Adapting Treatment Delivery to Improve Retention in Evidence-Based PTSD Treatment (CDA 21-191)

NCT06335589

July 23, 2024

Participant Name:	**Date:**
Study Title: Adapting Treatment Delivery to Improve Retention in Evidence-Based PTSD Treatment	
Principal Investigator: Stephanie Wells, PhD	**VAHCS**: Durham VAMC

Please read this form carefully. You are being asked to participate in this research study because you may have symptoms of posttraumatic stress disorder (VA) and may benefit from treatment. This study is voluntary and will include only people who choose to take part. Ask your study doctor or study staff to discuss this consent with you, please ask him/her to explain any words or information that you do not understand. It is important that you understand the information on this form.

The purpose of this study is to evaluate the feasibility (e.g., how easy and manageable it is) and acceptability (e.g., how well liked it is) of delivering two effective PTSD treatments (cognitive processing therapy [CPT] and prolonged exposure therapy [PE]) more frequently (e.g., at least three times per week), also known as "massed treatment". This will be compared to how they are usually offered in VA PTSD outpatient clinics (e.g., typically once per week).

Your participation in this study will involve engaging in PTSD treatment (e.g., CPT or PE) delivered in either a massed format (i.e., at least three times a week or more) or delivered once per week. You will be randomly assigned (using a process like flipping a coin) to one of these two groups (i.e., massed delivery or treatment as usual). You will be asked to complete 12 sessions of CPT or PE, although you may finish early or do additional sessions if it is determined to be appropriate by your therapist. You will also be asked to complete an assessment to determine eligibility, and if you are eligible, after treatment, three months after treatment, and do a semi-structured interview after treatment to hear more about your experiences with treatment.

Some risks of this study include the possibility of temporary distress associated with the PTSD treatments. You may also experience temporary distress during assessments that may ask you about your trauma history or other difficulties you may be having, such as feeling depressed.

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WHY IS THIS STUDY BEING DONE?

The study is being done to examine how feasible and acceptable it is to deliver PTSD treatments (CPT and PE) in a massed format (e.g., delivered at least three days per week). This will be compared to how these treatments are usually delivered, which is typically once per week. Massed treatments may be able to help people finish treatment more quickly and feel better sooner, and provide an additional option for how to receive care if it is determine to be effective and liked by Veterans and providers.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY

Approximately **30** people will be randomized in this study at the Durham VA Health Care System.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in this study will last on average 12 months, but it could be up to 18 months depending on the length of your treatment, and/or any missed appointments or cancellations. We will continue to collect follow-up information for 3 months after your last therapy visit.

WHAT IS INVOLVED IN THIS STUDY?

If you agree to participate in this research study you will be asked to sign and date this consent form. There will be 3 assessment visits, as well as therapy, as a part of this study. The first assessment visit will help to determine if you are eligible for the study. At this visit, you will be interviewed about your current PTSD symptoms, such as other psychiatric and substance use symptoms. These interviews will be audio-recorded for quality assurance purposes and saved in a folder that only study staff have access to. You will also be asked to complete questionnaires about your mental health symptoms, functioning, and related issues. This study session will take about 3 hours. This visit is typically done via video telehealth but can be done in-person, or over telephone.

If you are eligible after the first assessment, we will randomly assign you (in a process like flipping a coin) to one of the two study groups: 1) Massed treatment delivery (PTSD treatment delivered at least three days a week or more) or 2) treatment as usual in the clinic (PTSD treatment that is delivered weekly). The therapy for this study will be provided by clinicians in the Durham VA PTSD Clinic. The two therapies that are examined in this study are cognitive processing therapy (CPT) or prolonged exposure therapy (PE). The type of therapy that you will receive (CPT or PE) will be selected by you and a clinical provider. The random assignment will select how frequently you receive therapy (three or more days a week vs. once a week), but the therapy type (CPT or PE) will be the one you selected in consultation with a clinical provider. To be in this study, you will have selected one of these treatments with a clinic provider or be willing to do one of these treatments individually with a clinic provider. You will also select your

preferred delivery modality (e.g., telehealth, in-person, or hybrid of these) with the clinic providers. You will be asked to attend PTSD treatment (either CPT or PE) that you will decide on with your VA clinician in the clinic in the frequency that you were assigned to (i.e., massed [3 days a week or more] or treatment as usual [typically once per week]).

CPT and PE are PTSD treatments that are routinely provided in the VA. During these therapies, you will talk with your therapist about a traumatic event and how they may have affected your beliefs, behavior, or other aspects of your life. The therapist will work with you to provide you with skills to cope, and you will be given home practice assignments. Therapy sessions are usually 60 or 90 minutes. During therapy, you will also complete questionnaires that are routinely given by the therapists in the clinic. A standard course of therapy is 12 sessions, although your therapist may decide for you to do fewer or additional sessions depending on your response to treatment.

