Personalizing Cognitive Processing Therapy with a Case Formulation Approach to Intentionally Target Impairment in Psychosocial Functioning Associated with PTSD

NCT04407767

June 6, 2024

Participant Name: _____ Date:_____

Title of Study: Personalizing Cognitive Processing Therapy with a Case Formulation Approach to Intentionally Target Impairment in Psychosocial Functioning Associated with PTSD _

Principal Investigator for Multisite Study: [redacted]

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to participate in a research study that is funded by the Rehabilitation Research and Development Service of the VA Office of Research and Development and being conducted by [redacted] at the VA Boston Healthcare System and [redacted] at the Minneapolis VA Healthcare System. 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?

We are conducting a study to improve the treatment of PTSD for Veterans. This study will help us understand whether expanding PTSD therapy (specifically Cognitive Processing Therapy) to address life challenges that tend to occur with PTSD is more helpful than traditional PTSD treatment that focuses mostly on PTSD symptoms. We also hope to understand if one treatment might be best for some Veterans, while the other treatment is more beneficial for others. We will test two versions of an established treatment for PTSD (Cognitive Processing Therapy). The first is version focuses mostly on PTSD symptoms. The second version expands the therapy to focus on additional life challenges. Your participation in this research will last about 7-10 months.

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

- You will receive a therapy known to be helpful in the treatment of PTSD. This treatment could reduce your symptoms of PTSD and help you feel better overall.
- Your participation will help improve treatment of PTSD for other Veterans with PTSD and help therapists to personalize the approach to PTSD treatment.

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?

- 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 interviews or surveys.

- There is a risk of loss of privacy or confidentiality.
- If you have insurance copayments for your VA care, you may be responsible for those costs for the PTSD therapy appointments.

For a complete description of risks, refer to the Detailed Consent and/or Appendix.

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 [redacted] at the VA Boston Healthcare System and [redacted] at the Minneapolis VA Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is:

[redacted]

[redacted]

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

We are conducting this research study to improve the treatment of PTSD for Veterans who experience life problems beyond the symptoms of PTSD. The goal of this project is to determine whether expanding PTSD treatment to target additional life challenges and difficulties improves recovery from PTSD more so than traditional PTSD therapy that focuses more specifically on symptoms alone. We will also look to see if the severity of co-occurring problems, the types of co-occurring problems, and Veterans' preference for one treatment over another may impact which treatment works best for individual Veterans. The study findings will help therapists and Veterans make more personalized decisions about how to best treat PTSD and all of the difficulties and challenges that tend to occur with the disorder.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 3.5 years. Your individual participation in the project will take about 7-10 months.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

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

- Receive either the expanded Cognitive Processing Therapy for PTSD (called case formulation+ CPT) or the traditional Cognitive Processing Therapy for PTSD.
- Participate in one-on-one therapy for PTSD (in-person or through telehealth); treatment is weekly for about 12-15 weeks (although it might be shorter or longer depending on your response and preference). Treatment sessions last 60 minutes each.
- Agree to have your PTSD therapy sessions audio-recorded for study purposes. About 15% of approximately 2500 therapy sessions from all participants in the study will be reviewed by an independent expert to be sure that therapy is delivered correctly. No identifying information will be connected with any of the recordings (for example, your name or other information will not be included in the audio recordings).
- Complete four telephone or VA Video Connect (VVC) interviews over a one-year period. This includes:
  - a baseline interview that will determine if you are eligible for the study
  - an interview in the middle of therapy
  - an interview right after you finish the PTSD therapy
  - an interview 3 months after you finish the PTSD therapy
- Each interview takes about one to two hours. You may skip any question[s] you feel uncomfortable answering or discontinue the study at any time. These interviews will be audio recorded so that the study team can be sure that the quality and accuracy of the interviews is maintained throughout the study. It is possible that if too much time passes between your baseline interview and your first therapy session, you will be asked to complete a shortened version of the interview (about 30-45) minutes before starting therapy.
- If you are found not to be eligible for the study following the baseline interview, you will not complete any further study activities.

- Complete four survey questionnaires over a one-year period. Surveys can be completed online through a secure link sent to you by email. Or, paper and pencil surveys can be completed and returned to study staff by mail. These surveys include:
  - a baseline survey before you start treatment
  - a survey midway through treatment
  - a survey after you finish the PTSD therapy
  - a survey 3 months after you finish the PTSD therapy
- Each survey takes about 60 minutes to complete. You may skip any question[s] you feel uncomfortable answering or discontinue the study at any time.
- Agree to have your therapy materials collected for study purposes.
- You may receive some therapy materials by mail.
- You will receive phone calls, e-mail, mailings, and/or text messages to remind you to complete your research interviews and surveys.
- You will receive postcards and other mailings to thank you for your study participation between your scheduled assessments.

