Rapid Eye Movement Restoration and Enhancement for Sleep-deprived Trauma adaptation

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NCT06547086

University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

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Study Title for Participants: REM-REST Study

Formal Study Title: Rapid Eye Movement Restoration and Enhancement for Sleep-deprived Trauma adaptation

Lead Researcher: *Giulio Tononi, MD, PhD; Department of Psychiatry, 6001 Research Park Blvd., Madison WI 53719; Phone: 608 263 3447*

Institution: *University of Wisconsin-Madison, Wisconsin Institute for Sleep and Consciousness*

Study Sponsor: The U.S. Department of Defense is funding this study.

Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

Why are researchers doing this study?

In this study, we are trying to find out whether stimulating the brain with electrical current during naps can increase certain kinds of brain activity that happen during sleep and lead to improvements in emotional health and stress resilience. If so, we may be able to use this kind of stimulation to improve the emotional health of people who often do not have enough time to get a full night's rest—such as military personnel. We hope this will decrease the chances that these people would go on to develop PTSD (post-traumatic stress disorder).

In Phase I of this study, we tried out different kinds of electrical stimulation and nap lengths to identify the best combination. Now, in Phase II, we will be comparing measures of your emotional health on three distinct nap visits, in some of which you will receive this stimulation.
We invite you to take part in this research study because you are in good health and able to take naps during daytime.

What will I need to do in this study?

If you consent to participate in this study, we will ask you to attend up to 3 study visits, each of which may last up to 5 hours. During these visits, you will wear an hdEEG (high density electroencephalography) cap and take a nap. During some of these naps, we

will stimulate your brain with transcranial electrical stimulation. We may also acquire an MRI of your brain on one of these visits.

We expect that you will be in this research study for about a month.

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

What are some reasons I might – or might not – want to be in this study?

You may want to be in this study if you are:	You may NOT want to be in this study if you:
Comfortable having researchers ask questions about your medical history and sleep Comfortable performing behavioral tasks on the computer Able and willing to complete an MRI scan Able and willing to take a nap during daytime at the lab Have time for up to 3 study sessions Willing to undergo brain stimulation during sleep Interested in contributing to scientific knowledge even though you won't benefit directly from the study.	Prefer not to answer questions about your medical history and sleep Not able, comfortable, or willing to perform behavioral tasks on the computer Have any metal in your body, are afraid of tight spaces, or otherwise unable or willing to complete an MRI scan Do not want to or are not able to take a nap during daytime in a different environment Do not have time for the study visits Are nervous about undergoing brain stimulation or are concerned about unknown side effects of an investigational device If you are pregnant or plan to become pregnant in the next 6 months

Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide. **Even if you have a status relationship with one or more of the investigators (e.g. – they are involved with some aspect of your academic or professional assessment) your participation is completely voluntary. Your assessment will not be affected**

whether or not you choose to participate. You may withdraw from this study at any time.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

How is research different from health care?

When you take part in a research study, you are helping to answer a research question. Study tests and procedures are not for your health care.

Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to Stephanie Jones, a researcher on the study team. She can be reached by email at sgjones2@wisc.edu, phone at 608 263 3447, or you can write to her:

Stephanie Jones
Department of Psychiatry
6001 Research Park Blvd.
Madison WI 53719

If you have concerns about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. UW Staff not part of the study team will work with you to address concerns and assist in resolving any complaints.

If I take part in the study, what will I do?

All study visits will take place at WISPIC, located at 6001 Research Park Boulevard, Madison, WI 53719. During your first visit, the research team will go over the consent form with you in depth. If you still agree to participate, we will have you complete some surveys to tell us about your medical history. The medical history may include some questions about sensitive information, such as your mental health and whether you use prescription drugs that impact brain activity.

We will also acquire an MRI scan of your brain. The MRI scans take pictures of how the brain is built (structural scans) and the wiring of the brain while you are at rest. If at any point you feel uncomfortable during the MRI, you will have the option to immediately stop the scan or ask for a break in the middle. You will be in the scanner for about an hour, and during the MRI you will be able to talk to and hear the person running the scanner. Before the scan, you will receive earplugs and/or headphones that will block

out some of the noise from the scanner. For your convenience, the MRI scan may be scheduled separately from your consent visit if you prefer.

After the MRI, you will be taken to a private room and the research team will fit you with an hdEEG cap. This will involve putting gel in the electrodes of the cap. After the hdEEG setup is complete, you will be asked to take a nap on a bed in the room. You will be monitored by the study team for the entire visit and will be able to talk to them at any time. Before and after the nap, we will ask you to fill out some questionnaires about your sleep and have you perform behavioral tasks on a computer.

