SYRACUSE UNIVERSITY

Department of Communication Sciences and Disorders

Informed Consent for Adult Participants and Parents of Child Participants

Protocol Title: AI-Guided Treatment for Residual Speech Sound Disorder

Introduction of the Principal Investigator and Key Research Personnel:

Name and Title	Role	Contact information
Jonathan Preston, PhD CCC-SLP. Director, Speech Production Lab 621 Skytop Road Suite 1200, Syracuse NY 13244	Principal Investigator- responsible for coordinating the research at Syracuse University.	jopresto@syr.edu
Katelynn Carrol, MS CCC-SLP, Adjunct Instructor, Communication Sciences and Disorders 432 Western Avenue Albany NY 12203	Site Principal Investigator – responsible for coordinating the research at The College of Saint Rose	carrollk@strose.edu
Melissa Spring, MS CCC-SLP, Coordinator, Winkler Center at The College of Saint Rose, 432 Western Avenue Albany NY 12203	Responsible for resource scheduling for the Saint Rose data collection site.	springm@strose.edu
Nina R Benway, MS CCC-SLP Doctoral Candidate, Syracuse University 621 Skytop Road Suite 1200, Syracuse NY 13244	Will assist PI Preston in conducting research at Syracuse University and will assist PI Carroll in conducting research at The College of Saint Rose. Will be the treating clinician at both Syracuse University and The College of Saint Rose.	nrbenway@syr.edu

Note: The phrase “the participant” refers to you, if you are an adult participant between the ages of 18-21, or to your child, if you are the parent/guardian of a child participant aged 9-17.

The purpose of this form is to provide you with information about participation in a research study and offer you the opportunity to decide whether you wish to participate or allow your child to participate. You can take as much time as you wish to decide and can ask any questions you may have now, during, or after the research is complete. Participation is voluntary, so you may choose to participate or not. All information collected during the study is kept confidential.

Our lab is interested in learning more about different ways speech problems can be treated. In this study, we are researching if a computerized version of our therapy software, one that uses

artificial intelligence and speech recognition, can predict the decisions and feedback that a clinician would provide during “R” therapy. We are also examining how clients respond to the artificial intelligence clinician and therapy. Children/young adults in and around Syracuse, NY and Albany, NY will be asked to participate. We estimate that approximately 8 participants will take part in this research study.

What will I be asked to do?

If you (and, if applicable, your child) agree to participate in this study, the participant and/or the parent/guardian of child participants will be asked to participate in the following:

Screening.
If the participant passes the online screening, we will schedule an assessment session and send you a consent form asking you to consent to audio recording of assessment and treatment sessions. You will have an opportunity to review this information and ask questions of the study staff prior to your assessment visit.

Assessment: one 90-minute visit.
You will sign a copy of this consent form at this assessment visit, and if you are the parent of a child participant under the age of 18, we will ask your child to assent to their participation at this time. We will then ask you questions about the participant’s developmental history, educational history, and speech sound treatment history.
Nina Benway, a speech-language pathologist and Doctoral Candidate in the Speech Production Lab, will ask the participant to participate in several standardized tests of hearing, speech, and language. We will assess the participant’s hearing by asking them to indicate when they hear quiet beeps, and make sure the participant has an adequate range of motion of their tongue by asking them to stick their tongue out of their mouth and move it from side to side. The participant will also be asked to name pictures, read/repeat sounds, words, and sentences, follow directions when pointing to items in picture format, listen to the words “rake” and “wake” on a computer, and respond to a questionnaire about their views of speech therapy. The information from these standardized hearing, speech, and language measures will be used to determine the participant’s eligibility for the remainder of the study. It is possible that, based on the results from this first visit, the participant might not be eligible to participate in the remainder of the study. If this happens you will still be compensated for the time the participant spent doing our activities.

Pre-Treatment Recordings: 5-10, 5-10-minute sessions
If the participant is eligible to continue with the study, and you choose to continue with the study, we will need to make several recordings of the participant saying “r” words before they start treatment. The “r” word lists are 50 items long, with the participant recording each word once per session. Each recording session might take around 5-10 minutes and can be completed from your home during a Zoom call with the researcher. Different participants will be randomly assigned to a different number of pretreatment visits (not lower than 5, not higher than 10). Once treatment begins, all participants will follow the same treatment program.

Treatment: 10, 60-minute visits
Once treatment begins, all eligible participants will receive a total of ten 60-minute sessions of speech lessons here in the lab to improve the clarity of their “r” sound. The first session will

include an “Orientation to /r/” that is led by speech-language pathologist Nina Benway. During this session the participant will receive instruction on how to produce an accurate “r” sound.

