Title: Investigating the Effects of Rhythm and Entrainment on Fluency in People With Aphasia

NCT05248295

Document date: 03/04/2024

Protocol Title: Investigating the Effects of Rhythm and Entrainment on Fluency in People with Aphasia

Principal Investigator: Lauryn Zipse, PhD, CCC-SLP

Site Principal Investigator:

Description of Subject Population: adults with aphasia

# Key Information

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you are an adult who has aphasia. We are doing the research to find out whether some ways of speaking make it easier for people with aphasia to say words and sentences. If you agree, you will complete some tests of language, attention, and memory, and you will repeat lots of words and sentences. You will be in the study for 2 testing sessions if you decide to stay for the whole study.

The main risks of being in the study are that some of the tasks may be boring or frustrating.

You will be paid $75 for taking part in this research study. You will find more information about the payment amount for each visit and a plan if you do not complete all study visits later in this form.

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

**Lauryn Zipse, PhD, CCC-SLP** is the person in charge of this research study. You can call her at **617-643-3245 M-F 9-5**. You can also call **Lauryn at 617-871-9707 during non-business hours** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **Lauryn Zipse at 617-643-3245.**



**IRB Protocol No: 2018P001160** **IRB Expiration Date: 3/4/2026**
**Consent Form Valid Date: 3/4/2024** **IRB Submission: EXPCI1**

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

## About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

## Why is this research study being done?

We are doing this research study to find out whether speaking along with a recording makes it easier for people with aphasia to say words. We are also looking at whether speaking with a different rhythm makes it easier to speak. We are asking you to take part in this study because you have aphasia. A total of 100 people will be in this study, including 40 people with aphasia and 60 without aphasia. All of these people will take part in the study at the MGH Institute of Health Professions.

## How long will I take part in this research study?

One or two sessions will be needed to complete this research study. Each session will take about two hours. If cognitive and language test results from within the past year are available in your file at the Aphasia Center, only one session will be needed. If this information is not available, two sessions will be needed.

## What will happen in this research study?

At the start of the study, we will do some tests and procedures to see if you qualify to take part in this research study. We will ask you about your medical history and do a brief hearing screening. We will review the results of the hearing screening with you, and if you don't qualify for the study we will tell you why.

We will ask you to let us look at test results from the MGH IHP Aphasia Center, including results from language tests and tests of cognition. Based on the date of your most recent test results, we may ask you to complete all or some of the following tasks:

- Listen to short stories and answer questions about them.
- Listen to words and point to the picture that matches the word you hear.
- Follow simple directions to show that you understand them.
- Repeat sounds, words, and short sentences.
- Draw designs, complete mazes, and circle matching figures
- Perform some movements with your arms and legs, and make faces.

During your session, you will complete the following tasks:

- Tap along to music.
- Listen to some spoken sentences and repeat them. Your repetitions will be audio-recorded.
- Listen to spoken words or sentences, and then repeat them while listening to noise (static) through headphones. Your repetitions will be audio-recorded.
- Complete some short test of attention and memory.

Portions of the testing session will be audio recorded (repeating words and sentences). We will use the recordings to score how you do on these tasks. Collaborators at the Massachusetts Institute of Technology (MIT) may listen to the recordings to help analyze them. To protect your privacy, your name will not be on your recordings. The results will be stored with a code number. The key saying which name goes with which code number will be stored in a locked office at the MGH Institute of Health Professions. Recordings will be stored for 15 years.

## What are the risks and possible discomforts from being in this research study?

Some of the tasks might be difficult and frustrating. There is a risk to your privacy because you are providing personal information in this study. There may be other risks that are currently unknown.

## What are the possible benefits from being in this research study?

This study will not benefit you directly. We hope that the information we get from this study will help us to better understand aphasia. Specifically, we hope to learn whether producing phrases along with a recording helps people with aphasia speak or sing better. Ultimately, this could lead better treatments for people with aphasia.

## What other treatments or procedures are available for my condition?

This is not a treatment study, and you will not be given any speech-language therapy during this study. Various treatments are available for aphasia. Treatment selection depends in part on the type and severity of aphasia. Treatments aimed at increasing spoken output include Melodic Intonation Therapy, script training, the Sentence Production Program for Aphasia, and Response Elaboration Training.

## Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

## What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of 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.

## Will I be paid to take part in this research study?

You will be paid $75 for your participation. If you are not found to be eligible to complete the study during the first visit, you will be paid $30.

## What will I have to pay for if I take part in this research study?

You do not have to pay to take part in this research study. Charges for any ongoing or routine medical care you receive outside this study will be billed to you or to your insurance company in the usual way. You will be responsible for payment of any deductibles and co-payments required by your insurer for your routine medical care.

## What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

## If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Lauryn Zipse, Ph.D., CCC-SLP is the person in charge of this research study. You can call her at 617-643-3245 Monday through Friday during business hours (9 a.m. to 5 p.m.) with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Lauryn Zipse at 617-643-3245.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

## If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

### In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

### Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research

- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

## Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

# Informed Consent and Authorization

**Statement of Person Giving Informed Consent and Authorization**

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

## Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

| _____ | _____ | _____ |
|---|---|---|
| Subject | Date | Time (optional) |

## Signature of Study Doctor or Person Obtaining Consent:

**Statement of Study Doctor or Person Obtaining Consent**

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

| _____ | _____ | _____ |
|---|---|---|
| Study Doctor or Person Obtaining Consent | Date | Time (optional) |

Consent Form Version: 04/17/22