Parenting Strength at Home- Parents Pilot

Informed Consent Document

NCT03403153

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Department of Veterans Affairs	RESEARCH CONSENT FORM		
SUBJECT NAME		DATE (MM/DD/YYYY)	
TITLE OF STUDY	*Adaptation, Refinement, and Open Trial of Parent Training for Veterans with PTSD Strength at Home – Parents Pilot*		
PRINCIPAL INVESTIGATOR	Suzannah Creech, PhD	VAMC	**CTVHCS**

DESCRIPTION OF RESEARCH BY INVESTIGATOR **1.** Purpose of study and how long it will last: **2.** Description of study including procedures to be used: **3.** Description of procedures that may result in discomfort or inconvenience: **4.** Expected risks of study: **5.** Expected benefits of study: **6.** Other treatment available: **7.** Use of research results: **8.** Special circumstances:

The study you are being asked to volunteer to take part in involves research. This research study takes place through the Central Texas Veterans Health Care System (CTVHCS). It is important that you read and understand the information on this form.

PURPOSE

The purpose of this research is to develop and pilot test a group treatment to improve parent-child functioning in Veterans who may have experienced trauma and who report problems with parenting. Our goal for this study is to learn if Veterans feel the group program is helpful to those who are working on improving their relationship with their child.

This research study is a local research project which will study approximately 80patients/subjects. Your participation in this study participation will only take about 4 months and the study itself will occur over a period of 4 years.

PROCEDURES -

1. If you consent to be in this study, all assessment and group treatment sessions (describe in more detail below) will be completed remotely through VA-approved video technology. All questionnaires will be completed remotely through a secure web-based survey application.
2. You will first complete a baseline assessment which will determine final eligibility for the study.
3. The baseline assessment measures include questions about parenting stress, family functioning, your impression of your child, your mental health symptoms and any problems you have had with head injuries.
4. If you are not eligible for the study after the baseline assessment, we will help you with any referrals you need and your participation will be concluded.
5. If you are eligible for the study, next you will participate in an interview. The interview portion will be audio-recorded for review by an expert clinician to ensure you are receiving the best care possible. All recordings will be kept confidential except as needed for training purposes and for coding.
6. This assessment visit will take about 1.5 hours in total.
7. After the assessment visit, you will participate in an 8-week group program (weekly group, 1-2-hour session) with other Veterans. Topics discussed in the group program include: child development, relationship enhancement, skills for discipline, and health family functioning. Each week there will be an

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8. Each week you will be asked for you feedback on the group program (things you liked and things you didn't like), this will take about 10 minutes.
9. At the end of the group program (8 weeks later), you will be asked to complete a follow-up assessment, which will take about 30 minutes. Even if you stop attending the group, we will attempt to contact you to invite you to complete a follow-up.
10. This study also includes a partner assessment. Only with your consent, we will attempt to outreach to a parenting partner to find out his/her perspective on parenting stress and how your child is doing. We will keep what you say, and what your partner says confidential.
11. Because this is a new treatment program we do not know all its bad effects. You should contact Dr. Suzannah Creech at 254-297-3025 if you have any bad effects. We (I) cannot guarantee that you will be able to continue receiving this treatment after this study is over.
12. If you become disruptive to the group or you need a different type of treatment, your participation may be terminated by us without your consent.
13. You are free to withdraw from the study at any time, you can withdraw by letting us know verbally or in writing at any time.

DISCOMFORTS AND RISKS

1. Psychological risks. Only mild, transient side effects related to emotional distress related to completing the assessments and treatment are expected because of the study procedures. It is possible that you become aware of new problems in your parent-child functioning or family functioning that you did not know of, which can lead to negative feelings. In addition, you could experience some discomfort discussing details of your personal life in a group setting. On occasion, some individuals may become quite upset and wish to speak with a mental health provider beyond the scope of the group, in this case our staff can make a referral. Participation may involve other physical, psychological, social, financial or other risks to you that are currently unforeseeable.

