ATLANTA VA Health Care System
Consent to be a Research Subject

TITLE: A Randomized Controlled Trial Comparing Trauma Center-Trauma Sensitive Yoga and Cognitive Processing Therapy for PTSD and Associated Symptoms in Women Veterans

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SPONSOR'S NAME: Veterans Affairs Administration

INTRODUCTION/PURPOSE:
You are being asked to volunteer in a research study because you have been diagnosed with PTSD related to military sexual trauma (MST), are interested in treatment for your PTSD symptoms and also experience insomnia (difficulty sleeping) and possibly chronic pain. This study is being conducted by Dr. Ursula Kelly, a Nurse Practitioner in the Atlanta VA Trauma Recovery Program (TRP), in order to compare two different types of treatment for women with PTSD related to MST.

One treatment group in the study is the **experimental group**, meaning that more information is needed through research studies like this to better understand the impact of the treatment on PTSD symptoms. The experimental group in this study is a type of yoga known as **Trauma Center-Trauma Sensitive Yoga (TC-TSY).** The other treatment group will serve as a comparison or **control group**. In this study, the control group will receive an evidence based treatment called **Cognitive Processing Therapy (CPT).**

You will be randomly chosen (like the flip of a coin) to take part in the TC-TSY group **OR** the CPT group. The study team does not have control over which group you will be assigned. At the end of the study, information collected from the two groups will be compared to see how the groups differ in regards to helping women with PTSD. There are five assessment visits that take place while you are in the study (described in detail in the next section) in addition to the weekly treatment sessions. If you complete the study, your participation will last up to seven months. At the end of the study, you will be given the option to participate in whichever group you did not complete the first time (i.e., CPT will be offered to those who completed TC-TSY and vice versa). We will ask that you complete some questionnaires prior to treatment, midway through treatment and after treatment.

We hope to enroll 210 women Veterans from the Atlanta VA Health Care System (AVAHCS) over the next three years. If you decide to participate, you will be asked to complete this screening visit to see if you qualify for the study.

PROCEDURES:
Please read this consent form. Before you decide to take part, discuss any questions or concerns with the research team. If you agree to be in this study, you will need to sign and date this consent form and the HIPAA form before completing anything else. All visits and procedures will either occur at the Atlanta VA Health Care System, located at 1670 Clairmont Road (5th floor lab, or the Clinical Studies Center), *OR* the AVAHCS Trauma Recovery Program, located at 2296 Henderson Mill Road, Suite 402 (Henderson Mill Annex). Prior to each visit, study staff will provide information about where each visit will occur and any special instructions. Note: If you complete a study visit or procedures at the Henderson Mill location, data will be transported back to the main VA in a locked bag and those records will then be stored in a locked office.

If you participate in the study, the following visits and study procedures will occur in addition to your participation in treatment (TC-TSY or CPT):

TIMELINE OF STUDY VISITS

TIME 0: Screening/Consent Visit
Duration: **1.5-**2 hours
When: This is the first study visit you will complete.

Information gathered during this visit will be used to determine if you are eligible to continue in the study.

At this visit, after you have signed this form and the HIPAA form, you will be asked to meet with study staff to complete several questionnaires and interview-based assessments about your mental health/history and medical information.

TIME 1: Enrollment/Randomization Visit
Duration: 2-3 hours
When: This visit will occur before your first group session. In some cases, the Screening/Consent Visit and the Enrollment/Randomization Visit will occur on the same day. If this is the case, you will receive compensation for both visits.

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At this visit you will:

- Meet with study staff to complete several questionnaires and review any changes to your medications and health since the first visit.
- Participate in a psychophysiological task (this is described in more detail at the bottom of page 3).
- Have a blood sample taken (~2 teaspoons) to measure the level of inflammation in your body.
- Have an electrocardiogram (ECG) which measures the activity of your heart
- Be randomly assigned to TC-TSY or CPT after the above study procedures have been completed.
- Be given a take-home device called the “Bodyguard” (and instructions) that you will wear continuously for two days which will measure information about your heart rate.

