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DEPARTMENT OF VETERANS AFFAIRS
VISN 17 Center of Excellence for Research on Returning War Veterans
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Consulting after Combat: Interviewing Service Members and Veterans to Develop a Therapy to Restore Functioning and Reintegration after Moral Injury Events

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NCT ID: NCT05020587

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Department of Veterans Affairs	RESEARCH CONSENT FORM		
SUBJECT NAME		DATE (MM/DD/YYYY)	
TITLE OF STUDY	*Consulting after Combat: Interviewing Service Members and Veterans to Develop a Therapy to Restore Functioning and Reintegration after Moral Injury Events*		
PRINCIPAL INVESTIGATOR	Sheila Frankfurt, PhD (254) 400-6742	VAMC	**CTVHCS**

DESCRIPTION OF RESEARCH BY INVESTIGATOR **1.** Purpose of study and how long it will last: **2.** Description of study including procedures to be used: **3.** Description of procedures that may result in discomfort or inconvenience: **4.** Expected risks of study: **5.** Expected benefits of study: **6.** Other treatment available: **7.** Use of research results: **8.** Special circumstances:

The study you are being asked to volunteer to take part in involves research. This research study takes place at the Central Texas Veterans Health Care System (CTVHCS) and is funded by the VA Office of Rehabilitation Research and Development. It is important that you read and understand the information on this form.

PURPOSE

The purpose of this research is to develop a group talk therapy treatment manual that will target functioning and quality of life among Veterans who are impacted by high magnitude potentially morally injurious events. Potentially morally injurious events are military traumas that are distressing because they involve violations of a sense of right and wrong, or a sense of betrayal. This project employs user-centered design methods that continuous gathers Veterans' experiences during treatment development, with the goal of increased usability and effectiveness. You are being asked to participate in an open pilot test of the group therapy manual. Your feedback about your experiences in this therapy will be used to revise the therapy manual.

This research study is a local research project which will involve approximately 50 Veterans, total. This study has three stages: (1) interviewing 20 Veterans who are potential users of this group talk therapy; (2) interviewing former users of the PI's informal moral injury-focused group talk therapy (approximately 18 Veterans); and (3) piloting the group talk therapy manual twice, with approximately 12 Veterans.

1. **You are being asked to participate in Stage (3) of this research project.**
2. **This study will last approximately 1 year.**
3. **You will complete a battery of assessments prior to the therapy beginning, throughout the course of the therapy, after the therapy is over, and approximately 6 months after the therapy group is finished. You will be compensated for completing assessments, even if you do not complete the therapy.**
4. **You will participate in an approximately 24-session group talk therapy that involves talking about and processing your potentially morally injurious combat trauma experiences with other Veterans. You will be in a group with approximately 6-8 other Veterans.**

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PROCEDURES

1. **If you consent to participate in this research study, you will complete a series of eligibility screening measures. If eligible, you will participate in an approximately 24 session group talk therapy, conducted by the study PI and a VA clinician associated with this study.**
2. Potential participants are male and female, English-speaking Veterans, 18 years of age or older, enrolled in CTVHCS, and with a service of combat deployments.
3. To determine your eligibility, you will complete measures asking about moral injury events and related impairments and how you are functioning in a variety of domains. We will also ask you about your thinking, current substance use, and a routine clinical assessment of suicide. The eligibility screening interview should take approximately 30-45 minutes.
4. To participate in the study, Veterans must (1) report a history of potentially morally injurious events, (2) report functional impairment associated with the impact of the potentially morally injurious event, (3) agree to participate in a trauma processing group therapy and complete study measures.
5. Veterans will be excluded who report (1) current substance abuse or dependence (other than caffeine or tobacco dependence); (2) severe suicidal or homicidal ideation that requires immediate intervention; or (3) evidence of cognitive impairment severe enough to influence ability to participate in the study.
6. **This study does involve participating in a novel, experimental group talk therapy focusing on improving functioning and quality of life following potentially morally injurious combat traumas.**
7. This study involves approximately 24-sessions of a 90-minute group therapy, which will be led by Dr. Frankfurt and a VA clinician associated with this study. This study does not involve invasive medical techniques or restriction of normal activities. We will follow-up with you approximately one month, three months, and six months post-therapy to check in and offer any referrals, as needed or requested.
8. This study also involves completing a packet of psychological assessments prior to therapy beginning, brief measures following each therapy session as part of clinical care, and a battery of measures following the end of therapy and approximately 6 months after therapy is over.
9. Results from the suicide assessment tool – the Columbia Suicide Severity Rating Scale – will be charted in your medical record, along with any routine suicide prevention-related follow-up assessments.
10. This study does not involve medical care.
11. The total duration of the study commitment, including completing screening assessments, is approximately 12 months. You will complete an assessment battery prior to the study, after the therapy is over, and 6-months after the therapy is done; the assessment takes approximately 1.5 hours. The group therapy sessions will be 90-minutes each.

