C-STAR Project 2
Stimulating Language in Subacute StrokE (SLISSE)
NCT02674490

Consent Form
November 14, 2019

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Effects of transcranial direct current stimulation (tDCS) plus language therapy for naming in subacute left hemisphere stroke

Application No.: IRB00089018

Sponsor: National Institute on Deafness and Communication Disorders

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1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

- 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.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.
- During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.
- The person being asked to be in this research study may not be able to give consent to be in this study. You are therefore being asked to give permission for this person to be in the study as his/her decision maker.

2. Why is this research being done?

This research is being done to help us understand whether and how the application of transcranial direct current stimulation (tDCS) along with language therapy, may affect recovery of language problems in people with language problems caused by stroke ("aphasia").

tDCS is the application of a very weak electrical current on the surface of the scalp. Our aim is to find out whether tDCS in combination with language therapy will improve task performance while participants retrieve words. Another goal of this study is to find out if their medications change the effect of tDCS plus language therapy. A third goal is to find out if tDCS affects brain "connectivity" (how areas of the brain are activated together during rest, seen on MRI) in people with language problems after stroke. This will enable us to better understand how people recover from aphasia and whether and how interventions with tDCS work.

People diagnosed with aphasia caused by stroke may join.

How many people will be in this study?

About 50 people are expected to take part.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Participants will receive active tDCS or "sham" tDCS by random assignment, like flipping a coin. One half of the participants (1 in 2) will receive "sham" tDCS and one half (1 in 2) will receive active tDCS. For the "sham" tDCS, the electrodes will be placed on your skin but electrical current will be administered only for the first few seconds. All participants, whether they receive active tDCS or "sham" tDCS, will receive the same language therapy.

Cognitive and language tasks:

Before having tDCS, you will be asked to complete both cognitive and language tasks. You will have a neurological exam and screening assessments to see if you are eligible to be in the study. The assessments will include tDCS and MRI safety screening. If the screening procedures show you are eligible to continue, you will have speech and language diagnostic testing.

These evaluations will be completed over two sessions. If we need to stop because of a medical procedure, meal, or visitor, we can begin again later. The evaluation will take about 90-120 minutes.

Then you will have MRI if there are no contraindications to you having an MRI. If you do not want to have MRI or have a contraindication for MRI you can still participate in the study.

You may also be asked to take part in one or more functional Near-Infrared Spectroscopy (fNIRS) sessions. If you do not want to have fNIRS, you can still participate in the study.

tDCS:
We will prepare you for the application of tDCS. This is conducted while you are engaged in a computer-delivered language therapy. You will be randomized to active tDCS or a "sham" electrical stimulation.

For the tDCS, we will apply small sponge electrodes (metal disks) that have been soaked with water, to your head: one electrode will be placed on the left side of your head and the other electrode will be placed on the right side of your head.

Once the electrodes are in place, you will be asked to do the computer-delivered word retrieval task while a small electrical current will be passed between the electrodes.

Most individuals do not find the procedure uncomfortable, and there are no known long-term risks of tDCS. When the tDCS current goes through the electrodes, you may feel an itching or tingling sensation under the electrodes or see slight light flashes, or you may not feel anything at all. If the sensation is unpleasant, please let us know immediately. If you find the procedure too uncomfortable, you may stop it at any time. This will last for 20 minutes and all this time you will be asked to continue performing the naming therapy. The language therapy will last 45 minutes.

You will engage in naming therapy for 15 sessions over the course of 3 weeks, depending on your availability. The therapy session will last 45 minutes.

Language Re-Evaluations (within 1 week, 5 weeks, and 20 weeks after tDCS intervention):
You will be asked to name words out loud. The words you are asked to name will be presented as pictures. You may be asked to complete other standard language tasks.

You will have a neurological examination at Visits 1, 8, 13, and 18.

Optional Sample Collection for Genetic Testing
You will be asked to provide a saliva sample for the purpose of genetic analysis. It is thought that some people may be more responsive to therapy due to certain genetic factors. To investigate this, we will ask you to provide a small sample (2mL) of your saliva. This sample will be collected in a small tube, and will be sent offsite to a research laboratory to be tested for this factor. After testing, your sample will be discarded. You will be asked to refrain from eating, drinking, smoking or chewing gum for 30 minutes prior to collect of your saliva sample.

You may be asked to provide this sample during initial testing, or any time after that. Should you have completed all phases of the study, we may ask that you agree to provide a sample at a later date. If this is the case, we will meet you either at the SCORE Lab at Johns Hopkins, or your residence to obtain this sample. If you are not living in the Baltimore metropolitan area, we may ship a saliva collection kit to you. In this case, we will provide all instructions in writing for you. We will also provide packaging and return postage for your to send this sample back to the SCORE Lab.

