Consent Form (includes HIPAA Authorization)

Title of Research Study: Combining cerebellar tDCS and constraint-induced language therapy in non-fluent aphasia: a novel approach to target discourse

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Sharyl Samargia-Grivette PhD Investigator Departmental Affiliation: Communication Sciences and Disorders Phone Number: 218-726-8347 Email Address: samargia@d.umn.edu	Student investigators: Madelyn Graham and Haley Evans Phone Number: 218-726-8347 Email Address: evan0574@d.umn.edu and graha745@d.umn.edu

Supported By: This research is supported by the Department of Communication Sciences and Disorders.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

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 have a history of stoke and have been diagnosed with non-fluent aphasia.

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 researchers are looking for a way to help those who have been diagnosed with non-fluent aphasia. There are a few different types of treatment therapies currently available for those with non-fluent aphasia, however, those treatments rarely provide complete language recovery. In this study, the researchers want to learn if combining two treatments will provide a better outcome. The two treatments include behavioral language activity and Transcranial Direct Current Stimulation (tDCS). While tDCS has not been used in combination with behavioral language activities before it is considered to be safe.

This investigational treatment may or may not help you, but there is a chance that the information gained during this study will help someone else with non-fluent aphasia in the future.

How long will the research last?

We expect that you will be in this research study for about 2 months.

What will I need to do to participate?

If you choose to participate in this study you will be asked to attend a total of 17 study visits. The first visit will be a screening/consenting visit. You will have 4 sessions that will be related to data collection and assessments (baseline and follow up sessions), and 12 that are intervention sessions. There is also a "washout" period where you will have a break from all study interventions.

Table 1. Schedule of Research Activities.								
	Screen / Consent	Baseline 1	Intervention Real or Sham	Follow-Up 1	Washout/ Break period	Baseline 2	Intervention Real or Sham	Follow-Up 2
Day/Week	Visit 1	Visit 2	Visits 3-8	Visit 9	4 weeks no study visits	Visit 10	Visits 11-16	Visit 17
Screening & consent	x							
Eligibility assessments	If needed							
Assessments		X		X		X		X
Resting state EEG task		X		X		X		X
Quality of Life Survey		X		X		X		X
Adverse Events			X	X			X	X
Sham OR Real Intervention & behavioral language			X				X	

Screening/Consent visit: To determine if you are eligible for the study, the researcher will ask you some questions to confirm your eligibility. The screening questions may be asked over the phone if it is more convenient for you or during an in-person visit. You will be asked to provide some documentation of your diagnosis or complete an additional assessment with the researchers to confirm your diagnosis. Lastly, if you are a person who can get pregnant, you will have a urine pregnancy test. If you are eligible for the study, the researchers will spend some time going through this consent form with you. You will have an opportunity to discuss the study with the researchers and be able to ask any questions you may have. Reviewing the consent form will be done in person and may last between 30 and 90 minutes.

If you decide to participate in the study you will be asked to sign this consent form. If your screening/ consent meeting is in person you can sign during this visit. If your screening/consent visit is over the phone or via zoom, you will be asked to sign the consent form at your next visit.

Baseline and Follow up visits: During these visits, you will be asked to complete several tasks including re-telling a story, describing a picture sequence, a word finding task, and a working memory test on an iPad. These tasks will take approximately 20-30 minutes. You will have the chance to take breaks whenever you need to. After these assessments are complete, your head will be measured. You will be fitted for an EEG cap and you will be asked to rest with your eyes open while the EEG is running. The EEG portion will take approximately 20-30 minutes. Finally, you will be asked to complete a questionnaire

about how your stroke and aphasia has impacted your life. Additionally, if it's a follow up visit you will be asked about any symptoms you are experiencing. This is called an 'adverse events survey'. The baseline and follow up visits will last about 60-75 minutes. These sessions will be videotaped.

Intervention sessions: Participants in this study will be divided into two groups. One group will undergo Transcranial Direct Current Stimulation (tDCS) during the first portion of the study and some participants will undergo sham (or fake) tDCS sessions. After 6 intervention sessions you will go thought a 'washout' period. During the washout period, you will be asked not to engage in any Speech, Language or Pathology services. After the washout period is over, those who had real tDCS will have a sham tDCS and those who had the sham tDCS will receive the real tDCS. You will not know which group you are in and your experiences will be the same.

During their intervention visits, people in both groups will have electrodes soaked in saline solution placed on their scalp at the start of the visit. After the electrodes are placed, if you are receiving the real tDCS you will have a low level of electrical stimulation applied to your brain, if you are part of the sham group no electrical stimulation will be sent though the electrodes. During the real and sham stimulation, individuals have reported feeling no pain or discomfort, only a slight tingling on their scalp.

