Official Title: Neural Control and Cardiac-Vascular Function in Women Veterans with PTSD

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Subject Name: _____ Date: _____

Title of Study: Neural Control and Cardiac-Vascular Function in Women with PTSD

Principal Investigator: Geetha Shivakumar, MD

Co-Investigator(s): Alina Suris, PhD, ABPP; Ellen Morris, PhD

Study Coordinators: Elizabeth Anderson, MRC; Jessica Wiblin BA; Kylie Sligar, B.S.

Before agreeing to take part in this research study, it is important that you read and understand the proposed research explained below. It describes the procedures, benefits, risks and discomforts of the study. It also describes other treatments that are open to you and your right to withdraw from the study at any time. It is important for you to understand that no promises can be made about the results of the study.

1. WHAT IS THIS RESEARCH STUDY ABOUT?

The purpose of this research is to look at the role of the sympathetic nervous system (responsible for the "fight-or-flight response") and heart health in women with and without posttraumatic stress disorder (PTSD). We also want to find out if exercise and healthy eating decreases this "fight-or-flight response," improves heart health, and improves psychiatric symptoms and quality of life in women Veterans with PTSD. This study is being done because research has shown that PTSD increases the risk of heart disease, but it is not known why. It is also unknown whether exercise and health eating can reduce heart health risks in women with PTSD. The expected duration of your participation is approximately 19 weeks.

This is a multisite study that is taking place at the Dallas VA and at the Institute for Exercise and Environmental Medicine (IEEM) at the Texas Health Presbyterian Hospital in Dallas. Texas Health Presbyterian Hospital is an affiliate of the University of Texas Southwestern Medical Center (UTSW). Research staff at the Dallas VA will do all the psychiatric assessments while the UTSW research staff will do all the physiological assessments and will provide education regarding exercise and healthy eating. This consent form is for the procedures to be done by the Dallas VA research staff only. You will be asked to sign a separate consent form for the physiological measurements and exercise and healthy eating education that will be done by the UTSW research staff at the IEEM.

The approximate number of research participants involved in this study is 20 people.
The Harry S. Moss Heart Trust is providing funding for this study.

SUBJECTS IDENTIFICATION (last name, first, middle and full SSN)

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2. WHAT WILL HAPPEN DURING THE STUDY?

If you volunteer to take part in this research study, you will be asked to sign two consent forms, one for the psychiatric assessments done by Dallas VA Research staff and another for the physiological procedures and education for exercise and healthy eating done by the UTSW research staff at the IEEM. The following table is a summary of visits, procedures, location, the time it takes to complete the visit and the staff doing the visit. Note: This consent is only for the procedures done at the Dallas VA by Dallas VA Research Staff. This table is an overview of the entire study done by both VA and UTSW staff.

Visit	Psychiatric Evaluation	UTSW Physical Screen	UTSW Visit 1	UTSW Visit 2	Weeks 2, 4, 6, 8, & 10 of 12 week intervention	Mental Health Follow Up	UTSW Visit 3	UTSW Visit 4
Location/Staff	**VA**	IEEM	IEEM	IEEM	Phone/**VA**	**VA**	IEEM	IEEM
Time Length	1.5 hours	1.5-2 hours	4-5 hours	2 hours	15 minute per phone call/1.25 hours total	1.5 hours	4-5 hours	2 hours

Screening Procedures

VA Screening Procedures

The initial screening visit will take place at the Dallas VA Medical Center. To help decide if you qualify to be in this study, researchers will ask questions about your psychiatric history including suicidal thoughts and general health, including questions about alcohol and drug use. Some questionnaires, such as mood and PTSD questionnaires, will be filled out by you. We will also ask you about psychiatric medications you take and psychiatric treatment you are receiving including group therapy and /or individual therapy. Your screening evaluation may last up to 90 minutes.

The specific procedures done during the screening visit are:

- A psychiatric evaluation to confirm your PTSD diagnosis. This will involve asking you to speak briefly about your most distressing traumatic life experience and answer questions about the frequency and intensity of PTSD symptoms.
- You will fill out PTSD, depression, suicidal thoughts and quality of life self-report questionnaires to determine the presence of symptoms and how severe they are.
- We will ask about your psychiatric medication and treatment status as well as general health information.

This visit will require 1.5 to 2 hours.

