Permission to Take Part in a Human Research Study
Do not sign this consent if today’s date is later than the stated expiration date above.

Title of Research Study: Functional MRI Study of Transcranial Electrical Stimulation in Healthy Adults

Investigator: Amber M. Leaver, Ph.D.

Supported By: This research is supported by the National Institutes of Health and the Brain and Behavior Research Foundation.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you are a healthy adult.

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.

Why is this research being done?
The purpose of this research study is to understand how a kind of neuromodulation, called transcranial electrical stimulation (tES), affects brain function.

tES delivers low electrical current to the head, and is described as a “neuromodulation” or “neurostimulation” technique. This study uses two kinds of tES. One is called “transcranial direct current stimulation,” or tDCS, where a constant (unchanging) electrical current is passed between two electrodes on the head. The other is called “transcranial alternating current stimulation,” or tACS, where a varying electrical current is passed between two electrodes on the head. For simplicity, we will use the more general term “tES” in this form.

In research studies, neuromodulation methods like tES have shown promise in changing healthy brain function with the goals of understanding how the brain works, understanding how neuromodulation works, and in some cases improving perception, thinking, and/or memory in healthy adults. In research studies, neuromodulation methods like tES have also shown promise in improving the symptoms of some brain disorders (like chronic pain, depression, stroke, and others). However, how neuromodulation changes brain function remains unclear. To better understand how tES works, we will use MRI (a type of brain scan) to measure brain function during tES in healthy adults.

There are no potential benefits to you or others should you choose to participate in this research study.
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The use of tES and MRI in this research study is for investigational purposes only. The USFDA has not approved tES for use in research studies.

How long will the research last and what will I need to do?
We expect that you will be in this research study for one study visit lasting approximately 3 hours. You may also choose to have an optional hearing test, which will last approximately 1 hour for a total time commitment of four hours.

You will be asked to fill out questionnaires asking about your medical history and complete simple tests of perception and cognition. You will be asked to have one MRI scan during which tES will be applied. You will be asked to come for one study visit.

More detailed information about the study procedures can be found under the section What happens if I say “Yes, I want to be in this research”?

Is there any way being in this study could be bad for me?
MRI and tES may be uncomfortable. During MRI, you will lay on your back in an enclosed space (the MRI scanner) for one hour. During tES, you may feel tingling or slight discomfort under the electrodes. Filling out questionnaires regarding your medical history may cause emotional distress or embarrassment.

More detailed information about the risks of this study can be found under “Is there any way being in this study could be bad for me? (Detailed Risks)”

Will being in this study help me any way?
There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include contributing to knowledge that may one day improve tES as a therapy for brain conditions.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (312) 694-2966 or inmri@northwestern.edu.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

• Your questions, concerns, or complaints are not being answered by the research team.
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- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?
We expect about 20 people here will be in this research study out of 20 people in the entire study nationally.

What happens if I say “Yes, I want to be in this research”?
You will participate in one study visit at the Center for Translational Imaging (CTI) at Northwestern University, located at the Olson Pavilion, 710 N Fairbanks Ct in Chicago. During your study visit, you will interact with trained study staff, as well as trained MRI and administrative staff at the CTI.

Your study visit will last approximately three (3) hours. If you agree to the optional hearing test, your visit will last approximately four (4) hours. During this visit, you will:

- Review all study procedures with study staff and ask any questions you have about study procedures at any time
- Complete questionnaires about your medical history on the following topics:
  - MRI safety
  - tES safety
  - Experiences and conditions that can affect brain function, including neurodevelopmental disorders, neurological injury and disorders, psychiatric and/or mood disorders, and overall health
- Complete brief tests of perception and thinking at a computer, including a hearing test
- Have tES electrodes placed on your head
- Have one (1) MRI session lasting one (1) hour. During this MRI session, tES will be applied for 5-30 minutes and changes in brain function will be recorded with functional MRI during three types of scans:
  - During one MRI scan, active transcranial direct current stimulation (tDCS) will be applied, where the tES device will be turned on and will stay on for 5-30 minutes.
  - During one MRI scan, active transcranial alternating current stimulation (tACS) will be applied, where the tES device will be turned on and will stay on for 5-30 minutes.
  - During one MRI scan, “sham” tES will be applied, where the tES device will be turned on for only approximately 60 seconds.

