COVER PAGE – CONSENT FORM

Title: Cranial electrotherapy stimulation: Piloting a road to PTSD prevention in first responders

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BUTLER HOSPITAL CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

Cranial electrotherapy stimulation: Piloting a road to PTSD prevention in first responders

Sponsorship

This study is being paid for by a grant from the National Institute of General Medical Sciences.

Research Project Summary

You are invited to take part in a research study, because you are an active-duty firefighter in the State of Rhode Island and are between 18 and 56 years old. The purpose of the study is to find out if the at-home use of Alpha Stim Cranial Electrotherapy Stimulation (CES) is an appropriate and acceptable intervention for firefighters, and whether CES may change how firefighters feel. The main benefits of this study are to help researchers and clinicians develop future interventions such as CES for the prevention of posttraumatic stress disorder or other mental health issues often seen in first responders. Although this is not a treatment study, CES delivered by the Alpha Stim device has been used to treat anxiety and/or insomnia (difficulty sleeping). You will need to own a smartphone to take part in this study. If you choose to take part, you will be asked to make two visits to our research office at Butler Hospital where you will be asked questions about how you feel, get trained in how to use the CES device and how to answer survey questions on your phone. You will also be asked to wear a biosensor ring which will measure your heart rate and sleep pattern. You will be asked to make two visits to the MRI Research Facility at Brown University, once before starting the four weeks of CES and once after, where you will get a scan of your brain (MRI: Magnetic Resonance Imaging). The visits to Butler Hospital will each last about two to three hours. The two visits to the MRI Research Facility will last about one hour each. In between these visits, we will ask you to use the CES device for four weeks on the days that you are not on duty, complete daily surveys on your phone, and wear the biosensor ring while you sleep, again only on nights you are not on duty. In total, this study will last about two months. We will pay you up to $304 for your time if you complete most surveys and all CES sessions. Risks include feeling uncomfortable and frustrated answering a lot of personal questions during your visits to Butler Hospital and in the daily surveys and discomfort from lying in the MRI scanner during the brain scans. Possible CES side effects include mild dizziness, nausea, or headache and which can happen in about 1%-25% of people, but the device can be adjusted during the first session to resolve these effects. You have the right not to answer questions that bother you. Taking part in this research is voluntary. You don't have to participate and can stop at any time. More detailed information is found below.

It is important that you know enough about what's involved in this study so you can decide whether you want to be a part of it. This consent form describes what you will be expected to do and what the researchers will do. Below you can learn about possible risks and benefits of this study. A member of the research team will go over this information with you, too. They should talk to you about all parts of this study: why it's being done, what will happen, possible risks and possible benefits for people who are in the study, and what you can do instead of being part of the study. This form may have words that you do not understand. Please ask the researchers to explain any words or information that you do not fully understand. Once you know about the study and your questions have been answered, you will decide if you want to be a part of the study. If so, you must sign this form. [People in a study are called "participants" in this consent form.]

Description of Procedures

If you decide to participate, and after you sign this form, you will be asked to do the following:

Visit Day 1: Butler Hospital (3 hours): At your first visit, we will ask you to complete interviews with one of our study team members. During these interviews, we will ask you about mental health symptoms you might be having and about your past experiences, such as traumatic experiences that you may have experienced. You will also be asked to complete questionnaires about your sleep, feelings of anxiety and mood, and other emotions. We will also ask you some questions about your physical health. The information you provide at this visit will help us decide whether this study is a good fit for you.

If this study is a good fit for you, we will explain how you use the CES device for four weeks at home. To use the CES device, you will clip two electrodes that are wetted to each of your earlobes, and which will deliver a small amount of electrical current. We will set the intensity of the device together at this first visit. This means that once we turn the device on, we will go up to a level that makes you feel a bit dizzy, like walking while on a boat. Once we get to that level, the stimulation intensity will be reduced right away until you stop feeling dizzy; this is how we find the level of stimulation that will be comfortable for you to use every day. Once a comfortable stimulation level is determined for you, you will then have the device on for about one hour, which is the length of stimulation you will use at home. We do this to make sure that you know how to use the device and are feeling comfortable using it at home. If you find you cannot bear the sensations from the device at any level, or if it becomes clear to us that you find it too difficult to operate the device, we will stop your participation in this study, and you will still be paid for this visit.

