choose to disenroll from the study if you want. If you enroll but later become pregnant, you would still be eligible to participate in the data collection and receive participant incentives.
- **Follow up Visit after 6 months:**
  - You will be asked to return for a Follow-up visit either in person (if permitted due to COVID) or by video conferencing (program such as Zoom, Microsoft Teams, or WebEX), or over the telephone, as preferred, after 6 months.
  - This visit will take approximately 60 minutes.
  - You will be asked to complete a follow-up survey online or by phone.
  - *o* Then, we conduct a brief 20-30 minute qualitative interview over video-conferencing (programs such as Zoom, Microsoft Teams, or WebEx), or by telephone (if preferred) with you about your experiences receiving texts for diabetes self-management support so you can tell us what you liked and did not like about ANNIE-DM, and what you think we might want to improve upon. We will record this interview portion if you give us permission to do so so that we can correctly capture your feedback to help improve Annie-DM.
- This study is being overseen by NAME, the Principal Investigator (the study leader) at the SITE NAME IN SITE CITY, STATE, Site PI, NAME at SITE NAME IN SITE CITY, STATE , and Site PI, NAME at SITE NAME IN SITE CITY, STATE . You will receive all instructions and contact information from a research coordinator at SITE NAME or SITE NAME .
- Researchers and study coordinators at SITE NAME and in SITE NAME will have access to your information, so they can oversee the study and the examine the impact of Annie-DM on Veterans health outcomes.
- The research team will also look at records of your text messages to and from our study.
- Because this study is at two (2) VA Medical Centers, a Monitoring Board will review the study progress during yearly meetings and advise the team on any concerns.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Some expectations for participation in this study are as follows:
    - Please plan to attend the Follow Up Visit after 6 months. If you need to reschedule your Follow Up Visit, please contact the investigator or research staff to reschedule as soon as you can.
    - Complete surveys at enrollment and follow-up. When completing any survey, you are free to skip any question you do not wish to answer.
    - *o* Ask questions as you think of them.
    - *o* Tell the investigator or research coordinator if there is another major change to your health status (for example, if you become pregnant).
    - *o* Tell the investigator or research coordinator if you change your mind about staying in the study.

ARE THERE ANY RISKS OR DISCOMFORTS?

- Expected discomforts or inconveniences related with this study are minimal.
- You may get annoyed by some types of text messages, or not want to read them right when they are sent. You can choose to read them later at another time that is convenient for you. You can PAUSE the messages if you need to take a break from them.
- You may feel tired or bored by some of the questions we ask at the Baseline and Follow-Up visits. You can take breaks at any time you choose. You can also refuse to answer questions you do not want to answer, and you can withdraw from the study at any time.
- Loss of confidentiality is a possible risk of taking part in any study. In order to protect you, we will do everything we can to keep your research records confidential. You have been assigned a unique code, which will be used to identify the interview notes. The code will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.). The master list linking names to these codes will be kept separately from the research data.
- For women Veterans: Recommended diabetes self-management changes during pregnancy. It will be extremely important to let us (the study team) and your doctors know right away if you become pregnant. There is a risk your care would not be adequate if you take Annie's advice instead of your healthcare team's advice.

Your identity will not be revealed in any reports or publications resulting from this study.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

ARE THERE ANY BENEFITS?

You may or may not learn new things about diabetes self-management as a result of participating in this trial and receiving text messages. Although there are no guaranteed immediate direct benefits to participating in this study, others may ultimately benefit from your willingness to test and help us improve ANNIE-DM. The knowledge obtained in this research project will help improve the development of text-based support for other complex chronic conditions as well.

WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?

All research information will be kept in locked files or on secure VA computer servers at all times. Your identity will not be revealed in any reports or publications resulting from this study. Only authorized persons will have access to the information gathered in this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Data collected for the purpose of this research study will be kept as confidential as possible. If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. Your study files will be maintained according to VA requirements. Full measures will be taken to ensure the confidentiality of your identity as well as the confidentiality of all collected data. All information about you that is gathered during the research, including audio recordings, will be coded without the use of personally identifiable information. A master list matching your personal information with your research code will be kept separate from your study data. Paper files will be stored in locked cabinets. All electronic data will be stored on a private drive on a secure VA server that can be accessed only by a few authorized VA researchers. Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Your interview(s) may be audio recorded so that we can ensure that we accurately document your experiences with Annie-DM. The recording will be transcribed by an approved VA transcriptionist/service. Disclosure to a VA approved transcriptionist will be done in accordance with VA policy. Steps will be taken to ensure that recordings and transcripts remain confidential.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

- You will receive $30 for your participation in the baseline visit.
- You will receive $50 for your completion of both the follow-up assessment and interview. If you complete only the follow-up assessment survey you will receive $30. You can choose to receive payment by **gift card** or by **direct deposit**.
- If you are interested in being paid by direct deposit, we will assist you in setting up direct deposit. You will be asked to complete a 10091 form that asks for your social security number and banking information.
- If you do not have an unlimited texting plan and are concerned about the costs of sending and receiving text messages, please let us know and we may be able to help you with those costs.

WHO CAN I TALK TO ABOUT THE STUDY?

In the event of a research related injury, the VA will provide necessary medical treatment at no cost to you unless the injury is due to noncompliance with with study procedures or if the research is conducted by VA under contract with an individual or non-VA institution. Please immediately contact the Project Manager at CURRENT NUMBER if you have a study-related injury.

If you have any questions at any time during the study, please feel free to contact the main researchers.NAMES AT CURRENT NUMBERS.If you do not feel comfortable contacting one of the main researchers regarding any concerns or questions, you may contact the IRB Coordinator at VA Bedford Healthcare System, NAMEat CURRENT NUMBER.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.