INFORMED CONSENT DOCUMENT

PARENT PERMISSION TO PARTICIPATE IN RESEARCH

Efficacy of External Trigeminal Nerve Stimulation (TNS) for Treatment of ADHD

NCT05374187

09/29/2025

UNIVERSITY OF CALIFORNIA, LOS ANGELES

PARENT PERMISSION TO PARTICIPATE IN RESEARCH

Efficacy of External Trigeminal Nerve Stimulation (TNS) for Treatment of ADHD

"TNS & ADHD"

INTRODUCTION

Sandra Loo, Ph.D., James McGough, M.D. and associates from the Department of Psychiatry & Biobehavioral Sciences in the David Geffen School of Medicine at the University of California, Los Angeles, are conducting a research study. This study is being paid for by a grant from the National Institute of Mental Health. Equipment and study supplies are provided by NeuroSigma, Inc., the company that manufactures the TNS device. NeuroSigma has no involvement in the design or conduct of this study.

WHAT SHOULD I KNOW ABOUT A RESEARCH STUDY?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

The research team is asking your child to be in this study because he or she has difficulties due to symptoms of inattention, hyperactivity, and/or impulsivity. Your child might also have been previously diagnosed with Attention-Deficit/Hyperactivity Disorder (ADHD) or you think your child might have ADHD.

WHY IS THIS RESEARCH BEING DONE?

This study will test if a non-medication treatment called Trigeminal Nerve Stimulation (or TNS) is helpful for children with attention-deficit/hyperactivity disorder and a range of other problems related to memory, concentration, sleep, and mood. The study will also assess ways in which TNS improves brain activity, predictors of TNS treatment response, and how long benefits last after treatment stops.

The device used in this study is known as the NeuroSigma Monarch eTNS™ System. It is a non-invasive medical device that stimulates the trigeminal nerve using an external electric conductive patch, which resembles a band-aid, directly on the forehead. *TNS is an FDA cleared treatment for ADHD.*

HOW LONG WILL THE RESEARCH LAST AND WHAT WILL I NEED TO DO?

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

The initial clinical study will last approximately 4 weeks. There will be two follow-up phone calls at 3-months and 6 months after treatment has been completed.

After evaluation and meeting entry requirements, you and your child will be instructed on applying the device to administer TNS. Treatment will be given every night during sleep for 4 weeks. You will be contacted by the researchers once each week during this period to assess response. Your child's teacher will be asked to complete behavior ratings 2 or 3 times. All parent and teacher ratings scales are completed via on-line platforms. After 4 weeks, TNS treatment will end. You and your child will return to clinic when treatment ends to assess treatment effects on brain, thinking, and behavior.

More detailed information about the study procedures can be found under ***"*What Will Happen If I Take Part In This Study?*"***

ARE THERE ANY RISKS IF I PARTICIPATE?

Known risks and discomforts:

Risks of TNS: The device is safe and designated by the U.S. FDA as a "non-significant risk device." The risks of using it are similar to the risks you experience in everyday life. Your child might experience some discomfort on the forehead during the initial visit while staff adjusts the level of stimulation. Some patients experienced tingling or pressure in the scalp or teeth, headaches, and eye blinking. If your child has these problems, notify staff right away and we will adjust the device to eliminate them. Some patients with sensitive skin, darker pigment, or skin conditions have developed skin rash or discoloration under the site where the strips were applied. When it has occurred, these rashes have gone away with decreased wear times and cortisone cream.

Risk of Cell phone use at night during TNS: The TNS System should not be used in the presence of cell phones, because the phone's low levels of electromagnetic energy may interrupt the therapy.

Risks of medication washout: clinical trials of ADHD treatment routinely include washout and is done in close coordination with study clinicians and caregivers; potential participants whose ADHD severity would pose risks if washed out will not be included.

Risks of Behavioral Worsening: Both the active and sham treatment groups could improve or have no improvement. While nothing suggests this is likely, ADHD symptoms or other behaviors could also worsen. Finally, if your child improves during the study it is unknown how long improvements will last.

