Empowering Veterans to Self-Manage PTSD Symptoms Following Completion of Trauma Focused Therapy [EMPOWER]

NCT05797441

CIRB Approved on November 17, 2022

Participant Name: _____ Date:_____

Title of Study: Empowering Veterans to Self-Manage PTSD Symptoms Following Completion of Trauma Focused Therapy [EMPOWER]

Principal Investigator: [LSI name] VA Facility: [LSI site name]

Principal Investigator for Multisite Study: [PI name]

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the VA Health Services Research & Development. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn how best to meet Veterans' treatment needs after they complete trauma-focused therapy for PTSD (Prolonged Exposure or Cognitive Processing Therapy). We will compare the impact of approaches to of treatment on veterans' PTSD symptoms and use of mental health services. The first treatment version involves the therapist's usual treatment recommendations or referrals following a veteran's completion of trauma-focused therapy. The second version involves the patient learning to self-manage their PTSD symptoms (with their therapist's support), practicing their trauma-focused therapy skills, and engaging in meaningful areas of their lives. Your participation in this research will last about 9 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

- You may find the treatment helpful in transitioning out of trauma-focused therapy and maintaining or building on treatment gains.
- Your participation may help improve PTSD outcomes during post-trauma focused therapy and access to PTSD treatment for other veterans with PTSD.

For a complete description of benefits, refer to the Detailed Information section of this consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

- You may be randomized to a more or less effective or preferred treatment option.
- It is possible that some of the topics discussed during therapy may cause some short-term emotional distress.
- You may be uncomfortable answering some of the questions asked during the research surveys or interview.

- If you have insurance copayments for your VA care, you may be responsible for copayment costs.

For a complete description of risks, refer to the Detailed Information section of this consent and/or Appendix.

For a complete description of alternate treatment/procedures, refer to the Detailed Information section of this consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is [PI name] at the Minneapolis VA Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study you can contact: [PI name] at [phone number] (Minneapolis VA) or [LSI name] at [phone number] (LSI site name).

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project, we hope to learn how best to meet Veterans' therapy needs following complete of trauma-focused therapy for PTSD. More evidence is needed to guide mental health providers in the best way to deliver ongoing treatment following their patients' completion of prolonged exposure (PE) or cognitive processing therapy (CPT). This study will compare how two treatments prepare and enable successful PE and CPT completers to step-down from involvement in mental health services. This will involve examination of how each treatment impacts veterans' PTSD symptoms and use of mental health services. The first treatment version involves the therapist's usual treatment recommendations or referrals following a veteran's completion of trauma-focused therapy. The second version involves the patient learning to self-manage their PTSD symptoms (with their therapist's support), practicing their trauma-focused therapy skills, and engaging in meaningful areas of their lives.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 2.75 years. Your individual participation in the project will take about 30 months.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you agree to participate, the following procedures will take place:

- You will either receive the EMPOWER self-management program or treatment as usual for 12 weeks following the completion of your current course of prolonged exposure (PE) or cognitive processing therapy (CPT).
- You will learn which treatment you will receive at your last PE or CPT session. Your current therapist has been assigned by chance (like the flip of a coin) to either deliver the EMPOWER program or to provide post therapy treatment as usual.
- A note will be placed in your VA medical record documenting your participation in this study.
- If you receive EMPOWER:
    - You will work (self-directed) through a patient workbook which includes reading materials and brief worksheet exercises
    - You will meet or speak with your therapist four times
    - The sessions with your EMPOWER therapist will be audio recorded for study purposes.
        - Audio-recordings of your treatment sessions will be listened to by experts in the assessment and treatment of PTSD who are part of the study team. They will listen to ensure the quality of that assessment or treatment. We don't expect there will be identifiable information (e.g., your or your doctors' name) in the recording, but we cannot rule out that possibility.
- If you receive treatment as usual, your therapist will work with you to determine the best next steps following your completion of PE or CPT. This may include continued treatment with your current therapist, a referral to another provider, or discharge from therapy.
- Regardless of which group you are in, you will complete four questionnaires over a 1-year period. The surveys will be completed online or by mail if you prefer. This includes:
    - A survey just before you complete PE or CPT
    - A survey 3-months after you complete PE or CPT
    - A survey 6-months after you complete PE or CPT
    - A survey 9-months after you complete PE or CPT
- Each questionnaire takes about 30 minutes to complete. You will be asked about your PTSD symptoms, non-VA mental health service usage, care satisfaction, and overall functioning and well-being. You may skip any question(s) you feel uncomfortable answering or discontinue the study at any time. You may skip any question[s] you feel uncomfortable answering or discontinue the study at any time.
- Some veterans will be assigned by chance to complete one phone interview which will be recorded. The recording will be transcribed by VA affiliated transcriptionists for study

purposes. We don't expect there will be identifiable information (e.g., your or your doctors' name) in the recording, but we cannot rule out that possibility.

  - The call interview will take about 45-60 minutes and will ask about your reactions to and recommendations to improve your post PE or CPT care.

- You will also receive other phone calls, e-mail, mailings, and/or text messages to remind you to complete your research surveys and interview.
- The study principal investigators and an independent board of experts in the treatment of PTSD use will monitor the study. The independent board will meet at least every six months. You will be immediately notified by mail of any safety concerns or new risks that are discovered.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Participate in all scheduled therapy sessions and activities
- Complete all study questionnaires as described above
- Complete the study telephone interviews (if you are selected) as described above
- Ask questions as you think of them
- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any treatment has possible risks and discomforts. The treatments in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

- As result of the treatment randomization of your therapist, you may be randomized to a more or less effective or preferred treatment option.
- There is the possibility that you may be uncomfortable answering some of the questions that are asked in the surveys or during the interview. They may ask about sensitive issues. You are fee to skip any questions you do not want to answer, or you may withdraw from the study at any time by calling [PI name] at [phone number] or [LSI name] at [phone number].

