Home Operations Utilizing Stimulation

NCT04484285
Informed Consent Form

July 19, 2020

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and
AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Home Operations Utilizing Stimulation

3. Who do you call if you have questions about this research study?

Principal Investigator:	Dr. Eric Porges (PI)—(352) 294-5838
Other research staff:	Dr. John Williamson (Co-Investigator)—(352) 294-4920

4. Who is paying for this research study?

The sponsor of this study is the Center for Cognitive Aging and Memory (CAM) in the McKnight Brain Institute (MBI).

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research? How long will you be involved?

The purpose of this research study is to develop home applications of nerve stimulation. This study consists of two one-and-a-half hour visits to the MBI and one-hour at-home application of stimulating electrodes for 4 – 7 days.

b) What is involved with your participation, and what are the procedures to be followed in the research?

- Several self-report questionnaires about overall demographics, state of health, state of mind, sleep quality, and cognitive functioning
- Training in using the non-invasive nerve stimulator
- Taking photographs of electrode applications when you are at home
- Potentially a 20-minute Zoom interview

c) What are the likely risks or discomforts to you?

- Questions on some of the questionnaires may make you feel uncomfortable
- Slight itching, discomfort, and mild local pain at stimulation site

d) What are the likely benefits to you or to others from the research?

- Potential short-term improved mood, sleep, and cognitive performance
- Benefits researchers to publish results and to better understand how these two types of stimulation affect cognition

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

- This is not a clinical study and does not involve any clinical treatment
- There are no appropriate alternatives unless you decide you do not wish to participate in this study

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study?

This study will not impact your normal clinical care.

7. What will be done only because you are in this research study?

All procedures will take place in the UF MBI and your own home. A research assistant will review this informed consent form with you. If you give your consent to continue, you will do the following:

If you are a woman of child-bearing age, you will complete a pregnancy test. If you do not qualify to continue at this point, your participation in this study will be concluded. If you continue in the study, a research assistant will place a heart rate monitor clip to your finger. You will fill out a self-report questionnaire asking about general demographics and your state of health. You will then complete

questionnaires asking about anxiety and sleep quality. You will also complete several assessments that test your thinking and memory abilities.

The researcher will then demonstrate where and how to apply electrodes and set the stimulator at an appropriate intensity. You will have two electrodes placed on your ear to administer a small electric current. Our research group is interested in two stimulation sites on the ear—every participant will be randomly assigned to one of these sites. During your visit at the MBI, we will calibrate the stimulation so that it is below an intensity you might find uncomfortable. Once you demonstrate an understanding of how to place the electrodes, the research assistant will show you how to take pictures of the electrodes on your ear. You will also wear a wristband to monitor heartrate while receiving stimulation. A research participant will show you how to wear the band and the best practices for keeping it on and charged. You will be provided with instructions for the stimulator, electrode application, and wristband to take home with you.

After you leave the first session, you will apply the electrodes to your left ear each night for 4 – 7 nights, as demonstrated at the research assistant during your visit at the MBI. You may be randomly selected to complete a 20 minute at-home tele-motivational interview with a staff member on your first night of applying the stimulation. This interview will consist of a question-and-response conversation with a licensed psychologist regarding with topics such as alcohol use, daily life, and your inner perception of your motivations towards things such as drinking. These electrodes will be turned on and will deliver a small amount of current for up to an hour before you sleep. You will receive a daily text message via SMS asking you to rate your sleep and reminding you to send the picture of your application of the electrodes. You may ask follow-up questions after responding to the reminders, and a research assistant will respond within an eighteen-hour window. If the picture of the application indicates improper placement, a researcher will contact you to review proper form.

After collecting at least 4 quality images, a researcher will contact you to schedule the return of the study equipment at the MBI. You will complete the same questionnaires and assessments as before, after which your payment will be distributed. When you return for your second visit, a researcher may ask about the quality of your experience.

Once this research study is completed, any information that could identify you will be removed from any identifiable private information collected. After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative. Questionnaires and research information connected to you will be labelled with a unique study ID code and contain no private or identifiable information.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect demographic information and a self-reported medical history. The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information <u>may</u> be shared with:

- the study sponsor (listed in Question 4 of this form);

- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- Government agencies which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this research study?

The first visit will last approximately an hour and a half. You will apply the electrodes and stimulation for 4 – 7 nights before you sleep and leave them on for up to an hour. The second visit will last approximately an hour and a half. This authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this research study?

Up to 50 participants, including potential screen fails.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this research study?

Non-invasive Vagal Nerve Stimulator: Previous studies using electrical stimulation found that some side effects may occur. These side effects include itching, discomfort, and local pain at the stimulation site. These side effects usually end shortly after stopping stimulation. If the electrodes are not well placed then you might experience mild pain, although the researchers will adjust the electrode placement if this happens. You will also be instructed in how to adjust the electrodes yourself for when you are at home.

Wearable Wrist Monitor: The wrist monitor is comparable to wearing a standard wristwatch. If the band is too tight, there is a risk of skin irritation. The band will be adjustable to ensure participant comfort.

Breach of Confidentiality. Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This Research Study may include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research

team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this research study?

This study offers no direct nor immediate benefit to you as the participant.

13b. How could others possibly benefit from this study?

This study will help researchers continue to understand the effects of nerve stimulation on improving learning and attention in disadvantaged populations.

13c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question #3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

There are no known conflicts of interest.

14. What other choices do you have if you do not want to be in this study?

Research participation is entirely voluntary. If you do not wish to participate, please tell the researcher staff member and do not sign this consent form.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- You do not meet the inclusion/exclusion criteria
- You may be withdrawn at the discretion of the attending researcher(s)

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

There are no costs associated with you if you choose to participate in this study.

17. Will you be paid for taking part in this study?

You may receive between $5 – $150 by the completion of this study. If you do not pass our screening, you will be compensated $5. If you are unable to demonstrate an ability to properly place the electrodes at the end of this intake session, you will be compensated $10. Once you complete the entire study and return the equipment, you will be given $100. If you are able to provide at least 4 quality recordings of proper electrode placement, you will be given an additional $50. Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information—which will include your name, address, date of birth, and SSN/UF ID (depending on the amount of money you are paid)—is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to ***nonresident aliens*** must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

If you have any problems regarding your payment contact the study coordinator.

18. What if you are injured because of this study?

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study. The Principal Investigator will determine whether your injury is related to your participation in this study.

If you are injured as a direct result of your participation in this study, all injury-related expenses (for example, medical bills) will be billed to you or your insurance provider. You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization | Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing | Date