The tDCS (real and sham) intervention will take 45 minutes. During the tDCS session (real or sham) is happening you will complete a behavioral language activity with a speech-language pathologist. The language activity will take 30 minutes. After the 30 minutes are complete the researchers will ask you questions about how you are feeling (the adverse event survey) and remove the electrodes.

The entire intervention visit takes about 60-75 minutes.

There will be a 4 week break between intervention blocks, called the "washout period". During this time, we ask you do not engage in additional or supplementary speech-language therapy services.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

There is a possibility you may experience fatigue, frustration, embarrassment or other challenges by participating in this study. You will be able to take breaks to help relieve some of these experiences. Additionally, participation is this study is completely voluntary and you may skip any study activity, assessment, or questions you wish.

There are safety guidelines in place for the use of tDCS. Those guidelines will be followed during this study. The electrode set up, intensity and duration of stimulation all fall within the safety guidelines. The most common adverse effect some people have reported when participating in similar protocols is a slight tingling and/or itching of the scalp at the location of the electrode. The research team member will add more saline solution to the electrode and that sensation typically goes away. If the feeling does not go away or is uncomfortable, please let the research team member know and stimulation will stop.

The tDCS protocol used in this study has not resulted in any other adverse effects other than the tingling sensation. However, there has been one report of a seizure following tDCS in a child who had a history of seizures using a different intensity and electrode location than this study. The risk of seizure after tDCS is extremely rare.

We will be measuring brain activity using electroencephalography (EEG) which requires placing saline

soaked “sponge” electrodes over your scalp using a cap to keep them in place. The use of saline solution rarely causes any irritation, but in a rare occasion, mild skin irritation at the site of the electrodes may occur.

There is also a small possibility for a loss of confidentially. The researchers will try to minimize this risk by using study IDs instead or your name or other identifier that could be linked to you. Additionally, if you choose to allow the study staff to contact you using text or unsecure email there may be additional risks associated with those types of communication methods. If you wish to allow staff to communicate via text or email, you will be asked to sign an additional document.

More detailed information about the risks of this study can be found ***“What happens to the information collected for the research?” section***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include some improvement in your language expression and working memory.

What happens if I do not want to be in this research?

You do not have to participate in this research. Instead of being in this research study, your choices may include continuing with your current SLP services.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 5 people here will be in this research study.

What are my responsibilities if I take part in this research?

While you are in this study you will be asked to stop any other speech-language therapy sessions outside of those that take place for this study. Please be aware that the Dr. Samargia-Grivette will work to ensure that you do not lose insurance benefits for missing 2 months of sessions.

What happens if I say “Yes”, but I change my mind later?

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care, your academic standing as a student, or your present or future employment.

Can I be removed from the research?

It’s possible that we will have to ask you to leave the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

What do I need to know about reproductive health and/or sexual activity if I am in this study?

You should not be or become pregnant while in this research study. If you are sexually active, and able to

get pregnant, you should use at least one effective means of birth control while participating in this research study. According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable, but least effective, methods of birth control include male condoms (with or without spermicide) and female condoms.

If you become pregnant while participating in this research study it is important that you tell the study doctor or other research team member immediately. You might be required to stop participation in this study; however, other clinical care options will be discussed with you at that time if necessary.

If you are considered to be postmenopausal, you are not required to use contraception while participating in this research study. Postmenopausal people rarely become pregnant. If you become pregnant while participating in this research study it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other clinical care options will be discussed with you at that time if necessary.

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.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☐ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records

and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☐ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)

☐ My HIV/AIDS testing records _____ (initial)

☐ My genetic testing records _____ (initial)

☐ My mental health diagnosis/treatment records ____ (initial)

☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;

- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);

- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;

- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and

- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data and when this study is over?

We will use and may share data for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements

of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting or a recording of your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting or a recording of your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- 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.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury

let the study physicians know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you up to $450 for your time and effort. You will receive $150 at the end of the first intervention phase, $150 at the end of the second intervention phase, and a $150 bonus if you complete both phases.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.
You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive a cardholder agreement. Be sure to read all of this information for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, and MasterCard, will be given your name, date of birth, address. They will use this information as part of the payment process. Greenphire will only need your social security number if the payment exceeds $599. Greenphire and MasterCard will not receive any information about your health status or the study in which you are participating.

Additionally, you will have the option to receive updates related to appointment reminders and payment reminders and updates via text message and email message (Standard text messaging rates will apply). You will have the opportunity to opt-in to receive these messages, you are not required to provide your cell phone or email address to be enrolled in the study or use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out. If you choose to receive any communications via texts or emails, you will be asked to sign a separate form.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

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.

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may contact me in the future to see whether I am interested in participating in other research studies by Dr. Samargia-Grivette
_____	_____	I would like to receive reminders using Greenphire.

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