Northwell Health

Consent for Participation in a Research Study

Protocol Title: Evaluating Anodal tDCS Preceding Aphasia Therapy
Principal Investigator: Bruce T. Volpe, MD
Sponsor: None (Investigator-Initiated with No Funding)

This consent form is written from the point of view of a research subject. If consent will be obtained from a legally authorized representative or next of kin, the words "you" and "your" should be read as "the research subject."

As the subject's legally authorized representative or next of kin, you are being asked to give consent for the subject to be in a research study. You are being asked to do this because the subject is not able to give consent. When making this decision you should take into account the wishes of the subject. If you agree to allow the subject to take part in this research, the subject will also be asked to give consent, but only if he/she regains the ability to make healthcare decisions.

INTRODUCTION: You are being asked to join a research study. The following information will explain the purpose of this study, what you will be asked to do, and the potential risks and benefits. It will also explain that you do not have to be in this study to receive medical care. You are encouraged to ask questions before deciding whether you wish to participate, or at any time during the course of the study. You will be told of any new findings that may change your decision to continue to participate.

Why is this research study being done? The goal of this research study is to improve and better understand language rehabilitation after stroke with the hope of developing new treatments that maximize this recovery. Specifically, we wish to examine if non-invasive brain stimulation with an investigational device called transcranial direct current stimulation (tDCS), followed by language therapy improves verbal expression in individuals with aphasia (e.g. language impairment from a brain injury or stroke).

How many people will take place in this study?
There will be 24 participants enrolled in this study.

How long will you be in this study? If you choose to participate in this research study, the duration of participation will be up to 6 weeks. During this time, there will be 14 study visits, up to 90 minutes each. These study visits will take place at the Feinstein Institute for Medical Research (350 Community Drive, Manhasset, NY).

What will happen in this research study? There are several procedures that you will be asked to complete during the study visits and are described below:

Screening questionnaire
You will be asked to complete a questionnaire about your health history to see if you have any risk factors that would prevent you from undergoing brain stimulation. This will take only a few minutes**Outcome measures**
You will complete a series of speech and language evaluations to assess your language abilities. This will take approximately 60 minutes.

Brain stimulation
Transcranial Direct Current Stimulation (tDCS): This is an investigational device. The investigator will place a plastic headband around your head. Two electrodes, each in a cotton sponge dampened with salt water, will be placed between your head and the plastic headband. One electrode will be placed on your right shoulder while the other one will be placed on the left side of your head, towards the front. The electrodes will be connected to a battery-driven stimulator. A small electrical current will be applied to your head for 20 minutes.

This is a cross-over design study, meaning that for half of the study you will be randomized to receive this brain stimulation with the electric current and for the other half of the study you will receive brain stimulation without the electric current ("sham" stimulation), in order to compare your performance with and without the stimulation. Randomization is a procedure used to assign research subjects, by chance (like flipping a coin), to a study group in a research study. It is used to make sure study results are not influenced by the selection of subjects or order of interventions for one group or another. You will have a 50/50 chance of receiving the brain stimulation or the sham stimulation.

Neither you nor the investigators will know if you are randomized to receive sham stimulation or real stimulation first or second. This is called double blinding and is a process used to prevent the researcher and the subject from knowing which study group a subject is in. It is used to make sure the study data will not be biased. You will be asked at two time-points in the study whether or not you believe you received brain stimulation or not at that time.

Sham stimulation has no actual electric current. It is compared to brain stimulation with electric current to see if the stimulation has a real effect. A sham is often used in research studies in order to "blind" the study so that the doctor and the subject are not biased by knowing the subject's study group. In case of emergency, the investigators can be "un-blinded" to find out which stimulation you are receiving.

Schedule of Visits
The schedule of study visits is below and describes what procedures will be done at each study visit:

Lead-in Period

- Week 1, Visit 1 (approximately 60 minutes)
    - Baseline outcome measures
    - Medical screening
    - Consent

- Week 2, Visit 2 (approximately 60 minutes each)
    - Baseline outcome measures

Training Period Phase I

- Week 3, Visit 3-6 (approximately 60 minutes)
    - 20 min of stimulation condition 1 (sham or anodal tDCS) and 20 min of computerized word-picture matching therapy
- Week 3, Visit 7 (approximately 90 minutes)
    - 20 min of stimulation condition 1 (sham or anodal tDCS) and 20 min of computerized word-picture matching therapy
    - Condition 1 discharge outcome measures