We will also ask you to download an app on your phone that will send you surveys once a day for the four weeks you will be using the electrotherapy stimulation device. Once a week you will be asked to complete two surveys in one day. You may also be asked to wear a biosensor ring at night while you sleep during the four weeks, which will be fitted on your finger of choice. If you are being asked to use the ring, we will ask you to download an app on your phone to connect to the ring. The ring is water resistant and can be charged when you are not using it. The biosensor ring will collect information about your sleeping patterns (such as deep, light and REM sleep), heart rate, body temperature, breathing rate, oxygen saturation, and activity levels while you are wearing it. The ring is not meant to detect any health problems you might have.

Visit Day 2: Brown University MRI Facility (1 hour): You will be asked to complete an MRI scan of your brain after your first visit. This MRI scan is not mandatory if it cannot be conveniently scheduled for you and we will not scan you if you are not eligible to complete MRI scanning (for example, you have metal in your body). If asked to complete this scan, you will meet a study staff member at the brain imaging facility at Brown University, where you will get a scan of your brain. You will discuss and sign a separate consent form at the Brown Facility for the MRI.

Cranial electrotherapy stimulation (CES), daily surveys, and biosensor ring: at home

We will ask you to use the CES device at home for four weeks like we showed you during Visit 1. We will ask you to only use the device on the days that you are off duty. This is because you should not operate any heavy machinery during or immediately after doing the CES, such as operating a fire truck. Study staff will reach out to you every four business days, or at least once a

week, to check in with you about whether you experience any difficulties, issues, or side effects from using the stimulation device. When you start using the device, you will also start the daily surveys. If we notice that you are not completing the surveys, we'll give you a call to check for reasons you are not completing the survey and if we can solve any issues. If we asked you to wear the biosensor ring, you will also start that at this time. Like the use of CES, you will only wear the ring while you are sleeping on the days you are off duty. This is because wearing a metal ring poses a safety risk for firefighters.

Visit Day 3: Brown University MRI Facility (1 hour): You may be asked to complete an MRI scan of your brain after the four weeks of using the CES device.

Visit Day 4: Butler Hospital: We will ask you to come back to Butler Hospital to return all the devices we gave you and delete the apps we installed on your phone. You will also be asked to fill out some of the same questionnaires you filled out during your first visit. Finally, we will go over what you thought of the study, what it was like using the CES device, fill out the daily surveys, and use the biosensor ring, and what you liked and didn't like about it.

Risks and Inconveniences

We will ask you a lot of personal questions during the interviews and questionnaires on Visit Days 1 and 4. Some of these questions may make you uncomfortable. You have the right not to answer questions that bother you. You can also ask for breaks or stop at any time.

You might find the daily surveys to be frustrating because they ask about the same things over and over again. The daily survey notifications can also be distracting, and we ask you not to answer survey questions if you do not have the time to do so, for example because you are working and/or responding to an emergency. You can silence the survey reminder when it arrives. You will then receive at least two repeat notifications, both a couple of hours later, so that you may complete the survey later when you have time. If you do not respond to either of these reminders the survey will expire, and you will not be able to respond to it. If a survey expires you will not be able to get credit for it.

There are risks associated with MRI and you will receive a separate MRI consent form to review and sign at the Brown MRI Facility.

The biosensor ring is made of metal and contains a battery. Like with any ring, it is possible to experience skin irritations or difficulty removing the ring. If that happens, please contact the study staff. When wearing the biosensor ring you should avoid working with batteries, or devices and/or machinery that contain batteries, because there is a risk of an electrical short circuit which can result in a potentially dangerous shock. The biosensor ring will collect information about your sleeping patterns (such as deep, light and REM sleep), heart rate, body temperature, breathing rate, oxygen saturation, and activity levels. Based on this data the app connected to this ring will give you specific "scores". You might find seeing these scores or your data upsetting or worrisome. However, you should know that these scores are based on your age, height, and weight and we do not enter this information in the biosensor ring app. This means that these scores are not correctly calculated and are therefore misleading. We advise you to ignore these scores.