Risks of Assessment Procedures: There is a chance you or your child might get upset during clinic visits due to 1) embarrassment or anxiety when asked to discuss personal

medical history, 2) anxiety about performance during testing, or 3) fatigue or boredom during tests. We also ask about suicidal thoughts or behaviors. If you or your child endorse that he or she has suicidal thoughts or behaviors, Dr. Loo, Dr. McGough, or the clinician under their supervision will talk to your child and take appropriate clinical steps (for example, going to the Emergency Room) to ensure your child's safety.

Risks of Breaches in Confidentiality: There is a rare possibility, as with any research study, that confidentiality will be breached and that individuals outside the study team will obtain information about you.

Unknown risks and discomforts:

TNS might have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to my child:

Your child may benefit from the study through improvement in ADHD symptoms and other behaviors. Your child will also receive an assessment that could be useful in school planning.

Possible benefits to others or society:

The results of the research may give more information about TNS treatment in ADHD, which has minimal risks to patients and is the first FDA cleared non-medication treatment for ADHD.

What other choices do I/my child have if my child does not participate?

Standard treatment for ADHD usually includes medication and might also include parent training, social skills training, and accommodations at school. FDA approved medications include stimulants, such as Concerta and Adderall, and non-stimulants such as Strattera and Intuniv. These treatments are readily available from physicians in the community.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you volunteer to participate in this study, the researcher will ask you to do the following:

Evaluation Visit

The Evaluation Visit will take 2 to 3 hours. During the evaluation we will ask you and your child a lot of questions about your child's behavior and ask you and your child to

complete numerous questionnaires and rating scales. We will also give your child some tests to see if he or she has learning problems. This evaluation can be completed in one or two meetings depending on what is more convenient for your family. This visit is completed via telehealth or in person, depending on your preference. Children who are currently well controlled with ADHD medication or have an immediate need to begin taking ADHD medication will not be eligible for this study. Participants who complete the evaluation activities but are ineligible for the study will receive $25.

Baseline Visit

If during the evaluation we find that your child meets study requirements, you will be invited to come into our office for a Baseline Visit. The Baseline Visit should take 3 to 3.5 hours. During this visit, we will measure your child's height and weight. We will ask you to complete some questionnaires and rating scales, and the doctor will ask you some questions about your child's behavior. We will also ask your child's teacher to complete a brief behavior rating form. We will obtain an EEG, a 45-60 minute exam that uses a cap with electrodes worn on the head to assess brain activity, to measure your child's brainwaves while taking some tests on a computer. We will also complete several measures of academic skills and mood with your child. Your child will receive $25 for completing this visit.

Participants in the study will be randomized to one of two groups. In one group, the "active group", your child will receive a type of brain stimulation that we believe will be medically effective for ADHD. In the other group, the "sham group", the device will deliver a type of brain stimulation that we believe will have no effect on ADHD symptoms. Your child will be assigned randomly to one group or the other in a manner similar to flipping a coin. **There is a 2:1 chance that your child will be in the active group.** Only one member of the study team will know which group your child is in. This is what we mean by a double-blind study in which neither you nor the research staff will know which group your child is in until the end of the study.

Staff will instruct you on how to use the device. The device is similar in size to an iPhone that you can clip to your child's t-shirt or pajamas. Small wires from the unit connect to strips that are a lot like Band-Aids that are placed on your child's forehead. We will give you a chance to practice putting this on and turning on the machine. Study staff will gradually adjust the stimulation strength. The most common sensation may be pressure or tingling in or near the eyebrows, but some people do not feel anything. If your child does feel something, he or she will be asked to describe and rate its intensity. If it is uncomfortable, the stimulation strength will be immediately decreased. It is not uncommon that your child might not feel anything during stimulation. Lack of sensation with the device does not mean it is not working. It is also common for children to feel the sensation at first but then get used to the stimulation and not really feel it anymore over time.

Your child will need to use TNS for about 7 to 9 hours each night. You should place and turn on the device 8 to 9 hours before your child's usual morning wakeup time. Most of the TNS will occur during sleep. Each morning you can throw away the connection

strips. You will use new ones each night. You will need to change the unit's battery every night.

