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Speech Motor Chaining: Randomized Controlled Trial of Treatment Intensities

Introduction of the Principal Investigator/Key Research Personnel:

Dr. Jonathan Preston is a speech-language pathologist and clinical researcher. He is the principal investigator for this research study. Several certified speech-language pathologists will be involved in data collection and analysis, including Nina Benway, Nicole Caballero, Benedette Herbst, Megan Leece, and Kerry McNamara. Other researchers who will assist with data analysis include Ben Munson, and Asif Salekin. You may contact the members of the research team at 315-443-1351 or SpeechProductionLab@syr.edu.

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. Your participation is voluntary.

What is the purpose for this research study?

- **Speech Motor Chaining is an evidence-based speech therapy approach for speech sound disorders. Past research has shown that many children and young adults can improve their speech sounds with this type of treatment. In**

this study, we are researching if different schedules of speech therapy affect how much children learn after 16 treatment sessions.

- **The study will also collect recordings of spoken words and sentences from study participants. These recordings will be rated by speech-language pathologists. The recordings and the listener ratings will be used to train a computer program to recognize speech sounds that are and are not clearly pronounced.**

What will I/my child be asked to do?

- **If you/you child agree to participate, data collection will occur face-to-face by research speech-language clinicians hired through Syracuse University. Sessions may take place in your homes or a local library, or at the Syracuse University Speech Production Lab. Participants must be within 20 miles of one of our research speech-language pathologists who will collect the data.**
- **A consent visit will take place online via Zoom. Once consent has been obtained, the parent/guardian will be sent a questionnaire related to demographic information (age, race, ethnicity, sex, gender), the participant's dialect and language exposure, medical and family history, history of speech therapy, and socio-emotional well-being. During this visit, participants will also complete the following:**
  - **Repeating syllables such as 'pa' 'ta' 'ka' as quickly as possible**
  - **Test of Integrated Language and Literacy Skills (TILLS) is a common standardized language assessment that involves listening and retelling stories.**

    Then, participants will complete the following:

  - **<u>Visit 1:</u> (about 90 minutes)**
    - **Hearing screening: Soft beeps are presented at a low level**
    - **Naming pictures, imitating and reading words and sentences to assess the "R" and "S" sounds.**
    - **Repeating syllables such as 'pa' 'ta' 'ka' as quickly as possible**
    - **We check the participant's mouth to be sure there are no unusual structural differences in the mouth.**
    - **The speech-language pathologist will screen for voice disorder during the above tasks. A participant with a significant voice disorder will not be eligible, but if the voice disorder resolves, they may participate if all other eligibility criteria are met.**

Participants who meet the above eligibility criteria will be invited to participate in the treatment study.

  - **<u>Visit 2:</u> Dynamic Assessment (45 minutes)**
    - **Participants will complete surveys about any impacts of speech and their perspective on learning and changing their speech**
    - **Instructions will be provided on how to produce the treated sound of /ɹ/ or /s/, and participants will be given opportunities to practice the target sound with extensive clinical feedback and personalized instruction.**
    - **Participants will imitate syllables containing the treated sound.**

- **Visits 3-18: Treatment (about one hour each): Participants will be randomized to receive 16 50-minute Speech Motor Chaining treatment sessions in one of the following conditions:**
  - **Intensive Treatment will involve 16 sessions distributed as follows:**
    - **Week 1: 8 sessions (2 sessions per day on 4 different days)**
    - **Week 2: 3 sessions (1 per day on 3 different days)**
    - **Week 3: 3 sessions (1 per day on 3 different days)**
    - **Week 4: 2 sessions (1 per day on 2 different days)**
  - **Distributed Treatment will involve 16 sessions distributed as follows:**
    - **Weeks 1-8: 2 sessions per week (1 per day on 2 different days)**
  - **Treatment Sessions. Each treatment session will consist of 50-minutes of active treatment with up to 10 minutes of interspersed break time, per the participant's discretion. Sessions will address only one speech sound (/ɹ/ or /s/) for all 16 sessions for a given participant. Each session will be led by a research-trained Speech-Language Pathologist and will include three parts:**
    - **Pre-practice (informal instruction to teach the sound in syllables, lasting 1-30 minutes depending on the participant's performance)**
    - **Speech Motor Chaining Structured Practice (structured practice of syllables, words, and phrases, with interspersed feedback, 20-40 minutes)**
    - **Random Practice (random presentation of the syllables, words and sentences with limited feedback, up to 9 minutes).**
- **Probe assessing /ɹ/ and/or /s/ (about 15 minutes). To monitor progress over the course of the study, participants will read and imitate words and sentences. Probes will be administered on 5 separate occasions. These include before treatment, after 2 weeks, 4 weeks, 8 weeks, and 10 weeks from the start of the study. They will occur at the start of specified treatment sessions or on separate visits if no treatment is scheduled, such as the 10 week outcome visit).**

Can I be withdrawn from the study?

