Project Title: Movement-Associated tVNS and Responsiveness Testing for Personalized Rehabilitation

NCT Number: NCT06335199

Date: 08/06/2025

Key Information for Movement-associated tVNS and responsiveness testing for personalized rehabilitation:

What Am I Being Asked To Do?

You are being asked to be a volunteer in a research study. This page will give you key information to help you decide if you would like to participate. Your participation of voluntary. As you read, please feel free to ask any questions you may have about the research.

What Is This Study About and What Procedures Will You be Asked to Follow?

The purpose of this study is to look at how a special device called tVNS works and affects your movements and your eyes. We will put small pads on your ears and ask you to move your arms or just relax. While you are doing this, we will send a mild electrical pulse to your ear. If you are a healthy adult, you will spend about 3 hours on this for one day. If you've had a stroke, it will be 3 hours for 2 days.

Are There Any Risks or Discomforts you Might Experience by Being in this Study?

You will feel quick, gentle electrical pulses on the outside of your ear using small electrodes. These pulses last only half a second each, much shorter than those used on people who might get the following symptoms from longer ones (30 seconds). The common symptom is local skin irritation due to electrode placement. Rare symptoms include headaches, cold, dizziness, facial drooping, and nausea. Even less likely are nausea, a fluttering feeling in your chest, irregular heartbeat, or slow heartbeat. To be extra safe, you need to confirm you don't have any heart problems. We won't use long pulses, just quick ones, and we'll keep an eye on your heart rate. If we notice anything unusual, we'll stop right away. You might feel a bit tired or notice your muscles getting tired or strained, but it's all temporary.

What Are the Reasons You Might Want to Volunteer For This Study?

You are not likely to benefit in any way from joining this study. However, your participation in this study may assist researchers in understanding how the nerve stimulation around the ear affects brain activity.

Do You Have to Take Part in the This Study?

It is fully your decision if you wish to be in this study or not. If you choose not to participate or choose to participate and later determine you no longer wish to, you will not lose any rights, services, or benefits as a result of your withdrawal. The study is completely voluntary.

CONSENT DOCUMENT FOR ENROLLING ADULT PARTICIPANTS IN A RESEARCH STUDY

Georgia Institute of Technology

Project Title: Movement-associated tVNS and responsiveness testing for personalized rehabilitation
Principal Investigator: Minoru Shinohara, PhD

You are being asked to be a volunteer in a research study.

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.

Purpose:
The purpose of this study is to examine the use of a neurostimulation system during movement and eye response in stroke survivors and healthy adults. We expect to enroll 21 people in this study.

Exclusion/Inclusion Criteria:
Participants must satisfy the following inclusion and exclusion criteria.

Inclusion criteria

- 18-89 years old across all races, genders, and ethnicities.
- Post-stroke participants will have persistent hemiparesis on the upper extremity (UE) with some residual UE voluntary movement

Exclusion criteria for able-bodied participants:

- Younger than 18 years old or older than 89 years old
- Current or history of cardiac disease
- Have a vision problem not corrected by glasses or contact lenses
- Have an implanted device such as a neurostimulator or cochlear implant
- Current or history of tympanic membrane perforation
- Had a stroke or lesion (including tumor) in your brain
- Had a head injury or brain surgery
- Suffer from frequent or severe headaches
- Had a fainting spell or syncope
- Have any metal in the head such as shrapnel, surgical clips, or fragments from welding or metal work
- Have any implanted device such as cardiac pacemakers, medical pumps, or intra-cardiac lines
- Had any brain-related conditions (i.e. multiple sclerosis, Parkinson, Alzheimer)

- Had any illness that caused brain injury (i.e. meningitis, aneurysm, brain tumor)
- Had any head trauma that was associated with a loss of consciousness or diagnosed as a concussion
- Being treated for any psychiatric condition (i.e. depression, anxiety, PTSD, schizophrenia)
- Suspected of pregnancy

