Mobile Intervention for Veterans With PTSD and Anger

NCT03733028

Informed Consent Form

Document Date: 8/9/2022

Participant Name:	**Date:**
Study Title: Developing a Mobile Intervention for Veterans with Posttraumatic Stress Disorder and Problematic Anger	
Principal Investigator: Kirsten H. Dillon, Ph.D.	**VAMC**: Durham

Please read this form carefully. It tells you important information about a **voluntary** research study. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. It is important that you understand the information on this form. If you would like to check that this study is approved by the Durham VAMC's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 176926.

WHY IS THIS RESEARCH BEING DONE?

The aim of this research study is to compare two mobile treatments for reducing anger. This study is being funded by the Research Rehabilitation Service in the Office of Research and Development, Department of Veterans Affairs

You are being asked to participate in this research study because you may have posttraumatic stress disorder (PTSD) and have difficulty controlling your anger. A total of 70 participants are expected to be screened for this study.

WHAT IS THE EXPERIMENTAL PART OF THIS RESEARCH STUDY?

The experimental part of this research is that you will receive one of two mobile treatments that have been designed to help reduce anger.

WHAT PROCEDURES, DRUGS, OR TREATMENTS ARE INVOLVED IN THIS RESEARCH 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 and complete a short task on the computer. We will also ask you to sign and date a Duke consent form agreeing to participate in the mobile intervention portion of this project. The entire visit will take approximately four to five hours.

We will use a procedure like flipping a coin to randomly assign you to one of the two mobile treatments that are being studied. One of these treatments is focused on changing mental habits that contribute to anger and the other one consists of exercises for practicing mindfulness skills to reduce anger. You will then use the assigned mobile intervention for a period of four weeks. You will be asked to wear a mobile heart rate monitor for a portion of this time. This procedure is described in more detail in the Duke consent form you will be asked to sign.

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 mobile treatment. This interview will be audio-recorded so that we can review your feedback in depth after the visit. This visit will take two to three hours. Three months later, 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 VA has recently approved use of an email program that will allow us to securely email you regarding study procedures. If you are comfortable receiving appointment reminders, study questionnaires, or other study messages via email, you can give your email address to the study coordinator or your study therapist.

Optional parts of study:
Option 1: If you agree, we will ask you to provide the name and contact information of someone close to you who will be asked to answer some questions about your anger and your relationship with them. These assessments will be completed over the telephone. We will contact them now and then again when you have used the mobile intervention for four weeks. If you choose not to do this portion of the study, you can still participate in the rest of the study.

I give permission to Dr. Dillon and/or her study staff to contact a family member or friend I identify about answering some questions about me.

YES ☐ NO ☐ Initials:_____ Date:_____

Option 2: Additional Data Repository: With your permission, if you have previously participated in the Post-Deployment Mental Health Data Repository (IRB # 01706), we would also like to add the data we are collecting today to that Repository so that the information can be used for additional and future research studies. The data collected that would be added to the repository includes: questionnaires, clinical interview results, information about your smoking behavior and your updated contact information. Combining the information you share with other research studies can help us better answer certain research questions. It may also help us understand post-deployment mental health issues from multiple perspectives.

I give permission for the data collected from me during this study to be entered into the Post-Deployment Database within the Post-Deployment Mental Health Data Repository for use in future mental health research studies.
YES NO Initials:_____ Date:_____

CAN I REFUSE TO BE IN THIS RESEARCH STUDY OR WITHDRAW AT A LATER TIME?

Absolutely. You do not have to join this or any other research study. If you do join and later change your mind, you may quit at any time. If you withdraw from the study, no new data about you will be collected for study purposes. If you refuse to join 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.

WHAT OTHER OPTIONS DO I HAVE?

Taking part in this study is your choice. You have the option not to participate.

HOW LONG WILL I BE IN THIS RESEARCH STUDY?

From start to finish, your participation will take 4 months.

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.

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 treatment to reduce anger. Additionally, your participation may lead to knowledge that will help others.

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?

You will receive up to $650 for completion of this study.

Money that you receive for participating in research is considered taxable income per Internal Revenue Service (IRS) regulations. The money may be reported to the IRS and you may receive an IRS Form 1099.

HOW WILL I BE COMPENSATED?

The study involves three assessment visits. Participants who are screened and found ineligible for the study will receive $40 for their time. Eligible participants will receive $150 for completing the first visit, $100 for attending and completing the second visit one month later, and $100 for completing the final visit three months later. You will be paid up to $300 when we receive your heart rate data and electronic diary data from Duke. These data will be shared with Dr. Dillon using an encrypted USB drive.

The way you receive this money will be according to VA procedures during the time you are in the study. A study team member will explain these options to you. The VA preferred method of payment is through electronic funds transfer (direct deposit into your bank account). This takes approximately 1-3 business days. Payment through electronic funds requires you to give the VA your bank account number. If you choose to receive your payment by check it will take approximately 4-6 weeks. Payments will be processed immediately after each in-person visit.

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.

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 VAMC 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 MY CLINICAL OR OTHER RESEARCH TEST RESULTS BE SHARED WITH ME?

We will let you know of any important discoveries made during this study which may affect you, your condition, or your 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 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. The study staff members' salaries are paid by this study.

HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

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.

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.

WILL ANYONE ELSE HAVE ACCESS TO MY RESEARCH DATA?

If results of this study are reported to others, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

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 Duke University or 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.

ARE THERE ANY LIMITS TO THE PRIVACY AND CONFIDENTIALITY OF MY RESEARCH INFORMATION?

If during the study any information reveals suicidal intent, depression, or other major clinical findings, your primary physician will be notified. In addition, if you reveal current intent to harm yourself or someone else, we may be required to escort you or have you escorted to this hospital's emergency room to be seen by staff in the Psychiatric Emergency Clinic (PEC). If during the course of the study you discuss or mention anything that gives us cause to suspect abuse or neglect of any child, elderly adult, or person with a disability, we are required by federal law to report the suspected abuse to your local Department of Social Services.

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) 286-0411 x177870 during the day. 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 17632.

AFFIRMATION FROM PARTICIPANT

Participant Name:	**Date:**
Study Title: Developing a Mobile Intervention for Veterans with Posttraumatic Stress Disorder and Problematic Anger	
Principal Investigator: Kirsten H. Dillon, Ph.D.	**VAMC**: Durham

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.

Participant's Signature	**Date**
Signature of Person Obtaining Consent	**Date**