If you are able to take a nap on your first visit, we will invite you for two more visits that will each be scheduled approximately one week apart. During these visits, you will again wear the hdEEG cap and take a nap (about 90min long). In some of these visits, we will carry out transcranial electric stimulation, and in some we will not be applying any stimulation. This stimulation will be delivered through the hdEEG cap, and you may feel an itching, tingling, or warm sensation at the electrode locations while it is happening. We will deliver brief pulses of electrical stimulation before and after your nap as well as during the time that you are asleep. During the stimulation periods before and after your nap, we will ask you to sit still and listen to a pre-selected audiobook recording. Additionally, before and after your nap, we will ask you to fill out some questionnaires about your sleep and have you perform behavioral tasks on computer. Each of these visits may take up to 5 hours.

Protected health information (PHI) used in this study
Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

Results of tests or procedures done as part of the study
Things you tell the researchers about your health

What happens if I say yes, but I change my mind later?

You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Stephanie Jones, a researcher on the study team, at **6001 Research Park Blvd., Madison WI 53719.**

Will being in this study help me in any way?

Being in this study is unlikely to benefit you directly. The stimulation might not affect you at all, or it might have unknown side effects. However, your participation in this study may help other people in the future by helping us learn more about brain stimulation and how it affects sleep, emotional health and stress resilience.

What are the study risks?

The main risk of taking part in this study is that your study information could become known to someone who is not involved in performing or monitoring this study. A breach of confidentiality could result in damage to you or your reputation, but the chances that this will happen are very small. Although we will likely share data with other researchers at other universities, when we do this, we will not share any information that identifies your (name, date of birth, etc.). All your data is stored with a code, and only study staff have access to this code. Risks associated with procedures include:

EEG recordings: EEG is considered a safe and non-invasive way of measuring brain electrical activity. The only risks are some discomforts from preparing the scalp for the recording electrodes, and an extremely low risk of a minor scratch where the scalp is prepared. Extended wear of the net can also be uncomfortable.
Questionnaires: You may feel uncomfortable answering some of the questions, particularly about sensitive health topics. You may skip over these if you want to.

MRI Procedure:
Magnetic Resonance Imaging (MRI) is a non-invasive medical imaging technique that uses a strong magnetic field and radio waves to create detailed images of the body's internal structures. It is generally considered safe for most individuals. However, there are a few risks and contraindications to be aware of:

1. Magnetic field interactions: The strong magnetic field generated by the MRI machine can interact with metal objects in or on the body. This can pose risks for individuals with:
   a. Implanted medical devices, such as pacemakers, cochlear implants, or neurostimulators.
   b. Metal fragments in the body, especially in or near the eyes.
   c. Certain types of surgical clips or metal implants.
2. Claustrophobia: Some individuals may experience anxiety or claustrophobia due to the confined space inside the MRI machine. In such cases, sedation or an open MRI may be considered.
3. Noise exposure: MRI machines can generate loud noises during the scanning process, which may be uncomfortable or distressing. Earplugs or headphones are usually provided to minimize noise exposure.
4. Pregnancy: Although there is no definitive evidence that MRI poses risks to the developing fetus, it is generally avoided during the first trimester of pregnancy as a precautionary measure.

TES-TI procedure: TES-TI is a new procedure, and its safety profile has not yet been well-documented. However, it is very similar to an older procedure called TES that is generally considered safe for most individuals. There are some potential risks and side effects associated with TES that may also happen with TES-TI, namely:

1. Skin irritation: The application of electrodes on the scalp can cause mild skin irritation, redness, itching, or tingling sensations. This can be minimized by using proper electrode preparation and skin care procedures.
2. Discomfort: Some individuals may experience mild discomfort during stimulation due to the sensation of the electrical current or the pressure of the electrodes on the scalp.
3. Headaches: A small percentage of individuals may experience headaches during or after stimulation sessions, which are usually mild and temporary.
4. Dizziness or lightheadedness: Some individuals may experience dizziness or lightheadedness during or after stimulation, although these symptoms are typically mild and transient.
5. Phosphenes: Some participants may perceive brief flashes of light or other visual phenomena (phosphenes) during stimulation, particularly if the stimulation is applied over the visual cortex.
6. Unknown long-term effects: As transcranial electrical stimulation is a relatively recent technique, the long-term effects of repeated stimulation sessions are not yet fully understood. More research is needed to determine whether there are any potential risks associated with long-term use.
7. Seizure risk: Although the risk of seizures induced by transcranial electrical stimulation is considered very low, individuals with a history of epilepsy or seizures are excluded from participation.