Exclusion criteria for *post-stroke participants:*

- Younger than 18 years old or older than 89 years old
- Current or history of cardiac disease
- Have a vision problem not corrected by glasses or contact lenses
- Have any implanted devices such as a neurostimulator or cochlear implant
- Current or history of tympanic membrane perforation
- No persistent hemiparesis on the upper extremity (UE)
- No residual UE voluntary movement
- A first stroke less than 4 months prior to the participation
- Serious uncontrolled medical conditions
- Excessive pain in any joint of the more affected extremity
- Unable to stand independently for 2 min., transfer independently to and from the toilet or perform sit-to-stand
- Suffer from frequent or severe headaches
- Had a fainting spell or syncope
- Have any metal in the head such as shrapnel, surgical clips, or fragments from welding or metal work
- Have any implanted device such as cardiac pacemakers, medical pumps, or intra-cardiac lines
- Had any illness that caused brain injury (i.e. meningitis, aneurysm, brain tumor)
- Had any head trauma that was associated with a loss of consciousness or diagnosed as a concussion
- Being treated for any psychiatric condition (i.e. depression, anxiety, PTSD, schizophrenia)
- Suspected of pregnancy
- A score of less than 24 on the Folstein Mini-Mental State Examination
- Excessive frailty or lack of stamina (e.g., cannot attend to instructions, stay awake, engage in functional activities, etc.)
- Excessive pain in any joint of the more affected extremity that could limit ability to cooperate with the intervention

Procedures:

If you decide to be in this study, it will involve one visit (Experiment A) for a healthy participant or two visits (Experiments A & B) on different days for a post-stroke participant.

Experiment A for all participants

Before we begin the measurement, we kindly ask you to remove any earrings or attachments from your ears. Our team will then clean your ears using a combination of cleaning gel and alcohol. We will attach surface electrodes to both ears. We will also provide you with a finger device to monitor your heart activity. During the measurement, you may experience brief electrical stimulations to your ear, lasting less than a second. The experiment will gradually increase the stimulus, and you will be asked to indicate when you feel it. The experiment will gradually increase the stimulus, and you will be asked to indicate when you feel it. Once you feel pain, the stimulus stops increasing and remains below that level. Please note that you may stop the experiment anytime and for any reason. Additionally, while watching a computer screen, you will receive a series of brief stimulations to your ear. A special device called an eye tracker will record your eye movement. The stimulation site will vary randomly, and there will be breaks between stimulation blocks. After the stimulations, we will ask you how you felt during the stimulations. The visit will take a total of 2.5-3 hours, including preparation and cleaning. You may stop at any time.

Experiment B only for post-stroke participants (in addition to Experimet A)

You'll visit the lab on a different day than Experiment A. Just like Experiment A, we'll need you to remove any earrings or ear attachments. We'll clean your ear with a gentle cleaning gel and alcohol and then attach surface electrodes to both ears. Additionally, we'll need you to attach electrodes to your chest to monitor your heart activity. We'll administer brief electrical stimulations (less than a second) to your ear during the measurement. The stimulus will gradually increase, and I'll ask you to indicate when you feel pain. Then, I'll reduce the stimulus to below the pain threshold. You can stop the procedure at any time for any reason. While seated, I'll instruct you to move your upper limb. The task involves various movements, such as reaching, grasping, turning handles, making gross movements, flipping objects, simulating eating tasks, inserting objects, and opening containers. Some movements will be repeated multiple times. During some trials, we will monitor your heart activity while providing stimulation. With your permission, we will videotape your whole body during the movements. Please note that your identity will remain confidential. After the simulations, we will ask you how you felt during the process. The visit will take around 2.5-3 hours, including preparation and cleaning. Please keep in mind that you may stop at any time.

Risks or Discomforts:

The following risks or discomforts may occur as a result of your participation in this study.

