Developing a Team-Delivered Intervention for Smoking and Hazardous Drinking for Primary Care Veterans With Cardiovascular Diseases (CDA 18-006)

NCT05275582

October 12, 2023

Phase 2
Important Points to Cover During Informed Consent

1) I'm going to read some information to you and ask you if you agree to continue moving forward. If you have any questions at all, please ask me. At the end, I'm going to ask you if you verbally consent to be in the study. If you decide not to continue participating, there will be no consequences to you or your healthcare.

2) The purpose of this study is to learn how patients like yourself feel about and are impacted by a new approach for the primary care team to use when talking to patients about heart disease and health behaviors. We are looking to recruit around 52 Veterans from Buffalo and Syracuse to be in this study. This approach is experimental, so you might find it helpful or not. What it will entail is being randomly assigned to one of two conditions. If you are assigned to the first condition, your upcoming primary care appointment will be extended by about 5 minutes because a Health Educator will join the end of that appointment. If you are assigned to the second condition you would have your typical primary care appointment. Beyond that, both conditions are quite similar. You would have an individual meeting following your primary care appointment with the Health Educator, two phone booster meetings at 2 and 4 weeks, and information about an optional app that you have the choice to use to help you track some health behaviors . If you're in the condition where the Educator joins your appointment, you'll meet with them right after, and if you're in the other condition we'll call you to schedule that.

3) Let me go into a bit more detail about the study. This baseline session will take around 60 minutes and gather information on your background and various health behaviors. After that, there are two primary parts to the study. The first part is where we try out a new primary care approach I explained before. The second part of the study is where we check in on your health behaviors over time to see how the new approach worked. The second part happens all from the convenience of your home.

   The first part of the study will occur during or after an appointment you already have scheduled – your Primary Care appointment with Dr. _____ on _____ at _____(am/pm). You will attend that appointment, and depending on which condition you received, you may be introduced to our new communication approach during the appointment. Following your primary care appointment, either right after or at a later scheduled appointment, you will meet with a Health Educator for about 25 minutes to discuss an optional questionnaire activity that you can complete on your phone. This activity is completely optional, it's up to you if you want to use it. Then, the Health Educator will check in with you on the phone at 2 weeks and 4 weeks to see how you're doing.

4) The second part of the study you will be asked to complete this baseline and then then 3 follow-up assessments with a member of our research team to check in on some of your health behaviors. These assessments take about 30-60 minutes. happens at home. You will be compensated as a thank you for your time and effort. For the baseline meeting today, you will receive $30. For the 1.5-month assessment you would receive $30, for the 3- and 6-month assessments you would receive $20 each. Therefore, if you complete everything, you will receive a total of $100.

5) This study is completely confidential. Your name will not be recorded on any questionnaires, rather a random identification number will be used and this will not be connected with your name or other identifying information.

6) The app, if you choose to download it, will ask you to enter your name and email address to create an account. It is up to you what information you put (in other words, if you choose to put a fake name/email, that is up to you). This information **will not** be stored with the data that we receive from the app.

7) Since this study involves asking you more information about your mood and issues pertaining to your safety, we want you to know that if at any time we are concerned about your safety, we will discuss it with you, if possible, or seek help from your primary care provider or other emergency services.

   a. Be sure to emphasize confidentiality, normalize suicidal ideation

8) None of this information will have any bearing on the health care that you receive.

9) You can decide to stop participating in the study at any time without any consequences to you.

10) If any of the research staff determines that it is not in your best interest to continue in the study, your participation may be discontinued.

11) It's possible that you may feel some distress as a result of answering some of the questions during the interviews. If you begin to feel distressed, please discuss it with us. You are free to stop participating in this study at any time.

HIPAA

12) Because this study is concerned with your health behaviors, we need your permission to look into your medical chart and collect information about your recent medical diagnoses and treatments. Remember, all this information is kept strictly confidential and is not shared with anyone outside of the study. Additionally, being in this study will not affect your healthcare here at the VA in any way.

Consent to be audio-taped

13) Finally, we need your permission to audio-tape your sessions with the Health educator. Since this is an experimental approach, we'd like to provide supervision to the research staff by using those audiotapes and to audiotape your feedback to us so that we can review it later and improve our study. We maintain the audio files on the VA server and do not link the file with your name, just a random identification number. The audio recordings will not be disclosed outside of the VA for any reason. After the end of the study, we no longer need the files anymore.

If you have questions about this study, you can contact the principal investigator, Dr. Julie Gass at 716-834-9200 x25429. If you have general questions about giving consent or your rights as a participant, you can contact the Buffalo VAMC Institutional Review Board..

Do you have any questions? (answer any questions)

Would you like to participate in the research study? _____ yes _____ no

RA INITIAL HERE TO INDICATE COMPLETION: _____ DATE:_____