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1. You will be compensated $30 for completing each assessment battery (e.g., baseline, post-treatment, and 6-months posttreatment). Thus, you can earn up to $90 for participating in this study.
2. **If you report severe suicidal or homicidal ideation or significant distress on the Columbia Suicide Severity Rating Scale, or during the therapy or assessment sessions, or the study team member believes it is not in your best interest to stay in the study, your participation in the therapy (and this study) will be terminated. You will be provided immediate care either at your local VA medical center, local emergency, or through the Veterans Crisis Hotline.**
3. **You may withdraw from this study at any time. To withdraw during the therapy, you may tell the PI, the co-therapist, or the study coordinator at any time that you would like to stop. If you would like to withdraw from the study after completing your interview, please contact the study coordinator or PI. Any information collected prior to your withdrawal will not be destroyed.**

DISCOMFORTS AND RISKS

4. During the therapy, some increased discomfort may be expected as you will be encouraged to talk about previous upsetting experiences, your reactions to and beliefs about it, and to hear about and talk about other Veterans' previous upsetting experiences. Typically, increased discomfort occurs during the beginning of the treatment and may decrease after a few sessions or shortly thereafter. If you have trouble dealing with any increased distress or symptoms, start to experience any thoughts of hurting yourself or someone else, or if you feel you may cope in unhelpful ways, please contact the study team member and/or PI immediately.
5. You may not experience therapeutic relief from completing study activities.
6. Your confidentiality will be protected to the extent permitted by law. Data from this study will be covered by a Certificate of Confidentiality, which further protects the privacy of your data. However, there is always a risk of breach of confidentiality that may have psychological, social, or economic consequences. If you are a risk to yourself or someone else, study staff will take steps to protect you, which will include disclosing your intentions to another healthcare professional or to another person who could help keep you safe.
7. Results from the suicide assessment tool – the Columbia Suicide Severity Rating Scale – will be charted in your medical record, along with any routine suicide prevention-related follow-up assessments.
8. For participants who chose to use Azure RMS encrypted email to securely receive and send sensitive documents: you should know that there are inherent limitations in ensuring file encryption with certain file types once the email is opened and the content is saved to your device (e.g., computer, smartphone, etc). All documents will be encrypted during sending and receiving messages. However, after the file is opened and downloaded onto your personal device, we will no longer have access to that document and cannot guarantee that it will remain encrypted.

9. In addition to the risks described above, you may experience a previously unknown risk or side effect. These risks cannot be predicted.
10. This study is not expected to have any risks to physical health because this study involves group talk therapy and not medical procedures.

BENEFITS

1. Your participation in this study may help develop a new group talk therapy treatment to help Veterans recover their quality of life and functioning following distressing, morally injurious combat traumas.
2. **You may not personally be helped by taking part in this study, but your participation may lead to knowledge that will help others.**

OTHER TREATMENT AVAILABLE

1. If you do not want to take part in this study, there are other choices for treatment available. This may include PTSD treatments at your local VA such as Prolonged Exposure (PE) or Cognitive Processing Therapy (CPT) and will be under the supervision and recommendation of your doctor and other care providers. At this time, there are no currently validated treatments for the impact of moral injury events, or moral injury.

RESEARCH RESULTS

1. **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.**
2. Only approved study team members and appropriate Research Office staff at CTVHCS (e.g., the Research Compliance Officer) will have access to your study data. Your private information (such as name, birthday, address, or specific/unique details about your experience that someone else could identify) will be maintained according to this medical center's requirements. Participant confidentiality will be upheld through the assignment of patient identification numbers that will be used for all research records. All paper data will be kept in locked cabinets in a keycard-access-only room on the VA campus. All electronic data will be kept on secure servers behind the VA firewall that only study personnel will have access to. We have a predetermined Data Safety Monitoring Board (Drs. J. Irene Harris, Wyatt Evans, and Jonathan Yahalom; of the VA) who will be tasked with independently ensuring the safety of study participants and scientific goals. While the documents they will review will usually not include any of your personal information, there may be instances in which the DSMB may need to receive sensitive data as part of responding to a patient safety event.

