The University of New Mexico Health Sciences Center
Consent to Participate in Research

Targeted Transcranial Direct Current Stimulation (tDCS) to Enhance Speech-Language Treatment Outcomes in Persons with Chronic Post-Stroke Aphasia

V07/12/2022

Introduction

You are being asked to participate in a research study that is being done by Jessica D. Richardson, who is the Principal Investigator, from the Department of Speech and Hearing Sciences. This research is studying whether right hemisphere brain stimulation improves aphasia treatment outcomes. You will be asked to complete behavioral testing, electroencephalography (EEG), and magnetic resonance imaging (MRI). You will also be asked to participate in three weeks of speech-language therapy while receiving brain stimulation (called transcranial direct current stimulation, or tDCS). If it is not safe for you to receive an MRI you will be asked to complete everything except the MRI portion of the study.

You are being asked to take part in this study because you are a person who has aphasia as a result of a stroke. 90 people will take part in this study at the University of New Mexico and the Mind Research Network.

This form will explain the research study, and will also explain the possible risks as well as the possible benefits to you. We encourage you to talk with your family and friends before you decide to take part in this research study. If you have any questions, please ask one of the study investigators.

What will happen if I decide to participate?

If you agree to participate, the following things will happen:

You will first be assigned to the active brain stimulation group or the placebo brain stimulation group. This will be done randomly, like flipping a coin and choosing "heads" or "tails." You will not be told which group you are in. Then you will be asked to do the following:

Pre-treatment (Visit 1, 3-4 hours):

1. Review and sign consent form.
2. Review and sign brain stimulation and MRI safety-screening forms.
3. Complete behavioral testing.
4. Complete EEG.

Pre-treatment (Visit 2, 3-4 ½ hours):

1. Review and sign MRI screening form.
2. Complete behavioral testing.
3. Have MRI exam.

Treatment (Visits 3-17, 1 ½ hours each visit):

1. Receive 1 hour of language therapy.
2. Receive either 30 minutes (active) or 30 seconds (placebo) of brain stimulation during therapy.

Immediate Post-treatment (Visit 18, 3-4 hours):

1. Review and sign MRI screening form.
2. Complete behavioral testing.
3. Complete EEG.
4. Have MRI exam.

3-Month Follow-up (Visit 19, 3-4 hours):

1. Review and sign MRI screening form.
2. Complete behavioral testing.
3. Complete EEG.
4. Have MRI exam.

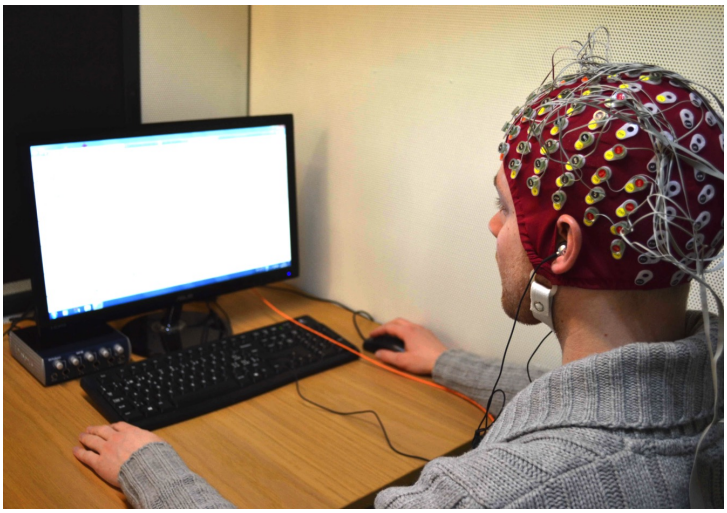
If you have difficulty getting around and/or if daily transportation is not possible, all study procedures except the MRI and EEG may be completed at your home.

The screening forms will ask questions about your medical history (like "have you ever had surgery on your head or neck?") and medical implants (like "Do you have any stents?") to make sure that brain stimulation and MRI are safe for you to complete.