TIME 2: ***Mid-Intervention Visit***
Duration: 1-2 hours
When: This visit will occur midway through your group sessions. If you are in the yoga group, you will come in for Time 2 between the 5th and 6th sessions. If you are in the CPT group, you will come in for this visit between the 6th and 7th sessions.

At this visit you will be asked to:
- Meet with study staff to update any changes in your medications or health status that have occurred since your previous visit and answer interview-based questionnaires
- Fill out questionnaires

TIME 3: ***2-Weeks Post-Intervention***
Duration: 2-3 hours
When: This visit will occur approximately 2 weeks after your last group session.

At this visit you will be asked to:
- Meet with study staff to update any changes in your medications or health status that have occurred since your previous visit and answer interview-based questionnaires
- Fill out questionnaires
- Participate in a psycho-physiological task.
- Have a blood sample taken (~2 teaspoons).
- Have an ECG.
- Wear the Bodyguard for two days and then return to study staff.

TIME 4: ***3-Month Follow-Up***
Duration: 2-3 hours
When: This visit will occur approximately 3 months after your last group session.

At this visit you will be asked to:
- Meet with study staff to update any changes in your medications or health status that have occurred since your previous visit and answer interview-based questionnaires
- Fill out questionnaires.
- Participate in a psycho-physiological task.
- Have a blood sample taken (~2 teaspoons).
- Wear the Bodyguard for two days and then return to study staff.
- Decide if you would like to participate in the group to which you were not assigned initially. If you opt out of this option, no other visits or procedures will occur. If you complete the second treatment group, you will be asked some questions about both groups and complete several questionnaires.

Description of the Psychophysiology Task
We will collect psychophysiological data at three visits. During this task, we will measure your body's response to sounds presented in our lab (via headphones). The responses we will measure include your heart rate, breathing, skin conductance (a measure of the sweat on

your palms) and your startle response (how strongly you blink your eyes in response to sounds). By measuring the strength of your eye-blink, we are able to see how easily you get startled. People with PTSD tend to have a stronger startle response than those without PTSD and one way to see if your symptoms are getting better over time is to look at changes in this response. By measuring your heart rate and skin conductance, we are able to gather additional information about your response to the cues we present.

We will measure these responses by placing electrodes--tiny metal discs with wires attached to them--on your skin. These electrodes will record information about your responses and send that information to a lab computer. Before placing the electrodes, a research member will clean the following areas with alcohol and/or a gritty gel: the left forearm, the right collarbone, and just below your right eye. The electrodes will then be placed below your eye and on your arm, collarbone, and fingers. Next, a brief hearing test will be conducted.

During this task, you will be seated in a sound-proof booth and given instructions for the task. Next, you will hear sounds through headphones while lights in the booth switch between “on” and “off.” The task lasts 10 minutes. You can end the task at any time for any reason.

Description of the ECG
At the Baseline Visit and again at Time 3, you will have an electrocardiogram (ECG) to test how your heart is working. During this procedure, your heart will be monitored by 12 leads connected to electrodes placed on your skin (chest, wrists and ankles). The ECG will be done by trained study staff and you will be informed of the results.

Audio Consent
While in the study, clinical interviews and treatment sessions may be recorded for research purposes. You will be informed of this before the interview/session takes place. The recordings will be used to make sure that all members of the research team are conducting the assessments correctly and according to the protocol. These recordings will not be disclosed outside the VA.

RISKS

Questionnaires/interview-based assessments:

- Some of the topics in the questionnaires and interviews may bring up painful emotions, such as sadness, worry, or anxiety.
- If you have trauma-related stress symptoms, you may have an increase in nightmares or flashbacks that relate to this.
- You are free not to answer any questions you wish and this will not impact your participation in the study.
- The risks involved with these questionnaires and interviews are somewhat likely. Steps will be taken to minimize the risk and provide support should you experience painful emotions or an increase in stress symptoms.

Psycho-physiological task:

- The volume levels and duration of the sounds you will hear through the headphones are not enough to cause any damage to the ear.

