Intention Treatment for Anomia: Investigating Dose Frequency Effects and Predictors of Treatment Response to Improve Efficacy and Clinical Translation

NCT04267198

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Informed Consent Template Version 7-1-20

Consent to be a Research Subject

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 80 people who are being studied at the Atlanta VA Health Care System.

Why is this study being done?

This study is being done to answer the question: What is the optimal treatment intensity and predictors of treatment response in people with post-stroke aphasia? You are being asked to be in this research study because you are 21-89 years old and have aphasia caused by stroke.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for up to 39 study visits lasting 2-3 hours each. The researchers will ask you to do the following:

- Up to 15 assessment sessions (before treatment, immediately after treatment, 3 months, and 6 months after treatment)
- 30 hours of aphasia treatment (2hrs/day, 5 days/week for 3 weeks or 1.25hrs/day, 2 days/week for 12 weeks)
- Up to two MRI scans of your brain (before treatment, after treatment), if applicable

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. You will also receive information about your language and cognitive function and 30 hours of aphasia treatment.

What are the risks or discomforts I should know about before making a decision?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include exposure to

magnetic fields, possible feeling of claustrophobia, exposure to loud noise, dizziness, faintness or anxiety, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the RISKS section of this document. A full list of expected risks, their frequency and severity are in the RISKS section of this document.

Alternatives to Joining This Study

You do not have to be in this study to receive treatment for aphasia. The study investigator can discuss alternative treatment options that may be available if you want this information.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Take time to consider this and talk about it with your family and friends.

TITLE: Intention Treatment for Anomia: Investigating Dose Frequency Effects and Predictors of Treatment Response to Improve Efficacy and Clinical Translation

PRINCIPAL INVESTIGATOR: [redacted]

SPONSOR'S NAME: Department of Veterans Affairs

PURPOSE:

You are being asked to volunteer in a research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. The decision to join or not join the research study will not cause you to lose any benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

The purpose of the study is to investigate treatment intensity and predictors of treatment response in people with post-stroke aphasia.

CLINICALTRIALS.GOV:

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 website will include a summary of the results. You can search this website at any time.

WHAT WILL I BE ASKED TO DO?:

You will be asked to take part in up to 15 assessment sessions (before treatment, immediately after treatment, 3 months, and 6 months after treatment). You will receive 30 hours of treatment. The treatment schedule will be 2hrs/day, 5 days/week for 3 weeks or 1.25hrs/day, 2 days/week for 12 weeks. You will also be asked to undergo up to two optional MRI scans of your brain (one before treatment, one after treatment). Each study session will be on a separate day and will last approximately 2-3 hours. All assessment and treatment visits will take place either by audio (phone) or video conference or face-to-face at the Atlanta

VA Health Care System (1670 Clairmont Rd. Decatur, GA 30033. MRI scanning will take place at Emory University Hospital or the Emory Health Sciences Research Building (HSRB-II).

Assessment Sessions
You will be asked to complete questionnaires about your medical history, physical, and cognitive functioning. Measurements of your height, body weight, blood pressure, and pulse may also be taken.

Cognitive and Language Assessment (up to 15 sessions)
We will ask you to complete tests that are designed to examine your memory and language abilities. Some will be paper and pencil tests, and some will require you to answer questions or complete tasks on a computer. We may audio record your responses. The recordings will be obtained for research purposes only. They will be used to score the tests. The recordings will not be disclosed outside of the VA. A research assistant will be with you at all times. You may request rest breaks between tests, and you may stop at any time. Assessments will be conducted before the treatment program begins, immediately after the treatment program, and 3 months and 6 months after the treatment program. If you have participated in [redacted] study entitled "Beyond lesion-language mapping in aphasia: A novel imaging-based prediction model" [redacted] or [redacted] studies entitled "Transcranial Direct Current Stimulation (tDCS) as an Adjuvant to Phonomotor Treatment for Aphasia" [redacted] "Prism Adaptation Treatment in Left Brain Stroke" [redacted] we may obtain your data on certain cognitive and language assessments. We will only share data from these assessments to decrease testing burden. All other assessment data will be collected only for this research study and will not be shared as outlined in confidentiality section.

