Study Title: **Rhythm-based Intervention in Aphasia**

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The University of Texas at Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research Project: Music-based intervention for aphasia

Investigators:	**Contact Number**
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Research Assistant: Matthew Heard	214-458-7255 (cell#)

Key Information: This is a consent form for research participation which involves behavioral assessments including surveys, functional magnetic resonance imaging (fMRI), and an experiment to examine whether a music-based aphasia intervention can lead to improvement in speech and language function. This study involves two different music-based intervention methods and the participants will be randomly assigned to one of the two groups. This form is intended for review by the participant's primary caregiver. Your consent to participate (and the consent of the participant) is voluntary and can be withdrawn at any time with no repercussions for you on behalf of the Speech, Language, and Music (SLAM) Lab at the University of Texas Dallas (UTD). All study-related information we collect will be kept confidential. There are no known risks to participating in any component of this study, but some exclusionary criteria apply to the participant's eligibility to participate in the MRI portion, e.g., mobility requirements, the presence of metallic objects—medical and otherwise—that are in or on the participant's body, as well as pregnancy. While it is possible that the participant may benefit from the intervention they receive, we cannot guarantee any benefit as this is an experimental intervention that requires validation. However, during the 10-week study, the participant cannot partake in any other forms of language therapy.

Purpose: The purpose of this research study is to develop a music-based rehabilitation program for participants with chronic aphasia, a condition in which participants have lost the ability to understand and/or express speech. We hope that persons with aphasia will improve their speech and language abilities through this novel intervention.

Description of Study: If you and the participant volunteer to participate in this study, we may ask you to do any, if not all, of the following activities:

Behavioral Testing:

If the participant is deemed eligible for the study, you and the participant will be invited to the Center for BrainHealth for in-person behavioral assessment. You will be asked about the participant's music and language background. The participant's hearing acuity may be measured using pure tone audiometry. The participant's cognitive and music abilities will also be assessed. Then, the participant will be administered standardized aphasia battery tests to determine the severity of their symptoms and whether or not they are eligible to participate. When the participant completes the intervention program, these measurements will be taken again so that we may compare their post-intervention scores to those obtained before intervention. Some, if not all, of these behavioral testing sessions will be video recorded.

fMRI Testing:

After completing the behavioral assessments, participants who are eligible will be invited to the BrainHealth Imaging Center for pre-intervention MRI scans (these participants will be re-invited for more MRI scans after the completion of the intervention). Before scanning, the participant will be asked to change into a set of scrubs provided to them. During scanning, participants will lie on a long narrow table for up to 1.5 hours. They may be asked to either passively attend to or actively make a response (e.g., lifting a finger, pressing a button, or making a verbal response) to speech and music stimuli. During this time, they will be exposed to magnetic fields and radio waves. They will hear a loud, repetitive tapping noise, and they will be required to wear earplugs and/or earphones to reduce the noise. Video recording may be done during some, if not all, of these fMRI testing sessions.

Functional MRI (fMRI) has become a major research tool in the developing science of brain, mind, and behavior. It is an imaging method that uses a strong magnetic field and radio waves to make pictures of the body. fMRI is a type of specialized MRI scan used to measure the change in blood flow related to brain activity. No X-rays or other contrast agents are used in fMRI. Furthermore, the MRI scan they will receive in this study is **not** intended to be diagnostic and does not replace a clinical MRI scan reviewed by a qualified radiologist. fMRI will take place in the BrainHealth Imaging Center, located at 2200 W Mockingbird Lane, Dallas, TX, 75235.

Aphasia Intervention:

At the conclusion of the initial fMRI assessment, you and the participant will be introduced to an aphasia intervention app that will be used for home-based daily intervention. We will provide enough time for you and the participant to be acquainted with the computerized intervention program as well as an opportunity to answer any questions you and the participant may have.

The participant will use the app for 8 weeks. All participants will be asked to complete practice sessions implemented in the app once per day for five days a week.