- **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's treatment to begin within 2 months of the first assessment. Participants may be withdrawn from the study if they are unable to adhere to the schedule agreed upon at the beginning of the study.**
- **Participants may also be withdrawn from the study if children refuse to participate during treatment sessions**

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

- **There are no known risks for the speech assessment and treatments used here.**

- **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.**
- **Frequent therapy sessions may result in some fatigue of the voice. We will provide short breaks during the sessions, and encourage hydration and vocal rest between visits.**
- **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 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, including during the submission of this form.**

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

- **As a result of the speech lessons, the participant may improve the clarity of his/her speech production.**
- **Researchers will learn how to structure speech therapy to get the best outcomes**
- **Researchers will use recordings to develop a computer system that can recognize clear and distorted productions of speech**

How will my privacy be protected?

- **Audio recordings will be collected during all sessions but the content will be scripted (e.g., reading or imitated speech); that is, we do not intend to record you providing personal information.**
- **Sessions will be one-on-one. Only approved study personnel will be in the room with the Participant.**
- **For participants seen in their homes, you may determine who is also in the home.**
- **For participants who attend in a laboratory setting, the sessions will be conducted with the door closed but unlocked. There are limitations to the protection of your privacy and the confidentiality of the data collected. For example, the waiting area for the research lab and the hallways are public spaces.**

How will my data be maintained to ensure confidentiality?

- **We will not store personally identifiable information on paper.**
- **Only key study personnel will have access to private information. This information is stored digitally in a Syracuse University database, a password-protected environment with two-factor authentication. Only key study personnel will have access to the key that can link study identifiers with private information.**
- **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 access group from the identifying**

information. The researchers acknowledge that due to the nature of audio recordings, this data cannot be made unidentifiable. However, audio recordings provided by all participants will be similar (i.e., recordings of words and sentences) and will not provide personally identifiable content.

- **Audio recordings during sessions will be made on computers that use the internet to send files to Syracuse University for 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 within our speech lab without additional consent from the participant or distributed to another approved investigator.**
- **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 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 audio or video recording be used?

- **Audio recordings will be collected for all sessions to assess the participant's speech and to be certain the researchers followed the treatment procedures properly. 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.**
- **Our data analysis involves tracking improvements in speech clarity, and this requires collecting recordings and having trained people listen to the 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, for the current study**
- **Sometimes the audio recordings will include screen recordings of the researcher's computers. These screen recordings will not include the participant's face unless you give us permission. Some of the audio will be played to other listeners who are members of the research team.**
- **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.**

- **Please respond to the questions at the bottom of this form regarding the use of audio and video. The responses will not affect your participation in the study.**

Will I receive compensation for participation?

- **Compensation will be provided in the form of a gift card. The participant may choose gift cards from one of the following: Amazon.com, Walmart, or Target. Gift cards will be mailed or electronic gift cards will be emailed to the individual who completes this consent document.**
- **Compensation will be distributed as follows:**
  - **$20/hr for Visit 1 (typically 45 minutes = $15)**
  - **$20/hr for Visit 2 (typically 90 minutes = $30)**
  - **$10 for completion of each probe session (up to 5 = $50)**
  - **$10 for completing all electronic surveys.**
  - **No compensation during treatment visits, but free speech therapy is provided.**
- **Total: about $105**
- **Gift cards will be mailed/emailed to the person signing this form at the completion of the study or after withdrawal from the study. If participants withdraw, they will get to keep the money they have earned for parts of the study already completed.**
- ***We have not set aside money to pay for related injuries. Signing this form does not waive any legal rights.***

Will clinically relevant research results be returned to the participant?

- **A brief (1-page) summary of performance on standardized speech and language tasks will be emailed or mailed to the participant after the completion of Visit 1.**
- **A brief (1-page) summary of performance during speech therapy will be emailed or mailed to the participant if all treatment sessions and probes are completed.**
- **Because this is a research study, we do not make specific educational recommendations**

Information about possible commercial profit.

- **It is possible that in the future the software that we plan to develop to detect speech errors could be commercialized.**

Information regarding Certificates of Confidentiality:

- **A Certificate of Confidentiality (CoC) protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside of this research.**
- **No one can be forced to share your identifiable information/recordings for a lawsuit.**
- **Your information cannot be used as evidence even if there is a court subpoena.**

The CoC does not prevent some disclosures:

- **You can still share information about yourself. You can also freely discuss your involvement in this research.**
- **The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.**
- **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, sexual misconduct, or intent to harm yourself or others.**

Voluntary participation and withdrawal:

- **The participant's participation in this study is voluntary. The participant or the parent/guardian 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.**

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 as a research participant?

- **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.**
- ***We have not set aside money to pay for related injuries. Signing this form does not waive any legal rights.***

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 Dr. Jonathan Preston at 315-443-3143 / jopresto@syr.edu or the members of research team at 315-443-1351 / SpeechProductionLab@syr.edu**
- **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.**

All of my questions have been answered, I am 18 years of age or older, and by signing this consent form, I agree to participate/have my child participate in this research study. I have received a copy of this form for my personal records.

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 wish to enroll in this study and have the participant's eligibility for the study fully evaluated.

- ○ Yes
- ○ No

Today's Date

* must provide value

M-D-Y

YYYY-MM-DD

Form Status

Complete?

Incomplete