2. Privacy: There is a chance that the information you provide to us during the study will not remain private and confidential. For example, although groups are confidential, there is a possibility that information discussed in group could be shared outside the group. Since this study uses video technology, there is a chance that group members do not maintain confidentiality at their location. Group member will be reminded about confidentiality of material prior to each group session. Another risk could be a data breach such as through hacking. We take every precaution we can to keep your data secure such as separating files with your name from files that have information about you (data), using password protection, enabling all available privacy and encryption modes when using video technology and saving documents behind the secure VA firewall. You will be notified if the risks for participating in this research change. We will

To further help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health of the United States Department of Health and Human Services. The Certificate of Confidentiality protects members of the research team from being forced, even under subpoena, to reveal your participation in this research in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Please note that a Certificate of Confidentiality does not imply that DHHS approves or disapproved of this research.

The protection offered by the Certificate of Confidentiality does not stop the research team from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threats of violence to self or others. If any member of the research team is given such information, he or she may be compelled to make a report to the appropriate authorities in accordance with applicable laws. Also, federal agencies may review study records under certain circumstances, such as a DHHS request for information for an audit, program evaluation, or investigation, or if release of this information is required under the Federal Food, Drug, and Cosmetics Act.

Even when a Certificate of Confidentiality is in place, you must still continue to actively protect your own privacy. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. Nor does it prevent you from giving the research team written permission to release information to whom you specifically approve the release of information. If you voluntarily give your written consent allowing the research team to reveal information about your participation in the research, then the research team may not use the Certificate of Confidentiality to withhold this information.

You will be asked to review, discuss, and sign another form that provides additional information about confidentiality efforts and the privacy of your health information, the form is titled Health Insurance Portability and Accountability Act of 1996 (HIPAA) Authorization. Some of the information in this consent form is repeated in the authorization form.

3. Social, Legal and Employment Risks: Should there be a breach of privacy, there is a chance that information you provide to us during the study could affect your social, legal, and employment status. Again, we will take steps to minimize these risks by the ways we handle this information.

4. Unknown Risks. There may be other risks that cannot be predicted.

BENEFITS

A potential benefit of being in the study is that you may acquire skills that might improve parent/child interpersonal relations. In addition, your participation may lead to knowledge that will help others with these problems in the future. Based on existing knowledge about Motivational Interviewing and research on psychological treatments, we believe that the potential benefits outweigh the potential risks and discomfort. It is ok if you do not agree and decide that you don't want to participate.

OTHER TREATMENT AVAILABLE

You may choose not to be in this study. If this is your decision, there are other treatments that you could get such as participating in individual therapy for PTSD, couples therapy, or other educational programs that could be helpful to you.

RESEARCH RESULTS

1. We (I) will let you know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study.

2. Taking part in this study will involve collecting private data about you. Data about you includes information in your medical record, your name, phone, and address, and your answers to the questions we ask. This data will be protected as mandated by local and national guidelines. Codes (not your name and social security number) will be used for all electronic data files and any reports generated, to help maintain your confidentiality. Your data will be combined with data from other people taking part in the study. If results of this study are reported in scientific journals or at meetings, we will write about the combined data we have gathered. Any talks or papers about this study will not identify you personally.

3. Data collected through the web-based survey application will be encrypted and stored on a secure server. These data will be entered into electronic databases that are stored on the VA's secure data server, behind the VA firewall. Audio recordings will be downloaded onto the secure server and stored in accordance with VA regulations at the time of data collection. The informed consent forms will be kept at the Waco VA in locked file cabinets in locked offices that are separate from where the data is being kept. Only the study staff will have access to these records.

4. De-identified copies of the data generated by this study may be transferred to other investigators conducting research in this area by request. A de-identified copy of the dataset will be transferred to the study PI (Dr. Creech) at her academic affiliate at the University of Texas at Austin.

1. Audio-recordings of the pre-treatment interview will be securely sent to Dr. Jordan Braciszewski at Henry Ford Healthcare System for analysis and coding. These audio files will be saved with code numbers only, password-protected, and stored on an encrypted device approved by Information Security and Privacy Officer at the Central Texas VA.

2. Any and all paper AND electronic documentation containing confidential, personally identifiable information, protected health information, and any other sensitive information will be disposed/destroyed according to current VA regulations at the time of disposal/destruction of documentation. Research files will be maintained, stored and destroyed in accordance with the Record Control Schedule (RCS-10-1) approved by the Archivist of the United States.

