Evaluating the Impact of Supplementing Residential Substance Use Treatment with Written Exposure Therapy for Veterans with Co-Occurring PTSD and Substance Use Disorders

NCT05536908

September 5, 2023

Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name: _____ **Date** _____

Title of Study: Evaluating the Impact of Supplementing Residential Substance Use Treatment with Written Exposure Therapy for Veterans with Co-Occurring PTSD and Substance Use Disorders

Principal Investigator: _____ **VAMC:** **Salem**

OVERVIEW AND KEY INFORMATION

- This research is evaluating the effectiveness of a PTSD treatment called Written Exposure Treatment (WET).
- The purpose of this study is to find out if completing WET for PTSD during residential substance use disorder treatment (DOM SUD) is feasible and may be effective.
- Your participation in this study will involve completing an interview to evaluate you for PTSD. After this screening, participants that are determined to be eligible for the study will be assigned to either complete WET or the standard treatment in the DOM SUD. You will be asked to complete an interview and some questionnaires at the beginning of your residential SUD treatment, at the end, one month after treatment, and three months after.
- A risk of this study is feeling emotionally upset while remembering or discussing traumatic events.
- Benefits cannot be guaranteed but may include a thorough evaluation for PTSD and potential relief from PTSD symptoms through treatment.
- Participation is voluntary, and you could receive the WET treatment during your residential SUD treatment without being in the study. There are several other effective treatments for PTSD you could receive following the DOM SUD program.

Please read this form carefully. You are being asked to participate in this research study because you reported PTSD symptoms. This study is voluntary and will include only people who choose to take part. Ask your study doctor or study staff to explain any words or information that you do not understand. It is important that you understand the information on this form.

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PURPOSE and PROCEDURES: This research is beginning to evaluate treatment for PTSD and Substance-use disorders. Specifically, the purpose of this study is to determine if it is helpful and feasible for Veterans with PTSD who are in residential substance use treatment (DOM SUD) to get PTSD treatment at the same time. The PTSD treatment we are evaluating is called Written Exposure Therapy (WET) and involves writing about the trauma that bothers you most.

If you decide to participate in this study, you will be asked to sign this consent form after you have had all your questions answered and understand what you will be asked to do.

Your participation in the study will involve an interview to evaluate you for PTSD and discuss your eligibility for the study. If you are eligible, you will be randomly assigned to either receive WET (two individual therapy sessions a week for five sessions of one hour or less) or to do the regular DOM SUD treatment without WET (no additional individual PTSD therapy during the residential program). If eligible, we will ask additional questions about your symptoms and functioning before starting either treatment.

If you are randomly assigned to receive WET, you will spend 30 minutes of each session writing about the traumatic event and additional time in session discussing the process of writing. WET and the regular DOM SUD treatment will both provide more information about PTSD and trauma symptoms. Everyone who decides to participate in the study will complete an interview at the beginning of DOM SUD treatment to determine eligibility, and, if eligible, will be asked to complete follow up interviews and questionnaires at the end of DOM SUD, one month after completing DOM SUD, and three months after completing DOM SUD. Each interview is expected to last approximately 2.5 hours. These interviews and questionnaires will assess substance use, PTSD symptoms, mood, treatment adherence and completion, quality of life, homelessness, and suicidal ideation and behaviors. You may also be asked to participate in a one-hour focus group to discuss your treatment experiences. Your provider will also ask you to complete measures for us to evaluate your symptoms during your treatment. These measures will assess symptoms associated with substance use, trauma, and mood.

RISKS: The risks of participating in this study are minimal. Writing or talking about trauma can bring up difficult emotions and cause people to be upset for a time. Although some upsetting feelings can arise, these are normal and expected parts of addressing trauma symptoms and, for most people, these are very temporary. All participants will have support available from DOM SUD clinical staff and more broadly VA Medical Center staff if severe distress were to occur.

BENEFITS: We cannot promise that you will receive any benefits from taking part in this Research study. However, possible benefits of participating in this study may include receiving a thorough evaluation for PTSD and follow up evaluations one and three months after completing treatment. Your participation may also help other Veterans by helping us determine if WET during residential substance use treatment is helpful and

feasible. You may also experience some symptom improvement by participating but this is something we are studying and cannot be guaranteed.