MRI Scans (up to 2 sessions)
You may be asked to undergo one MRI scan before treatment. You may also be asked to undergo an MRI scan after treatment. During the scans, you will be asked to lie quietly and to complete language tasks so we can take pictures of your brain and record brain activity. The scanning sessions will last up to 1.5 hours. If you have participated in [redacted] study entitled "Beyond lesion-language mapping in aphasia: A novel imaging-based prediction model" [redacted] or [redacted] "Transcranial Direct Current Stimulation (tDCS) as an Adjuvant to Phonomotor Treatment for Aphasia" [redacted] we may obtain your data from your MRI scan. We will only share this data to decrease participation burden.

Intention Treatment
You will receive a total of 30 hours of therapy. You will be randomly assigned to either 15 sessions over 3 weeks or 24 sessions over 12 weeks with a speech-language pathologist (SLP). There will be three phases of treatment. In Phase 1, you will sit facing a computer monitor with a small box to your left. A flashing star will appear on the monitor along with a

tone. You will lift a box lid with your left hand and push a red button located on a key pad inside the box. This button press will make a picture appear on the computer screen. You will have 20 seconds to name the picture. If you are correct, you will move to the next trial. If you are incorrect, the SLP will provide say the correct response and you will repeat the word while making a circular left-hand gesture. You will have three opportunities to produce a correct response. Phase 2 is identical to Phase 1 but there is only a flashing star to cue you to lift the box lid. Phase 3 is identical to Phase 2, but when the flashing star appears, you will make a circular left-hand gesture three times and a word will appear on the screen. The word represents a category, and you will be asked to generate a single member of the category (e.g., ANIMAL, “dog”).

Table of Study Activities

Study Visit	Activity	# of sessions	# of hours per session
Assessment I (Before treatment)	· Consenting · Cognitive and language tests · MRI scan (if applicable)	Up to 6	2-3
Treatment	· Intention Treatment	15 or 24	2-3
Assessment II (Immediately after treatment)	· Cognitive and language tests · MRI scan (if applicable)	Up to 3	2-3
Assessment III (3 months after treatment)	· Cognitive and language tests · MRI scan (if applicable)	Up to 3	2-3
Assessment IV (6 months after treatment)	· Cognitive and language tests	Up to 3	2-3

RISKS:

There may be side effects from the study device or procedures that are not known at this time.

The most common risks or discomforts of this study include:

MRI scanning:

- Pacemakers, infusion pumps, and other implanted biomedical engineering devices may malfunction in the scanner. We will ask you questions about such devices to determine if

you have one of them. If you do have one of these devices, you cannot participate in the MRI scan portion of this study.

- If you have other implanted biomedical devices that are influenced by magnetic fields or if you have shrapnel or metal from wounds or other sources that might be influenced by magnetic fields, you cannot participate in the MRI scan portion of this study.
- The space inside the scanner is somewhat confined. Therefore, if you experience significant claustrophobia (fear of enclosed spaces), you should not participate in the MRI scan portion of this study.

The less common risks or discomforts of this study include:

Language testing and treatment:
You may experience some frustration during testing of thinking or language functions. This frustration is tolerated well by most participants. If you become frustrated, you can ask to take a break to allow frustration to go away.

MRI scanning:
If you are a woman of child-bearing ability, risks of MRI scanning for an unborn child are unknown. Therefore, women who are pregnant or are trying to become pregnant may not take part in the MRI scan portion of this study.

Rare but possible risks or discomforts of this study include:

MRI scanning:
- There are loud noises during MRI scanning. A very small number of persons have experienced hearing loss after MRI scanning. You will be given earplugs while you are in the scanner to prevent hearing loss.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Participation in more than one research study may further increase risks to you. If you are already enrolled in another research study, please inform [redacted] or the person reviewing this consent before you enroll in this or any other research study.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

BENEFITS:

Taking part in this research study may not benefit you personally. However, you will receive information about your language and cognitive function. You will also receive 30 hours of aphasia treatment. This research study may help us better understand how distribution of treatment over time affects treatment outcomes and who responds best to Intention treatment, which can be used to help other people in the future.

COMPENSATION:

You will not pay for any of the study tests or procedures. You will be compensated $15 per session for assessment and treatment. Depending on the number of study visits, you may be compensated up to $635. Payments will be disbursed when baseline assessments are completed ($45-90), when the treatment and post-treatment assessments are completed ($270-405), after 3-month follow-up assessments ($45), and after 6-month follow-up assessments ($45). You will receive $25 for MRI scan appointments. Baseline scan payments will be disbursed with baseline assessment payments and post scan payments will be disbursed with 3-month follow-up assessment payments.

