Title of Study: Cognition and Psychotherapy in PTSD: Mechanisms and Functional Outcomes

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Name of Study Sponsor: VA Rehabilitation Research & Development

WHY AM I BEING ASKED TO VOLUNTEER?

You are being asked to voluntarily participate in a research study because you are a veteran who has posttraumatic stress disorder (PTSD) and are interested in getting a type of psychotherapy for PTSD called "Cognitive Processing Therapy" as part of your regular care. Your participation is voluntary, which means you can choose whether or not you want to take part. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The study doctor and/or a member of the research team will talk to you about the research study, and they will give you this consent form to read. You are encouraged to discuss this study and consent form with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form.

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this research study is to examine how certain factors affect treatment response and functional outcomes during and after Cognitive Processing Therapy for PTSD.

HOW LONG WILL I BE IN THE STUDY? HOW MANY PEOPLE WILL BE IN THE STUDY?

You will be involved with this study for up to six months. You will have a standard course of talk therapy (typically 12 visits) as part of your clinical care and six research visits as part of this study. We plan to enroll 140 Veterans from CMCVAMC.

WHAT AM I BEING ASKED TO DO?

If you decide to participate in this study, you will be getting a standard course of a type of talk therapy called Cognitive Processing Therapy for PTSD as part of your clinical care, a treatment that lasts for approximately 12 sessions (weeks). These sessions will be audio-recorded to supervise the therapists. **If you are uncomfortable with audio-recorded sessions, you should not participate in this study.**

Before starting this therapy, you will be asked to have an initial research visit, where we will ask you to take part in the following activities:

1) Interview and Self-Report Measures: You will be asked to answer some questions regarding your medical, mental health, and substance use histories, as well as those of your family. In addition, you will be asked to fill out rating forms regarding your mood and personality characteristics. You do not have to answer any questions that make you feel uncomfortable. These measures are experimental procedures that are not part of your routine clinical care. This will take approximately 2 hours.

2) Cognitive Testing: You will be asked to take a brief series of tests that assess your thinking abilities, including memory, attention, reasoning, and reaction time. These tests are research procedures that are not part of your routine clinical care, and therefore these tests will not be shared with you. These tests will take approximately 2 hours.

After this initial research visit, the study team may determine that you are not eligible for the study. If you are not eligible for the study, you can still receive Cognitive Processing Therapy as part of your usual clinical care. You will also receive compensation for participation in this visit.

If you are eligible for the study, we will also ask you to fill out brief questionnaires on four (4) separate weeks in which you have a therapy session throughout the course of treatment. The questionnaires will be given by research staff after therapy and will take between 10 and 30 minutes to complete.

At the end of the 12 weeks of therapy, you will be asked to have a separate visit with our study team in which you will complete some of the questionnaires and interviews that you completed at the initial study visit. This visit will take approximately 2 hours.

If you are unable to participate in a face-to-face visit for reasons such as the COVID-19 pandemic preventing or otherwise limiting in-person visits, study related procedures will be completed via telephone or virtual visits.

If at any time during the research visits you become upset or indicate suicidal ideas, we will ask you additional questions to evaluate your mood and mental state. In addition, some of the questionnaires you will fill out ask you about information concerning suicidal intent, depression, or other major clinical findings. If you indicate that you are experiencing suicidal or homicidal thoughts, a licensed psychologist or psychiatrist will perform a formal risk assessment. If the risk assessment indicates there is significant risk for you to harm yourself or someone else, you may be recommended for further evaluation and treatment planning. This may involve connecting

you directly to the Veterans Crisis Line. Your primary care physician (PCP) or referring provider will also be informed.

During the course of your participation in this study, we will collect data from your medical record.

You will be compensated for your participation in this study. You will receive $75 for the initial visit (if the initial visit is split into two separate visits, you will receive $30.00 for day one and $45.00 for day two), $25 for the mid-treatment research visit, $10 for each of three brief assessments during treatment, $100 for the final visit, and a $20 payment for completing all study procedures, for a total of up to $250. Payment will be provided in the form of a check, which will be mailed to your house.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?

Some people report anxiety, boredom, emotional stress, or fatigue from the research interviews. Please let research staff, the PI (Dr. Scott), or your therapist know if any procedures are causing you emotional stress. We will give you breaks as often as needed and discuss any difficulties with procedures, and you may decline to answer questions that make you uncomfortable. We will also do our best to schedule your appointments so that they are most convenient for you.

There are not any foreseeable major physical, social, economic, mental, or emotional risks of participation in this study.

Participation in research may involve a loss of privacy. Your research records will be kept as confidential as possible. If there is a breach of confidentiality with your data, you will be informed immediately and given information about what the CMCVAMC is doing to ensure continued data confidentiality. Your data will be kept secure throughout and after the study, so risks of a data breach are minimal.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?

You will not benefit from participating in this research study. However, your participation may benefit other veterans or individuals by virtue of contributing to scientific knowledge.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT PARTICIPATE?

You have the choice not to participate in this research study. Participation is voluntary and you do not have to participate if you do not want to. You can still receive the Cognitive Processing Therapy and not be part of this study.

FUTURE USE OF DATA AND RE-CONTACT.

