Official Title of the study: Effects of Altered Auditory Feedback on Speech Fluency

NCT Number: [NCT ID not yet assigned]

Date: 05/01/2023

CONSENT QUESTIONNAIRE

Please read and sign the consent form to participate.

Hello,

You are invited to participate in a research study on new audio-based approaches for people who stutter.

Here are some details about this research study:

Mumble Melody is an application delivering novel auditory feedback approaches for people who stutter. The app is available on the Apple App Store and has been developed for stuttering research. This study is a 1-month online study for which you will require:

(1) an Apple device through which you can download and use the Mumble Melody app

(2) A SEPARATE browser-supporting device with a microphone that you can use for our online questionnaire and voice recording platform

For this study, you will need to:

- Sign this consent form
- Answer a few further questions through a secondary form
- **1 session:** Perform a 15 minute initial screening evaluation to determine if you are eligible for the study
- Be shipped a pair of Apple headphones and a lighting-to-headphone-jack adapter
- Answer a 10-15 minute initial survey
- **1 session:** Complete a 40 minute online baseline testing session
- Use the Apple application as you would like for 28 days
- **4 sessions:** Complete 30 minute online testing sessions at the end of each week for 4 weeks
- Complete a 10-15 minute survey at the end of the study

During online testing sessions, we will be giving you instructions and collecting voice recordings. This study will be completely remote, meaning you can participate entirely at home or in whatever environment you feel comfortable in. Your voice will not be recorded by the app. The app will be linked to a unique subject ID and will log when you use the app, on which settings, and for how long.

Samples of your voice, survey question answers, and app usage timestamps will be collected.

In order to qualify for this study, you must:

1. **Identify as a person who stutters (PWS)**
2. **Be 18 years or older**
3. **Be a US citizen or green card holder currently residing in the US**
4. **Have one of the following Apple devices:**
    - **iPhone with iOS 12.0 or later**
    - **iPad with iPadOS 12.0 or later**
    - **iPod touch with iOS 12.0 or later**
    - **Mac with macOS 11.0 or later and an Apple M1 chip or later**
5. **Have a SEPARATE browser-supporting device with a microphone**
6. **Be able to conduct the study in English**
7. **Qualify based on an initial screening evaluation** - those who qualify for weekly testing sessions can only qualify if their stuttering is at a moderate to severe level during the initial screening process.

When the study is finished, you will receive compensation via an Amazon email gift card. and will be able to keep the pair of Apple headphones and lightning-to-headphone-jack adapter. You will receive up to $70 in payment for participation in the study, as well as a pair of free wired headphones and a lighting to headphone jack adapter. The payment includes $40 for completing all testing sessions, and an additional $7.50 per week if the app is used at least 4 out 6 days that week for a minimum of 5 minutes each day. You can only receive compensation if you are eligible based on our initial screening.

Informed Consent

Please read the study consent form (PDF link below) which describes the details of the study and what to expect if you choose to participate. After careful review of the consent form please indicate your willingness to participate in the study by signing your name in the space provided (using your mouse or touch screen) and confirming your consent.

If you have any questions upon review of the consent form please contact the study team at mumblemelody@mit.edu prior to making your decision about participation and we will make sure to answer your questions.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES:

<include consent form PDF here>

1) **First Name of Participant*: _____**
2) **Last Name of Participant*: _____**
3) **Email address (to be used for all study-related communications)*: _____**
4) **Name of Legal Representative (if applicable):**

By signing this form, I confirm that I:

- **Identify as a person who stutters**
- **Am 18 years or older**
- **Am a US permanent resident or citizen living in the United States**
- **Have one of the following Apple devices:**
    - **iPhone with iOS 12.0 or later**
    - **iPad with iPadOS 12.0 or later**
    - **iPod touch with iOS 12.0 or later**
    - **Mac with macOS 11.0 or later and an Apple M1 chip or later**
- **Have a SEPARATE browser-supporting device with a microphone**
- **Am able to conduct the study in English**

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. We separate all personal information (name, email address) from the data to respect your privacy. Your data will include voice data from testing sessions, surveys, and app usage logs.