- It is possible that some of the topics discussed during therapy may cause some short-term emotional distress. Your therapist will help you manage those feelings.
- There is a risk of loss of privacy or confidentiality. We make every effort to make sure that your information is kept private. All of your study information (e.g., your surveys, interview, audio-recordings) are only labelled with a study ID number, never your name. Only a few study staff members will know the link between your study ID and your name. However, we may have to break your confidentiality in order to prevent you from hurting yourself or others.

If you have insurance copayments for your VA care, you may be responsible for copayment costs.
There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include:

- You may find the treatment helpful in transitioning out of trauma-focused therapy and maintaining or building on treatment gains.
- Your participation may help improve PTSD outcomes following trauma-focused therapy and access to PTSD treatment for other veterans with PTSD.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

If you chose not to participate, you will be able to receive post-trauma-focused therapy treatment as usual outside of this study through your VA. You can discuss your options for care outside of the study with your health care provider.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

We make every effort to make sure that your information is kept confidential. All of your study information (e.g., your surveys, interviews, audio-recordings) are only labelled with a study ID number, never your name. Only a few study staff members will know the link between your study ID and your name. Access to any identifiable information will only be granted as is needed

for staff to complete their work. All study staff members will complete regular training on safeguarding research data and maintaining confidentiality. Your information will be stored on secure VA servers behind the VA firewall or in locked filing cabinets in locked offices.

We will include information about your study participation in your medical record.

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

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Institutional Review Board, the local VA medical facility Human Research Protections Program, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you. If you are selected for the phone interview, the audio recording will be sent to a VA affiliated team for transcription. The audio recording will not contain any information that could be used to identify you. The audio recordings of your therapy sessions will not be transcribed and will not be heard by anyone outside the study team. Audio-recordings of your therapy sessions may be listened to by experts in the treatments being delivered in order to ensure their quality.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, [LSI name] and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment, or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You or your insurance will not be charged for any treatments or procedures that are part of this study. If you have insurance copayments for your VA care, you may be responsible for copayment costs.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

As a thank you for your time, you will be compensated up to $190 if you complete all survey questionnaires. The payments for each survey are as follows: baseline survey = $40, 3-month survey = $45, 6-month survey = $50, and 9-month survey = $55. You will receive an additional $50 if you are selected for and complete the phone interview.

You may receive payment via direct deposit or debit card.

*To receive payment via **debit card**:*
You consent to the release of personally identifying information about you including your name, address, and social security number to the VA so that we may provide compensation to you. If receiving payment via debit card, you consent to disclosure of personally identifying information to Direct Express program of the U.S. Department of the Treasury. You can expect to receive a check or debit card within 2-6 weeks.

*To receive payment via **direct deposit**:*
You consent to the release of personally identifying information about you including your name, address, social security number and bank information (bank name, routing number, and account number) to the VA so that we may provide compensation to you. You can expect to receive the deposit within 1-4 weeks.

The government may garnish the compensation against outstanding debts a veteran has to the federal government.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you or your insurance unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

You do not give up any of your legal rights and you do release the VA from any liability by agreeing to participate in this not study.

If you should have a mental health concern as a result of taking part in this study, call:

DURING THE DAY:

Veterans Crisis Line at 988 or 1-800-273-8255

AFTER HOURS:

Veterans Crisis Line at 988 or 1-800-273-8255

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary. Refusal to take part in this study will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue taking part at any time, for any reason, without any penalty or loss of benefits. You may withdraw from the study and still receive post-trauma-focused therapy treatment as usual that you would otherwise have received.

The study investigators may continue to review data collected prior to any withdrawal, but cannot collect further information, except from public records, such as survival data.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The investigators may terminate your participation in this study in the event of a medical or psychiatric emergency that would take precedence over your ongoing treatment. You would continue to have access to VA mental health treatment at your study site following resolution of the medical or psychiatric emergency.

We may also have to end your participation in this study for the following reasons:

1. If you become ineligible for VA care.
2. The study is suspended or canceled.
3. You choose to withdraw consent.
4. You do not complete trauma-focused therapy as planned.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

In the event of a research related injury, please immediately contact [LSI name] at [phone number]. If you have any questions, comments or concerns about the research, please contact the study coordinator at [phone number] or [PI name] at [phone number]. You can also contact your local Patient Advocate at [phone number].

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at [phone number] if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Sometimes during the course of a research study, new information becomes available about the therapy that is being studied that might change a person's decision to stay in the study. If this happens, you will be notified by mail immediately. If you are in treatment at the time that information becomes available, your study therapist will also tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, you will be referred to your PTSD treatment team to coordinate care. If you decide to continue in the study, you might be asked to sign an updated informed consent form.

FUTURE USE OF DATA

Your information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: September 6, 2024

LSI Approval Date: N/A

LSI Verification Date: N/A

Participant Name: _____ Date:_____

Title of Study: Empowering Veterans to Self-Manage PTSD Symptoms Following Completion of Trauma Focused Therapy [EMPOWER]

Principal Investigator: [LSI name] VA Facility: [LSI site name]

Principal Investigator for Multisite Study: [PI name]

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The principal investigator, study coordinator, or research assistant has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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