8. Mania or hypomania: to our knowledge there has been one potential report of hypomania in the TES in the literature although its relationship to TES was unclear.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. You should not be or become pregnant or participate in sex that could result in pregnancy while on this research study.

What happens to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We will limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information.

However, we cannot promise complete confidentiality. We will share information with individuals or organizations identified in this consent form. Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for carrying out or monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for ensuring compliance, such as the Human Research Protection Program, and the U.S. Food and Drug Administration. Representatives of the U.S. Department of Defense will have access to research records as part of their responsibilities for human subjects protection oversight of the study. We may also share data with TI Solutions to aid in their refinement and understanding of the TES-TI device and software. Your information (both identifiable and de-identified) may be used to improve products including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others.

Also, with appropriate confidentiality protections, we might use information that we collect during this study for other research, or share it with other researchers without additional consent from you.

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.

Will information from this study go in my medical record?
None of the information we collect for this study will go in your medical record. The researchers are not required to release health information to you if it is not part of your medical record.

Will I receive the results of research tests?

Whenever an MRI of the brain is done, there is the chance of finding something unexpected. Unexpected findings can have clear clinical significance or uncertain clinical significance. Clear clinical significance means that the MRI shows a problem that may be treatable and we generally know what the risks are of not treating the problem. Uncertain clinical significance means that the imaging shows something unusual in the brain, but we do not know if it might affect your health, and treatment may not be appropriate or possible.

In this study, you can choose whether you would like to be informed of any unexpected findings from the MRI.

Please indicate your choice below.

☐ Yes, please give me results from the tests/procedures listed above.
☐ Please also notify my health care provider of these results.

☐ No, DO NOT notify me or my provider of results from the tests/procedures listed above.

The MRI we are using in this research study is not the same quality as a MRI that you may have as part of your health care. If you believe you are having symptoms that may require clinical imaging, you should contact your primary care physician.

In the case of a detected finding of potential clinical significance, and if you have opted in above, you will be contacted by either a study related clinician or the PI. At that time, you may choose to have your physician informed of any findings of clear clinical significance that we report to you. You may provide the contact information for your primary physician below to assist the process. Please note, however, that if you choose to have your physician informed of findings of clinical significance, that report will likely be placed in your medical records. We will discuss that with you at the time that you are informed.

Physician Contact Information (Optional):

_____

Name of primary physician

_____

City or clinic

_____

Health Care Provider

Can I be removed from the research without my agreement?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- signs of any adverse reaction or significant discomfort from the stimulation
- you do not follow the study rules or no longer meet the requirements to be in the study
- the study is stopped by the sponsor or the researchers.

What else do I need to know?

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

If it is an emergency, call 911 right away or go to the emergency room.

For non-emergency medical problems, inform the study team and contact your regular health care provider.

Call Stephanie Jones, a researcher on the study team, at 608 263 3447 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
Your health insurance company may or may not pay for this care.
No other compensation (such as lost wages or damages) is usually available.
UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

Will I receive anything for participating?
If you agree to take part in this research study, we will pay you $30/hour for your time and effort, for a total of up to $480.

Permission to communicate about the study by email
We are requesting your email address so we can contact you during the study about any scheduling issues that may arise. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Stephanie Jones, Lead Researcher, at 608 263 2447. You do not have to provide your email address to participate in this study.

We are also requesting your cell number so we can text you if we need to communicate any urgent scheduling issues. You do not have to provide your cell number to participate in this study. Please indicate your choice below.

○ Yes, you may use text messaging to contact me for this study.

○ No, I do not want to be contacted by text message.

How many people will be in this study?
We expect about 24 people will be in this research study.

Who is funding this study?
This research is being funded by U.S. Department of Defense (DoD).

Will my data be used for future research?

This study is collecting data from you. We would like to make your data available for other research studies that may be done in the future. The research may be about brain stimulation. However, research could also be about other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Your data may be shared with researchers around the world. Our goal is to make more research possible. We plan to keep your data indefinitely. To get your data, future researchers must seek approval from this institution and review by an IRB may be required. You can request to have your data removed from our data bank (so it cannot be further used or shared) by contacting the research team at any time.

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

Your name and identifying information will be removed from any data you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data.

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

Participating in this study means you agree to share your data. You can change your mind later, but researchers might still use your data if they have already been shared. If you do not want your data used for other research studies, you should not participate in this study.

Permission to contact you after your participation is over

After your participation is concluded, we would like your permission to contact you to address any concerns or questions you may have about your experience or to let you know about opportunities to participate in other research studies, focus groups, or media requests. We may contact you within two weeks after your final session to follow up about your experience.

- Yes, you may contact me again after I am done with the study.
- No, I do not want to be contacted after the study is over.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study. If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	