You will get emergency medical care if you get injured from being in this study. Under Federal Law, you will qualify for follow-up treatment if the injury was related to the research study. You may or may not get further compensation if you are injured in this study. This rule would not apply if you do not follow study procedures. If you believe you have been injured by this research, you should contact [redacted]

COSTS:

You will not be charged for any treatments or procedures that are part of this study. However, some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services that are not part of this study.

You will get necessary medical treatment if you get injured from being in this study. This requirement does not apply to:

(1) Treatment for injuries due to non-compliance by a subject with study procedures;

Or

(2) Research conducted for VA under a contract with an individual or a non-VA institution.

If you believe you have been injured by this research, you should contact [redacted]

ALTERNATIVES:

You do not have to be in this study to receive treatment for aphasia. The study investigator can discuss alternative treatment options that may be available if you want this information.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED:

We will keep information about you, including any research records we create, strictly confidential to the extent required by law.

We may be required to release your record if we receive a subpoena or a court order. The study staff will keep your study files locked in a file cabinet in a private office. We will use a study number rather than your name on study records when we can. Your name and other facts that might point to you will not appear when we present this study or publish its results. People other than those doing this research study may have access to your medical and study records including:

- Department of Veterans Affairs
- The Office for Human Research Protections
- The Government Accountability Office (GAO)
- The Office of Research Oversight (ORO)
- The Inspector General
- Emory University
- Any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above
- [redacted]
- [redacted]
- [redacted]

All research records and/or identifiers will be destroyed in accordance with the VA record retention schedule.

If you are a veteran who is a patient at the Atlanta VA Health Care System, a copy of your signed and dated consent and HIPAA forms may be placed in your medical record(s). If you are a non-veteran receiving clinical services (i.e., use of the laboratory, radiology, audiology, etc.) as part of this study, you will have an electronic medical record created for you. You will also be given a VA Notice of Privacy Practices (NOPP) and we will ask you to sign a form saying that you have received this notice.

If you are participating in a study where a test and/or procedure may be performed at Emory and you are not and have never been an Emory patient, you do not have an electronic medical record. Please note that an Emory medical record will be created if you have any services or procedures done by an Emory provider or facility for this study.

HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPAA):

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA 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 HIPAA 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 such as diagnoses, progress notes, lab or radiology findings.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include Department of Veterans Affairs

- The Office for Human Research Protections
- The Government Accountability Office (GAO)
- The Office of Research Oversight (ORO)
- The Inspector General
- Emory University
- Any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above
- [redacted]
- [redacted]
- [redacted]

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, [redacted] and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization. Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

RESULTS:

Upon request, the study team can give you copies of your MRI scans and your test scores without any clinical interpretation.

IDENTIFIABLE PRIVATE INFORMATION:

Identifiers might be removed from the identifiable private information or identifiable biospecimens that are collected. After that removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative

CONFLICT OF INTEREST: None

CONTACT PERSONS:

If you have any questions, concerns, or complaints about this study you can call a member of the study staff: [redacted]

If you have been harmed from being in this study call: [redacted]

If you want to speak to someone who is not a member of the study to discuss problems, ask questions or voice concerns, you can call:

The Research Compliance Officer at [redacted] or the Clinical Studies Center Manager at [redacted]

If you have any questions about your rights as a participant in this research study, call the Emory University Institutional Review Board at [redacted]

VOLUNTARY PARTICIPATION AND WITHDRAWAL:

The study doctors have the right to end your participation in this study for any of the following reasons: If it would be dangerous for you to continue, if you do not follow study procedures as directed by the study doctors, or if the sponsor decides to end the study.

Your participation is voluntary and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled. For your safety, however, you should consider the study doctor's advice about how to go off the study treatment.

The study doctor, investigator, or sponsor may stop you from taking part in this study at any time if they decide it is in your best interest or if you do not follow study instructions.

We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below**.**

RESEARCH PARTICIPANT'S SIGNATURE AND DATE:

_____
Research Participant's name (Print)

_____ _____
Research Participant's Signature Date