ClinicalTrials.gov Document Upload

DOCUMENT DATE (IRB APPROVAL):

26-Oct-2023

NCT NUMBER:

NCT05938816

OFFICIAL STUDY TITLE:

Feasibility and acceptability of stress induction, physiological data collection, and Mindfulness-Based
Stress Reduction among combat veterans with PTSD

INVESTIGATOR NAME:

Josh Kaplan, PhD, MCR

ORGANIZATION:

Oregon Health & Science University

IRB Approved: 10/26/2023
Approval Expires: 6/5/2026

OREGON HEALTH & SCIENCE UNIVERSITY

IRB#: 25508

CLINICAL RESEARCH CONSENT AND AUTHORIZATION SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: Feasibility and acceptability of stress induction, physiological data collection, and Mindfulness-Based Stress Reduction among combat veterans with PTSD

PRINCIPAL INVESTIGATOR: Joshua Kaplan, PhD, MCR *(503) 494-5650*

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not.

PURPOSE:

The purpose of the study is to learn about how mindfulness meditation may be helpful in treating posttraumatic stress disorder (PTSD). This is a randomized intervention trial that compares mindfulness meditation intervention also called Mindfulness-Based Stress Reduction (MBSR) to a discussion group that provides instructions on improving emotional and physical health or Health and Wellness Education (HWE) Intervention. We are hoping to find out if MBSR may improve PTSD symptoms, and physical reactions to stress and if the veterans find it acceptable.

DURATION:

Your participation in the study will consist of 9 intervention visits (8 weekly 150- minute sessions and 1 longer session that will take approximately 7 hours where you will receive either mindfulness intervention or health and wellness education. Additionally, there will be 3 laboratory visits which will take approximately two hours. Finally, there will be a focus group at the conclusion of the interventions.

PROCEDURES:

If you decide to participate, you will receive either the mindfulness intervention or the health and wellness education intervention.

You will have the following procedures during the study which will be conducted in a laboratory at OHSU:

1. Survey questionnaires asking about PTSD symptoms, mindfulness, resilience, stress.
2. Connection to small sensors that will record your breathing rate, heart rate and blood pressure
3. Arithmetic task on a computer

Following conclusion of the interventions, you will be requested to participate in a focus group with your fellow participants that will last approximately 2 hours where you will be asked questions about your experience with the interventions.

You will be encouraged to complete 30- minute home-practice sessions (self-guided meditation practice) or health and behavior changes depending on the group you are assigned to during your participation in the study.

RISKS:

You may experience some mild distress when reporting their PTSD symptoms. You may feel some discomfort or embarrassment discussing general experiences during the intervention. You may experience some frustration when completing the arithmetic task on the computer.

BENEFITS:

You may find it rewarding to engage in group-based interventions in which you are encouraged to share your experience with other veterans with similar struggles related to PTSD symptoms. If asked to participate in mindful medication, you may learn strategies for coping with stress and PTSD symptoms. You may also experience reduction in symptoms of PTSD, depression and anxiety as a result of participating in mindfulness meditation.

ALTERNATIVES:

You may choose not to participate in this study, may receive standard treatment; or participate in another study if one is available.

This is a voluntary research study. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the Investigator if you have any questions about the study or about this consent form.

END OF CONSENT SUMMARY

IRB Approved: 10/26/2023
Approval Expires: 6/5/2026

OREGON HEALTH&SCIENCE UNIVERSITY

IRB#: 25508

Research Consent and Authorization Form

TITLE**:** Feasibility and acceptability of stress induction, physiological data collection, and Mindfulness-Based Stress Reduction among combat veterans with PTSD

PRINCIPAL INVESTIGATOR: Joshua Kaplan, PhD, MCR (503) 494-5650

WHO IS PAYING FOR THE STUDY?:
NIH National Center for Advancing Translational sciences

DO ANY OF THE RESEARCHERS HAVE A CONFLICT OF INTEREST WITH THIS STUDY?:
No researchers or study personnel have a conflict of interest with this study.

WHY IS THIS STUDY BEING DONE?:
You have been invited to be in this research study because you are a veteran who is experiencing PTSD symptoms. The purpose of this study is to learn how mindfulness meditation compares to health and wellness education that might help veterans better manage symptoms like yours.

The mindfulness meditation we are studying is experimental and we want to learn more if this is an acceptable method and how it can be improved. We do not know if it is better than the usual approach (Health and Wellness Education Intervention) for treating physical responses to stress in veterans with PTSD symptoms.