5) **Check all that apply*:**
    - **I consent to having my audio recordings and survey answers shared only with the researchers of this study.**
    - **I consent to having my audio recordings and survey answers shared with the researchers of this study and other qualified researchers as well.**

- **I consent to having my audio recordings and survey answers shared with the researchers of this study, other qualified researchers, and shared publicly.**

6) **Recontact*:**
   - **I consent to being recontacted for further studies.**
   - **I do not consent to being recontacted for further studies.**
7) **Date and time*:**
8) **Signature of Participant*: _____**

* must provide value

CONSENT FORM DOCUMENT:

CONSENT TO PARTICIPATE IN NON-BIOMEDICAL RESEARCH

Effects of altered auditory feedback on speech fluency

You have been asked to participate in a research study conducted by Pr. Satrajit S, Dr. Rebecca Kleinberger, and Alisha Kodibagkar from the McGovern Institute for Brain Research at the Massachusetts Institute of Technology (M.I.T.). You were selected as a possible participant in this study because you self-identify as an adult who stutters (AWS) and you are interested in furthering voice-physiology interaction research.

The information below provides a summary of the research. Your participation in this research is voluntary and you can withdraw at any time.

- Purpose
  The purpose of the proposed study is to use altered auditory vocal feedback to increase fluency in people who stutter and to examine changes in this effect over the course of a one month period occurring outside the laboratory setting.
- Study Procedures
  The study will have 3 components: (1) daily sessions on your mobile device using an iOS app (time flexible) (2) a 10-15 minute survey at the beginning of the study and a 10-15 minute survey at the end of the study (3) A 15 minute eligibility screening session, one 40 minute baseline session at the beginning of week 1, and four 30min testing sessions at the end of each week, on your computer using a web platform for a period of 4 weeks.
- Risks & Potential Discomfort
  During the daily sessions, your voice will not be recorded but the app will log each time it is being opened, on which setting, and for how long. During the weekly sessions, your voice will be recorded and later analyzed. To some, hearing one's own

voice in an altered manner can initially be experienced as disconcerting; the device is not invasive and does not present risks beyond that of listening to sound via headphones.

You should read the information below, and ask questions about anything you do not understand before deciding whether or not to participate.

- **PARTICIPATION AND WITHDRAWAL**

Your participation in this study is completely voluntary and you are free to choose whether to be in it or not. If you choose to be in this study, you may subsequently withdraw from it at any time without penalty or consequences of any kind. The investigator may withdraw you from this research if circumstances arise. Your eligibility to participate in the weekly testing sessions will be determined in part by the fluency assessment during the online screening session. You will qualify for weekly testing sessions only if your stuttering is of sufficient quantity/severity at baseline (stutter-like disfluencies in more than 3% of total spoken syllables). In the 30-minute sessions, you will be required to demonstrate proficiency in operating the device(s), iOS-based applications, and other associated technology.

- **PURPOSE OF THE STUDY**

The purpose of the proposed study is to use altered auditory vocal feedback to increase fluency in people who stutter and to examine changes in this effect over the course of a one month period occurring outside the laboratory setting. Our lab has demonstrated a short-term fluency benefit in people who stutter when their vocal self-perceptions are altered. To accomplish this, speech is captured by a microphone, the acoustic properties are manipulated through computerized transformations, and the new sounds are played back to the speaker via headphones, all in real-time. We have shown several different types of vocal transformations - termed “modes” - to be fluency-inducing. Examples include modulations designed to mimic changes in room effects (i.e., reverberation), whispering, or adding musical elements such as vocal harmonies. The effective translation of these effects outside the laboratory setting is not known. A useful therapy for dysfluent speech in people who stutter would need to be effective in the real world over time scales spanning days to weeks, if not longer.

The purpose of this study is to examine the effectiveness of these vocal feedback modes over the course of one month in a semi-controlled setting occurring at your home (i.e., outside the laboratory). Demonstrating a persistent fluency benefit would support further development of this vocal feedback method as a novel treatment for stuttering.

Previous research has looked at the effects of simple vocal transformations - particularly pitch/frequency shifts and delays - but none have altered the acoustic landscapes using digital technologies that enable more complexity and nuance. The long-term benefits from altered auditory feedback from pitch and frequency shifts are limited by a relatively unpleasant listening and speaking experience. Our data shows our novel modes to have extended benefits compared with pitch shifts and delays in terms of effects, pleasantness, and control.