ALTERNATIVES: WET is one of several effective treatments for PTSD. Even if you are not interested in participating in the study or receiving PTSD treatment while you are in the residential treatment program, we can refer you to be evaluated for WET or other effective treatments for PTSD after you complete the DOM SUD. Also, if you participate in the study and are assigned to receive the regular DOM SUD treatment without WET, we can help you get WET or other treatments for PTSD after you complete the DOM SUD if you are interested. You may choose to not participate in this study. This choice will not affect your medical treatment or your participation in the DOM SUD program in any way. You are free to end your participation in this study at any time without any penalty. It is important that you understand that your benefit status and/or medical treatment will not be affected in any way.

CONFIDENTIALITY: In any research, there is always a chance that confidentiality of the collected information may be breached. However, study staff will store all data in a secure location. Paper records from the study will be kept in a locked cabinet in a locked, secure office. Electronic data will be stored on secured, password-protected servers. We plan to summarize data collected and publish our findings but this will not include any data specifically linked to any participant. We do partner with the Center for Biostatistics and Health Data Science at Virginia Tech who will aid the research team in conducting data analysis. This shared data will not include any information that would identify any research participant.

As part of this research study, you will be asked to sign an Authorization for Use and Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research. This authorization will allow us we will access your past and present individually identifiable health information (IIHI) in the form of 1) information from your VA Health Records such as diagnoses, progress notes, medications, and lab findings; 2) specific information concerning alcohol and/or drug abuse; 3) demographic information such as name, age, and race; 4) diagnostic assessments and interviews conducted as part of the standard intake and treatment procedures. Signing the authorization is completely voluntary—however, your authorization (permission) is necessary to participate in the study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign the authorization. We are committed to protecting your privacy and the confidentiality of information related to your health care, and this information will be used for the purpose of data analysis.

To evaluate your response to treatment, we may invite you to a focus group to discuss the experience of treatment. In order to carefully review this feedback, we plan to audio record the focus groups. These recordings will be stored on secured, password-protected servers. Although you can decide what you want to share, participating in the focus groups also means that you may be discussing your experience in treatment with other veterans present.

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The Salem VA Research & Development Committee and its subcommittees (i.e. Institutional Review Board {IRB} and Safety Committee {SRS} which are committees that oversee research and protect the safety of research subjects) will have access to the records. Federal agencies including, but not limited to the, Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), Office of Research & Development (ORD), Office of General Counsel (OGC), Government Accountability Office (GAO), and the VA Office of the Inspector General (OIG) may have access to the records.

Finally, although confidentiality is very important, there are certain situations where we are required to break confidentiality. Specifically, if we believe you are at great risk of harming yourself or someone else, we are required to act to prevent this. We may break confidentiality only in order to ensure your safety and the safety of others in this situation. We are also mandated reporters of child abuse and/or abuse of elderly or disabled persons.
The purpose of the data containing 38 USC 7332 information is for scientific research only and there will be no attempt to identify directly or indirectly any subjects in the research data. In addition, Privacy Act Authority will be required.

RESEARCH-RELATED INJURIES:

- The VA has not set aside compensation payable in the event of physical injury or illness resulting from participation in this research study.

- VA medical facilities, including joint VA-DoD federal health care centers, must provide necessary medical treatment (i.e., not just emergency treatment) to a research subject injured as a result of participation in a research study approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. This requirement does not apply to (1) treatment for injuries that result from non-compliance by a research subject with study procedures or (2) research conducted for VA under a contract with an individual or a non-VA institution.

- Care for VA research subjects with research-related injuries must be provided in VA medical facilities, except in the following situations: (1) If VA facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required, VA medical facility Directors shall contract for the needed care; (2) If inpatient care must be provided to a non-Veteran research subject with a research-related injury, VA medical facility Directors may contract for such care; or (3) If a research subject needs treatment in a medical emergency for a research-related injury, VA medical facility Directors must provide reasonable reimbursement for the emergency treatment in a non-VA facility.

In the event of research related injury, please contact one of the following individuals:

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For after-hours care contact Salem Emergency Department, ext. 2910

VOLUNTARY PARTICIPATION STATEMENT:

- participation in this research study is voluntary
- refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
- the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

TERMINATION OF SUBJECT'S PARTICIPATION: If your initial screen shows you are eligible to participate in the study, there are only a few reasons researchers would remove you from the study. Your participation could be terminated if you develop a psychological condition (for example, mania or intent to hurt yourself) that makes continuing unsafe or impossible to continue. It is also possible you would not be allowed to continue if it was determined that you were no longer eligible for VA care for some reason. Finally, if we are unable to reach you for one of your follow up interviews for two weeks or more it is possible that you will not be eligible to complete that portion of the study.