At this visit, we will give you sufficient strips and batteries for the next 4 weeks. You need to bring the stimulator as well as any unused strips and batteries when you return for the end of treatment each visit.

If the device breaks, we ask that you contact us as soon as possible so that it can be replaced. You will have no financial responsibility for the device if it becomes damaged or lost, although we do ask that you do your best to care for it.

It is important that you keep the stimulator safely away from others, such as other children in the family. Do not share your device with others.

There are some precautions your child should follow while wearing the device. Always place the strips over the forehead, directly above the eyebrows, as directed by the study staff. Never place the electrodes on the chest, neck, or other body parts. Never place the electrodes over broken skin. Always turn the device off before removing the strips. Your child should not take a shower or bath or go swimming while wearing the device. Your child should not use a cellular phone while wearing the device.

Treatment Visits 1-3

These weekly visits should require approximately 15-20 minutes of time. We will ask you to complete some rating forms. The study doctor will ask you questions about your child's behavior.

If you have access to the Internet and if you prefer, you will have an option to complete Visit 1, 2 and 3 ratings without coming to UCLA. If you choose to do this, the study investigator will contact you by phone to obtain additional ratings and assess your child's health and safety. If you complete the doctor visit/call and ratings within the required window, you will receive $25 for each visit.

Treatment Visit 4

This visit will require approximately 2-3 hours of time. We will measure your child's height and weight. We will ask you and your child to complete some rating forms. The study doctor will ask you questions about your child's behavior. We will ask you to have your child's teacher fill out a brief rating form about how your child has been doing. At this visit, we will obtain a second EEG with your child and administer measures of their academic skills and mood.

At the end of this visit, the study doctor will find out which treatment group (active or sham TNS treatment) your child was assigned to and will give you that information.

Children assigned to the sham condition who do not show a significant response to TNS will have the option to remain in the study for an additional 4 weeks and to receive active TNS treatment during that time. A stimulator and supplies will be returned to you and your child will be able to resume nightly treatment. You will be asked to complete rating scales and the study physician will ask questions about your child's progress during each week of treatment so that response can be assessed. We will ask you to have your child's teacher fill out a brief rating form about how your child has been doing.

If you have access to the Internet and if you prefer, you will have an option to complete Visit 1, 2 and 3 ratings without coming to UCLA. If you choose to do this, the study investigator will also contact you by phone to obtain additional ratings and assess your child's health and safety. If you complete the ratings within the required window, you will receive $25 for each visit.

Treatment will end after 4 weeks and you will be asked to return the device and any remaining supplies.

At 3- and 6-months after TNS treatment study has ended, the study investigator will contact you by phone to obtain additional ratings and assess your child's health and safety. After the 6-month follow-up, study participation will end.

3-month extension

Children who improve sufficiently after active TNS treatment in the initial clinical trial will be eligible for 3-months of TNS supplies at no additional cost to ensure continuity of care. During this time, we will provide instructions on how to transition treatment back to their primary care physician or mental health professional. ADHD and other medications with CNS effects will be allowed as needed. The same 3- and 6- month phone calls will occur as detailed above. We will contact you to arrange for the device and any unused supplies to be returned at the end of the 3-month extension period.

If the device breaks, we ask that you return it as soon as possible so that it can be replaced. You will have no financial responsibility for the device if it becomes damaged or lost, although we do ask that you do your best to care for it.

You are free to discontinue participation in the 3-month extension at any time. If you choose to discontinue TNS, we ask that you let us know and that you return the device and any remaining supplies.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

Use of personal information that can identify you:

We will need to collect some personal information from you so that we can contact you about study visits and requirements. We will also ask your permission to call you in the future if there is another study you might qualify for. This information will be kept in a locked file that is only available to study staff.

How information about you will be stored:

Research data from this study will be entered into an electronic database that is protected by a password. Only information that is important for this research will be entered into this database. Your data will be identified by a code only and will not be directly linked to anything that could identify you.