The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or health-related employment discrimination based on genetic information.

The law provides that health insurance companies and group health plans

- may not ask for genetic information from this research and
- may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law does not apply to other types of insurance (such as life, disability or long-term care).

Despite the GINA protections and the best efforts of the research team to protect your information, you may still be at risk if information about you were to become known to people outside of this study.

Genetic information is unique to you and your family, even without your name or other identifiers. Johns Hopkins follows procedures to prevent people who work with your DNA information from being able to discover it belongs to you. However, new techniques are constantly being developed that may in the future make it easier to re-identify genetic data, so we cannot promise that your genetic information will never be linked to you

You may "opt out" of the genetic testing. That is, you can decline to have the genetic testing, and it will not affect your participation in the remainder of the study. **Please check box and sign to indicate your choice below:**

YES _____ I want to provide a saliva sample for the purpose of genetic analysis
Signature of Participant

NO _____ I do not want to provide a saliva sample for the purpose of genetic analysis
Signature of Participant

Magnetic Resonance Imaging (MRI):

As part of your participation in this research study, you will also be asked to have a Magnetic Resonance Imaging exam before the tDCS intervention, 1 week after tDCS, and 4-5 weeks after tDCS intervention ends. You may decline to have the MRI exams and still participate in the study. This part of the study may not be available to you.

If the MRI scanner is not available, or if you have a contraindication (such as implanted metal) we may not ask you to have any MRI exam.

MRI scans create images of the body using a magnet and radio waves. While the procedure is much like a CT scan, there is no radiation involved in an MRI exam. If you have one or more MRI exams as part of this research, the MRI exams will take about 60 minutes. Prior to your exam, you will be asked to complete a standard questionnaire. The purpose of this questionnaire is to ensure that you are able to safely enter the MRI area.

If you have a history of metal in your head or eyes, you cannot take part in this imaging.

To start your MRI test, you will lie on a padded table. The table on which you are lying will be moved to the center of an MRI magnet, which looks like a long narrow tube. Even though the tube is open, some people feel confined in small places. If this bothers you, please notify the staff. You may end your participation in this study at any time by telling the staff. When MRI is done, radio-signals and magnetic fields are used. When this happens, it is normal for the machine to make loud, banging, and clicking noises. You will be asked to wear earplugs or headphones for your comfort during the exam. During the exam, the staff is able to see and hear you. You will be able to hear the staff. The staff will be talking to you throughout your exam and may issue simple instructions regarding holding your breath, maintaining position, etc. You will generally be requested to lie perfectly still throughout the exam.

If you or your physician would like to see the results of the MRI or language tests, we will make the results available.

functional Near-Infrared Spectroscopy (fNIRS) exam

As part of your participation in this research study, you may also be asked to have a functional Near-Infrared Spectroscopy (fNIRS) exam the day you enroll. You may decline to have the fNIRS exam and still participate in the study.

If you have an fNIRS exam as part of this research, each exam will take approximately 30-60 minutes. The NIRS device is portable, so the exam will take place in the same room where you complete the language assessments. fNIRS uses light to measure brain activity. At the beginning of the exam, we will place a cap onto your head that holds light sources and detectors (which are called "optodes"). The sources carry light from the NIRS device to your brain (through your scalp) and the detectors measure the amount of light in your brain and send it back to the NIRS device. Measuring changes in the amount of light that travels to and from your brain allows us to calculate how much oxygen is in a region of the brain underneath the cap, which can tell us about brain function. After we place the cap onto your head, we may need to readjust it to improve the NIRS signal. We may also dim the lights or cover windows in the room to improve the NIRS signal. If for whatever reason we cannot obtain a satisfactory signal, we will stop the fNIRS exam.

After the cap is in place, we will ask you to do one or more of a variety of different tasks. While you are doing these tasks, we will monitor the activity of your brain using the NIRS device. Each set of tasks that you will be asked to do is called a "task sequence." Each task sequence will be 1 to 15 minutes long, and the study will consist of a series of up to 10 task sequences. During these tasks, you will be asked to name pictures, listen to sentences, and participate in other tasks.

You may also be asked to have an fNIRS exam before the tDCS intervention, as well as 1 week, 4-5 weeks, and 20 weeks after tDCS intervention ends; these later exams might include tasks like the first exam, if you are willing and able to do the tasks. If you do not wish to have any one or more of the fNIRS exams, you may decline and still participate in the study.