FINANCIAL COMPENSATION: You will be compensated for your participation in this study. You will be paid for each portion of the study (i.e., pre-treatment, post-treatment, 1-month, 3-month, and focus group). If you withdraw from the study at any time or your participation is terminated, you are still entitled to the compensation that you have earned through the point at which you withdraw or are terminated from the study.

You will be compensated at a set rate described in the table below. Payment is based on an estimated rate of $25/hour for the expected time required to complete each session.

Payment Schedule	
Study screening	$25.00
Pretreatment interviews for eligible participants	$37.50
Posttreatment interview	$62.50
One-month follow up interview	$62.50

Three-month follow up interview	$62.50
Focus group	$25.00

Should you choose to end a procedure early without completing it, you will be paid $25/hour for time spent, up to the scheduled payment for that procedure. The maximum compensation for each individual in this study is $275. Payments will be made either with cash or check. If payment is distributed with a check, the VA will be identified as the payer through VA Finance Service Center, and your name, address, and social security number will be disclosed to the Salem VA Fiscal Service and Austin Financial Services Center.

If you receive $600 or more per calendar year as a result of your participation in one or more research studies, your name, address, social security number, and amount of payment will be submitted to the Internal Revenue Service for tax reporting purposes.

CONSEQUENCES OF WITHDRAWAL FROM STUDY: You are free to end your participation in this study at any time without any penalty. Your benefit status and/or other medical treatment through the VA will not be affected in any way.

RESEARCH SUBJECT COSTS: You will not be asked to pay any costs related to this research.

NEW FINDINGS: Significant new findings developed during the course of this research study that may relate to your willingness to continue participation will be provided to you. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study.

NUMBER OF SUBJECTS: We will screen up to 125 participants to enroll 50 participants in treatment.

FUTURE USE OF IDENTIFIABLE DATA:

We plan to keep your data connected to a participant number which would allow us to identify you for follow up studies if desired. Your data and identity will always be kept in separate locked rooms in locked filing cabinets.

- **Withdrawal of Data for Future Use**
  If you agree to allow your data with information that would link the data to you to be kept for future research or for re-contacting, you can change your mind at any time. To withdraw your data, contact _____ in writing and let them know you are withdrawing permission for your identifiable data to be used for future research. _____ mailing address is:

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Salem VA Medical Center (116C)
1970 Roanoke Blvd
Salem, VA 24153

RESEARCH SUBJECT'S RIGHTS:

- You have read, or have had read to you, all of the above information. Study staff explained the study to you and has answered all your questions. The risks or discomforts and possible benefits and the alternatives of the study have been explained to you.

- The results of this study may be published but your identity and records will not be revealed unless required by law.

- In case there are any medical problems or if you have questions, concerns, and/or complaints about the research study, you can call _____, or a member of the study staff, at ext. ____ during the day. In case there are any medical problems, please call your primary care provider, come to the emergency room, or contact 9-1-1.

- In the event of illness or injury that you believe to be related to the study, or if you have any questions about your rights as a research subject, complaints or concerns, you can contact the Chairperson of the Institutional Review Board (IRB) or designee at _____, ext.___ or the Research and Development Office at _____, ext. ____.

- If you wish to contact someone other than the research study staff, you may call the Research & Development office at _____, ext. ____ or contact the Research Compliance Officer at _____, ext. _____.
- If you wish to verify that this is an approved Salem VAMC research study or you are unable to reach the research study team during normal business hours, you may call the Research & Development office at _____, ext. ____.

- 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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- No guarantees or assurances have been given to you since the results and the risks of an investigation are not always known beforehand. However, every reasonable precaution will be taken to protect your well-being. You have not released this institution from liability for negligence.

STATEMENT OF CONSENT: I have read/have been read this informed consent document and have been given the opportunity to ask questions. I understand that I will receive a signed copy of this informed consent document and the original signed document will be placed in my case history in the investigator files. I authorize the use of my identifiable information as described in this form.

I voluntarily consent to participate in this study. This research study and my rights as a research participant have been explained to me.

_____ _____
Signature of Subject Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of Person Obtaining Consent Date