*The **TESTS** and **QUESTIONNAIRES** will involve:*

Speaking tasks	Naming pictures and objects Repeating words Picture description Answering questions
Listening tasks	Answering questions Following directions
Problem-solving tasks	Reasoning Design matching
Questions about activities and life roles that involve communication	Participation in social situations Changes in life roles Barriers to communication Confidence in communication

Brain wave recording (EEG):



An elastic cap with sensors attached to it will be placed on your head and the sensors will be filled with a gel. You will also have sensors attached around your nose and eye area. You will sit in front of a computer while pictures and words will be shown to you, or you will listen to sounds on headphones. You will be asked to make decisions about the information presented to you. The EEG takes about 1 hour.

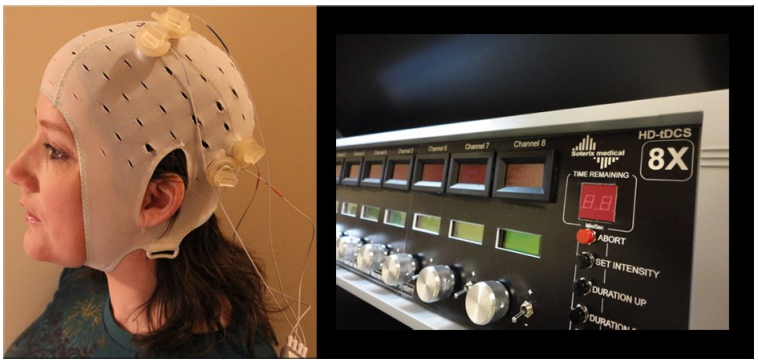
Brain Imaging - Magnetic Resonance Imaging (MRI):

During the study you will undergo a brain study called MRI. If the MRI results are unclear, you may be asked to have an additional MRI done. For this study, you will lie down on a table and will then be placed into a long donut-shaped magnet. During the study you will hear loud rapping and knocking noises coming from the magnet. You may

feel warm during this procedure. In order to obtain good pictures, it is important that you do not move during the procedure. Although you should not talk during the MRI procedure, you will be able to talk with the technician during breaks or in case of emergency by pressing a call button or similar device. This takes about 1 hour. If you could be pregnant we will ask you to take a pregnancy test before the MRI procedure.

The MRI scan is being done to answer research questions, not to examine your brain for medical reasons. This MRI scan is not a substitute for a clinical scan (the type a doctor would order). The research scan may not show problems that may be picked up by a clinical MRI scan. However, all research MRI scans will be read by a doctor with experience reading MRI scans unless you have been scanned at MRN in the previous six months. If the scan is read, you will receive the official report by mail. If we find an abnormality that requires urgent follow-up, we will contact you and your doctor (with your permission) by phone to help answer questions. Our Medical Director or the research team is always available to answer any questions you may have about your scan.

Brain Stimulation - Transcranial Direct Current Stimulation (tDCS):



tDCS is a low electrical current that slightly changes the way the brain works for a short period of time. tDCS applied to the head does this by giving a very weak electrical current through your scalp and into your brain. An elastic cap (like the one used for EEG) will be used to place the electrodes on your scalp with a special conductive gel. The electrodes will give a very weak electrical current for 30 minutes, which may cause a tingling and/or itching feeling at the electrode sites.

Language Therapy:

For three weeks you will be asked to attend daily therapy sessions (5 sessions per week). These sessions will be led by a certified speech therapist, or by a graduate student directly supervised by a certified speech therapist. During therapy you will be asked to name and give information about pictures. For example, you might be asked to tell how many syllables the word has, or how you use the pictured item. You will receive tDCS while completing the therapy.

How long will I be in this study?

Participation in this study will take a total of about 40 hours over 19 visits over a period of 3 months.

What are the risks or side effects of being in this study?

Brain Wave Recording (EEG):

There is a very small possibility that if you have sensitive skin (e.g., contact dermatitis) you may experience some skin irritation from the EEG gel or metal sensors. Throughout the session, assistants will be attending to you to keep you from becoming uncomfortable.