Upon completion of the rehabilitation intervention, the same behavioral and neuroimaging tests that we administered before the intervention will be administered as post-intervention assessments. Later, a survey will be sent to you asking about the general use of the intervention.

Follow-up Testing:

Approximately 3 months following completion of the intervention, we would like to bring you and the participant back to the Center for BrainHealth for a brief follow-up appointment. We will administer the same behavioral tests as we did during the pre- and post-intervention behavioral testing. fMRI will not be used during this follow-up test.

Questionnaires to Assess COVID-19 Symptoms and Exposure:

The investigators will be conducting pre-screening (before the in-person visit) and post-screening (after the in-person visit) questionnaires to assess your symptoms and exposure to COVID-19. The pre-screening questionnaire will be completed approximately 24 hours before the in-person visit and again when you arrive for your session, and the post-screening questionnaires will be completed approximately 5 days and 14 days after the in-person visit. If you experience any symptoms related to COVID-19 or receive positive test results after your participation in this

research study, you are strongly encouraged to contact the investigators or the IRB Office.

Number of Participants: 30 participants will complete the experiment.

Length of Participation: The overall time commitment will last approximately 10 weeks. This includes 1 week of pre-intervention measurements, 8 weeks of intervention, and 1 week of post-intervention measurement. Approximately 3 months after the completion of intervention, we ask that you return for one more session of behavioral measurement. However, if you decide to stop participating in the study, we encourage you to tell the researchers. *During the approximately 10-week study period consisting of pre-intervention measurement, meeting with speech language pathologist, practicing at home, and post-intervention measurement, the participant cannot partake in any forms of language therapy.*

Inclusion / Exclusion Criteria: This study focuses specifically on people who are experiencing speech and language deficits as a result of brain damage from stroke, i.e., aphasia. To be included in the study, the participant's limb motor function, at least on the left side, should be relatively intact. To complete the MRI portion of the experiment, we will require participants to change into medical scrubs and to lie down on a bed without assistance from experimenters. Furthermore, all participants must not suffer from any other type of neurological disease. The participant must be 6 or more months post-stroke.

MRI experiments have many exclusionary criteria designed to keep both the participant and experimenters safe. Since the MRI uses strong magnetic fields and radio waves, people with any of the following are not eligible to participate: biomedical devices including cardiac pacemakers and cochlear implants; certain types of metallic clips in their body (i.e., an aneurysm clip in the brain); experience working with metal or have had a piece of metal removed from their eye(s); shrapnel, bullets, or buckshot in their body. As the effects of MRI on fetuses are not extensively studied, people who are or are trying to become pregnant are excluded from participation. Furthermore, special considerations must be taken for people with extensive dental work (e.g. braces, veneers, fillings, etc.).

Possible Risks:

COVID-19:

The novel coronavirus, COVID-19, has been declared a worldwide pandemic by the World Health Organization. COVID-19 is extremely contagious and is believed to spread by the kind of person-to-person contact that you may engage in by participating in this research study. Thus, as with any activity involving person-to-person contact, there is a risk that you might contract the virus and expose other individuals that you might come in contact with after participation in this study. Older adults and people of any age who have serious underlying medical conditions like heart disease, diabetes, cancer, or a weakened immune system, are at a higher risk for getting very sick from COVID-19.

The University of Texas at Dallas continues to follow the CDC guidelines and recommendations related to COVID-19 prevention. While individuals are not required to wear face masks while on campus, they are encouraged to do so. If you do not have a facial covering and would like wear one during your experimental session, please let your investigator know and one will be provided to you.

COVID-19 Vaccine Disclosure:

The number of fully vaccinated individuals continues to grow, but there remains a portion of the population that has yet to be vaccinated. Studies indicate COVID-19 vaccines are effective at preventing disease and reduce the risk of people spreading the virus. However, some people who are fully vaccinated against COVID-19 will still get sick because no vaccine is 100% effective. Experts continue to monitor and evaluate how often this occurs, how severe their illness is, and how likely a vaccinated person is to spread COVID-19 to others.