People and agencies that will have access to your information:
In general, only the research team will have access to any information about you. Authorized UCLA personnel and regulatory agencies such as the Food and Drug Administration (FDA), may have access to study data and records to monitor the study. Any information from this research project that personally identifies you will not be released or disclosed by these agencies without your separate consent, unless required by law. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

Certificate of Confidentiality:
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit 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.

How long information from the study will be kept:
Once the study ends, we will destroy any personal data that is linked to your research records. Research data will be kept for as long as it seems to be useful to answer related scientific questions.

USE OF DATA FOR FUTURE RESEARCH

Your data including de-identified data may be kept for use in future research.

WILL I BE PAID FOR MY PARTICIPATION?

If you take part in this study, there would be no cost to you and no cost to your insurance company for the research procedures. You will be provided with a voucher for UCLA parking each clinic visit. You will also be given a $25 stipend at each visit to cover time and other related expenses of participation. It is expected that your child will be given some or all of this compensation, at an amount you determined is appropriate. Participants who complete the evaluation activities but are ineligible for the study will receive $25. The total compensation if your child completes all study visits is $125, or $225 if your child was assigned to the sham condition and is eligible to participate in the 4 week open-label treatment phase at study end.

WHAT OTHER THINGS SHOULD I CONSIDER BEFORE PARTICIPATION?

Researcher Financial Interests in this Study

UCLA has a patent on the use of the stimulator and might receive financial benefits if it proves useful in ADHD. However, study investigators will not benefit financially from the results of this study.

WHO CAN I CALL IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:
If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. You may contact Andrea Dillon at 310-825-3735 or email AndreaDillon@mednet.ucla.edu with any questions or concerns about the research or your participation in this study. You can also reach the study investigators Dr. Loo at 310-825-9204 or email SLoo@mednet.ucla.edu or Dr. McGough at 310-794-7841 or email JMcGough@mednet.ucla.edu. After hours or on weekends, Dr. McGough can be reached through the UCLA page operator at 310-825-6301 if any emergencies arise.

UCLA Office of the Human Research Protection Program (OHRPP):
If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

Public Information about this Study:
ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

UNIVERSITY OF CALIFORNIA LOS ANGELES
RESEARCH PARTICIPANT'S
BILL OF RIGHTS

These rights are the rights of every person who is asked to be in a medical research study. As a research participant, I have the following rights:

1. I have the right to be told what the research is trying to find out.
2. I have the right to be told about all research procedures, drugs, and/or devices and whether any of these are different from what would be used in standard practice.
I have the right to be told about any risks, discomforts or side effects that might reasonably occur as a result of the research.
4. I have the right to be told about the benefits, if any, I can reasonably expect from participating.
5. I have the right to be told about other choices I have and how they may be better or worse than being in the research. These choices may include other procedures, drugs or devices.
6. I have the right to be told what kind of treatment will be available if the research causes any complications.
7. I have the right to have a chance to ask any questions about the research or the procedure. I can ask these questions before the research begins or at any time during the research.
8. I have the right to refuse to be part of the research or to stop at any time. This decision will not affect my care or my relationship with my doctor or this institution in any other way.
9. I have the right to receive a copy of the signed and dated written consent form for the research.
10. I have the right to be free of any pressure as I decide whether I want to be in the research study.

If I have any questions or concerns I can ask the researcher or the research assistant. I can also contact the Office of the Human Research Protection Program (OHRPP), which helps protect research study participants. I can reach the OHRPP by calling 310-825-5344 from 8:00 AM to 5:00 PM, Monday to Friday or participants@research.ucla.edu. If I call this office and do not speak English or Spanish, I should have someone available who can interpret for me. I may also write OHRPP, 10889 Wilshire Blvd., Suite 830, Los Angeles, CA 90095-1406.

05/2021

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you want to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant's Bill of Rights to keep.

- ❑ I agree to be contacted in the future if there is another study I might be interested in or eligible for. _____ (Initial)

- ❑ I do not want to be contacted for future studies. _____ (Initial)

SIGNATURE OF THE PARENT

_____
Name of Child

_____
Name of Parent or Legal Guardian

_____ _____
Signature of Parent of Legal Guardian Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____
Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date