Video Recording:
During some of the naming tasks, you will speak into a microphone and be video-recorded.

- You may request that the video recording be stopped at any time.
- If you agree to allow the video recording and then change your mind, you may request that the recording be destroyed. If the recording has had all identifiers removed, we may not be able to do this.
- These video recordings will be used for the purposes of this research and will not be published for any other reason.

Incidental Findings
The MRI you are having as part of this research study will be reviewed by a qualified person just as it would be if you were having the imaging as part of your routine medical care.

There is a possibility that while reviewing your MRI we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."
We will let you or your legal representative know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail or by phone. In the case of a potential serious emergency, someone may go to your home.

A qualified person (Argye E. Hillis, MD) will talk to you if there is an incidental finding. You do not have an option to decline information about an incidental finding.

If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious.
- Since an incidental finding will be part of your medical record, it may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.
- The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

How long will you be in the study?
You will be in this study for 6 months including follow-up testing, depending on your availability.

4. What are the risks or discomforts of the study?

tDCS
tDCS has been used in humans and animals for many years. In recent studies that involved several hundred people, there were no side effects other than itching under the electrode that went away when the current was stopped, and slight light flashes with stimulation.

There is no danger of heat to the brain during tDCS. However, there is a slight risk of an electric burn. One patient without adequate protection had a small burn on the ear, which healed in several days. To eliminate this risk we will use insulated electrodes. If you develop any problem during any of the experiments, we will stop the stimulation immediately. Any effect on brain function will be brief.

MRI
The effects of magnetic fields in MRI scanner have been extensively studied, and there are no known significant risks with an MRI exam. You may, however, be bothered by feelings of confinement (claustrophobia), and by the noise made by the magnet during the procedure. You may become anxious or uncomfortable in the MRI scanner. You will be asked to wear ear plugs or earphones while in the magnet.

You may not participate in this study if you have a pacemaker, an implanted defibrillator or certain other implanted electronic or metallic devices. It is important for you to advise the staff if you have had brain surgery for a cerebral aneurysm, implanted medical or metallic devices, shrapnel, or other metal, such as metal in your eye.

If you want to be removed from the MRI scanner, you can push a button that will be given to you, or simply say out loud that you want out, and you will be removed. You are not required to complete the MR examination

fNIRS
The NIRS brain-measuring device we will use is a relatively new way to measure activity in the brain. No one has reported harmful effects from using the NIRS system. There may be other side effects that are currently unknown. The intensity (amount) of the near-infrared light used to monitor your brain is considered to be harmless. The amount of light produced by the NIRS device is less than the intensity of light your brain receives during an outdoor walk on a sunny day. The primary risk of the fNIRS exam is boredom.

Questions/Language Evaluation
You may get tired or bored when we are asking you questions or you are completing language evaluation. If you feel tired or frustrated, you may take a break.. You do not have to answer any question you do not want to answer.

Confidentiality: There is the risk that information about you may become known to people outside this study. We will try to protect your confidentiality, as described below.

5. Are there risks related to pregnancy?

If you are pregnant during your participation in this study, we will not do any MRI scans, although there are no known risks of the procedures to the fetus. This research may hurt an embryo or fetus in ways we do not currently know.

6. Are there benefits to being in the study?

There may or may not be directly benefit to you from being in this study.

If you take part in this study, you may help others in the future.

7. What are your options if you do not want to be in the study?

If you decide not to join this study, other options are available. You do not have to join this study to get treatment. Other treatments include referral to a speech-language pathologist for treatment of naming deficits.

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

No.

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet).

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

9. Will you be paid if you join this study?

You will be paid $40 per visit to cover your transportation to the hospital and parking, if you provide your own transportation. If we provide transportation, you will not be paid. We will pay you at the first follow-up session (within 1 week after tDCS ends) and at the final follow-up session (20 weeks after tDCS ends), or within two weeks of your final session if you are unable to complete the tDCS sessions.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory will know your identity and that you are in the research study. Other people at Johns Hopkins, incuding your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

14. What if there is a Certificate of Confidentiality for this study?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

15. What treatment costs will be paid if you are injured in this study?

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

16. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Argye Hillis at 410-614-2381. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call at 410-614-2381 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call Dr. Argye Hillis at 614-2381 during regular office hours and at 410-812-6716 after hours and on weekends.

d. What happens to Data and Biospecimens that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

17. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant (Print Name) Date/Time

Signature of Person Obtaining Consent (Print Name) Date/Time

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time
For ADULTS NOT CAPABLE of GIVING CONSENT (*Persons from the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative)*

Relationship of LAR to Participant (indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law) Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian (Print Name) Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).