- **PROCEDURES**

If you volunteer to participate in this study, we would ask you to do the following things:

I - Virtual screening evaluation (15 minutes)

- You will receive a URL toward a web platform to perform the study from home
- You will receive an additional explanation of the study.
- You may be asked to answer a few preliminary questions about your physical state, health, and vocal fluency.
- Your vocal baseline will be recorded via audio.
- If you qualify for additional sessions, you will be given additional information

II - Initial virtual baseline session (40 minutes)

- You will receive a URL toward a web platform to perform the study from home
- You will receive an additional explanation of the study.
- We will ask you to wear a pair of wired headphones
- You may be asked to answer a few preliminary questions about your physical state, health, and vocal fluency.
- Your vocal baseline will be recorded via audio.
- You will be asked to speak under several different conditions that will be explained by the online platform while hearing a mediated version of your voice in real-time.
- After the study, you may be asked some questions about your experience

III - Download an iOS app and use it daily undirected using wired headphones/earphones (recommended: 15 minutes each, at least once a day, 7 days per week during one month)

- You will receive a link to download the app
- You may be asked to use it once a day while talking, with wired headphones, for a period of 15 minutes
    - Your use of the app will be undirected and you can use it while reading out loud, while conversing on zoom, or with a conversational partner.
- Your voice will not be recorded by the app
- The app will be linked to a unique subject ID and will log when it is being used, on which settings, and for how long

IV - Virtual testing sessions (30 minutes, at the end of each week, 4 times total)

- You will receive a URL toward a web platform to run the session from home
- You may be asked to answer a few preliminary questions about your physical state, health, and vocal fluency.
- We may ask you to wear a pair of wired headphones
- Your vocal baseline will be recorded via audio.
- You will be asked to speak under several different conditions that will be explained by the online platform while hearing a mediated version of your voice in real-time.
- After the study, you may be asked some questions about your experience

IV - Surveys (10-20 minutes each, 2 total)

- You will receive a URL toward a web platform to answer survey questions

- **POTENTIAL RISKS AND DISCOMFORTS**

To some, hearing one's own voice in an altered manner can initially be experienced as disconcerting or even unpleasant. The theoretical risks are very minimal, but if this effect persists, you can stop the session. Use of the iOS-based application or wearable device can cause the experience of mild discomfort in the ear, comparable to that of other off-the-shelf headphones. This is to be minimized with the use of ergonomic, comfortable earbuds, and by limiting the duration of sessions to 30 minutes. Even though you will be in control of the recordings, there exists the possibility that the recording of home-based sessions may accidentally capture auditory information with sensitive content that you do not want stored as research data (e.g., conversation, background information). Should this occur, you are instructed to inform the researchers and we will delete the specific data immediately once the device is returned. If the researchers overhear a recording that contains legally-reportable content (e.g., suggesting an immediate threat to self or others, child abuse, etc), the researchers will report the contents to the appropriate authorities. If you ask for a recording to be deleted after it has been heard by a researcher, the researcher can only delete contents that are not reportable as required by law. For example, child abuse, self-harm, harming others are required by law to be reported to the authority. All your recorded data sessions will be stored with a unique code that does not contain identifying information (except the sound of the voice). The data is being collected for research purposes only and the study staff are not trained clinicians; if your data reveals information that is recognized as having potential clinical implications, you will be informed and asked to discuss it with her/his physician.

Incidental Findings

The experimental procedure(s) performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project are not clinicians

who may not be trained to perform medical diagnoses, and are not responsible for failure to find existing abnormalities.

- **POTENTIAL BENEFITS**

You may experience fluency benefits, learn more about how vocal feedback influences your speech, and/or may enjoy contributing to the development of fluency-based technology. This study offers the potential to identify a novel method for reducing dysfluent speech in people who stutter. It promises to teach us about the behavioral/speech impact of vocal auditory modulations in a home-based environment.

- **PAYMENT FOR PARTICIPATION**

You will receive up to $70 in payment for participation in the study, as well as a pair of free wired headphones and a lighting to headphone jack adapter. The payment includes $40 for completing all testing sessions, and an additional $7.50 per week if the app is used 4 out 6 days that week for a minimum of 5 minutes each day.