The Alpha Stim® CES device is FDA cleared for at home use (https://alpha-stim.com). The most common side effects include feeling dizzy like being on a boat (vertigo), nausea, and headache. These side effects are mild and can happen in a quarter (25%) of people, but they typically occur when the stimulation level is set too high. More severe but less common side effects, about 1% of the time, are skin irritation where the ear clips are attached to your ears, ear pain, pulsing or tingling sensations on ears, and tender ears. You should not use CES if you have a pacemaker or implanted or wearable defibrillators, and you should not try to open or modify the device or accessories as doing so could result in injury. You should also not stimulate directly on the eyes or press the ear clips over the carotid sinus (on the neck near the larynx). Application of the electrodes near the chest may increase the risk of cardiac fibrillation (abnormal heart rhythm).

No one can know ahead of time who might have a side effect from a treatment or procedure. Any type of treatment may occasionally result in a harmful side effect. If you have any unexpected side effects or think that something in this study might be harmful to you, you should tell the study staff. They need to know what you are experiencing and will help get you treatment, if needed. If the researchers learn something new that might impact whether you want to continue to be in this study, they will tell you.

Note Regarding Pregnancy:

CES and MRI are not recommended for use during pregnancy. CES and MRI may be harmful to a developing fetus. Therefore, if you are a woman, you will be asked about pregnancy at the time of admission to the study, before each MRI, and before starting the four weeks of CES. Study staff will discuss with you the importance of not becoming pregnant while you are in this study. If you change your mind and decide to become pregnant during the study, you should tell the study staff.

Benefits

You may not benefit directly from participation in this study. The main benefits of this study are to help researchers and clinicians develop future interventions such as CES for the prevention of posttraumatic stress disorder or other mental health issues often seen in first responders.

Economic Considerations

You will receive $50 for Visit Day 1 and $50 for Visit Day 4. You will receive an additional $40 for each MRI scan on Visit 2 and Visit Day 3.

You can earn an additional $124 in bonuses for completing all daily and weekly surveys and CES sessions as follows:

- Every CES session you complete will be awarded $2. So, if you complete no sessions, you earn $0 and if you complete all 20 sessions you will earn $40.
- Every daily and weekly survey you complete will be awarded $2. If you complete 6 or all of the 7 daily surveys in one week you get an additional $5 for that week.

Your total payment is up to $304. You can choose to get compensation in checks or gift cards. If you choose compensation through checks, we will need to collect additional sensitive data (e.g., your home address).

If you are paid $600 or more in any calendar year for all Care New England research studies, the Care New England Research Accounting Department is required by law to notify the IRS of the total amount of money you were paid. Please ask study staff for more information if you have questions about this.

Alternative Treatments/Alternative to Participation

No treatments are being offered in this study.

Voluntary Participation

You are free to decide if you want to take part in this study. You are also free to stop being in the study at any time. If you decide you do not want to be a part of this study, or you decide in the future to stop being in the study, that will not have any impact on your care at Butler Hospital or Care New England. The researchers may take you out of the research study for any reason, without your consent. The reason for that would be explained to you.

Sharing Results of this Research with Participants

Clinically relevant results of this research, including results about you as an individual, may not be shared with you.

Confidentiality

You will not be personally identified in any reports or published information that comes from this study. We will follow state and federal laws to keep the information you give us confidential. If you tell us something that makes us believe that you or others have been or may be harmed or in danger, study staff may report that information to the appropriate agencies.

Study staff will take the following steps to keep your information safe: Every effort will be made to keep the information we learn about you private. We are required to report, without your consent, information that would identify you if we find out that you are in imminent danger of harming yourself or another person. If we think that you are in imminent danger of harming yourself or another person, we will escort you to Butler Hospital's Patient Assessment Services. Any information that could identify you that is obtained in connection with this study is strictly confidential, will remain confidential, and will be disclosed only with your permission or as permitted by U.S. or State law. In all the records for the study, you will be identified only by a number. Only the researchers will know your name. When the results of the research are published or discussed in conferences, there will be no information that would reveal your identity. Information collected on the computer is saved on password protected servers at Butler Hospital and the University of Rhode Island. Representatives from the Institutional Review Board (which review, approve, and monitor research) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

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 visit this Web site any time

Daily surveys are sent and stored through LifeData, a survey platform designed by researchers, for the collection of daily data and secure transmission of those data. The app icon itself will not

be clear to others not enrolled in the study. The app includes no protected health information and no sensitive information regarding any possible diagnoses or health issues. Answers to prior surveys on this app will not be available. Data from the biosensor ring will be collected and stored through the Oura app and their cloud-based platform, which uses encryption to protect the data.