Brain Imaging (MRI):

Radio and magnetic waves associated with MRI scans are not associated with any known adverse effects. MRI is non-invasive and considered minimal risk by the FDA. However, the scanner is a large magnet, so it could move objects with iron in them in the room during the scan. This means that loose metal objects, like coins or key chains, are not allowed in the MRI room. If you have a piece of metal in your body such as a pacemaker, nerve stimulator, piercings or certain metal surgical implants, you will not be allowed into the MRI room and cannot have an MRI. While in the scanner, you may be bothered by feelings of claustrophobia (fear of small spaces). If you feel uncomfortable (nervous or upset stomach) in the MRI scanner for any reason, tell the research staff. The MRI also makes loud 'drum' beating noises during the study. Headphones will be provided for your safety and comfort. There is a speaker in the MRI scan room as well as a window so that the operator can see you during the MRI. This allows the assistants to hear and see you at all times to make sure that you are comfortable and to allow them to respond if you are uncomfortable. You can stop the scan at any time.

No long-term harmful effects from MRI are known. However, since the effect of MRI on early development of the fetus is unknown, subjects who are pregnant should not go in the MRI. If you are a woman 18 years of age or older and there is a possibility that you may be pregnant, you will be asked to take a urine pregnancy test before being allowed to participate in the study. Rarely, large or recent tattoos can heat up during an MRI scan

and cause skin irritation like a sunburn, so the MRI technologist will want to see any tattoos you have prior to the scan.

Due to the very high sensitivity of MRI in detecting abnormalities, there is a risk of false-positive findings, identifying something on imaging studies that may or may not be important. This may result in anxiety and additional testing, possibly including a recommendation for clinical scans at your cost. The radiology report or other study data will not be put into your medical record unless you provide it to your physician. If the radiology report becomes part of your personal medical record, it may or may not have an effect on getting health insurance or life insurance in the future.

Brain Stimulation (tDCS):

We will be using a weak electrical current called tDCS to non-invasively stimulate your brain. At the tDCS dose used in this study, no long-term harmful effects are known. tDCS has been safely administered to many people for the last several decades. Most subjects report only mild, transient tingling at the stimulation site. In a few cases, people have reported minor skin damage or irritation at the electrode site. In rare cases, the skin damage resembles a burn, much like sunburn, that may result in a scab or skin discoloration (resembling a suntan) at the electrode site that can last several days. If any of these are observed, we will postpone or terminate your participation in the study.
In addition to the tingling feeling at the start of tDCS, there may also be a warming sensation on the scalp. You will be encouraged to tell us about any pain or discomfort at the electrode sites throughout the tDCS procedure. If you tell us that the warming sensation becomes a burning sensation, the tDCS procedure will be stopped. If there are any signs of redness or irritation of the scalp, the tDCS will also be stopped. There is the chance of receiving a small shock and a sensation of a short light flash if tDCS is stopped suddenly. To help keep this from happening we will ask you to keep as still as possible during the experiment. Also, if the electrodes are placed where they are uncomfortable in

any way, please ask the research assistant to move the electrodes; do not try to do this by yourself.

Assessment and Therapy:

Some people may become tired or frustrated during testing and treatment. They may also become more aware of their communication problems, which can be upsetting.

We will make every effort to be sure you are as comfortable as possible during testing. You can take a break at any time. If the session is too long, the length of the session and number of sessions can be changed according to your needs.

Other:

Participation in this study may produce emotional stress, inconvenience or an invasion of privacy. In addition, there may also be side effects or risks to study participation that are unexpected and not known at this time. Every effort will be made to protect the information you give us. However, there is a small risk of loss of confidentiality that may result in stigmatization or hardship. Procedures we will use to protect the information you give us are described below.

What are the benefits to being in this study?

In this study we are providing treatment for communication difficulties. We hope that you will experience improvements in your communication abilities as a result of this treatment. However, not all individuals with aphasia respond to this therapy - we do not know if you will benefit. It is hoped that the information gained from this study will help researchers and clinicians understand how brain stimulation affects treatment response. You will be informed of your performance on speech-language assessments after the study has ended. You will also be provided a CD with a copy of your MRI scans for your records.

What other choices do I have if I do not want to be in this study?

You have the option not to take part in this study. There will be no penalties involved if you choose not to take part in this study. If you choose not to participate you will be given a list of community resources that also provide speech-language therapy for adults with aphasia.