The order of these scans will be chosen by chance (at random) by a computer. Neither you or study staff will choose the order. You will receive both active and sham tES scans during this MRI session. You will not be told whether active or sham tES will come first; however, study staff will know. The total duration of active tES will not be more than 30 minutes during the MRI session. For example, if you have active tACS for 20 minutes, you would have active tDCS for 10 minutes or less.

You may also schedule an optional hearing test at Northwestern’s Audiology Services. This visit will last approximately one (1) hour and will take place at the Galter Pavilion Suite 15-200, located at 675 North Saint Clair Street in Chicago. Audiology Services is located near CTI, and this optional hearing test can be scheduled before or after your study visit at CTI, or at another time convenient to your schedule.
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Two devices are used during this study. Both are for experimental (investigational) use only in this study, and include:

- MRI scanner (manufactured by Siemens)
- tES device (manufactured by Soterix Medical)

If you are found to have symptoms of depression or other mood disorder, you will be referred to a clinical psychologist. Please note, however, that the questionnaires used in this research study are not diagnostic and should not be considered a substitute for clinical care by your physician.

Please note that you will be asked to indicate at the end of this consent form whether you are interested in being contacted for future studies like this one. Your answer will not affect your ability to participate in this current study.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to:

- arrive to study visits on time and
- follow study instructions.

What happens if I say “Yes”, but I change my mind later?
You can leave the research at any time; it will not be held against you. If you decide to leave the research, contact the investigator at (312) 694-2966 or inmri@northwestern.edu so that the investigator can cancel any remaining study visits.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment, your class standing (for students enrolled in a class at NU), or your present or future employment (for employees at NU or its affiliates).

Detailed Risks: Is there any way being in this study could be bad for me?
This research may hurt you in the following ways:

Physical risks
- tES might be uncomfortable. Potential risks and discomforts associated with tES include tingling, mild irritation, or a light itching sensation under the electrodes. This is a natural, non-painful sensation associated with the passing of electrical current through the skin, sometimes likened the flow of water on the skin. You may also experience redness under tES electrodes. For many people, these sensations lessen or disappear soon after the start of stimulation, and are rarely reported as unpleasant or painful. However, if you become uncomfortable, please inform the staff and tES can be terminated immediately.

Alert study staff immediately if:
- you feel uncomfortable tingling after the first 30-60 seconds of tES and wish to stop
- you feel heating or burning under tES electrodes during tES-MRI at any time
- you have skin condition, injury, or sensitivity on your scalp

Rarely, people have reported headache, fatigue, or trouble sleeping after tES. However, these were reported after both active tES and sham tES (electrode placement with little or no stimulation), and so it is unclear whether headache, fatigue, or trouble sleeping was related to tES in these studies. tES uses a low level of electrical current, and has been used with no
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significant long-lasting or damaging side effects in research laboratories worldwide for the last
30-40 years in healthy adults and for the treatment of tinnitus (a chronic ringing in the ear),
depression, anxiety, chronic pain, and stroke. Established safety procedures for tES will be
strictly followed in this study.

- **MRI scans might be unsafe if you have metal or implants in your body.** The MRI scanner uses
magnetic fields to take pictures, and this can attract and influence certain metals. Therefore,
people with metal in their body that cannot be removed (like pacemakers, infusion pumps,
aneurysm clips, metal prostheses, metal joints, rods, plates, or other metallic objects) will be
excluded from this study. **You must tell the investigators supervising this protocol if you
have any of these types of devices in your body.** The metal used in dental fillings is less
susceptible and is therefore allowed. You will be asked to change into a hospital gown and/or
hospital “scrub” pants prior to your MRI scan.

- **MRI and pregnancy.** MRI is not known to pose risks to a pregnancy or fetus. However, having
an MRI while pregnant may hurt a pregnancy or fetus in ways that are unknown. Possible that
there are risks about which the investigators are unaware or cannot foresee. Because of this,
pregnant women and women who are trying to become pregnant are excluded from this study.

- **MRI is loud.** The sound of the MRI scanner can also be quite loud, and prolonged exposure
has the potential to damage your hearing. So, you will be given special ear plugs and/or
headphones to minimize this noise.

- **MRI scans might be uncomfortable.** Although some people find MRI to be a comfortable
experience, others might become uncomfortable. You will be asked to lay on your back for
the duration of the scan, and special padding or foam might be used to help keep your head
still. Some people may feel claustrophobia or anxiety from being a tight, enclosed space. If
you become uncomfortable for any reason, please inform the staff and the MRI can be
terminated immediately.