Electrical stimulation of the ear is completely safe and well-tolerated, even in individuals without heart disease. You should not experience any discomfort or pain, as the stimulus intensity is kept low. We will communicate with you throughout the process and, if necessary, decrease the intensity to minimize any discomfort. However, we will take all necessary precautions to ensure your safety and comfort. In rare cases (1-3%), if the stimulation is applied continuously for 30 seconds or more, you may experience

headache, cold symptoms, dizziness, facial drooping, or nausea. If the stimulation lasts for 30 seconds or more, there is a rare chance, less than 0.2%, of experiencing heart fluttering, irregular heartbeat, or slow heart rate. However, the stimulation you will receive is much shorter, less than one second. We will monitor your heart activity, and if we notice any unusual patterns, we will halt the stimulation.

Other risks/discomforts, aside from electrical stimulation, may be possible in rare cases: The tape and gel used to attach electrodes (medical grade surgical tape) may irritate the skin in a small percentage of people. This effect will last no longer than a day or so. If you participate in Experiment B, the limb movement tasks may increase your heart rate, and you may feel general fatigue, muscle fatigue, or muscle strains, which are normal responses to muscle contraction.

Benefits:

You are not likely to benefit in any way from joining this study. However, this study has the potential to benefit society. We hope that what we learn will someday help better the lives of individuals suffering from impaired motor function (e.g., elderly, stroke victims).

Compensation to You:

There will be no compensation for participating in this study.

Storing and Sharing your Information:

Your participation in this study is gratefully acknowledged. It is possible that your information/data will be enormously valuable for other research purposes. By signing below, you consent for your de-identified information/data to be stored by the researcher and to be shared with other researchers in future studies. If you agree to allow such future sharing and use, your identity will be completely separated from your information/data. Future researchers will not have a way to identify you. Any future research must be approved by an ethics committee before being undertaken.

Use of Photographs, Audio, or Video Recordings:

We may want to use some of the photographs, audio, or video recordings of you in public presentations related to the research. We will not use any videotapes, photographs, recordings, or other identifiable information about you in any future presentation or publication without your consent.

Confidentiality:

The following procedures will be followed to keep your personal information confidential in this study: We will comply with any applicable laws and regulations regarding confidentiality. To protect your privacy, your records will be kept under a code number rather than by name. Your records will be kept in locked files and unless you give specific consent otherwise, only study staff will be allowed to look at them. Your name and any other fact that might point to you will not appear when results of this study are presented or published. However, in the future, we may strip your data of all information that could

identify you. If this is done, we will share the de-identified information for purposes of future research without obtaining additional consent from you. To make sure that this research is being carried out in the proper way, the Georgia Institute of Technology IRB may review study records. The Office of Human Research Protections may also look at study records.

Costs to You:
There are no costs to you, other than your time, for being in this study.

Questions about the Study:
If you have any questions about the study, you may contact Dr. Minoru Shinohara at telephone (404) 894-1030 or shinohara@gatech.edu.

In Case of Injury/Harm:
If you are injured as a result of being in this study, please contact Dr. Minoru Shinohara at telephone (404) 894-1030. Neither the Principal Investigator nor Georgia Institute of Technology has made provision for payment of costs associated with any injury resulting from participation in this study.

Questions about Your Rights as a Research Participant:

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will be given a copy of this consent form to keep.
- You do not waive any of your legal rights by signing this consent form.

If you have any questions about your rights as a research participant, you may contact the Georgia Institute of Technology Office of Research Integrity Assurance at IRB@gatech.edu.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

_____
Participant Name (printed)

_____ _____
Participant Signature Date Time

_____ _____
Signature of Person Obtaining Consent Date

Consent to Store and Share your Information:

I agree that my de-identified information/data may be stored and shared for future, unspecified research.

SIGNATURE _____

I do not allow my de-identified information/data to be stored and shared for future, unspecified research. These may only be used for this specific study.

SIGNATURE _____