- **PRIVACY AND CONFIDENTIALITY**

Any information obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. In addition, your information may be reviewed by authorized MIT representatives to ensure compliance with MIT policies and procedures. You will be assigned a participant code and your data will be associated with this code number. All data with identifying information will be stored on password-protected computers. Data being analyzed will be de-identified by participant codes and identifying information will be removed except for your voice. Assistants and others working on the project will be educated about the importance of strictly respecting the participants' rights to confidentiality. If you want to see your own data, however, we will make it available to you upon request. Also, you will be free to show your data publicly, if you so desire.

If photographs, videos, or audio-tape recordings of you will be used for educational purposes, your identity will be protected or disguised, unless you have authorized us to share.

Audio recordings made during the testing procedure will be coded numerically. The recordings will only be accessible to the experimenters for research purposes. If any data are shared with investigators outside the team, they will be stripped of any Health Insurance Portability and Accountability Act (HIPAA) identifiers.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. This website will not include any information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

- **IDENTIFICATION OF INVESTIGATORS**

If you have any questions or concerns about the research, please feel free to contact the mumble melody team (mumblemelody@mit.edu), Rebecca Kleinberger (email: rebklein@mit.edu, phone 857 253 9292) or Alisha Kodibagkar (akodiba1@mit.edu , phone 214 597 3346)

- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

If you feel you have suffered an injury, which may include emotional trauma, as a result of participating in this study, please contact the person in charge of the study as soon as possible.

In the event you suffer such an injury, M.I.T. may provide itself, or arrange for the provision of, emergency transport or medical treatment, including emergency treatment and follow-up care, as needed, or reimbursement for such medical services. M.I.T. does not provide any other form of compensation for injury. In any case, neither the offer to provide medical assistance, nor the actual provision of medical services shall be considered an admission of fault or acceptance of liability. Questions regarding this policy may be directed to MIT's Insurance Office, (617) 253-2823. Your insurance carrier may be billed for the cost of emergency transport or medical treatment, if such services are determined not to be directly related to your participation in this study.

- **RIGHTS OF RESEARCH SUBJECTS**

You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you feel you have been treated unfairly, or you have questions regarding your rights as a research subject, you may contact the Chairman of the Committee on the Use of Humans as Experimental Subjects, M.I.T., Room E25-143B, 77 Massachusetts Ave, Cambridge, MA 02139, phone 1-617-253 6787.

As part of your participation, we will collect certain personal information about you, including: name, age / date of birth, contact information, speech and fluency background, musical background and preferences, and basic vocal recordings.

The purpose of the data collection is to evaluate the effects of modulated feedback on fluency. The information you provide will only be available to MIT and Brigham and Women's Hospital researchers. Your data will be secured through the following methods: Each participant will be

assigned a participant code and their data will be associated with this code number. All data with identifying information will be stored on password-protected computers.
Data being analyzed will be de-identified by participant codes and identifying information will be removed except you or your partner's face or voice. In addition, face blurring or obscuring vocal identity can be implemented upon request. Assistants and others working on the project will be educated about the importance of strictly respecting the participants' rights to confidentiality. however, if you want to see your own data, we will make it available to you upon request. You will be free to show your data publicly if you so desire.

This information will be retained for an indefinite amount of time. You have the right to withdraw your data from the study at any time. To do so, contact the mumble melody team (mumblemelody@mit.edu) or Rebecca Kleinberger (rebklein@media.mit.edu). If you withdraw from the study, no new information will be collected about you or from you by the study team. In the future, your data might be used anonymously for future research on stuttering.

SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

I have read (or someone has read to me) the information provided above and I understand the procedures described above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. A copy of this form is available at ...

____ I consent to having my data shared with other qualified researchers.

____ I consent to having my data shared publicly.

____ I consent to being recontacted for further studies

By signing this consent form, I acknowledge my understanding and consent to the collection, storage and transfer (if applicable) of my personal information to the United States.

_____

Name of Subject

_____

Name of Legal Representative (if applicable)

_____ _____

Signature of Subject Date

_____ _____

Signature of Legal Representative (if applicable) Date

SIGNATURE OF PERSON OBTAINING INFORMED CONSENT

_____

Name of Person Obtaining Informed Consent

_____ _____

Signature of Person Obtaining Informed Consent Date