This study requires 8 weekly intervention visits where you will receive one of the randomized interventions you are assigned to and one extended session or a retreat. In addition, there are 3 visits to the lab that will include completion of survey questionnaires, completion of an arithmetic test and the recording of blood pressure, heart rate and respiration. All interventions and data collection will take place at OHSU. At the conclusion of the interventions, you will participate in a one-time focus group with fellow participants.

A total of 20 Veterans will be enrolled in the study that will be conducted at OHSU.

WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?

During your visit:

9 intervention visits: (150 minutes)

1. Mindfulness meditation or health and wellness education intervention: You will be randomized to receive either a brief mindfulness meditation or health and wellness education intervention. There will be an extended session or a retreat at the end of week 8 which will take approximately 6.5-7 hours. This retreat will involve longer and more intensive mindfulness practice for the MBSR group and an extended trip to a community site for the Health and Wellness intervention group.

3 laboratory visits: (120 minutes)

2. Survey questionnaires: We will ask you to complete a set of questionnaires in the laboratory. They will ask questions about your PTSD symptoms, mindfulness experience, stress, and others.
3. Connection to physical data recording devices: We will connect you to a set of small sensors that will measure and record your breathing rate, blood pressure, and heart rate.
4. Arithmetic task on a computer
5. Clinician-administered interview

Focus group: (120 minutes)

Following conclusion of the interventions, you will be asked to participate in a focus group with your fellow participants that will last approximately two hours. During this interview, study personnel will ask you various questions about your experience during the intervention. This interview will be recorded for data collection, but you will not be identified in any way. You will not be able to inspect the recordings before they are released.

Home-Practice assignments:

You will be requested to complete 30-minute daily practice-sessions involving self-guided meditation practice if you are in the mindfulness meditation group throughout your participation in the study. You will receive audio CDs and a DVD to help guide meditation practice. If you are in the health wellness education intervention group, you will also be expected to complete homework regarding health behavior changes throughout your participation in the study.

Study Schedule

Visits	Lab visit 1	Wk1[b]	Wk2	Wk3	Wk4	Wk5/ Lab visit 2	Wk6	Wk7	Wk8/ Lab visit 3	Retreat	Post-interven-tion Wk9
Informed consent	X										
MBSR/HWE[a]		X	X	X	X	X	X	X	X	X	
Study Visit Questionnaires[c]	X					X			X		
Clinical - administered interview	X					X			X		
Vitals	X					X			X		
Arithmetic test	X					X			X		
Focus group interview											X

Approximate total time	120 mins	150 mins	150 mins	150 mins	150 mins	270 mins	150 mins	150 mins	270 mins	7 hours	120 mins

a. Participants are randomized at week 1 to either MBSR or HWE. 30-minute home practice assignments daily.
b. Week 1 of the interventions will occur within one week of completing Lab Visit 1 for all participants.

This is a randomized study. Neither you nor the investigator can choose what you are assigned to receive as this is done by a computer

In the future, your data may be given to researchers for other research studies. The information will be labeled as described in the **WHO WILL SEE MY PERSONAL INFORMATION?** section.

WILL I RECEIVE RESULTS FROM THIS STUDY?

You will be given the opportunity to view their heart rate and blood pressure when it is taken at the laboratory at baseline, unless you prefer not to. However, if you demonstrate pathological blood pressure during the course of the study, you will be notified and referred to your primary care provider or urgent care. If your blood pressure reaches hypertensive crisis, you will be referred to the emergency department. You would be responsible for all costs associated with any follow-up testing and medical care.

While the study is in progress, we do not plan to share your any other individual data with you or anyone other than approved members of the study team because it is outside the purpose of this research to manage or share data on an individual level, and we simply do not have the time and resources to do so. The research is still in an early phase and the reliability of the results is unknown. We interpret the data when we combine all subjects' data together, and if you are interested in the findings, we encourage you to search for articles published by the lab in the future. (Search http://scholar.google.com for "Joshua Kaplan,OHSU"). Once the study is complete, with your permission, we will share your data in a repository.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?:

The questionnaires may cause fatigue and some emotional stress. Some of the questions may seem personal or embarrassing. Some of these questions may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions that you do not wish to answer. If the questions make you very upset, we will help you to find a counselor.

