

**NCT Number:** NCT01928732

**Document Title:** CSP 591 Research Consent Form

**Document Date:** October 13, 2017



Participant Name: \_\_\_\_\_ Date: \_\_\_\_\_

Title of Study: Comparative Effectiveness Research in Veterans with PTSD (CERV-PTSD)

Principal Investigator: \_\_\_\_\_ VA Facility: \_\_\_\_\_

Principal Investigator for Multisite Study: Paula P. Schnurr, PhD

**INTRODUCTION**

You are being invited to take part in a research study that is funded by the Department of Veterans Affairs. 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.

Read the information below carefully, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

**BACKGROUND AND PURPOSE**

**WHY IS THIS RESEARCH BEING DONE?**

The purpose of this research study is to compare two types of individual therapies for the symptoms of Posttraumatic Stress Disorder (PTSD). One of the treatments is Prolonged Exposure (PE) and the other is Cognitive Processing Therapy (CPT). Both therapies are routinely used in the VA and have been found to be effective with Veterans in prior studies. However, the two therapies have never been compared to one another in Veterans.

PE involves learning a method of dealing with traumatic memories and stressful situations to help you overcome the distress in a safe manner. The other treatment, CPT, looks at the impact the traumatic event has had on your life and helps you to examine and change your unhelpful thoughts and feelings related to the event, yourself, others and the world. The purpose of this research study is to compare the effectiveness of these two therapies on PTSD symptoms, along with related symptoms such as depression and anxiety, to see which treatment is better. The study will also try to determine if there are people who respond better to one treatment or the other.

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**WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?**

You are being asked to take part in this research study because you are over 18 and you may have PTSD. PTSD is a psychological disorder in some people who have had a trauma experience such as combat, sexual abuse, physical abuse, or natural disasters.

**WHO IS CONDUCTING THE RESEARCH STUDY?**

This study is sponsored by the Department of Veterans Affairs. The study is directed by Paula P. Schnurr PhD, a researcher at the White River Junction VA Medical Center. Co-directors are Kathleen M. Chard, PhD at the Cincinnati VA Medical Center and Josef Ruzek, PhD at the Palo Alto VA. They are assisted by staff at the White River Junction VA Medical Center, the Palo Alto VA Cooperative Studies Program Coordinating Center (CSPCC), the Boston VA Medical Center, and your local VA hospital.

**HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?**

The CERV-PTSD study team at your medical center will ask Veterans like you to provide consent to participate in this research study. Study participation involves two parts. The first part is to go through screening procedures that will determine if you are eligible to receive PTSD therapy (PE or CPT) as part of the study. The second part of study participation is randomization to either PE or CPT treatment (“randomization” is described below in “Study Procedures”) and post-treatment follow-up. Not everybody who signs a consent form and goes through screening will qualify and receive PTSD therapy. We expect that approximately half of the participants will be eligible to receive study treatment. Up to 2550 Veterans at 17 or more VA sites across the country will be enrolled in this study, with up to 150 participants enrolled at each site.

**DURATION OF THE RESEARCH**

The study will last four years, but you will be in the research study for approximately one year.

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**STUDY PROCEDURES**

**WHAT IS INVOLVED IN THE RESEARCH STUDY?**

On your first visit you will be asked some questions to find out if you might be eligible for the study. The questions include background information and questions about your current mood and how you are coping. If it seems you are eligible for the study, you will fill out some additional paper-and-pencil questionnaires about PTSD, depression, anger, health and general well-being.

After this visit an assessor located in Boston or Long Beach will contact you by telephone for a clinical interview designed to determine if you have PTSD and other related symptoms. You also will be asked about your preferences for treatment, but this will not affect which treatment you receive. You do not need to return to the VA for this interview. However, if you do not have access to a phone you must agree to come to the local VA clinic for the phone interview. This phone call interview will take between two and four hours and can be done in two sessions. After this assessment it will be decided if you are eligible to participate in the study.