The research personnel conducting this experiment have been fully vaccinated. However, while available COVID-19 vaccines have demonstrated high efficacy at preventing severe and/or symptomatic COVID-19, there is currently limited information on how much the vaccines might reduce transmission and how long protection lasts. In addition, the efficacy of the vaccines against emerging SARS-CoV-2 variants is not known.

Additional guidance from the Center for Disease Control (CDC) indicates there many things we are still learning about the vaccine, such as:

- How effective the vaccines are against variants of the virus that causes COVID-19. Early data show the vaccines may work against some variants but could be less effective against others.
- How well the vaccines protect people with weakened immune systems, including people who take immunosuppressive medications.
- How long COVID-19 vaccines can protect people.

Investigators are taking extra precautions based on CDC recommendations. If you have questions about the safety measures that are in place, the investigators can provide you with this information. These measures have been approved by the Institutional Review Board.

Behavioral Testing:

At this time, there are no known significant risks with any behavioral procedures. The participant may experience boredom or frustration with behavioral tasks. We understand that some of the questions in this study and some audio clips may lead to unpleasant feelings. At any time during this study, you and the participant can take a break, skip questions, or stop participating and both you and the participant will still receive full credit for your participation. If you or the participant feel uncomfortably distressed while filling out any questionnaires or completing laboratory tasks, please let us know.

fMRI Testing:

There are no known significant risks with this procedure at this time since the magnetic fields, at the strengths used, are felt to be without harm. There are conservative Federal Guidelines for radio wave exposure and our examinations fall within those guidelines. We feel these are safe levels and less hazardous than a comparable x-ray computed tomography examination (CT scan). Exceptions include if a person has a cardiac pacemaker or a certain type of metallic clip in their body (i.e., an aneurysm clip in the brain); if a person has worked with metal or had a piece of metal removed from the eye(s); or if a person has shrapnel, bullets, or buckshot in their body. For the

safety of yourself and the participant, you will not be permitted into the room containing the MRI. You will be asked to wait in a nearby waiting room.

All metallic objects must also be removed from the participant prior to entering the magnet room or approaching the magnet to prevent them from being pulled by the magnet. This includes keys, jewelry, pocketknives, money clips, paper clips, safety pins, hairpins, and barrettes. In addition, objects such as watches, credit cards, and hearing aids could be damaged in the presence of the magnetic field. A locker will be provided for the participant to secure all their items and valuables.

If the participant is or is trying to get pregnant, the effects of the scan on a fetus are unknown and, therefore, we will not perform the examination at this time.

All imaging hardware and software being used to perform scans in the BrainHealth Imaging Center at UTD are approved by the FDA for medical applications.

A call button is provided such that the participant may have the scan stopped at any time during the study.

There is a risk of heating of metal objects such as wires from exposure to radio waves. We will ask the participant to report any heating/burning sensation **immediately**. If this occurs, the participant may have the scan stopped at any time by using the call button.

There is a possibility that the participant will experience small twitching sensations due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, if this occurs the participant may have the scan stopped at any time by using the call button.

Dizziness and nausea may occur momentarily when the participant's head is moved in or out of the tunnel of the magnet. The sensation should disappear quickly. If not, the participant may stop the scanning at any time.

The participant may experience claustrophobia, i.e., the fear of having no escape and being closed in. The participant may discontinue the scan at any time.

If you or the participant experience a life-threatening event, a medical doctor will not be in the facility; 911 will be called.

The MRI scan the participant will receive during the course of this study is for research purposes only. It is not a clinical scan intended for diagnostic or therapeutic purposes. The BrainHealth Imaging Center is a research center. It is **not** a clinical MRI facility in a hospital. There are no neuroradiologists at the BrainHealth Imaging Center, therefore the staff are unable to make any medical comments about the participant's scan. Should you or the participant want to know if their scan is normal or abnormal, the staff will not be able to tell you or the participant. However, all structural scans obtained in normal research subjects are sent to a Neuroradiologist for blind review. In the rare event the neuroradiologist detects an abnormality he will be given

your name and contact information, or that of a physician of your choice, so he can explain and discuss the finding with you and the participant.