The devices used to measure heart rate, breath rate, and blood pressure may be mildly uncomfortable. Remaining seated and still for the duration of the study visit may cause slight discomfort.

Although we have made efforts to protect your identity, there is a small risk of loss of confidentiality. If the results of these studies were to be accidentally released, it might be possible that the information we will gather about you as part of this study could become available to an insurer or an employer, or a relative, or someone else outside the study. Even though there are certain discrimination and confidentiality protections in both Oregon law and federal law, there is still a small chance that you could be harmed if a release occurred.

WHO WILL SEE MY PERSONAL INFORMATION?

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. We will be assigning codes that will be used instead of any personal identifier that could identify you like your name or your medical record number.

We will create and collect health information about you as described in the WHY IS THIS STUDY BEING DONE? and the WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY? sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study and store in a repository, conduct future research.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The funder of this study National Center for Advancing Translational Sciences
- The Office for Human Research Protections, a federal agency that oversees research involving humans

Those listed above may also be permitted to review and copy your records.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

To help us protect your privacy, we will obtain a Certificate of Confidentiality to protect your privacy even from people who try to get your information using a court order. One exception is if you agree that we can give out research information with your name on it. Another exception is information about child or elder abuse or neglect and harm to yourself or others or communicable disease reporting. Note that this doesn't prevent you from releasing the information yourself.

Under Oregon law, suspected child or elder abuse must be reported to appropriate authorities.

OHSU complies with Oregon state requirements for reporting certain diseases and conditions to local health departments.

When we send information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your specimens or information could be used and re-released without your permission.

We may continue to use and disclose your information as described above indefinitely.

WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT?

Information including audiotapes about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY
There will be no cost to you or your insurance company to participate in this study.

You may receive up to $125 via for participation in this research study. $20 gift cards will be given at each laboratory visit and post intervention visit (4 totalx20=$80), and $5 will be added for each intervention session attended and retreat (9 totalx5=$45) for a total possible compensation amount of $125. Compensation will be prorated for completed visits. If you withdraw from the study at any time, you will be compensated for the visits you completed.

You may receive payment via a debit card or a clincard. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in a separate card member agreement and FAQ sheet.

We may request your social security number in order to process any payments for participation.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?:
If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact study team at (503) 593-3421.
If you are injured or harmed by the study procedures, you will be treated. OHSU and the funder, do not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.
If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.
This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

WHERE CAN I GET MORE INFORMATION?:
If you have any questions, concerns, or complaints regarding this study now or in the future, contact PI Joshua Kaplan, (503) 494-8181 or other members of the study team at (503)-593-3421.

This research has been approved and is overseen by an Institutional Review Board ("IRB"), a committee that protects the rights and welfare of research subjects. You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

WHAT ARE MY RESPONSIBILITIES IN THIS STUDY?
You will be requested to complete study logs while at home for the duration of the study.

DO I HAVE TO TAKE PART IN THIS STUDY?
Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

We are asking you to provide information for a data bank, also called a repository. This information will be stored indefinitely and may be used and disclosed in the future for research. You may opt out of your information's storage in this repository.

We would like your permission to save the data collected in this study in the Oken Cognitive Neuroscience Laboratory Repository (IRB#7436). A research repository collects and stored data for use in future research. Data stored the repository may be shared with other investigators for future research studies. A code number will be assigned to your information Other investigators who may receive your information for research will be given only the code number which will not identify you. Information will be stored in the repository indefinitely. Storing your data in the repository is optional. You can choose not to store your data in the repository but still participate in the rest of the study.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?
If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. You can choose to withdraw from the optional part of this study without withdrawing from the whole study. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study or change which parts of the study you are participating in.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Josh Kaplan, PhD (kaplajos@ohsu.edu)
3181 SW Sam Jackson Park Road

CR-120
Portland, OR 97239

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If in the future you decide you no longer want to participate in this research, we will remove your name and any other identifiers from your information, but the material will not be destroyed and we will continue to use it for research.

You may be removed from the study if the investigator or funder stops the study, you do not follow study instructions, etc.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

SIGNATURES:

PARTICIPANT OPTIONS
The optional portions of this study are described in detail throughout this consent form and listed here as a summary. Please read the options and place your initials next to *your choices/one of the choices below*]. You can still participate in the main part of the study even if you choose not to participate in the optional parts.

_____ I give my consent for my data and information to be stored in a repository and used for future research studies.

State: Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

Subject Printed Name	Subject Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date