To be eligible for the study you must meet the following criteria:

- be enrolled in the VA system and referred to the study by a VA staff member,
- be a Veteran with a current diagnosis of PTSD due to any trauma during your military service,
- agree to be placed in either treatment (PE or CPT),
- agree to not receive other psychotherapy or counseling for PTSD while you are receiving therapy as part of this study,
- agree to let us access your medical record so we can learn about how much you are using VA services before and during the study,
- have regular access to a telephone or agree to come into the VA clinic for telephone interviews,
- agree to have your telephone interviews and treatment sessions recorded, and
- be at least eighteen years of age.

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If more than 30 days go by between this telephone interview and your first study therapy session, you will be asked to re-do part of this interview. While receiving therapy as part of the study, you will be allowed to attend self-help groups, have brief check-in visits with any therapist or counselor you have now, seek treatment for substance abuse and mental health problems other than PTSD, and take medication for PTSD and other mental or physical conditions.

You will not be eligible for the study if you (1) have any current psychotic symptoms, (2) have plans to harm yourself or someone else or are making plans to do so, (3) have mania that is not in remission, (4) have current drug or alcohol dependence, or (5) show severe problems with memory or other problems with thinking and reasoning. If you are currently dependent on drugs or alcohol you will be referred to an appropriate clinic. You will be considered for the study one month after you are no longer dependent on drugs or alcohol. If you are currently suicidal or homicidal with intent and a plan we will help you obtain mental health care and you may be eligible for the study at a later time.

If you are eligible for the study you will be "randomized" into one of the two treatments described below. Randomization means that you are put into one treatment or the other completely by chance. It is like flipping a coin. If you take part in the study, you will be assigned to either PE or CPT with a trained therapist. You will have the same therapist for the entire study. Both therapies are commonly used in the clinical care of PTSD. They both involve 10-14 sessions that last 90 minutes in PE or 60 minutes in CPT. Sessions will be scheduled weekly, although you may attend some sessions more than once a week or skip a week (for a scheduling conflict, for example). You and your therapist will determine what frequency works best for you. Both therapies require practice assignments between sessions. At each session you will be asked to fill in two paper-and-pencil questionnaires.

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The schedule for study assessments will be as follows:

	Enrollment (On-site)	Baseline (Phone)	Therapy (8-14 sessions)	Mid-treatment (Phone)	Post-treatment (Phone)	Post-Treatment (On-site)	3 months post-treatment (Phone)	3 months post-treatment (On-site)	6 months post-treatment (Phone)	6 months post-treatment (On-site)
PTSD symptom questionnaires		X	X	X	X		X		X	
General mental health questionnaires	X	X	X			X		X		X
Life history questionnaires	X	X								
Mood questionnaires	X					X				X
End of study forms						X				X

Halfway through your study treatment sessions, you will receive a telephone clinical interview that lasts about 1.5 hours. Within one week after the end of therapy you will be asked to come to the VA clinic for a post-treatment follow-up and have another telephone interview. You will also be asked to return for a follow-up assessment and complete phone interviews three and six months after you complete the treatment. The post-treatment and follow-up assessments will include all of the measures you filled in on your first visit, with the exception of the general background questions. These visits will last one to two hours for the questionnaires in the clinic and about 1.5 hours for the telephone interviews. If you do not have access to a telephone we will ask you to come into the VA clinic for the telephone interview. This part of the study happens over the phone to make sure that the clinicians asking you certain types of questions are “blinded” – that is, that they do not know which treatment you were assigned to.

All treatment and questionnaire assessments will take place at your local VA. The interviews will be conducted on the telephone. All assessments will be digitally recorded

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and all therapy sessions will also be digitally recorded to ensure the quality of services being provided to you. You are free to skip any questions on any of the paper-and-pencil questionnaires that you would prefer not to answer. If you miss any of the treatment and questionnaire assessments the site coordinator will try to reschedule them by contacting you initially by phone (up to 5 times) and then by mail with a letter. If you are unable to attend a follow-up assessment at your local VA (for example, if you move out of the area), you may choose to complete some questionnaires by mail instead of in person).

You will meet with several people as part of your research participation, including your study-assigned therapist, local site coordinator, and telephone assessor. Your local site coordinator will explain the potential risks and benefits of your participation. Study staff including the leaders of the project and your local site coordinator will monitor your treatment and whether undesirable events result from your participation. They will also alert you if there is a problem with the treatment. Your therapist will provide your PTSD therapy and also document your clinical course while you receive the treatment.