The remaining 9 speech lessons will be based on Speech Motor Chaining, a treatment that has previously been shown to be effective in helping some children/young adults improve their /r/ sounds. However, Speech Motor Chaining when controlled by an artificial intelligence clinician is an experimental approach. Each session will have elements that are similar to traditional speech therapy. The participant will be prompted to say a word or phrase with the /r/ sound out loud. The clinician will provide cues and feedback to help the participant recognize and produce a clear “r” sound. However, the treatment in this study differs from traditional speech therapy in some ways. The Speech Motor Chaining software adapts in difficulty to the participant’s /r/ accuracy. The participant will also receive cues and feedback determined by an artificial intelligence-controlled clinician we have developed within our lab, based on our lab’s clinical practices. Finally, at the end of each session the participant will participate in a recording session where they say a list of “R” words, which will take approximately 5 minutes. After all treatment sessions are over, we will ask the participant, and the parent/guardian of child participants, what they liked or did not like about speech therapy with artificial intelligence.

Post-Treatment Recordings: 3, 5-10 minute sessions
We will need to make three more recordings of the participant saying “r” words after the end of treatment. Similar to the pre-treatment recordings, each recording session might take around 5-10 minutes and can be completed from your home during a Zoom call with the clinician. Everyone in the study will complete 3 such recordings.

It is very important for the study that we follow the prescribed schedules. We recognize that scheduling can be difficult, and we will work with you to identify a point at which we could start the speech lessons that would be convenient for you, such as a school vacation or summer, but would also meet the needs of the study. If the participant meets all of the criteria for inclusion in our study, we will ask to schedule the participant for two 60-minute treatment sessions per week for approximately 5 weeks. Participants may be withdrawn from the study if they are unable to adhere to the schedule agreed upon at the beginning of the study.

Where will the study take place?

Assessment and treatment sessions will take place at the Syracuse University Speech Production Lab (621 Skytop Road, Ste 1200, Syracuse, NY) or The Winkler Center at The College of Saint Rose (432 Western Avenue, Albany, NY).

Pre-treatment and post-treatment recordings will take place on a Zoom call with the researcher.

What are the possible risks of participation in this research study?

<u>Speech-Language testing and Speech Lessons</u>

There are no known risks for using Speech Motor Chaining or computerized feedback during speech therapy. Because some of the speech and language tasks may be challenging, the participant may experience some frustration. Breaks will be offered, and the participant may

choose not to complete any of the tasks they find too frustrating. We do not expect that there will be any further risks associated with taking part in this study for the participant.

Use of the Internet and Email

Whenever one works with email or the internet there is always the risk of compromising privacy,confidentiality, and/or anonymity. Your confidentiality will be maintained to the degree permittedby the technology being used. It is important for you to understand that no guarantees can be made regarding the interception of data sent via the Internet via third parties.

COVID-19 Considerations

Our research sites follow all recommended federal, state, local, and university guidelines for COVID-19.

What are the possible benefits of participation in this research study?

The participant will receive speech therapy using Speech Motor Chaining, a treatment that has evidence of good outcomes for children who have difficulty with the /r/ sound. As a result of the speech lessons, the participant may improve the clarity of his/her speech production.

Indirectly, the advancement of scientific knowledge may improve our understanding of speech difficulties and the methods that can be used to effectively treat them.

How will my privacy be protected?

- All assessment and treatment tasks happen in a private, closed-door space with the opportunity for parents to observe the session from a remote location.
- Only key study personnel will be in the treatment room with the Participant.
- However, there are limitations to the protection of your privacy as access to the treatment room involves entering shared spaces and hallways.

How will my data be maintained to ensure confidentiality?

- Only key study personnel will have access to your private information, such as name, date of birth, and contact information. This information is stored digitally in a password protected environment.
- The participant will be assigned a numeric study ID (e.g., 1101). Only key study personnel will have access to the key that can link study identifiers with private information. This key is stored digitally in a password protected environment.
- Only approved lab members will have access to de-identified study information, such as the scores from the assessment tasks and the spoken word recordings, which are linked only to the Participant's numeric study ID (and not a name). These files are stored digitally in a separate password protected environment than the private information. The researchers acknowledge that due to the nature of audio recordings, this data cannot be made unidentifiable because of the sound of the participant's voice.
- The speech recognition in the artificial intelligence requires audio recordings of the participant's speech to be made during treatment. The treatment computer uses the internet to send these files to Syracuse University for speech recognition processing and storage. All audio processing and storage happens on password protected platforms at Syracuse University.

- The speech audio collected during the study might be removed from the identifiable private information and, after such removal, the information/biospecimens could be used for future research studies or distributed to another approved investigator for future research studies without additional consent from the participant or the legally authorized representative.
- Under Syracuse University policy, faculty and researchers are considered mandated reporters. *We will keep your study data as confidential as possible with the exception of certain information we must report for legal or ethical reasons such as child abuse, elder abuse, sexual misconduct, or intent to harm yourself or others.*

Will photographs, audio, video, or film recording be used?

