UNIVERSITY OF WISCONSIN-MADISON
Department of Psychiatry
Wisconsin Institute for Sleep and Consciousness
6001 Research Park Blvd., Madison, WI 53719

Subject CONSENT to Participate in Research
And AUTHORIZATION to Use and/or Disclose
Identifiable Health information for Research

Title of Study: Using peripheral sensory stimuli to induce sleep slow waves and improve cognitive function

IRB Protocol Number: HS-IRB #2015-0337

Study Investigators: Giulio Tononi, M.D.,Ph.D. Stephanie Jones, PhD, [1]; Brady Riedner, PhD,[1] ;

6001 Research Park Blvd., Madison, WI 53719

Title of the Study: Using peripheral sensory stimuli to induce sleep slow waves and improve cognitive function.

IRB Protocol Number: HS-IRB #2015-0337

Principal Investigators: Giulio Tononi, M.D., Ph.D. Stephanie Jones, PhD, [1]; Brady Riedner, PhD,[1];

Version and Date of Consent Form: 8/16/2019

INVITATION

You are invited to participate in this research study about how auditory stimulation during sleep impacts both sleep quality during the night and cognitive performance during the following day. Subjects will be asked to wear a device that looks like a headband (called the SmartSleep device) while sleeping at home five nights a week for eight weeks and to perform one 3-minute and one 20-min cognitive assessment each day after wearing the device. These assessments will be accompanied by brief surveys, and subjects will also be asked to respond to a sleepiness scale three times per day via text message. The SmartSleep device will, on some nights, deliver soft tones that are supposed to help deepen sleep or enhance sleep quality. These tones will be delivered at different volumes and frequencies on different nights to help us assess which kind of stimulation is most effective at enhancing sleep. The SmartSleep device will also record brain activity during sleep.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how your data information will be used for this study and for other research in the future and requests your authorization (permission) to use this information. Please ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn whether: 1) we can improve sleep by increasing sleep slow-waves, a special kind of sleep rhythm, during the night by playing different kinds of audio tones, and 2) whether increasing sleep slow-wave activity leads to an improvement in cognitive performance during the day. Previous studies have indicated that auditory stimulation during sleep can lead to increased slow-wave activity. In this study, we hope to assess the magnitude of this effect and whether and to what extent it impacts cognitive functioning while awake.

WHO CAN PARTICIPATE IN THIS STUDY?

Adults between the ages of 25 and 49 who speak English, are in good health, are restricted sleepers (regularly feel like they don't get enough sleep on week nights and sleep one or more hours longer when given the opportunity) or good sleepers (sleep 7-9 hours with regular bedtimes), and are willing not to nap on weekdays during the study are able to participate in this study. We also ask that participants have access to a cell phone so that we can sent text message reminders when it is time to perform a cognitive assessment.

You may not participate in this study if you:

☐Do not have internet access at home.

☐Are taking medications that may affect your sleep patterns.

☐Are pregnant.

☐Are a night shift worker.

☐Have recently (<2 weeks) traveled where you encountered a time zone shift greater than 3 hours or intend to do so during the study.

☐Have a current severe or chronic medical condition, mental health condition, or sleep disorder that may affect your sleep patterns.

☐Have a history of any such condition that a researcher determines may be likely to recur during the study.

☐Have a history of recurrent seizures or epilepsy or family history of hereditary epilepsy or have a history of medical conditions that could increase the chance of seizures (e.g. stroke, aneurysm, brain surgery, structural brain lesion).

☐Are a smoker.

☐Have self-reported sleep onset latency > 30 minutes more than one night a week.

☐Have self-reported wake time after sleep onset > 30 minutes.

☐Have severe contact dermatitis or allergy to silicone, nickel or silver.

☐Have moderate hearing loss.

☐Have BMI > 35 kg/m^2

☐Have a history of excessive alcohol intake (> 21 drinks / wk) or binge alcohol consumption (>5 drinks per day).

☐Have a history of excessive caffeine consumption (> 7 cups combining all caffeinated drinks regularly absorbed during workdays). Caffeine intake must be regular and maintained throughout study and on testing days.

☐Have a high risk of obstructive sleep apnea, restless legs syndrome, or insomnia based on questionnaires completed during screening/training visit.

Before you decide to participate, please read this form very carefully and ask questions on aspects of the study that are not clear to you. You may take as much time as you wish to think over your participation. Participation in the study is entirely voluntary.

WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this research, your involvement in the study is estimated to last approximately eight weeks and will involve the following components:

1. A consent and training visit. Usually, this screening visit will occur during the day and take up to two hours. During this session, we will ask you some questions about your medical history, sleep disorder

symptoms, sleep and daytime habits, and work hours. You will also be given all the necessary equipment to run the study at your home, including:

- Self-applying headband that contains an EEG amplifier and integrated headphones
- A laptop on which you will do the cognitive tasks and upload sleep data
- (May include) Wrist actigraphy -- a watch that records your movements

During this visit you will be trained on how to use the equipment. We may also establish your minimum and maximum auditory thresholds using the SmartSleep device, and you will practice the cognitive assessments. If included, you will be asked to wear the actigraphy watch throughout the entire study to verify the consistency of your sleep patterns.

For some subjects, the consent and training visit may be offered remotely. If this is the case, you will receive an email invitation to a WebEx virtual meeting and we will arrange to get you the study equipment and paper copies of the consent form in advance of the virtual meeting. The virtual visit will follow the same process as described above, except we will additionally ask you to show us the signed consent form so we can take a screenshot of it. We will then ask you to mail the signed form to us.

2. Recording sleep at home on five nights during each of the next eight weeks. On the days that you are doing sleep recordings, you will apply the SmartSleep device provided and start the sleep program before going to sleep. In the morning you will get up at your usual time, stop the program, and attach the device to the laptop computer provided so that researchers can remotely upload the data from your night of sleep to the laptop we have given you. You will be asked to complete one 3-minute and one 20-minute cognitive assessment each day after sleep is recorded. These assessments will begin with short computerized surveys about your night of sleep (morning) and alertness level (both). You will also be asked to respond to a one-item sleepiness scale three times a day and comment on your previous night's sleep. Reminders will be sent via text messaging when it is time to perform a cognitive assessment or respond to the sleepiness survey. At the end of each week, you will be asked to complete a short survey about device comfort and whether/when menstruation began (if applicable), as menstruation may affect sleep patterns.
3. Due to the duration of this study, we will ask you to bring the laptop to back to the laboratory every two weeks, if you are willing, so that we can back up the data from the laptop to our secure server.

We are inviting you to agree that the data collected as part of this study (EEG recordings and cognitive assessment results) can be used for unspecified future research. This data will be kept indefinitely by Dr. Tononi to learn more about the effect of peripheral stimuli on sleep.

How we will use your protected health information (PHI)

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
- Demographic information including your date of birth and contact information (phone number, address, email)
- Things you tell us about your health, medical history, sleep patterns, etc.

Others at UW-Madison and its affiliates who may need to use your health information in the course of this research:

- UW-Madison regulatory and research oversight boards and offices
- Accounting and billing personnel at the UW-Madison
- Research support services staff at the UW-Madison and its affiliates

Others <u>outside</u> of UW-Madison and its affiliates who may receive your health information in the course of this research:

This study is sponsored in part by NASA. Sponsors of this research and their affiliates will have access to the results of this study. They will also have access to the data generated during your visit. However, when we share data with them, it is shared in a way that makes it so you cannot be directly identified by anyone outside the UW. Your data will be labeled with a code and the link will be kept at the UW.

We may also **share data** from this study with other researchers a UW Madison or other institutions who are interested in similar research topics. For this study, we are collaborating with the University of Pennsylvania, where a similar study is being run. Whenever you complete Cognition tests and subtests on your study laptop, the results will upload from your home to their secure server. This data will be encrypted with a 256 AES algorithm while "in-motion" to the server. Only authorized researchers at UPenn will have access to your data. Right now, we don't have any plans to share with any additional researchers besides those at UPenn, but this may happen in the future. If so, it will be shared in such a way that you cannot be identified.

Authorizing the research team to use your PHI means that we can release it only to the people or groups listed above, and only for the purposes described in this form. However, 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, if ALL information that can identify you is removed from the health information collected in this study, then it is no longer PHI and this authorization will no longer limit how the remaining information can be used. This means the information could be used or shared for reasons other than the ones described in this form, such as a research study about another kind of disease.

HOW WILL RESEARCHERS KEEP MY INFORMATION CONFIDENTIAL?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

Paper records will be kept in individual binders, labeled only with a subject number. All personal information (including full name and contact information) are kept in a separate folder. All subject binders, when unsupervised, will be kept in a locked area accessible only to investigators. Electronic records will be kept on password-protected computers accessible only by authorized users.

HOW LONG WILL I BE IN THIS STUDY?

This study will involve eight weeks of sleep recording. If you go on vacation during the study, you will be asked to discontinue study procedures while you are on vacation and resume them when you go back to your usual schedule. If recording problems are encountered, you may be asked to make up some nights. All extra nights are voluntary and you would be paid for completing them.