For both the LifeData app and the Oura ring app we will set up the accounts for you to make sure we do not collect identifying information. This means we will turn off specific app settings like location services and for the biosensor ring notification alerts, sharing and integration with other health apps on your phone will also be turned off. It is thus important that you do not alter these app settings. You will only have access to these apps and accounts while you are participating in this study. The research team will download your data within a week after you finish the study, and then delete your Oura ring account.

This study will use Care New England's instance of REDCap for the collection, storage, and retrieval of study data in a fully encrypted, HIPAA compliant environment. CNE's REDCap instance is hosted in our HIPAA-compliant data center, which has 24/7/365 support. All network data transmissions are also fully encrypted. For more information about REDCap visit http://www.projectredcap.org.

This research is covered by a **Certificate of Confidentiality**. This means that the researchers cannot release or use information, documents, or samples that may identify you in any legal action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Scientific Data Sharing, Storing and Reuse

This study is collecting data and biospecimens from you. We would like to make your data and biospecimens available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Our goal is to

make more research possible. We plan to keep your data and biospecimens for 6 years after the study has been completed.

Your de-identified data and biospecimens may be shared with researchers around the world. However, the decision to share your data and biospecimens is controlled by the Principal Investigator of this study, [redacted]. To get your data and biospecimens, future researchers must seek approval from [redacted]. The researchers must agree not to try to identify you.

We will protect the confidentiality of your information to the extent possible. Your data and biospecimens will be coded to protect your identity before they are shared with other researchers. The investigators of this study will have a code key that can be used to link to your identifying information. The code key will be securely stored.

It is your choice whether or not to let researchers share your data and biospecimens for research in the future. If you say "yes," you can change your mind later. If you say "no," you can still fully participate in this study. If you change your mind and no longer wish to have us store or share your data and biospecimens, you should contact [redacted] at [redacted], [redacted] at [redacted] and/or [redacted] at [redacted]. We will do our best to honor your request and to retrieve any data and biospecimens that have been shared with other researchers. However, there may be times we cannot. For example, if we do not have a way to identify your data and biospecimens we will not be able to retrieve them. In addition, if the data and biospecimens have already been used for new research, the information from that research may still be used. We will destroy any biospecimens we have or are able to retrieve.

Please initial next to your choice.
(Insert initials) _____ Yes, use my data and biospecimens in other research studies
_____ No, do NOT use my data and biospecimens in other research studies

Risks and Benefits of Data Sharing, Storage and Reuse

We will do our best to protect your data and biospecimens during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data and biospecimens. In either case, we cannot reduce the risk to zero.

You will not receive any direct benefit from sharing your data and biospecimens. However, sharing your data and biospecimens may contribute to research that could help others in the future.

Personal identifiers will be removed from any private information about you (and/or your biospecimens) in the final research dataset created by this study. The de-identified information (often called "data") and biospecimens from this study may be used for future research studies or distributed to other investigators for future research studies without additional informed consent from you (or from your legally authorized representative).

Questions

It is up to you if you want to be a part of this study, or not. Please talk to study staff about any questions you have about being a part of this study. You should take as much time as you need to decide. If you decide to take part in this study, you must sign this form.

Authorization:

By signing this consent form, you indicate that you are voluntarily choosing to take part in this research. You understand what this study is about and your questions have been answered. You will be given a copy of this document for your records and a copy will be kept with the study records. If you have any questions about the study, now or after you sign this form, you can contact the study team.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

_____ _____

Signature of Principal Investigator Date

~or~

_____ _____

Signature of Person Obtaining Consent Date

Telephone Number of Principal Investigator or Person Obtaining Consent_____

If you have further questions about this project or about research-related injuries, please contact [redacted]. If you have questions about your rights as a research subject, please contact [redacted] Chair, Butler Hospital Institutional Review Board, at [redacted]

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED BY THE IRB OFFICE

THIS FORM IS VALID UNTIL

DATE: August 31, 2025

IRBNET ID# 2091269

BUTLER IRB REFERENCE# 2309-001

BY (ADMINISTRATOR): [redacted]