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3. **Any and all paper AND electronic documentation containing confidential, personally identifiable information, protected health information, and any other sensitive information will be disposed/destroyed according to current VA regulations at the time of disposal/destruction of documentation. Research files will be maintained, stored and destroyed in accordance with the Record Control Schedule (RCS-10-1) approved by the Archivist of the United States.**
4. **If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. Your private information will be maintained according to this medical center's requirements**. **There is a possibility that the Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), VA Office of Inspector General (OIG), Veterans Health Administration (VHA), other oversight agencies including the Office of Research Oversight (ORO), the Research Compliance Officer, Institutional Review Board members or other research staff may have access to your research and/or medical records or may inspect the records.** Every effort will be made to keep information about you both private and confidential. Codes (not your name and social security number) will be used for all reports generated, to help maintain your confidentiality.

SPECIAL INFORMATION

1. **You are not required to take part in this study: your participation is entirely voluntary**. **You can refuse to participate now or you can withdraw from this study at any time after giving your consent. Refusal to participate now or discontinuation of participation at any time will involve no penalty or loss of benefits to which you are otherwise entitled.**
2. **Veteran participants and non-Veteran participants do not pay for treatment associated with participation in a VA research project except in accordance with federal law. There will be no costs to you for any of the treatment or 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.**
3. **VA must provide necessary medical treatment to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, the necessary care must be provided in VA Medical facilities. Exceptions include: situations where VA facilities are not capable of furnishing the care or services required; and situations involving a non-veteran research subject. Under these circumstances, Directors *may* contract for such care. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures.** All regulations pertaining to the participation of veterans as participants, including requirements for indemnification in case of research-related injury, pertain to non-veteran

participants enrolled in VA-approved research. (For additional information on research related injuries, see 38 CFR 17.85). Please note that for Department of Defense-sponsored research, Department of Defense components may have stricter requirements than the Common Rule requirements for research-related injury.

6. **In case there are medical problems, research related injuries, or questions, you may call Dr. Sheila Frankfurt at 254-400-6742 during the day and the Central Texas Veterans Healthcare System at 254-778-4811 after hours. If any medical problems occur in connection with this study, the VA will provide emergency care.**
7. **Payment: You will be paid $30 for participating in each assessment (pre-treatment, post-treatment, and at a 6-month follow-up post-treatment). Additionally, you will be reimbursed for your milage to and from each therapy session you attend at the standard VA reimbursement rate. The current reimbursement rate is 41.5 cents per mile and is calculated using Bing maps to determine the shortest routes available from your home to the nearest VA. Thus, total payment can reach $90 for participating in this study and additional reimbursements based on their travel distance.** Authorized study staff will need to securely submit some of your information (name, social security number) to Agent Cashier's Office for you to be paid for your volunteered time. In addition, the U.S. Department of Treasury, under 31 CFR Part 208, now requires Federal payments to be made electronically. You may receive a Form 1099 from the IRS as a result.
8. **Termination of Subject's Participation:** You may be removed from the study if you are not able to follow the directions, we find that your participation in the study is more of a risk than a benefit to you, or the agency paying for the study chooses to stop the study early.
9. **Consequences of Withdrawal from the Study:** Withdrawal from this study at any time will not negatively affect any future treatment sought at the Central Texas Veterans Healthcare System or any other VA facilities. You may stop the interview at any time. Please let the PI, the study co-therapist, or another study team member know if you want to withdraw.
10. **Future Use of Data:** Your research records and the information within them will not be used for any purpose other than that described in this study as approved by the IRB. Your information, even if identifiers are removed, will not be used or distributed for future research studies.
11. **Re-contact:** Your contact information will not be retained specifically for the purposes of recruitment for participation in future studies. You may appear on a screening list for a future VA study using new and possibly different criteria, in which case you may be contacted by a different VA study team.
12. **Disclosure of Results:** You will not receive a report of the results from this study or any individual results from your participation. The questionnaires and assessments are completed for research purposes and are not meant to provide clinical information.
13. **As a research participant in this study, if you have a complaint about any issue regarding the study, or the research investigator; or, if you have questions about your rights as a research participant, you may contact** the Institutional Review Board Chairperson at (254) 654-6758.

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CONFLICTS OF INTEREST

1. **The study is sponsored by the VA Office of Rehabilitation Research and Development.**
2. **The sponsor provides a fixed payment to the VA Hospital for performing the study**.

AFFIRMATION FROM SUBJECT

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above. Dr. Sheila Frankfurt ([254] 400-6742) or an authorized study team member has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

I understand my rights as a research participant. I understand what the study is about and how and why it is being done. I voluntarily consent to participate in this study. I know I will receive a signed copy of this consent form.

_____ _____

Research Participant's Signature Date

_____ _____

Signature of Person Obtaining Consent Date

Date Last Revised: *Version 7, 10/12/23*

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