Telehealth Treatment of Veterans with Alcohol Misuse at Risk for Cardiovascular Disease (CDA 19-035)

NCT04838457

March 11, 2025

Participant Name:	**Date:**
Study Title: Acceptability and Feasibility of an Intervention to Reduce Alcohol Misuse and CVD Risk in Veterans_Aim4	
Principal Investigator: Daniel Blalock, PhD	**VAHCS**: Durham VAMC

OVERVIEW AND KEY INFORMATION

Please read this form carefully. You are being asked to participate in this research study because you have documented in your chart alcohol use and high blood pressure This study is voluntary and will include only people who choose to take part. Ask your study doctor or study staff to discuss this consent with you, please ask him/her to explain any words or information that you do not understand. It is important that you understand the information on this form.

The purpose of this study is to develop an intervention aimed at helping Veterans improve several health behaviors that are associated with increased risk for cardiovascular disease, including decreasing alcohol consumption as desired.

Your participation in this study will involve an initial interview and questionnaires in which you will be asked questions over the phone; questionnaires may also be sent via mail if requested. You will then have 5 to 6 weekly treatment sessions (one every 2 weeks) via phone or video. This will be followed by a once-a-week text message and 1-4 brief daily text messages. There will also be two follow up interviews via telephone. The first will be about 2 months after you complete the 5-6 treatment sessions, and the last one will be about 6 months following the treatment sessions.

The greatest risk of this study is that some questions asked as part of this study may make you feel uncomfortable or increase distress. This discomfort or increased distress is usually temporary and well tolerated. You do not have to answer questions and you can take a break at any time.

WHY IS THIS STUDY BEING DONE?

The study is being done to develop an intervention aimed at helping Veterans improve several health behaviors associated with an increased risk for cardiovascular disease in patients who consume alcohol. Alcohol use itself can increase cardiovascular risk, and so is one of several potential health behaviors that may be changed if desired.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 25 people will be enrolled in this study at the Durham VA Health Care System.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in this study will last for approximately 16 weeks total, with two brief follow-up assessments in the 6 months after those 10 weeks*.*

WHAT IS INVOLVED IN THIS STUDY?

If you agree to participate in this research study, you will be asked to sign (via mail or electronically via DocuSign) and date this consent form.

Immediately following screening and informed consent (Session 0/ Visit 1), you will complete baseline self- report measures, either over the phone or electronically. The screening questions will take 1-2 minutes; if it is determined that you do not qualify for the study, no compensation will be provided. You may choose to opt out of the study at this time if you choose not to complete the screening questions.

You will then begin the active treatment, which consists of once-a-week video or phone treatment sessions for a period of about 12 weeks (weeks 2-12, every other week). Each of these sessions will last 45 minutes to 1 hour. Video versus telephone sessions will be determined by your preference and availability of video conferencing means. These up to 6 video or phone calls are aimed to give participants cognitive-behavioral skills to improve health behaviors. The focus of these calls will be collaboratively set with the treatment provider, who is a licensed social worker. Each treatment session will be individualized to each participant based on your responses to the interviews and questionnaires, and desired outcomes.

Weeks ~7-16 consist of receiving a once-a-week text message and 1-4 brief daily text messages. Participants will receive text messages about their health behaviors based on what they and the treatment provider have discussed and agreed upon. You will be invited to sign up for personalized text messaging support using the VA Annie app, available to all Veterans on MyHealtheVet. Annie is an automated, short message service (SMS) text message system designed to promote Veteran self-care. These text messages will be individually developed for you, with input from you as to what information you would find helpful in reminder/ informative text messages.

You will also complete an interview and questionnaires at the end of treatment, and the same interview and questionnaires around 2 months and 6 months after treatment. The interviews and questionnaires will be completed EITHER by phone or electronically, depending on your preference and accessibility to a

computer. Questionnaires may also be completed via hard copy sent by tracked United States Postal Service (none of your personal information is included on any form). The purpose of the interview is to gather your input on the strengths and weaknesses of the program.

Visit 1 (Week 1): Screening phone call and consent, baseline measures
Weeks 2-12: Telehealth treatment session, 1 time bi-weekly (lasting 30-60 minutes)
Weeks ~7-16 (depending on earlier sessions): Once a week text message and 1-4 daily text messages
Around Week 22 (about 2 months after end of telehealth sessions): End of study assessment
Around Week 38 (about 6 months after end of telehealth sessions): 6 month follow up call/ assessment

Audio recordings will be used during the assessment and treatment sessions for only study staff and will be used to supplement the written notes taken by the secondary interviewer. Recording of the assessment (interview) and intervention sessions will be conducted utilizing VA approved software approved, installed, and configured by VA Office of Information and Technology (OI&T) personnel. No one outside the study will have access to the recordings, and **no** identifiable information will be used. Recordings will be stored in a locked, password protected electronic study folder that only the study staff will have access to. You may opt out of having your sessions audio recorded.

Do you consent to having your sessions audio recorded?

☐ Yes
☐ No

FUTURE USE OF DATA AND CONTACT FOR FUTURE RESEARCH:

You may be contacted by this study staff in the future for additional portions of this study. You are not obligated to participate. We will store your data in a locked, password protected electronic study folder that only the study staff will have access to. Your data will not be used for any future research. All of your information will be de-identified.

I agree to be re-contacted about participating in future research studies: ☐ Yes ☐ No

All identifiers will be removed from your identifiable private information and, after removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the you.

WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY?

There are no known physical risks associated with this study. There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential. Some questions asked as part of this study may make you feel uncomfortable or increase distress. This discomfort or increased distress is usually temporary and well tolerated. You do not have to answer questions and you can take a break at any time. You can call the study team at any time if you experience any discomfort related to the research.

One limit of confidentiality is if study staff or therapist believe there is imminent risk of harm to yourself or others, in which case study staff or therapist may need to breach confidentiality to ensure the safety of a participant or others. This may occur by way of contacting your Primary Care Provider (PCP), the Emergency Department (ED), or our study physician.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

There is a possibility that by participating fully in the study, you **may** be able to improve your overall cardiovascular health by decreasing blood pressure, and by decreasing alcohol consumption if desired. You may not personally benefit from taking part in this study, but your participation may lead to knowledge that will help people in the future.

WHAT OTHER OPTIONS OR ALTERNATIVES DO I HAVE?

Taking part in this study is your choice. You may choose to not participate. If you choose not to participate, this will not affect your regular care at the VA**.** If you choose not to participate but would still like to receive treatment, one option would be to seek clinical treatment.

HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

Your information used for this study will be kept confidential as required by law. The results of this study may be used for scientific purposes or for publication, but these results will not include any information that would identify you. Your identity will not be disclosed without your consent, or unless required by

law. Your research records will be maintained and destroyed according to VHA records retention requirements.

Your research records may be reviewed by Durham VA staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of the Inspector General (OIG), and the Office of

Research Oversight (ORO). We will not share any information with these groups outside the VHA unless they agree to keep the information confidential and use it only for the purposes related to the study. Any information shared with these outside groups may no longer be protected under federal law. These groups may disclose your information to other groups. If the sponsor receives identified information, it is then the sponsor, and not the VA, who is responsible for the security of the information.

DOES PARTICIPATION IN THIS RESEARCH STUDY COST ANYTHING?

There will be no costs to you for any of the research treatment or research testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

WILL I RECEIVE ANY COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN THIS RESEARCH STUDY?

We are offering ***up to*** $260 as a thank you for your time and participation ($50 once successfully screened into the study, $10/session for each of up to six (average 4-6) telehealth treatment sessions, $50 for the end of telehealth interview, and $50 each for follow-up assessments). If you are screened for the study but do not qualify, you will not be compensated, as the screening process is only a 5 minute or less questionnaire over the phone. You may choose to opt out at that time.

Initial Visit screening / questionnaires $50
Treatment Visits (*up to* 6; via phone or video) $10 each/ *up to* $60 total
End of study interview $50
2 month follow up interview $50
6 Month follow up interview $50

WHAT WILL HAPPEN IF I AM INJURED WHILE PARTICIPATING IN THE RESEARCH STUDY?

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VA Health Care System or arrangements may be made for contracted care at another facility. Every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at 919-286-6957.

WILL CLINICALLY RELEVANT RESEARCH RESULTS BE PROVIDED TO ME?

We do not expect any research results to be directly clinically relevant to participants. All participants' relevant clinical information will be discussed during treatment.

WHAT ARE MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You can choose to not be in this study, or, if you agree to be in the study, you can withdraw at any time. If you withdraw from the study, no new data about you will be collected for study purposes. We will keep and use the data that we already collected before you withdrew your consent.

If you choose to not be in the study or if you withdraw from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

COULD I BE WITHDRAWN FROM THE STUDY?

You may be withdrawn from the study without your consent if your eligibility or exclusion criteria change during treatment. Discontinuation will only occur if additional treatments are sought by the patient that would interfere with the current treatment in some way.

These include:

1. Current enrollment in another trial for CVD risk reduction or medication adherence specifically.
2. Current participation in other alcohol misuse treatment programming.
3. Any recent or impending procedures that would warrant inpatient hospital stays or considerable changes to current medications (e.g., any changes other than altered doses).

Withdrawal of Data for Future Use

If you agree to allow your data with information that would link the data to you to be kept for future research or for re-contacting, you can change your mind at any time. To withdraw your data, contact Dan Blalock in writing and let him know you are withdrawing permission for your identifiable data to be used for future research. Dan Blalock's mailing address is:

HSR&D, Durham VA Health Care System
411 West Chapel Hill Street, 6th Floor
Durham, NC 27701

You can also call 919-286-6936 and explain that you are withdrawing your permission for your data to be used for future studies.

If your identifying information, such as your name or medical record number, are removed, we will no longer be able to identify and withdraw your data.

WILL THE RESULTS OF THIS RESEARCH STUDY BE SHARED WITH ME?

You will receive treatment personalized to you based on your responses in the assessments. You will have access to any publications that may come out of the study, which will not include any identifiable information.

WHERE CAN I FIND OTHER INFORMATION ABOUT THIS RESEARCH STUDY?

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

WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THE RESEARCH STUDY?

If you have questions about the study or need to talk to the study team, you can contact Laurel Koss at (919)-286-0411 extension 175648. If you have questions about the research or your rights as a research participant, or have other concerns or complaints, you may contact the administrative officer of the research service at (919) 286-0411, extension 177632. If you would like to check that this study is

approved by the Durham VAHCS's Institutional Review Board, please call the research office at (919) 286-0411, extension 176926.

AFFIRMATION FROM PARTICIPANT

I have read this form or it has been read to me. My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.

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Signature of Participant/ Date

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Signature of Person Obtaining Consent/ Date