Informed Consent Form

Study Title: Narrative Exposure Therapy for Justice-Involved Veterans

NCT Number: NCT03777553

Document Date: 3/13/2020

Participant Name:	**Date:**
Study Title: Narrative Exposure Therapy for Justice-involved Veterans	
Principal Investigator: Elizabeth Van Voorhees	**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 6926.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to examine the effects of Narrative Exposure Therapy (NET) on posttraumatic stress disorder (PTSD) symptoms and related outcomes, like anger, aggression, depression, and quality of life in veterans with PTSD. You are being asked to participate in this research study because 1) you are a veteran, 2) you either have been diagnosed with PTSD or think you may have PTSD, and 3) you reported that you have used physical aggression to harm someone . This study is being run by Dr. Elizabeth Van Voorhees at the Durham VA Medical Center. About 20 veterans will participate in this study.

WHAT IS THE EXPERIMENTAL PART OF THIS RESEARCH STUDY?

The experimental part of this study is that we will ask you to come to the laboratory for a baseline visit, ten individual treatment visits, and a follow up visit. You will also be asked to complete follow up questionnaires by mail 3 months after you complete your last treatment visit. As part of the in-person follow up visit, you will be asked to provide feedback about your experience with the therapy and whether you believe the treatment was helpful. Your feedback about the treatment will be audio recorded. You will not be audio recorded during any other study activities.

WHAT PROCEDURES, DRUGS, OR TREATMENTS ARE INVOLVED IN THIS RESEARCH STUDY?

SCREENING/BASELINE VISIT. If you agree to participate in this research study, you will participate in some interviews about your current psychological health. These interviews will include questions about your mood, including feelings of anger, sadness, and nervousness. They also include questions about traumatic events you may have experienced and how they may have impacted you over time. During this session you will complete a series of questionnaires that will ask you more questions about your mood, anger, trauma history, current and past justice involvement, current use of substances, and demographic information. This visit will take about 3 – 5 hours of your time, and you will be paid $70 for this visit.

NARRATIVE EXPOSURE THERAPY (NET). If you decide to participate in the study, you will be asked to attend 10 sessions of individual trauma-focused therapy for PTSD. These sessions will be held either once a week. You will be asked to complete questionnaires about your PTSD symptoms at each treatment session. You will be compensated $10 for each set of assessments you complete. Each treatment visit will last for 90 minutes. You may stop attending the treatment sessions at any time.

POST-TREATMENT FOLLOW UP VISIT., Approximately one to two weeks after your final treatment visit or final phone call, you will be asked to participate in an interview about your experience in the study where you will be asked to provide your opinions about the therapy. You will be audio recorded only when providing your opinions about the therapy. You will also be asked to complete many of the same questionnaires you filled out during the screening session. This visit will take about 3 – 4 hours to complete, and you will be compensated $80. Only members of our study staff will have access to your data.

3-MONTH FOLLOW UP. Three months after your post-treatment follow up visit, we will send you a packet of questionnaires through the mail. The packet will include some of the questionnaires you completed during your initial and/or post-treatment visits and a stamped envelope to use to return the packet to us. It will take you about 1 hour to complete the packet. If you would rather complete the questionnaires in person, we will schedule an appointment for you to come in and complete them. We will compensate you $35 for completing and returning the packet.

If you agree to participate in the study, you also agree to let us review your VA electronic medical record. We will review this record to see how often you have been involved in mental health treatment here.

While you're in the study, you may find that you'd like to refer another Veteran to participate. In order to encourage you to refer other Veterans to the study, we'll give you three referral coupons that are marked with an identification number that is unique to you. You can give these referral coupons to any Veteran you think might be interested in the study. If that Veteran comes in for a screening visit and brings us his/her coupon, we'll offer you a $15 payment for taking the time to make the referral. Please note that we won't be able to tell you whether or not a specific Veteran uses your coupon. We ask that you not discuss with others whether you think/believe a Veteran you have referred may be participating in the study. You can choose not to distribute the coupons we give you, and you can refuse to even receive the coupons.