Information that could identify you will be removed from this stored data so that the information

can be used for future research studies or distributed to another investigator for future research without additional informed consent.

While this study is open, we may wish to contact you in the future about participating in other research studies that Dr. Scott or his Co-Investigators are conducting.

☐ I **AGREE** to be contacted for future research studies.

☐ I do **NOT** agree to be contacted for future research studies.

WILL I HAVE TO PAY FOR ANYTHING IF I PARTICIPATE IN THIS STUDY?

You will not have to pay for any research procedures or tests that result from participating in this study.

WHO CAN SEE OR USE MY INFORMATION? HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

Information that will be used: During the course of this study, we will collect personal information such as your telephone number, email address, mailing address, social security/medical record number, birth date, dates of visits, information about medications you are taking, medical history, mental health history, and information about alcohol and drug use.

Your name and social security/medical record number will be used only as necessary within the CMCVAMC. But other private information may be disclosed to the study sponsor, VA Rehabilitation Research & Development, including summaries of participant age, gender, race, and mental health symptoms.

If you have an accident or reaction during the course of the study, your entire medical record may be used and disclosed as clinically necessary.

Internal monitors from the CMCVAMC Institutional Review Board (IRB), a research oversight committee, may inspect study records for quality assurance.

The results of this study may be published; however, you will not be identified by name or other personal identifiers. Further, your medical records will not be revealed unless required or authorized by law.

All research information collected for this study will be secured in locked files in a locked office at the CMCVAMC or on secure VA servers . The computerized neuropsychological battery will be briefly stored on a secure server at the University of Pennsylvania before transfer to the CMCVAMC. No identifiable information will be stored at the University of Pennsylvania. Only authorized research staff will have access to the information gathered in this study.

If you are a Veteran **not** registered at the CMCVAMC and you would like to participate in this study, you will need to register for clinical care at the CMCVAMC. Notes from your visits, procedures, and laboratory tests will be included in a medical record. In addition to the research team, VA clinical or benefit staff and other researchers may be granted approval to access this information in the future. Federal laws and regulations that protect privacy of medical records will apply to your VA record.

All research records, including the investigator's research records, must be retained according to the National Archives and Records Administration VHA's Records Control Schedule.

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.

SPECIAL CIRCUMSTANCES

Significant new findings developed during the course of the research, which may relate to your willingness to continue participation, will be provided to you.

WHAT SHOULD I DO IF I HAVE BEEN INJURED OR EXPERIENCE A MEDICAL PROBLEM?

It is important that you tell the study doctor, Dr. J. Cobb Scott, if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call him at 215-823-5800, extension 7138. If you should experience any other injury or medical problem, you should inform Dr. Scott or the study personnel immediately, and you are encouraged to inform your VA or non-VA Primary Care Physician.

WHEN IS THE STUDY OVER? CAN I LEAVE THE STUDY BEFORE IT ENDS?

You understand that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. If you withdraw, you may be asked to return for a final study visit. Even if you withdraw, we can continue to use information about you that has been collected up to that point.

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time without your consent because:

- ✓ The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- ✓ You have not followed study instructions such as missing therapy visits or responding to the measures in a way that is not valid.
- ✓ The Sponsor or the Principal Investigator has decided to stop the study.

If you choose to withdraw from the research, please inform someone from our research staff. You will still be able to continue treatment as recommended by your therapist.

WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?

You have read or have had read to you all of the above. Dr. J. Cobb Scott or a member of his research team has explained the study to you and answered all of your questions. 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.

In case there are medical problems, research related injuries or questions, you should call Dr. J. Cobb Scott at 215-823-5800, extension 7138, during the day or after hours call the CMCVAMC operator at 215-823-5800 and ask for the psychiatrist on call.

If you would like to discuss problems, complaints, concerns, or questions with someone who is not directly associated with your participation in this study or you have any questions regarding your rights as a research subject or you want to check the validity of the study and its personnel within the VA, you should contact the Research Compliance Officer at 215-823-7847 or the Patient Representative at 215-823-5803 from 8:00 AM to 4:30 PM Monday through Friday.

If you have concerns or complaints about the research study, you should contact the research staff involved with this study at (215) 823-5800, extension 7138.

As a Veteran, we value your input into how research is conducted at the CMCVAMC. If you would like to offer suggestions and opinions, or if you would like to participate in future discussions of research in Philadelphia, please call the Research and Development (R&D) Administrative Officer at (215) 823-6020 or R&D Associate Chief of Staff at (215) 823-5893. Every reasonable safety measure will be used to protect your well-being. The CMCVAMC will provide necessary medical care and treatment for any injury that is a result of participation in this study for Veterans. Compensation for such an injury may be permitted by applicable federal laws and/or regulations. The VA is not required to provide treatment for injuries in research studies if the injuries are caused by your non-compliance with study procedures.

There will be no cost to you for participation in this study. However, some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study. If you decide to participate in this study, you cannot be charged, nor your insurance billed for research-related interventions or procedures that are required by the protocol.

You voluntarily consent to participate in this study. You confirm that you have read this consent document, or it has been read to you and that it explains what this research project is about and

how and why it is being done. You will receive a copy of this document via email, secure messenger or United States Postal Service Priority mail with tracking.