How will my information be kept confidential?

We will take measures to protect the security of all your personal information, but we cannot guarantee confidentiality of all study data. This study may result in presentations and publications, but steps will be taken to make sure you are not identified by name. You will be identified on all research records solely by a unique participant number. Your data will be secured in the following ways:

1. Videocameras with your recordings, written materials, and brain scan media will be kept in locked file cabinets in locked offices.
2. Audiorecordings will be secured on password-protected computers or a file server maintained by UNM and accessible only to the study staff.
3. Digital files with the above information will be maintained on a password-protected computer or file server maintained at UNM or stored securely in restricted and protected databases following MRN information security policies and accessible only to the study staff.
4. MRI scans will be secured on password-protected computers or a file server maintained by UNM and accessible only to the study staff or stored securely in restricted and protected databases following MRN information security policies. The record linking your name to your study ID number (which the study data is labeled with) will be kept indefinitely (forever) at the MRN in a confidential manner so that you may continue to have access to your MRI information.
5. If you agree to submit your data to the AphasiaBank online database, your information will be accessible to registered researchers by password.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, we will take steps allowable by law to protect the privacy of personal information. Information contained in your study records is used by study staff and, in some cases it will be shared with the sponsor of the study. The University of New Mexico Health Sciences Center Human Research Review Committee (HRRC) that oversees human subject research, and the Food and Drug Administration and/or other entities may be permitted to access your records. There may be times when we are required by law to share your information. However, your name will not be used in any published reports about this study. A copy of this consent form will be kept in your medical record.

What are the costs of taking part in this study?

The cost of the behavioral treatment and testing, including the scans, will be covered by the study. However, participants may have to pay for gas to travel to the University of New Mexico. If incidental findings from the study result in the need for further evaluation/treatment, then you or your insurance will be responsible for additional clinical evaluation/treatment that may be needed.

What will happen if I am injured or become sick because I took part in this study?

If you are injured or become sick as a result of this study, UNMHSC will provide you with emergency treatment, at your cost. No commitment is made by the University of New Mexico or Mind Research Network to provide free medical care or money for injuries to participants in this study.

In the event that you have an injury or illness that is caused by your participation in this study, reimbursement for all related costs of care will be sought from your insurer,

managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

It is important for you to tell the investigator immediately if you have been injured or become sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the Human Research Review Committee (HRRC) at the University of New Mexico Health Sciences Center, Albuquerque, New Mexico 87131, (505) 272-1129 for more information.

Will I be paid for taking part in this study?

You will be paid $40.00 for each assessment session and $75.00 per week of treatment ($15.00 per session). You will be paid at the end of session 2 for the first two assessment sessions, at sessions 8, 13, and 17 for the treatment sessions, and at sessions 18 and 19 for the two follow-up assessment sessions. If you decide to withdraw from the study, you will be paid for the sessions you have completed since the last payment was made. All payments will be made in the form of merchandise cards.

Authorization for Use and Disclosure of Your Protected Health Information (HIPAA)

As part of this study, we will be collecting health information about you and sharing it with others. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)

By signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include: previous medical history (including surgeries), current health status, medical diagnoses, and a list of implanted medical devices.

In addition to researchers and staff at UNM and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

Right to Withdraw Your Authorization

Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send letter notifying them of your withdrawal to:

Jessica D. Richardson MSC01 1195
1 University of New Mexico
Albuquerque New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

Refusal to Sign

If you choose not to sign this consent form and authorization for the use and disclosure of your PHI, you will not be allowed to take part in the research study.

How will I know if you learn something new that may change my mind about participating?

You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating. If the active brain stimulation group shows a benefit, participants in the

placebo brain stimulation group will be offered the active brain stimulation treatment if resources are available.

Can I stop being in the study once I begin?

You may refuse to participate or withdraw from the study at any time without affecting you future health care or services. The study investigators may stop your participation at any time if they decide it is in your best interest or if you are unable to follow study instructions. If you are removed from the study, an explanation will be given to you. If you wish to withdraw from the study, please notify a study team member at the time of participation, or Dr. Jessica Richardson by phone or email (505-277-1765 or jdrichardson@unm.edu) after you have participated.