Follow Up Testing Phase I

- Week 4, Visit 8 (approximately 60 minutes)
    - Condition 1 follow-up outcome measures

Training Period Phase II

- Week 5, Visit 9-12 (approximately 60 minutes)
    - 20 min of stimulation condition 2 (sham or anodal tDCS) and 20 min of computerized word-picture matching therapy
- Week 5, Visit 13 (approximately 90 minutes)
    - 20 min of stimulation condition 2 (sham or anodal tDCS) and 20 min of computerized word-picture matching therapy
    - Condition 2 discharge outcome measures

Follow Up Testing Phase II

- Week 6, Visit 14 (approximately 60 minutes)
    - Condition 2 follow-up outcome measures

Participation in this study also allows investigators access to your medical records. They will record your age, gender, date of stroke, and results of the medical imaging you had done following the stroke.

What are the risks of the research study? What could go wrong? tDCS is a safe and painless procedure for most people, but it has the potential to cause redness of the skin around the area of the electrode pads. Such reddening has been found to go away quickly after the stimulation ends. If you think it is needed, we can apply a cold compress over the red area. There may be a tingling sensation under the electrode pads when the stimulation begins. This sensation is not usually considered painful, but some people might find it uncomfortable.

Randomization: Your group may receive less effective treatment or have more side effects than the other group.

Unknown Risks: There may be risks that are unknown at this time

What are the benefits of this research study? We predict that you may experience improvements in word-finding and expressive communication following this rehabilitation study. However, we cannot guarantee you will experience direct benefits from the intervention. Knowledge gained may benefit patients with aphasia in the future.

Randomization: Your group might receive more effective treatment and/or have fewer side effects than the other treatment group(s).

If you do not take part in this research study, what are your other choices? If you do not join this study, you have other choices for treatment. Talk to your doctor about your choices. Your other choices may include:

- Enrolling in another aphasia research study
- Receiving outpatient aphasia therapy
- Declining further treatment
- Participating in an aphasia support group

Your doctor can also tell you the important risks and benefits associated with the alternative treatment.

Are there costs for being in this research study? You will not incur any additional costs associated with this study. All study-related procedures and medications will be provided at no cost to you. Costs related to standard medical practice will be billed as usual to you or your insurance carrier.

Will you receive any payments for participating in this research study? You will not be paid for participating in this study.

If the research produces marketable products, will you receive any payment? If this research produces a marketable product, there are no plans for you to receive any money.

What happens if you are injured while participating on this study? If you are hurt from being in the study, you will receive medical care and treatment as needed from the Northwell Health. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance and/or other forms of medical coverage. No money will be given to you.

What are your rights as a research participant? Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study, you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at the Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over? It is also possible that your participation in this study may end without your consent. This decision may be made by an investigator or the IRB. Reasons for withdrawal may include:

- Failure to follow instructions
- Failure to show up for study visits
- It is not in your best interests to continue on this study, or
- The study may be cancelled.

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new information will be collected.

What happens if new information is learned? You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study? If you agree to be in this study, we will collect health information that identifies you. We may collect the results of tests and interviews. We may also collect information from your medical record. We will only collect information that is needed for research. Such information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information? Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside the Northwell Health.

Investigators might share the results of your study tests and procedures with:

- Other researchers
- Clinical staff not involved in the study who may be involved in your treatment, health insurers or payers.

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies
- Representatives from the Northwell Health Institutional Review Board (IRB - the committee that reviews research at this institution)

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it will be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records? If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, or for any questions related to your health information, you may contact the Research Privacy Officer at 516-321-2100.

How long will your health information be kept? There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind? If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Bruce T. Volpe, MD
Feinstein Institute for Medical Research
350 Community Drive
Manhasset, NY 11030

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it

Will information about this study be available to the public? A description of this clinical trial will be available on http://www.Clinical Trials.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 website at any time.

Does the investigator of this study receive money if you take part? This is an Investigator funded study**. Compensation** is *not based* upon the number of people enrolled in the study. If your doctor is an investigator for this study s/he is interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor.

Who can answer your questions about this study? If you have any questions about the study, or about side effects or injury caused by research, call Bruce T. Volpe, MD at (516) 562-3384. If you need emergency care go to the nearest Emergency Department or dial 911. If you have

questions about your rights as a research subject you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 321-2100. A signed copy of this consent form will be given to you.