- If you find the noises uncomfortable, the session will be stopped immediately at your request.
- With regard to risk of discomfort associated with the darkness, the session will be stopped immediately at your request if you are uncomfortable with the darkness.
- Adhesives from the electrodes and the gels used to clean your skin may cause irritation, redness or mild swelling.
- The risks associated with this task are somewhat likely and, if experienced, should resolve shortly after the task is stopped

Heart Rate Variability

- There may be some temporary discomfort (redness, itching) at the site where the HRV electrodes are placed (collarbone and ribcage). In the event that this occurs, discomfort should subside within 1-2 days.

ECG

- There may be some temporary discomfort from the ECG stickers (electrodes) on the skin.

Venipuncture (blood draw):

- The blood draw may cause discomfort, bruising, redness, or mild swelling.
- Some individuals experience mild skin irritation with certain types of skin tape. Please notify the person performing the blood draw if you experience or have a history of skin irritation related to tape or bandages. Other forms of tape can be used to minimize or eliminate the risk of irritation.
- These procedures are only done by skilled personnel in order to reduce the risk of any negative reactions.
- The risks associated with the blood draw are unlikely and, if they occur, should resolve within a few days.

Trauma Sensitive Yoga (TC-TSY) intervention group:

- Because TC-TSY poses stretch and contract muscles and joints, you may experience some muscle or joint soreness in the beginning.
- This discomfort is generally mild and improves with practice.
- If you experience ongoing soreness or any pain, please tell the yoga teacher so that your poses can be modified. TC-TSY postures should not hurt.
- The risks associated with TC-TSY are somewhat likely depending on your past experience with yoga. Any soreness that occurs should improve and within a few weeks.

Cognitive Processing Therapy-Cognitive (CPT) intervention group:

- There is a moderate risk that the questions and topics discussed in the group may bring up painful emotions, such as sadness, anxiety, or depression.
- Please let the group leaders know if you are experiencing any of these emotions. They are available to help you process these emotions in the group or on a one-on-one basis, if needed.

Pregnancy:

- If you are pregnant or become pregnant while in the study, please inform the study staff.

- There are no known risks of Trauma Center-Trauma Sensitive Yoga or cognitive processing therapy to a fetus.
- If you are participating in the yoga intervention, modifications to the poses will be made if indicated.

Unknown:

- There may be unforeseeable risks associated with the interventions. It is very unlikely that any of these risks would be significant or not resolve completely within a few weeks.

You may stop being in the study at any time. This will not in any way affect your future medical or mental health care at the VA.

BENEFITS

Trauma Sensitive Yoga intervention:

- TC-TSY postures stretch muscles and joints. This may improve your strength and flexibility.
- TC-TSY breathing and relaxation exercises may improve your sleep and reduce your symptoms of PTSD, anxiety and stress.
- This type of yoga is tailored for all levels of participants. Most people can participate regardless of prior experience or physical condition.

Cognitive Processing Therapy-Cognitive intervention:

- CPT is an evidence-based psychological treatment for PTSD.
- This type of therapy may provide you with new ways of handling distressing thoughts.
- CPT may help you learn how trauma impacts the way you look at the world, yourself, and others and how these things directly affect how you think and act.
- Group therapy can provide a sense of belonging and lessen feelings of isolation.

Taking part in this study may not benefit you personally, but we may learn new things that will help others.

ALTERNATIVES

You do not have to be in this study to receive the treatment you are receiving for your PTSD, insomnia, and pain. You may continue to seek counseling and/or psychiatric treatment through the Trauma Recovery Program or discuss alternative treatments with your doctor.

CONFIDENTIALITY

We will keep information about you strictly confidential. The study staff will keep your study files locked in a file cabinet in a locked private office. People other than those doing this research study may have access to your medical and study records including:

- Veterans Administration
- Sponsors, companies or agencies paying for the study
- The Office for Human Research Protections
- The Government Accountability Office (GAO)

- The Office of Research Oversight (ORO)
- The Inspector General
- The Emory University Institutional Review Board and other offices in Emory University that help run and/or oversee studies
- The Atlanta Research and Education Foundation (AREF)
- The Atlanta VA Research Compliance Officer
- VA research staff within the VA Hospital or at Emory University (when data is stored at Emory)
- Any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above.
- De-identified data will be shared with co-investigators and consultants outside of the VA.