- **Research MRI is not diagnostic.** The brain images obtained from this research cannot be used
to screen for or diagnose medically significant brain abnormalities. Because these brain scans
are not designed to detect all possible brain abnormalities, you should not assume, based on
this research, that the scan of your brain was normal if this ever becomes an issue in your
future medical care. However, if the investigators do identify an unsuspected anomaly that
may be of potential medical significance, they will discuss this with you and suggest options
for medical follow-up such as you talking with or seeing your regular medical doctor.

**Psychological risks**

- **Completing questionnaires, hearing tests, or tests of perception and thinking might be boring
or uncomfortable.** During these tests, you will be sitting at a desk or table writing on paper or
typing at a computer. Some people might find this part of the study boring or tedious, and
others might be uncomfortable answering questions about their thoughts, feelings, or medical
history. Otherwise, we do not expect these questionnaires or tests to pose any significant risks
or discomforts.

**Privacy/Confidentiality risks**

- **Your privacy and confidentiality.** This study involves the use of your identifiable, personal
information and there is a chance that a loss of confidentiality could occur. The researchers
have procedures in place to lessen the possibility of this happening. See the section below
titled: “What happens to the information collected for the research?”. 
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What do I need to know about reproductive health and/or sexual activity if I am in this study?
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 while on this research study.

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?
There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include: contributing to knowledge that may one day improve tES as a therapy for brain conditions.

What happens to the information collected for the research?
Efforts will be made to 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. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution, the sponsor.

Study data will be retained after the study for future research. These data will be de-identified, meaning that they will not be linked to any information that could identify you, like your name or phone number. These data will be stored in secure, password-protected computers located in the PI’s laboratory in a secure suite only accessible by approved study staff. The data will be retained indefinitely for use in future research.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings; for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

A description of this clinical trial will be available at 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.

Data Sharing
De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.
Can I be removed from the research without my OK?
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 arriving late for study visits or
not following study instructions.

What else do I need to know?
If you become ill or get injured as a result of this study (devices or procedures), you should seek
medical treatment through your doctor or treatment center of choice. You should promptly tell
the study doctor about any illness or injury.

The researchers will not pay for medical care required because of a bad outcome resulting from
your participation in this research study. This does not keep you from seeking to be paid back
for care required because of a bad outcome.

If you agree to take part in this research study, we will pay you $75 for your time and effort. If
you agree to take part in the optional hearing test at Audiology Services, we will pay you an
additional $25. Should you choose to withdraw from the study, or if study staff withdraw you
from the study, before before the study is complete, you will be paid $6.25 per quarter-hour (15
minutes) you completed.

The Accounting Services at Northwestern University will be given your name, address, and
Social Security Number in order to issue a check for your study participation. Study payments
are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if
your total payments are $600 or more in a calendar year.

HIPAA Authorization
We are committed to respect your privacy and to keep your personal information confidential.
When choosing to take part in this study, you are giving us the permission to use your personal
health information that includes health information in your medical records and information that
can identify you. For example, personal health information may include your name, address,
phone number or social security number. Your health information we may collect and use for
this research includes:

- Surgical implants to determine MRI safety
- If you agree to the optional hearing test, your name, address, phone number, and date of
  birth to be used to schedule hearing tests at Northwestern’s Audiology Services for this
  research study. We will also access the results of your hearing test from your medical
  record. If you do not agree to the optional hearing test, we will not collect this information.

The following clinical providers may give the researchers information about you: all current and
previous health care providers, including but not limited to the Shirley Ryan AbilityLab
(SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and
Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with
the following offices or entities outside of Northwestern University and its clinical partners (or
affiliates): the Northwestern University Institutional Review Board Office and Office for
Research Integrity; the US Office of Research Integrity; the US Office for Human Research
Protections; the US Food and Drug Administration.
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Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator’s office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children’s Hospital of Chicago (Lurie Children’s). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of the research study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI’s Name: Amber Leaver, PhD
Institution: Northwestern University
Department: Radiology
Address: 737 N Michigan Ave Ste 1600, Chicago IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in the optional hearing test for this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.
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Optional Elements:
The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree        I disagree

I agree to have my hearing tested at Northwestern’s Audiology Services as part of this research study. This test will take approximately one hour and I will be paid an additional $25 for my time.

The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_______________________________________________      __________________
Signature of Participant                                                               Date

_______________________________________________
Printed Name of Participant

_______________________________________________      __________________
Signature of Person Obtaining Consent                                     Date

Printed Name of Person Obtaining Consent