WHAT IF I CHANGE MY MIND AND DON'T WANT TO BE IN THE STUDY ANY LONGER?

You do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. 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.

Your authorization for researchers to use your protected health information (PHI) will not expire. 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 Lead Researchers, Stephanie Jones, PhD or Brady Riedner, PhD at 6001 Research Park Boulevard, Madison, WI 53726

WILL BEING IN THIS STUDY HELP ME IN ANY WAY?

This research isn't expected to help you personally, but it may help us understand how to improve sleep through auditory stimulation and how this improvement in sleep quality impacts cognitive performance during the day.

ARE THERE ANY RISKS?

Confidentiality: 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 may share data with other researchers beyond those at the University of Pennsylvania, when we do this, we remove any information that identifies you (name, date of birth, etc.), and the Cognition data that uploads directly from your laptop to the University of Pennsylvania will be encrypted while "in motion" and stored on a secure server. All your data is stored with a code, and only study staff at the UW have access to this code.

Discomfort wearing SmartSleep device: Another risk is that you might be uncomfortable sleeping with the SmartSleep headband on at home, although this is unlikely. If you find the device uncomfortable, you may stop at any time during the study.

Sleep disruption: Although unlikely, there is a small chance that the auditory stimulation may disrupt your sleep instead of improving it as expected. If the effect on your sleep is too disruptive, you can always stop the experiment during the night and sleep the remainder of the night undisturbed. However, if you do unexpectedly lose a lot of sleep during the experimental nights, it could impair your ability to drive or safely perform other potentially dangerous tasks. For this reason, you should not drive or participate in these other tasks if you do not feel adequately well-rested after any recording nights, and you will be instructed to notify study personnel immediately.

Psychological discomfort: You may be uncomfortable answering some of our questions during the screening or grow bored while performing the cognitive assessments. You can stop answering questions or completing the cognitive assessments at any time.

WILL I BE PAID FOR MY PARTICIPATION?

You will receive $25 for the initial training visit and $50/day for every day you wear the device at home and complete the cognitive assessments during the eight weeks of the study. In addition, you will be eligible for a $100 completion bonus each week if you finish a week in the study having worn the headband at night and completed the cognitive assessments on five of the seven days.

HOW IS BEING IN THIS STUDY DIFFERENT FROM MY REGULAR HEALTH CARE?

We are conducting this study to determine whether it is possible to improve sleep by stimulating the senses to enhance slow waves during sleep and whether this stimulation results in improved cognitive performance during the day. This sleep study and the other things we are doing are not part of your health care.

FUTURE STUDIES AND DATA SHARING

Allowing us to share your data with other researchers, as we described above, is required to be part of this study. In addition, we would like to keep your contact information on file so that when future studies arise, we may contact you to see if you would like to participate in them. Your contact information will be kept in a secure location separate from your study information. This is completely voluntary. You can choose to have the study

team destroy your contact information after you have completed this study, and you will not be contacted again. Please indicate your preference by singing your initials on the appropriate line:

____Yes, the research team may keep our contact information for possible follow-up studies

____No, I do not want the research team to contact me again

If you change your mind, you may ask us not to contact you about future studies by emailing sleepresearch@psychiatry.wisc.edu

We are requesting your email address so we can easily arrange study visits with you. Email is generally not a secure way to communicate about your health because 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 research staff at 608.400.5004.

You do not have to provide your email address to participate in this study.

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

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

We are also requesting your cell number so we can send you reminder texts when it is time to perform the cognitive assessment (30-60 minutes after your reported wake-up time on weekdays). We do require you to provide a cell number in order to participate in the study so that we can send you reminder texts when it is time to perform the cognitive tasks.

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

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

WHAT IF I HAVE QUESTIONS OR CONCERNS?

If you have questions about this research, please contact the research team: Stephanie Jones, PhD at 608.263.3447 or Brady Reidner, PhD, at 608.232-3317.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

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, contact the study team for instructions or contact your regular health care provider. Call the Lead Researcher, Stephanie Jones, at 608.263.3447, to report your sickness or injury.

Authorization to participate in the research study:

I have read this consent and authorization form describing the research study procedures, risks, and benefits, what information will be collected, and how my information will be used. I have had a chance to ask questions about the research study, including the use of my information, and I have received answers to my questions. I agree to participate in this research study, and permit the researcher to use my health information as described above.

(Your signature will merely indicate for our records that your consent to participate in this study was voluntary and informed. Consent may be withdrawn at any time. By signing, you are not waiving any rights or privileges to which you would otherwise be entitled.)

_____

Name of participant (please print)

_____

Signature of participant Date

YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT.

_____

Signature of person obtaining consent and authorization Date