WILL ANY OF MY DATA, BLOOD, TISSUE OR OTHER SAMPLES BE STORED AND USED FOR FUTURE RESEARCH?

Option 1:

- Contact Database: 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 information will be used to determine if you may be eligible for future studies in the Traumatic Stress and Health Laboratory. We are also asking your permission to be contacted about these future studies for which you may qualify. These future studies include studies related to smoking, posttraumatic stress disorder (PTSD), and trauma. Whether or not you agree to be re-contacted will not affect your enrollment in the current study.

I give permission for my contact and interview information to be stored for the purpose of being contacted in the future about these other studies for which I might be qualified.
☐ Yes ☐ No Initials: _____ Date: _____

Option 2:

- Trauma Database: Data collected from you during participation in this study may also be entered into a large database called "Trauma Database." The information you provide may become part of this larger database, which will be used for future research. Information collected from many study participants (500 or more) from different studies will then be examined to inform researchers about the topic they are trying to learn more about. Topics of research change over time and, for that reason, the development of a combined research database is particularly useful. Your identifying information will only be available to research staff in the Traumatic Stress and Health Laboratory. Your choice to be included or not to be included will not affect your enrollment in the current study.

I give permission for the data collected from me during this study to be entered into the "Trauma Database" for use in future research.
☐ Yes ☐ No Initials: _____ Date: _____

Option 3:

- VISN 6 MIRECC Post-Deployment Mental Health Data Repository: *This section only applies to you if you previously participated in the Study on Post-Deployment Mental Health. If you did not participate in that study, please mark "N/A" below.* In the past you may have participated in a Study on Post-Deployment Mental Health (IRB #0933) in which you were asked and agreed to contribute your research data to a Post-Deployment Mental Health Data Repository

(IRB # 01706), and in which you were asked and agreed to be contacted for future research studies. If you participated in this prior study we would like to add the data we are collecting today to the Post-Deployment Mental Health Data Repository so that the information can be used for additional and future research studies, and so that the information we obtain today can be linked to your already collected data. The data collected that would be added to the repository includes: questionnaires, blood pressure, heart rate data, and information from clinical interviews. Combining the information you share from multiple VISN 6 MIRECC studies can help us better answer certain research questions. It may also help us better understand post-deployment mental health issues

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 ☐ N/A Initials: _____ Date: _____

Option 4:

- Re-Contact Database (RCD) of the Post-Deployment Mental Health Data Repository: *This section only applies to you if you were previously included in the Re-Contact Database (RCD) of the Post-Deployment Mental Health Repository. If you were not previously included in this database, please mark "N/A" below.* In the past you may have participated in a study on Post-Deployment Mental Health (IRB # 00933) in which you were asked and agreed to be re-contacted for future studies. If you did participate in the Study on Post-Deployment Mental Health we would like to update your contact information in the RCD of the Post-Deployment Mental Health Data Repository (IRB # 01706) so that this information remains current and so that you may be re-contacted for additional studies. The purpose of future studies is to learn more specific information about post-deployment mental health.

I give permission for my contact information to be updated in the Re-Contact Database in the Post-Deployment Mental Health Data Repository (IRB # 01706) for the purpose of updating or confirming the accuracy of the already stored information so that I may continue to be contacted for future research studies.

☐ Yes ☐ No ☐ N/A Initials: _____ Date: _____

Future Use of Data: If you agree to Options 1, 2, 3, and 4 above, your study data will be stored as described above.

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

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?

Your involvement in this study will take about 6 months.

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

- There is a risk of discomfort or increased distress in answering questions, especially questions related to trauma you have experienced, and to symptoms you have related to that trauma.
- There is also a risk of increased distress during the treatment phase of the study as you talk about traumatic events in your life. However, distress and discomfort related to questionnaire and to treatment are usually temporary and well-tolerated.
- There is a potential risk associated with the loss of confidentiality of study data.
- If you experience discomfort that you think may be related to the research, you can call the study team.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

There is a possibility that your PTSD symptoms may improve as a result of participating in this study, but this cannot be guaranteed. 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.