We will keep your records private to the extent required by law. However, we may be required to release your record if we receive a subpoena or a court order. We will use a study number rather than your name on study records. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Information about a suspicion of child or elder abuse or neglect will be reported to the Department of Family and Children's Services. If you tell us that you are going to hurt yourself or anyone else we may have to violate confidentiality to maintain the safety of you or someone else.

All research records and/or identifiers will be destroyed in accordance with the VA record retention schedule. You can request that your blood samples be destroyed at any time; submit this request in writing to Dr. Ursula Kelly. If you are a veteran who is a patient at the Atlanta VA Health Care System, a copy of your signed and dated consent and HIPAA forms may be placed in your medical record(s). If you are a non-veteran receiving clinical services (i.e., use of the laboratory, radiology, audiology, etc.) as part of this study, you will have an electronic medical record created for you. You will also be given a VA Notice of Privacy Practices (NOPP), and we will ask you to sign a form saying that you have received this notice.

If you are participating in a study where a test and/or procedure may be performed at Emory and you are not and have never been an Emory patient, you do not have an electronic medical record. Please note that an Emory medical record will be created if you have any services or procedures done by an Emory provider or facility for this study.

If you are in an FDA sponsored clinical trial: 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.

COMPENSATION

You will receive compensation for your time and effort related to the study. You will receive $40 each for the Screening/Consent, Baseline/Randomization and Midpoint Visits and $60 each for the two post-treatment visits. You will receive $15 for each treatment session that you attend. You will receive compensation in the form of a check or direct deposit, whichever you decide. Payment forms will be processed once you have completed a study visit or treatment session. For visits when you are given a heart rate monitor to take home, payment will be processed on the day that the device is returned to study staff. If you take part in the crossover intervention, you will not be compensated for those sessions or the questionnaires. Checks are mailed within 4-6 weeks of being processed. Direct deposits are typically made within 2-3 weeks of being processed. Depending on which group you are in, the total possible compensation you could receive if you complete all assessments and treatment sessions is $390-$420. *If you have to return to the VA to complete a study visit and this is due to limited study staff or other reason attributed to the study team, you will receive additional compensation of up to $20.*

You will get emergency medical care if you get injured from being in this study. Under Federal Law, you will qualify for follow-up treatment if the injury was related to the research study. You may or may not get further compensation if you are injured in this study. This rule would not apply if you do not follow study procedures. If you believe you have been injured by this research, you should contact Dr. Ursula Kelly at 404-321-6111, x202340.

CONFLICT OF INTEREST

None

COSTS

There will be no cost to you for being in this study.

Some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services that are not part of this study.

CONTACT PERSONS

If you have any questions, concerns, or complaints about this study you can call a member of the study staff: *Dr. Ursula Kelly at 404-321-6111, x202340*

If you have been harmed from being in this study call: *Dr. Ursula Kelly at 404-321-6111, x202340*

If you want to speak to someone who is not a member of the study to discuss problems, ask questions or voice concerns, you can call:

The Emory University Institutional Review Board (404) 712-0720 or toll free at 1-877-503-9797

Or

The Research Compliance Officer at (404) 321-6111 ext. 206964 or the Clinical Studies Center Director at (404) 321-6111 ext. 206933

If you have any questions about your rights as a participant in this research study, call the Emory University Institutional Review Board at (404) 712-0720 or toll free at 1-877-503-9797.

NEW FINDINGS

We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

The study doctors have the right to end your participation in this study for any of the following reasons: If it would be dangerous for you to continue, if you do not follow study procedures as directed by the study doctors, or if the sponsor decides to end the study.

Your participation is voluntary and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled. The study doctor/investigator and/or sponsor may stop you from taking part in this study at any time if they decide it is in your best interests or if you do not follow study instructions.

We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign on the following page.

RESEARCH PARTICIPANT'S SIGNATURE AND DATE

_____
Research Participant's name

_____ _____ _____
Research Participant's Signature Date Time
(to be entered by participant)

_____
Name of Approved Individual Obtaining Consent

_____ _____ _____
Signature of Approved Individual Obtaining Consent Date Time
(to be entered by Approved Individual)

An Approved individual is one who has completed HRPP training and is officially approved to consent subjects for this specific study. The signature and date of this individual certifies that this is the most current approved consent document for this study.