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. Tod Machover, Pr. Satrajit S, Ghosh and postdoctoral fellow Rebecca Kleinberger 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 stutter (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 two components: daily 15min sessions on your mobile device using an iOS app, and five 30min testing sessions at the end of each week and one baseline session at the beginning of week 1, a 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 at-home sessions will be determined in part by the baseline fluency assessment during the initial in-lab visit. You will qualify for additional home-based assessments only if your stuttering is of sufficient

quantity/severity (stutter-like disfluencies in more than 3% of total spoken syllables) In the teaching session, you will be required to demonstrate their 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 occuring 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 be less 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 - Download an iOS app and use it daily undirected using wired headphones/earphones

- You will receive a link to download the app
- You will 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 anonymized subject ID and will log when it is being used, on which settings, and for now long

I - Initial virtual baseline evaluation (30 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.
- You may be asked to answer a brief questionnaire.
- 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
- If you qualify for additional sessions, you will be given additional information
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II - At-home daily sessions (15 minutes each, up to once a day, 7 days per week during one month)

- You will be asked to find a quiet environment and be prepared to talk out loud (read, converse, etc.) for a period of 15 minutes either by yourself or with a conversational partner on the phone, video call, or physically present.

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

- You will receive a URL toward a web platform to run the session from home
- 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

- **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 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 is 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 not receive compensation for your participation in this study

- **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 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 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 their 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.

- **IDENTIFICATION OF INVESTIGATORS**

If you have any questions or concerns about the research, please feel free to contact Rebecca Kleinberger (email: rebklein@mit.edu, phone 857 253 9292)

- **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 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

_____ _____
Legal Representative (if applicable) Date

SIGNATURE OF PERSON OBTAINING INFORMED CONSENT

In my judgment, the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____
Name of Person Obtaining Informed Consent

_____ _____
Signature of Person Obtaining Informed Consent Date