If you decide to participate in the research study, it will be your responsibility to:

- Attend scheduled treatment sessions
- Attend scheduled assessment appointments, and contact the site investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Participate in the PTSD treatment process and complete treatment tasks as discussed with your therapist.
- Fill out your practice assignment forms as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the site investigator or research staff if you change your mind about staying in the study.
- Not take part in any other research project without discussion with the research staff. Taking part in another research study without first discussing it with the investigators of this study may invalidate the results of both research studies.

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**POSSIBLE RISKS OR DISCOMFORTS**

**WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?**

It is possible that during the assessments or therapy sessions you may feel some increase in unpleasant emotions while recalling and describing the traumatic event. Because you have PTSD you may have been trying to block or avoid thoughts and feelings. The goal of PE and CPT is to have you feel less stress and other painful emotions related to the traumatic event. We expect that any distress you may experience will be temporary. However it is possible that your condition may worsen. If at any time you are feeling overwhelmed or upset you may call the study staff between the hours of 8:00 AM and 4:00 PM, come to the main VA emergency room to be seen by a mental health professional, or call the Veterans Crisis Hotline at 1-800-273-8255.

If any significant new findings develop during the study that relate to your willingness to continue, you will be informed.

Risks of the usual care you receive (PE or CPT therapy for your PTSD) are not risks of the research. 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 RISKS OF STOPPING YOUR CURRENT TREATMENT?**

The only risk to stopping your current therapy is the discomfort you may feel at changing from one therapist to another. You may have some discomfort with discontinuing your current treatment, but brief check-ins with your current therapist will be allowed.

**ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?**

If you agree to take part in this research study, there may not be a direct benefit to you. The investigators hope the information learned from this research study will benefit you and other Veterans with PTSD in the future. Potential benefits to you may include a reduction in your PTSD symptoms over the course of therapy. The knowledge gained

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from this study will serve to guide future research and clinical care for Veterans. For society in general, this study will provide useful information regarding treatment effectiveness, recovery from trauma, and long-term benefits of therapeutic interventions.

**ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH**

**WHAT OTHER CHOICES FOR CARE ARE THERE?**

PE and CPT are not investigational therapies. Both of these PTSD treatments have been found to be effective in past studies and they are available to you even if you decide not to participate in this study. This research study will compare the two treatments to one another.

Instead of being in this research study, you have these options:

If you have PTSD you may request PE, CPT, or other types of PTSD treatment based on VA guidelines and availability at your local VA or Vet Center. If you do not have PTSD you may contact the mental health clinic at your local VA or Vet Center to discuss your eligibility for other services.

**CONFIDENTIALITY**

**HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?**

The information collected for this study will be kept confidential. We will include information about your study participation in your medical record. There are times when we might have to show your records to other people. For example, 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 Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

The data from the study may be published; however, you will not be identified by name. All data will be identified by code number. These data will be stored in locked file cabinets that will be accessible only to project staff.

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The key listing names and code numbers will be kept in a separate locked filing cabinet or separate secure computer drive. Destruction of all research records pertaining to this study will be in accordance with the Department of Veterans Affairs record retention schedule. The electronic recordings of the assessments and sessions will be stored in the VA system with password protection.

Your information will be combined with information from other people taking part in the study. We will write about the combined information we have gathered. Any talks or papers from this study will not identify you.

If you are a VA patient, you already have a VA medical record. If you are not a current VA patient, we will create a VA medical record for you. Also, the VA Cooperative Studies Program requires us to collect Social Security Numbers (SSNs) from everyone who participates in this study in case there is new information about this study in the future that needs to be told to the participants. You will not be able to participate in this study unless you give us your SSN.

We will put the following information about you from this study into your medical record: A note that you are receiving one of the treatments and the session you are on, and the PTSD Checklist that you will fill out each session. This electronic record will be kept for 75 years after your last contact with us. All authorized users in the national VA system can have access to your medical record. We will also collect demographic information and VA services that you have received from your medical record.