If the study team decides that you are still eligible to be part of the study, you will be scheduled for a screening appointment with the UTSW study team at the Institute for Exercise and Environmental Medicine in Dallas (IEEM). You will be asked to sign the UTSW consent form and they will ask you several questions. If they determine you are still eligible, you will complete visits 1 and 2 at the IEEM.

Group Assignment

After visits 1 and 2, You will be assigned randomly (like a flip of a coin) to receive either lifestyle modifications (exercise training and healthy eating) or no exercise and eating education. You will have a 50% chance (1 in 2) of receiving lifestyle modifications.

Regardless of which group you are assigned to, you will be contacted by VA researchers every two weeks while in the UTSW portion of the study. You will be given the same questions regarding symptoms of PTSD, depression, suicide, and quality of life that you answered in the screening portion of the study. These phone calls will last approximately 20 minutes.

Follow-Up Assessments

After 12 weeks, you will complete visits 4 and 5 at IEEM. You will be asked to meet with VA researchers to complete the mental health interview which includes the same interview and questionnaires you filled out the first VA screening. This final study appointment with Dallas VA researchers will last approximately 1.5 hours.

3. WHAT ARE MY RISKS?

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Psychological Stress: Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break or stop your participation in this study at any time. Our research staff are experts in assessing and treating PTSD and will work with you if you become upset.

Loss of Confidentiality: The risk of participation in this research activity could result from an unintentional release of confidential (sensitive) information. However, this will be minimized by maintaining all information that could identify individual patients including signed consent forms in a locked file cabinet which are, in turn, stored in a locked office and on the password-protected VA network server. Any information that is obtaining in this research that can be identified with a patient will remain confidential within the limits of the privacy law, and will only be disclosed with the patient's written permission. Only the research personnel will have access study confidential identifying information.

Unforeseen risks: A previously unknown problem could result from your taking part in this research. It is not possible to estimate the chances of such problems or how serious the problems could be. Any new findings will be given to you that may affect your willingness to take part in this study. If new findings are discovered, you will be asked to sign a new (updated) informed consent form to document that new information provided in the updated Consent Form has been explained to you.

4. WILL THE RESEARCH BENEFIT ME OR OTHERS?

If you agree to take part in this study, there may or may not be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research. Women with PTSD assigned to Lifestyle Modifications group may see improvements in physical and mental health over the course of the 12-week study.

We hope the information learned from this study will benefit other women with PTSD in the future. Information gained from this research could lead to a better understanding of the impact of PTSD on heart health risk and whether lifestyle modifications, such as exercise and health eating, can reduce this risk.

5. WHAT ARE MY ALTERNATIVES TO BEING A RESEARCH SUBJECT?

You do not have to participate in this research to receive care for your medical problem. If you decide not to participate in this study, you will be provided with appropriate referrals. Alternative treatments include:

- Psychotherapy (talk therapy)
- Medication(s)
- Begin an exercise program, after discussion with your doctor, without participation in this research.

Please talk to the study clinicians or your personal doctor about these options.

6. WILL I GET PAID?

Yes. Texas Health Presbyterian Hospital Dallas will pay you $25.00 per hour for completion of ***UTSW Visit #2, #3, #4*** and ***#5***. There is no payment for the mental health or physical screenings. If you are randomized to the Lifestyle Modifications group, you will receive a free membership to a fitness club for 12 weeks. If you stop taking part in this study or are withdrawn by the research team, you will receive payment for only the testing you have completed.

There are no funds available to pay for parking expenses, transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

Your Name and Social Security Number must be disclosed to UT Southwestern Medical Center and Texas Health Presbyterian Hospital Dallas employees in order to process any payments to you.

7. WILL I HAVE TO PAY?

Participants do not pay for treatment associated with participation in a VA research program.

8. DOES BEING PREGNANT OR THE POSSIBILITY OF BEING PREGNANT PREVENT ME FROM TAKING PART?

There are no contraindications for the possibility of pregnancy for taking part in the study. Should you become pregnant, we will work with your obstetrician and the UTSW research exercise physiologists to adjust your exercise routine if needed.

9. WHAT IF I GET INJURED?

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The VA has the obligation to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in the VA portion of the study, the VA will provide the necessary medical treatment in accordance with federal law.