COVER PAGE – MRI CONSENT ADDENDUM

Title: Cranial electrotherapy stimulation: Piloting a road to PTSD prevention in first responders Addendum

NCT number: NCT06203717

Document date: 08/09/2023

BROWN

BROWN UNIVERSITY
MRI RESEARCH FACILITY INFORMED CONSENT ADDENDUM

Cranial electrotherapy stimulation: Piloting a road to PTSD prevention in first responders
Addendum
Version 1, date 8/9/23

- **OVERVIEW**
  You are being asked to be in one or more Magnetic Resonance Imaging (MRI) scans for research. This document will give you important information about MRI scans, let you know what to expect when the MRI scans are done, and tell you how researchers will protect your safety.

- **BEFORE YOU GO IN THE MRI SCANNER**
  The MRI scanner uses a powerful magnet to take pictures of your body. MRI is generally considered safe but because of the strong magnetic force it may be dangerous to go into the MRI scanner if you have metal in or on your body or have certain medical devices, such as a pacemaker. Therefore, you will have to follow certain rules and answer some questions to make sure you can safely have an MRI scan. Before you have your MRI scan you will be asked to complete a checklist that asks you questions about your medical history. You will also be asked about any metal you might have in your body. For your safety, it is important to answer all of the questions as accurately and truthfully as you can. A researcher will go over the checklist with you.

  If you are able to become pregnant: Researchers do not know the safety of MRI during pregnancy. If you are, or might be, pregnant, you cannot get an MRI as part of this research.

  After a researcher talks about the checklist with you, and if it is safe for you to go in the MRI scanner, we will ask you to do these things to get ready:

  - Take off anything that could be made out of metal or have metal pieces such as: jewelry, watches, belts, hair holders, and eyeglasses.
  - Take everything out of your pockets such as: keys, wallets, money, and credit cards.
  - Take off your shoes.

  You might also be asked to:

  - Change into a hospital gown, “scrubs,” or other clothes that are best for being in the scanner. Some clothes have metal pieces in them that may heat up in the MRI scanner.
  - Take off eyeshadow or other makeup. Some makeup can have tiny metal pieces in it.

  A researcher will show you a secure place to store your things until the MRI scan is over.

- **IN THE MRI SCANNER**

  When you go into the MRI scanner, you will lie down on a table that will slide into a tube or tunnel that is a little bigger than your body. You will be asked to stay as still as possible while you are in the MRI scanner. You will be able to hear and talk to the researchers while you are in the MRI scanner. Some people feel nervous or afraid when they are in small spaces. If you think you will be nervous or afraid, please tell the researchers before you go in the MRI scanner. The MRI scanner also makes loud noises when it is taking pictures. The researchers will give you ear protection so that it does not sound as loud. If you do not like the way you feel or are uncomfortable when you are in the MRI scanner, please tell the researchers. If you want to stop, you can at any time for any reason.

  If other devices are being used that are not part of the MRI scanner, such as buttons to press or ways to monitor your heart beat, there is a very small chance that they might heat up while the MRI scanner is taking pictures. If you feel anything heating up or burning, please ask the researchers to stop the MRI scanner and let them know what you feel.

- **OTHER INFORMATION**

  The MRI scan you will get as part of this research is not meant to find health problems. This MRI scan cannot be used instead of a medical examination by a qualified healthcare provider. If you think that you might be sick or injured, you should not use this MRI scan as a way to determine whether or not you are well.

  The researchers for this project are not trained to make any medical diagnosis, and the MRI scans done in this research are not designed to find medical problems. The researchers and Brown University are not responsible for finding any abnormalities in your MRI scans. However, sometimes, a researcher may notice an MRI image that seems abnormal. If this happens, the researcher will let you know and recommend that you tell your primary care doctor. Only you and your doctor can decide whether or not you should have additional medical tests or treatment. The researchers and Brown University are not responsible for any medical attention that you decide to get based on the MRI images from this research. If you request it, the researchers will give MRI images to your doctor. However, because the MRI images were taken for research and not for medical purposes, they should not be used for medical decisions.

- **CONSENT TO PARTICIPATE**

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

Participant's Signature and Date / PRINTED NAME