Developing a Mobile Intervention to Reduce Suicidal Cognitions in Veterans

NCT04881903

Informed Consent Form

11/15/2023

Participant Name:	**Date:**
Study Title: Developing a Mobile Intervention to Reduce Suicidal Cognitions in Veterans	
Principal Investigator: Kirsten H. Dillon, Ph.D.	**VAHCS**: Durham VAMC

OVERVIEW AND KEY INFORMATION

Please read this form carefully. You are being asked to participate in this research study because you may have recently experienced thoughts of suicide. 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 a mobile treatment to reduce suicide risk.

Your participation in this study will involve three study visits. You will be asked to use two mobile treatments for a period of 4 weeks each (total of 8 weeks). You will also be asked to completed daily electronic diary entries twice a day for this time. The mobile interventions focus on thoughts about suicide and anger. You will be interviewed by a study team member about your experiences using each of the mobile interventions. The interviews will be audio-recorded.

The greatest risks of this study involve loss of confidentiality associated with audio recording, and temporary distress while completing the study interviews.

WHY IS THIS STUDY BEING DONE?

The aim of this research study is to develop a mobile treatment to reduce suicide risk. We are hoping to get feedback from you about the treatment and suggestions for how we can improve it. We also want to examine the effects of the treatment and another treatment for reducing anger on suicide risk and daily functioning. This study is being funded by the Health Services Research and Development Service, Department of Veterans Affairs

You are being asked to participate in this research study because you may have thoughts of suicide and difficulty controlling your anger.

The experimental part of this research is that you will receive two mobile treatments: one that has been designed to reduce suicidal thoughts (MIST intervention) and another that has been designed to help reduce anger (MARI intervention).

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY

Approximately 30 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 about 2 ½ months.

WHAT IS INVOLVED IN THIS STUDY?

If you agree to participate in this research study, you will be asked to sign and date this consent form. We will then determine if you are eligible to participate in the study by having you fill out a brief questionnaire and completing an interview. If you are eligible, we will then ask you to fill out some additional questionnaires. The entire visit will take approximately three hours.

You will then use the MIST intervention for a period of four weeks. We will also ask you to complete an electronic diary twice a day about your level of functioning and thoughts of suicide. The electronic diary will be completed using a survey system called Qualtrics. At the end of the four weeks, you will return to our lab for another visit. During this visit, you will complete questionnaires and we will ask you a series of questions about your experience with the MIST intervention. This interview will be audio-recorded so that we can review your feedback in depth after the visit. We will then also ask you to give us feedback on some of the written content of the intervention. This visit will take two hours.

Then you will use the MARI intervention for a period of four weeks, in addition to the diary entries twice a day. At the end of the four weeks, you will return to our lab for a final visit to complete some more questionnaires. The final visit will take one to two hours.

The study team will ask you if you would like to receive email notifications regarding your study participation. If you would like, we can send you appointment reminders and other study correspondence this way.

FUTURE USE OF DATA AND CONTACT FOR FUTURE RESEARCH:

If you consent to participate in this research study, we will collect information about how to contact you in the future. We will store this contact information along with your interview results in a database called "Contact Database." This database is stored at the DVAHCS. This information will be used to determine if you may be eligible for future studies run in the Traumatic Stress and Health Research Laboratory and to contact you about participation. These future studies include studies

related to smoking, posttraumatic stress disorder (PTSD), and trauma. This permission is optional. Your choice to give permission to be re-contacted or not to give permission to be re-contacted will not affect your enrollment in the current study. If you do not wish for us to keep your information, we will not contact you in the future about other studies.

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

Only if you grant permission, data collected from you during participation in this study may be entered into a large database called "Trauma Database." This data will be used for future research. Data will not include any identifying information, and will be stored at the DVAHCS.

I agree to future use of my data: ☐ Yes ☐ No

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

There are no known risks associated with completing the interviews and questionnaires. There is a potential risk for loss of confidentiality associated with being audio recorded. There is a risk of temporary distress related to completing the screening visit, in which you will be asked about your traumatic experience(s).

Not all risks of an intervention can be predicted. There may be risks or discomforts that are not yet known. If you experience discomfort that you think may be related to the research, please call the study team to discuss the problems you are having.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

You may benefit from completing the mobile treatments. Additionally, your participation may lead to knowledge that will help others.

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, you may or may not be eligible for treatment in the Trauma Recovery Program or Mental Health Clinic at the Durham VA.

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.

All study data will be kept in a secured file to which only study team members will have access. Hard copy paper records (that is, any forms you sign) will be stored in a locked filing cabinet in the study coordinator's locked office, within this research lab at the Durham Veterans Affairs Health Care System. Information collected during your visits will be entered into a computerized database. This database is stored on a VA secured computer server that is password-protected, and only accessible by Dr. Dillon and her study staff. An audio recording of your interview will be stored temporarily on the audio recorder, which is kept in our research laboratory's office in a locked filing cabinet. The recording will be moved to a VA secured computer server that is password-protected. From there, they may be moved to an encrypted DVD that is password-protected. Only study staff members have access to the passwords that protect your information.

Access to data stored at the Durham VA Health Care System will be limited to a small number of study team members who have been trained to preserve participant confidentiality. The key linking code numbers and identifying information will be kept in a locked office in the Durham VA, and will be maintained on password-protected computers behind the VA firewall on the VA secured server.

Any information collected from you may be used for future research studies or given to another investigator for future research studies. This information would be used only after any identifying information about you is removed.

There are VA rules (called records control requirements) about how long your research records are kept. Right now the rules say your research records cannot be destroyed. This may change in the future; at that time we will follow the new VA rules. Your research records (including audio recordings) 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?

Participants who are screened and found ineligible for the study will receive $40 for their time. Eligible participants will receive $100 for completing the first visit, $75 for completing the second visit, and $50 for completing the final visit. They will also be paid for completing the diary entries for the 8-week duration of the study. They will receive $30 for each week that they do the diary entries (8 weeks total) plus a $20 bonus each week that they complete at least 2/3rds of the prompted diaries. Participants can receive up to $625 for completion of the study.

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 VAHCS 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.

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.

ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

Dr. Dillon may take you out of the study without your consent for one or more of the following reasons: failure to follow the instructions of the study coordinator and study staff, inability to complete the study requirements, or other administrative reasons.

We will tell you about new information that may affect your health, condition, welfare, or willingness to participate in this study.

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

We do not routinely send out results of the research study. However, if you would like to receive copies of any journal articles that are written using the data we gather during this study, please tell the study coordinator. He/she/they will make note, and send you a copy of any article about this study.

DO ANY OF THE RESEARCHERS HAVE A FINANCIAL INTEREST RELATED TO THIS RESEARCH STUDY?

This study is funded by the Department of Veterans Affairs. A portion of the study staff members' salaries are paid by this study.

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 research or need to talk to the study team, you can contact Dr. Kirsten Dillon at (919) 384-8582 x 4040 during regular business hours If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, 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) 286-6926 or (888) 878-6890, 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**