Whom can I call with questions or complaints about this study?

If you have any questions, concerns or complaints at any time about the research study, contact the PI by phone or email (505-277-1765 or jdrichardson@unm.edu).

If you would like to speak with someone other than the research team, you may call the UNMHSC HRRC at (505) 272-1129.

Whom can I call with questions about my rights as a research participant?

If you have questions regarding your rights as a research participant, you may call the UNMHSC HRRC at (505) 272-1129. The HRRC is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human participants. For more information, you may also access the HRRC website at http://hsc.unm.edu/som/research/hrrc/.

Consent and Authorization

You are making a decision whether to participate in a study. Your signature below indicates that you read the information provided (or the information was read to you). By

signing this consent form, you are not waiving any of your legal rights as a research subject.

Optional:

→ With your permission, we would like to **video record** you taking these tests and during treatment so they can be reviewed at a later date. This does not give us permission to share your videos with anyone outside of the study team. Videos will not be used for commercial purposes. Please initial "yes" or "no".

_____**YES** _____**NO** I give the study investigators permission to video record the assessment and treatment sessions.

→ *AphasiaBank:* A group of researchers around the world (AphasiaBank consortium) is trying to develop better ways to evaluate communication in people with aphasia, to help learn whether different treatments work. We would like to put **recordings and written transcripts on a password-protected database**. This may allow others who are viewing the videos at a later date to identify you if you have met them in person. Videos will not be used for commercial purposes. Please initial "yes" or "no".

_____**YES** _____**NO** I give the study investigators permission to share my recordings and transcripts with AphasiaBank researchers.

→ *Scientific presentations and classroom teaching:* It is sometimes helpful to show certain speech or language characteristics or brain findings to scientific audiences at conferences, to clinicians in training, and to the general public to raise awareness. We would like to **play recordings and show brain scans** to ensure understanding of different types of communication disorders and non-disordered speech. This may allow others who are viewing the videos at a later date to identify you if you have met them in person. Please initial "yes" or "no".

_____**YES** _____**NO** I give the study investigators permission to show my **video** in **scientific journals or presentations.**

_____**YES** _____**NO** I give the study investigators permission to show my **brain scans** in **scientific journals or presentations.**

_____**YES** _____**NO** I give the study investigators permission to show my **video** in **classroom teaching.**

_____**YES** _____**NO** I give the study investigators permission to show my **brain scans** in **classroom teaching.**

_____**YES** _____**NO** I give the study investigators permission to show my **video** in **outreach or community presentations.**

_____**YES** _____**NO** I give the study investigators permission to show my **brain scans** in **outreach or community presentations.**

→ *Mind Research Network:* We would also like to request your permission to store all of the data that was collected in this study in The Mind Research Network Data Sharing Repository for other, future research. The stored data will include information such as your age and gender, as well as assessment and imaging data that were collected about you during the course of this study. It is possible that this information may remain linked to your name. It will be handled with the same care and confidentially as it is for the current study. Research done with information from the data repository could lead to improved diagnostic and treatment interventions for illnesses and brain disorders. If published, results will be presented in summary form only and will not include your name or other identifying information. If MRN and/or the investigators develop intellectual property and/or commercialize products or services, directly or indirectly, based on the results of the research done with your data, there are no plans to provide you with any financial compensation.

_____**YES** _____**NO** I give the study investigators permission to store my data in the MRN Data Sharing Repository for future research.

We would like to request your permission to contact you for participation in future studies at the Mind Research Network. If you agree, your contact information may be shared with other scientists at MRN.

_____**YES** _____**NO** I give the study investigators permission to contact me about participation in future MRN research studies.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, I agree to participate in this study. A copy of this consent form will be provided to you.

Name of Adult Subject (print)	Signature of Adult Subject	Date
Name of Legally Authorized Representative (print)	Signature of Legally Authorized Representative	Date

INVESTIGATOR SIGNATURE

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

Name of Investigator/ Research Team Member (type or print)	
(Signature of Investigator/ Research Team Member)	Date