A Sleep Intervention to Improve Rehabilitation in Veterans with Chronic mTBI

NCT03785600

November 15, 2023

Subject Name: _____ Date: _____

Title of Study: A sleep intervention to improve rehabilitation in Veterans with TBI.

IRB Number: 4002
Principal Investigator: Jonathan Elliott, PhD ICF Version Date: 11/02/2023

WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?

About the research, call the Research Coordinator at 503-220-8262 x58020 or the Principal Investigator, Dr. Jonathan Elliott, at 503-220-8262 x59187. If you become sick or injured or if you feel your privacy or confidentiality may have been violated (e.g., someone without authorization has received personal information about you), notify Dr. Elliott. To speak with someone not connected with this research study about your rights, discuss problems, concerns and questions, obtain information and/or offer input, please call the VA Portland Health Care System Research Office at (503) 273-5125, or the VA Regional Counsel at (503) 412-4580.

WHAT IS THE PURPOSE OF THIS STUDY?

The primary purpose of this study is to learn more about problems with sleep and pain in Veterans. This study is designed to test whether daily use of one of two devices, a lightbox and a negative ion generator, can improve sleep and/or pain in Veterans. Half of the total pool of devices with be inactivated; however you will not know whether the device you receive is active or inactive. The purpose of this design is to include a placebo condition because sometimes knowing that you are getting an intervention can change the results of the study. As sleep affects many other processes in the body, we are also interested in things like pain and quality of life. This is a randomized study. That means that neither you nor your doctor can choose whether you will receive the study device or the placebo, that will be decided by chance (like tossing a coin, heads could mean you get an active device and tails could mean you get an inactive device).

WHO IS PAYING FOR THIS STUDY?

This study is funded by the Department of Veteran Affairs (VA).

DO THE RESEARCHERS HAVE A PERSONAL FINANCIAL INTEREST IN THIS STUDY?

No.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 100 people will participate in this research study at the VA Portland Health Care System.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to join and do not withdraw from the study before all procedures are complete, your participation in this study will last for up to 6 months.

WHAT WILL HAPPEN DURING THIS STUDY?

The procedures described below will be done for research purposes and will not be completed if you decide not to take part in the study. None of the procedures will impact your usual care at the VAPORHCS. Study personnel will discuss the study with you and, if agreeable, you will sign the associated consent and authorization form. If you have not been receiving healthcare at the VA, we may also ask you for permission to request your health records to learn about your history with regards to sleep and brain injuries. After providing

verbal and written informed consent, you will participate in the following activities across at least 4 visits. Visits can be conducted remotely over video or phone conferencing, or in some cases we can travel and complete the visit in your home.

Visit 1 (~60 minutes)

- You will undergo informed consent and complete baseline paperwork.
- You will be given a special wristwatch called an actiwatch that tracks activity and light exposure, allowing us to better understand your natural sleep-wake cycle. This watch is fully waterproof and should be worn continuously for the full duration of the study.
- You will be given a study diary with instructions on how to complete it. You will make daily entries relating to when you go to bed and when you wake up.

Visit 2 (2 weeks after Visit 1; ~90 minutes):

- You will complete a series of questionnaires related to your sleep quality, pain, and quality of life. These may be mailed to you.
- You will be randomized (like flipping a coin) to receive a lightbox or negative ion generator.
- You will be asked in person or by phone about your history of traumatic brain injury (TBI/concussion). This is to establish an accurate diagnosis and history of your brain injury.
- You may undergo pressure pain testing. This pressure exam will take place using an instrument called a pressure algometer that gradually increases pressure on your non-dominant thumbnail.
- You may undergo an ice bath pain test. You will be asked to submerge your non-dominant hand in a cold ice bath and we will time how long you can keep your hand submerged.
- You may undergo a blood pressure cuff restriction pain test. For this test a blood pressure cuff would be inflated on your non-dominant upper arm and we will time how long you could tolerate the pressure.
- You will be compensated with $20 in gift cards or other cash equivalent.

At home (between Visit 2 and Visit 3; 4 weeks in duration):

- You will use the lightbox or negative ion generator for 60 min every morning, starting 14 days after receiving equipment. We will call or email you to remind you. This should be done as soon as possible after waking up. This can be combined with your normal routine, e.g., eating breakfast, reading the newspaper, etc.
- You will complete the study diary every day and will wear the actiwatch continuously.

Visit 3 (~4 weeks after Visit 2; ~90 minutes):

- You will return the actiwatch, lightbox/negative ion generator, and study diary
- You will complete a series of questionnaires.
- You will undergo pain testing.
- You will be compensated with $60 in gift cards or other cash equivalent.

Visit 4 (~4 weeks after Visit 3; ~60 minutes)

- You will complete a series of questionnaires.
- You will undergo pain testing.
- You will be compensated with $20 in gift cards or other cash equivalent.