- The speech recognition in the artificial intelligence requires audio recordings of the participant's speech to be made during treatment. We record the sound of the participant's voice saying one word at a time (example: "ride"). These audio files are labeled with the Participant's study ID, the session the file came from, and the word that was spoken. The participant's name is not stored with the audio. These recordings are stored on a password protected drive at Syracuse University. Only approved members of the research study will have access to the audio recordings.
- Some of the audio recordings will also include video of the computer screen so the researchers can see what the computer software is prompting the participant to do and how the participant's mouse is moving during the session. The video will not include the participant's face.
- Our data analysis involves tracking improvements in speech clarity, and this requires collecting recordings. By signing the consent, you agree to allow us to collect audio recordings for the purpose of listener judgments of speech sound correctness and analyzing the acoustic structure of the sound waves present in the participant's speech.
- You will be able to decide what happens with the audio recordings after the study is complete. One option is to provide consent for the recordings of the participant's voice saying one word at a time to be placed into a public database to be used for future research purposes that include training future speech recognition systems. This database will also have information about the participant such as their gender and age at the time they participated in the study. No identifying information is included in this database other than the sound of the participant's voice saying single words and short phrases. If you do not want the participant's speech added to this public database, the audio recordings will be retained indefinitely by the Speech Production Lab for future research purposes that include training future speech recognition systems, but we will not share the sound of the participant's voice outside of the Syracuse University Speech Production Lab. We will delete the participant's name, date of birth, and contact information from our records after 5 years.

Will I receive compensation for participation?

- We will reimburse you $20/hour (paid at $5 for each quarter hour) for assessment visits. During sessions in which we provide the free speech lessons, no reimbursement will be provided except for $5 to offset transportation costs. For participants who do not complete all aspects of the study or who withdraw, we will reimburse you for the time provided. A participant completing the study can expect to be compensated $75. All compensation will be made in cash, or a check mailed at the end of your participation in the study.

Voluntary participation and withdrawal:

The participant's participation in this study is voluntary. The participant, or the parent/guardian of a child participant, may decide not to participate or stop participating at any time, without penalty or loss of benefits already conferred. If you decide to leave the study, please tell the study staff.

Alternatives to study participation:

The participant does not have to participate in this study to receive treatment for speech. You may instead seek treatment from another speech-language pathologist in the school or private clinic setting. You may also opt to have no treatment for the participant's speech errors.

What are my rights and the rights of child participants in research?

- Your participation, and the participation of child participants, is voluntary.
- The participant or the parent/guardian of a child participant may skip and/or refuse to answer any question for any reason.
- The participant or the parent/guardian of child participants are free to withdraw from this research study at any time without penalty.

Whom may I contact with questions now, during, or after the research is complete?

- For questions, concerns or more information regarding this research you may contact Nina R. Benway and/or Dr. Jonathan L. Preston using the contact information at the top of this form.
- If you have questions or concerns about your rights as a research participant, you may contact the Syracuse University Institutional Review Board at (315) 443-3013.

By signing this form, I confirm the following:

- I have read this consent form and know what is involved in the study.
- All of my questions have been answered to my satisfaction.
- I/my child can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my child's personal health information and study information as described in this form.
- I agree to allow permission to audio record the participant's assessment and treatment sessions. I understand that these recordings will be used for data collection and analysis purposes, and that they will be rated for accuracy by outside listeners recruited to complete speech rating tasks.
- I will be given a copy of this signed consent form to keep.
- I do not give up any legal rights by signing this form.

I am 18 years of age or older and I understand what my/my child's participation in this research involves. I also acknowledge that audio recording of sessions is required in order to be part of the study.

_____ Date: _____
Printed Name of the Person Providing Consent

_____
Signature of the Person Providing Consent

_____

Printed name of child (in the instance of child participants)

---------- Date: _____
Printed Name of the Researcher

_____
Signature of the Researcher

Please answer the following questions by placing your initials next to your choice below. Your responses will not affect the participant's eligibility for participation in the study.

1. Will you allow us to contact the participant's speech pathologist to share information about the participant's history of speech-language treatment and current speech-language abilities?

_____ YES _____ NO
(initials) (initials)

2. Will you allow us to share audio recordings of the participant saying short words/phrases (without his/her name) with outside listeners as part of a future study?

_____ YES _____ NO
(initials) (initials)

3. Will you allow us to use audio recordings of the participant's saying short words or phrases (without his/her name) in academic contexts to train current/future speech language pathologists (i.e., at a conference or in a classroom)?

_____ YES _____ NO
(initials) (initials)

4. Will you allow us to include audio recordings of the participant saying short words/phrases (without his/her name) in a publicly-available database of speech samples?

_____ YES _____ NO

(initials) (initials)

5. May we contact you about further research opportunities?

_____ YES _____ NO
(initials) (initials)