[SIGNATURE PAGE TO FOLLOW]

SUMMATION & SIGNATURES: You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____	_____	_____
Subject's Printed Name	Subject's Signature	Date
_____	_____	_____
Witness's Printed Name	Witness's Signature	Date

Investigator's Statement: In addition to advising the above subject about the research study, I have offered an opportunity for further explanation of the risks and discomfort which are, or may be associated with this study and to answer any further questions relating to it.

_____
Investigator's Printed Name

_____ _____
Investigator's Signature Date

OR

_____	_____
Subject's Printed Name	Date

_____	_____	_____
Legally Authorized Representative's or Next-of-Kin Printed Name	Legally Authorized Representative's or Next-of-Kin Signature	Date

Witness' Statement: I was present during the consent process of the above mentioned research study. A member of the research team explained the research study entirely and allowed ample opportunity for the subject to ask any questions or express any concerns. The subject was unable to sign the consent form due to a physical disability, however, voluntarily agreed to participate in the research study by providing verbal assent. By signing below, I attest to this statement.

_____	_____	_____
Witness #1 Printed Name	Witness #1 Signature	Date

Investigator's Statement: In addition to advising the above subject about the research study, I have offered an opportunity for further explanation of the risks and discomfort which are, or may be associated with this study and to answer any further questions relating to it.

_____
Investigator's Printed Name

_____	_____
Investigator's Signature	Date

OR

Legally Authorized Representative's or Next-of-Kin Printed Name	Legally Authorized Representative's or Next-of-Kin Signature	Date

Description of signer's authority to act on behalf of the subject:

_____

Witness's Printed Name	Witness's Signature	Date

☐ Witness signature waived (signed consent emailed, faxed, or mailed to investigator)

Investigator's Statement: In addition to advising the above subject about the research study, I have offered an opportunity for further explanation of the risks and discomfort which are, or may be associated with this study and to answer any further questions relating to it.

_____
Investigator's Printed Name

_____ _____
Investigator's Signature Date

ASSENT BY ADULT SUBJECT WITH A LEGALLY AUTHORIZED REPRESENTATIVE

I have been asked to join this research study. I have the right to find out what will or might happen to me if I am in the study. I have the right to tell the doctor, and the person legally allowed to make decisions for me, that I do or do not want to participate.

The person legally allowed to make decisions for me will also be asked to give permission for me to join this study.

(Investigator's name)_____ and _____, the person legally allowed to make decisions for me, have explained what I will have to do in the study.

(Investigator's name)_____ and _____, the person legally allowed to make decisions for me, have explained the discomforts, risks and inconveniences I may have if I join the study.

I have asked any questions I had, and all my questions have been answered.

_____ I agree to be in this study.

_____ I do not want to be in this study.

_____
Subject's name

_____ _____
Put your name here ↑ Date

_____ _____ _____
Witness's Printed Name Witness's Signature Date

All procedures, risks and discomforts have been explained to the subject.

_____
Investigator's printed name

_____ _____
Investigator's Signature Date

Addendum to Consent by Research Proxy
for Continuing Participation in a Research Study

Protocol Title: Evaluating Anodal tDCS Preceding Aphasia Therapy
Principal Investigator: Bruce T. Volpe, MD
Sponsor: None (Investigator-Initiated with No Funding)

- I have been told that my research proxy gave consent for me to be in the above titled research study.
- I am now able to give my own consent to be in the research study.
- I have been told of the purpose of the research, what my participation will entail, as well as all of the potential risks and benefits.
- I have discussed the research study with the study doctor and have received satisfactory answers to any questions.
- I have been told that I may ask more questions at any time.
- I do not have to stay in this research study. My decision to continue is completely voluntary. If I wish to leave the study, I may have to undergo final follow-up tests to assure my well-being. If I leave the study I will not suffer any penalty or loss of benefits to which I am entitled.
- I have been told that all of the elements of informed consent in the attached consent form, signed by my research proxy, are still applicable.
- I have reviewed the consent document and have discussed all of the elements of informed consent with the study doctor. I agree to stay in the above titled research study.

_____ _____
Signature of Subject Date

_____
Printed Name of Subject

_____ _____
Witness Signature Date

_____
Printed Name of Witness

In addition to advising the above subject about the research study, I have offered an opportunity for further explanation of the risks and discomfort which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____
Investigator's Signature Date