NARRATIVE EXPOSURE THERAPY FOR VETERANS WITH PTSD

DR. ELIZABETH VAN VOORHEES 919.286.0411 ext. 134057 OR ext. 177028

INCLUSION CRITERIA:

⇒ Veteran

⇒ Meets current criteria for PTSD

⇒ Have used physical aggression towards another person, whether in combat, a fight, or a domestic dispute.

EXCLUSION CRITERIA:

⇒ Currently incarcerated

⇒ Current, active psychosis

⇒ Concurrent trauma-focused psychotherapy, including:

- Prolonged Exposure Therapy
- Cognitive Processing Therapy
- EMDR

⇒ Imminent risk for suicide or homicide

Participants will be asked to take part in an initial screening session, 10 weekly sessions of trauma -focused therapy, an in-person follow up session, and a 3-month mailed follow up survey.

Participants can earn up to $330 for completing study procedures.

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IRB Approved
DVAMC
Date 3/13/20

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

You will be paid $70 for completing the screening visit, $10 for completing the questionnaires at each treatment visit (up to a total of $100), $80 for completing the post-treatment follow up, and $35 for completing and returning the 3-month follow up packet by mail. You may be compensated up to $45 for referring other Veterans to the research study. In total, the maximum amount you could be compensated for participation in this study is $330. Payments will be made via direct deposit or mailed check.

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?

Payment for your participation will be issued by VA Financial Services. You will be paid $70 by direct deposit or check after the initial screening visit. After the first five weekly treatment visits or phone calls you will receive a lump sum direct deposit or check that includes a $10 payment for each of the assessments you completed (up to $50). Then, after you have completed the final five weekly study treatment visits or phone calls, you will receive another lump sum direct deposit or check for each of the assessments you completed (up to $50). After the post-treatment assessment visit a direct deposit or check for $80 will be sent to you.You will receive a $35 direct deposit or check for completing and returning the 3-month follow up packet. Finally, if we receive referral coupons with your identification code, a direct deposit will be made or a check will be mailed to you. Each check or direct deposit will take about four to six weeks to arrive.

ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

Dr. Van Voorhees may take you out of the study without your consent for one or more of the following reasons:

- you fail to follow the instructions of the study staff;
- you are unable to complete the study requirements;
- the study staff cannot reach you by telephone after multiple attempts; or
- the study staff believes that you are in imminent risk of killing yourself.

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. If important discoveries are made that affect you or your condition, we will share that information with your VA doctor.

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, and portions of 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 Medical Center (DVAMC). Information collected from you during the study 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. Van Voorhees and her study staff. Access to this data 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 audio recordings that are made during the study will be stored temporarily on the audio recorder, which is kept in a locked filing cabinet in a locked office at the DVAMC. The audio recordings are transferred by a staff member to a VA secured computer server. After some time, they will be moved to password protected, encrypted DVDs and stored in a locked filing cabinet in a locked office at the DVAMC.

Your research records 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.

As part of this study, coded data (that is, data that identifies you with only a study identification number) collected from you may be moved to a secured server at Duke University Medical Center. This information will be encrypted while being moved and while stored and will only be available to Dr. Van Voorhees and/or her study staff. Data will be moved for the purposes of data analysis.

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.

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

If during the study any information reveals suicidal intent or other major, previously unknown, 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.

Participant Name:	**Date:**
Study Title: Narrative Exposure Therapy for Justice-involved Veterans	
Principal Investigator: Elizabeth Van Voorhees	**VAMC:** Durham

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. Van Voorhees at 919-286-0411, extension 176435 during regular business hours, and at (919) 213-1544 at night, on weekends, or on holidays. 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.

AFFIRMATION FROM PARTICIPANT

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**