As a part of your participation in the study, after you have finished the PTSD therapy, you will be asked to participate in a post-treatment assessment visit. The post-treatment assessment visit will include completing a clinician-administered interview about your mental health symptoms and self report questionnaires. This should take about 2 hours. You will also be asked to complete an approximately 60-minute interview about your current PTSD symptoms. The interview will be audio recorded for quality assurance purposes and only study staffs will have access to the recording, and it will be stored behind the VA firewall.

You will be asked to also attend a 3-month follow-up visit three months after ending therapy and complete a clinician-administered interview about your PTSD symptoms and self-report questionnaires. This visit should last about 2 hours. The interview will be audio recorded for quality assurance purposes and only study staff will have access to the recording, and it will be stored behind the VA firewall.

We cannot guarantee that you will be able to continue receiving these therapies after this study is over, although CPT and PE are routinely offered in the VA. We can help place a referral to a VA clinic after the study is over, if needed. We may also contact your VA mental health providers to let them know about your research participation to help coordinate mental health care. As a part of your participation in the study, we may access your medical records or add notes to your charts to communicate with other providers.

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

There are no known physical risks associated with this study. There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some questions asked as part of this study or as a part of the therapy you receive in the

clinic (which are routinely provided in VA for PTSD) may make you feel uncomfortable or increase distress. This discomfort or increased distress is usually temporary and well tolerated. You do not have to answer questions and you can take a break at any time, or you can choose to end participation in the therapy and/or study. You can call the study team at any time if you experience any discomfort related to the research. There is the economic risk for the loss of wages for study visits but you will be compensated for the baseline, post-treatment, 3-month follow-up, and qualitative interview if you participate to offset this.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

You may have reduced PTSD symptoms as a result of the treatments in this study. However, these benefits are not guaranteed to you. You may not personally benefit from taking part in this study, but your participation may lead to knowledge that will help other Veterans in the future. You may also benefit from sharing your opinions about your experiences in treatment but this cannot be guaranteed.

WHAT OTHER OPTIONS OR ALTERNATIVES DO I HAVE?

Taking part in this study is your choice. You may choose to not participate. If you choose not to participate, you may be eligible for other research studies or receive care in a clinic at the Durham VA Health Care System. The therapies offered through this study (CPT & PE) are routinely provided in VA.

HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

Your information used for this study will be kept confidential as required by law. The results of this study may be used for scientific purposes or for publication, but these results will not include any information that would identify you. Your identity will not be disclosed without your consent, or unless required by law. Your research records will be maintained and destroyed according to VHA records retention requirements. Data will be stored in an electronic folder behind the VA firewall that only study staff have access to or in locked filing cabinets in locked rooms that only VA study staff have access to. Each participant is given a random ID number that is used on study records and can link Veterans names with their ID but only study staff have access to this data that is stored in a folder behind the VA firewall.

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.

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.

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

You will be reimbursed up to **$200** for your participation in this study

- For completing assessment questionnaires and measures as a part of the baseline assessment, this pays $50.

- If you are eligible after the baseline assessment and participate in the study, you may also complete the following:
  - The post-treatment assessment. You would be paid $50 for completing assessment questionnaires and measures as a part of the post-treatment assessment.
  - A qualitative interview, which pays $50. You would be paid for participating in the qualitative interview.

  - The 3-month follow-up visit. You would be paid $50 for completing assessment questionnaires and measures as a part of the 3-month follow-up process.

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 VAHCS 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.

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WHAT ARE MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You can choose to not be in this study, or, if you agree to be in the study, you can withdraw at any time. If you withdraw from the study, no new data about you will be collected for study purposes. We will keep and use the data that we already collected before you withdrew your consent.

If you choose to not be in the study 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.

ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

The principal investigator may withdraw you from the study without your consent for one or more of the following reasons: You have serious side effects, your condition worsens, or your study doctor decides it is no longer in your best interest to continue in the study, or failure to follow instructions of investigator and/or study staff. We will tell you about new information that may affect your health, condition, welfare, or willingness to participate in this study.

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.

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.

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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. Stephanie Wells*** at **919-286-0411 x134053** during regular business hours. 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. If you would like to check that this study is approved by the Durham VAHCS's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 176926.

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AFFIRMATION FROM PARTICIPANT

I have read this form or it has been read to me. 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.

Signature of Participant _____ DATE _____

Signature of Person Obtaining Consent _____ DATE _____