We will contact you by phone at multiple time points during the study to answer any questions you may have, and to ask you how things are going. We may also communicate with your via encrypted email, if you would prefer. We will also be available via video conferencing.

WHAT ARE THE RISKS and POSSIBLE DISCOMFORTS of PARTICIPATION?

Information that identifies you will be collected in this study. All hard copies of your questionnaires and consent forms will be in a locked drawer of a filing cabinet in a locked room, inside of a secured access area at VAPORHCS. The research team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. It also could carry other risks, such as social embarrassment.

Lightbox: There are no reported major risks from using a lightbox. Some minor and very uncommon risks/discomforts may include eye irritation, irritability, headache, nausea, and dryness of skin. Although the lightbox emits very little blue light, people with macular degeneration should avoid exposure to blue light as it may increase retinal damage.

Negative Ion generator: There are no reported major risks from using a negative ion generator. Some minor and very uncommon risks/discomforts may include some static shocks when touched.

Actigraphy Watch: There are no reported major risks from wearing an actigraphy watch. A minor and very uncommon discomfort of skin irritation may occur from the watch wristband.

Questionnaires: Some of the questions may seem personal, embarrassing, or they may upset you. You may refuse to answer any of the questions. If your questionnaire answers indicate that you are reporting depression or have depressive symptoms during the course of the research study, we may refer you to VA mental health services or a counselor of your choosing. If you should ever express thoughts of wishing to harm yourself or considering suicide, you may call the National Suicide Hotline at 585-393-7938 or we may facilitate a transfer to that call for you.

Pressure sensitivity testing: You may feel momentary discomfort or pain during the pressure sensitivity testing. This test may cause a small area of redness, tenderness, or bruising.

Ice bath pain testing: You may feel momentary discomfort or pain during the cold sensitivity testing. This test may cause a small area of redness, tenderness, or bruising.

Blood pressure cuff pain testing: You may feel momentary discomfort or pain during the cold sensitivity testing. This test may cause a small area of redness, tenderness, or bruising.

WILL I BENEFIT BY PARTICIPATING?

You may or may not personally benefit from being in this study. However, by serving as a participant, you may help us learn how to benefit patients in the future.

DO I HAVE TO PARTICIPATE IN THIS STUDY?

No. You may choose not to be in this study. Your participation is 100% voluntary and will in no way affect your current and future treatment at the VAPORHCS.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Your identity will not be disclosed unless you give specific, separate consent or if required by law. All VA research records, both hard copy and electronic, will be held in accordance with the VA records control schedule. A study identification (ID) number will be assigned to your questionnaire data. Only the investigators named on this consent form will be authorized to link the study ID number to you. Identifiers related to you (i.e. information that can identify you) will be used in this research study and will include: First and last name, last four digits of SSN, mailing and email addresses, phone number date of VAPORHCS visits, demographic information like your identified race and ethnicity, birth date, and medical history relating to sleep disorders and other history relating to mental health such as depression, drug and alcohol abuse, traumatic brain injuries, and post traumatic stress. These identifiers may be used to obtain information about you and/or your health from VA records and from the health information sources listed on the HIPAA authorization. All other parties, including employers, insurance companies, personal physicians and relatives, will be refused access to the study data, unless you provide written permission or unless otherwise required by law.

By signing this informed consent, you give permission for your de-identified data to be deposited in the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System that was developed by the National Institutes of Health and the Department of Defense. Only de-identified data, which does not include anything that might directly identify you, will be shared with FITBIR users and the general scientific community for research purposes. To do this, we use a one-way tool that generates a Global Unique Identification (GUID) from your personal information; your identity cannot be derived from the GUID.

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A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

This study involves a device regulated by the US Food and Drug Administration (FDA), the FDA may choose to inspect research records that include identifiable medical records, identifying you as a subject of this study.

Possibility of Disclosure and Notice of Privacy Practices.
The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it may no longer be protected. Our Notice of Privacy Practices provides more information on how we protect your information. If you do not have a copy of the notice, the research team will provide one to you. (Notice of Privacy Practices available online at (https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=9946).

Mandatory reporting of suspected child or elder abuse. Under Oregon Law, suspected child or elder abuse must be reported to appropriate authorities.

WILL I BE ABLE TO SEE MY RESEARCH DATA?
During this research study, you will not be able to see the research data collected about you. After the study is complete and the study results are determined or published, you may request your health information.

WILL I BE TOLD ABOUT THE STUDY RESULTS?
You will be able to request a copy of research publications that result from this study data.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
A VA participant will not be required to pay for care and services received as a participant in a VA research project. There may be a small cost to operate the lightbox or ion generator from your home. This cost, which includes electricity, is estimated to total <45 cents over the course of the study.