Description of the therapy you will receive: Cognitive Processing Therapy is a brief therapy (usually about 12 sessions) specifically designed to treat PTSD. The primary goal of CPT is to understand the way that the experience of the trauma has impacted the trauma survivor's life including the impact on thoughts, beliefs, feelings, and behaviors. The therapy occurs in phases including education about PTSD and the goals of therapy, information gathering about the different ways that beliefs about the trauma may be keeping people stuck in PTSD, and learning skills and strategies to begin the process of change and recovery from PTSD. Therapists guide this process in session and provide many tools and aids for the patient to continue this work outside of session.

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

- Participate in all scheduled therapy sessions
- Complete all telephone or VA Video Connect (VVC) interviews as described above
- Complete all study questionnaires 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. 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.

- There is the possibility that you may be uncomfortable answering some of the questions asked. 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 [redacted]. 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, 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. This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This gives you an extra layer of protection. It means that we cannot release or use information that may identify you in any legal action or suit unless you say it is okay. We also cannot provide them as evidence unless you have agreed. In other words, we are protected from releasing information about illegal or sensitive issues you may share with us as part of the study. 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 those costs for the PTSD therapy appointments.

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?

You will receive a therapy known to be helpful in the treatment of PTSD. This treatment could reduce your symptoms of PTSD and help you feel better overall. It is possible you may not benefit from the treatment. Your participation will help improve treatment of PTSD for other Veterans with PTSD. Their therapists may also be able to provide more individualize advice about what kind of PTSD treatment would be most helpful.

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 treatment for PTSD outside of this study through your VA. You may be able to receive the same treatments delivered as part of this study, but they may not be available. You can discuss your options for care outside of the study with your health care provider. Options for care might include a different established treatment for PTSD such as Prolonged Exposure, medications, or non-trauma-focused therapy.

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.

After all identifiers are removed from your data, your deidentified data will be placed in a data repository located at VA Boston Healthcare System for other approved researchers to be used for their own study. There will be no way that the data made public would be able to be linked

back to you in any way. The audio recordings collected as part of the study will not be shared as part of this process, only your interview and survey responses.

We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.

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

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, social security number, 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. Audio-recordings of your therapy sessions may be listened to by experts in the treatments being delivered in order to ensure their quality. At the end of the study, your deidentified data will be placed in a local data repository for other approved researchers to be used for their own study; there will be no way that the data made public would be able to be linked back to you in any way.

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, [redacted] and their 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 will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

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

You will be compensated $400 in total if you complete all survey questionnaires and clinical interviews. You will receive a portion of this total payment each time you complete a questionnaire or interview. The payments for each activity are as follows; Baseline interview = $50, baseline survey = $25, mid-treatment interview=$50, mid-treatment survey = $25, post-treatment interview = $100, post-treatment survey = $25, 3-month follow-up interview = $100, 3-month follow-up survey = $25.

You may receive payment in via check, debit card, or direct deposit.

*To receive payment via **check or 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.

You can expect to receive a check or debit card within 2-6 weeks. The government may garnish the compensation against outstanding debts a veteran has to the federal government.

*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.

If payment is made to you by the VA (whether by check, direct deposit, or a VA issued debit card), an IRS Form 1099 will be generated regardless of the amount you are paid.

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 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 not release the VA from any liability by agreeing to participate in this study.

In the event of a research related injury, please immediately contact [redacted]. If you have any questions, comments or concerns about the research, please contact [redacted]

DURING THE DAY:

Dr./Mr./Ms. _____ at _____ and

AFTER HOURS:

Dr. /Mr./Ms._____ at _____.

DO I HAVE TO TAKE PART IN THE STUDY?

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 05/01/24

LSI Approval Date: N/A

LSI Verification Date: 06/06/24

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 PTSD treatment 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 the ongoing treatment of PTSD. You would continue to have access to VA mental health treatment at your study site, including non-study treatment for PTSD 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 don't attend PTSD therapy for more than six weeks, we will assume you have decided to discontinue treatment. You will still be invited to participate in the other research activities.
2. The study is suspended or canceled.
3. You choose to withdraw consent.

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

In the event of a research related injury, please immediately contact [redacted] You can also contact your local Patient Advocate at your facility.

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 [redacted] 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?

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 05/01/24

LSI Approval Date: N/A

LSI Verification Date: 06/06/24

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 PTSD 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 continue in the study, you might be asked to sign an updated informed consent form.

FUTURE USE OF DATA

A dataset including your fully de-identified interview and survey responses will be kept in a local (VA Boston Healthcare System) data repository. Researchers interested in accessing the data must submit a data request form. All requests will be evaluated by the VA BOSTON Institutional Review Board committee who will evaluate the scientific merit of the request and the qualifications of those requesting the data. The stored data will not include any information that could identify your or link you to study participation. No audio-recordings obtained during the course of the study will be included in the repository.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The study staff 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. A copy of this signed consent will also be put in your medical record.

I agree to participate in this research study as has been explained in this document. This includes consent to be audio-recorded as described above.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 05/01/24

LSI Approval Date: N/A

LSI Verification Date: 06/06/24