By signing this document, you authorize the Veterans Health Administration (VHA) to permit (insert name of Site Investigator) and his or her research team to use and disclose the following information about you and to contact and discuss your research activities with your referring VA clinician to mutually address any clinical needs:

- Information about you that is created during the research study. This includes the number of times you have used VA services, the results of diagnostic exams that become part of the study records, and information collected as part of interviews you have with the study staff and questionnaires you fill out during the study.

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- Information in your medical record that is needed for this research study. This might include the results of past physical exams, diagnostic interviews, lists of medications you are currently taking, diagnostic procedures and your medical, social, and psychiatric history.

**WHAT IS A CERTIFICATE OF CONFIDENTIALITY?**

To further protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

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 and neglect, elder abuse or neglect, or harm to self or others. The Certificate does not prevent you or your family from releasing data about yourself or your involvement in this study.

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.

**COSTS TO PARTICIPANTS AND PAYMENT**

**WHAT ARE YOUR COSTS TO BE IN THIS STUDY?**

There are no costs for your participation in the study. All study therapy is free of charge to study participants. Department of Veterans Affairs patients may be financially responsible for non-study related care at the Department of Veterans Affairs. Some Veterans are required to pay co-payments for medical care and services; these co-payment requirements will continue to apply to medical care and services provided by the Department of Veterans Affairs that are not part of this study.

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**WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?**

You will be paid \$30 for the screening. If it seems you are eligible for the study, you will be paid \$20 for the baseline questionnaire measures before treatment and \$50 for the initial telephone interview. You will receive \$50 for the telephone interview during treatment and \$75 for the phone interview and questionnaires at the end of treatment. At the three month follow-up, you will receive \$85, and at the final assessment at 6 months, you will receive \$100. Payments will be either in cash, gift card or check depending on the rules for each VA hospital in the study. If you receive payments for being a part of this research study, you may be asked to complete an Internal Revenue Service (IRS) form. The amount you receive may count as income and may affect your income taxes. Your social security number may be required to complete the IRS 1099 form. You will also be reimbursed for travel over 50 miles.

**MEDICAL TREATMENT AND COMPENSATION FOR INJURY**

**WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?**

Every reasonable safety measure will be used to protect your well-being. 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 was due to your not following the study procedures. Financial compensation is not available for such things as lost wages, disability or discomfort due to an injury. The Department of Veterans Affairs does not normally provide any other form of compensation for injury. You have not released this institution from liability for negligence.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: *(List local site contacts)*

**DURING THE DAY:**

Dr./Mr./Ms. \_\_\_\_\_ at \_\_\_\_\_ and

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**AFTER HOURS:**

Dr. /Mr./Ms. \_\_\_\_\_ at \_\_\_\_\_.

Emergency and ongoing medical treatment will be provided as needed.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

**PARTICIPATION IS VOLUNTARY**

It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or decide to leave the study early, you will not lose any benefits to which you are entitled. If you do not take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

If you decide to withdraw from therapy you will be asked to complete remaining assessments, but again, this is voluntary and you will not be penalized for declining. If you withdraw from the study, data that has already been collected as part of the study can be utilized by the study team, but no future data will be collected without your permission.

**RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION**

The investigative team may terminate your participation in the study if they believe it is in your best interest or if you are not following study requirements for treatment or assessments. If so, your therapist will explain the reasons and arrange for your usual medical care to continue. Termination from the study will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

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**PERSONS TO CONTACT ABOUT THIS STUDY**

**WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?**

If you have any questions regarding this study, if you experience side effects or want to report a research-related injury or illness, or if you have any additional concerns or complaints while you are participating in this study, you can contact the site investigator [insert SI name here] at [(xxx) xxx-xxxx].

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 participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

**SIGNIFICANT NEW FINDINGS**

Sometimes during the course of a research study, new information becomes available about the therapies being studied that might change a person's decision to stay in the study. If this happens, your therapist will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your therapist will arrange for your mental health care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form.

**AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY**

[insert SI name here] or a member of his/her research team 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.

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You voluntarily consent to participate 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
_____	_____	_____
Name of person obtaining authorization and consent	Signature of person obtaining authorization and consent	Date

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