3. Your private information will be maintained according to this medical center's requirements. Your medical and research records will be maintained according to this medical center's requirements. There is a possibility that the Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), VA Office of Inspector General (OIG), Veterans Health Administration (VHA), Rehabilitation Research and Development (RR&D), other oversight agencies including the Office of Research Oversight (ORO), the Research Compliance Officer, Institutional Review Board members or other research staff may have access to your research and/or medical records or may inspect the records. Every effort will be made to keep information about you both private and confidential. Codes (not your name and social security number) will be used for all reports generated, to help maintain your confidentiality.

SPECIAL INFORMATION

1. You are not required to take part in this study: your participation is entirely voluntary. You can refuse to participate now or you can withdraw from this study at any time after giving your consent. Refusal to participate now or discontinuation of participation at any time will involve no penalty or loss of benefits to which you are otherwise entitled.

2. Veteran participants and non-Veteran participants do not pay for treatment associated with participation in a VA research project except in accordance with federal law. There will be no costs to you for any of the treatment or 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.

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3. VA must provide necessary medical treatment to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, the necessary care must be provided in VA Medical facilities. Exceptions include: situations where VA facilities are not capable of furnishing the care or services required; and situations involving a non-veteran research subject. Under these circumstances, Directors *may* contract for such care. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. All regulations pertaining to the participation of veterans as participants, including requirements for indemnification in case of research-related injury, pertain to non-veteran participants enrolled in VA-approved research. (For additional information on research related injuries, see 38 CFR 17.85). Please note that for Department of Defense-sponsored research, Department of Defense components may have stricter requirements than the Common Rule requirements for research-related injury.

4. **In case there are medical problems, research related injuries, or questions, you may call Dr. Suzannah Creech at 254-297-3025 or 512-495-5277 during the day and 979-255-6687 after hours. If any medical problems occur in connection with this study, the VA will provide emergency care.**

5. **Payment offered for participation. As being in this study requires time and effort, you will be paid for completing assessments and forms in the following amounts: $50 for the baseline assessment. If you meet eligibility for the study, you will be paid $10 per post-intervention assessment. You will be paid $50 for completing a post-treatment assessment for a total of $180.**

6. **Termination of Subject's Participation** In rare cases we may ask you to withdraw from the study. This would only be if we believed that the study was no longer in your best interest. Your treatment team would decide what treatment you would receive.

7. **Consequences of Withdrawal from the Study** Your decision whether or not to participate in this study, or a decision to withdraw will not involve any penalty or loss of benefits to which you are entitled. It is possible that your participation may provide no benefits to you directly or may result in a worsening of your symptoms. It is your decision whether you choose to continue or to discontinue participation. You may choose to stop your participation in this study at any time. If you choose to withdraw from this research study, please inform a member of the study team stating that you are choosing to withdraw from the study. This may be done by speaking to any study person in-person, calling any study personnel, sending a letter through the mail or delivering it by hand to the Central Texas VA Medical Center. The investigator and staff will provide appropriate referrals as indicated upon your withdrawal, if you choose.

8. **Future Use of Data** Once the study is completed, the data will be stored in a locked filing cabinet in the principal investigator's office behind a locked door. Electronic files will be stored under the VA firewall on a secure server. Only study personnel will have access to this data.

9. **Re-contact** You may be contacted and asked if you are interested in participating in future studies. You are not obligated to participate in any future studies.

10. **Disclosure of Results You will not receive a report of the aggregate results but may request them at a later date by contacting the PI.**

11. **As a research participant in this study, if you have a complaint about any issue regarding the study, or the research investigator; or, if you have questions about your rights as a research participant, you may contact** Institutional Review Board Chairperson at (254) 654-6758

CONFLICTS OF INTEREST

1. **The study is sponsored by** Rehabilitation Research and Development.
2. **The sponsor provides a fixed payment to the VA Hospital for performing the study**.

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RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above. _____ _____has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

I understand my rights as a research participant. I understand what the study is about and how and why it is being done. I voluntarily consent to participate in this study. I know I will receive a signed copy of this consent form.

_____ _____
Research Participant's Signature Date

_____ _____
Signature of Person Obtaining Consent Date

Date Last Revised: 8/5/2020

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