In case the participant is planning to obtain or change health insurance coverage in the future, you must be aware that in the unlikely event an incidental finding is detected, discovery of a previously unknown condition might be construed as a "pre-existing condition" by the new health care provider/insurer.

You and the participant will be informed about new research that provides additional information about risks or that may influence their decision to continue participation in this research.

Compensation for Injury: Compensation for an injury resulting from participation in this research is not available from The University of Texas at Dallas. However, you and the participant retain your legal rights during participation in this research.

Possible Benefits to the Participant: It is possible that the intervention will assist the participant with their speech and language skills, however benefits are not guaranteed as the intervention is experimental and requires validation.

Removal from Study: We may decide to remove you and the participant from this study if you or the participant are unable to keep appointments or follow the researcher's instructions.

Alternatives to Participation: Individuals may choose not to participate without penalty or loss of benefits to which you and the participant are otherwise entitled.

Payments to Participate: By law, payments to subjects are considered taxable income. The pro-rated compensation will be $10/hour for the behavioral experiments and $20/hour for fMRI experiments. During the intervention, the participant will be compensated $5 for each daily practice session they complete. Participants will be paid via an Amazon gift card sent to their email after study completion.

Voluntary Participation: All individuals have the right to agree or refuse to participate in this study. Individuals who consent to participate also have the right to change their minds while experiencing the experimental procedure. Participants may tell the investigator that they no longer wish to participate. Refusal or withdrawal of participation will not involve any penalty or loss of benefits to which non-participants are entitled. Refusal to participate will not affect participants' legal rights or the quality of education they may wish to receive at UTD.

Records of Participation in this Research: All of the information participants provide to investigators as part of this research will be protected and held in confidence within the limits of the law and institutional regulation. All identifiable data, such as name, date of birth, etc., will be coded with the participant's subject ID and stored separate from the participant's task performance and questionnaire data. When the results of the research are published or discussed in conferences, no information will be included that would reveal the participant's identity.

Identifiable Private Information / Identifiable Biospecimens: During the MRI portion of the experiment, private information that can be used to identify the participant (specifically, MRI images including their face) will be removed from brain images using de-facing algorithms. After such removal, the de-identified data could be used by Investigators for future research studies or distributed to another investigator for future research studies without additional informed consent.

If you or the participant test positive for COVID-19, investigators may be required to notify local health authorities that you and the participant have been on the UTD Campus. If investigators have to report this, they will only provide the minimum information necessary and will not provide any details about the reason(s) for the participant's visit. By signing this form, you and the participant are agreeing that the investigator may do so without an additional signed release.

Information Available to Others: Members and associated staff of the Institutional Review Board (IRB) of The University of Texas at Dallas may review the records of you and the participant's participation in this research. An IRB is a group of people who are responsible for assuring the community that the rights of participants in research are respected. A representative of the UTD IRB may contact you or the participant to gather information about participation in this research. If you or the participant wish, you and the participant may refuse to answer questions the representative of the IRB may ask.

Publications Associated with this Research: The results of this research may appear in publications but individual participants will not be identified.

Research Results: Upon request, we will inform you and the participant of the outcome of the research program.

Contact People: Participants who want more information about this research may contact any of the investigators listed at the top of page 1 of this document. Participants who want more information about their rights as a participant or who want to report a research related injury may contact:

The University of Texas at Dallas Institutional Review Board UTD Office of Research	972-883-4579

Signatures

Your (the caretaker's) signature indicates that you and the participant have read, or listened to, the information provided above and that you have received answers to your questions. The signature also indicates that you and the participant have freely decided to participate in this research and that both you and the participant know you both have not given up any of their legal rights.

_____
Participant's Name (printed)

_____ _____
Participant's Caretaker Signature Date

_____
Name of Researcher Obtaining Consent

_____ _____
Signature of Researcher Obtaining Consent Date