SYRACUSE UNIVERSITY

Department of Communication Sciences and Disorders

Oral Consent for Parents of Child Participants

Protocol Title: An Alternative Service Delivery Model and Target Selection Approach for Treatment of /s/ Errors

Principal Investigator/Key Research Personnel:

Name and Title	Role	Contact Information
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Introduction:
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. 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 by contacting the researchers at bmherbst@syr.edu or at 315-443-1351. Your participation is voluntary.

What is the purpose of this research study?
We are interested in learning about different ways of treating speech problems. In this study, we are researching if an alternative treatment schedule of four, 10-minute sessions provided weekly can be used to help children learn to produce the /s/ sound more consistently. Additionally, we are researching if there are any differences among children treated on /s/ in both the initial and final position of syllables versus treating /s/ in the initial position of syllables only. We estimate that approximately 24 participants will take part in this study.

This study will also involve the collection of speech recordings from a variety of children who have difficulty with the /s/ sound. These recordings will be played to speech-language pathologists to listen and rate for mispronunciations in order to track children's progress and to train artificial intelligence systems to recognize speech sounds as spoken clearly or distorted. Being in this study means we will use the collected audio recordings to track your child's progress and also to use them for building speech classifiers that can recognize speech errors.

What will I and my child be asked to do?

If you agree to have your child participate in this study, you and your child will be asked to participate in the following:

Consent & Orientation to /s/ Visit (approximately 45 minutes):

Your child passed the online screening, so next we will determine full study eligibility. In our first visit, your child will also participate in a 30-minute "Orientation to S" speech session. This session will include direct instruction regarding /s/ sound production, as well as the opportunity to practice producing the /s/ sound will cueing and feedback. After 30 minutes of the instruction/practice, participants will complete syllable and word level recordings for the /s/ sound for eligibility purposes.

Evaluation Visit (approximately 60 minutes):

If your child is deemed eligible to continue based on the results of the orientation session recordings, a second Zoom visit will be scheduled. In the second visit, we will confirm eligibility for the study, which is expected to take about an hour. During this visit, we will assess your child's oral-motor structure and function. Your child will also be asked to name pictures, say sounds, words and sentences, follow directions, listen to words on the computer, and respond to a questionnaire. The information we collect will be used to determine eligibility for the remainder of the study; it is possible that, based on the results of the tests, your child might not be eligible to participate in the remainder of the study.

Recording Session 1:

If your child qualifies for the remainder of the study, and you and your child choose to continue with the study, we will need to make several recordings of your child saying /s syllables and words. The pre-treatment recording session (Recording Session 1) should take about 30 minutes and will be completed during a Zoom call with the researcher.

Treatment Sessions:

All participants will receive a total of 32 ten-minute speech sessions (4 sessions per week for 8 weeks). These speech sessions will use a treatment approach that has previously shown to be effective in helping some children improve their /s/ sounds. Some participants will be randomized to receive treatment of /s/ in the initial position only, while other participants will be randomized to receive treatment of /s/ in both the initial and final positions simultaneously. Each session will have elements that are similar to traditional speech therapy. Your child will be prompted to say a word or phrase with the /s/ sound out loud. The clinician will provide cues and feedback to help your child recognize and produce a clear /s/ sound. Your child may also be asked to rate the accuracy of their own productions of /s/.

You must agree to be willing to have your child participate in any treatment schedule to which he or she is assigned. Unfortunately, you do not get to choose which treatment schedule your child will receive - the researchers will randomly assign your child to one of the two treatment schedules, either the immediate treatment schedule or the delayed treatment schedule. These two schedules are displayed in the table below.

Week	Immediate Treatment Group	Delayed Treatment Group
1	• Consent/Assent & Orientation Session • Evaluation Session • Recording Session 1	• Consent/Assent & Orientation Session • Evaluation Session • Recording Session 1
2	• Four 10-minute treatment sessions	• No sessions
3	• Four 10-minute treatment sessions	• No sessions
4	• Four 10-minute treatment sessions	• No sessions
5	• Four 10-minute treatment sessions	• No sessions
6	• Four 10-minute treatment sessions	• No sessions
7	• Four 10-minute treatment sessions	• No sessions
8	• Four 10-minute treatment sessions	• No sessions
9	• Four 10-minute treatment sessions • Recording Session 2	• Recording Session 2
10	• No sessions	• Four 10-minute treatment sessions
11	• No sessions	• Four 10-minute treatment sessions
12	• No sessions	• Four 10-minute treatment sessions
13	• No sessions	• Four 10-minute treatment sessions
14	• No sessions	• Four 10-minute treatment sessions
15	• No sessions	• Four 10-minute treatment sessions
16	• No sessions	• Four 10-minute treatment sessions
17	• Recording Session 3	• Four 10-minute treatment sessions • Recording Session 3

It is very important for the study that we follow the prescribed schedules.If your child has to miss a session for any reason, we will attempt to make-up the missed session that week. If you are unable to make-up the missed session that week, we will not be able to make-up the session in a following week. We cannot extend treatment past 8 weeks. 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 your child meets all of the criteria for inclusion in our study, we will ask to schedule four 10-minute treatment sessions per week for 8 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.