None of the participants will pay for the lightbox/negative ion generator and/or actigraphy watch because they are only for research study purposes. Some Veterans are also required to pay co-payments for medical care and services provided by VA ***that are not part of this study*** (e.g., normal hospital and prescription expenses that are not part of the research study, any treatment that is standard clinical treatment for your condition). For example, you would receive the overnight sleep test and intake questionnaire even if you were not in this study, because they are part of standard care for your potential condition and are not part of this study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid the following amounts in gift cards or other cash equivalent for compliance in our study:

- Visit 2: $20
- Visit 3: $60
- Visit 4: $20

Total: $100

WHAT WILL HAPPEN IF I AM HURT?

Every reasonable effort to prevent any possible injury from this study will be taken. In the event the study results in any physical, mental or emotional injuries to you, the VA will provide necessary medical treatment (not just emergency care) at no cost to you. This does not apply to treatment for injuries that result from if you do not follow the study procedures. Additional compensation, beyond paying for treatment, has not been set aside. The VA will also provide all necessary assistance in the event of any violation of confidentiality or privacy (for example, identity theft resulting from the loss of a social security number by anyone associated with this study). For eligible Veterans, compensation damages may be payable under 38 United States Code 1151. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with the provisions of the Federal Tort Claims Act. For additional information concerning claims for damages, you may contact VA Regional Counsel at 503-412-4580. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

WHO SHOULD I CONTACT IF I AM INJURED DUE TO THE RESEARCH?

If you believe that you may have suffered a research related injury (physical, mental or emotional injury or injury caused by loss of confidentiality or privacy), contact Dr. Jonathan Elliott at 503-220-8262 x59187. **In the event of a life-threatening emergency, call 911 or go to the Emergency Department (ED).**

WHAT ARE MY RIGHTS?

You may ask questions about research or about your rights as a participant. The research coordinator at 503-220-8286 x58020 will answer any questions you may have about this research study. If you have any questions regarding your rights as a research participant, you may contact the VA Portland Health Care System Research Office at 503-273-5125, or VA Regional Counsel at 503-412-4580.

Participation is voluntary. Your participation in this research study is voluntary. The VA Authorization for Use and Release of Individually Identifiable Health Information (Collected) for VHA Research to use your protected health information is also voluntary. You may refuse to sign this consent form and the authorization. However, in order to participate in this study, you must sign this consent form and the authorization. Dr. Miranda Lim is a researcher on this study and may also be your health care provider. She is interested in both the clinical

welfare of their patients who participate in this study and in the conduct of this study overall. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another provider who is in no way associated with this study. You are not under any obligation to participate in any research study offered by your health care provider.

What if I decide not to participate? You do not have to join this or any other research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or if you drop out of the study at any time, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

CAN I DROP OUT (WITHDRAW) AFTER I SIGN THIS CONSENT FORM?

You may withdraw from this study entirely at any time. This will not affect your rights as a VHA patient or your eligibility for medical care and benefits for which you are otherwise eligible with this institution or with the VHA.

To withdraw, you must provide verbal (in-person or call 503-220-8262 x59187) or written intent to Dr. Elliott or a member of the research team.
Write to: VA Portland Health Care System
3710 SW US Veterans Rd
Portland, OR, 97239
Mailcode: P3-RD42, Attn: Jonathan Elliott

If you do withdraw, we will not look at your medical record for purposes of the research anymore and will not collect any more information about you. However, we will keep and use the data that we already collected before you withdrew your consent.

If you tell us you wish to withdraw, we will ask you if you wish to have continued follow-up to see how you are doing and if we may continue to collect information about you. We will continue to protect your privacy and will keep all your information confidential.

Can someone else stop me from being in the study?

Your participation may be terminated by the investigator if there is any reason to believe you cannot or will not comply with all study requirements.

WILL I BE TOLD IF THERE IS NEW INFORMATION THAT MIGHT CAUSE ME TO WANT TO QUIT THIS STUDY?

Yes, we will provide new information during this study that might affect your choice to continue in the study.

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Signature

A study investigator has explained the study to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I have been told I do not have to take part in this study and refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are medical problems or questions, I have been told I can call Dr. Lim at 503-220-8262 x57404 from 08:00 to 17:00, Monday through Friday. If any medical problems occur in connection with this study, the VA will provide emergency care.

By consenting to participate, I authorize the use of my questionnaire data and other study data, and for this deidentified data to be deposited into the FITBIR database.

My signature below indicates that I have read, or had read to me, all of the above information about the study, and that my rights as a research subject have been explained to me. I authorize the use of my study data as described in this form. In the future, if I decide that I no longer wish to participate in this research study, I agree that my study data, which were already collected, may continue to be used only for this research by removing all identifying information. However, identifiers may be stored separately and held in accordance with the VA records control schedule.

I voluntarily consent to participate in this study. I have been told that I will receive a copy of this consent form.

_____
Printed Name of Subject

_____ _____ _____
Signature of Subject Date Time

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Date Time

Do not change anything below this line, including bottom margin.
VAPORHCS Research Service Template Date: 9/23/2018