10. ARE MY RESEARCH RECORDS SAFE FROM THE PUBLIC?

The study doctors keep your research records private in the same way as your other medical records. No one has access to your records except as required by law. You are, however, authorizing The University of Texas Southwestern Medical Center, Texas Health Presbyterian Hospital Dallas – Institute for Exercise and Environmental Medicine, the Dallas VA Institutional Review Board (IRB), the Dallas VA Research and Development Committee and the members of the Dallas VA Research Office to inspect your medical and research records. These committees, people, and offices at the Dallas VAMC are responsible for overseeing human research studies.

If you choose to take part in the study, certain government agencies (such as the FDA or VA) may look at your research records.

This is a collaborative study that will combine VA research activities and data with UTSW and Institute for Exercise and Environmental Medicine (non-VA) research activities and data. Information about you may be combined with information from other people taking part in this study, both at the VA and at an affiliate site, to allow us to write about the combined data we have gathered. Your name as a subject in this study is private, and will not be included in any report prepared as a result of this study.

11. DO I HAVE TO TAKE PART IN THIS STUDY, OR CAN I WITHDRAW FROM THE STUDY?

Taking part in this study is voluntary and you may refuse to take part without penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw your consent and stop taking part at any time. Not taking part in the study will in no way affect the quality of care you receive now or in the future from the VA. This will also not affect your right to take part in other studies. The study doctors will answer any questions you may have about the study.

Your doctor may also take you out of the study without your consent for medical or administrative reasons. Any significant new findings that develop during the course of the research study that the

study doctor thinks may affect your willingness to continue to take part will be given to you as soon as possible.

12. WHOM SHOULD I CONTACT FOR QUESTIONS OR PROBLEMS?

If you have any questions about this study or have any bad effects of your treatment, you should call Dr. Alina Suris or a member of the research team at 214-857-1014. You should also contact the study doctor or a member of the research team to discuss problems, concerns you may presently have, or offer input about the research.

If you have any questions about whether this is a VA North Texas Healthcare System-approved research study, you may contact the Research Compliance Officer at 214-857-0341.

If you have any questions about your rights as a patient, complaints about your treatment or general concerns about the conduct of the research study, of if you have questions, complains, concerns you may contact the Dallas VAMC Patient Representatives at 214-857-0482. The Patient Representative will guide you in resolving your question or complaint.

If you have a medical emergency you should immediately call 911 for assistance.

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RESEARCH SUBJECT'S RIGHTS:

I have read or have had read to me all of the above. The study has been explained to me and all of my questions have been answered. If I have questions later, it has been explained to me that I can contact Dr. Alina Suris. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment open to me.

It has been explained to me that I do not have to take part in this study and my refusal to take part will involve no penalty or loss of rights to which I am entitled. I may withdraw at any time without penalty or loss of VA or other benefits to which I am entitled. The study doctor can take me out of the study at any time if it appears to be medically harmful to me, if I fail to follow directions for taking part in this study, if it is discovered that I do not meet the study requirements, or if the study is canceled.

In case there are medical problems or questions, I have been told I can call Dr. Alina Suris or a member of the study team at 214-857-1014 during the day or at 800-725-4436 after hours.

I was informed of my rights as a research subject, and I voluntarily consent to take part in this study. I authorize the use of my identifiable patient health information as described in this form. I will receive a signed copy of this consent form.

_____	_____
Participant's Signature	Date

_____	_____	_____
Name of person obtaining consent	Signature of person obtaining consent	Date

Research Subject's Bill of Rights

1. Be informed of the nature and purpose of the research.

2. Be clearly told of the procedures to be followed in the medical research, and any drug or device to be used.

3. Be clearly told of any discomforts and risks that might be expected from the research.

4. Be clearly told of any benefits that the patient might expect from the research.

5. Be clearly told of any other appropriate procedures, drugs, or devices that might be helpful to the patient, and their risks and benefits.

6. Be clearly told how to get medical treatment, if needed, after the research is finished if problems should arise.

7. Be given the chance to ask any questions about the research or the procedures involved.

8. Be clearly told that consent to take part in the medical research and/or release of identifiable patient health information may be taken back at any time. The patient may stop taking part in the medical research without any penalty or loss of VA or other benefits.

9. Be given a copy of the signed and dated written consent form.

10. Be given the chance to decide to consent or not to consent to a medical research study without any force, fraud, deceit, duress, coercion, or undue influence on the patient's decision.