We will have 3 recording session to track your child's progress: before treatment, after 8 weeks, and after 17 weeks.. Your child will be asked to produce the same /s/ syllables and words they produced in Recording Session 1. This recording session should take about 30 minutes and will be completed during a Zoom call.

At the last session, we will also ask you and your child what you liked or did not like about the short, frequent speech sessions.

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

Because some of the speech and language tasks may be challenging, your child may experience some frustration. However, there are no known risks. Breaks will be offered, and your child may choose not to complete any of the tasks.

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 permitted by 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.

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

- As a result of the speech lessons, your child may improve the clarity of his/her speech production.
- The advancement of scientific knowledge may improve our understanding of speech difficulties and how to treat them.

How will my (and my child's) privacy be protected?

- All sessions will occur using a HIPAA-compliant Zoom account
- Only key study personnel will be in the Zoom session with your child
- The speech-language pathologist conducting the sessions will do so from a private, closed-door space using a headset.
- To protect your privacy further, we recommend you have your child join our Zoom sessions from a private space with the door closed and while wearing a headset.

How will my (and my child's) data be maintained to ensure confidentiality?

- Only key study personnel will have access to your and your child's private information, such as name, date of birth, and contact information. This information will be stored digitally in a password protected environment.
- Your child 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, which will be linked only to your child's assigned numeric study ID (and not their 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 the audio recordings, this data cannot be made unidentifiable because of the sound of the participant's voice.

- The Speech Motor Chaining website will use 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 (after being scrubbed of identifying information) could be used for future research studies without additional consent from the participant or the legally authorized representative, if consent is provided in responses to the questions at the end of this form.
- 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?

- We will make audio recordings of the participant. We record the sound of your child's voice saying one word at a time (example: "side") or a short sentence (e.g., It's by my side). 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, date of birth, address, etc, are 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 the target and feedback assigned to each trial through the Speech Motor Chaining treatment. The video will **not** include your child's face.
- Our data analysis involves tracking improvements in speech clarity, and this requires collected recordings. By consenting, you agree to allow us to collect audio recordings for the purpose of listener judgements of speech sound correctness and analyzing the acoustic structure of the sound waves present in the participant's speech. Being in this study means we will use the collected audio recordings to track your child's progress and also to use them for building speech classifiers that can recognize speech errors.
- 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 to better understand the speech of children. 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 10 years.

Will I receive compensation for participation?

For participants who attend the first virtual session, a gift card of up to $60 will be mailed to the physical address or emailed to the email address specified by the parent/guardian during the

consenting process. The child participant will choose between Amazon.com, Target, or Walmart.

- Completion of the online screener alone = no compensation
- $20/hr for the consent/assent & orientation session
    - Paid at a rate of $5 per 15 minutes
- $20/hr for the evaluation session
    - Paid at a rate of $5 per 15 minutes
- $20/hr for the final probe recording session
    - Paid at a rate of $5 per 15 minutes

Therefore, completing all visits = $60 gift card

If the participant decides to leave the study, the participant will get to keep the money already earned. We will send the gift card to the store of the participant's choice (Amazon.com, Target, or Walmart) after all study-related tasks are completed.

Voluntary participation and withdrawal:

You and your child's participation in this study is voluntary. You or your child may decide not to participate or stop participating at any time, without penalty. If you decide to leave the study, please tell me.

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

- Your participation, and the participation of your child, is voluntary.
- You or your child may skip and/or refuse to answer any question for any reason.
- You 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 Benedette Herbst at bmherbst@syr.edu or at 315-443-1351 or Dr. Jonathan Preston at jopresto@syr.edu or at 315-443-3143.
- 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.

Do you have any questions?

Are you 18 years or older?

What is the name of the child for which you are providing consent?

Do you understand that all assessment and treatment sessions will be audio recorded?

Will you allow us to use audio recordings of your child saying short words or phrases (without his/her name) with outside researchers as part of a future study?

Will you allow us to use audio recordings of your child saying short words or phrases (without his/her name) in academic contexts to train current speech-language pathologists or students (e.g., in a classroom, at a conference)?

Will you allow us to use audio recordings of no more than 2 minutes of your child saying short words or phrases (without his/her name) as supplemental media along with a scientific paper?

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?

May we contact you for future research opportunities?

Do you agree to have your child participate?

How can I provide you with a copy of this consent script?